Información Técnica	Nombre del producto	Expediente	Fecha
	exeol OPA		03/10/2024

1. **Formula cualitativa básica y secundaria.**

Nomenclatura (Para cosméticos en formato INCI)	Concentración (%)
o-Phthalaldehyde (OPA), Excipientes.	0,55 %

2. **Especificaciones organolépticas, físico químicas y estudio de estabilidad.**

Análisis fisicoquímico y organolépticas	Resultado
pH	7 - 8
Estado físico	Líquido
Apariencia	Claro.
Color	Azul
Olor	Perfumado - Flor de algodón
Perfume	Sintético

Nota: El estudio de estabilidad de presenta como anexos.

3. **Justificaciones de las bondades y proclamas.**
   - Solución lista para usar a base de ortoftalaldehído para la desinfección final por inmersión de dispositivos médicos termosensibles reutilizables, semicríticos y críticos, invasivos y no invasivos previamente limpiados.
   - exeol OPA está previsto para la desinfección final por inmersión de dispositivos médicos termosensibles reutilizables, semicríticos y críticos, invasivos y no invasivos previamente limpiados.
   - Los dispositivos médicos reutilizables que se pueden retratar con exeol OPA son, por ejemplo: equipos de diálisis, endoscopios semicríticos (colonoscopios, gastroscopios, broncoscopios, etc.) y endoscopios críticos (coledoscopios, cistoscopios, ureteroscopios, etc.)
   - Solución lista para usar.
   - Control de la validez mediante tira de prueba (medición del nivel de ortoftalaldehído).
   - Tiempo de contacto a partir de 10 minutos.
   - Activo sobre las esporas de Clostridium difficile.
   - Solución ligeramente perfumada.

Norma	Microorganismo evaluado	Tiempo de eliminación
EN 13727 EN14561	Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae	5 Min
EN 13624 EN 14562	Candida albicans. Aspergilus brasiliensis	
EN 14348 EN 14563	Mycobacterium terrae, Mycobacterium avium	
EN 14476 EN 17111	Poliovirus, Adenouvirus,Norovirus Adenovirus, Norovirus	10 Min
EN 17126	Clostribium dificile	15 Min
EN 17126	Bacillus subtillis, Bacillus cereus	90 min

4. Proyecto de rotulado.

exeol OPA

Desinfectante de alto nivel

Solución lista para usar a base de ortoftalaldehído para la desinfección final por inmersión de dispositivos médicos termosensibles reutilizables, semicríticos y críticos, invasivos y no invasivos previamente limpiados.

Propiedades microbiológicas

Condiciones de limpieza, listo para usar, 20°C:
Bactericida (5 min.): EN 13727, EN 14561.
Fungicida (5 min.): EN 13624, EN 14562.
Micobactericida (5 min.): EN 14348, EN 14563.
Virucida (10 min.): EN 14476, EN 17111.
Esporicida contra *Clostridium difficile* (15 min.): EN 17126.
Esporicida (90 min.): EN 17126.

Instrucciones de uso

exeol OPA está listo para usar. **exeol OPA** se utiliza sin diluir en dispositivos médicos limpiados previamente. **exeol OPA** puede utilizarse durante un máximo de 14 días. Controlar regularmente la validez del baño con las tiras de control **exeol strips OPA**. Antes de usar **exeol OPA**, realizar una limpieza previa o una limpieza mecánica completa y un aclarado intermedio de los dispositivos médicos que se van a tratar.
Cuando se use por primera vez, retirar el anillo de inviolabilidad y luego desenroscar el tapón.
1. Desenroscar el tapón del bidón y transvasar el contenido a la bandeja. Volver a cerrar el bidón después de su uso. **2.** Colocar los dispositivos médicos abiertos y desmontados en la solución y asegurarse de que estén totalmente sumergidos. Asegurar la irrigación de los canales si están presentes. Cubrir la bandeja. **3.** Tiempo de contacto: a partir de 10 min., según el espectro de actividad deseado. **4.** Aclarar cuidadosamente con agua estéril o filtrada (0,2 µm) antes de volver a utilizarlo. **5.** Antes de almacenar, secar los dispositivos mediante aire médico sobre una superficie seca limpiada previamente.

SOLO PARA USO PROFESIONAL

EXS EXEOL OPA 5L - MASTER ETQ ES AM LAT-R-01

INSTRUMENTOS ENDOSCOPIA

LISTO PARA USAR

REMOJO MANUAL

TIRAS DE PRUEBA

5L

CE 0459

MD

SANTÉ exeol
UNA DIVISIÓN DE SODEL

exeol OPA

Composición
o-Phthalaldehyde (OPA) al 0,55 % y excipientes.

Precauciones
Contiene: o-Phthalaldehyde (OPA) (CAS: 643-79-8). Puede provocar una reacción alérgica. Nocivo para los organismos acuáticos, con efectos nocivos duraderos. Evitar su liberación al medio ambiente. En caso de irritación o erupción cutánea: Consultar a un médico. Eliminar el contenido y el recipiente en un punto de recogida de residuos peligrosos o especiales, de acuerdo con la normativa local. - Utilizar guantes de manga larga. No mezclar con otros productos. Antes de usar, comprobar la fecha de caducidad que figura en la etiqueta. Cualquier incidente grave relacionado con el dispositivo médico debería comunicarse a Sodel y a la autoridad competente del Estado miembro en el que estén establecidos el usuario y/o paciente. Archivo del producto disponible en www.exeol.fr
Marcado CE obtenido en 2023.

UFI: NW49-107C-K00T-QXET

EXS EXEOL OPA 5L - MASTER ETQ ES AM LAT-V-01

Sodel
190 rue René Barthélemy
14100 Lisieux, France.
TEL: +33 (0)2 31 31 10 50
www.exeol.fr

Distribuido por:

5°C - 25°C
ALMACENAJE

FABRICADO EN FRANCIA

SANTÉ exeol
UNA DIVISIÓN DE SODEL

5. **Stiker importador**

Importado por **ALKAMEDICA® S.A.S**
Parque Industrial Juanchito, Terraza 6 - Bodega B · Manizales, Caldas - Colombia.
Teléfonos: (6) 863 2740 · **Celular:** (+57) 301 571 1865
servicioalcliente@alkamedica.com ·www.alkamedica.com

6. **Instrucciones de uso**

Para exeol OPA:

- exeol OPA está listo para usar. exeol OPA se utiliza sin diluir en dispositivos médicos limpiados previamente.
- exeol OPA puede utilizarse durante un máximo de 14 días.
- Verificar la validez del principio activo mediante las tiras de control Exeol Strips OPA.
- Antes de usar exeol OPA realizar una limpieza previa o una limpieza mecánica completa y un aclarado intermedio de los dispositivos médicos que se van a tratar. Cuando se use por primera vez, retirar el anillo de inviolabilidad y luego desenroscar el tapón.

1. Desenroscar el tapón del bidón y transvasar el contenido a la bandeja. Volver a cerrar el bidón después de su uso.

2. Colocar los dispositivos médicos abiertos y desmontados en la solución y asegurarse de que estén totalmente sumergidos. Asegurar la irrigación de los canales si están presentes. Cubrir la bandeja.

3. Tiempo de contacto: a partir de 10 min., según el espectro de actividad deseado.

4. Aclarar cuidadosamente con agua estéril o filtrada (0,2 µm) antes de volver a utilizarlo.

5. Antes de almacenar, secar los dispositivos mediante aire médico sobre una superficie seca limpiada previamente

- El envase debe conservarse bien cerrado, a una temperatura entre +4°C y +30°C, protegido del sol y la humedad.
- El periodo de validez es de 2 años.
- Volver a cerrar el envase lo antes posible después del uso para conservar las cualidades, propiedades y características de exeol strips OPA.

- Plazo de conservación después de la apertura: hasta la fecha de caducidad.

Instrucciones de uso de exeol strips OPA

1. Sumergir la tira de control exeol strips OPA durante 1 segundo en exeol OPA.
2. Sacudir ligeramente la tira de inmediato para eliminar el exceso de líquido.
3. Exactamente 60 segundos después de la extracción de exeol OPA, observar el color del área de prueba y compararlo con la imagen de referencia de abajo. Nunca se debe interpretar el color antes de 60 segundos (1 minuto) después de la extracción

Color del indicador: rosa uniforme (de manera ocasional pueden observarse pequeñas manchas blancas)
Color del indicador: rosa con manchas blancas

La tira exeol strips OPA es sensible y específica al 100 %, siempre que se cumplan las instrucciones de uso.

7. Material de envase (Presentación).

Empaque Primario: Bidón 5L, Tubo 50 tiras de control exeol strips OPA

Empaque secundario: Caja 4 x 5L

Empaque terciario: NA.

8. Datos del fabricante.

Sodel

190 rue René Barthélemy 14100 Lisieux, France.

Tel: +33 (0)2 31 31 10 50

www.exeol.fr

9. Datos del importador.

Alkamedica ® Parque industrial Juanchito terraza 6 bodega B Manizales. Colombia.

Tel.: (606) 863 2740

Email: direcciontecnica@alkamedica.com

exeol OPA
Desinfectante de alto nivel

Abril 2024

Dossier de registro Dispositivos Médicos

Colombia

ALKAMEDICA

Sodel
190 rue René Barthélemy
14100 Lisieux, France.
TEL: +33 (0)2 31 31 10 50
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SANTÉ exeol
UNE DIVISION SODEL

exeol OPA

Desinfectante de alto nivel

INDICE

exeol OPA

Desinfectante de alto nivel

- Solución lista para usar a base de ortoftalaldehído para la desinfección final por inmersión de dispositivos médicos termosensibles reutilizables, semicríticos y críticos, invasivos y no invasivos previamente limpiados.

Instrucciones de uso

SANTÉ exeol
UNA DIVISIÓN DE SODEL

Sodel
190 rue René Barthélemy
14100 Lisieux, France.
TEL: +33 (0)2 31 31 10 50
www.exeol.fr

Para recibir las notificaciones de la actualización del dossier del producto, regístrese en nuestro sitio web con este código QR.

Los informes de ensayos que se mencionan a continuación, así como la ficha de datos de seguridad (FDS) se suministran por separado previa solicitud.

Tabla de contenidos

Significado de los símbolos utilizados en la documentación

Símbolo / Pictograma	Significado
exeol OPA:	
CE 0459	Especifica que el dispositivo médico comercializado por Sodel cumple con el Reglamento (UE) 2017/745 y que la documentación técnica ha sido evaluada por el organismo notificado GMED (0459)
MD	Especifica que el producto es un dispositivo médico
REF	Especifica la referencia de catálogo del producto
LOT	Indica el Número de lote del producto
	Identifica el fabricante/responsable de la comercialización y sus datos de contacto
	Indica la fecha de caducidad
	Señala un dispositivo sensible a la humedad
	Indica que el producto debe conservarse entre 5°C y 25°C
	Indica que el producto es listo para usar
	Indica la necesidad de usar tiras de control para comprobar la estabilidad del baño durante el uso
	Indica una utilización mediante remojo manual / inmersión
	Indica que es obligatorio llevar guantes de protección

Símbolo / Pictograma	Significado
exeol strips OPA:	
	Expresa un número de unidades (50 tiras en este caso)

Símbolo / Pictograma	Significado
	Indica que el producto debe conservarse entre 4°C y 30°C
	Señala un dispositivo sensible a la humedad

Presentación

Ámbito de uso

- **exeol OPA** está previsto para la desinfección final por inmersión de dispositivos médicos termosensibles reutilizables, semicríticos y críticos, invasivos y no invasivos previamente limpiados.
- Los dispositivos médicos reutilizables que se pueden retratar con **exeol OPA** son, por ejemplo: equipos de diálisis, endoscopios semicríticos (colonoscopios, gastroscopios, broncoscopios, etc.) y endoscopios críticos (coledoscopios, cistoscopios, ureteroscopios, etc.).

Usuarios destinatarios

- Utilización exclusiva por profesionales sanitarios en hospitales o entornos similares y en el contexto del reprocesamiento de dispositivos médicos reutilizables según las recomendaciones de sus fabricantes. Estos usuarios están formados en el uso de productos higiénicos por profesionales con conocimientos adquiridos mediante un diploma adecuado.

Ventajas del producto

- Solución lista para usar.
- Control de la validez del baño mediante tira de prueba (medición del nivel de ortoftalaldehído).
- Tiempo de contacto a partir de 10 minutos.
- Activo sobre las esporas de *Clostridium difficile*.
- Solución ligeramente perfumada.

Formatos comercializados

- Caja 4 x 5L: EXS0095
- Tubo 50 tiras de control **exeol strips OPA**:
  - AC0217

Accesorios adecuados y características

Accesorios suministrados por Sodel por pedido (no suministrados con la caja de 4x5L)

- Tubo 50 tiras de control **exeol strips OPA**:
  - AC0217

Estas tiras de control son específicas para la concentración de sustancia activa en la solución **exeol OPA**.

La tira **exeol strips OPA** es sensible y específica al 100 %, siempre que se cumplan las instrucciones de uso.

No utilizar otras tiras de control.

Accesorios utilizados por iniciativa de los usuarios

- Bandeja de remojo: de acero inoxidable o polipropileno o otros materiales analizados como compatibles o reconocidos como inertes (p. ej.: Corian); con cubierta; de preferencia graduada.

El usuario es el responsable de garantizar que el accesorio seleccionado es productivo y adecuado para el producto **exeol OPA** según la información del fabricante del accesorio, la información del fabricante del dispositivo médico reutilizable tratado y de la información proporcionada por Sodel.

Información reglamentaria

Informaciones según el Reglamento (UE) 2017/745 (sobre los dispositivos médicos)

- **exeol OPA** es un dispositivo médico de clase IIb.
- Marcado CE obtenido en 2023

  CE 0459

  MD
- Como dispositivo médico de clase IIb, el etiquetado y la documentación técnica de **exeol OPA** cumplen con los requisitos del anexo I del Reglamento (UE) 2017/745.
- Cualquier incidente grave relacionado con el dispositivo médico debería comunicarse a Sodel y a la autoridad competente del Estado miembro en el que estén establecidos el usuario y/o paciente.
- Beneficios clínicos (indirectos) esperados:
  - Prevención de las tasas de infecciones asociadas a la atención sanitaria y, en particular, las principales infecciones hospitalarias discapacitantes.
  - Uso con total seguridad de los dispositivos medicos reutilizables tras su reprocesamiento para reducir las rehospitalizaciones y los costes asociados.

Informaciones de trazabilidad

- **Para exeol OPA:**

  El etiquetado del producto indica el UDI, la referencia del producto, el número de lote y la fecha de caducidad de cada fabricación, de la siguiente manera :

UDI (01)EAN(17)AAMMDD(10)aSxxNzzzz

REF EXSXXXXxx

LOT aSxxNzzzz

AAAA-MM-DD

Para exeol strips OPA:

El etiquetado del producto indica el número de lote y la fecha de caducidad de cada fabricación, de la siguiente manera :

REF ACXXXX

LOT AARRR

AAAA-MM-DD

Definición de los datos detrazabilidad:

EXSXXXXxx = código artículo de**exeol OPA**:

- EXS = rango exeol santé;
- XXXX = número consecutivo;
- xx = código de idioma o país.

aSxxNzzzz = número de lote de **exeol OPA**:

- a = última cifra del año;
- Sxx = número de la semana;
- Nzzzz = número consecutivo.

ACXXXX = código artículo de **exeol strips OPA**:

- AC = Accesorios;
- XXXX = número consecutivo;

AARRR = número de lote de **exeol strips OPA**:

- AA = 2 últimas cifras del año;
- RRR = referencia interna.

AAAA-MM-DD = fecha de caducidad:

- AAAA = año;
- MM = mes;
- DD = día.

Definición de los datos del UDI (Datamatrix):

→ (01) = 0EAN13 o EAN14 o UDI-DI

→ (17) = fecha de caducidad:

- AA = 2 últimas cifras del año;
- MM = mes;
- DD = día.

→ (10) = número de lote:

- a = última cifra del año;

- Sxx = número de la semana;
- Nzzzz = número consecutivo.

- UDI-DI de **exeol OPA**:

Bidón 5L	:	• EXS0095CO: 03268240055601 • EXS0095MX: 03268240055618 • EXS0095PY: 03268240055625 • EXS0095UY: 03268240055632 • EXS0095VE: 03268240055649 • EXS0095PE: 03268240055656
Caja 4 x 5L	:	• EXS0095CO: 13268240055608 • EXS0095MX: 13268240055615 • EXS0095PY: 13268240055622 • EXS0095UY: 13268240055639 • EXS0095VE: 13268240055646 • EXS0095PE: 13268240055653

Informaciones según el Reglamento (CE) 1272/2008 (CLP)

- Utilizar guantes de manga larga.

- Consultar la ficha de datos de seguridad (FDS) disponible en www.exeol.fr

Uso

Instrucciones de uso de exeol OPA

- **exeol OPA** está listo para usar.

  exeol OPA se utiliza sin diluir en dispositivos médicos limpiados previamente.

- **exeol OPA** puede utilizarse durante un máximo de 14 días.

- Controlar regularmente la validez del baño con las tiras de control **exeol strips OPA**.

  Antes de usar **exeol OPA** realizar una limpieza previa o una limpieza mecánica completa y un aclarado intermedio de los dispositivos médicos que se van a tratar.

  Cuando se use por primera vez, retirar el anillo de inviolabilidad y luego desenroscar el tapón.

  1. Desenroscar el tapón del bidón y transvasar el contenido a la bandeja. Volver a cerrar el bidón después de su uso.
  2. Colocar los dispositivos médicos abiertos y desmontados en la solución y asegurarse de que estén totalmente sumergidos. Asegurar la irrigación de los canales si están presentes. Cubrir la bandeja.
  3. Tiempo de contacto: a partir de 10 min., según el espectro de actividad deseado.
  4. Aclarar cuidadosamente con agua estéril o filtrada (0,2 µm) antes de volver a utilizarlo.
  5. Antes de almacenar, secar los dispositivos mediante aire médico sobre una superficie seca limpiada previamente.

Instrucciones de uso de exeol strips OPA

1. Sumergir la tira de control **exeol strips OPA** durante 1 segundo en **exeol OPA**.
2. Sacudir ligeramente la tira de inmediato para eliminar el exceso de líquido.
3. Exactamente 60 segundos después de la extracción de **exeol OPA**, observar el color del área de prueba y compararlo con la imagen de referencia de abajo.

Nunca se debe interpretar el color antes de 60 segundos (1 minuto) después de la extracción.

 CONFORME

Color del indicador: rosa uniforme (de manera ocasional pueden observarse pequeñas manchas blancas)

 NO CONFORME

Color del indicador: rosa con manchas blancas

La tira **exeol strips OPA** es sensible y específica al 100 %, siempre que se cumplan las instrucciones de uso.

Precauciones

- Todas las informaciones relativas a la seguridad figuran en la ficha de datos de seguridad (FDS) que puede consultarse en el sitio web www.exeol.fr.
- Estas informaciones se encuentran en la etiqueta del producto **exeol OPA**:

  Contiene: o-Phthalaldehyde (OPA) (CAS: 643-79-8). Puede provocar una reacción alérgica. Nocivo para los organismos acuáticos, con efectos nocivos duraderos. Evitar su liberación al medio ambiente. En caso de irritación o erupción cutánea: Consultar a un médico. Eliminar el contenido y el recipiente en un punto de recogida de residuos peligrosos o especiales, de acuerdo con la normativa local.

Efectos secundarios indeseables

Para el usuario:

- Puede provocar una coloración de la piel en caso de contacto con la piel.
- Puede provocar una reacción alérgica.

Para el paciente:

- La presencia de residuos de ortoftalaldehído en el dispositivo médico reutilizable expone al paciente a una reacción alérgica que puede llegar al choque anafiláctico.

Restricciones/Advertencias

Restricciones de uso

- No mezclar con otros productos.
- No utilizar directamente sobre el paciente.
- No usar en lavadora desinfectadora.
- No utilizar en dispositivos médicos que deban esterilizarse (no termosensibles).

Advertencias para el uso

- Conservar el recipiente bien cerrado, en su envase y etiquetado de origen.
- Utilizar guantes de manga larga para evitar el contacto con la piel.
- Antes de usar, comprobar la fecha de caducidad que figura en la etiqueta.
- Para el uso de **exeol OPA**, las cubetas deben limpiarse y aclararse cuidadosamente.
- Antes de cualquier utilización, controlar la validez del baño con las tiras de control **exeol strips OPA**.
- La solución de **exeol OPA** debe renovarse como máximo cada 14 días, o en cuanto la tira de control **exeol strips OPA** indique un resultado no conforme.
- En caso de duda sobre las instrucciones de uso, comuníquese con el servicio comercial.
- En caso de duda sobre el aspecto de la solución (coloración o floculación) o de almacenamiento en condiciones ambientales no recomendadas, no utilizar la solución y eliminarla.
- No utilizar el dispositivo médico procesado si hay depósitos visibles, en tal caso, comuníquese con el servicio comercial.
- Los dispositivos médicos reutilizables deben enjuagarse a fondo después de la fase de desinfección por **exeol OPA** para evitar cualquier efecto secundario para el paciente.
- Si la etiqueta está dañada, aislar el bidón e informar al servicio comercial.

Manipulación - Puesta en servicio - Almacenamiento

Para exeol OPA:

- El envase debe conservarse bien cerrado, a una temperatura entre +5°C y +25°C, en un lugar bien ventilado.
- Si el producto se encuentra, en condiciones accidentales, cerca de una fuente intensa de calor durante largo tiempo, es preferible no reutilizarlo, ya que podría ser degradado en sus cualidades, propiedades y características.
- La caducidad del producto antes de abrirlo es de 2 años a partir de la fecha de fabricación cuando **exeol OPA** se conserva de conformidad en las condiciones descritas anteriormente y en la ficha de datos de seguridad disponible en www.exeol.fr:

	**Fecha de caducidad**
	2 años después de la fecha de fabricación, indicada en la etiqueta del siguiente modo: AAAA-MM-DD (Año-Mes-Día)

- Volver a cerrar el envase lo antes posible después del uso para conservar las cualidades, propiedades y características de **exeol OPA**.
- Plazo de conservación después de la apertura: 6 meses.

Para exeol strips OPA:

- El envase debe conservarse bien cerrado, a una temperatura entre +4°C y +30°C, protegido del sol y la humedad.
- El periodo de validez es de 2 años.
- Volver a cerrar el envase lo antes posible después del uso para conservar las cualidades, propiedades y características de **exeol strips OPA**.
- Plazo de conservación después de la apertura: hasta la fecha de caducidad.

Dispersión accidental - Eliminación

Eliminación del recipiente

- Vaciar el recipiente por completo sin aclarar.
- Conservar la etiqueta en el envase.
- Eliminar de acuerdo con la normativa oficial. Evitar su liberación en el medio ambiente.
- Los residuos deben gestionarse sin poner en peligro la salud humana ni perjudicar el medio ambiente y, en particular, sin crear ningún riesgo para el agua, el aire, el suelo, la fauna o la flora.

Eliminación de residuos

- Eliminar de acuerdo con la normativa oficial. Evitar la entrada en sistemas de agua pluviales o cursos de agua. Evitar su liberación en el medio ambiente.
- Los residuos deben gestionarse sin poner en peligro la salud humana ni perjudicar el medio ambiente y, en particular, sin crear ningún riesgo para el agua, el aire, el suelo, la fauna o la flora.

Eliminación del baño

- La eliminación de los líquidos residuales debe hacerse conforme a las leyes en vigor y sin poner en peligro la salud humana ni perjudicar el medio ambiente y, en particular, sin crear ningún riesgo para el agua, el aire, el suelo, la fauna o la flora. Como tal, el baño puede eliminarse en el sistema de tratamiento de aguas residuales de un hospital. No obstante, cabe señalar que el hospital es plenamente responsable de sus aguas residuales y debe garantizar la compatibilidad de sus aguas residuales globales con su desagüe de rechazo (estación depuradora) y según la orden prefectoral vigente (autorización de explotación).

Eliminación del tubo de 50 tiras exeol strips OPA

- Eliminar de acuerdo con la normativa oficial. Evitar su liberación en el medio ambiente.
- Los residuos deben gestionarse sin poner en peligro la salud humana ni perjudicar el medio ambiente y, en particular, sin crear ningún riesgo para el agua, el aire, el suelo, la fauna o la flora.

Toxicovigilancia

- La fórmula de **exeol OPA** se encuentra registrada en el portal del Servicio de Información Toxicológica europeo (PCN).
- Código UFI para comunicar a los Centros de Información Toxicológica:

UFI: NW49-107C-K00T-QXET

Datos fisicoquímicos

Composición

- o-Phthalaldehyde (OPA) al 0,55 % y excipientes.

Características fisicoquímicas

- pH: 7 - 8
- Perfume*: Perfumado - Flor de algodón
- Color: Azul

**Perfume sintético*

Datos microbiológicos

exeol OPA es bactericida, fungicida, micobactericida, virucida, esporicida contra *Clostridium difficile* y esporicida.

Ensayos de determinación de la actividad bactericida

Norma NF EN 13727+A2 (diciembre 2015)

Condiciones de ensayo	
Cepa(s):	*Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae*
Sustancias(s) interferente(s):	Condiciones de limpieza (0,3 g/L de albúmina bovina)
Tiempo de contacto:	5 minutos ± 10 segundos
Temperaturas:	20±1 °C

Informe: 22-1886

Conclusión: Para el producto **exeol OPA**, la concentración bactericida para productos de desinfección de dispositivos médicos, determinada de conformidad con la norma NF EN 13727+A2 (diciembre 2015), en las condiciones obligatorias, tras 5 minutos de contacto a 20°C, en condiciones de limpieza (0,3 g/L de albúmina bovina), sobre tres cepas de prueba, *Staphylococcus aureus* CIP 4.83, *Pseudomonas aeruginosa* CIP 103467 y *Enterococcus hirae* CIP 58.55, es del 50% (v/v).

Norma NF EN 14561 (marzo 2007)

Condiciones de ensayo	
Cepa(s):	*Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae*
Sustancias(s) interferente(s):	Condiciones de limpieza (0,3 g/L de albúmina bovina)
Tiempo de contacto:	5 minutos ± 10 segundos
Temperaturas:	20±1 °C

Informe: 22-1888M (FR) & 22-1888 (EN)

Conclusión: Para el producto **exeol OPA**, la concentración bactericida, para las necesidades específicas, determinada conforme a la norma NF EN 14561 (marzo 2007) a 20 °C, con un tiempo de contacto de 5 minutos, en condiciones de limpieza (0,3g/L de albúmina bovina), sobre las cepas

de *Staphylococcus aureus* CIP 4.83, *Pseudomonas aeruginosa* CIP 103467 y *Enterococcus hirae* CIP 58.55, es del 50% (v/v).

Ensayos de determinación de la actividad fungicida

Norma NF EN 13624 (noviembre 2021)

Condiciones de ensayo	
Cepa(s):	*Candida albicans*, *Aspergillus brasiliensis*
Sustancias(s) interferente(s):	Condiciones de limpieza (0,3 g/L de albúmina bovina)
Tiempo de contacto:	5 minutos ± 10 segundos
Temperaturas:	20±1 °C

Informe: 23-2082

Conclusión: Para el producto **exeol OPA**,

- la concentración fungicida para productos de desinfección de instrumentos, determinada según la norma NF EN 13624 (noviembre 2021), en las condiciones obligatorias, tras 5 minutos de contacto a 20 °C, en condiciones de limpieza (0,3 g/L de albúmina bovina), con respecto a *Candida albicans* DSM 1386 y *Aspergillus brasiliensis* CBS 733.88, es del 70 % (v/v).
- la concentración levuricida para productos de desinfección de instrumentos, determinada según la norma NF EN 13624 (noviembre 2021), en las condiciones obligatorias, tras 5 minutos de contacto a 20 °C, en condiciones de limpieza (0,3 g/L de albúmina bovina), con respecto a *Candida albicans* DSM 1386 es del 70 % (v/v).

Norma NF EN 14562 (septiembre 2006)

Condiciones de ensayo	
Cepa(s):	*Candida albicans*, *Aspergillus brasiliensis*
Sustancias(s) interferente(s):	Condiciones de limpieza (0,3 g/L de albúmina bovina)
Tiempo de contacto:	5 minutos ± 10 segundos
Temperaturas:	20±1 °C

Informe: 22-1930

Conclusión: Para el producto **exeol OPA**,

- la concentración fungicida, para las necesidades específicas, conforme a la norma NF EN 14562 (septiembre 2006) a 20 °C, con un tiempo de contacto de 5 minutos, en condiciones de limpieza (0,3g/L de albúmina bovina), sobre las cepas de *Candida albicans* DSM 1386 y *Aspergillus brasiliensis* CBS 733.88, es del 70% (v/v).
- la concentración levuricida, para las necesidades específicas, determinada conforme a la norma NF EN 14562 (septiembre 2006) a 20 °C, con un tiempo de contacto de 5 minutos, en

condiciones de limpieza (0,3 g/L de albúmina bovina), sobre la cepa de *Candida albicans* DSM 1386, es del 70% (v/v).

Ensayos de determinación de la actividad micobactericida

Norma EN 14348 (enero 2005)

Condiciones de ensayo	
Cepa(s):	*Mycobacterium terrae*, *Mycobacterium avium*
Sustancias(s) interferente(s):	Condiciones de limpieza (0,3 g/L de albúmina bovina)
Tiempo de contacto:	5 minutos
Temperaturas:	20±1 °C

Informe: VX-TR-23-0003

Conclusión: exeol OPA ha mostrado la reducción microbiana necesaria de ≥4,0 $\log_{10}$ contra las cepas del ensayo *Mycobacterium avium* ATCC 15769 y *Mycobacterium terrae* ATCC 15755 conforme a la norma EN 14348:2005 (E) a concentraciones del 70,00% y el 80,00% tras 5 y 10 minutos en las condiciones indicadas.

Norma EN 14563 (noviembre 2008)

Condiciones de ensayo	
Cepa(s):	*Mycobacterium terrae*, *Mycobacterium avium*
Sustancias(s) interferente(s):	Condiciones de limpieza (0,3 g/L de albúmina bovina)
Tiempo de contacto:	5 minutos
Temperaturas:	20±1 °C

Informe: VX-TR-23-0023

Conclusión: exeol OPA ha mostrado la reducción microbiana necesaria de ≥4,0 $\log_{10}$ contra las cepas del ensayo *Mycobacterium avium* ATCC 15769 y *Mycobacterium terrae* ATCC 15755 conforme a la norma EN 14563:2008 (E) a concentraciones del 70,00% y el 80,00% tras 5 y 10 minutos en las condiciones indicadas.

Ensayos de determinación de la actividad virucida

Norma EN 14476:2013+A2 (julio 2019) sobre Adenovirus, Norovirus y Poliovirus

Condiciones de ensayo	
Cepa(s):	Adenovirus tipo 5, Poliovirus tipo 1, Norovirus cepa S-99
Sustancias(s) interferente(s):	Condiciones de limpieza (0,3 g/L de albúmina bovina)
Tiempo de contacto:	10 minutos
Temperaturas:	20±1 °C

Informe: VX-TR-23-0457

Conclusión: exeol OPA ha mostrado la reducción vírica necesaria de ≥4,0 log10 contra las cepas del ensayo de adenovirus de tipo 5 ATCC VR-5, norovirus murino FLI-RVB-0651 y virus de la poliomielitis de tipo 1 NIBSC-01/528, conforme a la norma EN 14476:2013+A2: 2019 a concentraciones del 100,00 %* y el 70,00 %, tras 10 minutos en las condiciones indicadas.

Norma EN 17111 (octubre 2018) sobre Adenovirus, Norovirus

Condiciones de ensayo	
Cepa(s):	Adenovirus tipo 5, Norovirus cepa S-99
Sustancias(s) interferente(s):	Condiciones de limpieza (0,3 g/L de albúmina bovina)
Tiempo de contacto:	10 minutos
Temperaturas:	20±1 °C

Informe: VX-TR-23-0488

Conclusión: exeol OPA ha mostrado la reducción vírica necesaria de ≥4,0 log10 contra las cepas del ensayo adenovirus ATCC VR-5 y norovirus murino FLI-RVB-0651 conforme a la norma EN 17111:2018 (E) a concentraciones del 80,00 % y el 70,00 %, tras 10 minutos en las condiciones indicadas.

Ensayos de determinación de la actividad esporicida

Norma EN 17126 (diciembre 2018) sobre *Clostridium difficile*

Condiciones de ensayo	
Cepa(s):	*Clostridium difficile*
Sustancias(s) interferente(s):	Condiciones de limpieza (0,3 g/L de albúmina bovina)
Tiempo de contacto:	15 minutos
Temperaturas:	20±1 °C

Informe: VX-TR-23-0503

Conclusión: exeol OPA ha mostrado la reducción microbiana necesaria de ≥4,0 $\log_{10}$ contra la cepa del ensayo *Clostridium difficile* NCTC 13366 conforme a la norma EN 17126:2018 (E) a concentraciones del 70,00% y el 80,00% tras 15 y 30 minutos en las condiciones indicadas.

Norma EN 17126 (diciembre 2018)

Condiciones de ensayo	
Cepa(s):	*Bacillus cereus*, *Bacillus subtilis*
Sustancias(s) interferente(s):	Condiciones de limpieza (0,3 g/L de albúmina bovina)
Tiempo de contacto:	90 minutos
Temperaturas:	20±1 °C

Informe: 137D57-2022-02

Conclusión: Según la norma EN 17126 (diciembre de 2018), el producto **exeol OPA** ha demostrado actividad esporicida sobre las cepas de referencia *Bacillus cereus* y *Bacillus subtilis* cuando se utiliza a una concentración del 80%, durante un tiempo de contacto de 90 minutos, a 20°C, en condiciones de limpieza (0,3 g/L de albúmina bovina).

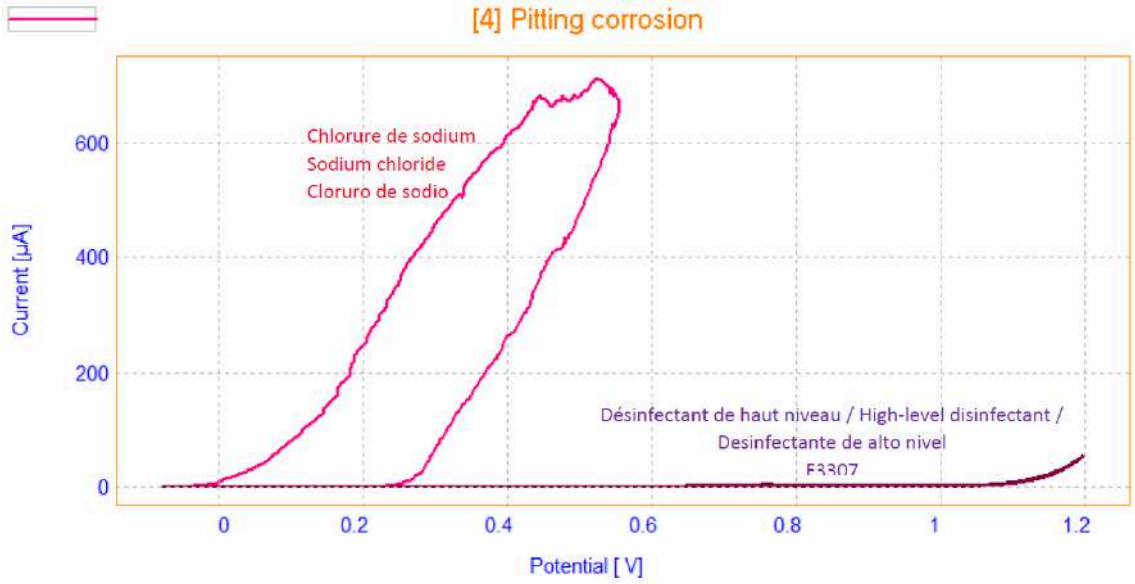
Datos de compatibilidad

Estudio de la acción corrosiva (electroquímica) según la norma NF S94-402-1 (mayo 2004)

Informe: RPELEC2022_F3307_006 (2022-04-28)

Objeto del estudio: Evaluación mediante la técnica electroquímica del poder corrosivo por picadura de un producto sobre el acero inoxidable, que s el material del que están hechos los instrumentos médicoquirúrgicos metálicos reutilizables. La técnica electroquímica es una técnica potenciodinámica que consiste en hacer variar linealmente el potencial del electrodo de trabajo en función del tiempo dentro de un intervalo de potencial definido, para determinar los potenciales de picadura y de repasivación del producto analizado.

Parámetros	Desinfectante de alto nivel exeol OPA	Solución de cloruro de sodio (control negativo)
Potencial de picadura	*1109 mV*	*256 mV*
Potencial de repasivación	*1088 mV*	*39 mV*



Conclusión: Los valores de picadura (1109 mV) y de repasivación (1088 mV) obtenidos para el desinfectante de alto nivel F3307 demuestran que este producto no es corrosivo sobre el acero inoxidable, material del que están hechos los instrumentos médico-quirúrgicos metálicos reutilizables. Hay dos parámetros que permiten confirmar este resultado: los valores de los

potenciales de picadura y de repasivación muy electropositivos en comparación con el cloruro de sodio. Cabe señalar que, debido a una respuesta electroquímica totalmente inerte del desinfectante F3307, en comparación con la solución de cloruro de sodio, su curva electroquímica tiene un aspecto plano.

Evaluación de la compatibilidad con el policarbonato mediante Stress cracking

Informe: RPCRAC2022_F3307_003 (2022-05-03)

Objeto del estudio: La caracterización de la compatibilidad de un producto con el policarbonato se lleva a cabo mediante la aplicación de tensión física y el posterior remojo de las probetas de policarbonato en una solución del producto a analizar a su concentración de empleo durante un tiempo de contacto definido. La evaluación de la compatibilidad se realiza comparando con controles/productos de referencia neutros para el policarbonato (control negativo y/o líderes del mercado definidos) y un control positivo (etanol puro) no compatible con el policarbonato.

Conclusión: El desinfectante de alto nivel F3307 no es compatible con el policarbonato, ya que presenta un comportamiento idéntico al control positivo (etanol) y al control comparativo, líder del mercado, para una misma aplicación.

exeol OPA

Desinfectante de alto nivel

Solución lista para usar a base de ortoftalaldehído para la desinfección final por inmersión de dispositivos médicos termosensibles reutilizables, semicríticos y críticos, invasivos y no invasivos previamente limpiados.

- **Solución lista para usar.**
- **Control de la validez del baño mediante tira de prueba (medición del nivel de ortoftalaldehído).**
- **Tiempo de contacto a partir de 10 minutos.**
- **Activo sobre las esporas de *Clostridium difficile*.**
- **Solución ligeramente perfumada.**

INSTRUMENTOS ENDOSCOPIA

PRODUCTO

ALTO NIVEL

PH NEUTRO

BUENAS PRÁCTICAS

LISTO PARA USAR

REMOJO MANUAL

TIRAS DE PRUEBA

Instrucciones de uso

- **exeol OPA** está listo para usar.
- **exeol OPA** se utiliza sin diluir en dispositivos médicos limpiados previamente.
- **exeol OPA** puede utilizarse durante un máximo de 14 días.

Controlar regularmente la validez del baño con las tiras de control **exeol strips OPA**.

Antes de usar **exeol OPA** realizar una limpieza previa o una limpieza mecánica completa, y un aclarado intermedio de los dispositivos médicos que se van a tratar.

Cuando se use por primera vez, retirar el anillo de inviolabilidad y luego desenroscar el tapón.

1. Desenroscar el tapón del bidón y transvasar el contenido a la bandeja. Volver a cerrar el bidón después de su uso.

2. Colocar los dispositivos médicos abiertos y desmontados en la solución y asegurarse de que estén totalmente sumergidos. Asegurar la irrigación de los canales si están presentes. Cubrir la bandeja.

3. Tiempo de contacto: a partir de 10 min., según el espectro de actividad deseado.

4. Aclarar cuidadosamente con agua estéril o filtrada (0,2 µm) antes de volver a utilizarlo.

5. Antes de almacenar, secar los dispositivos mediante aire médico sobre una superficie seca limpiada previamente.

exeol strips OPA:

1. Sumergir la tira de control **exeol strips OPA** durante 1 segundo en **exeol OPA**.

2. Sacudir ligeramente la tira de inmediato para eliminar el exceso de líquido.

3. Exactamente 60 segundos después de la extracción de **exeol OPA**, observar el color del área de prueba y compararlo con la imagen de referencia en el envase.

Nunca se debe interpretar el color antes de 60 segundos (1 minuto) después de la extracción.

La tira **exeol strips OPA** es sensible y específica al 100 %, siempre que se cumplan las instrucciones de uso.

Archivo del producto disponible en www.exeol.fr

DM de clase IIb

Marcado CE obtenido en 2023.

CE 0459

MD

SANTÉ exeol
UNA DIVISIÓN DE SODEL

exeol OPA

Desinfectante de alto nivel

Propiedades microbiológicas

Condiciones de limpieza, listo para usar, 20°C:

	ENSAYOS	CEPAS	TIEMPO DE CONTACTO
Bactericida	EN 13727 EN 14561	*Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae*	5 min.
Fungicida	EN 13624 EN 14562	*Candida albicans, Aspergillus brasiliensis*	5 min.
Micobactericida	EN 14348 EN 14563	*Mycobacterium terrae, Mycobacterium avium*	5 min.
Virucida	EN 14476	Poliovirus, Adenovirus, Norovirus	10 min.
	EN 17111	Adenovirus, Norovirus	
Esporicide contra *Clostridium difficile*	EN 17126	*Clostridium difficile*	15 min.
Esporicida	EN 17126	*Bacillus subtilis, Bacillus cereus*	90 min.

Presentación comercial

- Caja 4 x 5L: EXS0095
- Tubo 50 tiras de control **exeol strips OPA**: AC0217

Composición	Características	Precauciones
o-Phthalaldehyde (OPA) al 0,55% y excipientes.	▪ pH: 7 - 8 ▪ Perfume*: Perfumado - Flor de algodón ▪ Color: Azul *Perfume sintético	Lea siempre la etiqueta y la información sobre el producto antes de usarlo. **UFI : NW49-107C-K00T-QXET**

SOLO PARA USO PROFESIONAL

FABRICADO EN FRANCIA

Sodel
190 rue René Barthélemy
14100 Lisieux, France.
TEL: +33 (0)2 31 31 10 50
www.exeol.fr

SANTÉ exeol
UNA DIVISIÓN DE SODEL

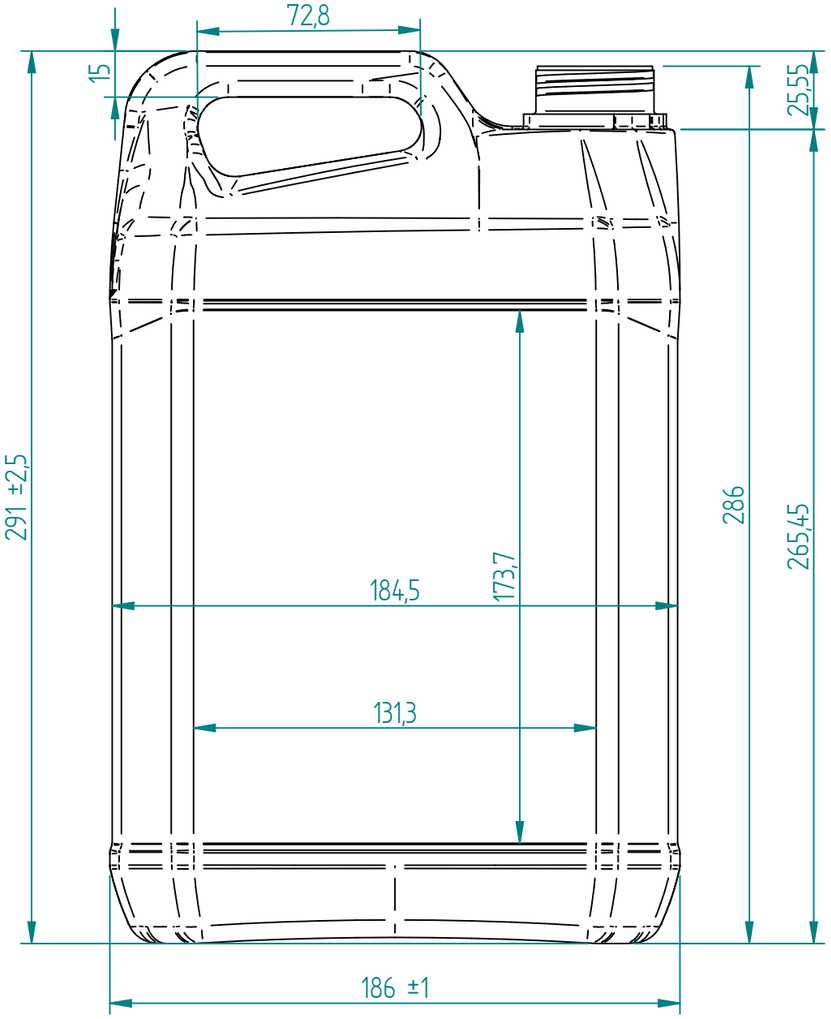
FT-EXEOL OPA-ES AM LAT-00.1_AAAA-MM

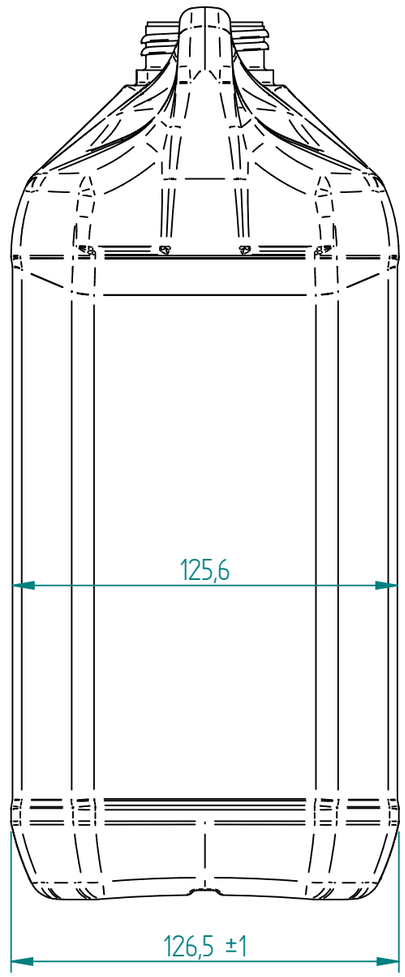
exeol OPA

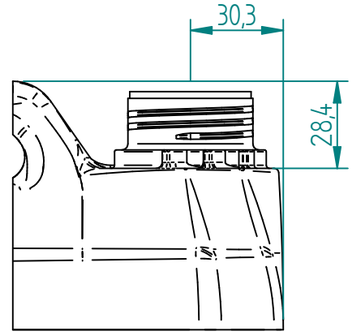

exeol OPA
Désinfectant de haut niveau
Solution prête à l'emploi à base d'orthophtalaldéhyde pour la désinfection finale par immersion des dispositifs médicaux réutilisables thermosensibles invasifs et non-invasifs préalablement nettoyés.
Propriétés microbiologiques
Conditions de propreté, prêt à l'emploi, 20°C:
Bactéricide (5 min.): EN 13727, EN 14561.
Fongicide (5 min.): EN 13624, EN 14562.
Mycobactéricide (10 min.): EN 14348, EN 14563.
Virucide (10 min.): EN 14476, EN 17111.
Sporicide contre Clostridium difficile (15 min.): EN 17126.
Sporicide (90 min.): EN 17126.
Mode d'emploi
exeol OPA est prêt à l'emploi.
exeol OPA s'utilise non dilué sur des dispositifs médicaux préalablement nettoyés.
exeol OPA est utilisable pendant 14 jours maximum.
exeol OPA est utilisable pendant la validité du pack avec les bandelettes de contrôle exeol strips OPA. Avant l'utilisation de exeol OPA, contrôler régulièrement la validité du pack avec les bandelettes de contrôle exeol strips OPA.
Contrôler régulièrement le nettoyage mécanique complet et un pré-nettoyage ou un nettoyage mécanique à traiter.
réaliser un pré-nettoyage des dispositifs médicaux à traiter.
et un rinçage intermédiaire des dispositifs médicaux à traiter.
Lors de la première utilisation, retirer la bague d'inviolabilité puis dévisser le bouchon. 1. Dévisser le bouchon du bidon et transvaser le contenu dans le bac. Refermer le bidon après utilisation. 2. Placer les dispositifs médicaux ouverts, et démontés dans la solution en s'assurant qu'ils soient complètement immergés. 3. Temps de contact : dès 10 min, présents. Couvrir le bac. Assurer l'irrigation des canaux si selon le spectre d'activité recherché. 4. Rincer soigneusement avec de l'eau stérile ou filtrée (0,2µm) avant réutilisation. 5. Avant stockage, sécher les dispositifs à l'air médical sur une surface sèche préalablement nettoyée.
UNIQUEMENT À USAGE PROFESSIONNEL
INSTRUMENTS ENDOSCOPIE
5L
CE 0459
MD
SANTÉ exeol


exeol OPA
Composition
o-Phtalaldéhyde (OPA) 0,54% et excipients.
Précautions
Contient: o-Phtalaldéhyde (OPA) (CAS: 643-79-8). Peut produire une réaction allergique. Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme. Éviter le rejet dans l'environnement. En cas d'irritation ou d'éruption cutanée: consulter un médecin. Éliminer le contenu et le récipient dans un centre de collecte de déchets dangereux ou spéciaux, conformément à la réglementation locales.
Utiliser des gants à manchettes longues. Ne pas mélanger à d'autres produits. Avant toute utilisation, vérifier la date de péremption figurant sur l'étiquette. Tout incident grave survenu en lien avec le dispositif médical doit faire l'objet d'une notification à Sodel et à l'autorité compétente de l'État membre dans lequel l'utilisateur et/ou le patient est établi. Dossier produit disponible sur www.exeol.fr
Marquage CE obtenu en 202X.
UFI: NW49-107C-K00T-QXET
FABRIQUÉ EN FRANCE
SANTÉ exeol
UDI (01) EAN13(10)XSXXNZZZZ(17)YYMMDD
REF EXSXXXXXXX
LOT XSXXNZZZZ
YYYY-MM-DD

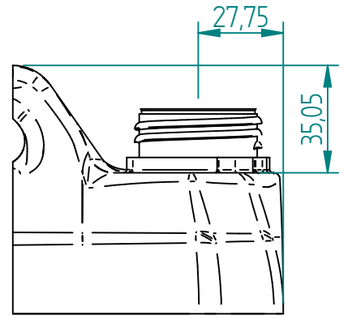
exeol OPA



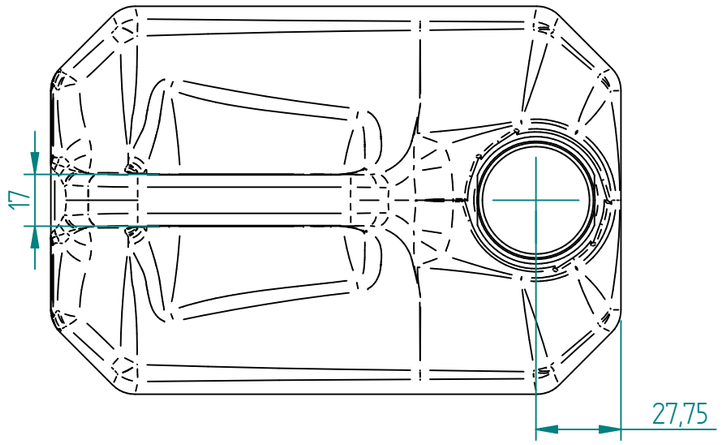


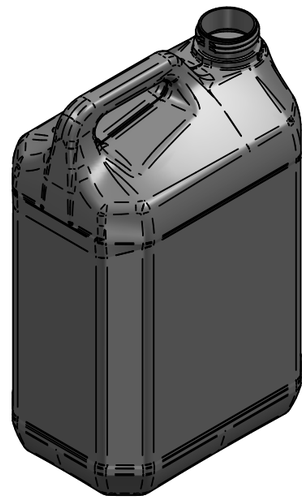


Col DIN 45



Col d42v





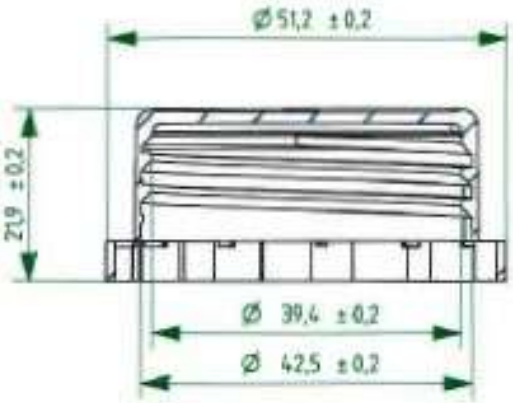
CT0135 PLAN JERRICAN 5L STYLE.pdf

Indice F	03/02/2020	Ajout Col DIN 45 + Col d42v
Indice E	06/01/2020	Modification pentes au dessus etiquette + ajout renfort PJ derrière goulot
Indice D	06/06/2019	Ajout galbe faces inférieures
Indice C	05/04/2019	Augmentation epaisseur arrière poignée
Indice B	28/09/2018	Ajout renffort pognée
Indice A	14/09/2018	Création

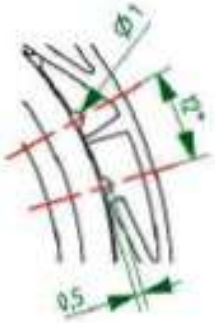
5L Style

Echelle 1/2		Matière : PEHD	Spécifications : Capacité :

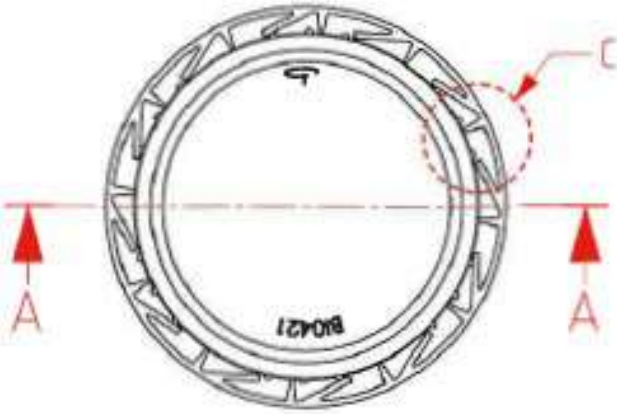
FE0080 PLAN SCREW CAP for CT0084.pdf



SECTION A-A



DETAIL C
SCALE 2:1



PRODUCT INFORMATION

THREAD: 1 start
Pitch: 4 mm
KNURLS: 18
LINER: See specification

SCALE 1:1

Drawing date: 14/01/2016 – Revision A

Checking Date: 21/07/2017

Product Specification

o-Phthalaldehyde Test Strips for Sodel

1. Description

Test strips for the determination of *o*-Phthalaldehyde in disinfectant solutions.

Presentation: 50 test strips per aluminum container with polyethylene desiccant stopper.

2. Technical Drawing

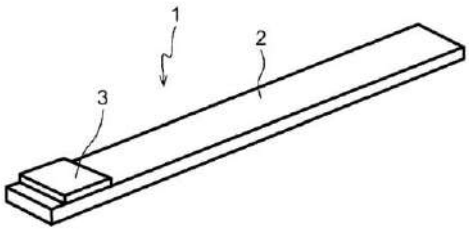


Figure 1: [1] Test strip; [2] Carrier foil, [3] Reactive test paper

Test strip dimension: 5.5 x 95 mm
Reactive test paper dimension: 5.5 x 5.0 mm

3. Test strip specification

Carrier material: PVC
Test paper material: Ultra Pure Paper (Cellulose)

Test paper composition: Phosphate buffer (< 1 % w/w)
Sodium sulfite (< 1 % w/w)
Phenolphthalein (< 0.01 % w/w)

4. Gradation

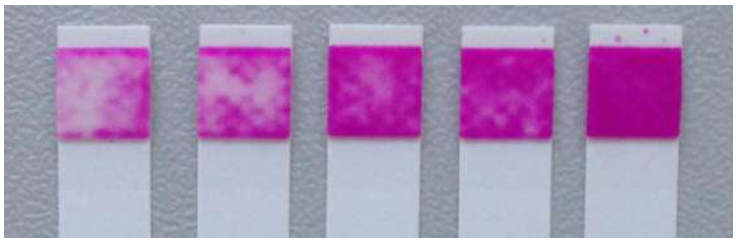


Figure 2: from left to right: 0.40 - 0.45 - 0.50 - 0.55 - 0.60% o-Phthalaldehyde (in original Sodel solution).

Evaluation:

≤0.40%	→	White test pad with pink spots
0.45%	→	White test pad with little pink spots
0.50%	→	Pink test pad with several white spots
0.55%	→	Pink test pad with little white spots
≥0.60%	→	Pink test pad without white spots (occasionally small white spots can be observed)

5. Test procedure

1. Dip test strip 1 s into the test solution.
2. Shake off gently to remove excess liquid.
3. After 60 seconds compare color to reference visuals on the label.

6. Chemical reaction principle

(1) $C_6H_4[CHO]_2 + 2\ Na_2SO_3 + 2\ H_2O \rightarrow C_6H_4[CH(SO_3Na)OH]_2 + 2\ NaOH$
(2) $2\ NaOH + Phenolphthalein \rightarrow 2\ Na^+ + Phenolphthalein^{2-}$ (pink color) $+ 2\ H_2O$

7. Shelf Life

2 years. No reduced shelf life after initial opening of the container.

8. Storage Temperature

4-30 °C.

9. Storage Conditions

Avoid exposing the test strips to sunlight and moisture.

Rapport de validation
d'une méthode analytique

VALIDATION DE METHODE ANALYTIQUE

SPECIFICITE ET SENSIBILITE

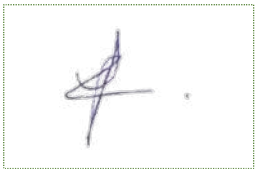
DES BANDELETTES UTILISEES POUR LA VERIFICATION

DES BAINS D'ORTHOPHTALALDEHYDE (F3307)

RAPPORT DE VALIDATION RPVALI2023_BAND_OPA_016

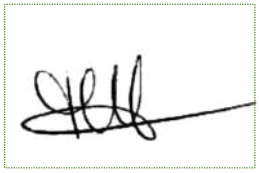
Rédigé par Cyrielle HOURNON ..... Le 12/10/2023..... Visa

Fonction : Responsable Chimie Analytique.....



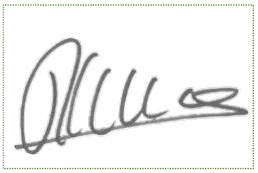
Vérifié par Marlène HORGNIES ..... Le 12/10/2023..... Visa

Fonction : Directrice Affaires Réglementaires et Microbiologie.....



Approuvé par Gaétan RAUWEL ..... Le 12/10/2023..... Visa

Fonction : Directeur Scientifique et Stratégie Produits .....



Sodel
HYGIÈNE · DÉSINFECTION · SURODORANTS

Rapport de validation d'une méthode analytique

HISTORIQUE DES MODIFICATIONS

Modification	Date	Description
/	12 oct 2023	Création

Rapport de validation d'une méthode analytique

ORGANISATION

Formule :	**F3307 (RD0209E36)** **Bandelettes OPA réf : 913814.141439**
Analyses	**Validation de la spécificité et de la sensibilité des bandelettes utilisées pour les bains d'orthophtalaldéhyde (OPA)**
Lieu des essais	**SODEL** 190 Rue René Barthélemy 14104 LISIEUX CEDEX FRANCE
Responsable de l'étude	HOURNON Cyrielle +33 (0)2 31 31 10 25 cyrielle.hournon@sodel-sa.eu
Directeur Scientifique et Stratégie produits	RAUWEL Gaétan +33 (0)7 83 16 40 67 gaetan.rauwel@sodel-sa.eu

Etape	Responsabilités
Réalisation des essais / Rapport de résultats / participation aux investigations	Technicien Chimie Analytique
Rédaction du rapport de validation / Vérification des résultats / Participation aux investigations	Responsable Chimie Analytique
Vérificateur du rapport de validation	Directrice Affaires Réglementaires et Microbiologie
Approbateur de l'étude	Directeur Scientifique et Stratégie Produits

Sodel
HYGIÈNE · DÉSINFECTION · SURODORANTS

Rapport de validation d'une méthode analytique

I. OBJECTIF ET DOMAINE D'APPLICATION

Ce rapport présente les résultats des essais réalisés pour valider la spécificité et la sensibilité des bandelettes de contrôle utilisées pour la vérification des bains d'orthophtalaldéhyde (F3307).

Les essais de validation réalisés sont décrits dans le protocole de validation PTVALI2023_BAND_OPA_016 approuvé le 05 octobre 2023.

Cette étude a été réalisée selon les référentiels suivants :

- Anses guide de validation des méthodes analytiques ANSES/PR3/07/01 version a (2015)
- SANCO/3030/99 rev 5 du 23/03/2019
- Procédure PM4.7 Validation de méthode d'analyse
- Mode opératoire MM4.27
- FM4.43 Protocole de validation PTVALI2023_BAND_OPA_016

II. DEFINITIONS

CLHP : Chromatographie Liquide haute performance. Technique analytique permettant la séparation, l'identification et le dosage de composés présents dans un mélange ; la séparation se fait par entraînement du produit dans une phase mobile liquide sur une phase stationnaire.

Phase mobile : Phase permettant l'entraînement du produit dissout dans un solvant le long de la phase stationnaire.

Phase stationnaire : phase traitée afin d'avoir une affinité avec les composés du mélange que l'on souhaite séparer. Dans le cas de la LC, il s'agit d'une colonne.

OPA : Orthophalaldéhyde (CAS#643-79-8)

III. PRINCIPE

Les essais de spécificité et de sensibilité des bandelettes utilisées dans le cadre de la vérification des bains d'OPA (F3307) ont été réalisées avec des solutions préalablement dosées.

La spécificité des bandelettes d'OPA a été vérifiée avec la solution de blanc de formulation afin de déterminer le pourcentage de vrais négatifs.

La sensibilité des bandelettes d'OPA a été vérifiée avec la solution échantillon de référence à 0,54% afin de déterminer le pourcentage de vrais positifs.

Pour chaque paramètre vérifié 10 bandelettes ont été testées.

IV. METHODE

1. BLANC DE FORMULATION ET ECHANTILLON

L'échantillon et le blanc de formulation ont été fabriqués par le service R&D de chez Sodel

Produit / lot	Date de fabrication	Date de peremption	Aspect	Conditionnement	Volume de l'échantillon
Echantillon (F3307) 0209E037231009C	9 octobre 2023	24 mois	Liquide bleu clair	Flacon en verre	100 mL
Blanc de formulation 0209E036231009]	9 octobre 2023	Not applicable	Liquide bleu clair	Flacon en verre	100 mL

2. SUBSTANCE DE REFERENCE ET BANDELETTES

Produit	fournisseur	Lot	Titre %	Date de péremption
Orthophtalaldéhyde	Sigma aldrich	Réf : P1378 BCCF5794	98,0	Janvier 2025
Bandelettes OPA	Macherey Nagel	réf : 913814.141439 lot 41102	/	/

3. REAGENTS/SOLVENTS/MATERIAL

Solvant/materiel	Fournisseur / référence	Qualité / Lot	Date de péremption
Acétonitrile	VWR Ref: 20060.42	HPLC grade Batch :23A114009	10 janvier 2026
Filtre PTFE	PALL Réf : 4501T	Batch : 14399447A	Non applicable

4. EQUIPEMENTS

Equipement	Marque	Internal number
Balance	Radwag	BAL046 Vérification date : 07/2023

Equipement CLHP	Système
Marque	Shimadzu system (LC-2050C)
Pompe et auto injecteur détecteur, four	Bloc chromatographique numéro de série : L22976150275
Software pour l'acquisition et le traitement	LabSolutions, Version 5.117 Licence : L54756100574

Type de colonne	Numéro interne	Numéro fournisseur
HyPURITY C18 25 cm x 4,6mm; 5µm	LC01	Numéro de série : 20338301 Marque : Thermoscientific

V. VALIDATION

1. Dosage de l'OPA dans l'échantillon

But

Le but de cet essai est de démonter l'absence d'OPA dans la solution blanc de formulation et de déterminer la concentration en OPA dans la solution échantillon utilisée pour lire les bandelettes d'OPA.

Conformité de système

En prérequis à l'analyse de l'OPA, une vérification de la conformité de système a été réalisée sur le système chromatographique.

Un test de précision, le CV sur les aires de l'orthophtalaldéhyde des 5 premières injections du Témoin 1 doit être ≤ 2.0 %
Un test d'exactitude des témoins ≤ 2,0%
Test de reproductibilité du système, le CV sur les aires de l'OPA de l'ensemble des témoins de la séquence (T1 et T2 rapporté à MT1) doit être ≤ 2,5 %.

Date d'analyse	Test	Temps de rétention (min)	Précision du système (≤ 2.0%)	Exactitude du système (≤ 2.0%)	Reproductibilité RSD % (≤ 2.5%)
09 octobre 2023	Vérification de la teneur en OPA dans l'échantillon et absence d' OPA dans le blanc de formulation	9,734	0,1%	0,7%	0,3%

Résultats

La solution blanc de formulation ne présente aucun pic au temps de rétention de l'OPA.

Echantillon Lot 0209E037231009C	Masse de l'échantillon en g	Surface OPA	Teneur en OPA % (m/m)
Sample 1	0,9032	9831079	0,54
Sample 2	0,9197	10106505	0,55
Ecart entre les 2 determinations (≤ 2,0%)			1,0
Moyenne entre les 2 déterminations en % (m/m)			0,54

2. Spécificité

But

La spécificité d'une procédure analytique est sa capacité à permettre l'évaluation univoque de la substance à analyser, en présence de composés susceptibles de l'accompagner. Ces composés comprennent typiquement, la matrice, les impuretés…. Il s'agit de retrouver de façon significative les résultats positifs dans les objets d'essai conçus par le laboratoire pour être négatifs ou positifs. La spécificité vise à évaluer la capacité de la méthode soumise à validation à ne pas donner de réponse quand la cible n'est pas présente.

Protocole :

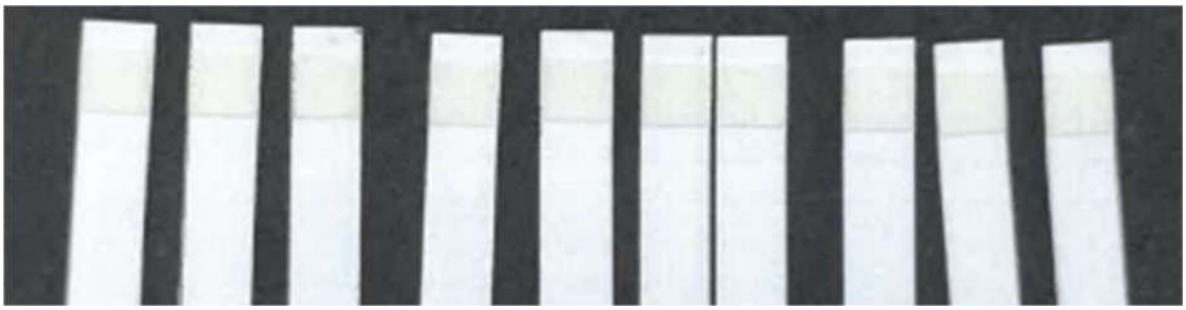
Les bandelettes ont été immergées pendant 1 seconde dans la solution blanc de formulation. L'excès du liquide a été éliminé en secouant les bandelettes.

Les bandelettes ont été lues à 60 secondes.

Interprétation : Une bandelette rose uniforme affiche un résultat positif tandis qu'une bandelette blanche ou rose avec des tâches blanche affiche un résultat négatif.

Résultats sur 10 bandelettes :

Photos des 10 bandelettes testées



Les bandelettes sont toutes de couleur blanche, elles présentent un résultat négatif.

Exploitation des résultats :

Les 10 bandelettes testées indiquent un vrai résultat négatif.

Le pourcentage de spécificité avec la solution blanc de formulation est de 100%.

3. Sensibilité

But

La sensibilité correspond au pourcentage de résultats positifs trouvés parmi les résultats positifs attendus. Dans tous les cas, la sensibilité vise à évaluer la capacité de la méthode soumise à validation à donner une réponse positive quand la cible est présente.

Protocole :

Les bandelettes ont été immergées pendant 1 seconde dans la solution échantillon à 0,54% d'OPA. L'excès du liquide a été éliminé en secouant les bandelettes.

Les bandelettes ont été lues à 60 secondes.

Interprétation : Une bandelette rose uniforme affiche un résultat positif tandis qu'une bandelette blanche ou rose avec des tâches blanche affiche un résultat négatif.

Résultats sur 10 bandelettes :

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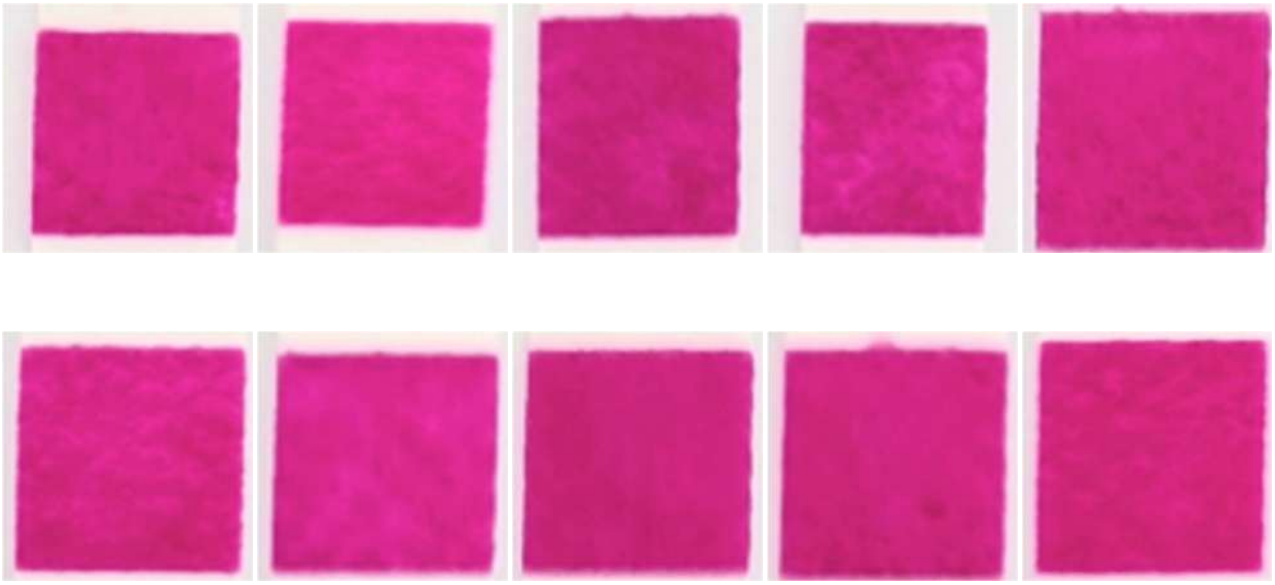


Les bandelettes sont toutes de couleur rose, elles présentent un résultat positif.

Exploitation des résultats :

Les 10 bandelettes testées indiquent un vrai résultat positif.
Le pourcentage de sensibilité avec la solution échantillon à 0,54 % d'OPA est de 100%.

VI. CONCLUSION

Résumé des résultats obtenus

	Solution échantillon d'OPA à 0,54%	**Solution blanc de formulation**
Test positif	Vrai Positif = VP **Résultat 10**	Faux Positif = FP Résultat 0
Test négatif	Faux Négatif = FN **Résultat 0**	Vrai Négatif = VN **Résultat 10**
Somme	VP + FN = N+ **N+ = 10**	FP + VN = N- **N- = 10**

Le pourcentage de spécificité des bandelettes d'OPA est de 100%
Le pourcentage de sensibilité des bandelettes d'OPA est de 100%.

VII. ARCHIVES

Le protocole, le rapport et les données brutes de ces essais de validation seront conservés au moins 10 ans.

VIII. REFERENCES AND DONNEES BRUTES

Test	**Technicien**	**Cahier de laboratoire**	**Pages**	**Commentaires**
Dosage de l'OPA 10 octobre 2023	Marion Darras	03	148 à 150	/
Specificité 11 octobre 2023			150	/
Sensibilité 11 octobre 2023			156	/

exeol strips OPA

Bandelettes de contrôle
Strips control

FR Bandelettes de contrôle du taux de o-Phtalaldéhyde (OPA) pour la solution **exeol OPA.**

1. Immerger la bandelette de contrôle **exeol strips OPA** pendant 1 seconde dans **exeol OPA**.
2. Secouer immédiatement et légèrement la bandelette pour éliminer l'excédent de liquide.
3. Exactement 60 secondes après le retrait de **exeol OPA**, observer la couleur de la zone test et la comparer aux visuels de référence ci-dessous.
Ne jamais interpréter la couleur avant 60 secondes (1 minute) après le retrait.

EN O-Phthalaldehyde (OPA) test strips for **exeol OPA** solution.

1. Immerse the **exeol strips OPA** control strip for 1 second in **exeol OPA**.
2. Immediately shake the strip lightly to remove excess liquid.
3. Exactly 60 seconds after removing **exeol OPA**, observe the colour of the test area and compare it to the reference visuals below.
Never interpret color before 60 seconds (1 minute) after removal.

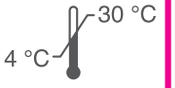
FR EN

CONFORME / COMPLIANT

Couleur de l'indicateur : rose uniforme (occasionnellement de petites tâches blanches peuvent être observées)
Indicator color: uniform pink (occasionally small white spots may be observed)
La bandelette **exeol strips OPA** est sensible et spécifique à 100%, si le mode d'emploi est respecté.

NON CONFORME / NON COMPLIANT

Couleur de l'indicateur : rose avec des tâches blanches.
Indicator color : pink with white spots.
The **exeol strips OPA** test strip is 100% sensitive and specific when instructions for use are followed.



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Sodel
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14100 Lisieux, France.
TEL: +33 (0)2 31 31 10 50
www.exeol.fr

SANTÉ exeol
UNE DIVISION SODEL

ETQAC0176Z1S-03

LOT

REF AC0176

INSTRUCCIONES DE USO

LISTO PARA USAR

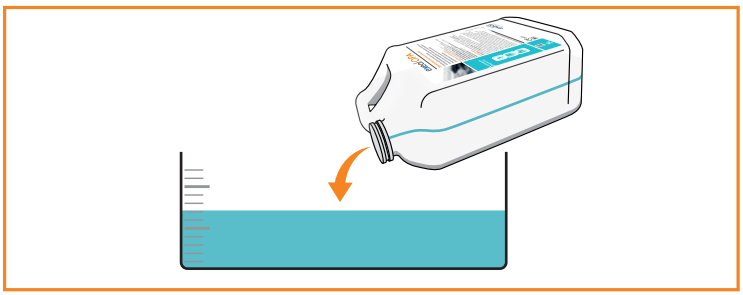
INSTRUMENTOS ENDOSCOPIA

exeol OPA

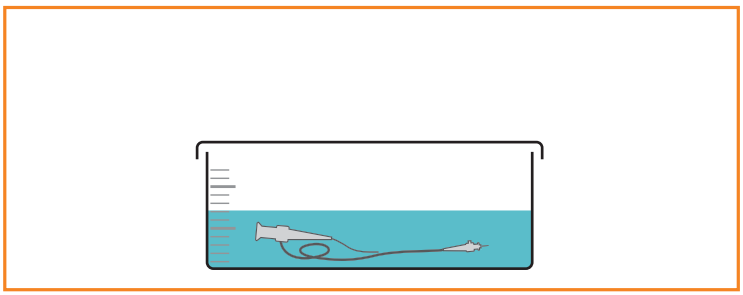
Desinfectante de alto nivel

Solución lista para usar a base de ortoftalaldehído para la desinfección final por inmersión de dispositivos médicos termosensibles reutilizables, semicríticos y críticos, invasivos y no invasivos previamente limpiados.

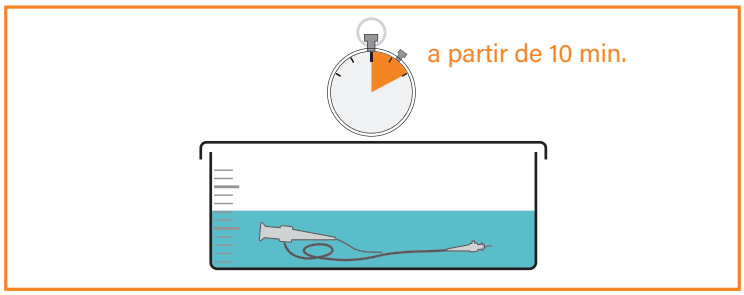
Antes de usar, comprobar la fecha de caducidad que figura en la etiqueta.
exeol OPA puede utilizarse durante un máximo de 14 días.
Controlar regularmente la validez del baño con las tiras de control **exeol strips OPA**.
Antes de usar **exeol OPA** realizar una limpieza previa o una limpieza mecánica completa, y un aclarado intermedio de los dispositivos médicos que se van a tratar.
Utilizar guantes de manga larga.



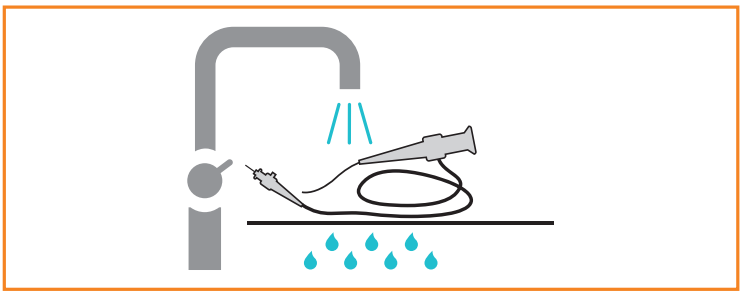
1 Cuando se use por primera vez, retirar el anillo de inviolabilidad y luego desenroscar el tapón. Desenroscar el tapón del bidón y transvasar el contenido a la bandeja. Volver a cerrar el bidón después de su uso.



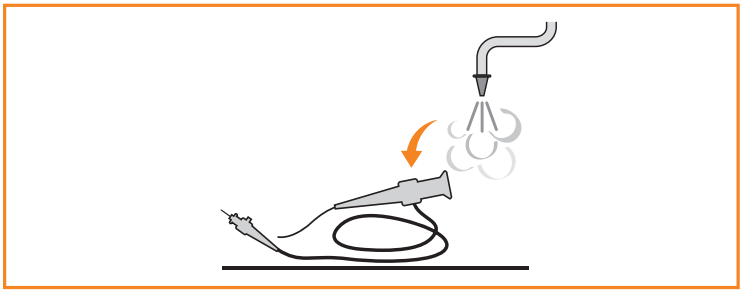
2 Colocar los dispositivos médicos abiertos y desmontados en la solución y asegurarse de que estén totalmente sumergidos. Asegurar la irrigación de los canales si están presentes. Cubrir la bandeja.



3 Tiempo de contacto: a partir de 10 min., según el espectro de actividad deseado.



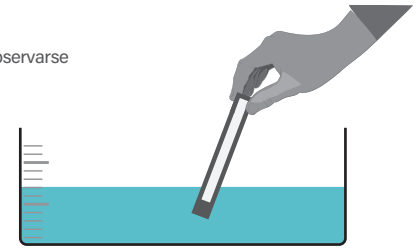
4 Aclarar cuidadosamente con agua estéril o filtrada (0,2 µm) antes de volver a utilizarlo.



5 Antes de almacenar, secar los dispositivos mediante aire médico sobre una superficie seca limpiada previamente.

CONFORME
Rosa uniforme
(de manera ocasional pueden observarse pequeñas manchas blancas)

NO CONFORME
Rosa con manchas blancas



1. Sumergir la tira de control **exeol strips OPA** durante 1 segundo en **exeol OPA**.
2. Sacudir ligeramente la tira de inmediato para eliminar el exceso de líquido.
3. Exactamente 60 segundos después de la extracción de **exeol OPA**, observar el color del área de prueba y compararlo con la imagen de referencia de arriba.
Nunca se debe interpretar el color antes de 60 segundos (1 minuto) después de la extracción.
La tira **exeol strips OPA** es sensible y específica al 100 %, siempre que se cumplan las instrucciones de uso.

Leer siempre la etiqueta y la información sobre el producto antes de usarlo.

SOLO PARA USAR PROFESIONAL

Archivo del producto disponible en www.exeol.fr

Sodel
190 rue René Barthélemy
14100 Lisieux, France.
TEL: +33 (0)2 31 31 10 50
www.exeol.fr

Marcado CE obtenido en 2023
DM de clase IIb
CE 0459
MD

FABRICADO EN FRANCIA

SANTÉ exeol
UNA DIVISIÓN DE SODEL

PRT-EXEOL OPA-ES AM LAT-001_AAAA-MM

SECCIÓN 1: Identificación de la sustancia o la mezcla y de la sociedad o la empresa

1.1. Identificador de producto

Forma del producto	:	Mezcla
Nombre comercial	:	ORTHOPHTALALDEHYDE 0,57%
UFI	:	NW49-107C-K00T-QXET
Código de producto	:	3307-112-2
Tipo de producto	:	Desinfectante de alto nivel
Grupo de productos	:	Producto comercial

1.2. Usos pertinentes identificados de la sustancia o de la mezcla y usos desaconsejados

1.2.1. Usos pertinentes identificados

Categoría de uso principal	:	Uso profesional
Uso de la sustancia/mezcla	:	Desinfectante de alto nivel

1.2.2. Usos desaconsejados

No se dispone de información adicional

1.3. Datos del proveedor de la ficha de datos de seguridad

Fabricante

SODEL
190 rue René Barthélemy
FR– 14100 LISIEUX
FRANCE
T +33(0)2 31 31 10 50 - F +33(0)2 31 31 80 60
info@sodel-sa.eu - www.sodel-sa.eu

1.4. Teléfono de emergencia

País	Organismo/Empresa	Dirección	Número de emergencia	Comentario
España	Unidad de Toxicología Clínica Servicio de Urgencias	Hospital Clinic I Provincial de Barcelona C/Villarroel, 170 08036	+34 93 227 98 33 +34 93 227 54 00 bleep 190	
España	Servicio de Información Toxicológica Instituto Nacional de Toxicología y Ciencias Forenses, Departamento de Sevilla	Carretera de San Jerónimo Km 0,4 41080	+34 91 562 04 20	

SECCIÓN 2: Identificación de los peligros

2.1. Clasificación de la sustancia o de la mezcla

Clasificación según Reglamento (UE) n° 1272/2008 [CLP]

Peligroso para el medio ambiente acuático – Peligro crónico, categoría 3 H412

Texto completo de las frases H y EUH: ver sección 16

Efectos adversos fisicoquímicos, para la salud humana y el medio ambiente

Nocivo para los organismos acuáticos, con efectos nocivos duraderos.

2.2. Elementos de la etiqueta

Etiquetado según el Reglamento (CE) n° 1272/2008 [CLP]

Palabra de advertencia (CLP) : -

Indicaciones de peligro (CLP)	:	H412 - Nocivo para los organismos acuáticos, con efectos nocivos duraderos.
Consejos de prudencia (CLP)	:	P273 - Evitar su liberación al medio ambiente. P333+P313 - En caso de irritación o erupción cutánea: Consultar a un médico. P501 - Eliminar el contenido y el recipiente en un punto de recogida de residuos peligrosos o especiales, de acuerdo con la normativa local, regional, nacional y/o internacional.
Frases EUH	:	EUH208 - Contiene o-Phthalaldehyde (OPA)(643-79-8). Puede provocar una reacción alérgica.

2.3. Otros peligros

No contiene sustancias PBT/mPmB ≥ 0.1% evaluadas con arreglo al Anexo XIII de REACH

La mezcla no contiene sustancia(s) incluidas en la lista establecida con arreglo al artículo 59, apartado1, debido a sus propiedades de alteración endocrina, ni se ha identificado que tengan propiedades de alteración endocrina con arreglo a los criterios establecidos en el Reglamento Delegado (UE) 2017/2100 de la Comisión y en el Reglamento (UE) 2018/605 de la Comisión en una concentración igual o superior al 0,1%.

SECCIÓN 3: Composición/información sobre los componentes

3.1. Sustancias

No aplicable

3.2. Mezclas

Nombre	Identificador de producto	%	Clasificación según Reglamento (UE) n° 1272/2008 [CLP]
o-Phthalaldehyde (OPA)	N° CAS: 643-79-8 N° CE: 211-402-2 REACH-no: 01-2120800347-62	≥ 0,1 – < 1	Flam. Sol. 1, H228 Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg de peso corporal) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Texto completo de las frases H y EUH: ver sección 16

SECCIÓN 4: Primeros auxilios

4.1. Descripción de los primeros auxilios

Medidas de primeros auxilios general	:	De forma general, en caso de duda o si persisten los síntomas, llamar siempre a un médico. No administrar nada por vía oral a las personas en estado de inconsciencia.
Medidas de primeros auxilios en caso de inhalación	:	Transportar a la persona al aire libre y mantenerla en una posición que le facilite la respiración.
Medidas de primeros auxilios en caso de contacto con la piel	:	Lavar la piel con abundante agua.
Medidas de primeros auxilios en caso de contacto con los ojos	:	Aclarar los ojos con agua como medida de precaución.
Medidas de primeros auxilios en caso de ingestión	:	Llamar a un centro de información toxicológica o a un médico en caso de malestar. Enjuagarse la boca. No provocar el vómito.

4.2. Principales síntomas y efectos, agudos y retardados

No se dispone de información adicional

4.3. Indicación de toda atención médica y de los tratamientos especiales que deban dispensarse inmediatamente

Tratamiento sintomático.

SECCIÓN 5: Medidas de lucha contra incendios

5.1. Medios de extinción

Medios de extinción apropiados : Agua pulverizada. Polvo seco. Espuma. Dióxido de carbono.

5.2. Peligros específicos derivados de la sustancia o la mezcla

Peligro de incendio : No inflamable.

Productos de descomposición peligrosos en caso de incendio : Posible emisión de humos tóxicos. No respirar los humos.

5.3. Recomendaciones para el personal de lucha contra incendios

Protección durante la extinción de incendios : No intervenir sin equipo de protección adecuado. Aparato autónomo y aislante de protección respiratoria. Protección completa del cuerpo.

SECCIÓN 6: Medidas en caso de vertido accidental

6.1. Precauciones personales, equipo de protección y procedimientos de emergencia

6.1.1. Para el personal que no forma parte de los servicios de emergencia

Procedimientos de emergencia : Ventilar la zona de derrame.

6.1.2. Para el personal de emergencia

Equipo de protección : No intervenir sin equipo de protección adecuado. Para más información, ver sección 8 : "Control de la exposición-protección individual".

6.2. Precauciones relativas al medio ambiente

Evitar su liberación al medio ambiente. Evitar la entrada en sistemas de aguas pluviales o cursos de agua.

6.3. Métodos y material de contención y de limpieza

Para retención : Cubrir el derrame con un material incombustible, p. e. arena, tierra o vermiculita.

Procedimientos de limpieza : Absorber el líquido derramado mediante un producto absorbente.

Otros datos : Eliminar los materiales o residuos sólidos en un centro autorizado.

6.4. Referencia a otras secciones

Para más información, ver sección 13.

SECCIÓN 7: Manipulación y almacenamiento

7.1. Precauciones para una manipulación segura

Precauciones para una manipulación segura : El puesto de trabajo ha de estar bien ventilado.

Medidas de higiene : No comer, beber ni fumar durante su utilización. Lavarse las manos después de cualquier manipulación.

7.2. Condiciones de almacenamiento seguro, incluidas posibles incompatibilidades

Condiciones de almacenamiento : Almacenar en un lugar bien ventilado. Mantener en lugar fresco. Conservar únicamente en el recipiente original. Mantener el recipiente herméticamente cerrado.

Temperatura de almacenamiento : 5 – 25 °C

Lugar de almacenamiento : Proteger del calor.

7.3. Usos específicos finales

No se dispone de información adicional

SECCIÓN 8: Controles de exposición/protección individual

8.1. Parámetros de control

8.1.1 Valores límite nacionales de exposición profesional y biológicos

Éter diisopropílico (108-20-3)	
España - Valores límite de exposición profesional	
Nombre local	Isopropiléter (Éter diisopropílico)
VLA-ED (OEL TWA) [1]	1060 mg/m³
VLA-ED (OEL TWA) [2]	250 ppm
VLA-EC (OEL STEL)	1310 mg/m³
VLA-EC (OEL STEL) [ppm]	310 ppm
Referencia normativa	Límites de Exposición Profesional para Agentes Químicos en España 2023. INSHT

hidróxido de sodio (1310-73-2)	
España - Valores límite de exposición profesional	
Nombre local	Hidróxido de sodio
VLA-EC (OEL STEL)	2 mg/m³
Referencia normativa	Límites de Exposición Profesional para Agentes Químicos en España 2023. INSHT

d-limoneno (5989-27-5)	
España - Valores límite de exposición profesional	
Nombre local	d-Limoneno
VLA-ED (OEL TWA) [1]	168 mg/m³
VLA-ED (OEL TWA) [2]	30 ppm
Comentarios	Sen (Sensibilizante), vía dérmica (Indica que, en las exposiciones a esta sustancia, la aportación por la vía cutánea puede resultar significativa para el contenido corporal total si no se adoptan medidas para prevenir la absorción. En estas situaciones, es aconsejable la utilización del control biológico para poder cuantificar la cantidad global absorbida del contaminante).
Referencia normativa	Límites de Exposición Profesional para Agentes Químicos en España 2023. INSHT

Citral (5392-40-5)	
España - Valores límite de exposición profesional	
Nombre local	Citral
VLA-ED (OEL TWA) [2]	5 ppm

Citral (5392-40-5)	
Comentarios	Vía dérmica (Indica que, en las exposiciones a esta sustancia, la aportación por la vía cutánea puede resultar significativa para el contenido corporal total si no se adoptan medidas para prevenir la absorción. En estas situaciones, es aconsejable la utilización del control biológico para poder cuantificar la cantidad global absorbida del contaminante), Sen (Sensibilizante), FIV (Fracción inhalable y vapor. La notación FIV señala a aquellos agentes químicos que se pueden presentar en el ambiente de trabajo, tanto en forma de materia particulada como vapor, por lo que las dos fases pueden coexistir, contribuyendo ambas a la exposición. Esta situación se puede dar, principalmente, en los siguientes casos: • Cuando el agente en cuestión tiene un valor “intermedio” de presión de vapor (en estos casos se tiene en cuenta la relación entre su concentración en el aire saturado de vapor y el valor del VLA-ED® y la nota se asigna, generalmente, cuando el cociente entre ambas cantidades se encuentra entre 0.1 y 10). • Por razón de la forma de uso del agente químico (por ejemplo, pulverización). • En los procesos que conlleven cambios importantes de temperatura que puedan afectar al estado físico del agente químico. • En los procesos en los que una fracción significativa del vapor puede disolverse o adsorberse en las partículas de otra sustancia, a semejanza de lo que ocurre con los agentes solubles en agua en ambientes con humedad elevada).
Referencia normativa	Límites de Exposición Profesional para Agentes Químicos en España 2023. INSHT

Anhídrido ftálico (85-44-9)	
UE - Valor límite de exposición profesional indicativo (IOEL)	
Nombre local	Phtalic anhydride
Comentarios	Respiratory sensitizer; skin sensitizer. (Year of adoption 2010)
Referencia normativa	SCOEL Recommendations
España - Valores límite de exposición profesional	
Nombre local	Anhídrido ftálico
VLA-ED (OEL TWA) [1]	6 mg/m³
VLA-ED (OEL TWA) [2]	1 ppm
Comentarios	Sen (Sensibilizante).
Referencia normativa	Límites de Exposición Profesional para Agentes Químicos en España 2023. INSHT

BHT (128-37-0)	
España - Valores límite de exposición profesional	
Nombre local	2,6-Diterc-butil-p-cresol
VLA-ED (OEL TWA) [1]	10 mg/m³
Referencia normativa	Límites de Exposición Profesional para Agentes Químicos en España 2023. INSHT

8.1.2. Métodos de seguimiento recomendados

No se dispone de información adicional

8.1.3. Contaminantes del aire formados

No se dispone de información adicional

8.1.4. DNEL y PNEC

No se dispone de información adicional

8.1.5. Bandas de control

No se dispone de información adicional

8.2. Controles de la exposición

8.2.1. Controles técnicos apropiados

Controles técnicos apropiados:
El puesto de trabajo ha de estar bien ventilado. Prever fuentes de emergencia para el lavado de ojos y duchas de seguridad en las áreas con riesgo de exposición.

8.2.2. Equipos de protección personal

Equipo de protección individual:
Guantes.

Símbolo/s del equipo de protección personal:

8.2.2.1. Protección de los ojos y la cara

Protección ocular:
Evítese el contacto con los ojos. En caso de peligro acrecentado, utilizar una pantalla para proteger el rostro. El uso de gafas correctoras no constituye una protección. No es obligatorio llevar gafas protectoras. Si sus protocolos recomiendan usarlo, use protección para los ojos diseñada contra salpicaduras de líquidos que cumplan con la norma EN166. Deberán estar presentes aparatos para el aclarado de ojos y duchas de seguridad en las áreas donde se pueda producir algún contacto con productos nocivos

8.2.2.2. Protección de la piel

Protección de las manos:
La selección de los guantes se debe realizar según la aplicación y la duración del uso en el puesto de trabajo. Guantes resistentes a químicos (conformes al standard Europeo ISO 374-1 o equivalente). Guantes de protección largos, que cubran las mangas

Otra protección para la piel

Ropa de protección - selección del material:
Evitar el contacto con la piel. Lavar todas las zonas del cuerpo que hayan estado en contacto con el producto. En caso de riesgo de salpicaduras, usar ropa de protección química (tipo 6) conforme a la norma EN13034 para evitar cualquier contacto con la piel. La ropa del personal debe lavarse con regularidad. El uso de ropa protectora no es obligatorio, pero si su protocolo lo requiere, use ropa de protección química adecuada

8.2.2.3. Protección respiratoria

Protección respiratoria:
No es obligatorio el uso de mascarilla o respirador. Si sus protocolos recomiendan usar uno, use un respirador adecuado

8.2.2.4. Peligros térmicos

No se dispone de información adicional

8.2.3. Controles de exposición medioambiental

Controles de exposición medioambiental:
Evitar su liberación al medio ambiente.

SECCIÓN 9: Propiedades físicas y químicas

9.1. Información sobre propiedades físicas y químicas básicas

Estado físico	:	Líquido
Color	:	Azul.
Apariencia	:	Claro.
Olor	:	Perfumes, fragancias.
Umbral olfativo	:	No disponible
Punto de fusión	:	No aplicable
Punto de congelación	:	No disponible
Punto de ebullición	:	No disponible
Inflamabilidad	:	No aplicable
Límite inferior de explosividad	:	No disponible
Límite superior de explosividad	:	No disponible
Punto de inflamación	:	> 65 °C

Temperatura de auto-inflamación	:	No disponible
Temperatura de descomposición	:	No disponible
pH	:	7 – 8
Viscosidad, cinemática	:	No disponible
Solubilidad	:	No disponible
Coeficiente de partición n-octanol/agua (Log Kow)	:	No disponible
Presión de vapor	:	No disponible
Presión de vapor a 50°C	:	No disponible
Densidad	:	1,004 – 1,008 g/ml
Densidad relativa	:	No disponible
Densidad relativa de vapor a 20°C	:	No disponible
Características de las partículas	:	No aplicable

9.2. Otros datos

9.2.1. Información relativa a las clases de peligro físico

No se dispone de información adicional

9.2.2. Otras características de seguridad

Contenido de COV	:	0 % (Directiva de la UE 2010/75)
Índice de refracción	:	1,3354 – 1,336

SECCIÓN 10: Estabilidad y reactividad

10.1. Reactividad

El producto no es reactivo en condiciones normales de utilización, almacenamiento y transporte.

10.2. Estabilidad química

Estable en condiciones normales.

10.3. Posibilidad de reacciones peligrosas

No se producen reacciones peligrosas conocidas en condiciones normales de utilización.

10.4. Condiciones que deben evitarse

Ninguna en las condiciones de almacenamiento y de manipulación recomendadas (véase la sección 7).

10.5. Materiales incompatibles

No se dispone de información adicional

10.6. Productos de descomposición peligrosos

En condiciones normales de almacenamiento y utilización, no deberían de generarse productos de descomposición peligrosos.

SECCIÓN 11: Información toxicológica

11.1. Información sobre las clases de peligro definidas en el Reglamento (CE) n.° 1272/2008

Toxicidad aguda (oral)	:	No clasificado
Toxicidad aguda (cutánea)	:	No clasificado
Toxicidad aguda (inhalación)	:	No clasificado

o-Phthalaldehyde (OPA) (643-79-8)	
DL50 cutánea rata	> 2000 mg/kg de peso corporal Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity)

Corrosión o irritación cutáneas	:	No clasificado pH: 7 – 8
Lesiones oculares graves o irritación ocular	:	No clasificado pH: 7 – 8
Sensibilización respiratoria o cutánea	:	No clasificado

Mutagenicidad en células germinales	:	No clasificado
Carcinogenicidad	:	No clasificado
Toxicidad para la reproducción	:	No clasificado
Toxicidad específica en determinados órganos (STOT) – exposición única	:	No clasificado

o-Phthalaldehyde (OPA) (643-79-8)	
Toxicidad específica en determinados órganos (STOT) – exposición única	Puede irritar las vías respiratorias.

Toxicidad específica en determinados órganos (STOT) – exposición repetida	:	No clasificado
Peligro por aspiración	:	No clasificado

11.2. Información sobre otros peligros

No se dispone de información adicional

SECCIÓN 12: Información ecológica

12.1. Toxicidad

Ecología - general	:	Nocivo para los organismos acuáticos, con efectos nocivos duraderos.
Peligro a corto plazo (agudo) para el medio ambiente acuático	:	No clasificado
Peligro a largo plazo (crónico) para el medio ambiente acuático	:	Nocivo para los organismos acuáticos, con efectos nocivos duraderos.

No fácilmente degradable

o-Phthalaldehyde (OPA) (643-79-8)	
CE50 - Crustáceos [1]	0,11 mg/l Test organisms (species): Daphnia magna

12.2. Persistencia y degradabilidad

No se dispone de información adicional

12.3. Potencial de bioacumulación

No se dispone de información adicional

12.4. Movilidad en el suelo

No se dispone de información adicional

12.5. Resultados de la valoración PBT y mPmB

No se dispone de información adicional

12.6. Propiedades de alteración endocrina

No se dispone de información adicional

12.7. Otros efectos adversos

No se dispone de información adicional

SECCIÓN 13: Consideraciones relativas a la eliminación

13.1. Métodos para el tratamiento de residuos

Métodos para el tratamiento de residuos	:	Eliminar el contenido/recipiente de acuerdo con las instrucciones de reciclaje del recolector homologado.
Recomendaciones para la eliminación de las aguas residuales	:	Eliminar de acuerdo con la normativa oficial.

Recomendaciones para la eliminación de productos/envases	:	Vaciar completamente el envase. Conservar la(las) etiqueta(s) en el envase. Eliminar de acuerdo con la normativa oficial. Evitar su liberación al medio ambiente. Evitar la entrada en sistemas de aguas pluviales o cursos de agua. La gestión de los residuos se realiza sin poner en peligro la salud humana y sin perjudicar el medioambiente, y en especial, sin crear riesgos para el agua, el aire, el suelo, la fauna o la flora.

SECCIÓN 14: Información relativa al transporte

En conformidad con ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. Número ONU o número ID				
No aplicable	No aplicable	No aplicable	No aplicable	No aplicable
14.2. Designación oficial de transporte de las Naciones Unidas				
No aplicable	No aplicable	No aplicable	No aplicable	No aplicable
14.3. Clase(s) de peligro para el transporte				
No aplicable	No aplicable	No aplicable	No aplicable	No aplicable
14.4. Grupo de embalaje				
No aplicable	No aplicable	No aplicable	No aplicable	No aplicable
14.5. Peligros para el medio ambiente				
No aplicable	No aplicable	No aplicable	No aplicable	No aplicable
No se dispone de información adicional				

14.6. Precauciones particulares para los usuarios

Transporte por vía terrestre

No aplicable

Transporte marítimo

No aplicable

Transporte aéreo

No aplicable

Transporte por vía fluvial

No aplicable

Transporte ferroviario

No aplicable

14.7. Transporte marítimo a granel con arreglo a los instrumentos de la OMI

No aplicable

SECCIÓN 15: Información reglamentaria

15.1. Reglamentación y legislación en materia de seguridad, salud y medio ambiente específicas para la sustancia o la mezcla

15.1.1. Normativa de la UE

Anexo XVII de REACH (condiciones de las restricciones)

No contiene ninguna sustancia incluida en el Anexo XVII de REACH (Condiciones de restricción)

Anexo XIV de REACH (lista de autorizaciones)

No contiene ninguna sustancia incluida en el Anexo XIV de REACH (Lista de autorizaciones)

Lista de sustancias candidatas extremadamente preocupantes (SVHC) de REACH

No contiene ninguna sustancia incluida en la lista de sustancias candidatas de REACH

Reglamento PIC

No contiene ninguna sustancia incluida en la lista PIC (Reglamento UE 649/2012 relativo a la exportación e importación de productos químicos peligrosos)

Reglamento COP (Contaminantes orgánicos persistentes)

No contiene ninguna sustancia incluida en la lista COP (Reglamento UE 2019/1021 sobre contaminantes orgánicos persistentes)

Agotamiento de la capa de ozono

No contiene ninguna sustancia incluida en la lista de sustancias que agotan la capa de ozono (Reglamento UE 1005/2009 sobre las sustancias que agotan la capa de ozono)

Directiva COV (Directiva 2004/42/CE sobre los compuestos orgánicos volátiles)

Contenido de COV : 0 % (Directiva de la UE 2010/75)

Reglamento sobre los precursores de explosivo (UE 2019/1148)

No contiene ninguna sustancia incluida en la lista de precursores de explosivos (Reglamento UE 2019/1148 sobre la comercialización y la utilización de precursores de explosivos)

Reglamento sobre precursores de drogas (CE 273/2004)

No contiene ninguna sustancia incluida en la lista de precursores de drogas (Reglamento CE 273/2004 relativa a la fabricación y puesta en el mercado de determinadas sustancias utilizadas para la fabricación ilícita de estupefacientes y sustancias psicotrópicas)

15.1.2. Normativas nacionales

No se dispone de información adicional

15.2. Evaluación de la seguridad química

No se ha llevado a cabo la Evaluación de la Seguridad Química

SECCIÓN 16: Otra información

Abreviaturas y acrónimos:	
ADN	Acuerdo europeo relativo al transporte internacional de mercancías peligrosas por vías navegables interiores
ADR	Acuerdo europeo relativo al transporte internacional de mercancías peligrosas por carretera
ATE	Estimación de la toxicidad aguda
FBC	Factor de bioconcentración
VLB	Valor límite biológico
DBO	Demanda bioquímica de oxígeno (DBO)
DQO	Demanda química de oxígeno (DQO)
DMEL	Nivel derivado con efecto mínimo
DNEL	Nivel sin efecto derivado
N° CE	número CE
CE50	Concentración efectiva media
EN	Norma europea
CIIC	Centro Internacional de Investigaciones sobre el Cáncer
IATA	Asociación Internacional de Transporte Aéreo
IMDG	Código Marítimo Internacional de Mercancías Peligrosas
CL50	Concentración letal para el 50 % de una población de pruebas
DL50	Dosis letal para el 50 % de una población de pruebas (dosis letal media)
LOAEL	Nivel más bajo con efecto adverso observado

Abreviaturas y acrónimos:	
NOAEC	Concentración sin efecto adverso observado
NOAEL	Nivel sin efecto adverso observado
NOEC	Concentración sin efecto observado
OCDE	Organización para la Cooperación y el Desarrollo Económicos
VLA	Límite de exposición profesional
PBT	Sustancia persistente, bioacumulativa y tóxica
PNEC	Concentración prevista sin efecto
RID	Reglamento relativo al transporte internacional de mercancías peligrosas por ferrocarril
FDS	Ficha de Datos de Seguridad
STP	Estación depuradora
DTO	Necesidad teórica de oxígeno (BThO)
TLM	Tolerancia media limite
COV	Compuestos orgánicos volátiles
N° CAS	Número del Servicio de resúmenes químicos (CAS)
N.E.P	No especificado en otra parte
mPmB	Muy persistente y muy bioacumulable
ED	Propiedades de alteración endocrina

Otros datos : Dado que no conocemos las condiciones de trabajo del usuario, las informaciones que figuran en la presente ficha de seguridad se basarán en el estado de nuestros conocimientos y en las normativas tanto nacionales como comunitarias. La mezcla no debe ser utilizada para otros usos que no sean los especificados en la sección 1 sin haber obtenido previamente instrucciones de manipulación por escrito. El usuario es totalmente responsable de tomar todas las medidas necesarias para responder a las exigencias de las leyes y normativas locales.

Texto íntegro de las frases H y EUH:	
Acute Tox. 3 (Oral)	Toxicidad aguda (oral), categoría 3
Aquatic Acute 1	Peligroso para el medio ambiente acuático – Peligro agudo, categoría 1
Aquatic Chronic 1	Peligroso para el medio ambiente acuático – Peligro crónico, categoría 1
EUH208	Contiene o-Phthalaldehyde (OPA)(643-79-8). Puede provocar una reacción alérgica.
Eye Dam. 1	Lesiones oculares graves o irritación ocular, categoría 1
Flam. Sol. 1	Sólidos inflamables, categoría 1
H228	Sólido inflamable.
H301	Tóxico en caso de ingestión.
H314	Provoca quemaduras graves en la piel y lesiones oculares graves.
H317	Puede provocar una reacción alérgica en la piel.
H318	Provoca lesiones oculares graves.
H335	Puede irritar las vías respiratorias.
H400	Muy tóxico para los organismos acuáticos.
H410	Muy tóxico para los organismos acuáticos, con efectos nocivos duraderos.
H412	Nocivo para los organismos acuáticos, con efectos nocivos duraderos.

Texto íntegro de las frases H y EUH:	
Skin Corr. 1C	Irritación o corrosión cutáneas, categoría 1, subcategoría 1C
Skin Sens. 1	Sensibilización cutánea, categoría 1
STOT SE 3	Toxicidad específica en determinados órganos – Exposición única, categoría 3, irritación de las vías respiratorias

La clasificación cumple : ATP 12

Ficha de datos de seguridad (FDS), UE

Esta información se basa en nuestro conocimiento actual y tiene como finalidad describir el producto para la tutela de la salud, seguridad y medio ambiente. Por lo tanto, no debe ser interpretada como garantía de ninguna característica específica del producto.

SPECIFICATIONS PRODUIT ISSUES DE LA CONCEPTION
PRODUCT SPECIFICATIONS FROM DESIGN
ESPECIFICACIONES PRODUCTO PROCEDIENDO DE LA CONCEPCIÓN

FM4.49 v6

Désignation X3 : *X3 designation :* *Designación X3 :*	Désinfectant de haut niveau *High level disinfectant* *Desinfectante de alto nivel*	N° Formule : *Formula no. :* *N° Fórmula :*	F3307
Code Projet : *Project code :* *Código Proyecto* :	RD0209E36	Catégorie produit : *Product category :* *Categoría producto :*	DM MD DM

Paramètre contrôlé *Parameter verified* *Parámetro controlado*	**Paramètre libératoire** *Release parameter* *Parámetro de liberación*	**Tolérance basse** *Low tolerance* *Tolerancia baja*	**Valeur cible** *Target value* *Valor objetivo*	**Tolérance haute** *High tolerance* *Tolerancia alta*	**Unités** *Units* *Unidades*	**Conditions opératoires** *Operating conditions* *Condiciones operativas*	**Méthode de Référence** *Reference method* *Método de referencia*
Aspect *Appearance* *Apariencia*	Oui Yes Sí	-	Liquide limpide *Clear liquid* *Líquido limpido*	-	-	22°C +/- 3°C	organoleptique *organoleptic* *organoléptico*
Couleur *Color* *Color*	Oui Yes Sí	-	Bleue *blue* *azúl*	-	-	22°C +/- 3°C	organoleptique *organoleptic* *organoléptico*
Odeur *Smell* *Olor*	Oui Yes Sí	-	Parfumé *fragrant* *perfumado*	-	-	22°C +/- 3°C	organoleptique *organoleptic* *organoléptico*
Indice de réfraction *Refractive index* *Indice de refracción*	Oui Yes Sí	1,3354	1,3357	1,3360	sans dimension *no unit* *sin dimensión*	20°C +/- 1°C	MR5.05
Masse volumique *Density* *Densidad*	Oui Yes Sí	1,004	1,006	1,008	g/mL	20°C +/- 1°C	MR5.05
Teneur en Ortho-phtalaldéhyde *Ortho-phthalaldehyde content* *Contenido de Orto-ftalaldehído*	Oui - DM Yes - MD Sí - DM	0,54	0,57	0,60	%m/m	-	MM4.41
pH	Oui Yes Sí	7,00	7,50	8,00	UpH	20°C +/- 1°C	MR5.05
Contrôle propreté microbiologique *Microbiological cleanliness control* *Control de limpieza microbiológica*	Oui Yes Sí	-	Bactérie Gram négatif *Gram negative bacteria* *Bacteria Gram negativa* < 1	-	UFC/mL	22°C +/- 3°C	MR5.17
Contrôle propreté microbiologique *Microbiological cleanliness control* *Control de limpieza microbiológica*	Oui Yes Sí	-	Bactérie Gram positif *Gram positive bacteria* *Bacteria Gram positiva* < 100	-	UFC/mL	22°C +/- 3°C	MR5.17
Contrôle propreté microbiologique *Microbiological cleanliness control* *Control de limpieza microbiológica*	Oui Yes Sí	-	Levures et moisissures *Yeasts and fungi* *Levaduras y mohos* < 10	-	UFC/mL	22°C +/- 3°C	MR5.17

SUIVI DES MODIFICATIONS / *TRACK CHANGES / SEGUIMIENTO DE CAMBIOS*

Version / *Versión*	**Date / *Fecha***	**Justification / *Justificación***
m0	04/07/2022	Création / creation / creación
m1	25/07/2023	mise en place formulaire version 6 / setting up form version 6 / configuración formulario versión 6
m2		
m3		

VALIDATION / *VALIDACIÓN*

Rédigé par (R&D) / *Written by (R&D) / Redactado por (I+B)*	**Vérifié par / *Checked by / Verificado por***	**Approuvé par / *Approved by / Aprobado por***
Fonction + Nom / *Position + Name / Función + Nombre*	Fonction + Nom / *Position + Name / Función + Nombre*	Fonction + Nom / *Position + Name / Función + Nombre*
Responsable R&D / Responsable Chimie Analytique *R&D Manager / Analytical Chemistry Manager* *Responsable I+D / Responsable Química Analítica* **C. RENARD / C. HOURNON**	Directeur Scientifique et Stratégie produits *Scientific Director & Products strategy* *Director Científico y Estrategia Producto* **G. RAUWEL**	Directrice Qualité / *Quality Director / Directora Calidad* **A. NGUYEN**
Date et Signature / *Date and Signature / Fecha y Firma*	Date et Signature / *Date and Signature / Fecha y Firma*	Date et Signature / Date and Signature / *Fecha y Firma*
31/07/2023	31/07/2023	31/07/2023

Transmettre une copie au Contrôle Qualité
Send a copy to Quality Control
Mandar una copia al Control Calidad

Rapport d'essai – Compatibilité matériau

Test report – Material compatibility

Informe del ensayo - Compatibilidad del material

Rapport édité à Lisieux, le 30 mai 2022
Report printed in Lisieux, 30 May 2022
Informe editado en Lisieux, el 30 de mayo de 2022

RAPPORT D'ESSAI N° RPCOMP2022_F3307_010

TEST REPORT No. RPCOMP2022_F3307_010

INFORME DEL ENSAYO N.° RPCOMP2022_F3307_010

Titre de l'essai

Test title

Título del ensayo

Etude de compatibilité matériaux

Material compatibility study

Estudio de compatibilidad del material

Type Produit

Product type

Tipo de producto

Désinfectant de haut niveau

High-level disinfectant

Desinfectante de alto nivel

Code formule

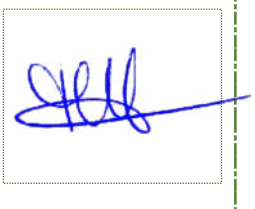
Formula code

Código de formula

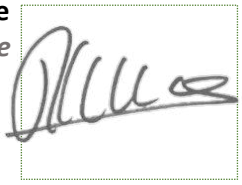
F3307

Rapport d'essai – Compatibilité matériau
Test report – Material compatibility
Informe del ensayo - Compatibilidad del material

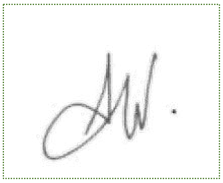
Rédigé par Marlène HORGNIES ..... **Le 30/05/2022**..... **Signature**
Written by Marlène HORGNIES ..... *On 30/05/2022* ..... *Signature*
Redactado por Marlène HORGNIES ..... *El 30/05/2022* ..... *Firma*
Fonction Directrice Affaires Règlementaires et Microbiologie
Position Regulatory Affairs and Microbiology Director
Función Directora de Asuntos Regulatorios y Microbiología



Vérifié par Gaétan RAUWEL ..... **Le 30/05/2022**..... **Signature**
Checked by Gaétan RAUWEL..... *On 30/05/2022* ..... *Signature*
Verificado por Gaétan RAUWEL ..... *El 30/05/2022* ..... *Firma*
Fonction Directeur scientifique & Stratégie Produits
Position Scientific Director and Product Strategy
Función Director Científico y Estrategia Productos



Approuvé par Annick NGUYEN ..... **Le 30/05/2022**..... **Signature**
Approved by Annick NGUYEN..... *On 30/05/2022* ..... *Signature*
Aprobado por Annick NGUYEN..... *El 30/05/2022* ..... *Firma*
Fonction Directeur Qualité
Position Quality Director
Función Director de Calidad



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I. OBJET DE L'ÉTUDE / *PURPOSE OF THE STUDY* / *OBJETO DEL ESTUDIO*

Dans le cadre du Règlement (UE) 2017/745, l'obtention du marquage CE prend en compte la compatibilité puisqu'il comporte une Exigence Générale de Sécurité et de Performance spécifique (EGSP 10.3) « Les dispositifs doivent être conçus et fabriqués de manière à pouvoir être utilisés en toute sécurité avec les matériaux […] avec lesquels ils rentrent en contact au cours de leur utilisation prévue »

L'évaluation de la compatibilité avec un désinfectant donné est effectuée par les fabricants de dispositifs médicaux en vue de l'obtention du marquage CE puisque ceux-ci sont censés indiquer le mode de traitement de leurs DM réutilisables dans la notice (en se positionnant au minimum sur la famille chimique utilisable : aldéhydes, oxydants…).

L'EGSP 23.4 du Règlement (UE) 2017/745 précise à ce sujet que: « si le dispositif est réutilisable, les informations relatives aux procédés appropriés pour permettre sa réutilisation, notamment le nettoyage, la désinfection, le conditionnement […]. Des informations sont fournies permettant de déterminer quand un dispositif ne devrait plus être réutilisé, comme par exemple les signes de dégradation matérielle ou le nombre maximal de réutilisations admissibles ».

« Il en résulte que le fabricant, en fonction des matériaux utilisés et de la conception du produit, doit valider le processus de retraitement à appliquer afin de garantir que le dispositif médical ne subira pas d'altération, fonctionnera comme prévu et ne comportera pas de risque pour un certain nombre de réutilisations. »

La compatibilité chimique entre un désinfectant et un dispositif médical (DM) ou une surface à désinfecter peut se définir comme l'absence d'altération rapide et importante du DM ou de la surface par le produit désinfectant.

Pour un DM, la compatibilité avec les produits de désinfection permet l'utilisation de ce DM pendant une période de temps donnée jugée « acceptable » malgré des traitements répétés tout au long de la durée de vie de ce DM. A force d'être soumis aux effets du produit désinfectant, liés à la succession de retraitements, le DM se trouve inévitablement altéré. Ces altérations qui sont une usure du matériel ne doivent pas être confondus avec une incompatibilité entre le produit désinfectant et le DM.

La formule F3307 est un désinfectant de haut niveau à base d'orthophtalaldéhyde (0,54%) prêt à l'emploi pour la désinfection finale par immersion des DM réutilisables thermosensibles invasifs et non-invasifs préalablement nettoyés.

L'orthophtalaldéhyde est un désinfectant alternatif au glutaraldéhyde 2%. Il est plus stable, pratiquement inodore, n'émet pas de fumées nocives, et a une meilleure activité mycobactéricide. Il n'endommage pas les équipements, mais comme les autres aldéhydes, il peut tacher et réticuler les protéines.

Compte tenu des éléments ci-dessus, l'objectif de ce rapport est de justifier de la compatibilité de la formule F3307 avec les dispositifs médicaux thermosensibles tels que les endoscopes et les sondes d'échographie. Cette justification est apportée par la consolidation des informations disponibles sur l'usage de l'orthophtalaldéhyde pour la désinfection des dispositifs médicaux pour démontrer qu'il est :

- largement utilisée comme désinfectant (Annexe 1)
- reconnu comme compatible avec les endoscopes et les sondes d'échographie par la majorité des fabricants de ces dispositifs médicaux (Annexe 2).

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La compatibilité de la formule F3307 avec les instruments chirurgicaux fait l'objet d'un rapport spécifique RPELE2022_F3307_006 selon la NF S94-402-1 (Mai 2004).

As set out in Regulation (EU) 2017/745, the process of acquiring CE marking takes account of compatibility. The Regulation includes a specific General Safety and Performance Requirement (GSPR10.3), which states that "Devices must be designed and manufactured in such a way that they can be used safely with the materials [...] with which they come into contact during their intended use."

Medical device manufacturers need to assess compatibility with a given disinfectant in order to obtain CE marking, given that they are required to include the appropriate processing method for their reusable medical devices in the instructions for use (at least with respect to the compatible chemical family: aldehydes, oxidants, etc.).

GSPR 23.4 of Regulation (EU) 2017/745 states in this regard that: "if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging [...]. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses".

"This implies that the manufacturer, on the basis of the materials used and the design of the product, must validate the reprocessing process to be applied in order to ensure that the medical device will not be altered, that it will perform as intended and will be safe for a certain number of re-uses."

The chemical compatibility between a disinfectant and a medical device (MD) or a surface to be disinfected can be defined as the absence of rapid and significant alteration of the MD or the surface by the disinfectant product.

For an MD, compatibility with disinfectant products means that it can be used for the period of time that is deemed "acceptable", despite repeated treatments throughout its service life. The MD is inevitably altered by repeated exposure to the disinfectant through successive treatments. These changes, which cause the material to wear, must not be confused with incompatibility between the disinfectant product and the MD.

Formula F3307 is a ready-to-use, high-level ortho-phthalaldehyde-based disinfectant (0.54%), for final disinfection by immersing previously cleaned reusable, heat-sensitive invasive and non-invasive medical devices.

Ortho-phthalaldehyde is an alternative disinfectant to 2% glutaraldehyde. It is more stable, virtually odourless, emits no harmful fumes, and is a more effective mycobactericide. It does not damage equipment, but it can stain and cross-link proteins, like other aldehydes.

Reflecting the above, the purpose of this report is to demonstrate the compatibility of formula F3307 with heat-sensitive medical devices such as endoscopes and ultrasound probes. It will do this by consolidating available information on the use of ortho-phthalaldehyde for the disinfection of medical devices, showing that it is:

- *widely used as a disinfectant (Appendix 1)*
- *recognised as compatible with endoscopes and ultrasound probes by most manufacturers of these medical devices (Appendix 2).*

The compatibility of formula F3307 with surgical instruments is described in a specific report RPELE2022_F3307_006 in compliance with NF S94-402-1 (May 2004).

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En el marco del Reglamento (UE) 2017/745, para la obtención del marcado CE se tiene en cuenta la compatibilidad, ya que ello comporta un Requisito general de seguridad y funcionamiento (10.3) «Los productos se diseñarán y fabricarán de modo que puedan utilizarse con seguridad con los materiales […] con los que vayan a entrar en contacto durante su uso previsto.»

La evaluación de la compatibilidad con un desinfectante determinado la realizan los fabricantes de los productos sanitarios para obtener el marcado CE, y deben indicar el modo de tratamiento de sus PS en las instrucciones de uso (posicionándose al menos sobre la familia química utilizable: aldehídos, oxidantes, etc.).

Respecto a esto, el Requisito general de seguridad y funcionamiento 23.4 del Reglamento (UE) 2017/745 indica lo siguiente: «si el producto es reutilizable, información sobre los procedimientos apropiados que permitan su reutilización, incluida la limpieza, desinfección, embalaje […]. Se facilitará información para saber en qué momento no debe utilizarse más el producto, como signos de degradación o número máximo de reutilizaciones.»

Por tanto, en función del material utilizado y del diseño del producto, el fabricante debe validar el proceso de retratamiento a aplicar para garantizar que el producto sanitario no sufra alteraciones, que funcionará según lo previsto y que no supondrá ningún riesgo para un número determinado de reutilizaciones. »

La compatibilidad química entre un desinfectante y un producto sanitario (PS) o una superficie a desinfectar puede definirse como la ausencia de alteración rápida e importante del PS o la superficie por parte del producto desinfectante.

En el caso de un PS, la compatibilidad con los productos de desinfección permite el uso del PS durante cierto periodo de tiempo considerado «aceptable» pese a los tratamientos repetidos a lo largo de la vida útil de dicho PS. Tras someterse repetidamente a los efectos del producto desinfectante durante los tratamientos, el PS sufre una alteración inevitable. Estas alteraciones, que consisten en el desgaste normal del material, no deben confundirse con la incompatibilidad entre el producto desinfectante y el PS.

La fórmula F3307 es un desinfectante de alto nivel a base de ortoftalaldehído (0,54 %) listo para usar en la desinfección final por inmersión de los PS reutilizables termosensibles invasivos y no invasivos previamente limpiados.

El ortoftalaldehído es un desinfectante alternativo al glutaraldehído al 2 %. Es más estable, prácticamente inodoro, no emite humos nocivos, y tiene una mejor actividad actividad micobactericida. No daña los equipos, aunque, como el resto de los aldehídos, puede alterar y reticular las proteínas.

A tenor de los elementos anteriores, el propósito de este informe es justificar la compatibilidad de la fórmula F3307 con productos sanitarios termosensibles como los endoscopios y las sondas ecográficas. Esta justificación se consigue por la consolidación de la información disponible sobre el uso del ortoftalaldehído en la desinfección de los productos sanitarios para demostrar que:

- *se utiliza de forma generalizada como desinfectante (Anexo 1)*
- *se ha reconocido su compatibilidad con los endoscopios y las sondas ecográficas por parte de la mayoría de los fabricantes de estos productos sanitarios (Anexo 2).*

La compatibilidad de la fórmula F3307 con los instrumentos quirúrgicos se incluye en un informe específico RPELE2022_F3307_006 según la norma francesa NF S94-402-1 (mayo de 2004).

II. DOCUMENTS DE REFERENCE / *REFERENCE DOCUMENTS* / *DOCUMENTOS DE REFERENCIA*

1. State of the Art_2022
2. World Gastroenterology Organisation/ World Endoscopy Organization Global Guidelines : Endoscope disinfection— a resource-sensitive approach February 2011
3. NF S94-402-1 (Mai 2004) - Instruments chirurgicaux - Étude de l'action corrosive d'un pré-désinfectant ou d'un nettoyant ou d'un désinfectant sur les instruments médico-chirurgicaux réutilisables - Méthodes d'essai - Partie 1: acier inoxydable.
4. An evaluation of chemical disinfecting agents used in endoscopy suites in the NHS, HSE Book 2006.

1. *State of the Art_2022*
2. *World Gastroenterology Organisation/ World Endoscopy Organization Global Guidelines : Endoscope disinfection— a resource-sensitive approach February 2011*
3. *NF S94-402-1 (Mai 2004) - Instruments chirurgicaux - Étude de l'action corrosive d'un pré-désinfectant ou d'un nettoyant ou d'un désinfectant sur les instruments médico-chirurgicaux réutilisables - Méthodes d'essai - Partie 1: acier inoxydable.*
   NF S94-402-1 (May 2004) - Surgical instruments – Examination of the corrosive effect of a decontaminant, cleaning agent or disinfectant on reusable medico-surgical instruments – Test methods – Part 1: stainless steel.
4. *An evaluation of chemical disinfecting agents used in endoscopy suites in the NHS, HSE Book 2006.*

1. *State of the Art_2022*
2. *World Gastroenterology Organisation/ World Endoscopy Organization Global Guidelines : Endoscope disinfection— a resource-sensitive approach February 2011*
3. *NF S94-402-1 (Mai 2004) - Instrumentos quirúrgicos. Estudio de la acción corrosiva de un predesinfectante o un limpiador o un desinfectante en los instrumentos médico-quirúrgicos reutilizables. Métodos de ensayo. Parte 1: acero inoxidable.*
4. *An evaluation of chemical disinfecting agents used in endoscopy suites in the NHS, HSE Book 2006.*

III. RESPONSABILITES / *RESPONSIBILITIES* / *RESPONSABILIDADES*

Ce rapport a été rédigé par le secteur de Recherche et Développement de la société Sodel située à LISIEUX (14100).
This report was written by the Research and Development department of Sodel, in Lisieux, north-west France (14100).
Este estudio fue redactado por el departamento de Investigación y Desarrollo de la empresa Sodel en LISIEUX (14100).

Rapport d'essai – Compatibilité matériau
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Informe del ensayo - Compatibilidad del material

Etape *Stages* *Etapa*	Responsabilités *Responsibilities* *Responsabilidades*
Rédaction du rapport d'essai *Drafting of the test report* *Redacción del informe del ensayo*	Directrice Affaires Réglementaires et Microbiologie *Regulatory Affairs and Microbiology Director* *Directora de Asuntos Regulatorios y Microbiología*
Vérification du rapport d'essai *Checking of the test report* *Verificación del informe del ensayo*	Directeur Scientifique et Stratégie Produits *Scientific Director and Product Strategy* *Director Científico y Estrategia Productos*
Approbateur de l'étude *Study approved by* *Aprobador del estudio*	Directeur Qualité *Quality Director* *Director de Calidad*

IV. DEROULEMENT DE L'ESSAI / *TEST PROCEDURE* / *DESARROLLO DEL ENSAYO*

Non applicable
Non applicable
No aplicable

V. CONCLUSION / *CONCLUSION* / *CONCLUSION*

La liste des désinfectants à base d'orthophtalaldéhyde enregistrés auprès de la FDA permet de justifier de l'utilisation répandue de cette substance (Annexe 1).
Les informations fournies par les fabricants de DMR permettent de justifier de la compatibilité de leurs équipements avec l'orthophtalaldéhyde (Annexe 2).
La formule F3307 est compatible avec les équipements médicaux qui peuvent être retraités par une solution de d'orthophtalaldéhyde à 0.54% ou plus.

The list of ortho-phthalaldehyde-based disinfectants registered with the FDA is evidence of the widespread use of this substance (Appendix 1).
The information provided by RMD manufacturers shows the compatibility of their equipment with ortho-phthalaldehyde (Appendix 2).
Formula F3307 is compatible with medical equipment that can be reprocessed using an ortho-phthalaldehyde solution at a concentration of 0.54% or higher.

La lista de desinfectantes a base de ortoftalaldehído registrados en la FDA permite justificar el uso extendido de esta sustancia (Anexo 1).
La información proporcionada por los fabricantes de productos sanitarios reutilizables (PSR) permite justificar la compatibilidad de sus equipos con el ortoftalaldehído (Anexo 2).
La fórmula F3307 es compatible con los productos sanitarios que pueden tratarse con una solución de ortoftalaldehído al 0,54 % o más.

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VI. ANNEXES / *APPENDICES* / *ANEXOS*

1. Usage reconnu de l'orthophtalaldéhyde comme désinfectant de haut niveau / *Recognised use of ortho-phthalaldehyde as a high-level disinfectant= / Uso reconocido del ortoftalaldehído como desinfectante de alto nivel*

Source / Source / Fuente : FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices | FDA

K120306 Rapicide OPA-28 High Level Disinfectant			
Minntech Corporation	0.575% *ortho*-phthalaldehyde	**No indication for device sterilization.** Passes the Modified AOAC Sporicidal Activity Test in 32 hrs at 20°C and 25°C.	**For Manual Processing:** 10 min at 20°C 28 days Maximum Reuse **For processing in a legally marketed Automated Endoscope Reprocessor capable of maintaining solution temperature at 25°C:** 5 min at 25°C 28 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K140703 OPA 30 Solution			
Ciden Technologies, LLC	0.6% *ortho*-phthalaldehyde	**No indication for device sterilization.** Passes the Modified AOAC Sporicidal Activity Test in 32 hrs at 20°C and 25°C.	**For Manual Processing:** 12 min at 20°C 30 days Maximum Reuse **For processing in a legally marketed Automated Endoscope Reprocessor capable of maintaining solution temperature at 25°C:** 5 min at 25°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K032959 Cidex® OPA Concentrate			
Advanced Sterilization Products	5.75% *ortho*-phthaldehyde (OPA)	**No indication for device sterilization.** In-Use solution (0.05% OPA) passes the AOAC Sporicidal Activity Test in 32 hrs at 50°C.	5 min at 50°C Single use – diluted by system **For use in the EvoTech Integrated Endoscope Disinfection System only.** Contact conditions established by simulated use testing with endoscopes.

K030004 Cidex OPA Solution			
Advanced Sterilization Products	0.55% *ortho*-phthaldehyde	**No indication for device sterilization.** Passes the AOAC Sporicidal Activity Test in 32 hrs at 20°C and 25°C.	**Manual Processing** 12 min at 20°C 14 days Maximum Reuse **Automated Endoscope Reprocessor (AER)** 5 min at 25°C 14 days Maximum Reuse (For processing in an AER only with FDA-cleared capability to maintain solution temperature at 25°C.) Contact conditions established by simulated use testing with endoscopes.
K991487 °Cidex®OPA Solution High Level Disinfectant			
Advanced Sterilization Products	0.55% *ortho*-phthaldehyde	**No indication for device sterilization.** Passes the AOAC Sporicidal Activity Test in 32 hrs at 20°C.	12 min at 20°C 14 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
K070627 Opaciden Solution			
Ciden Technologies, LLC	**0.60% *ortho*-phthalaldehyde (OPA)**	**No indication for device sterilization.** *In-Use solution passes the AOAC Sporicidal Activity Test in 32 hrs at 21 ° C and 32 hrs at 25-27°C.*	**For Manual Processing:** 12 min at 20°C 14 days Maximum Reuse **For processing in a legally marketed Automated Endoscope Reprocessor capable of maintaining solution temperature at 25°C:** 5 min at 25°C 14 days Maximum Reuse *Contact conditions established by simulated use testing with endoscopes.*

2. Données de compatibilité des fabricants de Dispositifs Médicaux Réutilisables / *Compatibility data from manufacturers of Reusable Medical Devices* / *Datos de compatibilidad de los fabricanteS de productos sanitarios reutilizables*

2.1. OLYMPUS (endoscopie/ *endoscopy* / *endoscopia*)

https://www.yumpu.com/en/document/view/15379810/compatibility-statement-olympus-flexible-olympus-keymed

OLYMPUS
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COMPATIBILITY STATEMENT
OLYMPUS FLEXIBLE ENDOSCOPES

4. CIDEX OPA & OPA-C

Cidex OPA is an ortho-phthalaldehyde. This solution has undergone evaluation by Olympus Corporation's Research & Development group, the conclusion of which is that the solution has been added to Olympus' list of compatible disinfectant agents.

OPA-C is a concentrated form of OPA, for use in automatic washer/disinfectors that require a 'single-shot' of disinfectant. Although not tested by Olympus' R&D group, and so is not included on Olympus' list of compatible agents, its similarity in chemical content to OPA makes it unlikely that any compatibility problems exist. As such, the use of OPA-C will not lead to restrictions on the provision of loan instruments or service contracts.

In May 2004, the UK MHRA issued a Medical Device Alert relating to Cidex OPA, reference MDA/2004/022, identifying that manual reprocessing of urological instruments with Cidex OPA may have led to hypersensitivity in some patients with a history of bladder cancer undergoing repeated cystoscopy. As a result, J&J ASP has informed users of Cidex OPA that it is now contraindicated for the reprocessing of urological instruments.

For further information, contact:
Johnson & Johnson
Advanced Sterilization Products
Coronation Road
Ascot, Berks SL5 9EY

Tel: 01344 871131
Fax: 01344 872135
Web: www.cidex.com

2.2. FUJIFILM (endoscopie/ *endoscopy* / *endoscopia*)

Microsoft Word - Fujifilm Reprocessing Guide 3.23.12.doc (sgna.org)

IV. High-Level Disinfection:

Manual High-Level Disinfection

Flexible GI endoscopes (and bronchoscopes) which normally come into contact with mucous membranes are considered semi-critical medical devices that require at least high-level disinfection. Use only those liquid chemical germicides which have been FDA-cleared as high-level disinfectants and are recognized as compatible for the specific instruments intended to be reprocessed.

It should be noted that channel flushing aids are not labeled for use as disinfecting devices or as disinfectors; these products are intended to assist in the flushing of detergent solution, water and/or air during manual cleaning – they are not intended for endoscope disinfection. Check all product claims and IFUs with the OEM.

A. Check Minimum Effective Concentration (MEC) of the high-level disinfectant per manufacturer's labeling
B. Immerse the entire endoscope and scope components in a high-level disinfectant prepared per germicide manufacturer's recommendations
C. Attach the supplied Fujinon/Fujifilm channel disinfecting adapters to the endoscope
D. Avoid introduction of air bubbles during the subsequent flushing process
E. Flush the disinfectant into EACH channel (regardless of whether used clinically or not); ensure contact of disinfectant with all channel surfaces including:
    a) Suction/instrument channel (primary and secondary channels on two-channel scopes)
    b) Air and water channels
    c) Water jet channel

FRG-120323 **Endoscopy Division** 4
10 High Point Drive • Wayne, New Jersey 07470

2.3. PENTAX (endoscopie/ *endoscopy* / *endoscopia*)

https://www.pentaxmedical.com/pentax/download/fstore/uploadFiles/Pdfs/Other%20Documents/S021_R04.pdf

4-1. PENTAX Medical Compatible Reprocessing Systems/Agents

The information below is based upon material compatibility and functionality studies performed by HOYA Corporation- PENTAX Medical Division, Japan. Reference to specific brand name products is not an endorsement of their efficacy. Tests have shown these solutions to be compatible with materials used in the construction of PENTAX Medical endoscopes, provided that the manufacturers' instructions for use are followed. This document has been prepared by PENTAX Medical Company for PENTAX Medical customers in the United States, Canada and Latin America.

High Level Disinfectants

The following liquid chemical germicides have received FDA 510(k) clearance for claims of high level disinfection (HLD). Some HLD products may have multiple label claims and/or may be FDA-cleared only for use in a legally marketed AER machine that can attain specific use parameters (e.g., temperature).

Product Brand Name	Manufacturer
Cidex® OPA Cidex® OPA-C (used exclusively in EvoTech ECR) Cidex® Activated Dialdehyde Solution(14-Day Glutaraldehyde)	Advanced Sterilization Products
MetriCide® (Glutaraldehyde - may also be marketed as Omnicide NS or MaxiCide® NS)	Metrex Research Corporation
Sporicidin® (Glutaraldehyde)	Contec Incorporated
Rapicide® (Glutaraldehyde)	Medivators Inc.
Wavicide®-01 (Glutaraldehyde)	Medical Chemical Corporation

2.4. CIVCO (échographie/ *ultrasound / ecografía*)
https://www.civco.com/blog/how-to-high-level-disinfect-ultrasound-transducers-part-i/

HIGH-LEVEL DISINFECTANTS:

If you determine that your **probe requires high-level disinfection**, then you need to choose an appropriate high-level disinfectant.

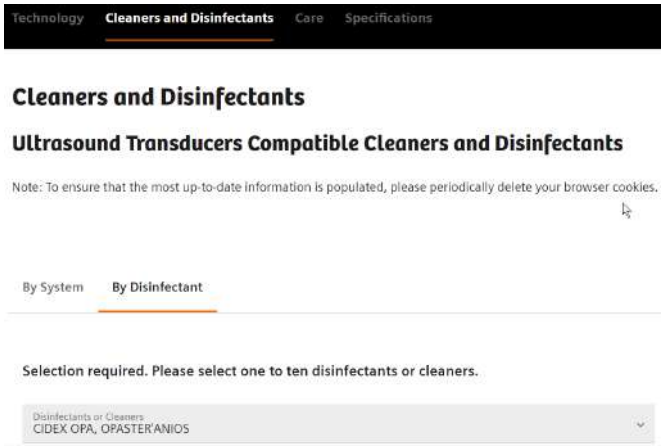
The Food and Drug Administration (FDA) has approved ortho-phthaladehyde (OPA), hydrogen peroxide, glutaraldehyde, and peracetic acid with hydrogen peroxide as high-level disinfectants. See the FDA's list of approved high-level disinfectants.

2.5. SIEMENS (échographie/ *ultrasound / ecografía*)
https://www.siemens-healthineers.com/ultrasound/ultrasound-transducer-catalog

La liste de sondes compatibles avec des solutions de désinfection à base d'orthophtalaldéhyde comme par exemple Cidex OPA et OPASTER'ANIOS sont disponibles sur le site.

The list of probes compatible with ortho-phthalaldehyde-based disinfection solutions, such as Cidex OPA and OPASTER'ANIOS is available on the website.

La lista de sondas compatibles con las soluciones de desinfección a base de ortoftalaldehído, por ejemplo, Cidex OPA y OPASTER'ANIOS, está disponible en su sitio web.



2.6. PHILIPS (échographie/ *ultrasound / ecografía*)
https://www.usa.philips.com/c-dam/b2bhc/master/whitepapers/ultrasound-care-and-cleaning/disinfectant-tables-manuals/new-dt-fr.pdf

Disinfectants and Cleaning Solutions Compatibility

Solution/ System	Country or Region of Origin	Qualified Use	Active Ingredient	Disinfectant Type	Compatibility Columns 1	2	3	4	5	6	7	8
Cidex OPA	US	Soak [1]	Ortho-phthalaldehyde	HLD	T,C[8]	T,C[8]	N	T	T	T	T,C[8]	T
OPAL	AU	Trempage[1]	Ortho-phthalaldéhyde	HLD	T,C[8]	T,C[8]	N	T	T	T	T,C[8]	T
RAPICIDE OPA/28	US	Trempage[1]	Ortho-phthalaldéhyde	HLD	T,C[8]	T,C[8]	N	T	T	T	T,C[8]	T

========== Fin du rapport d'essai ==========

========== End of test report ==========

========== Fin del informe ==========

Sodel
HYGIÈNE · DÉSINFECTION · SURODORANTS

Rapport d'essai – Electrochimie
Test report – Electrochemistry
Informe del ensayo - Electroquímica

Rapport édité à Lisieux, le 28 avril 2022
Report printed in Lisieux, 28 April 2022
Informe editado en Lisieux, el 28 de abril de 2022

RAPPORT D'ESSAI N° RPELEC2022_F3307_006
TEST REPORT No. RPELEC2022_F3307_006
INFORME DEL ENSAYO N.° RPELEC2022_F3307_006

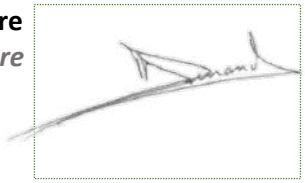
Titre de l'essai
Test title
Título del ensayo
Étude de l'action corrosive d'un désinfectant prêt à l'emploi vis-à-vis de l'acier inoxydable
Study of the corrosive action of a ready-to-use disinfectant on stainless steel
Estudio de la acción corrosiva de un desinfectante listo para usar sobre acero inoxidable

Type Produit
Product type
Tipo de producto
Désinfectant de Haut Niveau
High-level disinfectant
Desinfectante de alto nivel

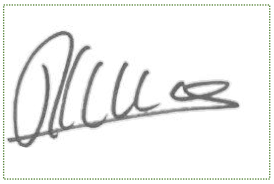
Code formule
Formula code
Código de formula
F3307

Rapport d'essai – Electrochimie
Test report – Electrochemistry
Informe del ensayo - Electroquímica

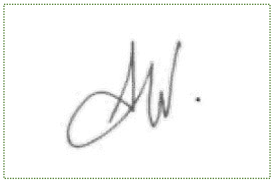
Rédigé par Dominique DURAND..... **Le 28/04/2022** ..... **Signature**
Written by Dominique DURAND..... ***On 28/04/2022*** ..... ***Signature***
Redactado por Dominique DURAND..... ***El 28/04/2022*** ..... ***Firma***
Fonction Responsable R&D
Position R&D Manager
Función: Responsable I+D



Vérifié par Gaétan RAUWEL..... **Le 28/04/2022** ..... **Signature**
Checked by Gaétan RAUWEL..... ***On 28/04/2022*** ..... ***Signature***
Verificado por Gaétan RAUWEL ..... ***El 28/04/2022*** ..... ***Firma***
Fonction Directeur scientifique & Stratégie Produits
Position Scientific Director and Product Strategy
Función Director Científico y Estrategia Productos



Approuvé par Annick NGUYEN..... **Le 28/04/2022** ..... **Signature**
Approved by Annick NGUYEN..... ***On 28/04/2022*** ..... ***Signature***
Aprobado por Annick NGUYEN..... ***El 28/04/2022*** ..... ***Firma***
Fonction Directrice qualité
Position Quality Director
Función: Directora de Calidad



Sodel
HYGIÈNE · DÉSINFECTION · SURODORANTS

Rapport d'essai – Electrochimie
Test report – Electrochemistry
Informe del ensayo - Electroquímica

SOMMAIRE

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Rapport d'essai – Electrochimie
Test report – Electrochemistry
Informe del ensayo - Electroquímica

I. OBJET DE L'ÉTUDE / *PURPOSE OF THE STUDY* / *OBJETO DEL ESTUDIO*

Evaluation par la technique électrochimique du pouvoir corrosif par piqure d'un détergent, désinfectant ou détergent désinfectant vis-à-vis de l'acier inoxydable, matériau constitutif des instruments médico-chirurgicaux métalliques réutilisables. La technique électrochimique est une technique potentiodynamique qui consiste à faire varier le potentiel de l'électrode de travail linéairement en fonction du temps dans un domaine de potentiel défini afin de déterminer les potentiels de piqure et de repassivation du produit objet de l'essai.

Electrochemical assessment of the pitting corrosion potential of a detergent, disinfectant or disinfectant detergent on stainless steel, the material used to make reusable metal medical and surgical instruments. This electrochemical assessment is a potentiodynamic technique that involves varying the potential of the working electrode linearly as a function of time within a set potential range in order to determine the pitting and repassivation potential of the product tested

Evaluación mediante la técnica electroquímica del poder corrosivo por picadura de un detergente, desinfectante o detergente desinfectante sobre el acero inoxidable, que s el material del que están hechos los instrumentos médico-quirúrgicos metálicos reutilizables. La técnica electroquímica es una técnica potenciodinámica que consiste en hacer variar linealmente el potencial del electrodo de trabajo en función del tiempo dentro de un intervalo de potencial definido, para determinar los potenciales de picadura y de repasivación del producto analizado.

II. DOCUMENTS DE REFERENCE / *REFERENCE DOCUMENTS* / *DOCUMENTOS DE REFERENCIA*

Norme NF S94-402-1 (mai 2004).
Étude de l'action corrosive d'un pré-désinfectant ou d'un nettoyant ou d'un désinfectant sur les instruments médico-chirurgicaux réutilisables
NF S94-402-1 Standard (May 2004).
Examination of the corrosive effect of a decontaminant, cleaning agent or disinfectant on reusable medico-surgical instruments
Norma NF S94-402-1 (mai 2004).
Estudio de la acción corrosiva de un predesinfectante o un limpiador o un desinfectante en los instrumentos médico-quirúrgicos reutilizables.

III. RESPONSABILITES / *RESPONSIBILITIES* / *RESPONSABILIDADES*

Cette étude du pouvoir corrosif par piqure d'un produit a été conduite par le secteur de Recherche et Développement de la société Sodel située à LISIEUX (14100).
This report was written by the Research and Development department of Sodel in Lisieux, north-west France (14100).
Este estudio del poder corrosivo por picadura del producto fue realizado por el departamento de Investigación y Desarrollo de la empresa Sodel en LISIEUX (14100).

Etapes *Stages* *Etapas*	Responsabilités *Responsibilities* *Responsabilidades*
Rédaction du rapport d'essai *Drafting of the test report*	Responsable R&D *R&D Manager*

Rapport d'essai – Electrochimie
Test report – Electrochemistry
Informe del ensayo - Electroquímica

Redacción del informe del ensayo	*Responsable I+D*
Vérification du rapport d'essai *Checking of the test report* *Verificación del informe del ensayo*	Directeur Scientifique et Stratégie Produits *Scientific Director and Product Strategy* *Director Científico y Estrategia Productos*
Approbateur de l'étude *Study approved by* *Aprobador del estudio*	Directeur Qualité *Quality Director* *Director de Calidad*

IV. DEROULEMENT DE L'ESSAI / *TEST PROCEDURE* / *DESARROLLO DEL ENSAYO*

1. Principe du l'étude, matériel et méthodes / *Principle of the study, equipment and methods* / *Principio del estudio, material y métodos*

Les méthodes d'essais électrochimiques sont destinées à évaluer le pouvoir corrosif par piqûre d'un produit sur un matériau métallique prédéfini. Le pouvoir corrosif d'un détergent, désinfectant ou détergent désinfectant sera caractérisé par la valeur de ses potentiels de piqure et de repassivation (chronoampérométrie).
Pour effectuer ces mesures de chronoampérométrie à variation linéaire de potentiel, on utilise un dispositif expérimental spécifique constitué de :

- Trois électrodes :
  - une électrode de travail constituée par le matériau (acier inoxydable),
  - une électrode de référence à potentiel constant,
  - une contre-électrode dans laquelle passe le courant faradique.
- Cellule d'électrochimie thermostatée (OrigaCell, refX14OGL010)
- Potentiostat – Galvanostat (RigaFlex – OGF01A, ref X13OGL002CIAL)
- Logiciel de pilotage (rigaFlex – OGFDRV, ref X13OGL004CIAL)

Electrochemical test methods are used to assess the pitting corrosion potential of a protect on a predefined metallic material. The corrosive potential of a detergent, disinfectant or disinfectant detergent will be characterised by the value of its pitting and repassivation potentials (chronoamperometry).
To make these chronoamperometry measurements based on a linear variation in potential, we use a specific test set-up comprising:

- *Three electrodes:*
  - *one working electrode made of stainless steel,*
  - *one reference electrode of constant potential,*
  - *a counter-electrode to which the faradic current is applied.*
- *Thermostated electrochemistry cell (OrigaCell, refX14OGL010)*
- *Potentiostat - Galvanostat (RigaFlex - OGF01A, ref X13OGL002CIAL)*
- *Control software (rigaFlex - OGFDRV, ref X13OGL004CIAL)*

Los métodos de ensayo electroquímico están pensados para evaluar el poder corrosivo por picadura de un producto sobre un material metálico predefinido. El poder corrosivo de un detergente, desinfectante o detergente desinfectante se caracterizará por el valor de sus potenciales de picadura y de repasivación (cronoamperometría).

Rapport d'essai – Electrochimie
Test report – Electrochemistry
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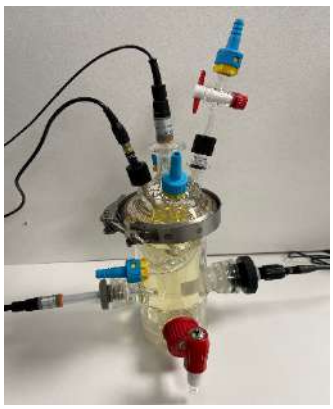
Para estas mediciones de cronoamperometría con variación lineal del potencial, se utiliza un dispositivo experimental específico que consta de:

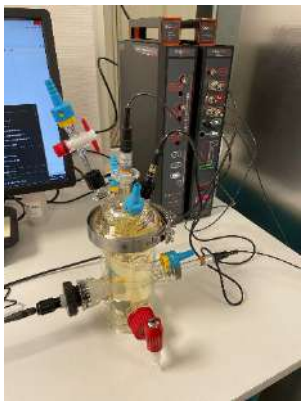
- *Tres electrodos:*
  - *un electrodo de trabajo hecho del material (acero inoxidable),*
  - *un electrodo de referencia de potencial constante,*
  - *un contraelectrodo por el que pasa la corriente faradaica.*
- *Celda electroquímica con termostato (OrigaCell, refX14OGL010)*
- *Potenciostato – Galvanostato (RigaFlex – OGF01A, ref X13OGL002CIAL)*
- *Software de control (rigaFlex – OGFDRV, ref X13OGL004CIAL)*

Photo de la cellule d'électrochimie et du montage complet

Photo of the electrochemical cell and complete set-up

Fotografía de la celda electroquímica y del montaje completo





Rapport d'essai – Electrochimie
Test report – Electrochemistry
Informe del ensayo - Electroquímica

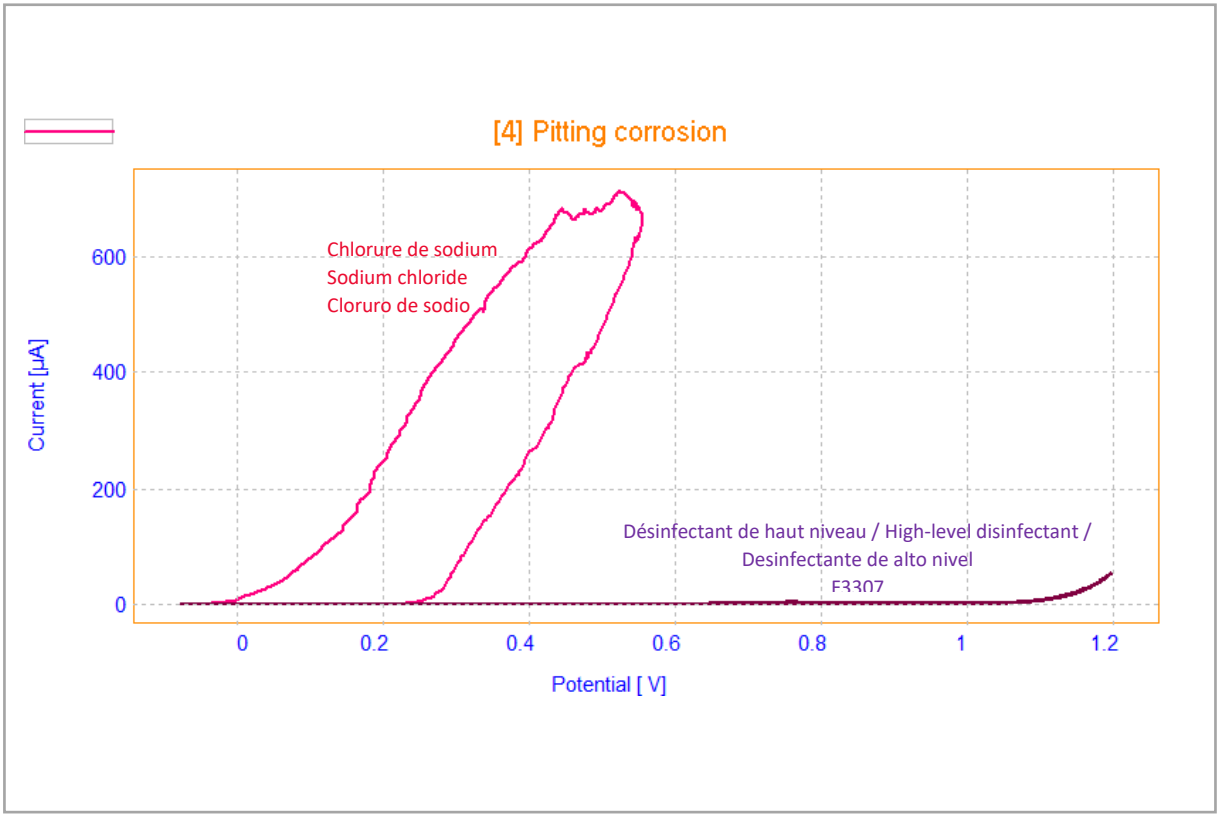
2. Description des échantillons soumis à l'essai / *Description of test samples* / *Descripción de las muestras enviadas para el ensayo*

Type de produit *Product type* *Tipo de producto*	Désinfectant de haut niveau *High-level disinfectant* *Desinfectante de alto nivel*
Code formule *Formula code* *Código de formula*	F3307
Numéro du lot *Batch number* *Número de lote*	0209E036220322H
Dose d'emploi *Application dose* *Dosis de empleo*	Produit prêt à l'emploi *Product ready-to-use* *Producto listo para usar*
Acier inoxydable (nuance et état de surface) *Stainless steel (grade and surface finish)* *Acero inoxidable (matiz y estado de la superficie)*	Austénitique 304L, poli brillant *Austenitic 304L, bright polished* *Austentítico 304L, polibrillante*
Température de l'essai *Test temperature* *Temperatura del ensayo*	+22°C ± 3°C
Vitesse de balayage en potentiel *Potential scan rate* *Velocidad de barrido en potencial*	0,2 $mV.s^{-1.}$
Valeur maximale de densité de courant *Maximum current density value* *Valor máximo de densidad de corriente*	500 $\mu A.cm^{-2}$
Témoin *Control sample* *Control*	Solution de chlorure de sodium à 0,1% en eau de réseau *0.1% sodium chloride solution in tap water* *Solución de cloruro de sodio al 0,1 % en agua corriente*

Rapport d'essai – Electrochimie
Test report – Electrochemistry
Informe del ensayo - Electroquímica

3. Résultats des essais / *Test results* / *Resultados de los ensayos*

Paramètres ***Parameters*** ***Parámetros***	**Désinfectant de haut niveau** ***High-level disinfectant*** ***Desinfectante de alto nivel*** **F3307**	***Solution de chlorure de sodium*** ***Sodium chloride solution*** ***Solución de cloruro de sodio***
Potentiel de piqure *Pitting potential* *Potencial de picadura*	*1109 mV*	*256 mV*
Potentiel de repassivation *Repassivation potential* *Potencial de repasivación*	*1088 mV*	*39 mV*



V. CONCLUSION / *CONCLUSION* / *CONCLUSIÓN*

Les valeurs de piqure (1109 mV) et de repassivation (1088 mV) obtenues pour le désinfectant de haut niveau F3307 démontrent que ce produit n'est pas corrosif vis-à-vis de l'acier inoxydable, matériau constitutif des instruments médico-chirurgicaux métalliques réutilisables. Deux paramètres nous permettent de confirmer ce résultat ; des valeurs de potentiels de piqure et de repassivation à valeur très électropositives par comparaison avec le chlorure de sodium. Il est à noter que du fait d'une réponse totalement inerte en électrochimie du désinfectant F3307 en comparaison à la solution de chlorure de sodium, sa courbe électrochimique est d'apparence plane.

The pitting (1109 mV) and repassivation (1088 mV) values obtained for the high-level disinfectant F3307 show that this product is not corrosive to stainless steel, the material used to make reusable medical and surgical instruments. This result is confirmed by two parameters: the pitting and repassivation potential values of high electroposivity compared to the sodium chloride. Note that owing to the totally inert electrochemical response of the disinfectant F3307 compared to the sodium chloride solution, its electrochemical curve appears to be flat.

Los valores de picadura (1109 mV) y de repasivación (1088 mV) obtenidos para el desinfectante de alto nivel F3307 demuestran que este producto no es corrosivo sobre el acero inoxidable, material del que están hechos los instrumentos médico-quirúrgicos metálicos reutilizables. Hay dos parámetros que permiten confirmar este resultado: los valores de los potenciales de picadura y de repasivación muy electropositivos en comparación con el cloruro de sodio. Cabe señalar que, debido a una respuesta electroquímica totalmente inerte del desinfectante F3307, en comparación con la solución de cloruro de sodio, su curva electroquímica tiene un aspecto plano.

==========Fin du rapport d'essai ==========

==========End of test report ==========

==========Fin del informe ==========

Rapport d'essai – Electrochimie
Test report – Electrochemistry
Informe del ensayo - Electroquímica

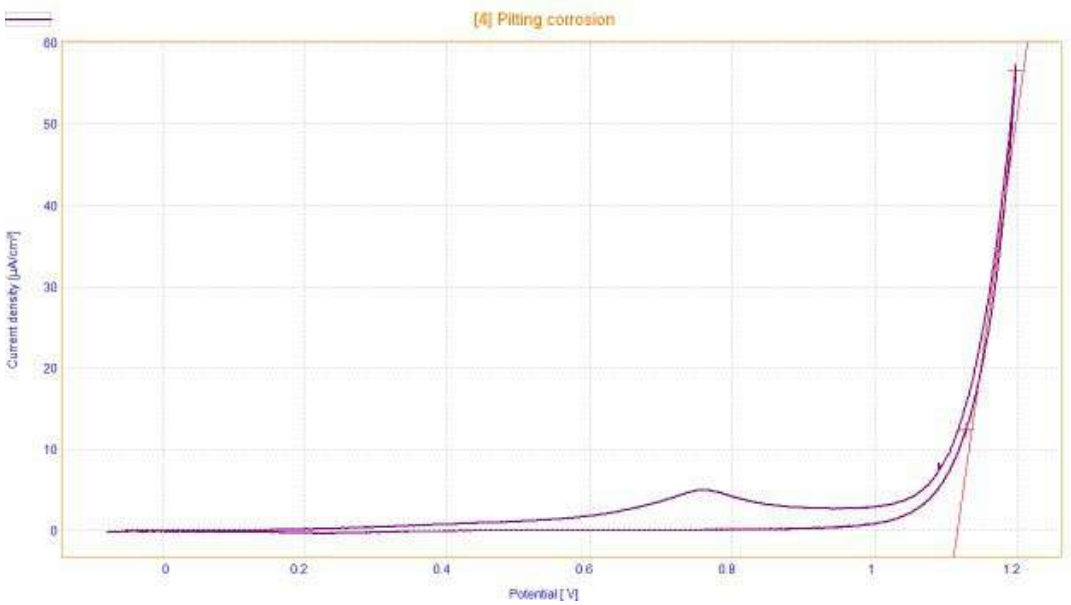
VI. ANNEXE / *APPENDICES* / *ANEXO*

Détermination des potentiels de piqure et de repassivation

Determination of pitting potentials and repassivation

Determinación de los potenciales de picadura y repasivación

F3307



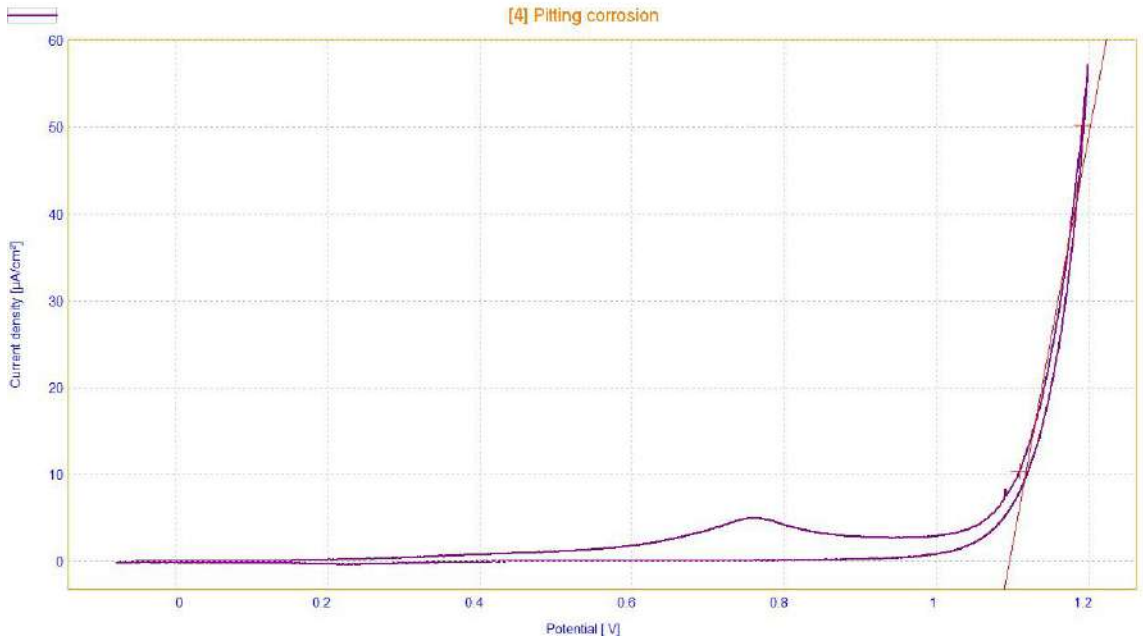
Potentiel de piqûre : 1,109V

Pitting potential: 1.109 V

Potencial de picadura : 1,09V

Rapport d'essai – Electrochimie
Test report – Electrochemistry
Informe del ensayo - Electroquímica

F3307



Potentiel de passivation : 1,088V
Passivation potential: 1.088V
Potencial de pasivación : 1,088V

Rapport d'essai – Stress cracking
Essay report – Stress cracking
Informe del ensayo – Stress cracking

Rapport édité à Lisieux, le 03 mai 2022
Report printed in Lisieux, 03 May 2022
Informe editado en Lisieux, el 03 de mayo de 2022

RAPPORT D'ESSAI N° RPCRAC2022_F3307_003
ESSAY REPORT NO. RPCRAC2022_F3307_003
INFORME DEL ENSAYO N.º RPCRAC2022_F3307_003

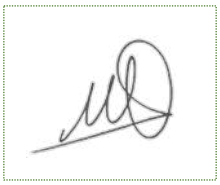
Titre de l'essai
Essay title
Título del ensayo
Evaluation de la compatibilité avec le polycarbonate par Stress cracking
Assessment of polycarbonate compatibility by stress cracking
Evaluación de la compatibilidad con el policarbonato mediante stress cracking

Type Produit
Product type
Tipo de producto
Désinfectant de haut niveau
High-level disinfectant
Desinfectante de alto nivel

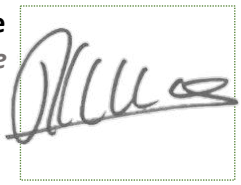
Code formule
Formula code
Código de formula
F3307

Rapport d'essai – Stress cracking
Essay report – Stress cracking
Informe del ensayo – Stress cracking

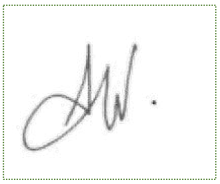
Rédigé par Christophe RENARD	**Le 03/05/2022**	**Signature**
Written by Christophe RENARD	*On 03/05/2022*	*Signature*
Redactado por Christophe RENARD	*El 03/05/2022*	*Firma*
Fonction Responsable R&D		
Position R&D Manager		
Función Responsable de I+D		



Vérifié par Gaétan RAUWEL	**Le 03/05/2022**	**Signature**
Checked by Gaétan RAUWEL	*On 03/05/2022*	*Signature*
Verificado por Gaétan RAUWEL	*El 03/05/2022*	*Firma*
Fonction Directeur scientifique & Stratégie Produits		
Position Scientific Director and Products Strategy		
Función Director Científico y Estrategia Productos		



Approuvé par Annick NGUYEN	**Le 03/05/2022**	**Signature**
Approved by Annick NGUYEN	*On 03/05/2022*	*Signature*
Aprobado por Annick NGUYEN	*El 03/05/2022*	*Firma*
Fonction Directrice qualité		
Position Quality Director		
Función Directora de calidad		



Rapport d'essai – Stress cracking
Essay report – Stress cracking
Informe del ensayo – Stress cracking

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I. OBJET DE L'ÉTUDE / *PURPOSE OF STUDY* / *OBJETO DEL ESTUDIO*

La caractérisation de la compatibilité d'un produit avec le polycarbonate est réalisée par la mise sous contrainte physique puis en trempage d'éprouvettes de polycarbonate dans une solution du produit à tester à sa concentration d'emploi pour un temps de contact défini.

L'incompatibilité du produit vis-à-vis du polycarbonate se caractérise par l'apparition de fissurations. A l'inverse, l'absence de fissuration confirme la compatibilité.

L'évaluation de la comptabilité est faite par comparaison à des témoins/produits de référence neutre vis-à-vis du polycarbonate (témoin négatif et/ou leaders du marché définis) et un témoin positif (éthanol pur) non compatible avec le polycarbonate.

The characterisation of a product's compatibility with polycarbonate is carried out by physical stress and then by soaking polycarbonate test specimens in a solution of the product to be tested at its use concentration for a defined contact time.

The product's incompatibility with polycarbonate is characterised by the appearance of cracks. Conversely, the absence of cracking confirms compatibility.

The compatibility assessment is made by comparison with neutral reference controls/products with respect to polycarbonate (negative control and/or defined market leaders) and a positive control (pure ethanol) not compatible with polycarbonate.

La caracterización de la compatibilidad de un producto con el policarbonato se lleva a cabo mediante la aplicación de tensión física y el posterior remojo de las probetas de policarbonato en una solución del producto a analizar a su concentración de empleo durante un tiempo de contacto definido.

La incompatibilidad del producto con el policarbonato se caracteriza por la aparición de fisuras. Por el contrario, la ausencia de fisuras confirma la compatibilidad.

La evaluación de la compatibilidad se realiza comparando con controles/productos de referencia neutros para el policarbonato (control negativo y/o líderes del mercado definidos) y un control positivo (etanol puro) no compatible con el policarbonato.

II. DOCUMENTS DE REFERENCE / *REFERENCE DOCUMENTS* / *DOCUMENTOS DE REFERENCIA*

- ISO 22088-1 (août 2006) : Plastiques - Détermination de la fissuration sous contrainte dans un environnement donné - Partie 1 : Lignes directrices générales
- ISO 22088-3 (août 2006) : Plastiques - Détermination de la fissuration sous contrainte dans un environnement donné - Partie 3 : méthode de l'éprouvette courbée
- Mode opératoire MM4.16 v1

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- *ISO 22088-1 (August 2006): Plastics - Determination of stress cracking in a given environment - Part 1: General Guidelines*
- *ISO 22088-3 (August 2006): Plastics - Determination of stress cracking in a given environment - Part 3: curved test piece method*
- *Procedure MM4.16 v1*

- *ISO 22088-1 (agosto 2006): Plásticos. Determinación de la resistencia a la fisuración bajo esfuerzo en un medio ambiente activo. Parte 1: Guía general*
- *ISO 22088-3 (agosto 2006): Plásticos. Determinación de la resistencia a la fisuración bajo esfuerzo en un medio ambiente activo. Parte 3: Método de la probeta curvada*
- *Procedimiento MM4.16 v1*

III. RESPONSABILITES / *RESPONSIBILITIES* / *RESPONSABILIDADES*

Cette étude de stress cracking a été conduite par le secteur de Recherche et Développement de la société Sodel située à LISIEUX (14100).
This stress cracking study was conducted by the Research and Development area of Sodel located in LISIEUX (14100).
Este estudio de stress cracking fue realizado por el departamento de Investigación y Desarrollo de la empresa Sodel en LISIEUX (14100).

Etapes *Stages* *Etapas*	Responsabilités *Responsibilities* *Responsabilidades*
Rédaction du rapport d'essai *Drafting of the assay report* *Redacción del informe del ensayo*	Responsable R&D *R&D Manager* *Responsable I+D*
Vérification du rapport d'essai *Checking of the assay report* *Verificación del informe del ensayo*	Directeur Scientifique & Stratégie Produits *Scientific Director and Products Strategy* *Director Científico y Estrategia Productos*
Approbateur de l'étude *Study Approver* *Aprobador del estudio*	Directeur Qualité *Quality Director* *Director de Calidad*

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IV. DEROULEMENT DE L'ESSAI / *CONDUCTING OF THE ESSAY* / *DESARROLLO DEL ENSAYO*

1. Description des échantillons soumis à l'essai / *Description of samples submitted for test* / *Descripción de las muestras enviadas para el ensayo*

Matériaux / Materials / Material

Matériau de l'éprouvette *Test piece material* *Material de la probeta*	Référence *Reference* *Referencia*	Dimension *Dimensions* *Dimensiones*	Fournisseur *Supplier* *Proveedor*
Polycarbonate *Polycarbonate* *Policarbonato*	*68595*	*80 x 12 x 1 mm*	*Rochollo GmbH*

- **Produit fini objet de l'essai / *Finished product tested* / *Producto terminado analizado***

Type de produit *Product type* *Tipo de producto*	Désinfectant de haut niveau *High-level disinfectant* *Desinfectante de alto nivel*
Code formule *Formula code* *Código de formula*	F3307
Numéro du lot *Batch number* *Número de lote*	0209E036220322H
Dose d'emploi *Dose to be used* *Dosis de empleo*	Prêt à l'emploi *Ready for use* *Listo para usar*
Substances actives *Active substances* *Sustancias activas*	Ortho-phtalaldéhyde 0,57% (m/m) *Ortho-phtalaldehyde 0.57% (m/m)* *Ortoftalaldehído al 0,57% (m/m)*
Date de fabrication du produit *Product manufacturing date* *Fecha de fabricación del producto*	22/03/2022
Date de péremption *Expiry date* *Fecha de caducidad*	21/03/2024

- **Témoin positif / *Positive control* / *Control positivo***

Type de produit *Product type* *Tipo de producto*	Alcool éthylique 99,9% *Ethyl alcohol 99.9%* *Alcohol etílico al 99,9 %*

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Référence *Reference* *Referencia*	MP0029
Numéro du lot *Batch number* *Número de lote*	FR152115307
Dose d'emploi *Dose to be used* *Dosis de empleo*	Pure *Pure* *Puro*
Date de péremption *Expiry date* *Fecha de caducidad*	Tereos Alcools *Tereos Alcohols* *Tereos Alcoholes*

- ***Témoin négatif / Negative control / Control negativo***

Type de produit *Product type* *Tipo de producto*	Eau déminéralisée *Demineralised water* *Agua desmineralizada*
Référence *Reference* *Referencia*	MP0054
Numéro du lot *Batch number* *Número de lote*	Non applicable *Non applicable* *No aplicable*
Dose d'emploi *Dose to be used* *Dosis de empleo*	Pure *Pure* *Puro*
Fournisseur *Provider* *Proveedor*	Sodel

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2. Conditions de réalisation des essais / *Test execution conditions* / *Condiciones de realización de los ensayos*

Date de réalisation des essais *Assay execution date* *Fecha de realización de los ensayos*	31/03/2022
Température de réalisation des essais *Assay execution temperature* *Temperatura de realización de los ensayos*	22°C ± 3°C
Condition d'essais *Condition of assays* *Condiciones de los ensayos*	20 cycles successifs de trempage de 15 minutes et de séchage de 5 minutes avec observation des éprouvettes tous les 5 cycles. *20 successive 15-minute soaking and 5-minute drying cycles with test specimens observed every 5 cycles.* *Veinte (20) ciclos consecutivos de remojo de 15 minutos y secado de 5 minutos, con observación de las probetas cada 5 ciclos.*
Durée des essais *Duration of assays* *Duración de los ensayos*	6H40
Référence de la méthode d'essai *Assay method reference* *Referencia del método de ensayo*	MM4.16 v1

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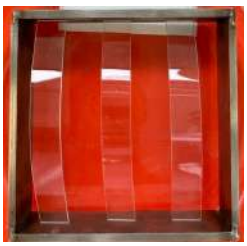
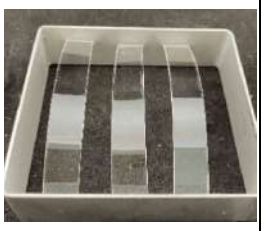
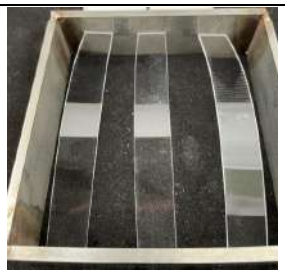
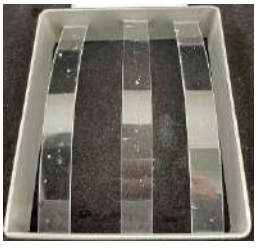
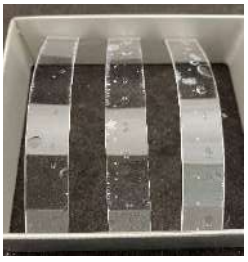
3. Résultats des essais / *Test results* / *Resultados de los ensayos*

Etude comparative des éprouvettes de polycarbonate :
Comparative study of polycarbonate test specimens:
Estudio comparativo de las probetas de policarbonato:

	Témoin positif (éthanol) *Positive control (ethanol)* *Control positivo (etanol)*	Témoin négatif (eau déminéralisée) *Negative control (demineralised water)* *Control negativo (agua desmineralizada)*	F3307	Témoin comparatif (leader du marché*) *Comparator control (market leader*)* *Control comparativo (líder del mercado*)*
à t=0 *at t=0* *en t=0*				
Zoom X2 *Zoom X2* *Zoom X2*				
observations *observations* *observaciones*	Polycarbonate mis sous contrainte. Absence de fissures à t=0 *Stressed polycarbonate* *No cracks at t=0* *Policarbonato en condiciones de estrés.* *Ausencia de fisuras en t=0*			
à t=20 cycles *at t=20 cycles* *en t=20 ciclos*				

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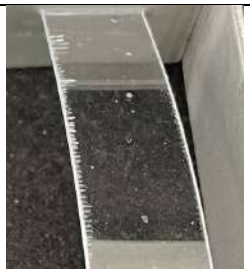
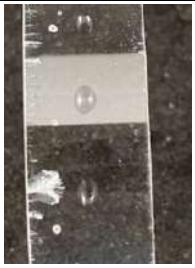
Zoom X2 *Zoom X2* *Zoom X2*				
Observations *Observations* *Observaciones*	Présence de fissures *Presence of cracks* *Presencia de fisuras*	Absence de fissures *No cracks* *Ausencia de fisuras*	Présence de fissures sur les côtés *Cracks on the sides* *Presencia de fisuras en los lados*	Présence de fissures sur les côtés *Cracks on the sides* *Presencia de fisuras en los lados*

*leader du marché : Opaster Anios
**market leader: Opaster Anios*
**líder del mercado: Opaster Anios*

V. CONCLUSION / *CONCLUSION* / *CONCLUSION*

Le désinfectant de haut niveau F3307 n'est pas compatible avec le polycarbonate car il présente un comportement identique au témoin positif (éthanol) et au témoin comparatif, leader du marché pour une même application.

The high-level disinfectant F3307 is not compatible with polycarbonate because it behaves identically to both the positive control sample (ethanol) and the comparative control sample, market leader for the same application.

El desinfectante de alto nivel F3307 no es compatible con el policarbonato, ya que presenta un comportamiento idéntico al control positivo (etanol) y al control comparativo, líder del mercado, para una misma aplicación.

========== Fin du rapport d'essai ==========

========== End of essay report ==========

========== Fin del informe ==========

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Final study report
Informe final del estudio

Numéro d'étude
Study number
Número del estudio
N°STAB2022084

Rapport édité à Lisieux, 23 mai 2023
Edited report at Lisieux, 23 mai 2023
Informe editado en Lisieux, 23 de mayo de 2023

RAPPORT FINAL D'ETUDE RSTAB2022084
FINAL REPORT STUDY
INFORME FINAL DEL ESTUDIO

Etude de Stabilité du produit
Stability study of the product
Estudio sobre la estabilidad del producto

Produit
Désinfectant de haut niveau
Product
High level disinfectant
Producto
Desinfectante de alto nivel

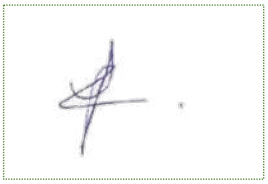
Code formule
Formula

Código de formula

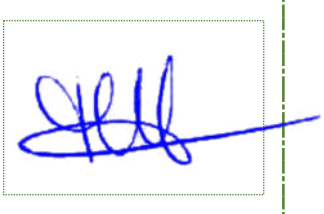
F3307

Rapport final d'étude
Final study report
Informe final del estudio

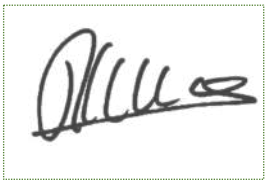
Rédigé par Cyrielle HOURNON ..... Le 23/05/2023..... Signature
Written by Cyrielle HOURNON ..... On 23/05/2023..... Signature
Redactado por Cyrielle HOURNON..... El 23/05/2023 ..... Firma
Fonction : Responsable Chimie Analytique
Position : Analytical Chemistry Manager
Función: Responsable de Química Analítica



Vérifié par Marlène HORGNIES ..... Le 23/05/2023..... Signature
Checked by Marlène HORGNIES ..... On 23/05/2023..... Signature
Verificado por Marlène HORGNIES ..... El 23/05/2023 ..... Firma
Fonction : Directrice affaires réglementaires et Microbiologie
Position : Regulatory Affairs and Microbiology Director
Función: Directora Asuntos Regulatorios y Microbiología



Approuvé par Gaétan RAUWEL ..... Le 23/05/2023 ..... Signature
Approved by Gaétan RAUWEL ..... On 23/05/2023..... Signature
Aprobado por Gaétan RAUWEL ..... El 23/05/2023 ..... Firma
Fonction Directeur scientifique & Stratégie Produits
Position: Scientific Director and Products Strategy
Función: Director científico y Estrategia Productos



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I. OBJET ET DOMAINE D'APPLICATION / *OBJECTIVE SCOPE* / OBJETO Y ÁMBITO DE APLICACIÓN

Ce rapport présente les résultats de stabilité en condition accélérées du désinfectant de haut niveau, F3307 (RD0209E236) du lot 2S43N3497.
Cette étude a été conduite un lot pilote conditionné en laboratoire dans l'emballage commercial pour vérifier la stabilité du produit à + 40 °C (± 2 °C) et à 4 °C (± 2 °C) pendant 8 semaines.
Des résultats conformes aux spécifications ainsi qu'une variation de la teneur en substances actives de ± 10 % par rapport aux valeurs du T0 permettent de revendiquer une stabilité du produit de 2 ans à température ambiante.

This report presents the accelerated stability results for the product high level disinfectant, F3307 (RD0209E36), batch 2S43N3497.
This study is designed to verify the stability of the product at + 40 °C (± 2 °C) and at + 4 °C (± 2 °C) for 8 weeks in the commercial packaging.
Conform results to the specification and a substance active variation of ± 10 % from T0 value allow to claim a product stability for 2 years at ambient temperature.

Este informe presenta los resultados de estabilidad acelerada del desinfectante de alto nivel F3307 (RD0209E236) del lote piloto 2S43N3497.
Este estudio se ha llevado a cabo con un lote piloto acondicionado en el laboratorio en su envase comercial para verificar la estabilidad del producto a +40 °C (±2 °C) y +4 °C (±2 °C) durante 8 semanas.
Los resultados conforme a las especificaciones y la variación del contenido de sustancias activas de ± 10 % con respecto a T0 permiten afirmar la estabilidad del producto a temperatura ambiente durante 2 años.

II. DOCUMENTS DE REFERENCE / *REFERENCE TEXTS* / *DOCUMENTOS DE REFERENCIA*

OECD ENV/JM/MONO(2015)32 : 15 dec-2016 Guidance document for storage stability testing of plant protection and biocidal products – Guidance used in support of pre-registration data requirements for plant protection and biocidal end-use products. Series on testing & assessment No.223, series on Biocides No.10.

L'ECHA : Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C Version 2.1 March 2022.

CIPAC MT 46.4 accelerated storage procedure.

FM4.44_v1 PSTAB2022084_F3307 : Stability protocol

PM5.04 « Traitement des non-conformités et des ACPA ».

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III. RESPONSABILITES / *RESPONSIBILITIES* / *RESPONSABILIDADES*

Cette étude de stabilité a été conduite par le laboratoire de chimie analytique de la société Sodel située à LISIEUX (14100).

This stability study has been managed by the analytical chemistry laboratory of Sodel company located in LISIEUX (14100).

Este estudio de estabilidad fue realizado por el laboratorio de química analítica de la empresa Sodel en LISIEUX (14100).

Etape *Step* *Etapa*	Responsabilités *Responsibilities* *Responsabilidades*
Stockage de l'échantillon *Sample storage* *Almacenamiento de la muestra*	Service R&D *R&D department* *Departamento I+D*
Analyse de l'échantillon *Sample analysis* *Análisis de la muestra*	Technicien Chimie Analytique *Analytical Chemistry Technician* *Técnico Química Analítica*
Rédaction du rapport de stabilité *Edition of stability report* *Redacción del informe de estabilidad*	Responsable Chimie Analytique *Analytical Chemistry Manager* *Responsable Química Analítica*
Vérification du rapport de stabilité *Verification of stability report* *Comprobación del informe de estabilidad*	Directrice affaires réglementaires et Microbiologie *Regulatory Affairs and Microbiology Director* *Directora Asuntos Regulatorios y Microbiología*
Approbateur de l'étude *Overall responsibility* *Aprobador del estudio*	Directeur Scientifique et Stratégie Produits *Scientific Director & Products Strategy* *Director científico y Estrategia Productos*

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IV. DEROULEMENT DE L'ETUDE/ *TIMELINE OF STUDY / DESARROLLO DEL ESTUDIO*

1. Détails du lot/ *Batch details* / Detalles del lote

➢ **Produit fini**/ *finished product / Producto terminado*

Type de produit *Product type* *Tipo de producto*	Désinfectant de haut niveau Dispositif médical *High level disinfectant high level* *Medical device* Desinfectante de alto nivel Producto sanitario
Code formule *Formula code* *Código de fórmula*	F3307 (RD0209E36)
Numéro du lot *Batch number* *Número de lote*	2S43N3497
Type de formulation *Formulation type* *Tipo de formulación*	Liquide prêt à l'emploi *Liquid Ready to use* Líquido listo para usar
Type et Volume du contenant *Packaging Type and Volume* *Tipo y volumen del envase*	Bidon 5 L *5 L jerrican* Bidón de 5L
Matériau du contenant *Packaging Material* *Material del envase*	Jerrican 5L PEHD blanc 160g col 40/42 (CT0135) *Jerrican 5L white HDPE 160g neck 40/42 (CT0135)* Bidón de 5L de HDPE blanco de 160g cuello 40/42 (CT0135)
Type de fermeture *Closure type* *Tipo de cierre*	Bouchon en plastique vissé Bouchon 5 L BLANC D.37 JOINTE (FE0080) *Cap 5 L white, D.37 JOINTE (FE0080)* *Plastic screwed cap* *Tapón de plástico de rosca* *Tapón 5L BLANCO D.37 JUNTA (FE0080)*
Date de fabrication du produit *Manufacturing date* *Fecha de fabricación*	25 et 26 octobre 2022 *25 and 26 october 2022* 25 y 26 de octubre 2022
Date de péremption *Expiration date* *Fecha de caducidad*	2 ans 2 years 2 años
Date du certificat d'analyse *Certificate of analysis date* *Fecha del certificado de análisis*	Non applicable *Not applicable* No aplicable
Début de l'étude *Start of study* *Inicio del estudio*	13 décembre 2022 *13 december 2022* 13 de diciembre 2022

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Fin de l'étude *End of study* *Final del estudio*	07 février 2023 *07 February 2023* 07 de febrero 2023

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➢ ***Substance active matière première*** */ Raw material active substance / Sustancias activas materias primas*

Substance active *Active substance* *Sustancia activa*	0,57% (Orthophtalaldéhyde / *Ortho-phthalaldehyde* / *Ortoftalaldehído*)
Numéro interne de la substance active *Internal number of active substance* *Número interno de la sustancia activa*	MP0332
N° CAS de la substance active *Active substance CAS number* *N° CAS de la sustancia activa*	643-79-8
Lot de substance active *Active substance batch* *Lote de sustancia activa*	LBOP6A6038
Fournisseur de la substance active *Origin of active substance* *Proveedor de la sustancia activa*	ESIM

V. PROGRAMME DE STABILITE / *STABILITY STUDY PROGRAMME / PROGRAMA DE ESTABILIDAD*

1. Condition, fréquence des essais et nombre d'échantillon stockés

Condition, frequency of testing and number of samples incubated

Condiciones, frecuencia de los ensayos y número de muestras almacenadas

Condition de stockage *Storage conditions* *Condiciones de almacenamiento*	Période en semaines *Period in weeks* *Periodo en semanas*	Nombre de flacons stockés* *No of bottles incubated** *Número de frascos almacenados**
+ 40 °C (± 2 °C)	0-4-6-8	1
+ 4 °C (± 2 °C)	0-4-6-8	1

*Le lot étudié est un lot pilote conditionné en laboratoire dans l'emballage commercial. A chaque échéance un aliquot est prélevé pour les analyses puis le bidon est remis en étuve.

**This study is performed with a pilot batch packed in commercial packaging at each time point an aliquot is drawn for analysis then the jerrican is put back into the incubator.*

**El estudio se ha llevado a cabo con un lote piloto acondicionado en el laboratorio en el envase comercial. Para los análisis, se extrajo una alícuota en cada punto temporal y luego el bidón se volvió a dejar en la incubadora.*

Sodel
HYGIÈNE • DÉSINFECTION • SURODORANTS

Rapport final d'étude
Final study report
Informe final del estudio

2. Temps de l'étude / *Study duration* / Duración del estudio

Cette étude est d'une durée de 8 semaines dans les deux conditions de températures, + 40 °C (± 2 °C) et + 4 °C (± 2 °C).

This study is conducted up to 8 weeks for the 2 sets of temperatures, + 40 °C (± 2 °C) and + 4 °C (± 2 °C).

La duración de este estudio es de 8 semanas en las dos condiciones de temperatura siguientes: +40 °C (±2 °C) y +4 °C (±2 °C).

VI. ESSAIS DE STABILITE / *STABILITY TEST* / *RESULTADOS DE ESTABILIDAD*

Etude de stabilité + 40 °C (± 2 °C) formule F3307 lot 2S43N3497 ***Stability study at + 40 °C (± 2 °C) Formula F3307 batch 2S43N3497*** ***Estudio de estabilidad a +40 °C (±2 °C) Fórmula F3307 lote 2S43N3497***						
Essai *Assay* *Ensayo*	Méthodes / *Methods /* *Métodos*	Spécifications à péremption *Shelf life Specifications* Especificaciones al final del periodo de validez	T0 (initial)	4 semaines 4 *weeks* 4 semanas	6 semaines 6 *weeks* 6 semanas	8 semaines 8 *weeks* 8 semanas
Vérification du conditionnement / *Packaging control* / *Verificación del acondicionamiento*						
Aspect du conditionnement *Appearance packaging* *Aspecto del envase*	Visuelle *Visual* *Visual*	Aspect intact, *Appearance intact* Aspecto intacto	Aspect intact, *Appearance intact* Aspecto intacto	Aspect intact, *Appearance intact* Aspecto intacto	Aspect intact, *Appearance intact* Aspecto intacto	Aspect intact, *Appearance intact* Aspecto intacto
Étanchéité du conditionnement *Sealing packaging* *Estanqueidad del envase*	Visuelle *Visual* *Visual*	Absence de fuite *Absence of leak* Sin fuga	Absence de fuite *Absence of leak* Sin fuga	Absence de fuite *Absence of leak* Sin fuga	Absence de fuite *Absence of leak* Sin fuga	Absence de fuite *Absence of leak* Sin fuga
Tests physico-chimiques / *physico-chemical test* / ***Ensayos fisicoquimicos***						
Aspect *Appearance* *Aspecto* *at 20 °C* *and 101,3 kPa*	Visuelle *Visual* *Visual*	liquide limpide, bleu clair parfumé *Limpid liquid light blue with fragrant* Líquido transparente azul claro con perfume	liquide limpide, bleu clair parfumé *Limpid liquid light blue with fragrant* Líquido transparente azul claro con perfume	liquide limpide, bleu clair parfumé *Limpid liquid light blue with fragrant* Líquido transparente azul claro con perfume	liquide limpide, bleu clair parfumé *Limpid liquid light blue with fragrant* Líquido transparente azul claro con perfume	liquide limpide, bleu clair parfumé *Limpid liquid light blue with fragrant* Líquido transparente azul claro con perfume
pH	MM4.47	7.0 – 8.0 UpH	7.3	7.3	7.1	7.1
Masse volumique *Relative density* *Densidad*	MM4.42	1,004 – 1,008g/mL	1.005	1.005	1.005	1.005
Indice de réfraction *Réfraction indice* *Índice de refracción*	MM4.46	1,3354 – 1,3360 (sans dimension/*dimensionless/* *sin dimensión*)	1.3358	1.3356	1.3355	1.3357
Dosage de la substance active *Assay of active substance*	MM4.41	Valeur nominale / *Nominal value / Valor nominal* **0.57%**	(0.55-0.55) % $\bar{X}$ = 0.55%	(0.54-0.54) % $\bar{X}$ = 0.54	(0.54-0.54) % $\bar{X}$ = 0.54%	(0.53-0.53) % $\bar{X}$ = 0.53%

Dosis de la sustancia activa		(m/m)/*(w/w) (p/p)* ± 10% par rapport à la valeur du T0 / *from T0 value / Respecto a T0*	*From the nominal value* *Con respecto al valor nominal* *-3,5%*	*From the T0 value* *Respecto a T0* *-1.8%*	*From the T0 value* *Respecto a T0* *-1.8%*	*From the T0 value* *Respecto a T0* *-3,6%*

Etude de stabilité + 4 °C (± 2 °C) formule F3307 lot 2S43N3497 ***Stability study at + 4 °C (± 2 °C) Formula F3307 batch 2S43N3497*** ***Estudio de estabilidad a +4 °C (±2 °C) Fórmula F3307 lote 2S43N3497***						
Essai *Assay* *Ensayo*	Méthodes / *Methods /* *Métodos*	Spécifications à péremption *Shelf life Specifications* Especificaciones al final del periodo de validez	T0 (initial)	4 semaines *4 weeks* 4 semanas	6 semaines *6 weeks* 6 semanas	8 semaines *8 weeks* 8 semanas
Vérification du conditionnement / *Packaging control / Verificación del acondicionamiento*						
Aspect du conditionnement *Appearance packaging* *Aspecto del envase*	Visuelle *Visual* *Visual*	Aspect intact, *Appearance intact* *Aspecto intacto*	Aspect intact, *Appearance intact* *Aspecto intacto*	Aspect intact, *Appearance intact* *Aspecto intacto*	Aspect intact, *Appearance intact* *Aspecto intacto*	Aspect intact, *Appearance intact* *Aspecto intacto*
Étanchéité du conditionnement *Sealing packaging* *Estanqueidad del envase*	Visuelle *Visual* *Visual*	Absence de fuite *Absence of leak* *Sin fuga*	Absence de fuite *Absence of leak* *Sin fuga*	Absence de fuite *Absence of leak* *Sin fuga*	Absence de fuite *Absence of leak* *Sin fuga*	Absence de fuite *Absence of leak* *Sin fuga*
Tests physico-chimiques / *physico-chemical test/* ***Ensayos fisicoquimicos***						
Aspect *Appearance* *Aspecto* *at 20 °C* *and 101,3 kPa*	Visuelle *Visual* *Visual*	liquide limpide, bleu clair parfumé *Limpid liquid light blue with fragrant* *Líquido transparente, azul claro, perfumado*	liquide limpide, bleu clair parfumé *Limpid liquid light blue with fragrant* *Líquido transparente, azul claro, perfumado*	liquide limpide, bleu clair parfumé *Limpid liquid light blue with fragrant* *Líquido transparente, azul claro, perfumado*	liquide limpide, bleu clair parfumé *Limpid liquid light blue with fragrant* *Líquido transparente, azul claro, perfumado*	liquide limpide, bleu clair parfumé *Limpid liquid light blue with fragrant* *Líquido transparente, azul claro, perfumado*
pH	MM4.47	7.0 – 8.0 UpH	7.3	7.5	7.6	7.4
Masse volumique *Relative density*	MM4.42	1,004 – 1,008g/mL	1.005 g/mL	1.005	1.005	1.005

Densidad						
Indice de réfraction *Réfraction indice* *Índice de refracción*	MM4.46	1,3354 – 1,3360 (sans dimension/*dimensionless/ sin dimensión*)	1.3358	1.3355	1.3356	1.3357
Dosage de la substance active *Assay of active substance* *Dosis de la sustancia activa*	MM4.41	Valeur nominale / *Nominal value* / Valor nominal 0.57% (m/m/*(w/w) (p/p)* ± 10% par rapport à la valeur du T0 / *from T0 value / Respecto a T0*	(0.55-0.55) % $\bar{X}$ = 0.55%	(0.55-0.55) % $\bar{X}$ = 0.55	(0.54-0.55) % $\bar{X}$ = 0.54%	(0.55-0.55) % $\bar{X}$ = 0.55%
			From the nominal value *Con respecto al valor nominal* *-3,5%*	*From the T0 value* *Respecto a T0* *-0.0%*	*From the T0 value* *Respecto a T0* *-1.8%*	*From the T0 value* *Respecto a T0* *-0.0%*

VII. CONCLUSION DU RAPPORT D'ETUDE DE STABILITE / *FINAL STABILITY REPORT CONCLUSION / CONCLUSIÓN DEL INFORME DEL ESTUDIO DE ESTABILIDAD*

L'étude STAB2022084 décrite dans ce rapport a été réalisée sur un lot pilote de la formule F3307 (RD0209E36).
Cette étude a été réalisée à + 40 °C (± 2 °C) et à + 4 °C (± 2 °C) en condition accélérée sur 8 semaines sur le lot 2S43N3497. Les résultats obtenus correspondent aux spécifications du produit et sont en accord avec les résultats obtenus durant la conception.
Les résultats de cette étude montrent que le produit testé est stable à + 40 °C (± 2 °C) et à + 4 °C (± 2 °C) pendant 8 semaines. En effet, les tests de conformité visuelle et les résultats des analyses physico-chimiques en fin d'étude sont conformes aux spécifications du produit. De plus, la variation de la concentration de la substance active (OPA) est inférieure à 10 %, ce qui est conforme aux exigences du guide de l'ECHA. Les conditions de stockage normales proposées pour le produit sont donc : 2 ans à température ambiante.

Selon le guide l'ECHA Vol 1 les données générées par l'étude de stabilité accélérée indiquent que le dispositif médical peut être considéré comme stable 2 ans à température ambiante.

The study STAB2022084 described in this report was performed on the pilot batch of formula F3307 (RD0209E36).
This study was achieved at + 40 °C (± 2 °C) and at + 4 °C (± 2 °C) in accelerated condition for 8 weeks on pilot batch (batch 2S43N3497).
The results observed during the stability study are in accordance with the results obtained during the design step.
The results obtained indicate that the product tested is stable at 40 °C (± 2 °C) and at + 4 °C (± 2 °C) for 8 weeks. Indeed, the visual conformity tests and the physical chemical tests at the end of the study are compliant to the product specifications. In addition, the variation of the active substance (OPA) content is below 10 %, which is in accordance with ECHA Vol 1 guideline. The normal storage conditions proposed for the product are 2 years at ambient temperature.

The results obtained on active substance are in accordance with ECHA Vol 1 guideline. The accelerated storage data generated indicate that the medical device product will be considered stable for two years at ambient temperature.

El estudio STAB2022084 descrito en este informe se llevó a cabo con un lote piloto de la fórmula F3307 (RD0209E36).
En el estudio, el lote piloto 2S43N3497 se expuso a +40 °C (±2 °C) y a +4 °C (±2 °C) durante 8 semanas, en condiciones aceleradas. Los resultados obtenidos concuerdan con las especificaciones del producto y coinciden con los resultados obtenidos durante el diseño.
Los resultados de este estudio demuestran que el producto analizado es estable durante 8 semanas a +40 °C (±2 °C) y a +4 °C (±2 °C). De hecho, los resultados de las pruebas de conformidad visual y los análisis fisicoquímicos al final del estudio son conformes con las especificaciones del producto. Además, variación de la concentración de la sustancia activa (OPA) es inferior al 10 %, por lo que cumple los requisitos de la guía ECHA. Las condiciones de conservación normales propuestas para el producto son las siguientes: 2 años a temperatura ambiente.

Según la guía ECHA Vol 1, los datos generados en el estudio de estabilidad acelerada apuntan a que el producto sanitario puede considerarse estable durante 2 años a temperatura ambiente.

========== **Fin du Rapport /***End of Report / Fin del informe* **==========**

exeol OPA

Desinfectante de alto nivel

Solución lista para usar a base de ortoftalaldehído para la desinfección final por inmersión de dispositivos médicos termosensibles reutilizables, semicríticos y críticos, invasivos y no invasivos previamente limpiados.

Propiedades microbiológicas

Condiciones de limpieza, listo para usar, 20°C:
Bactericida (5 min.): EN 13727, EN 14561.
Fungicida (5 min.): EN 13624, EN 14562.
Micobactericida (5 min.): EN 14348, EN 14563.
Virucida (10 min.): EN 14476, EN 17111.
Esporicida contra *Clostridium difficile* (15 min.): EN 17126.
Esporicida (90 min.): EN 17126.

Instrucciones de uso

exeol OPA está listo para usar. **exeol OPA** se utiliza sin diluir en dispositivos médicos limpiados previamente. **exeol OPA** puede utilizarse durante un máximo de 14 días. Controlar regularmente la validez del baño con las tiras de control **exeol strips OPA**. Antes de usar **exeol OPA**, realizar una limpieza previa o una limpieza mecánica completa y un aclarado intermedio de los dispositivos médicos que se van a tratar.
Cuando se use por primera vez, retirar el anillo de inviolabilidad y luego desenroscar el tapón.
1. Desenroscar el tapón del bidón y transvasar el contenido a la bandeja. Volver a cerrar el bidón después de su uso. **2.** Colocar los dispositivos médicos abiertos y desmontados en la solución y asegurarse de que estén totalmente sumergidos. Asegurar la irrigación de los canales si están presentes. Cubrir la bandeja. **3.** Tiempo de contacto: a partir de 10 min., según el espectro de actividad deseado. **4.** Aclarar cuidadosamente con agua estéril o filtrada (0,2 µm) antes de volver a utilizarlo. **5.** Antes de almacenar, secar los dispositivos mediante aire médico sobre una superficie seca limpiada previamente.

SOLO PARA USO PROFESIONAL

INSTRUMENTOS ENDOSCOPIA

LISTO PARA USAR

REMOJO MANUAL

TIRAS DE PRUEBA

5L

CE 0459
MD

SANTÉ exeol
UNA DIVISIÓN DE SODEL

EXS EXEOL OPA 5L - MASTER ETQ ES AM LAT-R-01

0 mm 50 mm 100 mm

19/04/2024 eureka.fr

eureka
PRODUCTEUR D'IDÉES + + +
PRINT | PACK | WEB

Client	SODEL		
Brand	EXEOL SANTÉ		
Ref.	EXEOL OPA 5L - ES - AMÉRIQUE		
LATINE - RECTO - AVRIL 2024			
Clt ref.	ETQEXSMASTER		
Designer	Corinne FAURANT		
Phase	EXÉ 3	Phase SODEL	00.3

Support	Étiquette opaque blanche		Printing	-
Scale	1/1	Size (in mm)	L 120 x H 150 mm	Colors 4

Primary colors	Cyan	Magenta	Yellow	Black
Direct colors (Pantone®)	- -	- -	- -	- -
Technical colors	Découpe - -	- -	- -	- -

Informations : Blanc de soutien sur calque séparé à gérer par l'imprimeur en fonction des contraintes techniques.

Informations : Back white on separate copy must be managed by the printer according to the technical constraints.

Ce fichier est un document technique d'exécution en haute définition. L'utilisation des tons directs et/ou de leur équivalence est laissé à la responsabilité du photograveur (ou de l'imprimeur) selon ses contraintes techniques. Les défonces, recouvrements et surimpressions ne sont pas pris en compte.
La gestion des grossis/maigris/blanc de soutien est également à la charge de l'imprimeur. Il est indispensable de procéder à une étape de photogravure et à la réalisation d'une épreuve contractuelle, **ce fichier ne constituant pas un document prêt à flasher.**

This file is a high definition technical document. Spot colors and their equivalence are under the responsibility of the photo-engraver (or printer) in accordance with his technical constraints. Trapping, overprinting or overlapping aren't managed in the file. If needed, a white ink backing must also be taken care of by the printer.
It is required to proceed to a photoengraving stage and to output a contractual proof for approval. **This file is not a ready to print document.**

Eureka | 4, rue Jean Wiener 78260 Achères - France | Tél. : +33 (0)1 39 22 41 70 | studio@eureka.fr

exeol OPA

Composición
o-Phthalaldehyde (OPA) al 0,55 % y excipientes.

Precauciones
Contiene: o-Phthalaldehyde (OPA) (CAS: 643-79-8). Puede provocar una reacción alérgica. Nocivo para los organismos acuáticos, con efectos nocivos duraderos. Evitar su liberación al medio ambiente. En caso de irritación o erupción cutánea: Consultar a un médico. Eliminar el contenido y el recipiente en un punto de recogida de residuos peligrosos o especiales, de acuerdo con la normativa local. - Utilizar guantes de manga larga. No mezclar con otros productos. Antes de usar, comprobar la fecha de caducidad que figura en la etiqueta. Cualquier incidente grave relacionado con el dispositivo médico debería comunicarse a Sodel y a la autoridad competente del Estado miembro en el que estén establecidos el usuario y/o paciente.
Archivo del producto disponible en www.exeol.fr
Marcado CE obtenido en 2023.

UFI: NW49-107C-K00T-QXET

EXS EXEOL OPA 5L - MASTER ETQ ES AM LAT-V-01

Sodel
190 rue René Barthélemy
14100 Lisieux, France.
TEL: +33 (0)2 31 31 10 50
www.exeol.fr

Distribuido por:

5°C 25°C ALMACENAJE

FABRICADO EN FRANCIA

SANTÉ exeol
UNA DIVISIÓN DE SODEL

0 mm 50 mm 100 mm

18/04/2024 eureka.fr

eureka
PRODUCTEUR D'IDÉES +++
PRINT | PACK | WEB

Client	SODEL
Brand	EXEOL SANTÉ
Ref.	EXEOL OPA 5L - ES - AMÉRIQUE
	LATINE - VERSO - AVRIL 2024
Clt ref.	ETQEXSMASTER
Designer	Corinne FAURANT
Phase	EXÉ 2 — Phase SODEL 00.2

Support	Étiquette opaque blanche		Printing	-
Scale	1/1	Size (in mm) L 120 x H 150 mm		Colors 4
Primary colors	Cyan	Magenta	Yellow	Black
Direct colors (Pantone®)	-	-	-	-
	-	-	-	-
Technical colors	Découpe	-	-	-
	Zone marquage distributeur			-

Informations : Blanc de soutien sur calque séparé à gérer par l'imprimeur en fonction des contraintes techniques.

Informations : Back white on separate copy must be managed by the printer according to the technical constraints.

Ce fichier est un document technique d'exécution en haute définition. L'utilisation des tons directs et/ou de leur équivalence est laissé à la responsabilité du photograveur (ou de l'imprimeur) selon ses contraintes techniques. Les défonces, recouvrements et surimpressions ne sont pas pris en compte.
La gestion des grossis/maigris/blanc de soutien est également à la charge de l'imprimeur. Il est indispensable de procéder à une étape de photogravure et à la réalisation d'une épreuve contractuelle, **ce fichier ne constituant pas un document prêt à flasher.**

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It is required to proceed to a photoengraving stage and to output a contractual proof for approval. **This file is not a ready to print document.**

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 35009 rev. 3

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

SODEL
190 rue René Barthélémy
14100 LISIEUX FRANCE

pour les activités
for the activities

Conception, fabrication, contrôle, conditionnement et commercialisation de produits désinfectants pour dispositifs médicaux.

Design, manufacturing, control, packaging and sale of disinfectants for medical devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

SODEL
190 rue René Barthélémy 14100 LISIEUX FRA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité */ Effective date :* **October 21st, 2021 (included)**
Valable jusqu'au */ Expiry date :* **November 19th, 2024 (included)**
Etabli le */ Issued on :* **October 21st, 2021**

DocuSigned by:
Béatrice LYS
EF33BBA9BAA04A3...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

cofrac CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2018

GMED N° 35009–3
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 35009-2

CERTIFICAT UE DE SYSTEME DE GESTION DE LA QUALITE
Règlement (UE) 2017/745, Annexe IX Chapitres I et III

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
Regulation (EU) 2017/745, Annex IX Chapters I and III

Certificat/*Certificate:* N° 39301 rev. 1

Délivré le/*Issued on:* November 13th, 2023

Certificat délivré à/*Certificate issued to:* **SODEL**
190 rue René Barthélémy
14100 LISIEUX FRANCE
SRN: FR-MF-000000367

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit du système de gestion de la qualité référencé(s) P605209 - P605177 - P605203 - P605204 - P605207, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/745 pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) referenced P605209 - P605177 - P605203 - P605204 - P605207, the quality management system complies with the relevant provisions of the regulation (EU) 2017/745 for the following products:

Solutions désinfectantes pour dispositifs médicaux invasifs et non invasifs.
Lingettes désinfectantes pour les dispositifs médicaux invasifs et non invasifs.

Disinfectant solutions for invasive and non invasive medical devices.
Disinfectant wipes for invasive and non invasive medical devices.

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de classe IIb implantables et/ou de classe III, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/745 est requis.

For the purpose of placing on the market implantable class IIb and / or class III devices, another certificate issued in accordance with the provisions of the regulation (EU) 2017/745 is required.

Début de validité /*Effective date:* November 13th, 2023 (included)

Valable jusqu'au /*Expiry date:* May 16th, 2028 (included)

La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and from the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

GMED - 39301 rev. 1
Modifie le certificat 39301-0

RDM 07-01-75 rev 2

Addendum au certificat n°39301 rev. 1
Addendum of the certificate n°39301 rev. 1
Dossier / *File* N° P605209 – P605177 – P605203 – P605204 – P605207

1. **Le cas échéant, le nom et l'adresse du mandataire /** *If applicable, the name and address of the authorised representative:*
   Non applicable / *Not applicable*

2. **Identification des sites /** *Identification of sites:*
   SODEL – 190 rue René Barthélemy - 14100 LISIEUX - FRANCE

3. **Identification des dispositifs /** *Identification of devices:*

Nom du dispositif médical *Medical device name*	Nom commercial *Commercial name*	Classe du DM *MD Class*
Détergent désinfectant sans alcool pour surfaces et dispositifs médicaux *Disinfectant detergent alcohol-free for surfaces and medical devices*	**exeol surf optimal**	**IIa**
Désinfectant des empreintes dentaires par pulvérisation *Disinfectant for dental impressions by spraying*	**exeol D print**	**IIa**
Désinfectant de surfaces et dispositifs médicaux *Disinfectant for surfaces and medical devices*	**exeol surf 30**	**IIa**
Détergent désinfectant pH neutre *Neutral pH disinfectant detergent*	**exeol sept first**	**IIa**

DocuSigned by:
Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

GMED GROUPE LNE

Addendum au certificat n°39301 rev. 1
Addendum of the certificate n°39301 rev. 1
Dossier / *File* N° P605209 – P605177 – P605203 – P605204 – P605207

Nom du dispositif médical *Medical device name*	Nom commercial *Commercial name*	Classe du DM *MD Class*
Détergent désinfectant enzymatique pH neutre *Neutral pH enzymatic disinfectant detergent*	**exeol sept E2**	**IIa**
Détergent désinfectant des instruments rotatifs *Disinfectant detergent for rotating instruments*	**exeol D drill**	**IIa**
Détergent désinfectant des systèmes d'aspiration dentaire *Disinfectant detergent for dental suction systems*	**exeol D aspi**	**IIa**
Lingettes détergentes désinfectantes de surfaces et dispositifs médicaux, sans alcool *Disinfectant detergent wipes for surfaces and medical devices, alcohol-free*	**exeol wipes optimal**	**IIa**

DocuSigned by:
Béatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Addendum au certificat n°39301 rev. 1
Addendum of the certificate n°39301 rev. 1
Dossier / *File* N° P605209 – P605177 – P605203 – P605204 – P605207

Nom du dispositif médical *Medical device name*	Nom commercial *Commercial name*	Destination *Intended use*	Classe du DM *MD Class*
Désinfectant de surfaces et dispositifs médicaux *Disinfectant for surfaces and medical devices*	**exeol surf 60**	**Solution prête à l'emploi pour la désinfection finale de niveau intermédiaire des surfaces des sondes d'échographie endocavitaires, préalablement nettoyées.** *Ready-to-use solution for final intermediate-level disinfection of previously cleaned surfaces of endocavity ultrasound probes*	**IIb**
Lingettes désinfectantes *Disinfectant wipes*	**exeol wipes 60**	**Lingettes pré-imprégnées pour la désinfection finale de niveau intermédiaire par essuyage humide des surfaces des sondes d'échographie endocavitaires, préalablement nettoyées.** *Pre-impregnated wipes for the final intermediate-level disinfection by wet wiping of the previously cleaned surfaces of endocavity ultrasound probes.*	**IIb**
Désinfectant de haut niveau *High level disinfectant*	**exeol GTA 2%**	**Solution prête à l'emploi à base de glutaraldéhyde pour la désinfection finale par immersion des dispositifs médicaux thermosensibles semi-critiques et critiques réutilisables invasifs et non-invasifs, préalablement nettoyés** *Ready-to-use glutaraldehyde based solution for final disinfection by immersion of pre-cleaned semi-critical and critical reusable invasive and non-invasive heat-sensitive medical devices*	**IIb**
Désinfectant de haut niveau *High level disinfectant*	**exeol OPA**	**Solution prête à l'emploi à base d'orthophtalaldéhyde pour la désinfection finale par immersion des dispositifs médicaux thermosensibles semi-critiques et critiques réutilisables invasifs et non-invasifs, préalablement nettoyés** *Ready-to-use orthophtalaldehyde based solution for final disinfection by immersion of pre-cleaned semi-critical and critical heat-sensitive invasive and non-invasive reusable medical devices*	**IIb**

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

4. Historique du certificat / *Certificate history:*

Référence au certificat précédent *Reference to the preceeding certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
39301 rev. 0	**17/05/2023** *05/17/2023*	**Ajout de dispositif(s) au sein d'une catégorie de dispositif existante** *Addition of device(s) to the existing device's category*

5. Le cas échéant, les informations spécifiques relatives aux limitations de la validité du certificat / *If applicable, specific information relating to the limitations to the validity of the certificate:*
Non applicable / *Not applicable*

6. Le cas échéant, les informations spécifiques relatives à la surveillance effectuée dans le cadre du maintien du certificat / *If applicable, specific information relating to the surveillance carried out in the context of maintaining the certificate:*
Non applicable / *Not applicable*

DocuSigned by:
Béatrice Lys
EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Toulouse, April 14th 2022

TEST REPORT N° 22-1886

STUDY 21-3071

NF EN 13727 + A2 (December 2015)
CHEMICAL DISINFECTANTS AND ANTISEPTICS
QUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF BACTERICIDAL ACTIVITY IN THE MEDICAL AREA
(Phase 2, step 1)

DESINFECTION OF MEDICAL DEVICES

Obligatory conditions - Clean conditions
S. aureus, P. aeruginosa and E. hirae

Client	**SODEL** **190 Rue René Barthélémy** **14100 LISIEUX** **FRANCE**
Assay Laboratory	**FONDEREPHAR** **Faculté des Sciences Pharmaceutiques** **35 Chemin des Maraîchers** **31062 TOULOUSE Cedex 09** **FRANCE**

Pr **Christine ROQUES** Assay Manager	Dr **Jocelyne BACARIA** Quality Manager

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COFRAC is a signatory of the multilateral recognition agreements of EA[1] and/or of ILAC[2] and/or of IAF[3] for testing activities.
1. European co-operation for Accreditation
2. International Laboratory Accreditation Cooperation
3. International Accreditation Forum

I - IDENTIFICATION OF ASSAY LABORATORY

FONDEREPHAR
Faculté des Sciences Pharmaceutiques
35 Chemin des Maraîchers
31062 Toulouse cedex 9
France

II – IDENTIFICATION OF TEST PRODUCT

Product :	**F3307**
Batch :	0209E036211124B
Expiry date:	Not precised
Date of receipt :	Nov/30/2021
Internal code :	**21-3071-1**
Active substances :	Orthphtaldehyde 0,54%
Manufacturer :	SODEL
Period of testing :	January 2022

Storage conditions during the period of testing : Room temperature

III – TEST

Method : **Dilution – neutralization**

Neutralizer 1: Polysorbate 80 (10%), Saponin (2%), Lecithin (2%), Natrium Thiosulfate (0,5%), QSP Trypcase Soy Broth (Internal preparation – Batch 1195)

Neutralizer 2: Polysorbate 80 (10%), Saponin (6%), Lecithin (2%), Natrium Thiosulfate (0,5%), L-histidine (0,2%), QSP Trypcase Soy Broth (Internal preparation – Batch 10823)

Method : **Filtration on membrane**
Membrane: 0,45µm nitrocellulose (Millipore - Batch F1JB15006)
Rinsing liquid: Sterile distilled water (Internal preparation – Batch 8223) – 2 rinsing with 100mL

Count(s) per ml : 1 or 2 for $N/10^{-6}$

Appearance of the product : liquid, clear, blue
Aspect of solutions under assay : Clear

IV – EXPERIMENTAL CONDITIONS

Product diluent : Water for injectables preparations
Interfering substance: 0,3 g/L bovine albumin (clean conditions)

Obligatory conditions :

Tests-organisms :	*Staphylococcus aureus* CIP 4.83 *Pseudomonas aeruginosa* CIP 103467 *Enterococcus hirae* CIP 58.55
Concentrations of the product:	**80%**, **50%** and **0,1% (v/v)**
Test temperature :	20°C ± 1°C
Contact time :	5 minutes ± 10 seconds

Incubation temperature : 36°C ± 1°C

Aspect of solutions during assay : Clear

V – RESULTS

STAPHYLOCOCCUS AUREUS CIP 4.83 – Preliminary tests Dilution-Neutralization Method

VALIDATION AND CONTROLS					TEST SUSPENSION		ESSAI				
	Validation suspension **Nvo** **NvB**	Experimental conditions control **A**	Neutralizer control **B**	Method validation Product conc. 80% **C**	N			Concentration of product % (v/v)			
					10^{-6}	10^{-7}		**Contact time**	**80%**	**50%**	**0,1%**
Vc1-Vc2	**Nvo** 94-110	-	**Neut1** 101 - 130 **Neut2** 112 - 123	**Neut1** 8 - 12 **Neut2** 17 - 19	-	-	Vc1 – Vc2	**5 minutes**	-	-	-
$\bar{x}$	**Nvo** 102	-	**Neut1** 116 **Neut2** 118	**Neut1** 10 **Neut2** 8	-		$\bar{x}$	**5 minutes**	-	-	-
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0,5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0,5 $\bar{x}$ of NvB	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	-		Na= $\bar{x}$ x10	**5 minutes**	-	-	-
					7,17≤lg N/10 ≤ 7,70		lg Na	**5 minutes**	-	-	-
							lg R	**5 minutes**	-	-	-

Date of the test: Jan/05/2022

Vc = Count per ml (1 plate or 2 for $N/10^{-6}$)

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

Dilution-Neutralization Method – Not Compliant

STAPHYLOCOCCUS AUREUS CIP 4.83 – Filtration Method

VALIDATION AND CONTROLS					TEST SUSPENSION		ESSAI				
	Validation suspension **Nvo**	Experimental conditions control **A**	Filtration control **B**	Method validation Product conc. 80% **C**	N			Concentration of product % (v/v)			
					10^{-6}	10^{-7}		**Contact time**	**80%**	**50%**	**0,1%**
Vc1-Vc2	131 - 148	123 - 136	111 - 129	131 - 137	482-481	52 - 55	Vc1 – Vc2	**5 minutes**	0 – 0	0 – 0	>330->330
$\bar{x}$	140	130	120	134	$\bar{x}$ wm = 486,36.10^6 lg N = 8,69		$\bar{x}$	**5 minutes**	< 14	< 14	>330
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0, 5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0, 5 $\bar{x}$ of NvB	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	N/10 = 486,36.10^5 lg N/10 = 7,69		Na= $\bar{x}$ x10	**5 minutes**	< 140	< 140	> 3300
					7,17≤lg N/10 ≤ 7,70		lg Na	**5 minutes**	< 2,15	< 2,15	> 3,52
							lg R	**5 minutes**	**> 5,54**	**> 5,54**	**< 4,17**

Date of the test: Jan/18/2022

Vc = Count per ml (1 plate or 2 for N/10^{-6})

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

PSEUDOMONAS AERUGINOSA CIP 103467 – Dilution-Neutralization Method (Neutralizer 1)

VALIDATION AND CONTROLS					TEST SUSPENSION		ESSAI				
	Validation suspension **Nvo** **NvB**	Experimental conditions control **A**	Neutralizer control **B**	Method validation Product conc. 80% **C**	N			Concentration of product % (v/v)			
					10^{-6}	10^{-7}		Contact time	80%	50%	0,1%
Vc1-Vc2	**Nvo** 125 - 148 **NvB** 128 - 155	138 - 161	97 - 127	115 - 119	370-327	39 - 57	Vc1 – Vc2	**5 minutes**	10^0 0 – 0 10^{-1} 0 – 0	10^0 0 – 0 10^{-1} 0 – 0	10^0 >330->330 10^{-1} >330->330
$\bar{x}$	**Nvo** 137 **NvB** 142	150	112	117	$\bar{x}$ wm = $360,45.10^6$ lg N = 8,56		$\bar{x}$	**5 minutes**	< 14	< 14	>3300
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0, 5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0, 5 $\bar{x}$ of NvB	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	N/10 = $360,45.10^5$ lg N/10 = 7,56		Na= $\bar{x}$ x10	**5 minutes**	< 140	< 140	> $3,3.10^4$
					7,17≤lg N/10 ≤ 7,70		lg Na	**5 minutes**	< 2,15	< 2,15	> 4,52
							lg R	**5 minutes**	**> 5,41**	**> 5,41**	**< 3,04**

Date of the test: Jan/18/2022

Vc = Count per ml (1 plate or 2 for $N/10^{-6}$)

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

ENTEROCOCCUS HIRAE CIP 58.55 - Dilution-Neutralization Method (Neutralizer 2)

VALIDATION AND CONTROLS					TEST SUSPENSION		ESSAI				
	Validation suspension **Nvo** **NvB**	Experimental conditions control **A**	Neutralizer control **B**	Method validation Product conc. 80% **C**	N			Concentration of product % (v/v)			
					10^{-6}	10^{-7}		**Contact time**	**80%**	**50%**	**0,1%**
Vc1-Vc2	**Nvo** 128-146 **NvB** 132-134	108 - 146	122 - 133	105 - 137	456-399	43 - 46	Vc1 – Vc2	**5 minutes**	10^{0} 0 – 0 10^{-1} 0 – 0	10^{0} 0 – 0 10^{-1} 0 – 0	10^{0} >330->330 10^{-1} >330->330
$\bar{x}$	**Nvo** 137 **NvB** 133	127	128	121	$\bar{x}$ wm = 429,09.10^{6} lg N = 8,63		$\bar{x}$	**5 minutes**	< 14	< 14	>3300
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0, 5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0, 5 $\bar{x}$ of NvB	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	N/10 = 429,09.10^{5} lg N/10 = 7,63		Na= $\bar{x}$ x10	**5 minutes**	< 140	< 140	> 3,3.10^{4}
					7,17≤lg N/10 ≤ 7,70		lg Na	**5 minutes**	< 2,15	< 2,15	> 4,52
							lg R	**5 minutes**	**> 5,49**	**> 5,49**	**< 3,11**

Date of the test: Jan/18/2022

Vc = Count per ml (1 plate or 2 for N/10^{-6})

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

VI – CONCLUSION

For the product **F3307 (batch 0209E36211124B)**, the bactericidal concentration for **disinfection of medical devices** determined according to the NF EN 13727+A2 (December 2015), obligatory conditions, after a 5 minutes contact time at 20°C, under clean conditions (0,3 g/L bovine albumin), against *Staphylococcus aureus* CIP 4.83, *Pseudomonas aeruginosa* CIP 103467 and *Enterococcus hirae* CIP 58.55, is **50%** (v/v).

The results hold only for the product under assay and apply to the sample as received.

Toulouse, May 10th 2022

TEST REPORT N° 22-1888

STUDY 21-3071

NF EN 14561 (March 2007)

QUANTITATIVE CARRIER TEST FOR THE EVALUATION OF BACTERICIDAL ACTIVITY OF CHEMICAL DISINFECTANTS USED FOR INSTRUMENTS IN THE MEDICAL AREA

Additional conditions
Clean conditions

Client	**SODEL** **190 Rue René Barthélémy** **14100 LISIEUX** **FRANCE**
Assay Laboratory	**FONDEREPHAR** **Facultés des Sciences Pharmaceutiques** **35 Chemin des Maraîchers** **31062 TOULOUSE Cedex 09** **France**

Dr **Catherine FEUILLOLAY** Assay Manager	Dr **Jocelyne BACARIA** Quality Manager

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I - IDENTIFICATION OF ASSAY LABORATORY

FONDEREPHAR
Faculté des Sciences Pharmaceutiques
35 Chemin des Maraîchers
31062 Toulouse cedex 9
France

II – IDENTIFICATION OF TEST PRODUCT

Product : **F3307**
Batch : 0209E036211124B
Expiry date: Not precised
Date of receipt : Nov/30/2021
Internal code : **21-3071-1**

Product : **F3307**
Batch : 0209E036220224G
Expiry date: Not precised
Date of receipt : Mar/09/2022
Internal code : **22-3071-2**

Active substances : Orthphtaldehyde 0.54%

Manufacturer : SODEL

Period of testing : January – March 2022

Storage conditions during the period of testing : Room temperature
Appearance of product : liquid, clear, blue

III – TEST

Method : Dilution – neutralization

Neutralizer 1 : Tween 80 (10%), Saponin (2%), Lecithin (2%), Natrium Thiosulfate (0,5%), QSP Trypcase Soja Broth (Internal preparation – Batch 1201 Exp. Apr/07/2022)

Neutralizer 2 : Tween 80 (10%), Saponin (6%), Lecithin (2%), Natrium Thiosulfate (0,5%), L-histidine (0,2%), QSP Trypcase Soja Broth (Internal preparation – Batch 10780 Exp. Dec/23/2022 and 10823 Exp. Feb/03/2022)

Neutralizer 3 : Tween 80 (10%), Saponin (6%), Lecithin (2%), Natrium Thiosulfate (1%), L-histidine (0,2%), Glycine (0,6%) QSP Trypcase Soja Broth (Internal preparation – Batch 10902 Exp. Mar/22/2022)

Count(s) per ml : 1 or 2 for $N/10^{-7}$

Appearance of the dilution of product : clear

Test surface : frosted glass carriers, 15mm x 60mm x 1mm, one surface sandblasted

IV – EXPERIMENTAL CONDITIONS

Product diluent :	Water for injectables preparations	
Concentrations of the product:	**100%** (v/v), **50%** (v/v) and 0,**1%** (v/v)	
Test-organisms :	*Pseudomonas aeruginosa* CIP 103467 *Staphylococcus aureus* CIP 4.83 *Enterococcus hirae* CIP 58.55	
Interfering substance:	0,3 g/L bovine albumin (clean conditions)	
Additional conditions :	Test temperature : Contact time :	20°C ± 1°C 5 minutes ± 10 seconds

Incubation temperature : 36°C ± 1°C

V – TEST RESULTS

STAPHYLOCOCCUS AUREUS CIP 4.83 – Batch 0209E036220224G

<table>
<tr><th colspan="5">VALIDATION AND CONTROLS</th><th colspan="3">TEST SUSPENSION</th><th colspan="5">TEST</th></tr>
<tr><td rowspan="2"></td><td rowspan="2">Validation suspension
Nvo</td><td rowspan="2">Experimental conditions control
A</td><td rowspan="2">Filtration control
B</td><td rowspan="2">Method validation Product conc. 100%
C</td><td colspan="2">N</td><td rowspan="2"></td><td colspan="4">Concentration of product % (v/v)</td></tr>
<tr><td>10^{-7}</td><td>10^{-8}</td><td>Contact time</td><td>100%</td><td>50%</td><td>0,1%</td></tr>
<tr><td>Vc1-Vc2</td><td>76 – 82</td><td>96 – 82</td><td>111 – 111</td><td>95 – 99</td><td>271 - 287</td><td>24 – 34</td><td>Vc1 – Vc2</td><td>5 minutes</td><td>10^0 0 - 0
10^{-1} 0 - 0
10^{-2} 0 - 0
10^{-3} 0 - 0</td><td>10^0 0 - 0
10^{-1} 0 - 0
10^{-2} 0 - 0
10^{-3} 0 - 0</td><td>10^0 >330->330
10^{-1}>330->330
10^{-2} >330->330
10^{-3} >330->330</td></tr>
<tr><td>$\bar{x}$</td><td>79</td><td>89</td><td>111</td><td>97</td><td colspan="2">$\bar{x}$ wm = $280{,}00.10^7$
lg N = 9,45

9,17 ≤ lg N ≤ 9,70</td><td>$\bar{x}$</td><td>5 minutes</td><td>< 14</td><td>< 14</td><td>>330.10^3</td></tr>
<tr><td rowspan="3"></td><td rowspan="3">$\bar{x}$ of Nvo between 30 and 160</td><td rowspan="3">$\bar{x}$ of A
≥ 0,5 $\bar{x}$ of Nvo</td><td rowspan="3">$\bar{x}$ of B
≥ 0,5 $\bar{x}$ of Nvo</td><td rowspan="3">$\bar{x}$ of C
≥ 0,5 $\bar{x}$ of Nvo</td><td colspan="2">Water control Nw</td><td>Na= $\bar{x}$ x10</td><td>5 minutes</td><td>< 140</td><td>< 140</td><td>>330.10^4</td></tr>
<tr><td>10^{-5}</td><td>10^{-6}</td><td rowspan="2">lg Na</td><td rowspan="2">5 minutes</td><td rowspan="2">< 2,15</td><td rowspan="2">< 2,15</td><td rowspan="2">> 6,52</td></tr>
<tr><td>109 - 159</td><td>18 - 19</td></tr>
<tr><td colspan="2">$\bar{x}$ x 10 = $138{,}64.10^6$
lg Nw = 8,14

7,15 ≤lg Nw ≤ lg N -1,3</td><td>lg R</td><td>5 minutes</td><td>> 5,99</td><td>> 5,99</td><td>< 1,62</td></tr>
</table>

Date of the test : Mar/15/2022

Vc = Count per ml (1 or 2 for $N/10^{-7}$)

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_w – lg Na)

PSEUDOMONAS AERUGINOSA CIP 103467 – Batch 0209E0362202246

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST				
	Validation suspension **Nvo**	Experimental conditions control **A**	Filtration control **B**	Method validation Product conc. 100% **C**	**N**			Concentration of product % (v/v)			
					10^{-7}	10^{-8}		**Contact time**	**100%**	**50%**	**0,1%**
Vc1-Vc2	158 – 145	115 – 91	147 – 136	98 – 92	504 - 493	43 – 49	Vc1 – Vc2	**5 minutes**	10^0 0 - 0 10^{-1} 0 - 0 10^{-2} 0 - 0 10^{-3} 0 - 0	10^0 2 - 0 10^{-1} 0 - 0 10^{-2} 0 - 0 10^{-3} 0 - 0	10^0 >330->330 10^{-1} >330->330 10^{-2} >330->330 10^{-3} >330->330
$\bar{x}$	152	103	142	95	$\bar{x}$ wm = 495,00.10^7 lg N = 9,69 9,17 ≤ lg N ≤ 9,70		$\bar{x}$	**5 minutes**	< 14	< 14	>330.10^3
	$\bar{x}$ of Nvo between 30 and 160	$\bar{x}$ of A ≥ 0,5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0,5 $\bar{x}$ of Nvo	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	**Water control Nw**		Na= $\bar{x}$ x10	**5 minutes**	< 140	< 140	>330.10^4
					10^{-4}	10^{-5}	lg Na	**5 minutes**	< 2,15	< 2,15	> 6,52
					232 - 205	16 – 18					
					$\bar{x}$ x 10 = 214,09.10^5 lg Nw = 7,33 7,15 ≤lg Nw ≤ lg N -1,3		**lg R**	**5 minutes**	**> 5,18**	**> 5,18**	**0,81**

Date of the test : Mar/15/2022

Vc = Count per ml (1 or 2 for N/10^{-7})

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_w – lg Na)

ENTEROCOCCUS HIRAE CIP 58.55 – Batch 0209E036211124B

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST				
	Validation suspension **Nvo**	Experimental conditions control A	Filtration control **B**	Method validation Product conc. 100% **C**	**N**			Concentration of product % (v/v)			
					10^{-7}	10^{-8}		**Contact time**	**100%**	**50%**	**0,1%**
Vc1-Vc2	130 – 124	134 – 124	149 – 124	131 – 122	425 - 419	37 – 54	Vc1 – Vc2	**5 minutes**	10^0 0 - 0 10^{-1} 0 - 0 10^{-2} 0 - 0 10^{-3} 0 - 0	10^0 0 - 0 10^{-1} 0 - 0 10^{-2} 0 - 0 10^{-3} 0 - 0	10^0 >330->330 10^{-1}>330->330 10^{-2} >330->330 10^{-3} >330->330
$\bar{x}$	127	129	137	127	$\bar{x}$ wm = 425,00.10^7 lg N = 9,63 9,17 ≤ lg N ≤ 9,70		$\bar{x}$	**5 minutes**	< 14	< 14	>330.10^3
	$\bar{x}$ of Nvo between 30 and 160	$\bar{x}$ of A ≥ 0,5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0,5 $\bar{x}$ of Nvo	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	**Water control Nw**		Na= $\bar{x}$ x10	**5 minutes**	< 140	< 140	>330.10^4
					10^{-4}	10^{-5}	lg Na	**5 minutes**	< 2,15	< 2,15	> 6,52
					>330->330	65 - 80					
					$\bar{x}$ x 10 = 72,50.10^6 lg Nw = 7,86 7,15 ≤lg Nw ≤ lg N -1,3		**lg R**	**5 minutes**	**> 5,71**	**> 5,71**	**< 1,34**

Date of the test : Jan/20/2022

Vc = Count per ml (1 or 2 for N/10^{-7})

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_w – lg Na)

VI – CONCLUSION

For the product **F3307 (batches 0209E036211124B and 0209E0362202246)**, the bactericidal concentration for specific needs determined according to the **NF EN 14561** (March 2007), after a 5 minutes contact time at 20°C under clean conditions, against the test-organisms *S. aureus* CIP 4.83, *P. aeruginosa* CIP 103467 and *E. hirae* CIP 58.55, is **50%** (v/v).

The results hold only for the product under assay and apply to the sample as received.

Toulouse, July 10th 2023

TEST REPORT N° 23-2082

STUDY 23-3465

NF EN 13624 (November 2021)
CHEMICAL DISINFECTANTS AND ANTISEPTICS
QUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF FUNGICIDAL ACTIVITY IN THE MEDICAL AREA
(Phase 2, step 1)

DESINFECTION OF INSTRUMENTS

Obligatory conditions - Clean conditions
C. albicans and A. brasiliensis

Client*	**SODEL** **190 Rue René Barthélémy** **14100 LISIEUX** **FRANCE**
Assay Laboratory	**FONDEREPHAR** **Faculté des Sciences Pharmaceutiques** **35 Chemin des Maraîchers** **31062 TOULOUSE Cedex 09** **FRANCE**

Dr **Catherine FEUILLOLAY** Assay Manager	Dr **Jocelyne BACARIA** Quality Manager

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I - IDENTIFICATION OF ASSAY LABORATORY

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Faculté des Sciences Pharmaceutiques
35 Chemin des Maraîchers
31062 Toulouse cedex 9
France

II – IDENTIFICATION OF TEST PRODUCT

Product* : **F3307**
Batch* : 0209E036221024W
Expiry date: Not precised
Date of receipt : Jun/30/2023
Internal code : **23-3465-1**

Active substances* : OPA 0,54%

Manufacturer* : SODEL

Period of testing : July 2023

Storage conditions during the period of testing : Room temperature

* Informations provided by the client

III – TEST

Method : Dilution – neutralization

Neutralizer : Polysorbate 80 (10%), Saponin (6%), Lecithin (2%), Natrium Thiosulfate (1%), L-histidine (0,2%), Glycine (0,6%) QSP Trypcase Soy Broth (Internal preparation – Batch 11665)

Count(s) per ml : 1 or 2 for $N/10^{-5}$ (*C. albicans*) and 3 for $N/10^{-5}$ (*A. brasiliensis*)

Appearance of the product : liquid, clear, blue

Aspect of solutions under assay : Clear

IV – EXPERIMENTAL CONDITIONS

Product diluent* : Water for injectables preparations

Interfering substance*: 0,3 g/L bovine albumin (clean conditions)

Obligatory conditions :
Tests-organisms* : *Candida albicans* DSM 1386
Aspergillus brasiliensis CBS 733.88

Concentrations of the product: **80%**, **70%** and **0,1% (v/v)**
Test temperature* : 20°C ± 1°C
Contact time* : 5 minutes ± 10 seconds

Incubation temperature : 30°C ± 1°C

Aspect of solutions during assay : Clear

V – RESULTS

CANDIDA ALBICANS DSM 1386

VALIDATION AND CONTROLS					TEST SUSPENSION		ESSAI				
	Validation suspension **Nvo** **NvB**	Experimental conditions control **A**	Neutralizer control **B**	Method validation Product conc. 80% **C**	N			Concentration of product % (v/v)			
					10^{-5}	10^{-6}		**Contact time**	**80%**	**70%**	**0,1%**
Vc1-Vc2	**Nvo** 102 - 95 **NvB** 108 - 95	98 - 88	105 - 89	85 - 85	318 - 326	29 - 46	Vc1 – Vc2	**5 minutes**	0 - 0	0 - 0	>330->330
$\bar{x}$	**Nvo** 99 **NvB** 102	93	97	85	$\bar{x}$ wm = 326,82.10^5 lg N = 7,51		$\bar{x}$	**5 minutes**	< 14	< 14	>330
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0, 5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0, 5 $\bar{x}$ of NvB	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	N/10 = 326,82.$10^{4,}$ lg N/10 = 6,51		Na= $\bar{x}$ x10	**5 minutes**	< 140	< 140	> 3,3.10^3
					6,17≤lg N/10 ≤ 6,70		lg Na	**5 minutes**	< 2,15	< 2,15	> 3,52
							lg R	**5 minutes**	**> 4,37**	**> 4,37**	**< 3,00**

Date of the test: Jul/05/2023

Vc = Count per ml (1 plate or 2 for N/10^{-5})

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

ASPERGILLUS BRASILIENSIS CBS 733.88

VALIDATION AND CONTROLS					TEST SUSPENSION		ESSAI				
	Validation suspension **Nvo** **NvB**	Experimental conditions control **A**	Neutralizer control **B**	Method validation Product conc. 80% **C**	N			Concentration of product % (v/v)			
					10^{-5}	10^{-6}		**Contact time**	**80%**	**70%**	**0,1%**
Vc1-Vc2	**Nvo** 70 - 62 **NvB** 73 - 79	47 – 33	80 – 98	62 – 66	183 - 176	26 – 18	Vc1 – Vc2	**5 minutes**	10 - 6	4 - 9	>165->165
$\bar{x}$	**Nvo** 66 **NvB** 76	40	89	64	$\bar{x}$ wm = $183{,}18.10^5$ lg N = 7,26		$\bar{x}$	**5 minutes**	< 14	< 14	> 165
	$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A ≥ 0, 5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0, 5 $\bar{x}$ of NvB	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	N/10 = $183{,}18.10^4$, lg N/10 = 6,26		Na= $\bar{x}$ x10	**5 minutes**	< 140	< 140	> $1{,}65.10^3$
					6,17≤lg N/10 ≤ 6,70		lg Na	**5 minutes**	< 2,15	< 2,15	> 3,22
							lg R	**5 minutes**	**> 4,12**	**> 4,12**	**< 3,05**

Date of the test: Jul/05/2023

Vc = Count per ml (1 plate or 3 for $N/10^{-5}$)

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_0 – lg Na)

VI – CONCLUSION

For the formula **F3307 (batch 0209E036221024W)**, the fungicidal concentration for **disinfection of instruments** determined according to the NF EN 13624 (November 2021), obligatory conditions, after a 5 minutes contact time at 20°C, under clean conditions (0,3 g/L bovine albumin), against *Candida albicans* DSM 1386 and *Aspergillus brasiliensis* CBS 733.88, is **70%** (v/v).

For the formula **F3307 (batch 0209E036221024W)**, the yeasticidal concentration for **disinfection of instruments** determined according to the NF EN 13624 (November 2021), obligatory conditions, after a 5 minutes contact time at 20°C, under clean conditions (0,3 g/L bovine albumin), against *Candida albicans* DSM 1386, is **70%** (v/v).

The results hold only for the product under assay and apply to the sample as received.

Toulouse, July 1st 2022

TEST REPORT N° 22-1930

STUDY 22-3187

NF EN 14562 (September 2006)

QUANTITATIVE CARRIER TEST FOR THE EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY OF CHEMICAL DISINFECTANTS USED FOR INSTRUMENTS IN THE MEDICAL AREA

Additional conditions
Clean conditions – *C. albicans* and *A. brasiliensis*

Client	**SODEL** **190 Rue René Barthélémy** **14100 LISIEUX** **FRANCE**
Assay Laboratory	**FONDEREPHAR** **Facultés des Sciences Pharmaceutiques** **35 Chemin des Maraîchers** **31062 TOULOUSE Cedex 09** **France**

Dr **Catherine FEUILLOLAY** Assay Manager	Dr **Jocelyne BACARIA** Quality Manager

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COFRAC is a signatory of the multilateral recognition agreements of EA[1] and/or of ILAC[2] and/or of IAF[3] for testing activities.
1. European co-operation for Accreditation
2. International Laboratory Accreditation Cooperation
3. International Accreditation Forum

I - IDENTIFICATION OF ASSAY LABORATORY

FONDEREPHAR
Faculté des Sciences Pharmaceutiques
35 Chemin des Maraîchers
31062 Toulouse cedex 9
France

II – IDENTIFICATION OF TEST PRODUCT

Product* :	**F3307**
Batch* :	0209E0362206070
Expiry date*:	Not precised
Date of receipt :	Jun/09/2022
Internal code :	**22-3187-1**
Active substances* :	Orthphtaldehyde 0,57%
Manufacturer* :	SODEL
Period of testing :	June 2022

Storage conditions during the period of testing : Room temperature

* Informations provided by the client

III – TEST

Method : **Dilution – neutralization**

Count(s) per ml : 1 or 2 for $N/10^{-6}$ (*C. albicans*) or 3 for $N/10^{-6}$ (*A. brasiliensis*)

Neutralizer (*A. brasiliensis*): Polysorbate 80 (10%), Saponin (2%), Lecithin (2%), Natrium Thiosulfate (0,5%), QSP Trypcase Soy Broth (Internal preparation – Batch 1212 Exp. Jul/20/2022)

Neutralizer (*C. albicans*): Polysorbate 80 (10%), Saponin (6%), Lecithin (2%), Natrium Thiosulfate (1%), L-histidine (0,2%), Glycine (0,6%) QSP Trypcase Soy Broth (Internal preparation – Batch 11160 Exp. Jul/13/2022)

Appearance of product : liquid, clear, blue

Appearance of the dilution of product : clear

Test surface : frosted glass carriers, 15mm x 60mm x 1mm, one surface sandblasted

IV – EXPERIMENTAL CONDITIONS

Product diluent : Water for injectables preparations

Concentrations of the product*: **80%** (v/v), **70%** (v/v) and **0,1%** (v/v)

Test-organisms* : *Candida albicans* DSM 1386
Aspergillus brasiliensis CBS 733.88

Interfering substance*: 0,3 g/L bovine albumin (clean conditions)

Additional conditions : Test temperature* : 20°C ± 1°C
Contact time* : 5 minutes ± 10 seconds

* Informations provided by the client

Incubation temperature : 30°C ± 1°C

NB. The obligatory conditions were not performed by the laboratory.

V – TEST RESULTS

CANDIDA ALBICANS DSM 1386

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST				
	Validation suspension **Nvo**	Experimental conditions control **A**	Neutralizer control **B**	Method validation Product conc. 80% **C**	**N**			Concentration of product % (v/v)			
					10^{-6}	10^{-7}		**Contact time**	**80%**	**70%**	**0,1%**
Vc1-Vc2	109 – 114	104 – 85	89 – 97	101 – 101	316 - 333	34 – 37	Vc1 – Vc2	**5 minutes**	10^0 0 - 0 10^{-1} 0- 0 10^{-2} 0 - 0 10^{-3} 0 - 0	10^0 0 - 0 10^{-1} 0- 0 10^{-2} 0 - 0 10^{-3} 0 - 0	10^0 >330->330 10^{-1}>330->330 10^{-2} >330->330 10^{-3} 266 - 271
$\bar{x}$	112	95	93	101	$\bar{x}$ wm = $327,27.10^6$ lg N = 8,51 8,17 ≤ lg N ≤ 8,70		$\bar{x}$	**5 minutes**	< 14	< 14	269.10^3
					Water control Nw		Na= $\bar{x}$ x10	**5 minutes**	< 140	< 140	269.10^4
	$\bar{x}$ of Nvo between 30 and 160	$\bar{x}$ of A ≥ 0, 5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0, 5 $\bar{x}$ of Nvo	$\bar{x}$ of C ≥ 0, 5 $\bar{x}$ of Nvo	10^{-3} 170 - 152	10^{-4} 13 - 15	lg Na	**5 minutes**	< 2,15	< 2,15	6,43
					$\bar{x}$ x 10 = $160,48.10^4$ lg Nw = 6,21 6,15 ≤lg Nw ≤ lg N -1,3		**lg R**	**5 minutes**	**> 4,06**	**> 4,06**	**0**

Date of the test : Jun/29/2022

Vc = Count per ml (1 or 2 for $N/10^{-6}$)

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_w – lg Na)

ASPERGILLUS BRASILIENSIS CBS 733.88

VALIDATION AND CONTROLS					TEST SUSPENSION		TEST				
	Validation suspension **Nvo**	Experimental conditions control **A**	Neutralizer control **B**	Method validation Product conc. 80% **C**	**N**			Concentration of product % (v/v)			
					10^{-6}	10^{-7}		**Contact time**	**100%**	**50%**	**0,1%**
Vc1-Vc2	110 – 75	90 – 78	82 – 64	67 – 73	313 - 353	37 – 32	Vc1 – Vc2	**5 minutes**	10^0 4 - 6 10^{-1} 0 - 0 10^{-2} 0 - 0 10^{-3} 0 - 0	10^0 7 - 14 10^{-1} 2 - 2 10^{-2} 0 - 0 10^{-3} 0 - 0	10^0 >330->330 10^{-1}>330->330 10^{-2} >330->330 10^{-3} 126-136
$\bar{x}$	93	84	73	70	$\bar{x}$ wm = $334,09.10^6$ lg N = 8,52 8,17 ≤ lg N ≤ 8,70		$\bar{x}$	**5 minutes**	< 14	< 14	131.10^3
					Water control Nw		Na= $\bar{x}$ x10	**5 minutes**	< 140	< 140	131.10^4
					10^{-3}	10^{-4}	lg Na	**5 minutes**	< 2,15	< 2,15	6,12
	$\bar{x}$ of Nvo between 30 and 160	$\bar{x}$ of A ≥ 0,5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0,5 $\bar{x}$ of Nvo	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	122 - 169	7 – 10					
					$\bar{x}$ x 10 = $146,00.10^4$ lg Nw = 6,16 6,15 ≤lg Nw ≤ lg N -1,3		**lg R**	**5 minutes**	**> 4,02**	**> 4,02**	**0**

Date of the test : Jun/22/2022

Vc = Count per ml (1 or 3 for $N/10^{-6}$)

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}$ wm = weighted mean of $\bar{x}$

R = Reduction (lg R = lg N_w – lg Na)

VI – CONCLUSION

For the product **F3307** (batch 0209E362206070), the fungicidal concentration for specific needs determined according to the NF EN 14562 (September 2006), after a 5 minutes contact time at 20°C under clean conditions, against the test-organisms *Candida albicans* DSM 1386 and *Aspergillus brasiliensis* CBS 733.88, is **70%** (v/v).

For the product **F3307** (batch 0209E362206070), the yeasticidal concentration for specific needs determined according to the NF EN 14562 (September 2006), after a 5 minutes contact time at 20°C under clean conditions, against the test-organism *Candida albicans* DSM 1386, is **70%** (v/v).

The results hold only for the product under assay and apply to the sample as received.

Test Report No.: VX-TR-23-0003
Copy No.: 1

DETERMINATION OF THE MYCOBACTERICIDAL ACTIVITY (EN 14348) OF F3307

Lab No.:	VX-268-22-0005
Sample Name:	**F3307**
Method:	EN 14348:2005 (E) Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – Test method and requirements (phase 2, step 1)
Client:	Sodel 190 Rue René Barthélémy 14100 Lisieux France
Sample Receipt Date:	27 September 2022
Report Date:	05 January 2023

Kuala Lumpur, 05 January 2023

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Date: 2023.01.06 16:35:07 +08'00'

Maizatul Ismail
Microbiologist

Materials and Method

Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area according to EN 14348:2005 (E)

1. Testing laboratory identification

Viroxy Sdn. Bhd.
6th Floor, Menara RKT
50300 Kuala Lumpur
Malaysia

2. Sample identification

2.1	Sample name:	F3307
2.2	Batch no.:	0209E036220919V
2.3	Product appearance:	Clear, bluish solution
2.4	Manufacturer:	Sodel 190 Rue René Barthélémy 14100 Lisieux France
2.5	Active substance(s):	0.54 % OPA
2.6	Sample receipt date:	27 September 2022
2.7	Storage conditions:	Room temperature
2.8	Product diluent:	Distilled water

3. Experimental conditions

3.1	Testing period:	14 December 2022
3.2	Test organism(s):	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755
3.3	Concentration / contact time:	0.10 % / 5 and 10 minutes 70.00 % / 5 and 10 minutes 80.00 % / 5 and 10 minutes
3.4	Loading:	0.30 g/L bovine albumin solution
3.5	Test temperature:	20 °C ± 1 °C
3.6	Counting method:	Spread plate
3.7	Incubation period:	21 days, 36 °C ± 1 °C

4. Test method and its validation

4.1	Testing method:	Dilution-neutralization
4.2	Inactivation combination:	30.00 g/L Tween 80 30.00 g/L Saponin 3.00 g/L Lecithin 50.00 g/L Glycine in tryptone soya broth

The results of validation tests A, B, and C proved the viability of the method in all cases.

5. Test results

The results are stated in Tables A and B.

6. Conclusion

F3307 showed the required microbial reduction of ≥4.0 $\log_{10}$ against test strain(s) *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 in accordance with EN 14348:2005 (E) at 70.00 % and 80.00 % concentration(s) after 5 and 10 minutes under the stated conditions. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance.

F3307 did not show the required microbial reduction of ≥4.0 $\log_{10}$ against test strain(s) *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 in accordance with EN 14348:2005 (E) at 0.10 % concentration(s) after 5 and 10 minutes under the stated conditions. According to the simple acceptance decision rule†, there is a minimal risk of false rejection.

Kuala Lumpur, 05 January 2023


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Maizatul Ismail
Microbiologist

7. Note

Mycobactericidal activity – the capability of a product to produce a reduction in the number of viable mycobacterial cells of relevant test organisms under defined conditions by at least 4 orders (10^4).

Tuberculocidal activity – the capability of a product to kill *Mycobacterium tuberculosis*, demonstrated by the capability to produce a reduction in the number of viable cells of *Mycobacterium terrae* under defined conditions by at least 4 orders (10^4).

$R = N_0/N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Table A: Evaluation of the mycobactericidal activity of F3307 on test strains according to EN 14348

Product: F3307
Loading: 0.30 g/L bovine albumin solution

Test strain: *Mycobacterium avium* ATCC 15769

N	V_{C1}	V_{C2}	Test suspension, N
10^{-7}	163	154	N: 1.58×10^9 N_0: 1.58×10^8 lg N_0: **8.20**
10^{-8}	16	14	

Test concentration (%) / contact time (min)	Dilution	V_{C1}	V_{C2}	Test procedure, N_a $N_a = \bar{x} \times 10$
80.00 / 5	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>6.05**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
70.00 / 5	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>6.05**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
0.10 / 5	10^0	>660	>660	N_a: $>6.60 \times 10^6$ lg N_a: **>6.82** lg R: **<1.38**
	10^{-1}	>660	>660	
	10^{-2}	>660	>660	
	10^{-3}	>660	>660	

Test concentration (%) / contact time (min)	Dilution	V_{C1}	V_{C2}	Test procedure, N_a $N_a = \overline{x} \times 10$
80.00 / 10	10^0	<14	<14	N_a: <1.40 x 10^2 lg N_a: **<2.15** lg R: **>6.05**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
70.00 / 10	10^0	<14	<14	N_a: <1.40 x 10^2 lg N_a: **<2.15** lg R: **>6.05**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
0.10 / 10	10^0	>660	>660	N_a: >6.60 x 10^6 lg N_a: **>6.82** lg R: **<1.38**
	10^{-1}	>660	>660	
	10^{-2}	>660	>660	
	10^{-3}	>660	>660	

Test strain: *Mycobacterium terrae* ATCC 15755

N	V_{C1}	V_{C2}	Test suspension, N
10^{-7}	154	151	N: 1.53×10^9 N_0: 1.53×10^8 lg N_0: **8.18**
10^{-8}	16	13	

Test concentration (%) / contact time (min)	Dilution	V_{C1}	V_{C2}	Test procedure, N_a $N_a = \bar{x} \times 10$
80.00 / 5	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>6.04**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
70.00 / 5	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>6.04**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
0.10 / 5	10^0	>660	>660	N_a: $>6.60 \times 10^6$ lg N_a: **>6.82** lg R: **<1.36**
	10^{-1}	>660	>660	
	10^{-2}	>660	>660	
	10^{-3}	>660	>660	

Test concentration (%) / contact time (min)	Dilution	V_{C1}	V_{C2}	Test procedure, N_a $N_a = \overline{x} \times 10$
80.00 / 10	10^0	<14	<14	N_a: <1.40 x 10^2 lg N_a: **<2.15** lg R: **>6.04**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
70.00 / 10	10^0	<14	<14	N_a: <1.40 x 10^2 lg N_a: **<2.15** lg R: **>6.04**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
0.10 / 10	10^0	>660	>660	N_a: >6.60 x 10^6 lg N_a: **>6.82** lg R: **<1.36**
	10^{-1}	>660	>660	
	10^{-2}	>660	>660	
	10^{-3}	>660	>660	

Table B: Control tests and method validation for Table A

Test strain	Validation suspension	Validation of experimental conditions	Neutralizer toxicity control	Method validation control
M. avium ATCC 15769	N_{V0}: 4.55 x 10^1	A: 5.45 x 10^1	B: 4.70 x 10^1	C: 4.60 x 10^1
M. terrae ATCC 15755	N_{V0}: 4.30 x 10^1	A: 4.05 x 10^1	B: 4.90 x 10^1	C: 5.60 x 10^1

Note

cfu: Colony forming units

V_C: Number of cfu counted per 1.0 ml sample

$\overline{x}$: Average V_{C1} and V_{C2} values

N: Number of cfu per ml in the test suspension

N_0: Number of cfu per ml at the beginning of the contact time

N_{V0}: Number of cfu per ml in the mixtures A, B, and C at the beginning of the contact time

N_a: Number of survivors per ml in the test mixture at the end of the contact time and before neutralization

A: Number of cfu per ml in the experimental conditions control

B: Number of cfu per ml in the neutralizer toxicity control

C: Number of cfu per ml in the dilution-neutralization method validation

Table C: Summary of the log reductions of the quantitative suspension test according to EN 14348

Test strain	Test concentration (%) / contact time (min)	Log reduction	Percentage reduction (%)	Associated risk†
M. avium ATCC 15769	80.00 / 5	**>6.05 ± 0.06**	**>99.9999**	Minimal risk of false acceptance
	80.00 / 10	**>6.05 ± 0.06**	**>99.9999**	Minimal risk of false acceptance
	70.00 / 5	**>6.05 ± 0.06**	**>99.9999**	Minimal risk of false acceptance
	70.00 / 10	**>6.05 ± 0.06**	**>99.9999**	Minimal risk of false acceptance
	0.10 / 5	**<1.38 ± 0.06**	**<95.83**	Minimal risk of false rejection
	0.10 / 10	**<1.38 ± 0.06**	**<95.83**	Minimal risk of false rejection
M. terrae ATCC 15755	80.00 / 5	**>6.04 ± 0.06**	**>99.9999**	Minimal risk of false acceptance
	80.00 / 10	**>6.04 ± 0.06**	**>99.9999**	Minimal risk of false acceptance
	70.00 / 5	**>6.04 ± 0.06**	**>99.9999**	Minimal risk of false acceptance
	70.00 / 10	**>6.04 ± 0.06**	**>99.9999**	Minimal risk of false acceptance
	0.10 / 5	**<1.36 ± 0.06**	**<95.63**	Minimal risk of false rejection
	0.10 / 10	**<1.36 ± 0.06**	**<95.63**	Minimal risk of false rejection

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Sodel
190 Rue René Barthélémy
14100 Lisieux
France

Efficacy of F3307 against *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 in a quantitative suspension test at 20 ˚C according to EN 14348:2005 (E) under clean condition

EXPERT OPINION*

This expert opinion is based on the test report VX-TR-23-0003 dated 05 January 2023.

The mycobactericidal activity of the disinfectant F3307 of Sodel against *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 was investigated by a quantitative suspension test according to EN 14348:2005 (E) under clean condition (0.30 g/L bovine albumin solution).

According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having mycobactericidal and/or tuberculocidal activity if the number of viable mycobacterial cells and/or *Mycobacterium terrae* cells is reduced by ≥4 $\log_{10}$ (inactivation ≥99.99 %) within the recommended exposure period.

F3307 was examined at 20 ˚C at the concentration(s) of 70.00 %, and 80.00 % for the exposure time(s) of 5 and 10 minutes. After the exposure time(s), the mycobacterial reduction exceeded 4 $\log_{10}$-steps in all assays. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance.

F3307 was examined at 20 ˚C at the concentration(s) of 0.10 % for the exposure time(s) of 5 and 10 minutes. After the exposure time(s), the mycobacterial reduction did not exceed 4 $\log_{10}$-steps in all assays. According to the simple acceptance decision rule†, there is a minimal risk of false rejection. Therefore, a mycobactericidal activity against *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 was measured as follows:

Clean condition	70.00 %	5 and 10 minutes
Clean condition	80.00 %	5 and 10 minutes

Kuala Lumpur, 05 January 2023

Digitally signed by RAJA MAIZATUL AKMAL BINTI RAJA ISMAIL
Date: 2023.01.06 16:35:44 +08'00'

Maizatul Ismail
Microbiologist

Digitally signed by YEW TUCK FAI
Date: 2023.01.06 16:21:04 +08'00'

Tuck Fai Yew
Microbiologist

* Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Appendix 1

QAU CERTIFICATE*

The results stated in test report VX-TR-23-0003 dated 05 January 2023 were compared to the raw data of the tests and checked for correct transfer. No deviations were detected.

Kuala Lumpur, 05 January 2023

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by YEW TUCK FAI
Date: 2023.01.06
16:21:17 +08'00'

Tuck Fai Yew
Microbiologist

* Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

Appendix 2 Raw data

Test Method	EN 14348:2005				
Product	F3307		**Batch No.**	0209E036220919V	
Product Diluent	Distilled water		**Lab No.**	VX-268-22-0005	
Test Organism	*Mycobacterium avium ATCC 15769*				
Interfering Substance	0.30 g/L bovine albumin solution				
Test Temperature (°C)	20	**Incubation Temperature (°C)**		36	
Neutralizer or Rinsing Liquid	30.00 g/L Tween 80, 30.00 g/L Saponin, 3.00 g/L Lecithin, 50.00 g/L Glycine in Tryptone soya broth				
Inactivation Method	Dilution-neutralization		**Plating Method**	Spread plate	
Test Date	14/12/2022	**Analyzed By**	NYE	**Verified By**	PCH

Test and Validation Suspension

		V_{C1}	V_{C2}		
Test Suspension (N)	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = N = 1.58E+09	N_0 = N/10
	10^{-7}	163	154	lg N_0 = 8.20	8.17 ≤ lg N_0 ≤ 8.70
	10^{-8}	16	14	Pass?	**Yes**

	V_{C1}	V_{C2}		
Validation Suspension (N_V)	V_{C1}	V_{C2}	N_{V0} = 45.5	N_{V0} = N_V/10
	41	50	30 ≤ N_{V0} ≤ 160	Pass? **Yes**
Validation Suspension (N_{VB})	V_{C1}	V_{C2}	N_{V0} =	N_{V0} = N_{VB}/1000
	-	-	30 ≤ N_{V0} ≤ 160	Pass? **N/A**

Validation and Control Procedures

	V_{C1}	V_{C2}		
Experimental Conditions Control (A)	V_{C1}	V_{C2}	A = 54.5	Pass? **Yes**
	55	54	A ≥ 0.5 x Nv/10	
Neutralizer Toxicity or Filtration Control (B)	V_{C1}	V_{C2}	B = 47.0	Pass? **Yes**
	43	51	B ≥ 0.5 x N_{VB}/1000 or Nv/10	
Method Validation (C)	V_{C1}	V_{C2}	C = 46.0	Pass? **Yes**
Concentration: 80.00 %	42	50	C ≥ 0.5 x Nv/10	

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg N_0 - lg Na
80.00 %	5	10^0	<14	<14	<1.40E+02	<2.15	>6.05
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
70.00 %	5	10^0	<14	<14	<1.40E+02	<2.15	>6.05
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
0.10 %	5	10^0	>660	>660	>6.60E+06	>6.82	<1.38
		10^{-1}	>660	>660			
		10^{-2}	>660	>660			
		10^{-3}	>660	>660			

Raw Data of Colony Count

	N $^{-7}$		N $^{-8}$		N_V		N_{VB}		A		B		C	
V_{C1}	84	79	10	6	20	21	-	-	30	25	24	19	20	22
V_{C2}	82	72	8	6	23	27	-	-	28	26	29	22	23	27

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
80.00 %	5	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
70.00 %	5	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
0.10 %	5	>330	>330	>330	>330	>330	>330	>330	>330
		>330	>330	>330	>330	>330	>330	>330	>330

Appendix 2 Raw data

Test Method	EN 14348:2005				
Product	F3307		**Batch No.**	0209E036220919V	
Product Diluent	Distilled water		**Lab No.**	VX-268-22-0005	
Test Organism	*Mycobacterium avium ATCC 15769*				
Interfering Substance	0.30 g/L bovine albumin solution				
Test Temperature (°C)	20	**Incubation Temperature (°C)**		36	
Neutralizer or Rinsing Liquid	30.00 g/L Tween 80, 30.00 g/L Saponin, 3.00 g/L Lecithin, 50.00 g/L Glycine in Tryptone soya broth				
Inactivation Method	Dilution-neutralization		**Plating Method**	Spread plate	
Test Date	14/12/2022	**Analyzed By**	NYE	**Verified By**	PCH

Test and Validation Suspension

		V_{C1}	V_{C2}		
Test Suspension (N)	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = N = 1.58E+09	N_0 = N/10
	10^{-7}	163	154	lg N_0 = 8.20	8.17 ≤ lg N_0 ≤ 8.70
	10^{-8}	16	14	Pass?	**Yes**

	V_{C1}	V_{C2}		
Validation Suspension (N_V)	V_{C1}	V_{C2}	N_{V0} = 45.5	N_{V0} = N_V/10
	41	50	30 ≤ N_{V0} ≤ 160	Pass? **Yes**
Validation Suspension (N_{VB})	V_{C1}	V_{C2}	N_{V0} =	N_{V0} = N_{VB}/1000
	-	-	30 ≤ N_{V0} ≤ 160	Pass? **N/A**

Validation and Control Procedures

	V_{C1}	V_{C2}		
Experimental Conditions Control (A)	V_{C1}	V_{C2}	A = 54.5	Pass? **Yes**
	55	54	A ≥ 0.5 x Nv/10	
Neutralizer Toxicity or Filtration Control (B)	V_{C1}	V_{C2}	B = 47.0	Pass? **Yes**
	43	51	B ≥ 0.5 x N_{VB}/1000 or Nv/10	
Method Validation (C)	V_{C1}	V_{C2}	C = 46.0	Pass? **Yes**
Concentration: 80.00 %	42	50	C ≥ 0.5 x Nv/10	

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg N_0 - lg Na
80.00 %	10	10^0	<14	<14	<1.40E+02	<2.15	>6.05
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
70.00 %	10	10^0	<14	<14	<1.40E+02	<2.15	>6.05
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
0.10 %	10	10^0	>660	>660	>6.60E+06	>6.82	<1.38
		10^{-1}	>660	>660			
		10^{-2}	>660	>660			
		10^{-3}	>660	>660			

Raw Data of Colony Count

	N $^{-7}$		N $^{-8}$		N_V		N_{VB}		A		B		C	
V_{C1}	84	79	10	6	20	21	-	-	30	25	24	19	20	22
V_{C2}	82	72	8	6	23	27	-	-	28	26	29	22	23	27

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
80.00 %	10	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
70.00 %	10	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
0.10 %	10	>330	>330	>330	>330	>330	>330	>330	>330
		>330	>330	>330	>330	>330	>330	>330	>330

Appendix 2 Raw data

Test Method	EN 14348:2005				
Product	F3307		**Batch No.**	0209E036220919V	
Product Diluent	Distilled water		**Lab No.**	VX-268-22-0005	
Test Organism	*Mycobacterium terrae ATCC 15755*				
Interfering Substance	0.30 g/L bovine albumin solution				
Test Temperature (°C)	20	**Incubation Temperature (°C)**		36	
Neutralizer or Rinsing Liquid	30.00 g/L Tween 80, 30.00 g/L Saponin, 3.00 g/L Lecithin, 50.00 g/L Glycine in Tryptone soya broth				
Inactivation Method	Dilution-neutralization		**Plating Method**	Spread plate	
Test Date	14/12/2022	**Analyzed By**	NYE	**Verified By**	PCH

Test and Validation Suspension

		V_{C1}	V_{C2}		
Test Suspension (N)	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = N = 1.53E+09	N_0 = N/10
	10^{-7}	154	151	lg N_0 = 8.18	8.17 ≤ lg N_0 ≤ 8.70
	10^{-8}	16	13	Pass?	**Yes**

Validation Suspension (N_V)	V_{C1}	V_{C2}	N_{V0} = 43.0	N_{V0} = N_V/10
	44	42	30 ≤ N_{V0} ≤ 160	Pass? **Yes**
Validation Suspension (N_{VB})	V_{C1}	V_{C2}	N_{V0} =	N_{V0} = N_{VB}/1000
	-	-	30 ≤ N_{V0} ≤ 160	Pass? **N/A**

Validation and Control Procedures

Experimental Conditions Control (A)	V_{C1}	V_{C2}	A = 40.5	Pass? **Yes**
	39	42	A ≥ 0.5 x Nv/10	
Neutralizer Toxicity or Filtration Control (B)	V_{C1}	V_{C2}	B = 49.0	Pass? **Yes**
	45	53	B ≥ 0.5 x N_{VB}/1000 or Nv/10	
Method Validation (C)	V_{C1}	V_{C2}	C = 56.0	Pass? **Yes**
Concentration: 80.00 %	62	50	C ≥ 0.5 x Nv/10	

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg N_0 - lg Na
80.00 %	5	10^0	<14	<14	<1.40E+02	<2.15	>6.04
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
70.00 %	5	10^0	<14	<14	<1.40E+02	<2.15	>6.04
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
0.10 %	5	10^0	>660	>660	>6.60E+06	>6.82	<1.36
		10^{-1}	>660	>660			
		10^{-2}	>660	>660			
		10^{-3}	>660	>660			

Raw Data of Colony Count

	N $^{-7}$		N $^{-8}$		N_V		N_{VB}		A		B		C	
V_{C1}	70	84	8	8	20	24	-	-	20	19	20	25	33	29
V_{C2}	71	80	7	6	21	21	-	-	25	17	26	27	30	20

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
80.00 %	5	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
70.00 %	5	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
0.10 %	5	>330	>330	>330	>330	>330	>330	>330	>330
		>330	>330	>330	>330	>330	>330	>330	>330

Appendix 2 Raw data

Test Method	EN 14348:2005				
Product	F3307		**Batch No.**	0209E036220919V	
Product Diluent	Distilled water		**Lab No.**	VX-268-22-0005	
Test Organism	*Mycobacterium terrae ATCC 15755*				
Interfering Substance	0.30 g/L bovine albumin solution				
Test Temperature (°C)	20	**Incubation Temperature (°C)**		36	
Neutralizer or Rinsing Liquid	30.00 g/L Tween 80, 30.00 g/L Saponin, 3.00 g/L Lecithin, 50.00 g/L Glycine in Tryptone soya broth				
Inactivation Method	Dilution-neutralization		**Plating Method**	Spread plate	
Test Date	14/12/2022	**Analyzed By**	NYE	**Verified By**	PCH

Test and Validation Suspension

		V_{C1}	V_{C2}		
Test Suspension (N)	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = N = 1.53E+09	N_0 = N/10
	10^{-7}	154	151	lg N_0 = 8.18	8.17 ≤ lg N_0 ≤ 8.70
	10^{-8}	16	13	Pass?	**Yes**

	V_{C1}	V_{C2}		
Validation Suspension (N_V)	V_{C1}	V_{C2}	N_{V0} = 43.0	N_{V0} = N_V/10
	44	42	30 ≤ N_{V0} ≤ 160	Pass? **Yes**
Validation Suspension (N_{VB})	V_{C1}	V_{C2}	N_{V0} =	N_{V0} = N_{VB}/1000
	-	-	30 ≤ N_{V0} ≤ 160	Pass? **N/A**

Validation and Control Procedures

	V_{C1}	V_{C2}		
Experimental Conditions Control (A)	V_{C1}	V_{C2}	A = 40.5	Pass? **Yes**
	39	42	A ≥ 0.5 x Nv/10	
Neutralizer Toxicity or Filtration Control (B)	V_{C1}	V_{C2}	B = 49.0	Pass? **Yes**
	45	53	B ≥ 0.5 x N_{VB}/1000 or Nv/10	
Method Validation (C)	V_{C1}	V_{C2}	C = 56.0	Pass? **Yes**
Concentration: 80.00 %	62	50	C ≥ 0.5 x Nv/10	

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg N_0 - lg Na
80.00 %	10	10^0	<14	<14	<1.40E+02	<2.15	>6.04
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
70.00 %	10	10^0	<14	<14	<1.40E+02	<2.15	>6.04
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
0.10 %	10	10^0	>660	>660	>6.60E+06	>6.82	<1.36
		10^{-1}	>660	>660			
		10^{-2}	>660	>660			
		10^{-3}	>660	>660			

Raw Data of Colony Count

	N $^{-7}$		N $^{-8}$		N_V		N_{VB}		A		B		C	
V_{C1}	70	84	8	8	20	24	-	-	20	19	20	25	33	29
V_{C2}	71	80	7	6	21	21	-	-	25	17	26	27	30	20

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
80.00 %	10	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
70.00 %	10	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
0.10 %	10	>330	>330	>330	>330	>330	>330	>330	>330
		>330	>330	>330	>330	>330	>330	>330	>330

Note

cfu: Colony forming units

V_C: Number of cfu counted per 1.0 ml sample

$\bar{x}$: Average V_{C1} and V_{C2} values

N: Number of cfu per ml in the test suspension

N_0: Number of cfu per ml at the beginning of the contact time

N_{V0}: Number of cfu per ml in the mixtures A, B, and C at the beginning of the contact time

N_a: Number of survivors per ml in the test mixture at the end of the contact time and before neutralization

A: Number of cfu per ml in the experimental conditions control

B: Number of cfu per ml in the neutralizer toxicity control

C: Number of cfu per ml in the dilution-neutralization method validation

Appendix 3 Summary of test description

1. Materials and reagents

1.1 Middlebrook and Cohn 7H10 agar (MCO, HiMedia, catalogue no. M199)

1.2 Tryptone, pancreatic digest of casein (Oxoid, catalogue no. LP0042)

1.3 Sodium chloride (Merck, catalogue no. 1.06404.0500)

1.4 Magnesium chloride ($MgCl_2$, Acros Organics, catalogue no. AC223211000)

1.5 Calcium chloride ($CaCl_2$, R&M Chemicals, catalogue no. 9924-00)

1.6 Sodium bicarbonate ($NaHCO_3$, Fisher Chemical, catalogue no. 10152780)

1.7 Bovine albumin fraction V (Merck, catalogue no. 1.12018.0100)

1.8 Defibrinated sheep blood (Thermo Scientific, catalogue no. SR0051B) (for dirty condition only)

1.9 Neutralizer

1.9.1 Tween (Fisher Chemical, catalogue no. 10498800)

1.9.2 Saponin (Nacalai Tesque, catalogue no. 30502-55)

1.9.3 Lecithin (Nacalai Tesque, catalogue no. 20335-65)

1.9.4 Glycine (HiMedia, catalogue no. MB013)

1.9.5 Tryptone Soya Broth (TSB, Oxoid, catalogue no. CM0129)

2. Apparatus and glassware

2.1 Autoclave (TOMY, model SX500)

2.2 Water baths (Memmert, model WNB 29)

2.3 Incubator (Binder, model BD 260)

2.4 pH-meter (Ohaus, model 3100 Meter with ST310)

2.5 Vortex® mixer (Biosan model Biosan V-1 Plus)

2.6 Petri dishes (Wanpow Plastic)

3. Test procedure

3.1 Test Na – Determination of mycobactericidal concentrations

3.1.1 Pipette 1.0 ml of interfering substance into a tube.

3.1.2 Add 1.0 ml of the test suspension.

3.1.3 Start the stopwatch immediately, mix and place the tube in a water bath controlled at the chosen test temperature θ for 2 minutes ± 10 seconds.

3.1.4 At the end of this time, add 8.0 ml of the product test solution.

3.1.5 Restart the stopwatch at the beginning of the addition.

3.1.6 Mix and place the tube in a water bath controlled at θ for the chosen contact time t.

3.1.7 Just before the end of t, mix again.

3.1.8 At the end of t, take 1.0 ml sample of the test mixture Na and transfer into a tube containing 8.0 ml neutralizer and 1.0 ml water.

3.1.9 Mix and place in a water bath controlled at 20 °C ± 1 °C.

3.1.10 After a neutralization time of 5 minutes ± 10 seconds, mix and immediately take a sample of 1.0 ml of the neutralized test mixture Na (containing neutralizer, product test solution, interfering substance, and test suspension) in duplicate and transfer approximately equal size onto two separate plates containing surface dried MCO, i.e. two plates per 1.0 ml sample.

3.1.11 Additionally, transfer 0.5 ml of this mixture into a tube containing 4.5 ml of neutralizer to obtain 10^{-1} dilution of Na. Mix and dilute accordingly to produce 10^{-2} and 10^{-3} dilutions of Na.

3.1.12 Take samples of 1.0 ml from each dilution tube in duplicate and transfer approximately equal amounts onto two separate plates containing MCO.

3.1.13 Incubate the plates for 21 days at 36 °C ± 1 °C.

3.1.14 Discard any plates which is not countable (for any reason). Count the plates and determine the number of cfu.

3.1.15 Do not recount plates which no longer show well separated colonies.

3.1.16 Note the exact number of colonies for each plate but record >330 for any counts higher than 330 and determine the V_C-values.

3.1.17 Perform the procedure using the other product test solutions at the same time.

3.2 Experimental conditions control A – Validation of the selected experimental conditions and/or verification of the absence of any lethal effect in the test conditions

3.2.1 Pipette 1.0 ml of interfering substance used in the test into a tube.

3.2.2 Add 1.0 ml of the validation suspension.

3.2.3 Start the stopwatch immediately, mix, and place the tube in a water bath controlled at θ for 2 minutes ± 10 seconds.

3.2.4 At the end of this time, add 8.0 ml of hard water (or water, in the case of ready-to-use products).

3.2.5 Restart the stopwatch at the beginning of the addition.

3.2.6 Mix and place the tube in a water bath controlled at θ for t.

3.2.7 Just before the end of t, mix again.

3.2.8 At the end of t, take a sample of 1.0 ml of this mixture A in duplicate and transfer approximately equal amounts onto two separate plates containing MCO.

3.2.9 Calculate the numbers of cfu/ml in the validation mixture A.

3.2.10 Verify according to Section 3.5.

3.3 Neutralizer control B – Verification of the absence of toxicity of the neutralizer

3.3.1 Pipette 8.0 ml of the neutralizer used in the test and 1.0 ml of water into a tube.

3.3.2 Add 1.0 ml of the validation suspension.

3.3.3 Start the stopwatch at the beginning of the addition and mix.

3.3.4 Place the tube in a water bath controlled at 20 °C ± 1 °C for 5 minutes ± 10 seconds.

3.3.5 Just before the end of this time, mix.

3.3.6 At the end of this time, take a sample of 1.0 ml of this mixture B in duplicate and transfer approximately equal amounts onto two separate plates containing MCO.

3.3.7 Calculate the numbers of cfu/ml in the validation mixture B.

3.3.8 Verify according to Section 3.5.

3.4 Method validation C – Dilution-neutralization validation

3.4.1 Pipette 1.0 ml of interfering substance used in the test into a tube.

3.4.2 Add 1.0 ml of the diluent.

3.4.3 Start the stopwatch, add 8.0 ml of the product test solution only of the highest concentration used in the test.

3.4.4 Mix and place the tube in a water bath controlled at θ for t.

3.4.5 Just before the end of t, mix again.

3.4.6 At the end of t, transfer 1.0 ml of the mixture into a tube containing 8.0 ml of neutralizer.

3.4.7 Restart the stopwatch at the beginning of the addition.

3.4.8 Mix and place the tube in a water bath controlled at 20 °C ± 1 °C for 5 minutes ± 10 seconds.

3.4.9 Add 1.0 ml of the validation suspension.

3.4.10 Start the stopwatch at the beginning of the addition and mix.

3.4.11 Place the tube in a water bath controlled at 20 °C ± 1 °C for 30 minutes ± 1 minute.

3.4.12 Just before the end of this time, mix again.

3.4.13 At the end of this time, take a sample of 1.0 ml of the mixture C in duplicate and transfer approximately equal amounts onto two separate plates containing MCO.

3.4.14 Calculate the numbers of cfu/ml in the validation mixture C.

3.4.15 Verify according to Section 3.5.

3.5 Basic limits

3.5.1 N is between 1.5 x 10^9 and 5.0 x 10^9 ($9.17 \leq \lg N \leq 9.70$)

3.5.2 N_0 is between 1.5 x 10^8 and 5.0 x 10^8 ($8.17 \leq \lg N_0 \leq 8.70$)

3.5.3 N_{V0} is between 30 and 160 (3.0 x 10^1 and 1.6 x 10^2)

3.5.4 N_V is between 3.0 x 10^2 and 1.6 x 10^3

3.5.5 A, B, C are equal to or greater than 0.5 x N_{V0}

3.5.6 Control of weighted mean counts: quotient is not lower than 5 and not higher than 15

4. Literature

4.1 EN 14348:2005 (E): Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity in the medical area including instrument disinfection – Test method and requirements (phase 2, step 1)

4.2 EN 14885:2018 (E): Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics

4.3 EN 12353:2013 (E): Chemical disinfectants and antiseptics – Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

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Test Report No.: VX-TR-23-0023
Copy No.: 1

DETERMINATION OF THE MYCOBACTERICIDAL OR TUBERCULOCIDAL ACTIVITY (EN 14563) OF F3307

Lab No.:	VX-268-22-0005
Sample Name:	**F3307**
Method:	EN 14563:2008 (E) Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area – Test method and requirements (phase 2, step 2)
Client:	Sodel 190 Rue René Barthélémy 14100 Lisieux France
Sample Receipt Date:	27 September 2022
Report Date:	05 January 2023

Kuala Lumpur, 05 January 2023

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Date: 2023.01.06 16:38:46 +08'00'

Maizatul Ismail
Microbiologist

Materials and Method

Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area according to EN 14563:2008 (E)

1. Testing laboratory identification

Viroxy Sdn. Bhd.
6th Floor, Menara RKT
50300 Kuala Lumpur
Malaysia

2. Sample identification

2.1	Sample name:	F3307
2.2	Batch no.:	0209E026220919V
2.3	Product appearance:	Clear, bluish solution
2.4	Manufacturer:	Sodel 190 Rue René Barthélémy 14100 Lisieux France
2.5	Active substance(s):	0.54 % OPA
2.6	Sample receipt date:	27 September 2022
2.7	Storage conditions:	Room temperature
2.8	Product diluent:	Distilled water

3. Experimental conditions

3.1	Testing period:	14 December 2022
3.2	Test organism(s):	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755
3.3	Concentration / contact time:	80.00 % / 5 and 10 minutes 70.00 % / 5 and 10 minutes 0.10 % / 5 and 10 minutes
3.4	Loading:	0.30 g/L bovine albumin solution
3.5	Test temperature:	20 °C ± 1 °C
3.6	Counting method:	Spread plate
3.7	Incubation period:	21 days, 36 °C ± 1 °C

4. Test method and its validation

4.1	Testing method:	Dilution-neutralization
4.2	Inactivation combination:	30.00 g/L Tween 80 30.00 g/L Saponin 3.00 g/L Lecithin 50.00 g/L Glycine in tryptone soya broth

The results of validation tests A, B, and C proved the viability of the method in all cases.

5. Test results

The results are stated in Tables A and B.

6. Conclusion

F3307 showed the required microbial reduction of ≥4.0 $\log_{10}$ against test strain(s) *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 in accordance with EN 14563:2008 (E) at 70.00 % and 80.00 % concentration(s) after 5 and 10 minutes under the stated conditions. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance.

F3307 did not show the required microbial reduction of ≥4.0 $\log_{10}$ against test strain(s) *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 in accordance with EN 14563:2008 (E) at 0.10 % concentration(s) after 5 and 10 minutes under the stated conditions. According to the simple acceptance decision rule†, there is a minimal risk of false rejection.

Kuala Lumpur, 05 January 2023

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Maizatul Ismail
Microbiologist

7. Note

Mycobactericidal activity – the capability of a product to produce a reduction in the number of viable mycobacterial cells of relevant test organisms under defined conditions by at least 4 orders (10^4).

Tuberculocidal activity – the capability of a product to kill *Mycobacterium tuberculosis*, demonstrated by the capability to produce a reduction in the number of viable cells of *Mycobacterium terrae* under defined conditions by at least 4 orders (10^4).

$R = N_w/N_a$ = the reduction in viability, or $\lg R = \lg N_w - \lg N_a$

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Table A: Evaluation of the mycobactericidal or tuberculocidal activity of F3307 on test strain(s) according to EN 14563

Product: F3307
Loading: 0.30 g/L bovine albumin solution

Test strain: *Mycobacterium avium* ATCC 15769

N	V_{C1}	V_{C2}	Test suspension, N
10^{-7}	163	154	N: 1.58×10^9 lg N: **9.20**
10^{-8}	16	14	

N_w	V_{C1}	V_{C2}	Water control, N_w
10^{-4}	205	203	N_w: 2.04×10^7 lg N_w: **7.31**
10^{-5}	20	20	

Test concentration (%) / contact time (min)	Dilution	V_{C1}	V_{C2}	Test procedure, N_a $N_a = \bar{x} \times 10$
80.00 / 5	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>5.16**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
70.00 / 5	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>5.16**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
0.10 / 5	10^0	>660	>660	N_a: $>6.60 \times 10^6$ lg N_a: **>6.82** lg R: **<0.49**
	10^{-1}	>660	>660	
	10^{-2}	>660	>660	
	10^{-3}	>660	>660	

Test concentration (%) / contact time (min)	Dilution	V_{C1}	V_{C2}	Test procedure, N_a $N_a = \overline{x} \times 10$
80.00 / 10	10^0	<14	<14	N_a: <1.40 x 10^2 lg N_a: **<2.15** lg R: **>5.16**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
70.00 / 10	10^0	<14	<14	N_a: <1.40 x 10^2 lg N_a: **<2.15** lg R: **>5.16**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
0.10 / 10	10^0	>660	>660	N_a: 7.90 x 10^4 lg N_a: **4.90** lg R: **2.41**
	10^{-1}	>660	>660	
	10^{-2}	78	80	
	10^{-3}	<14	<14	

Test strain: *Mycobacterium terrae* ATCC 15755

N	V_{C1}	V_{C2}	Test suspension, N
10^{-7}	154	151	N: 1.53×10^9 lg N: **9.18**
10^{-8}	16	13	

N_w	V_{C1}	V_{C2}	Water control, N_w
10^{-4}	23	23	N_w: 2.30×10^6 lg N_w: **6.36**
10^{-5}	<14	<14	

Test concentration (%) / contact time (min)	Dilution	V_{C1}	V_{C2}	Test procedure, N_a $N_a = \overline{x} \times 10$
80.00 / 5	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>4.22**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
70.00 / 5	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>4.22**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
0.10 / 5	10^0	>660	>660	N_a: 9.70×10^5 lg N_a: **5.99** lg R: **0.37**
	10^{-1}	>660	>660	
	10^{-2}	>660	>660	
	10^{-3}	100	94	

Test concentration (%) / contact time (min)	Dilution	V_{C1}	V_{C2}	Test procedure, N_a $N_a = \bar{x} \times 10$
80.00 / 10	10^0	<14	<14	N_a: <1.40 x 10^2 lg N_a: **<2.15** lg R: **>4.22**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
70.00 / 10	10^0	<14	<14	N_a: <1.40 x 10^2 lg N_a: **<2.15** lg R: **>4.22**
	10^{-1}	<14	<14	
	10^{-2}	<14	<14	
	10^{-3}	<14	<14	
0.10 / 10	10^0	>660	>660	N_a: 5.10 x 10^4 lg N_a: **4.71** lg R: **1.65**
	10^{-1}	>660	>660	
	10^{-2}	55	47	
	10^{-3}	<14	<14	

Table B: Control tests and method validation for Table A

Test strain	Validation suspension	Validation of experimental conditions	Neutralizer toxicity control	Method validation control
M. avium ATCC 15769	N_{V0}: 4.55 x 10^1	A: 4.90 x 10^1	B: 5.10 x 10^1	C: 4.10 x 10^1
M. terrae ATCC 15755	N_{V0}: 4.30 x 10^1	A: 5.25 x 10^1	B: 4.80 x 10^1	C: 4.50 x 10^1

Note

cfu: Colony forming units

V_C: Number of cfu counted per 1.0 ml sample

$\bar{x}$: Average V_{C1} and V_{C2} values

N: Number of cfu per ml in the test suspension

N_0: Number of cfu per ml at the beginning of the contact time

N_{V0}: Number of cfu per ml in the mixtures A, B, and C at the beginning of the contact time

N_a: Number of survivors per ml in the test mixture at the end of the contact time and before neutralization

A: Number of cfu per ml in the experimental conditions control

B: Number of cfu per ml in the neutralizer toxicity control

C: Number of cfu per ml in the dilution-neutralization method validation

Table C: Summary of the log reductions of the quantitative carrier test according to EN 14563

Test strain	Test concentration (%) / contact time (min)	Log reduction	Percentage reduction (%)	Associated risk†
M. avium ATCC 15769	80.00 / 5	**>5.16 ± 0.17**	**>99.999**	Minimal risk of false acceptance
	70.00 / 5	**>5.16 ± 0.17**	**>99.999**	Minimal risk of false acceptance
	0.10 / 5	**<0.49 ± 0.17**	**<67.641**	Minimal risk of false rejection
	80.00 / 10	**>5.16 ± 0.17**	**>99.999**	Minimal risk of false acceptance
	70.00 / 10	**>5.16 ± 0.17**	**>99.999**	Minimal risk of false acceptance
	0.10 / 10	**2.41 ± 0.17**	**99.611**	Minimal risk of false rejection
M. terrae ATCC 15755	80.00 / 5	**>4.22 ± 0.17**	**>99.994**	Minimal risk of false acceptance
	70.00 / 5	**>4.22 ± 0.17**	**>99.994**	Minimal risk of false acceptance
	0.10 / 5	**0.37 ± 0.17**	**57.342**	Minimal risk of false rejection
	80.00 / 10	**>4.22 ± 0.17**	**>99.994**	Minimal risk of false acceptance
	70.00 / 10	**>4.22 ± 0.17**	**>99.994**	Minimal risk of false acceptance
	0.10 / 10	**1.65 ± 0.17**	**97.761**	Minimal risk of false rejection

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Sodel
190 Rue René Barthélémy
14100 Lisieux
France

Efficacy of F3307 against *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 in a quantitative carrier test at 20 ˚C according to EN 14563:2008 (E) under clean condition

EXPERT OPINION*

This expert opinion is based on the test report VX-TR-23-0023 dated 05 January 2023.

The mycobactericidal or tuberculocidal activity of the disinfectant F3307 of Sodel against *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 was investigated by a quantitative carrier test according to EN 14563:2008 (E) under clean condition (0.30 g/L bovine albumin solution).

According to this carrier test, a disinfectant or a disinfectant solution at a particular concentration is considered as having mycobactericidal and/or tuberculocidal activity if the number of viable mycobacterial cells and/or *Mycobacterium terrae* cells is reduced by ≥4 $\log_{10}$ (inactivation ≥99.99 %) within the recommended exposure period.

F3307 was examined at 20 ˚C at the concentration(s) of 70.00 %, and 80.00 % for the exposure time(s) of 5 and 10 minutes. After the exposure time(s), the mycobacterial reduction exceeded 4 $\log_{10}$-steps in all assays. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance.

F3307 was examined at 20 ˚C at the concentration(s) of 0.10 % for the exposure time(s) of 5 and 10 minutes. After the exposure time(s), the mycobacterial reduction did not exceed 4 $\log_{10}$-steps in all assays. According to the simple acceptance decision rule†, there is a minimal risk of false rejection. Therefore, a mycobactericidal activity against *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 was measured as follows:

Clean condition	70.00 %	5 and 10 minutes
Clean condition	80.00 %	5 and 10 minutes

Kuala Lumpur, 05 January 2023

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Microbiologist

* Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Appendix 1

QAU CERTIFICATE*

The results stated in test report VX-TR-23-0023 dated 05 January 2023 were compared to the raw data of the tests and checked for correct transfer. No deviations were detected.

Kuala Lumpur, 05 January 2023

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* Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

Appendix 2 Raw data

Test Method	EN 14563:2008					
Product	F3307			**Batch No.**	0209E026220919V	
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0005	
Test Organism	*Mycobacterium avium ATCC 15769*					
Interfering Substance	0.30 g/L bovine albumin solution					
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Carrier Drying Time (min)**		14
Neutralizer	30.00 g/L Tween 80, 30.00 g/L Saponin, 3.00 g/L Lecithin, 50.00 g/L Glycine in Tryptone soya broth					
Inactivation Method	Dilution-neutralization			**Plating Method**		Spread plate
Test Date	14/12/2022	**Analyzed By**	MIS	**Verified By**		PCH

Test and Validation Suspension

Test Suspension (N)	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = N = 1.58E+09
	10^{-7}	163	154	lg N = 9.20 9.17 ≤ lg N ≤ 9.70
	10^{-8}	16	14	Pass? **Yes**

Validation Suspension (N_V)	V_{C1}	V_{C2}	N_{V0} = 45.5 N_{V0} = N_V/10
	41	50	30 ≤ N_{V0} ≤ 160 Pass? **Yes**

Validation and Control Procedures

Water Control (N_W)	N_W	V_{C1}	V_{C2}	$\bar{x}_{wm}$ x 10 = 2.04E+07
	10^{-4}	205	203	lg N_W = 7.31 6.15 ≤ lg N_W ≤ (lg N - 1.3)
	10^{-5}	20	20	Pass? **Yes**

Experimental Conditions Control (A)	V_{C1}	V_{C2}	A = 49.0 Pass? **Yes**
	49	49	A ≥ 0.5 x Nv/10
Neutralizer Toxicity Control (B)	V_{C1}	V_{C2}	B = 51.0 Pass? **Yes**
	47	55	B ≥ 0.5 x Nv/10
Method Validation (C)	V_{C1}	V_{C2}	C = 41.0 Pass? **Yes**
Concentration: 80 %	40	42	C ≥ 0.5 x Nv/10

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg Nw - lg Na
80.0 %	5	10^{0}	<14	<14	<1.40E+02	<2.15	>5.16
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
70.0 %	5	10^{0}	<14	<14	<1.40E+02	<2.15	>5.16
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
0.1 %	5	10^{0}	>660	>660	>6.60E+06	>6.82	<0.49
		10^{-1}	>660	>660			
		10^{-2}	>660	>660			
		10^{-3}	>660	>660			

Raw Data of Colony Count

	N $^{-7}$		N $^{-8}$		N_V		$N_W{}^{-4}$		$N_W{}^{-5}$		A		B		C	
V_{C1}	84	79	10	6	20	21	105	100	9	11	27	22	24	23	21	19
V_{C2}	82	72	8	6	23	27	96	107	10	10	26	23	26	29	22	20

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
80.0 %	5	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
70.0 %	5	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
0.1 %	5	>330	>330	>330	>330	>330	>330	>330	>330
		>330	>330	>330	>330	>330	>330	>330	>330

Appendix 2 Raw data

Test Method	EN 14563:2008					
Product	F3307			**Batch No.**	0209E026220919V	
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0005	
Test Organism	*Mycobacterium avium ATCC 15769*					
Interfering Substance	0.30 g/L bovine albumin solution					
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Carrier Drying Time (min)**		14
Neutralizer	30.00 g/L Tween 80, 30.00 g/L Saponin, 3.00 g/L Lecithin, 50.00 g/L Glycine in Tryptone soya broth					
Inactivation Method	Dilution-neutralization			**Plating Method**		Spread plate
Test Date	14/12/2022	**Analyzed By**	MIS	**Verified By**		PCH

Test and Validation Suspension

	N	V_{C1}	V_{C2}	
Test Suspension (N)				$\bar{x}_{wm}$ = N = 1.58E+09
	10^{-7}	163	154	lg N = 9.20 9.17 ≤ lg N ≤ 9.70
	10^{-8}	16	14	Pass? Yes

	V_{C1}	V_{C2}	
Validation Suspension (N_V)	41	50	N_{V0} = 45.5 N_{V0} = N_V/10 30 ≤ N_{V0} ≤ 160 Pass? Yes

Validation and Control Procedures

	N_W	V_{C1}	V_{C2}	
Water Control (N_W)				$\bar{x}_{wm}$ x 10 = 2.04E+07
	10^{-4}	205	203	lg N_W = 7.31 6.15 ≤ lg N_W ≤ (lg N - 1.3)
	10^{-5}	20	20	Pass? Yes

	V_{C1}	V_{C2}	
Experimental Conditions Control (A)			A = 49.0 Pass? Yes
	49	49	A ≥ 0.5 x Nv/10
Neutralizer Toxicity Control (B)	V_{C1}	V_{C2}	B = 51.0 Pass? Yes
	47	55	B ≥ 0.5 x Nv/10
Method Validation (C)	V_{C1}	V_{C2}	C = 41.0 Pass? Yes
Concentration: 80 %	40	42	C ≥ 0.5 x Nv/10

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg Nw - lg Na
80.0 %	10	10^{0}	<14	<14	<1.40E+02	<2.15	>5.16
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
70.0 %	10	10^{0}	<14	<14	<1.40E+02	<2.15	>5.16
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
0.1 %	10	10^{0}	>660	>660	7.90E+04	4.90	2.41
		10^{-1}	>660	>660			
		10^{-2}	78	80			
		10^{-3}	<14	<14			

Raw Data of Colony Count

	N^{-7}		N^{-8}		N_V		N_W^{-4}		N_W^{-5}		A		B		C	
V_{C1}	84	79	10	6	20	21	105	100	9	11	27	22	24	23	21	19
V_{C2}	82	72	8	6	23	27	96	107	10	10	26	23	26	29	22	20

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
80.0 %	10	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
70.0 %	10	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
0.1 %	10	>330	>330	>330	>330	40	39	4	1
		>330	>330	>330	>330	38	41	3	2

Appendix 2 Raw data

Test Method	EN 14563:2008					
Product	F3307			**Batch No.**	0209E026220919V	
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0005	
Test Organism	*Mycobacterium terrae ATCC 15755*					
Interfering Substance	0.30 g/L bovine albumin solution					
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Carrier Drying Time (min)**		13
Neutralizer	30.00 g/L Tween 80, 30.00 g/L Saponin, 3.00 g/L Lecithin, 50.00 g/L Glycine in Tryptone soya broth					
Inactivation Method	Dilution-neutralization			**Plating Method**		Spread plate
Test Date	14/12/2022	**Analyzed By**	MIS	**Verified By**		PCH

Test and Validation Suspension

Test Suspension (N)	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = N = 1.53E+09
	10^{-7}	154	151	lg N = 9.18 9.17 ≤ lg N ≤ 9.70
	10^{-8}	16	13	Pass? **Yes**

Validation Suspension (N_V)	V_{C1}	V_{C2}	N_{V0} = 43.0 N_{V0} = N_V/10
	44	42	30 ≤ N_{V0} ≤ 160 Pass? **Yes**

Validation and Control Procedures

Water Control (N_W)	N_W	V_{C1}	V_{C2}	$\bar{x}_{wm}$ x 10 = 2.30E+06
	10^{-4}	23	23	lg N_W = 6.36 6.15 ≤ lg N_W ≤ (lg N - 1.3)
	10^{-5}	<14	<14	Pass? **Yes**

Experimental Conditions Control (A)	V_{C1}	V_{C2}	A = 52.5 Pass? **Yes**
	56	49	A ≥ 0.5 x Nv/10
Neutralizer Toxicity Control (B)	V_{C1}	V_{C2}	B = 48.0 Pass? **Yes**
	43	53	B ≥ 0.5 x Nv/10
Method Validation (C)	V_{C1}	V_{C2}	C = 45.0 Pass? **Yes**
Concentration: 80 %	45	45	C ≥ 0.5 x Nv/10

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg Nw - lg Na
80.0 %	5	10^{0}	<14	<14	<1.40E+02	<2.15	>4.22
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
70.0 %	5	10^{0}	<14	<14	<1.40E+02	<2.15	>4.22
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
0.1 %	5	10^{0}	>660	>660	9.70E+05	5.99	0.37
		10^{-1}	>660	>660			
		10^{-2}	>660	>660			
		10^{-3}	100	94			

Raw Data of Colony Count

	N $^{-7}$		N $^{-8}$		N_V		$N_W{}^{-4}$		$N_W{}^{-5}$		A		B		C	
V_{C1}	70	84	8	8	20	24	10	13	2	1	23	33	20	23	25	20
V_{C2}	71	80	7	6	21	21	11	12	0	3	29	20	27	26	21	24

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
80.0 %	5	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
70.0 %	5	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
0.1 %	5	>330	>330	>330	>330	>330	>330	45	47
		>330	>330	>330	>330	>330	>330	55	47

Appendix 2 Raw data

Test Method	EN 14563:2008					
Product	F3307			**Batch No.**	0209E026220919V	
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0005	
Test Organism	*Mycobacterium terrae ATCC 15755*					
Interfering Substance	0.30 g/L bovine albumin solution					
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Carrier Drying Time (min)**		13
Neutralizer	30.00 g/L Tween 80, 30.00 g/L Saponin, 3.00 g/L Lecithin, 50.00 g/L Glycine in Tryptone soya broth					
Inactivation Method	Dilution-neutralization			**Plating Method**		Spread plate
Test Date	14/12/2022	**Analyzed By**	MIS	**Verified By**		PCH

Test and Validation Suspension

Test Suspension (N)	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = N = 1.53E+09
	10^{-7}	154	151	lg N = 9.18 9.17 ≤ lg N ≤ 9.70
	10^{-8}	16	13	Pass? **Yes**

Validation Suspension (N_V)	V_{C1}	V_{C2}	N_{V0} = 43.0 N_{V0} = N_V/10
	44	42	30 ≤ N_{V0} ≤ 160 Pass? **Yes**

Validation and Control Procedures

Water Control (N_W)	N_W	V_{C1}	V_{C2}	$\bar{x}_{wm}$ x 10 = 2.30E+06
	10^{-4}	23	23	lg N_W = 6.36 6.15 ≤ lg N_W ≤ (lg N - 1.3)
	10^{-5}	<14	<14	Pass? **Yes**

Experimental Conditions Control (A)	V_{C1}	V_{C2}	A = 52.5 Pass? **Yes**
	56	49	A ≥ 0.5 x Nv/10
Neutralizer Toxicity Control (B)	V_{C1}	V_{C2}	B = 48.0 Pass? **Yes**
	43	53	B ≥ 0.5 x Nv/10
Method Validation (C)	V_{C1}	V_{C2}	C = 45.0 Pass? **Yes**
Concentration: 80 %	45	45	C ≥ 0.5 x Nv/10

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg Nw - lg Na
80.0 %	10	10^{0}	<14	<14	<1.40E+02	<2.15	>4.22
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
70.0 %	10	10^{0}	<14	<14	<1.40E+02	<2.15	>4.22
		10^{-1}	<14	<14			
		10^{-2}	<14	<14			
		10^{-3}	<14	<14			
0.1 %	10	10^{0}	>660	>660	5.10E+04	4.71	1.65
		10^{-1}	>660	>660			
		10^{-2}	55	47			
		10^{-3}	<14	<14			

Raw Data of Colony Count

	N $^{-7}$		N $^{-8}$		N_V		$N_W{}^{-4}$		$N_W{}^{-5}$		A		B		C	
V_{C1}	70	84	8	8	20	24	10	13	2	1	23	33	20	23	25	20
V_{C2}	71	80	7	6	21	21	11	12	0	3	29	20	27	26	21	24

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
80.0 %	10	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
70.0 %	10	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0
0.1 %	10	>330	>330	>330	>330	25	26	3	3
		>330	>330	>330	>330	30	21	2	1

Note

cfu: Colony forming units

V_C: Number of cfu counted per 1.0 ml sample

$\bar{x}$: Average V_{C1} and V_{C2} values

N: Number of cfu per ml in the test suspension

N_0: Number of cfu per ml at the beginning of the contact time

N_{V0}: Number of cfu per ml in the mixtures A, B, and C at the beginning of the contact time

N_a: Number of survivors per ml in the test mixture at the end of the contact time and before neutralization

A: Number of cfu per ml in the experimental conditions control

B: Number of cfu per ml in the neutralizer toxicity control

C: Number of cfu per ml in the dilution-neutralization method validation

Appendix 3 Summary of test description

1. Materials and reagents

1.1 Middlebrook and Cohn 7H10 agar (MCO, HiMedia, catalogue no. M199)

1.2 Tryptone, pancreatic digest of casein (Oxoid, catalogue no. LP0042)

1.3 Sodium chloride (Merck, catalogue no. 1.06404.0500)

1.4 Magnesium chloride ($MgCl_2$, Acros Organics, catalogue no. AC223211000)

1.5 Calcium chloride ($CaCl_2$, R&M Chemicals, catalogue no. 9924-00)

1.6 Sodium bicarbonate ($NaHCO_3$, Fisher Chemical, catalogue no. 10152780)

1.7 Bovine albumin fraction V (Merck, catalogue no. 1.12018.0100)

1.8 Defibrinated sheep blood (Thermo Scientific, catalogue no. SR0051B) (for dirty condition only)

1.9 Neutralizer

1.9.1 Tween (Fisher Chemical, catalogue no. 10498800)

1.9.2 Saponin (Nacalai Tesque, catalogue no. 30502-55)

1.9.3 Lecithin (Nacalai Tesque, catalogue no. 20335-65)

1.9.4 Glycine (HiMedia, catalogue no. MB013)

1.9.5 Tryptone Soya Broth (TSB, Oxoid, catalogue no. CM0129)

2. Apparatus and glassware

2.1 Autoclave (TOMY, model SX500)

2.2 Water baths (Memmert, model WNB 29)

2.3 Incubator (Binder, model BD 260)

2.4 pH-meter (Ohaus, model 3100 Meter with ST310)

2.5 Vortex® mixer (Biosan model Biosan V-1 Plus)

2.6 Petri dishes (Wanpow Plastic)

3. Test procedure

3.1 Test Na – Determination of mycobactericidal or tuberculocidal concentrations

3.1.1 Pipette 10 ml of one of the product test solutions into a cylindrical screw tube placed in a water bath controlled at the chosen test temperature of *θ*.

3.1.2 Immerse an inoculated carrier immediately after the drying process has been finished.

3.1.3 Ensure that the inoculation square is completely covered by the product test solution.

3.1.4 Start the stopwatch and leave for the chosen contact time *t*.

3.1.5 At the end of *t*, transfer the carrier into a second cylindrical screw tube, placed in a water bath controlled at 20 ºC and filled with 10 ml of neutralizer and approximately 1 ml of glass beads.

3.1.6 Restart the stopwatch and mix for 15 seconds.

3.1.7 After a neutralization time of 5 minutes ± 10 seconds, mix and immediately take a sample of 1.0 ml of the neutralized test mixture Na (containing neutralizer, product test solution, interfering substance, test suspension) in duplicate and transfer approximately equal amounts onto two separate plates containing surface dried MCO, i.e. two plates per 1.0 ml sample.

3.1.8 Additionally transfer 0.5 ml of the test mixture Na into a tube containing 4.5 ml of neutralizer (10^{-1} dilution of Na), mix and dilute accordingly to produce 10^{-2} and 10^{-3} dilutions of Na with neutralizer.

3.1.9 Take samples of 1.0 ml from each dilution tube in duplicate and transfer approximately equal amounts onto two separate plates containing MCO.

3.1.10 Incubate the plates for 21 days at 36 °C ± 1 °C.

3.1.11 Discard any plates which is not countable (for any reason). Count the plates and determine the number of cfu.

3.1.12 Note the exact number of colonies for each but record >330 for any counts higher than 330 and determine the V_C-values.

3.1.13 Perform the procedure using the other product test solutions at the same time.

3.1.14 For the water control Nw, repeat Sections 3.1.1 to 3.1.12. but instead of the product test solution, use 10 ml of hard water. In the case of ready-to-use products, water instead of hard water. Deviating from Sections 3.17 to 3.1.8, produce 10^{-4} and 10^{-5} dilutions from the neutralized test mixture Nw for incubation and counting.

3.2 Experimental conditions control A – Validation of the selected experimental conditions and/or verification of the absence of any lethal effect in the test conditions

3.2.1 Pipette 1.0 ml of interfering substance used in the test into a tube.

3.2.2 Add 1.0 ml of the validation suspension.

3.2.3 Start the stopwatch immediately, mix, and place the tube in a water bath controlled at *θ* for 2 minutes ± 10 seconds.

3.2.4 At the end of this time, add 8.0 ml of hard water. In the case of ready-to-use products, water instead of hard water.

3.2.5 Restart the stopwatch at the beginning of the addition.

3.2.6 Mix and place the tube in a water bath controlled at *θ* for *t*.

3.2.7 Just before the end of *t*, mix again.

3.2.8 At the end of *t*, take a sample of 1.0 ml of this mixture A in duplicate and transfer approximately equal amounts onto two separate plates containing MCO.

3.2.9 Calculate the numbers of cfu/ml in the validation mixture A.

3.2.10 Verify according to Section 3.5.

3.3 Neutralizer control B – Verification of the absence of toxicity of the neutralizer

3.3.1 Pipette 8.0 ml of the neutralizer used in the test and 1.0 ml of water into a tube.

3.3.2 Add 1.0 ml of the validation suspension.

3.3.3 Start the stopwatch at the beginning of the addition and mix.

3.3.4 Place the tube in a water bath controlled at 20 °C ± 1 °C for 5 minutes ± 10 seconds.

3.3.5 Just before the end of this time, mix.

3.3.6 At the end of this time, take a sample of 1.0 ml of this mixture B in duplicate and transfer approximately equal amounts onto two separate plates containing MCO.

3.3.7 Calculate the numbers of cfu/ml in the validation mixture B.

3.3.8 Verify according to Section 3.5.

3.4 Method validation C – Dilution-neutralization validation

3.4.1 Pipette 1.0 ml of interfering substance used in the test into a tube.

3.4.2 Add 1.0 ml of the diluent.

3.4.3 Start the stopwatch, add 8.0 ml of the product test solution only of the highest concentration used in the test.

3.4.4 Mix and place the tube in a water bath controlled at θ for t.

3.4.5 Just before the end of t, mix again.

3.4.6 At the end of t, transfer 1.0 ml of the mixture into a tube containing 8.0 ml of neutralizer.

3.4.7 Restart the stopwatch at the beginning of the addition.

3.4.8 Mix and place the tube in a water bath controlled at 20 °C ± 1 °C for 5 minutes ± 10 seconds.

3.4.9 Add 1.0 ml of the validation suspension.

3.4.10 Start the stopwatch at the beginning of the addition and mix.

3.4.11 Place the tube in a water bath controlled at 20 °C ± 1 °C for 30 minutes ± 1 minute.

3.4.12 Just before the end of this time, mix again.

3.4.13 At the end of this time, take a sample of 1.0 ml of the mixture C in duplicate and transfer approximately equal amounts onto two separate plates containing MCO.

3.4.14 Calculate the numbers of cfu/ml in the validation mixture C.

3.4.15 Verify according to Section 3.5.

3.5 Basic limits

3.5.1 N is between 1.5×10^9 and 5.0×10^9 ($9.17 \leq \lg N \leq 9.70$)

3.5.2 Nw is not less than 1.4×10^6 ($\lg Nw \geq 6.15$) and not more than 0.05 x N ($\lg Nw \leq (\lg N - 1.3)$)

3.5.3 N_{V0} is between 30 and 160 (3.0×10^1 and 1.6×10^2)

3.5.4 N_V is between 3.0×10^2 and 1.6×10^3

3.5.5 A, B, C are equal to or greater than 0.5 x N_{V0}

3.5.6 Control of weighted mean counts: quotient is not lower than 5 and not higher than 15

4. Literature

4.1 EN 14563:2008 (E): Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments used in the medical area – Test method and requirements (phase 2, step 2)

4.2 EN 14885:2018 (E): Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics

4.3 EN 12353:2013 (E): Chemical disinfectants and antiseptics – Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

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Test Report No.: VX-TR-23-0457
Copy No.: 1

DETERMINATION OF THE VIRUCIDAL ACTIVITY (EN 14476) OF F3307

Lab No.:	VX-268-22-0011
Sample Name:	**F3307**
Method:	EN 14476:2013+A2:2019 (E) Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (phase 2, step 1)
Client:	Sodel 190 rue René Barthélemy 14100 Lisieux France
Sample Receipt Date:	13 December 2022
Report Date:	07 February 2023

Kuala Lumpur, 07 February 2023

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Dr Syazani Suhaimi
Microbiologist

Viroxy Sdn. Bhd. (1193371-A)
6th Floor · Menara RKT · 36 Jalan Raja Abdullah · 50300 Kuala Lumpur · Malaysia
Phone: +60 (0)3 2630 8888 · info@viroxy.com
www.viroxy.com

Materials and Method

Quantitative suspension test for the evaluation of virucidal activity in the medical area according to EN 14476:2013+A2:2019 (E)

1. Testing laboratory identification

Viroxy Sdn. Bhd.
6th Floor, Menara RKT
50300 Kuala Lumpur
Malaysia

2. Sample identification

2.1	Sample name:	F3307
2.2	Batch no.:	0209E036221028Z
2.3	Product appearance:	Clear, bluish solution
2.4	Manufacturer:	Sodel 190 rue René Barthélemy 14100 Lisieux France
2.5	Active substances:	0.54 % Orthophthalaldehyde
2.6	Sample receipt date:	13 December 2022
2.7	Storage conditions:	Room temperature
2.8	Product diluent:	Not applicable; ready-to-use product Distilled water; 70.00 % and 0.10 %

3. Experimental conditions

3.1	Testing period:	15 November 2022 – 20 January 2023
3.2	Test organism(s):	*Adenovirus type 5*, strain Adenoid 75, ATCC VR-5 *Murine norovirus*, strain S99 Berlin, FLI-RVB-0651 *Poliovirus type 1*, strain LSc2ab, NIBSC-01/528
3.3	Concentration/contact time:	100.00 %* / 10 minutes 70.00 % / 10 minutes 0.10 % / 10 minutes
3.4	Loading:	0.30 g/L bovine albumin solution
3.5	Test temperature:	20 °C ± 1 °C
3.6	Incubation period:	7 days, 36 °C ± 1 °C

4. Test method and its validation

4.3 Testing method: Quantal test

4.4 Inactivation method: Immediate dilution
Molecular sieving using MicroSpin™ S 400 HR

The results of validation tests A, B, and C proved the viability of the method in all cases.

5. Test results

The results are stated in Tables A and B.

6. Conclusion

F3307 showed the required viral reduction of ≥4.0 $\log_{10}$ against test strain(s) *Adenovirus type 5* ATCC VR-5, *Murine norovirus* FLI-RVB-0651 and *Poliovirus* type 1 NIBSC-01/528 in accordance with EN 14476:2013+A2:2019 (E) at 100.00 %* and 70.00 % concentration(s) after 10 minutes under the stated condition. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance.

F3307 did not show the required viral reduction of ≥4.0 $\log_{10}$ against test strain(s) *Adenovirus type 5* ATCC VR-5, *Murine norovirus* FLI-RVB-0651 and *Poliovirus* type 1 NIBSC-01/528 in accordance with EN 14476:2013+A2:2019 (E) at 0.10 % concentration(s) after 10 minutes under the stated condition. According to the simple acceptance decision rule†, there is a minimal risk of false rejection.

Kuala Lumpur, 07 February 2023

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Dr Syazani Suhaimi
Microbiologist

7. Note

Virucidal activity – the capability of a product to produce a reduction in the number of viable viruses belonging to reference strains under defined conditions by at least 4 orders (10^4).

$R = V_C/N_a$ = the reduction in viability, or $\lg R = \lg V_C - \lg N_a$

* The product can only be tested at 80.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

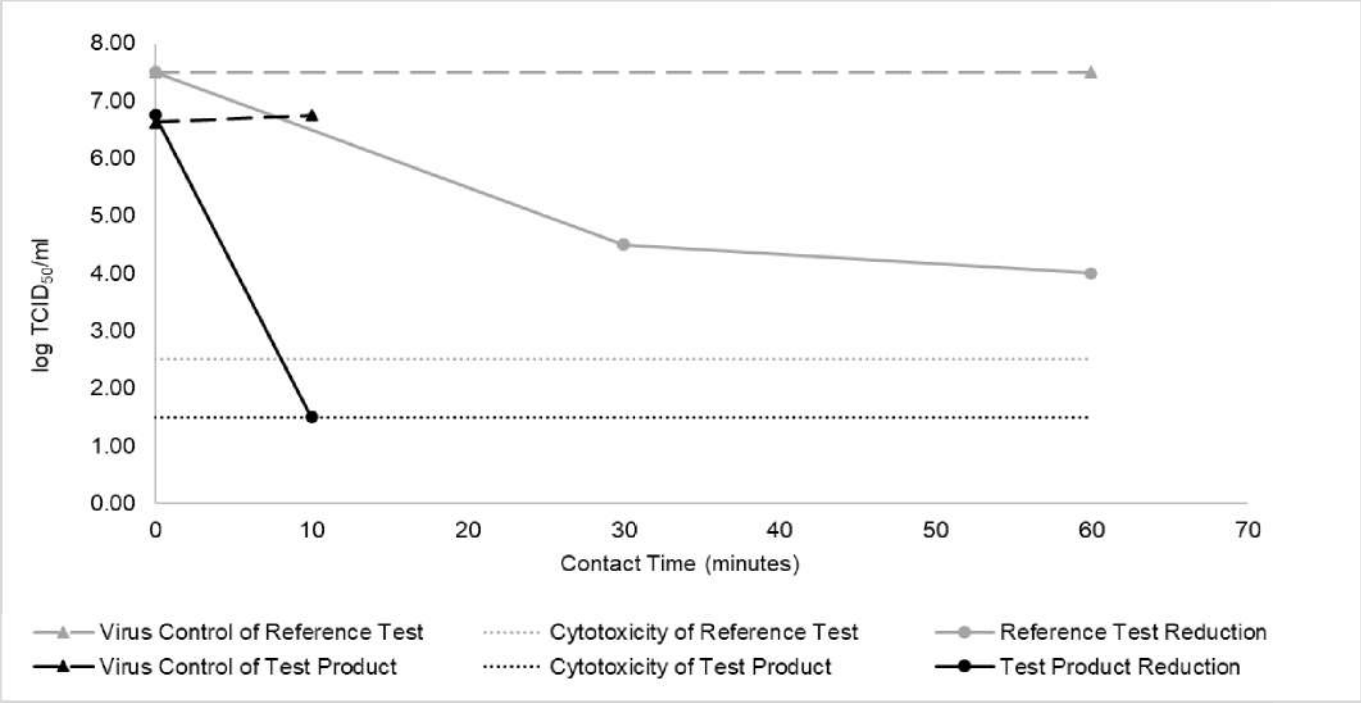
Table A: Evaluation of the virucidal activity of F3307 on test strains according to EN 14476

Product: F3307
Loading: 0.30 g/L bovine albumin solution

Test strain: *Adenovirus type 5* ATCC VR-5

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 6.75 ± 0.33 V_{C2}: 6.75 ± 0.33	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
100.00* / 10	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥5.25 ± 0.33**	N_{a2}: ≤1.50 ± 0.00 lg R_2: **≥5.25 ± 0.33**	lg R: **≥5.25 ± 0.33**

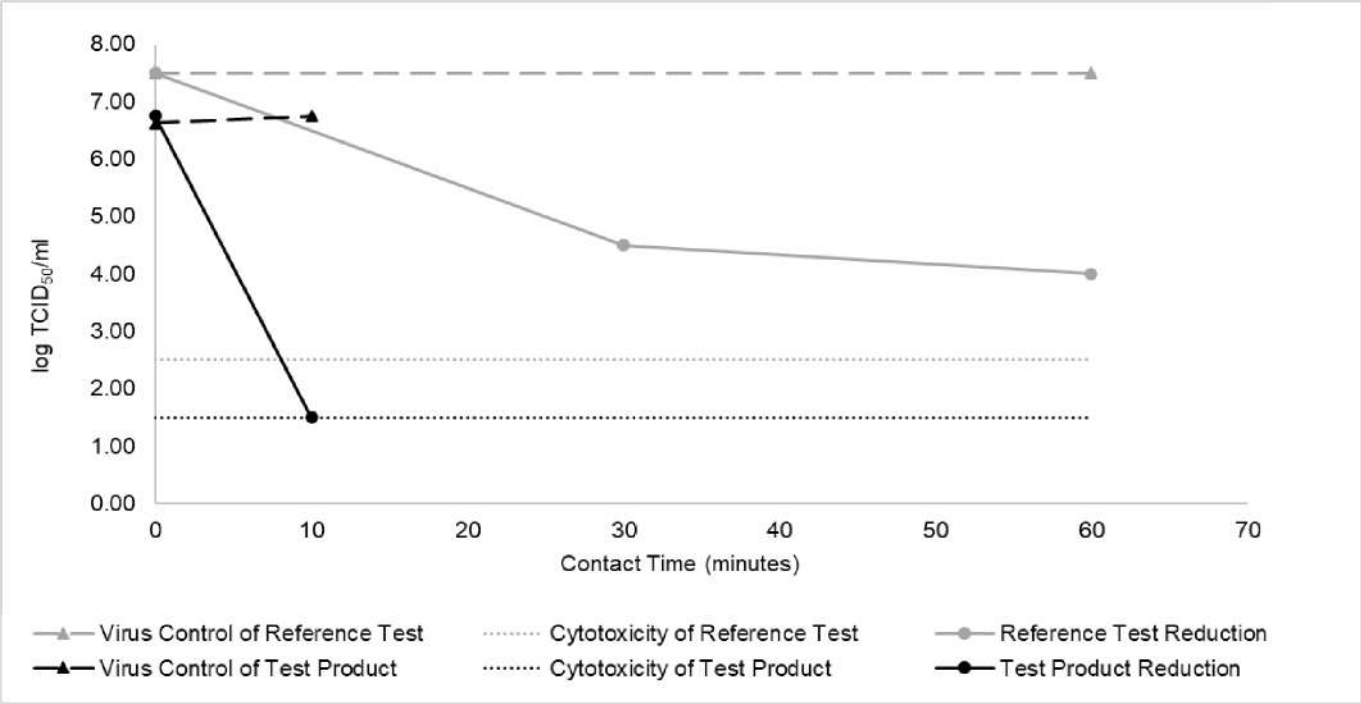


* The product can only be tested at 80.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

Test strain: *Adenovirus type 5* ATCC VR-5

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 6.75 ± 0.33 V_{C2}: 6.75 ± 0.33	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

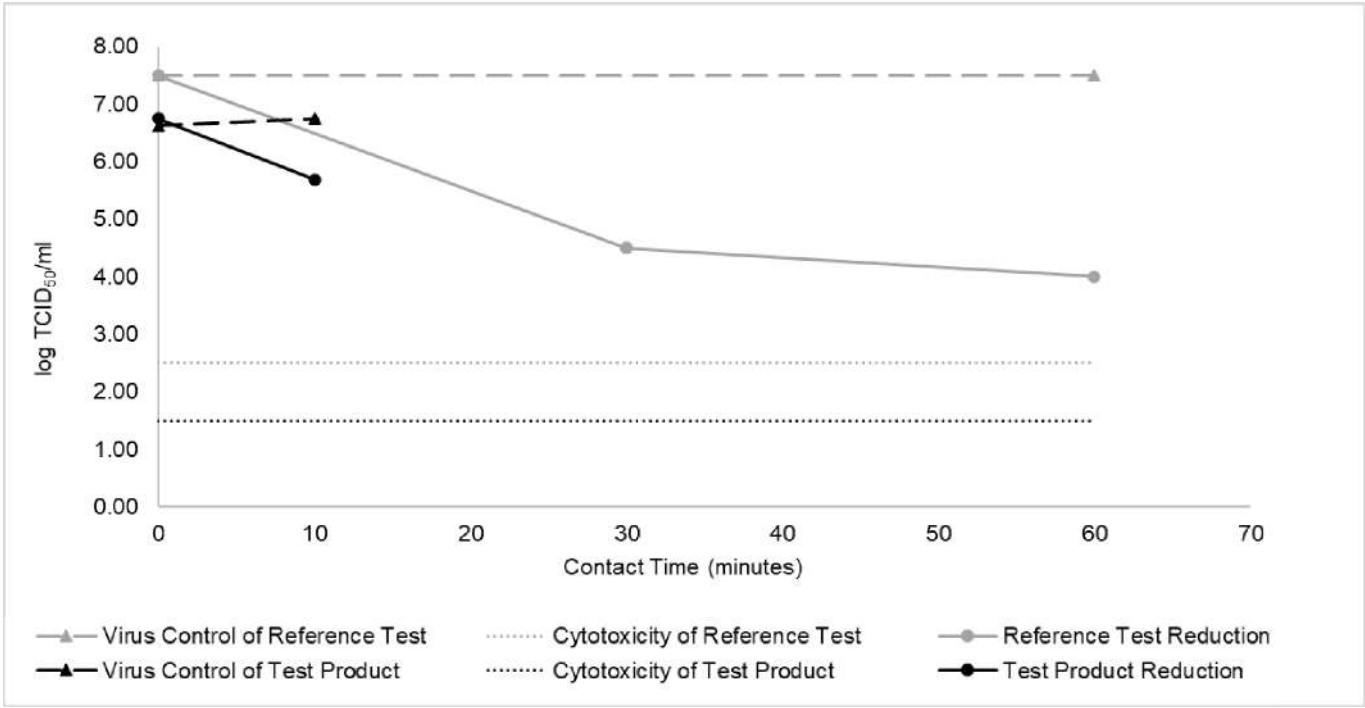
Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
70.00 / 10	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥5.25 ± 0.33**	N_{a2}: ≤1.50 ± 0.00 lg R_2: **≥5.25 ± 0.33**	lg R: **≥5.25 ± 0.33**



Test strain: *Adenovirus type 5* ATCC VR-5

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 6.75 ± 0.33 V_{C2}: 6.75 ± 0.33	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

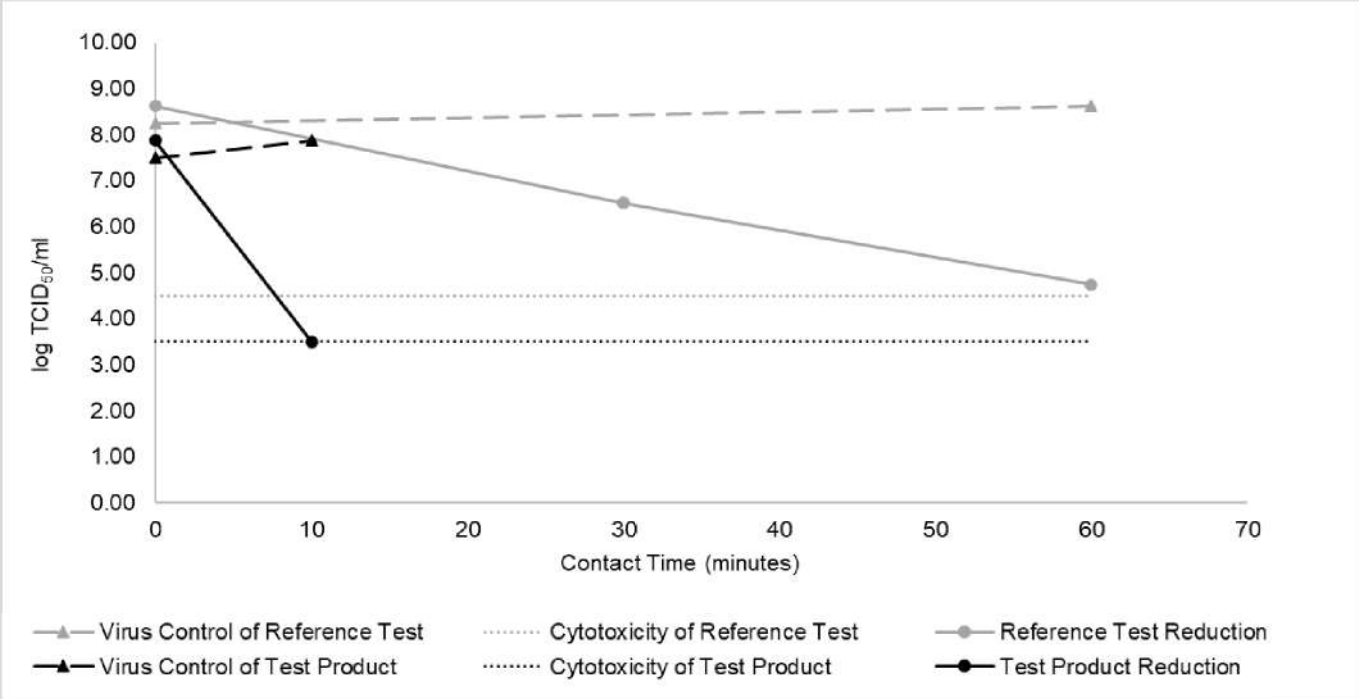
Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
0.10 / 10	N_{a1}: 5.88 ± 0.37 lg R_1: **0.88 ± 0.50**	N_{a2}: 5.50 ± 0.00 lg R_2: **1.25 ± 0.33**	lg R: **1.07 ± 0.42**



Test strain: *Murine norovirus* FLI-RVB-0651

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 7.88 ± 0.37 V_{C2}: 7.88 ± 0.37	CE_1: 3.50 ± 0.00 CE_2: 3.50 ± 0.00

Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
100.00* / 10	N_{a1}: ≤3.50 ± 0.00 lg R_1: **≥4.38 ± 0.37**	N_{a2}: ≤3.50 ± 0.00 lg R_2: **≥4.38 ± 0.37**	lg R: **≥4.38 ± 0.37**

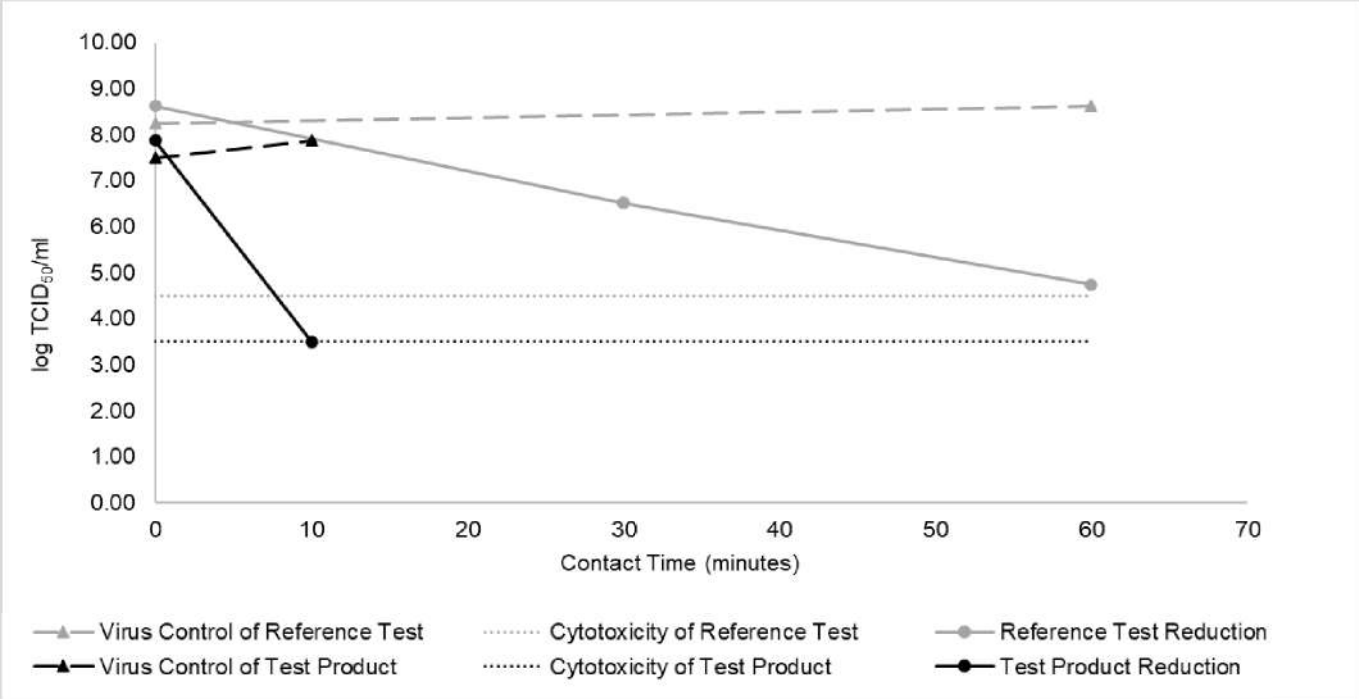


* The product can only be tested at 80.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

Test strain: *Murine norovirus* FLI-RVB-0651

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 7.88 ± 0.37 V_{C2}: 7.88 ± 0.37	CE_1: 3.50 ± 0.00 CE_2: 3.50 ± 0.00

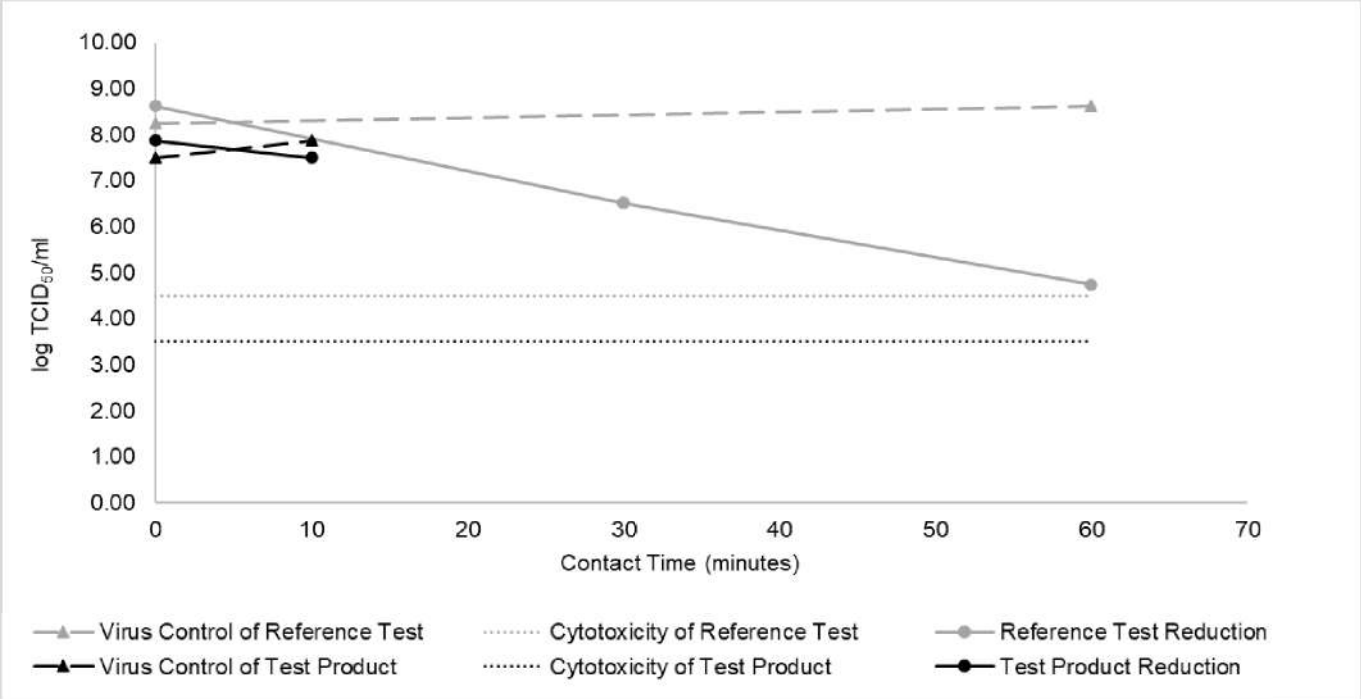
Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
70.00 / 10	N_{a1}: ≤3.50 ± 0.00 lg R_1: **≥4.38 ± 0.37**	N_{a2}: ≤3.50 ± 0.00 lg R_2: **≥4.38 ± 0.37**	lg R: **≥4.38 ± 0.37**



Test strain: *Murine norovirus* FLI-RVB-0651

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 7.88 ± 0.37 V_{C2}: 7.88 ± 0.37	CE_1: 3.50 ± 0.00 CE_2: 3.50 ± 0.00

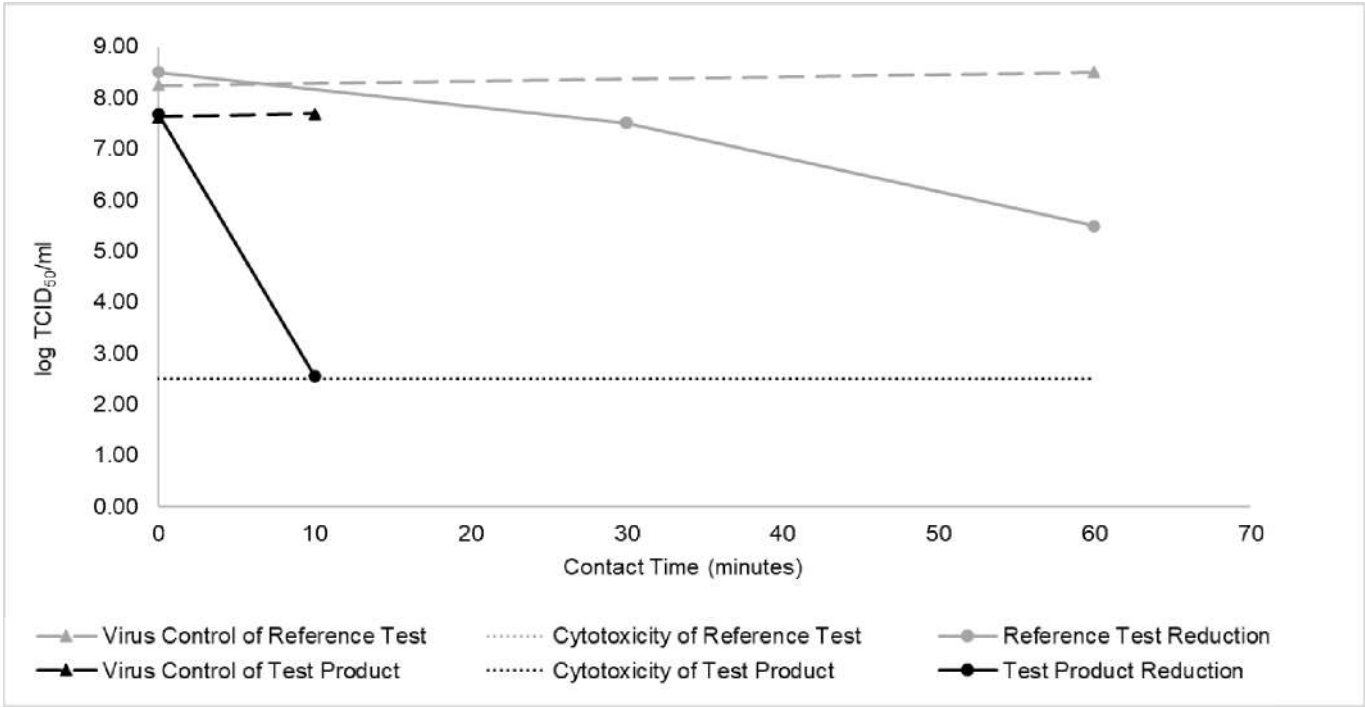
Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
0.10 / 10	N_{a1}: 7.50 ± 0.00 lg R_1: **0.38 ± 0.37**	N_{a2}: 7.50 ± 0.00 lg R_2: **0.38 ± 0.37**	lg R: **0.38 ± 0.37**



Test strain: *Poliovirus type 1* NIBSC-01/528

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 7.75 ± 0.33 V_{C2}: 7.63 ± 0.25	CE_1: 2.50 ± 0.00 CE_2: 2.50 ± 0.00

Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
100.00* / 10	N_{a1}: 2.63 ± 0.25 lg R_1: **5.13 ± 0.41**	N_{a2}: ≤2.50 ± 0.00 lg R_2: **≥5.13 ± 0.25**	lg R: **≥5.13 ± 0.34**

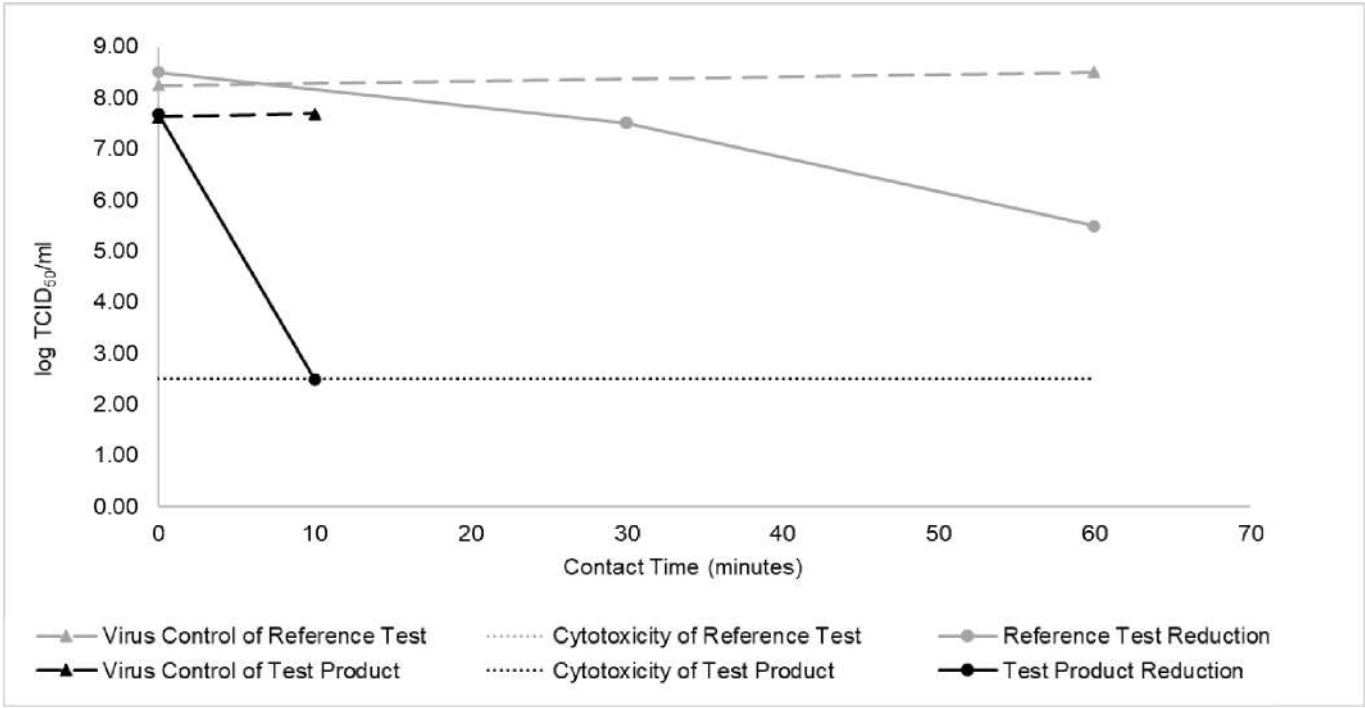


* The product can only be tested at 80.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

Test strain: *Poliovirus type 1* NIBSC-01/528

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 7.75 ± 0.33 V_{C2}: 7.63 ± 0.25	CE_1: 2.50 ± 0.00 CE_2: 2.50 ± 0.00

Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
70.00 / 10	N_{a1}: ≤2.50 ± 0.00 lg R_1: **≥5.25 ± 0.33**	N_{a2}: ≤2.50 ± 0.00 lg R_2: **≥5.13 ± 0.25**	lg R: **≥5.19 ± 0.29**



Test strain: *Poliovirus type 1* NIBSC-01/528

Virus control, V_C	Cytotoxicity effect, CE
V_{C1}: 7.75 ± 0.33 V_{C2}: 7.63 ± 0.25	CE_1: 2.50 ± 0.00 CE_2: 2.50 ± 0.00

Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
0.10 / 10	N_{a1}: 6.88 ± 0.37 lg R_1: **0.88 ± 0.50**	N_{a2}: 7.00 ± 0.38 lg R_2: **0.63 ± 0.45**	lg R: **0.76 ± 0.48**

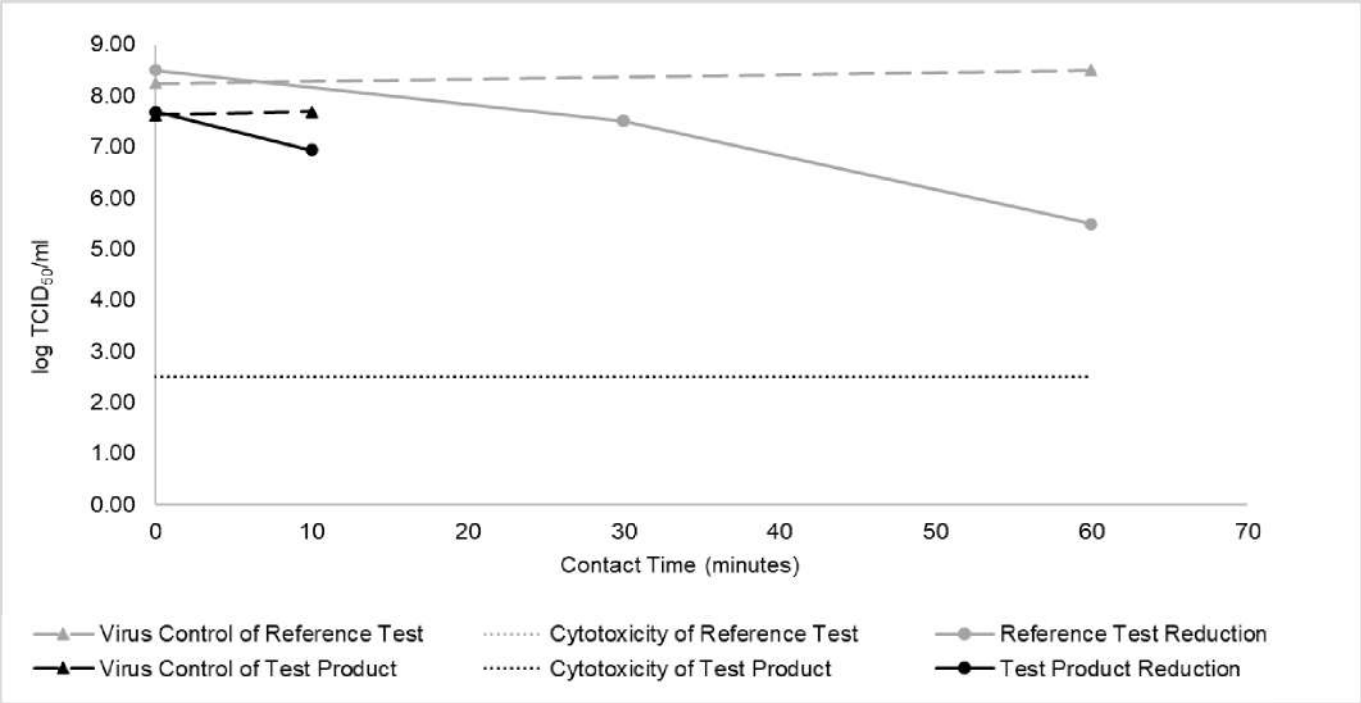


Table B: Control tests and method validation for Table A

Test strain	Cell susceptibility control	Suppression efficiency control	Reference test for virus inactivation
Adenovirus type 5 ATCC VR-5	A: 6.75 ± 0.33 A_{PBS}: 7.00 ± 0.38	B: 6.88 ± 0.37 V_C: 6.75 ± 0.33	C_{30}: 3.00 ± 0.00 C_{60}: 3.50 ± 0.38
Murine norovirus FLI-RVB-0651	A: 7.50 ± 0.00 A_{PBS}: 8.00 ± 0.38	B: 8.13 ± 0.37 V_C: 8.25 ± 0.33	C_{30}: 2.13 ± 0.25 C_{60}: 3.88 ± 0.41
Poliovirus type 1 NIBSC-01/528	A: 7.75 ± 0.33 A_{PBS}: 8.25 ± 0.33	B: 7.63 ± 0.25 V_C: 7.63 ± 0.25	C_{30}: 1.00 ± 0.00 C_{60}: 3.00 ± 0.00

Note

$TCID_{50}$: The dilution of the virus suspension that induces a cytopathic effect (CPE) in 50 % of cell culture units

CPE: The morphological alteration of cells and/or their destruction caused by the cytopathic effect of virus multiplication.

V_C: log_{10} $TCID_{50}$ per ml in the viral test suspension at the beginning and at the maximum contact time

N_a: log_{10} $TCID_{50}$ per ml in the test mixture at the end of the contact time

CE: The morphological alteration of cells caused by the cytotoxicity effect of the product test solution.

A: log_{10} $TCID_{50}$ per ml in the cell susceptibility control as compared to PBS

B: log_{10} $TCID_{50}$ per ml in the suppression efficiency control as compared to the virus control

C: log_{10} $TCID_{50}$ per ml in the reference test for virus inactivation after 30 and 60 minutes (5 and 15 minutes for vaccinia virus)

Table C: Summary of the log reductions of the quantitative suspension test according to EN 14476

Test strain	Test concentration (%) / contact time (min)	Log reduction ($TCID_{50}$/ml)	Percentage reduction (%)	Associated risk†
Adenovirus type 5 ATCC VR-5	100.00* / 10	**≥5.25 ± 0.33**	**≥99.999**	Minimal risk of false acceptance
	70.00 / 10	**≥5.25 ± 0.33**	**≥99.999**	Minimal risk of false acceptance
	0.10 / 10	**1.07 ± 0.42**	**91.48**	Minimal risk of false rejection
Murine norovirus FLI-RVB-0651	100.00* / 10	**≥4.38 ± 0.37**	**≥99.99**	Minimal risk of false acceptance
	70.00 / 10	**≥4.38 ± 0.37**	**≥99.99**	Minimal risk of false acceptance
	0.10 / 10	**0.38 ± 0.37**	**58.31**	Minimal risk of false rejection
Poliovirus type 1 NIBSC-01/528	100.00* / 10	**≥5.13 ± 0.34**	**≥99.999**	Minimal risk of false acceptance
	70.00 / 10	**≥5.19 ± 0.29**	**≥99.999**	Minimal risk of false acceptance
	0.10 / 10	**0.76 ± 0.48**	**82.62**	Minimal risk of false rejection

* The product can only be tested at 80.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

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14100 Lisieux
France

Efficacy of F3307 against *Adenovirus type 5*, strain Adenoid 75, ATCC VR-5, *Murine norovirus,* strain S99 Berlin, FLI-RVB-0651 and *Poliovirus type 1*, strain LSc2ab, NIBSC-01/528 in a quantitative suspension test at 20 °C according to EN 14476:2013+A2:2019 (E) under clean condition

EXPERT OPINION*

This expert opinion is based on the test report VX-TR-23-0457 dated 07 February 2023.

The virucidal activity of the disinfectant F3307 of Sodel against *Adenovirus type 5* ATCC VR-5, *Murine norovirus* FLI-RVB-0651 and *Poliovirus type 1* NIBSC-01/528 was investigated by a quantitative suspension test according to EN 14476:2013+A2:2019 (E) under clean condition (0.30 g/L bovine albumin solution).

According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virucidal activity if the virus titre is reduced by ≥4 $\log_{10}$ (inactivation ≥99.99 %) within the recommended exposure period.

F3307 was examined at 20 °C at the concentration(s) of 100.00 %**, 70.00 % and 0.10 % for the exposure time(s) of 10 minutes. After the exposure time(s), the viral reduction exceeded 4 $\log_{10}$-steps in all assays at 100.00 %** and 70.00 %. However, the viral reduction did not exceed 4 $\log_{10}$-steps in all assays at the concentration(s) of 0.10 %. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance at the concentration(s) of 100.00 %** and 70.00 % and a minimal risk of false rejection at concentration(s) of 0.10 %. Therefore, a virucidal activity against *Adenovirus type 5* ATCC VR-5, *Murine norovirus* FLI-RVB-0651 and *Poliovirus type 1* NIBSC-01/528 was measured as follows:

Clean condition	100.00 %**	10 minutes
Clean condition	70.00 %	10 minutes

Kuala Lumpur, 07 February 2023

SITI SYAZANI BINTI SUHAIMI 2023.02.10 14:51:35 +08'00'

Dr Syazani Suhaimi
Microbiologist

HUBERT YONG JUN FUNG 2023.02.10 19:04:02 +08'00'

Hubert Yong
Microbiologist

* Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

** The product can only be tested at 80.00 % concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

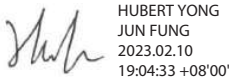
† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Appendix 1

QAU CERTIFICATE*

The results stated in test report VX-TR-23-0457 dated 07 February 2023 were compared to the raw data of the tests and checked for correct transfer. No deviations were detected.

Kuala Lumpur, 07 February 2023



Hubert Yong
Microbiologist

* Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

Appendix 2 Raw data

Test Method	EN 14476:2013+A2:2019			**Titration Method**	Quantal test		
Product	F3307			**Batch No.**	0209E036221028Z		
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0011		
Test Organism	Adenovirus, strain Adenoid 75, ATCC VR-5			**Passage No.**	2		
Cell Line	Vero cells, ATCC CCL-81			**Passage No.**	29		
Interfering Substance	0.30 g/L bovine albumin solution			**Inactivation Method**	Microspin Column		
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Dilution Method**	Standard		
First Assay Test Date	15/11/2022	**Second Assay Test Date**	30/11/2022	**Analyzed By**	HYO	**Verified By**	SSU

Validation and Control Procedures

	Product Concentration	Dilution	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\Delta TCID_{50}$ < 1 lg
Cell Susceptibility Control	PBS	Without	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 2 2 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.00 ± 0.38	Pass? **Yes**
	100.00 %	1:1000	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 3 1 4 2 4 2 4	2 0 0 0 3 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\lvert TCID_{50} - V_C \rvert$ ≤ 0.5 lg
Suppression Efficiency Control	100.00 %	30	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 2 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.88 ± 0.37	Pass? **Yes**
	Virus Control (V_C)	30	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	lg R = V_C - Na
Reference Test	0.70 % Formaldehyde	30	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	4.50 ± 0.00	3.00 ± 0.00
		60	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 0 0 4 4 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	4.00 ± 0.38	3.50 ± 0.38
	Virus Control (V_C)	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	1 4 4 4 3 3 2 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.50 ± 0.00	
		60	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 2 4 4 1 4 3 3	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	2.50 ± 0.00	

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	100.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	1.50 ± 0.00	V_{C1} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 3 2 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.50 ± 0.00	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d	n.d	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	100.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	1.50 ± 0.00	V_{C2} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d	n.d	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	lg R_1 = V_{C1} - Na_1	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	lg R_2 = V_{C2} - Na_2	Average Reduction (lg R)
Average Reduction (lg R)	100.00 %	10	≤1.50 ± 0.00	≥5.25 ± 0.33	≤1.50 ± 0.00	≥5.25 ± 0.33	≥5.25 ± 0.33

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	70.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	1.50 ± 0.00	V_{C1} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 3 2 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.50 ± 0.00	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d	n.d	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	70.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	1.50 ± 0.00	V_{C2} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d	n.d	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	First Assay (Na_1) lg $R_1 = V_{C1} - Na_1$	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	Second Assay (Na_2) lg $R_2 = V_{C2} - Na_2$	Average Reduction (lg R)
Average Reduction (lg R)	70.00 %	10	≤1.50 ± 0.00	≥5.25 ± 0.33	≤1.50 ± 0.00	≥5.25 ± 0.33	≥5.25 ± 0.33

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	0.10 %	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	5.88 ± 0.37	V_{C1} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 3 2 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.50 ± 0.00	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d	n.d	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	0.10 %	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 3 2 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	5.50 ± 0.00	V_{C2} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d	n.d	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	First Assay (Na_1) lg $R_1 = V_{C1} - Na_1$	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	Second Assay (Na_2) lg $R_2 = V_{C2} - Na_2$	Average Reduction (lg R)
Average Reduction (lg R)	0.10 %	10	5.88 ± 0.37	0.88 ± 0.50	5.50 ± 0.00	1.25 ± 0.33	1.07 ± 0.42

Appendix 2 Raw data

Test Method	EN 14476:2013+A2:2019			**Titration Method**	Quantal test		
Product	F3307			**Batch No.**	0209E036221028Z		
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0011		
Test Organism	Murine norovirus, strain S99 Berlin, FLI-RVB-0651			**Passage No.**	2		
Cell Line	RAW 264.7 cells, ATCC TIB-71			**Passage No.**	13		
Interfering Substance	0.30 g/L bovine albumin solution			**Inactivation Method**	Immediate dilution		
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Dilution Method**	Standard		
First Assay Test Date	11/01/2023	**Second Assay Test Date**	18/01/2023	**Analyzed By**	HYO	**Verified By**	SSU

Validation and Control Procedures

	Product Concentration	Dilution	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\Delta TCID_{50}$ < 1 lg
Cell Susceptibility Control	PBS	Without	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 2 2 0 0	0 0 0 0 0 0 0 0	n.d	n.d	8.00 ± 0.38	Pass? **Yes**
	100.00 %	1:1000	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 3 2 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\lvert TCID_{50} - V_C \rvert$ ≤ 0.5 lg
Suppression Efficiency Control	100.00 %	30	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 2 0 3 2 0 0	0 0 0 0 0 0 0 0	n.d	n.d	8.13 ± 0.37	Pass? **Yes**
	Virus Control (V_C)	30	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 0 3 2 2 0	0 0 0 0 0 0 0 0	n.d	n.d	8.25 ± 0.33	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	lg R = V_C - Na
Reference Test	0.70 % Formaldehyde	30	t t t t t t t t	t t t t t t t t	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	6.50 ± 0.00	2.13 ± 0.25
		60	t t t t t t t t	t t t t t t t t	t t t t t t t t	4 0 0 0 4 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	4.75 ± 0.33	3.88 ± 0.41
	Virus Control (V_C)	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 0 3 2 2 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	8.25 ± 0.33	
		60	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	8.63 ± 0.25	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	4.50 ± 0.00	

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	100.00 %	10	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	3.50 ± 0.00	V_{C1} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.63 ± 0.25	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.88 ± 0.37	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	3.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	100.00 %	10	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	3.50 ± 0.00	V_{C2} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 2 2 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.38 ± 0.25	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.88 ± 0.37	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	3.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	lg R_1 = V_{C1} - Na_1	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	lg R_2 = V_{C2} - Na_2	Average Reduction (lg R)
Average Reduction (lg R)	100.00 %	10	≤3.50 ± 0.00	≥4.38 ± 0.37	≤3.50 ± 0.00	≥4.38 ± 0.37	≥4.38 ± 0.37

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	70.00 %	10	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	3.50 ± 0.00	V_{C1} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.63 ± 0.25	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.88 ± 0.37	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	3.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	70.00 %	10	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	3.50 ± 0.00	V_{C2} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 2 2 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.38 ± 0.25	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.88 ± 0.37	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	3.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (minutes)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	lg R_1 = V_{C1} - Na_1	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	lg R_2 = V_{C2} - Na_2	Average Reduction (lg R)
	70.00 %	10	≤3.50 ± 0.00	≥4.38 ± 0.37	≤3.50 ± 0.00	≥4.38 ± 0.37	≥4.38 ± 0.37

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	0.10 %	10	t t t t t t t t	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	n.d	n.d	n.d	n.d	7.50 ± 0.00	V_{C1} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.63 ± 0.25	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.88 ± 0.37	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	3.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	0.10 %	10	t t t t t t t t	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	n.d	n.d	n.d	n.d	7.50 ± 0.00	V_{C2} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 2 2 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.38 ± 0.25	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.88 ± 0.37	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	3.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	lg R_1 = V_{C1} - Na_1	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	lg R_2 = V_{C2} - Na_2	Average Reduction (lg R)
Average Reduction (lg R)	0.10 %	10	7.50 ± 0.00	0.38 ± 0.37	7.50 ± 0.00	0.38 ± 0.37	0.38 ± 0.37

Appendix 2 Raw data

Test Method	EN 14476:2013+A2:2019			**Titration Method**	Quantal test		
Product	F3307			**Batch No.**	0209E036221028Z		
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0011		
Test Organism	Poliovirus, strain LSc 2ab			**Passage No.**	3		
Cell Line	Vero cells, ATCC CCL-81			**Passage No.**	29		
Interfering Substance	0.30 g/L bovine albumin solution			**Inactivation Method**	Immediate dilution		
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Dilution Method**	Standard		
First Assay Test Date	15/11/2022	**Second Assay Test Date**	22/11/2022	**Analyzed By**	HYO	**Verified By**	SSU

Validation and Control Procedures

	Product Concentration	Dilution	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\Delta TCID_{50}$ < 1 lg
Cell Susceptibility Control	PBS	Without	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 3 2 0 0	0 0 0 0 0 0 0 0	n.d	n.d	8.00 ± 0.38	Pass? **Yes**
	100.00 %	1:100	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	n.d	n.d	8.75 ± 0.33	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\lvert TCID_{50} - V_C \rvert$ ≤ 0.5 lg
Suppression Efficiency Control	100.00 %	30	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.63 ± 0.25	Pass? **Yes**
	Virus Control (V_C)	30	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.63 ± 0.25	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	lg R = V_C - Na
Reference Test	0.70 % Formaldehyde	30	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	n.d	n.d	n.d	7.50 ± 0.00	1.00 ± 0.00
		60	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	5.50 ± 0.00	3.00 ± 0.00
	Virus Control (V_C)	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 0 4 4 3 0	0 0 0 0 0 0 0 0	n.d	n.d	8.25 ± 0.33	
		60	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 3	0 0 0 0 0 0 0 0	n.d	n.d	8.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	2.50 ± 0.00	

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	100.00 %	10	t t t t t t t t	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	2.63 ± 0.25	V_{C1} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.75 ± 0.33	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	2.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	100.00 %	10	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	2.50 ± 0.00	V_{C2} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 3 2 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.50 ± 0.00	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.63 ± 0.25	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	2.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (minutes)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	lg R_1 = V_{C1} - Na_1	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	lg R_2 = V_{C2} - Na_2	Average Reduction (lg R)
	100.00 %	10	2.63 ± 0.25	5.13 ± 0.41	≤2.50 ± 0.00	≥5.13 ± 0.25	≥5.13 ± 0.34

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	70.00 %	10	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	2.50 ± 0.00	V_{C1} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.75 ± 0.33	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	2.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	70.00 %	10	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	2.50 ± 0.00	V_{C2} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 3 2 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.50 ± 0.00	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.63 ± 0.25	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	2.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (minutes)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	lg R_1 = V_{C1} - Na_1	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	lg R_2 = V_{C2} - Na_2	Average Reduction (lg R)
	70.00 %	10	≤2.50 ± 0.00	≥5.25 ± 0.33	≤2.50 ± 0.00	≥5.13 ± 0.25	≥5.19 ± 0.29

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	0.10 %	10	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 2 0 0 0	n.d	n.d	n.d	n.d	6.88 ± 0.37	V_{C1} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C1})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.75 ± 0.33	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	2.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	0.10 %	10	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 2 0 0 3 2 0 0	n.d	n.d	n.d	n.d	7.00 ± 0.38	V_{C2} - CE ≥ 4 Pass? **Yes**
	Virus Control (V_{C2})	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 3 2 2 3 3 2 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.50 ± 0.00	
		10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.63 ± 0.25	
	Cytotoxicity Effect (CE)	-	t t t t t t t t	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	n.d	n.d	n.d	2.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (minutes)	First Assay (Na_1) log_{10} $TCID_{50}$/ml	lg R_1 = V_{C1} - Na_1	Second Assay (Na_2) log_{10} $TCID_{50}$/ml	lg R_2 = V_{C2} - Na_2	Average Reduction (lg R)
	0.10 %	10	6.88 ± 0.37	0.88 ± 0.50	7.00 ± 0.38	0.63 ± 0.45	0.76 ± 0.48

Note

$TCID_{50}$: The dilution of the virus suspension that induces a CPE in 50 % of cell culture units

CPE: The morphological alteration of cells and/or their destruction caused by the cytopathic effect of virus multiplication. '0' denotes no CPE and '1' (approximately 25 % of cells) to '4' (all cells) denotes the degree of CPE per cell culture units.

V_C: log_{10} $TCID_{50}$ per ml in the viral test suspension at the beginning and at the maximum contact time

N_a: log_{10} $TCID_{50}$ per ml in the test mixture at the end of the contact time

CE: The morphological alteration of cells caused by the cytotoxicity effect of the product test solution. 't' denotes the presence of cytotoxicity per cell culture units.

A: log_{10} $TCID_{50}$ per ml in the cell susceptibility control as compared to PBS

B: log_{10} $TCID_{50}$ per ml in the suppression efficiency control as compared to the virus control

C: log_{10} $TCID_{50}$ per ml in the reference test for virus inactivation after 30 and 60 minutes (5 and 15 minutes for vaccinia virus)

Appendix 3 Summary of test description

1. Virus and cells

1.1. *Adenovirus type 5*, strain Adenoid 75, ATCC VR-5
- 1.1.1. Passage no.: 2
- 1.1.2. Cell line: Vero cells, ATCC CCL-81
- 1.1.3. Cell line passage no.: 29
- 1.1.4. Culture medium: EMEM

1.2. *Murine norovirus,* strain S99 Berlin, FLI-RBI-0651
- 1.2.1. Passage no.: 2
- 1.2.2. Cell line: Raw 264.7 cells, ATCC TIB-71
- 1.2.3. Cell line passage no.: 13
- 1.2.4. Culture medium: DMEM

1.3. *Poliovirus type 1*, strain LSc2ab, NIBSC-01/528
- 1.3.1. Passage no.: 3
- 1.3.2. Cell line: Vero cells, ATCC CCL -81
- 1.3.3. Cell line passage no.: 29
- 1.3.4. Culture medium: EMEM

2 Materials and reagents

2.1 Eagle's Minimal Essential Medium (EMEM, Sigma, catalogue no. M3024)
2.2 Dulbecco's Modified Eagle Medium (DMEM, Sigma, catalogue no. D7777)
2.3 Fetal Bovine Serum (FBS, Sigma, catalogue no. F7524)
2.4 Formaldehyde (Merck, catalogue no. 1.0.4003.2500)
2.5 Dulbecco's Phosphate Buffered Saline (PBS, Sigma, catalogue no. P3813)
2.6 Bovine albumin fraction V (Merck, catalogue no. K49238418733)
2.7 Defibrinated sheep blood (Hemostat, catalogue no. DSB100) (for dirty condition only)

3 Apparatus and glassware

3.1 CO_2 incubator (Memmert, model ICO 105)
3.2 Cooling water bath (Memmert, model WNB7 with CDP115)
3.3 Inverted microscope (Optika, IM-2)
3.4 Vortex® mixer (Biosan model Biosan V-1 Plus)
3.5 Microtitre plate (NEST)
3.6 Tissue culture flask (JET Biofil)

4 Test procedure

4.1 Preparation of test virus suspension

4.1.1 Cell monolayers shall be >90 % confluent before inoculation. Cell lines are selected in accordance with their sensitivity to the test organisms.

4.1.2 The test organisms and their stock cultures shall be prepared and kept in accordance with EN 12353:2013 (E).

4.1.3 The stock virus suspension is multiplied in an appropriate cell line that produces high titres of infectious viruses for 1 hour at 36 °C with intermittent tilting every 15 minutes.

4.1.4 The cells are subjected to 3 freeze/thaw cycles once cytopathic effect (CPE) is observed in 80 % of the cell population.

4.1.5 Separate the cells debris is by centrifugation at 400 g_N for 15 minutes.

4.1.6 Aliquot the supernatant containing the test virus suspension and store at -80 °C.

4.2 Test Na – Determination of virucidal concentrations

4.2.1 Pipette 1 ml of interfering substance into a container of suitable capacity for appropriate mixing.

4.2.2 Add 1 ml of the virus test suspension to the container, carefully avoiding the upper part of the sides. Mix well.

4.2.3 Add 8 ml of the product test solution to the container.

4.2.4 Mix, start a stopwatch at once, and place the container in a water bath controlled at the chosen test temperature.

4.2.5 Immediately at the end of the chosen contact time, mix, pipette 0.5 ml of the test mixture (virus suspension, interfering substance, and product test solution) into 4.5 ml ice-cold maintenance medium and put into an ice bath.

4.2.6 Within 30 minutes, prepare a series of ten-fold dilutions of this mixture (text mixture and maintenance medium).

4.2.7 Transfer 0.1 ml of each dilution into six or eight wells of a microtitre plate containing a confluent (>90 %) cell monolayer without any medium.

4.2.8 The last row of six or eight wells will receive 0.1 ml of culture medium and will serve as the cell control.

4.2.9 After 1 hour of incubation at 37 °C, 0.1 ml of cell culture medium is added to each well.

4.2.10 After incubation, the virus titre is calculated. The reduction of virus infectivity is determined from differences of $\log_{10}$ virus titres before and after treatment with the product.

4.3 Cytotoxicity effect – determination of the morphological alteration of cells caused by the product test solution

4.3.1 Mix 1 part of hard water and 1 part of interfering substances with 8 parts of the product test solution.

4.3.2 Serial dilutions are prepared in the culture medium and are inoculated into cell monolayers.

4.3.3 This test is done in parallel with Section 4.2.

4.3.4 Any microscopic changes in the cells are recorded when reading the tests for CPE.

4.3.5 If the cytotoxicity is so great that the residual infectivity titre is smaller than the required $\log_{10}$ $TCID_{50}$, special techniques have to be used, such as molecular sieving or ultrafiltration. Follow the instructions of the manufacturer.

4.4 Cell susceptibility control A – Verification of the susceptibility of the cells for virus infection is not influenced negatively by the treatment with the product test solution

4.4.1 Comparative virus titrations are performed on cells that have or have not been treated with product test solution to check the reduction of the sensitivity to viruses.

4.4.2 0.1 ml of the lowest apparently non-cytotoxic dilution (no microscopic alteration) of the product test solution or PBS and 0.1 ml of culture medium are distributed onto each of 6 established cell cultures in 96-well microtitre plates.

4.4.3 After 1 hour of incubation at 37 °C, the supernatant is discarded.

4.4.4 The virus is diluted from 10^{-1} to 10^{-10} and titrated on the treated or untreated cells.

4.4.5 Verify according to Section 4.8.

4.5 Suppression efficiency control B – Immediate dilution method validation

4.5.1 Immediately after preparation of the test mixture in Section 4.2, pipette 0.5 ml of the test mixture (virus suspension, interfering substance, and product test solution) into 4.5 ml of ice-cold maintenance medium.

4.5.2 Mix again and start the clock. Incubate the mixture in the ice bath for 30 minutes ± 10 seconds.

4.5.3 Immediately prepare dilutions up to 10^{-8} and titrate the virus.

4.5.4 This control is performed in parallel to the test.

4.5.5 Verify according to Section 4.8.

4.6 Reference test for virus inactivation C – Validation of the test system

4.6.1 2 ml of the test suspension shall be mixed with 8 ml of PBS and 10 ml of 1.4 % (w/v) formaldehyde.

4.6.2 Contact times are 30 and 60 minutes.

4.6.3 Immediately at the end of the contact time, mix and pipette 0.2 ml of the test mixture into a tube containing 1.8 ml ice-cold maintenance medium followed by a further 10-fold dilution.

4.6.4 Leave the mixture in the ice bath.

4.6.5 Dilutions up to 10^{-6} are prepared by pipetting the diluted test mixture into another tube containing ice-cold maintenance medium in the ice bath.

4.6.6 In exceptional cases, smaller volumes of the reagents and of the test suspension could be used, ensuring that the relative proportions are maintained.

4.6.7 The cytotoxic control of the formaldehyde shall be performed according to Section 4.3 whereby 8 ml of 1.4 % (w/v) formaldehyde is used instead of the product.

4.6.8 The mixture is further diluted to 10^{-5} in an ice bath.

4.6.9 Verify according to Section 4.8.

4.7 Titration of the virus control

4.7.1 The infectivity of the test suspension shall be determined under test conditions at the beginning of the contact time and at the maximum contact time used in the test.

4.7.2 Section 4.2 is repeated by substituting the product test solution with hard water or water for ready-to-use products.

4.7.3 Verify according to Section 4.8.

4.8 Verification of methodology

4.8.1 The titre of the test suspension (virus control) of at least 10^8 $TCID_{50}$/mL is sufficiently high to at least enable a titre reduction of 4 log to verify the method. The detectable titre reduction shall be at least 4 log.

4.8.2 Cytotoxicity of the product test solution does not affect cell morphology and growth or susceptibility for the test organism in the dilutions of the test mixtures which are necessary to demonstrate a 4-log reduction of the virus.

4.8.3 Comparative virus titration on cells cultures treated with test mixture dilutions and in parallel with PBS (cell susceptibility control) result in a difference of <1 log of virus titre.

4.8.4 The difference to the test suspension in the control of efficiency for suppression of products' activity shall be ≤0.5 log.

4.8.5 The difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test is:

4.8.5.1 Between -0.5 and -2.5 after 30 minutes and between -2 and -4.5 after 60 minutes for poliovirus

4.8.5.2 Between -3 and -5 after 30 minutes and between -3.5 and -5.5 after 60 minutes for adenovirus

4.8.5.3 Between -1 and -3 after 30 minutes and between -2 and -4 after 60 minutes for murine norovirus

4.8.5.4 Between 0.0 and -2.0 after 30 minutes and between -0.5 and -2.5 after 60 minutes for parvovirus

4.8.5.5 Between -0.75 and -3.5 after 5 minute and between -2.0 and ≥-4.0 after 15 minutes for vaccinia virus

5 Literature

5.1 EN 14476:2013+A2:2019 (E): Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (phase 2, step 1)

5.2 EN 14885:2015 (E): Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics

5.3 EN 12353:2013 (E): Chemical disinfectants and antiseptics – Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

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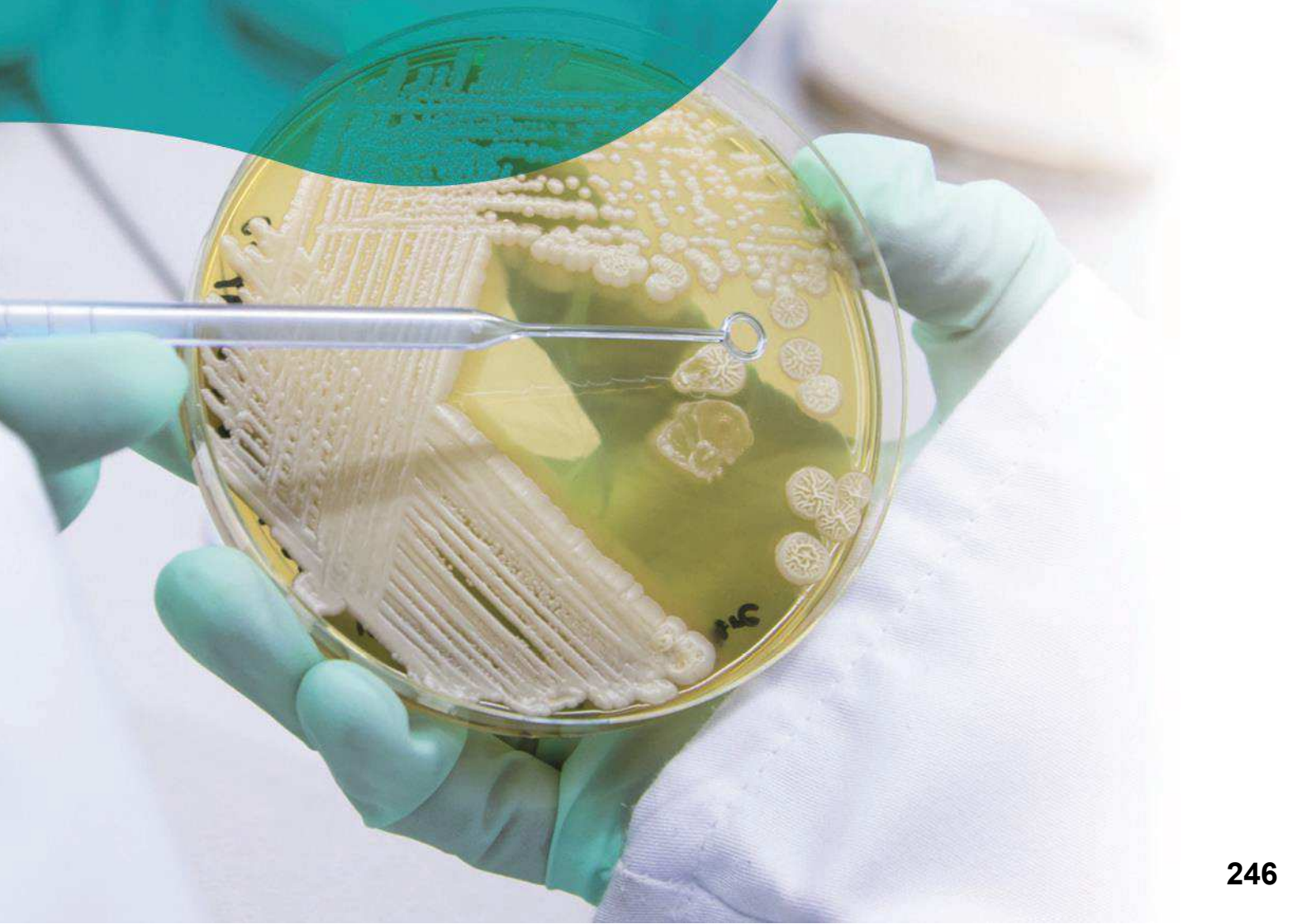

Test Report No.: VX-TR-23-0488
Copy No.: 1

DETERMINATION OF THE VIRUCIDAL ACTIVITY (EN 17111) OF F3307

Lab No.:	VX-268-22-0011
Sample Name:	**F3307**
Method:	EN 17111:2018 (E) Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)
Client:	Sodel 190 rue René Barthélemy 14100 Lisieux France
Sample Receipt Date:	13 December 2022
Report Date:	09 February 2023

Kuala Lumpur, 09 February 2023

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Dr Syazani Suhaimi
Microbiologist

Viroxy Sdn. Bhd. (1193371-A)
6th Floor · Menara RKT · 36 Jalan Raja Abdullah · 50300 Kuala Lumpur · Malaysia
Phone: +60 (0)3 2630 8888 · info@viroxy.com
www.viroxy.com

Materials and Method

Quantitative carrier test for the evaluation of virucidal activity for instrument in the medical area according to EN 17111:2018 (E)

1. Testing laboratory identification

Viroxy Sdn. Bhd.
6th Floor, Menara RKT
50300 Kuala Lumpur
Malaysia

2. Sample identification

2.1	Sample name:	F3307
2.2	Batch no.:	0209E036221028Z
2.3	Product appearance:	Clear, bluish solution
2.4	Manufacturer:	Sodel 190 rue René Barthélemy 14100 Lisieux France
2.5	Active substances:	0.54 % Orthophthalaldehyde
2.6	Sample receipt date:	13 December 2022
2.7	Storage conditions:	Room temperature
2.8	Product diluent:	Distilled water

3. Experimental conditions

3.1	Testing period:	10 January – 07 February 2023
3.2	Test organism(s):	*Adenovirus,* strain Adenoid 75, ATCC VR-5 *Murine norovirus, strain S99 Berlin,* FLI-RVB-0651
3.3	Concentration/contact time:	80.00 %, 70.00 % and 0.10 % / 10 minute
3.4	Loading:	0.30 g/L bovine albumin solution
3.5	Test temperature:	20 °C ± 1 °C
3.6	Incubation period:	7 days, 36 °C ± 1 °C

4. Test method and its validation

4.1 Testing method: Quantal test

4.2 Inactivation method: Immediate dilution

The results of validation test A, B, and C proved the viability of the method in all cases.

5. Test results

The results are stated in Tables A and B.

6. Conclusion

F3307 showed the required viral reduction of ≥4.0 $\log_{10}$ against test strain(s) *Adenovirus* ATCC VR-5 and *Murine norovirus* FLI-RVB-0651 in accordance with EN 17111:2018 (E) at 80.00 % and 70.00 % concentration(s) after 10 minutes under the stated condition. According to the simple acceptance decision rule†, there is < 50% risk of false acceptance for *Adenovirus* ATCC VR-5 and a minimal risk of false acceptance *Murine norovirus* FLI-RVB-0651.

F3307 did not show the required viral reduction of ≥4.0 $\log_{10}$ against test strain(s) *Adenovirus* ATCC VR-5 and *Murine norovirus* FLI-RVB-0651 in accordance with EN 17111:2018 (E) at 0.10 % concentration(s) after 10 minutes under the stated condition. According to the simple acceptance decision rule†, there is a minimal risk of false rejection.

Kuala Lumpur, 09 February 2023

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Dr Syazani Suhaimi
Microbiologist

7. Note

Virucidal activity – the capability of a product to produce a reduction in the number of viable viruses belonging to reference strains under defined conditions by at least 4 orders (10^4).

$R = N_w/N_a$ = the reduction in viability, or $\lg R = \lg N_w - \lg N_a$

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

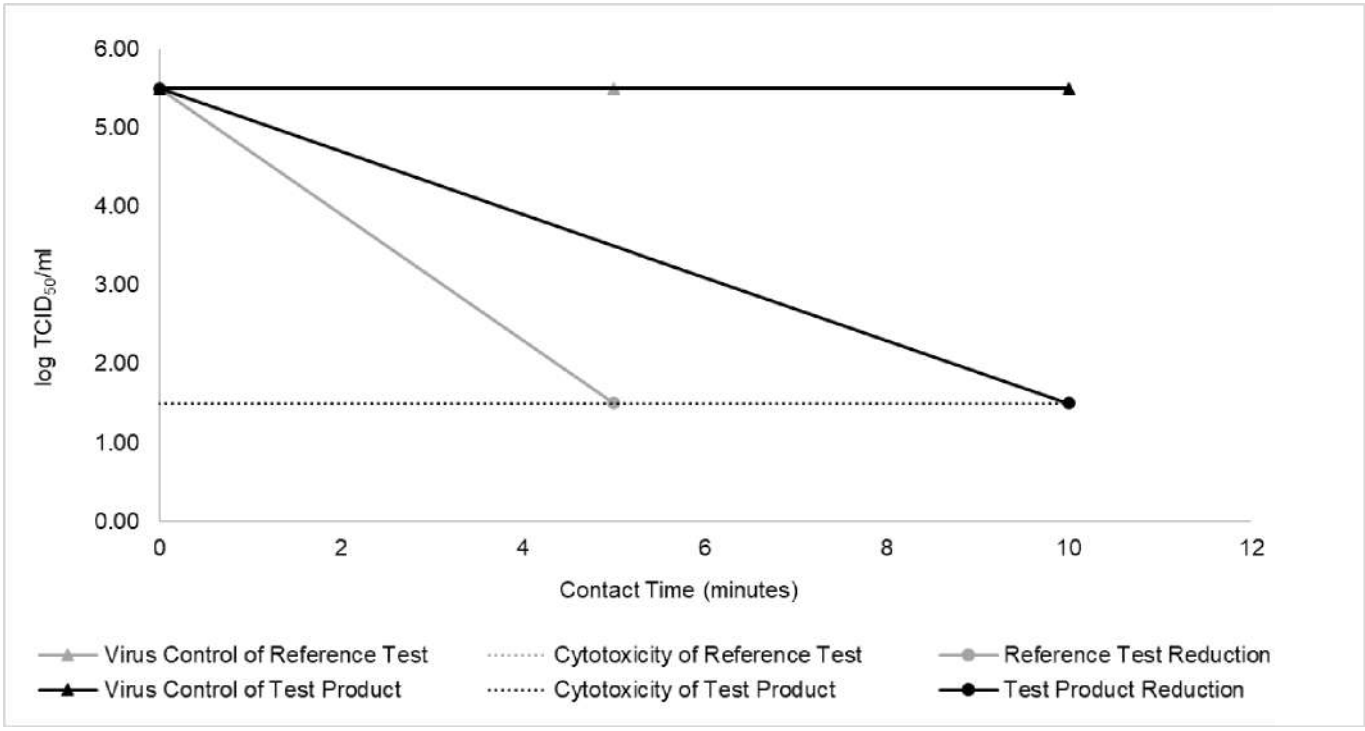
Table A: Evaluation of the virucidal activity of F3307 on test strains according to EN 17111

Product: F3307
Loading: 0.30 g/L bovine albumin solution

Test strain: *Adenovirus* ATCC VR-5

Water control, N_W	Cytotoxicity effect, CE
N_{w1}: 5.50 ± 0.00 N_{w2}: 5.50 ± 0.35	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

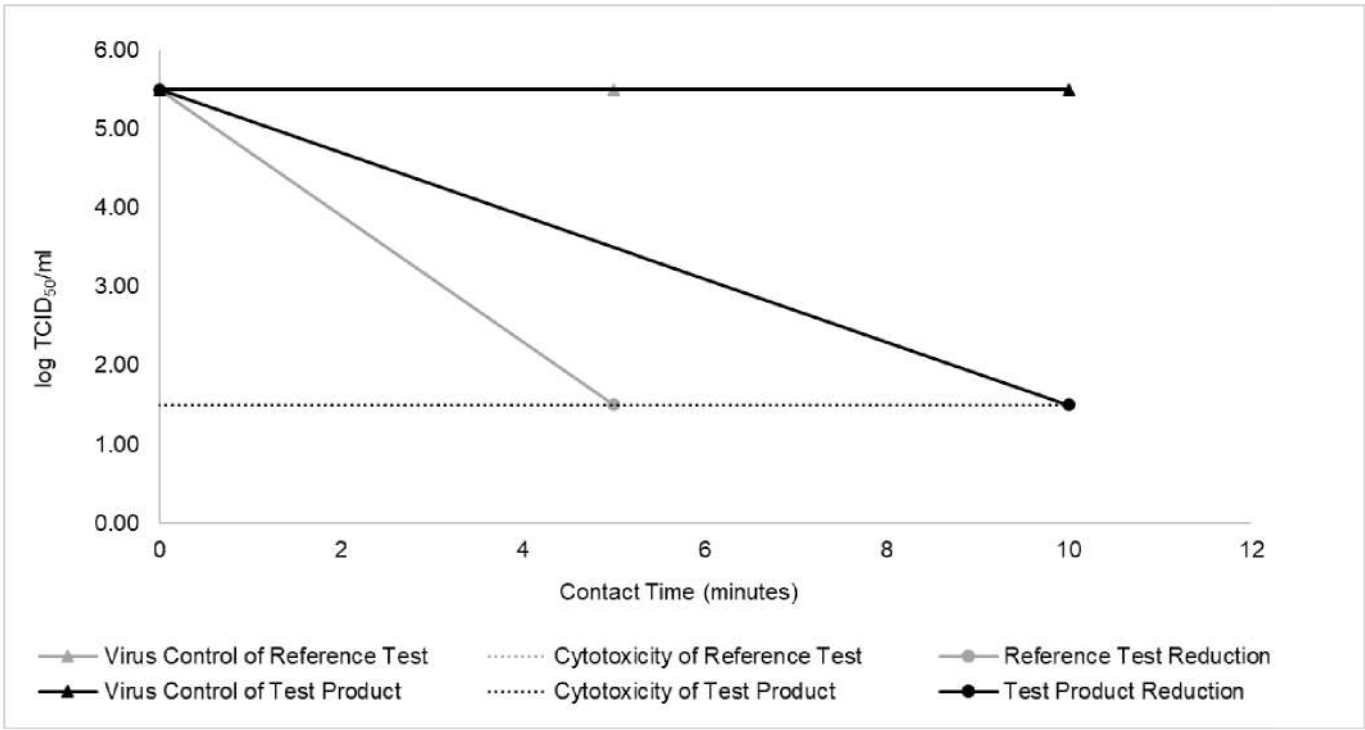
Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
80.00 / 10	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥4.00 ± 0.00**	N_{a2}: ≤1.50 ± 0.00 lg R_2: **≥4.00 ± 0.35**	lg R: **≥4.00 ± 0.25**



Test strain: *Adenovirus* ATCC VR-5

Water control, N_W	Cytotoxicity effect, CE
N_{w1}: 5.50 ± 0.00 N_{w2}: 5.50 ± 0.35	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

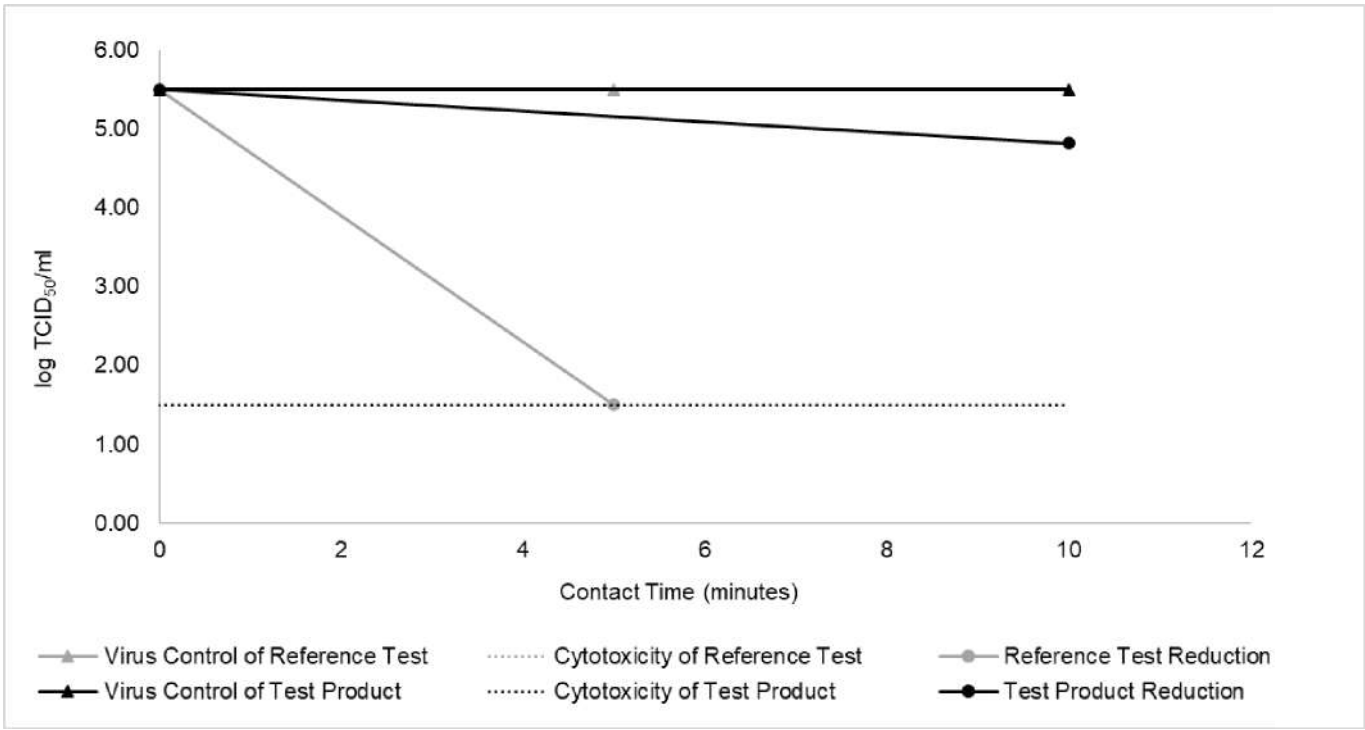
Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
70.00 / 10	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥4.00 ± 0.00**	N_{a2}: ≤1.50 ± 0.00 lg R_2: **≥4.00 ± 0.35**	lg R: **≥4.00 ± 0.25**



Test strain: *Adenovirus* ATCC VR-5

Water control, N_W	Cytotoxicity effect, CE
N_{w1}: 5.50 ± 0.00 N_{w2}: 5.50 ± 0.35	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

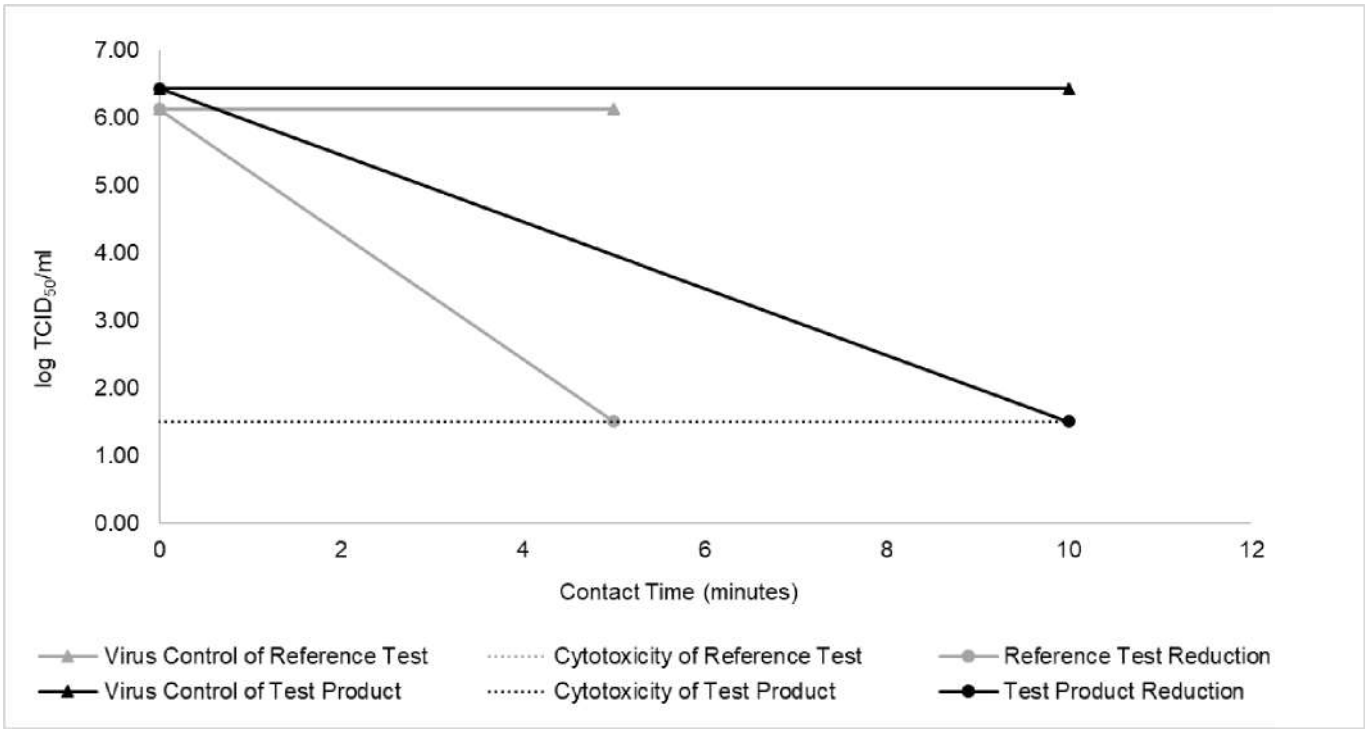
Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
0.10 / 10	N_{a1}: 4.63 ± 0.25 lg R_1: **0.87 ± 0.25**	N_{a2}: 5.00 ± 0.38 lg R_2: **0.50 ± 0.52**	lg R: **0.69 ± 0.41**



Test strain: *Murine norovirus* FLI-RVB-0651

Water control, N_W	Cytotoxicity effect, CE
N_{w1}: 6.13 ± 0.37 N_{w2}: 6.75 ± 0.33	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

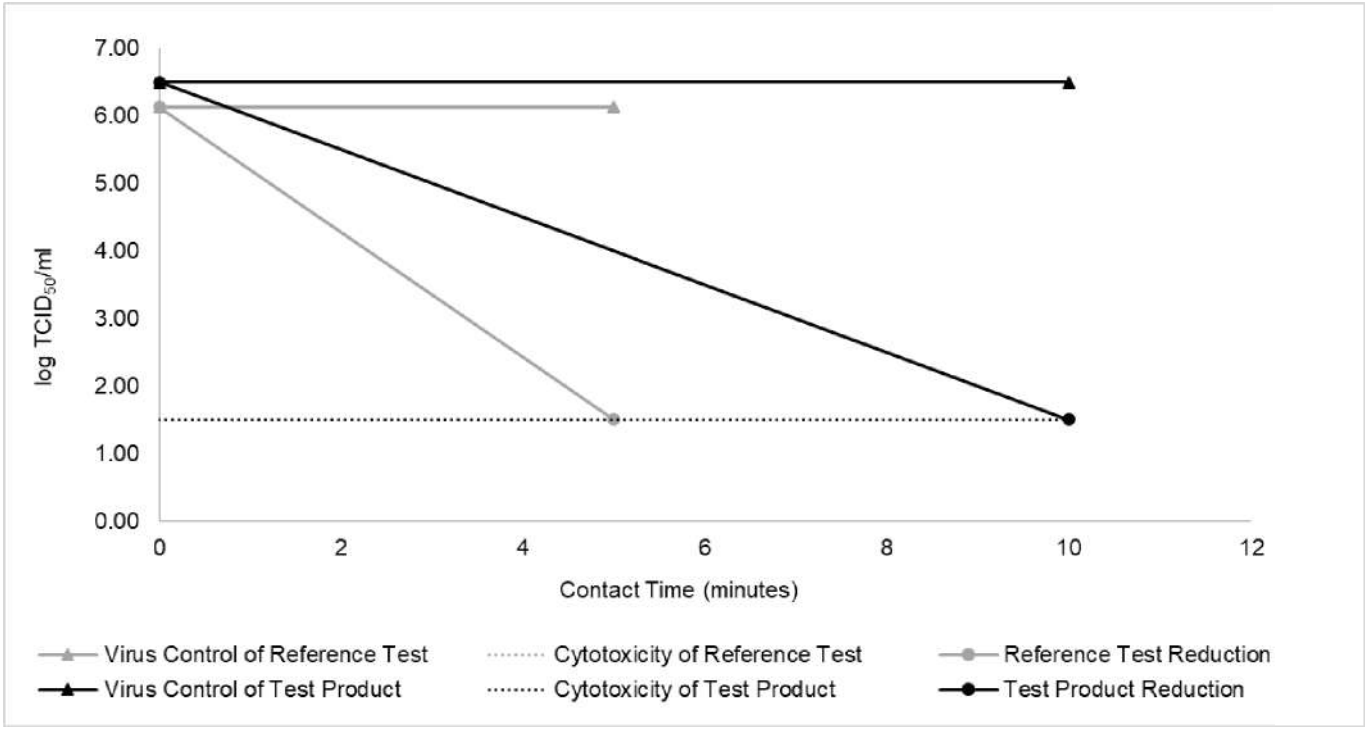
Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
80.00 / 10	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥4.63 ± 0.37**	N_{a2}: ≤2.50 ± 0.00 lg R_2: **≥5.25 ± 0.33**	lg R: **≥4.94 ± 0.35**



Test strain: *Murine norovirus* FLI-RVB-0651

Water control, N_W	Cytotoxicity effect, CE
N_{w1}: 6.13 ± 0.37 N_{w2}: 6.75 ± 0.33	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
70.00 / 10	N_{a1}: ≤1.50 ± 0.00 lg R_1: **≥4.63 ± 0.37**	N_{a2}: ≤1.50 ± 0.00 lg R_2: **≥5.25 ± 0.33**	lg R: **≥4.94 ± 0.35**



Test strain: *Murine norovirus* FLI-RVB-0651

Water control, N_W	Cytotoxicity effect, CE
N_{w1}: 6.13 ± 0.37 N_{w2}: 6.75 ± 0.33	CE_1: 1.50 ± 0.00 CE_2: 1.50 ± 0.00

Test concentration (%) / contact time (min)	First assay, N_{a1}	Second assay, N_{a2}	Average reduction
0.10 / 10	N_{a1}: 4.88 ± 0.37 lg R_1: **1.25 ± 0.52**	N_{a2}: 4.88 ± 0.37 lg R_2: **1.87 ± 0.50**	lg R: **1.56 ± 0.51**

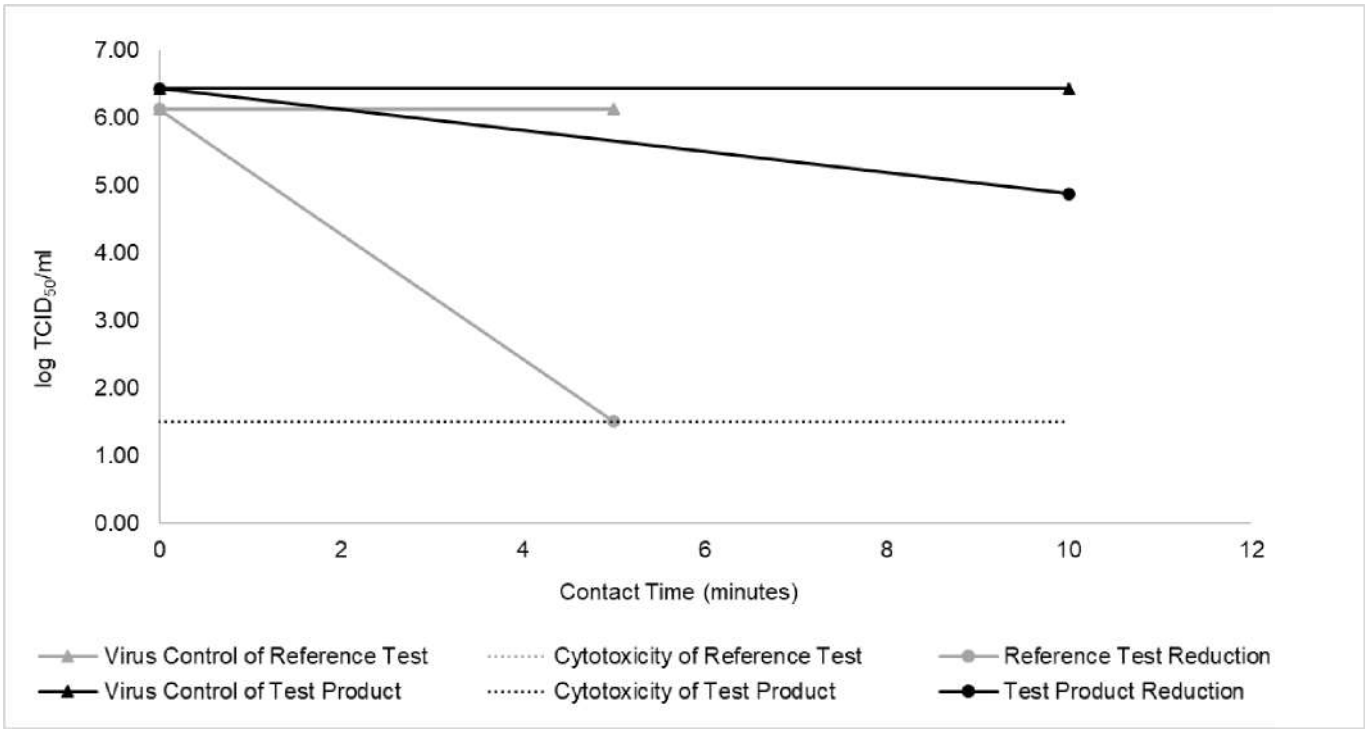


Table B: Control tests and method validation for Table A

Test strain	Cell susceptibility control	Suppression efficiency control	Reference test for virus inactivation
Adenovirus ATCC VR-5	A: 6.50 ± 0.35 A_{PBS}: 6.75 ± 0.33	B: 6.50 ± 0.00 V_C: 6.38 ± 0.25	$C_{5:}$ ≥4.00 ± 0.00
Murine norovirus FLI-RVB-0651	A: 7.50 ± 0.00 A_{PBS}: 7.00 ± 0.38	B: 7.00 ± 0.38 V_C: 7.00 ± 0.38	$C_{5:}$ ≥4.63 ± 0.37

Note

$TCID_{50}$: The dilution of the virus suspension that induces a cytopathic effect (CPE) in 50 % of cell culture units

CPE: The morphological alteration of cells and/or their destruction caused by the cytopathic effect of virus multiplication

V_C: log_{10} $TCID_{50}$ per ml in the viral test suspension at the beginning and at the maximum contact time

N_w: log_{10} $TCID_{50}$ per ml in water control at the end of the contact time

N_a: log_{10} $TCID_{50}$ per ml in the product test solution at the end of the contact time

CE: The morphological alteration of cells caused by the cytotoxicity effect of the product test solution

A: log_{10} $TCID_{50}$ per ml in the cell susceptibility control as compared to PBS

B: log_{10} $TCID_{50}$ per ml in the suppression efficiency control as compared to the virus control

C: log_{10} $TCID_{50}$ per ml in the reference test for virus inactivation after 5 minutes

Table C: Summary of the log reductions of the quantitative carrier test according to EN 17111

Test strain	Test concentration (%) / contact time (min)	Log reduction ($TCID_{50}$/ml)	Percentage reduction (%)	Associated risk†
Adenovirus ATCC VR-5	80.00 / 10	**≥4.00 ± 0.25**	**≥99.99**	< 50 % risk of false acceptance
	70.00 / 10	**≥4.00 ± 0.25**	**≥99.99**	< 50 % risk of false acceptance
	0.10 / 10	**0.69 ± 0.41**	**79.58**	Minimal risk of false rejection
Murine norovirus FLI-RVB-0651	80.00 / 10	**≥4.94 ± 0.35**	**≥99.99**	Minimal risk of false acceptance
	70.00 / 10	**≥4.94 ± 0.35**	**≥99.99**	Minimal risk of false acceptance
	0.10 / 10	**1.56 ± 0.51**	**97.25**	Minimal risk of false rejection

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Sodel
190 rue René Barthélemy
14100 Lisieux
France

Efficacy of F3307 against *Adenovirus, strain Adenoid 75,* ATCC VR-5 *Murine norovirus,* strain S99 Berlin, FLI-RVB-0651 in a quantitative carrier test at 20 °C according to EN 17111:2018 (E) under clean condition

EXPERT OPINION*

This expert opinion is based on the test report VX-TR-23-0488 dated 09 February 2023.

The virucidal activity of the disinfectant F3307 of Sodel against *Adenovirus,* ATCC VR-5 and *Murine norovirus* FLI-RVB-0651 was investigated by a quantitative carrier test according to EN 17111:2018 (E) under clean condition (0.30 g/L bovine albumin solution s).

According to this carrier test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virucidal activity if the virus titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥99.99 %) within the recommended exposure period.

F3307 was examined at 20 °C at the concentration(s) of 80.00 %, 70.00 % and 0.10 % for the exposure time(s) of 10 minutes. After the exposure time(s), the viral reduction exceeded 4 $\log_{10}$-steps in all assays at 80.00 % and 70.00 %. However, the viral reduction did not exceed 4 $\log_{10}$-steps in all assays at the concentration(s) of 0.10 %. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance for *Murine norovirus* FLI-RVB-0651 and < 50% risk of false acceptance for *Adenovirus* ATCC VR-5 at the concentration(s) of 80.00 % and 70.00 %; and a minimal risk of false rejection at concentration(s) of 0.10 %. Therefore, a virucidal activity against *Adenovirus,* ATCC VR-5 and *Murine norovirus* FLI-RVB-0651 was measured as follows:

Clean condition	80.00 %	10 minutes
Clean condition	70.00 %	10 minutes

Kuala Lumpur, 09 February 2023

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Dr Syazani Suhaimi
Microbiologist

HUBERT YONG JUN FUNG 2023.02.13 15:21:42 +08'00'

Hubert Yong
Microbiologist

* Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Appendix 1

QAU CERTIFICATE*

The results stated in test report VX-TR-23-0488 dated 09 February 2023 were compared to the raw data of the tests and checked for correct transfer. No deviations were detected.

Kuala Lumpur, 09 February 2023

HUBERT YONG JUN FUNG
2023.02.13 15:21:59 +08'00'

Hubert Yong
Microbiologist

* Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

Appendix 2 Raw data

Test Method	EN 17111:2018			**Titration Method**	Quantal test		
Product	F3307			**Batch No.**	0209E036221028Z		
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0011		
Test Organism	Adenovirus, strain Adenoid 75, ATCC VR-5			**Passage No.**	6		
Cell Line	Vero cells, ATCC CCL-81			**Passage No.**	7		
Interfering Substance	0.30 g/L bovine albumin solution			**Inactivation Method**		Immediate dilution	
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Carrier Drying Time (min)**		48	
Assay Test Date	31/01/2023		**Analyzed By**	SSU	**Verified By**		HYO

Validation and Control Procedures

	Product Concentration	Dilution	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\Delta TCID_{50}$ < 1 lg
Cell Susceptibility Control	PBS	Without	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 4 2 3 4 3 2 1	3 0 0 0 0 1 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.75 ± 0.33	Pass?
	100.00 %	1:1000	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 3 2 1 4 2 1 0	3 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.50 ± 0.35	**Yes**

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\lvert TCID_{50} - V_C \rvert$ ≤ 0.5 lg
Suppression Efficiency Control	100.00 %	30	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 3 3 4 3 2 4	4 4 4 4 4 4 3 4	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.50 ± 0.00	Pass?
	Virus Control (V_c)	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	1 2 4 0 3 4 3 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.25 ± 0.33	
		30	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 3 4 4 4 2	3 4 3 1 2 3 2 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	6.38 ± 0.25	**Yes**

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	lg R = N_W - Na
Reference Test	5000 ppm Gluteraldehyde	5	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	≥4.00 ± 0.00
	Water Control (N_W)	5	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 3 4 2 3 4 4 3	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	5.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	80.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
														N_W - CE ≥ 4
														Pass? **Yes**
	Water Control (N_{W1})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 3 4 2 3 4 4 3	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	5.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	80.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
														N_W - CE ≥ 4
														Pass? **Yes**
	Water Control (N_{W2})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 4 3 4 4 2 4 0	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	5.50 ± 0.35	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (minutes)	First Assay log_{10} $TCID_{50}$/ml	First Assay lg $R_1 = N_{W1} - Na_1$	Second Assay log_{10} $TCID_{50}$/ml	Second Assay lg $R_2 = N_{W2} - Na_2$	Average Reduction (lg R)
	80.00 %	10	≤1.50 ± 0.00	≥4.00 ± 0.00	≤1.50 ± 0.00	≥4.00 ± 0.35	≥4.00 ± 0.25

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	70.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
														N_W - CE ≥ 4
														Pass? **Yes**
	Water Control (N_{W1})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 3 4 2 3 4 4 3	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	5.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	70.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
														N_W - CE ≥ 4
														Pass? **Yes**
	Water Control (N_{W2})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 4 3 4 4 2 4 0	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	5.50 ± 0.35	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (minutes)	First Assay log_{10} $TCID_{50}$/ml	First Assay lg $R_1 = N_{W1} - Na_1$	Second Assay log_{10} $TCID_{50}$/ml	Second Assay lg $R_2 = N_{W2} - Na_2$	Average Reduction (lg R)
	70.00 %	10	≤1.50 ± 0.00	≥4.00 ± 0.00	≤1.50 ± 0.00	≥4.00 ± 0.35	≥4.00 ± 0.25

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	0.10 %	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 2 3	0 0 0 0 2 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	4.63 ± 0.25	N_W - CE ≥ 4 Pass? **Yes**
	Water Control (N_{W1})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 3 4 2 3 4 4 3	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	5.50 ± 0.00	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	0.10 %	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 3 4 2 3 2	2 1 0 0 2 3 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	5.00 ± 0.38	N_W - CE ≥ 4 Pass? **Yes**
	Water Control (N_{W2})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	2 4 3 4 4 2 4 0	2 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	5.50 ± 0.35	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	First Assay log_{10} $TCID_{50}$/ml	First Assay lg R_1 = N_{W1} - Na_1	Second Assay log_{10} $TCID_{50}$/ml	Second Assay lg R_2 = N_{W2} - Na_2	Average Reduction (lg R)
Average Reduction (lg R)	0.10 %	10	4.63 ± 0.25	0.87 ± 0.25	5.00 ± 0.38	0.50 ± 0.52	0.69 ± 0.41

Appendix 2 Raw data

Test Method	EN 17111:2018			**Titration Method**	Quantal test	
Product	F3307			**Batch No.**	0209E036221028Z	
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0011	
Test Organism	Murine norovirus, strain S99 Berlin, FLI-RVB-0651			**Passage No.**	2	
Cell Line	RAW 264.7 cells, ATCC TIB-71			**Passage No.**	13	
Interfering Substance	0.30 g/L bovine albumin solution			**Inactivation Method**	Immediate dilution	
Test Temperature (°C)	20	**Incubation Temperature (°C)**	36	**Carrier Drying Time (min)**	51	
Assay Test Date	10/01/2023		**Analyzed By**	SSU	**Verified By**	HYO

Validation and Control Procedures

	Product Concentration	Dilution	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\Delta TCID_{50}$ < 1 lg
Cell Susceptibility Control	PBS	Without	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 3 4	4 4 0 0 3 3 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.00 ± 0.38	Pass?
	100.00 %	1:1000	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 2 3 4 3 4 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.50 ± 0.00	**Yes**

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	$\lvert TCID_{50} - V_C \rvert$ ≤ 0.5 lg
Suppression Efficiency Control	100.00 %	30	t t t t t t t t	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 3 0 0 3 0 0 2	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.00 ± 0.38	Pass?
	Virus Control (V_c)	0	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 3 4	4 3 0 0 3 4 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.00 ± 0.38	
		30	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	3 4 0 0 4 0 2 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d	7.00 ± 0.38	**Yes**

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	lg R = N_W - Na
Reference Test	5000 ppm Gluteraldehyde	5	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	≥4.63 ± 0.37
	Water Control (N_W)	5	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 3 4 4 4 4	4 4 3 0 2 4 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	6.13 ± 0.37	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	80.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
														N_W - CE ≥ 4
														Pass? **Yes**
	Water Control (N_{W1})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 3 4 4 4 4	4 4 3 0 2 4 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	6.13 ± 0.37	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	80.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
														N_W - CE ≥ 4
														Pass? **Yes**
	Water Control (N_{W2})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 3 4	4 0 3 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	6.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (minutes)	First Assay log_{10} $TCID_{50}$/ml	First Assay lg $R_1 = N_{W1} - Na_1$	Second Assay log_{10} $TCID_{50}$/ml	Second Assay lg $R_2 = N_{W2} - Na_2$	Average Reduction (lg R)
	80.00 %	10	≤1.50 ± 0.00	≥4.63 ± 0.37	≤1.50 ± 0.00	≥5.25 ± 0.33	≥4.94 ± 0.35

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	70.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
														N_W - CE ≥ 4
														Pass? **Yes**
	Water Control (N_{W1})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 3 4 4 4 4	4 4 3 0 2 4 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	6.13 ± 0.37	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	70.00 %	10	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	
														N_W - CE ≥ 4
														Pass? **Yes**
	Water Control (N_{W2})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 3 4	4 0 3 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	6.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

Average Reduction (lg R)	Product Concentration	Contact Time (minutes)	First Assay log_{10} $TCID_{50}$/ml	First Assay lg $R_1 = N_{W1} - Na_1$	Second Assay log_{10} $TCID_{50}$/ml	Second Assay lg $R_2 = N_{W2} - Na_2$	Average Reduction (lg R)
	70.00 %	10	≤1.50 ± 0.00	≥4.63 ± 0.37	≤1.50 ± 0.00	≥5.25 ± 0.33	≥4.94 ± 0.35

Appendix 2 Raw data

Test Procedure

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
First Assay (Na_1)	0.10 %	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 3 0 0 0 4 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	4.88 ± 0.37	N_W - CE ≥ 4 Pass? **Yes**
	Water Control (N_{W1})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 3 4 4 4 4	4 4 3 0 2 4 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	6.13 ± 0.37	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	Dilution (log_{10}) 1	2	3	4	5	6	7	8	9	10	log_{10} $TCID_{50}$/ml	
Second Assay (Na_2)	0.10 %	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 0 0 4 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	n.d.	n.d.	4.88 ± 0.37	N_W - CE ≥ 4 Pass? **Yes**
	Water Control (N_{W2})	10	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4	4 4 4 4 4 4 3 4	4 0 3 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d.	n.d.	6.75 ± 0.33	
	Cytotoxicity Effect (CE)	-	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0	n.d	n.d.	n.d.	n.d.	n.d.	1.50 ± 0.00	

	Product Concentration	Contact Time (minutes)	First Assay log_{10} $TCID_{50}$/ml	First Assay lg $R_1 = N_{W1} - Na_1$	Second Assay log_{10} $TCID_{50}$/ml	Second Assay lg $R_2 = N_{W2} - Na_2$	Average Reduction (lg R)
Average Reduction (lg R)	0.10 %	10	4.88 ± 0.37	1.25 ± 0.52	4.88 ± 0.37	1.87 ± 0.50	1.56 ± 0.51

Note

$TCID_{50}$: The dilution of the virus suspension that induces a cytopathic effect (CPE) in 50 % of cell culture units

CPE: The morphological alteration of cells and/or their destruction caused by the cytopathic effect of virus multiplication

V_C: log_{10} $TCID_{50}$ per ml in the viral test suspension at the beginning and at the maximum contact time

N_w: log_{10} $TCID_{50}$ per ml in water control at the end of the contact time

N_a: log_{10} $TCID_{50}$ per ml in the product test solution at the end of the contact time

CE: The morphological alteration of cells caused by the cytotoxicity effect of the product test solution

A: log_{10} $TCID_{50}$ per ml in the cell susceptibility control as compared to PBS

B: log_{10} $TCID_{50}$ per ml in the suppression efficiency control as compared to the virus control

C: log_{10} $TCID_{50}$ per ml in the reference test for virus inactivation after 5 minutes

Appendix 3 Summary of test description

1. Virus and cells

1.1 *Adenovirus, strain Adenoid 75,* ATCC VR-5

1.1.1. Passage no.: 6

1.1.2. Cell line: Vero cells, ATCC CCL-81

1.1.3. Cell line passage no.: 7

1.1.4. Culture medium: EMEM

1.2. *Murine norovirus, strain S99 Berlin,* FLI-RVB-0651

1.2.1. Passage no.: 2

1.2.2. Cell line: RAW 264.7 cells, ATCC TIB-71

1.2.3. Cell line passage no.: 13

1.2.4. Culture medium: DMEM

2. Materials and reagents

2.1. Eagle's Minimal Essential Medium (EMEM, Sigma, catalogue no. M3024)

2.2. Dulbecco's Modified Eagle Medium (DMEM, Sigma, catalogue no. D7777)

2.3. Fetal Bovine Serum (FBS, Sigma, catalogue no. F7524)

2.4. Formaldehyde (Merck, catalogue no. 1.0.4003.2500)

2.5. Dulbecco's Phosphate Buffered Saline (PBS, Sigma, catalogue no. P3813)

2.6. Bovine albumin fraction V (Merck, catalogue no. K49238418733)

2.7. Defibrinated sheep blood (Hemostat, catalogue no. DSB100) (for dirty condition only)

3. Apparatus and glassware

3.1. CO_2 incubator (Memmert, model ICO 105)

3.2. Cooling water bath (Memmert, model WNB7 with CDP115)

3.3. Inverted microscope (Optika, IM-2)

3.4. Vortex® mixer (Biosan model Biosan V-1 Plus)

3.5. Microtitre plate (NEST)

3.6. Tissue culture flask (JET Biofil)

4. Test procedure

4.1. Preparation of test virus suspension

4.1.1. Cell monolayers shall be >90 % confluent before inoculation. Cell lines are selected in accordance with their sensitivity to the test organisms.

4.1.2. The test organisms and their stock cultures shall be prepared and kept in accordance with EN 12353:2013 (E).

4.1.3. The stock virus suspension is multiplied in an appropriate cell line that produces high titres of infectious viruses for 1 hour at 36 °C with intermittent tilting every 15 minutes.

4.1.4. The cells are subjected to 3 freeze/thaw cycles once cytopathic effect (CPE) is observed in 80 % of the cell population.

4.1.5. Separate the cells debris is by centrifugation at 400 g_N for 15 minutes.

4.1.6. Aliquot the supernatant containing the test virus suspension and store at -80 °C.

4.2. Test Na – Determination of virucidal concentrations

4.2.1. Pipette 1 part of interfering substance into a tube. Add 9 parts of the test suspension. Mix and pipette 0.05 ml of this mixture on the inoculation square of a carrier and distribute equally inside the square. Let the inoculum dry in the incubator until visible dryness but no longer than 60 minutes. Use the carrier immediately after the end of the drying time.

4.2.2. Pipette 10 ml of one of the product test solutions into a cylindrical screw tube placed in a water bath controlled at the chosen test temperature of θ.

4.2.3. Immerse an inoculated carrier immediately after the drying process has been finished. Ensure that the inoculation square is completely covered by the product test solution.

4.2.4. Start the stopwatch and leave for the chosen contact time t.

4.2.5. At the end of *t*, transfer the carrier into a second cylindrical screw tube placed in a water bath controlled at 20 ºC and filled with 5 ml of medium and approximately 1 ml of glass beads.

4.2.6. Restart the stopwatch and mix for 60 seconds.

4.2.7. Immediately after elution, prepare a series of ten-fold dilutions of the virus suspension in ice-cold maintenance medium.

4.2.8. Transfer 0.1 ml of each dilution into six or eight wells of a microtitre plate containing a confluent (>90 %) cell monolayer without any medium.

4.2.9. The last row of six or eight wells will receive 0.1 ml of culture medium and will serve as the cell control.

4.2.10. After 1 hour of incubation at 37 °C, 0.1 ml of cell culture medium is added to each well.

4.2.11. Perform the procedure using the other product test solutions at the same time.

4.2.12. Perform the procedure applying the other obligatory and – if appropriate – other additional experimental conditions.

4.3. **Water control Nw**

4.3.1. Perform Section 4.2 but instead of the product test solution, pipette 10 ml of distilled water. In the case of ready-to-use products, water instead of hard water.

4.3.2. Serial dilutions are prepared in the culture medium and are inoculated into cell monolayers.

4.3.3. After incubation, the virus titre is calculated. The reduction of virus infectivity is determined from differences of water control Nw and after treatment with the product Na.

4.4. **Cytotoxicity effect – determination of the morphological alteration of cells caused by the product test solution**

4.4.1. Mix 45 µl cell culture media with 2% FBS with 5 µl of interfering substance.

4.4.2. Inoculate the mixture on carrier and dry the surface.

4.4.3. Immerse the inoculated carrier immediately after the drying process in 10 ml of the product test solution, and placed in a water bath controlled at the chosen test temperature of θ.

4.4.4. Start the stopwatch and leave for the chosen contact time t.

4.4.5. At the end of t, transfer the carrier into a second cylindrical screw tube placed in a water bath controlled at 20 ºC and filled with 5 ml of medium and approximately 1 ml of glass beads.

4.4.6. Restart the stopwatch and mix for 60 seconds.

4.4.7. Immediately after elution, prepare a series of ten-fold dilutions of the virus suspension in ice-cold maintenance medium.

4.4.8. Any microscopic changes in the cells are recorded when reading the tests for CPE.

4.4.9. If the cytotoxicity is so great that the residual infectivity titre is smaller than the required $\log_{10}$ $TCID_{50}$, special techniques have to be used, such as molecular sieving or ultrafiltration. Follow the instructions of the manufacturer.

4.5. **Cell susceptibility control A – Verification of the susceptibility of the cells for virus infection is not influenced negatively by the treatment with the product test solution**

4.5.1. Comparative virus titrations are performed on cells that have or have not been treated with product test solution to check the reduction of the sensitivity to viruses.

4.5.2. 0.10 ml of the lowest apparently non-cytotoxic dilution (no microscopic alteration) of the product test solution or PBS and 0.10 ml of culture medium are distributed onto each of 6 established cell cultures in 96-well microtitre plates.

4.5.3. After 1 hour of incubation at 37 °C, the supernatant is discarded.

4.5.4. The virus is diluted from 10^{-1} to 10^{-10} and titrated on the treated or untreated cells.

4.5.5. Verify according to Section 4.9.

4.6. **Suppression efficiency control B – Immediate dilution method validation**

4.6.1. Pipette 1 part of interfering substance into a tube. Add 1 part of cell culture media with 2% FBS and mix with 8 parts of the product test solution.

4.6.2. Pipette 0.50 ml of the mixture into 4.0 ml ice-cold medium. Add 0.50 ml of the test virus suspension. Mix again and start the clock. Incubate the mixture in the ice bath for 30 minutes ± 10 seconds.

4.6.3. Immediately prepare dilutions up to 10^{-8} and titrate the virus.

4.6.4. This control is performed in parallel to the test.

4.6.5. Verify according to Section 4.9.

4.7. **Reference test for virus inactivation C – Validation of the test system**

4.7.1. A control of the test system using Glutardialdehyde as a reference are performed according to 4.2.

4.7.2. All tests shall be done for 5 minutes.

4.7.3. Verify according to Section 4.9.

4.8. **Titration of the virus control**

4.8.1. The infectivity of the test suspension shall be determined under test conditions at the beginning of the contact time and at the maximum contact time used in the test.

4.8.2. The product test solution is substitute with hard water or water for ready-to-use products.

4.8.3. Verify according to Section 4.9.

4.9. **Verification of methodology**

4.9.1. The titre of the test suspension of at least 10^8 $TCID_{50}$/mL is sufficiently high to at least enable a titre reduction of 4 log to verify the method (Nw-Na). The detectable titre reduction shall be at least 4 log.

4.9.2. Cytotoxicity of the product test solution does not affect cell morphology and growth or susceptibility for the test organism in the dilutions of the test mixtures which are necessary to demonstrate a 4-log reduction of the virus.

4.9.3. Comparative virus titration on cells cultures treated with test mixture dilutions and in parallel with PBS (cell susceptibility control) result in a difference of <1 log of virus titre.

4.9.4. The difference to the test suspension in the control of efficiency for suppression of products' activity shall be ≤0.5 log.

4.9.5. The difference between the logarithmic titre of the virus control and the logarithmic titre of the test organism in the reference inactivation test is ≥ 4 log within 5 minutes.

5. Literature

5.1. EN 17111:2018 (E): Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)

5.2. EN 14885:2015 (E): Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics

5.3. EN 12353:2013 (E): Chemical disinfectants and antiseptics – Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

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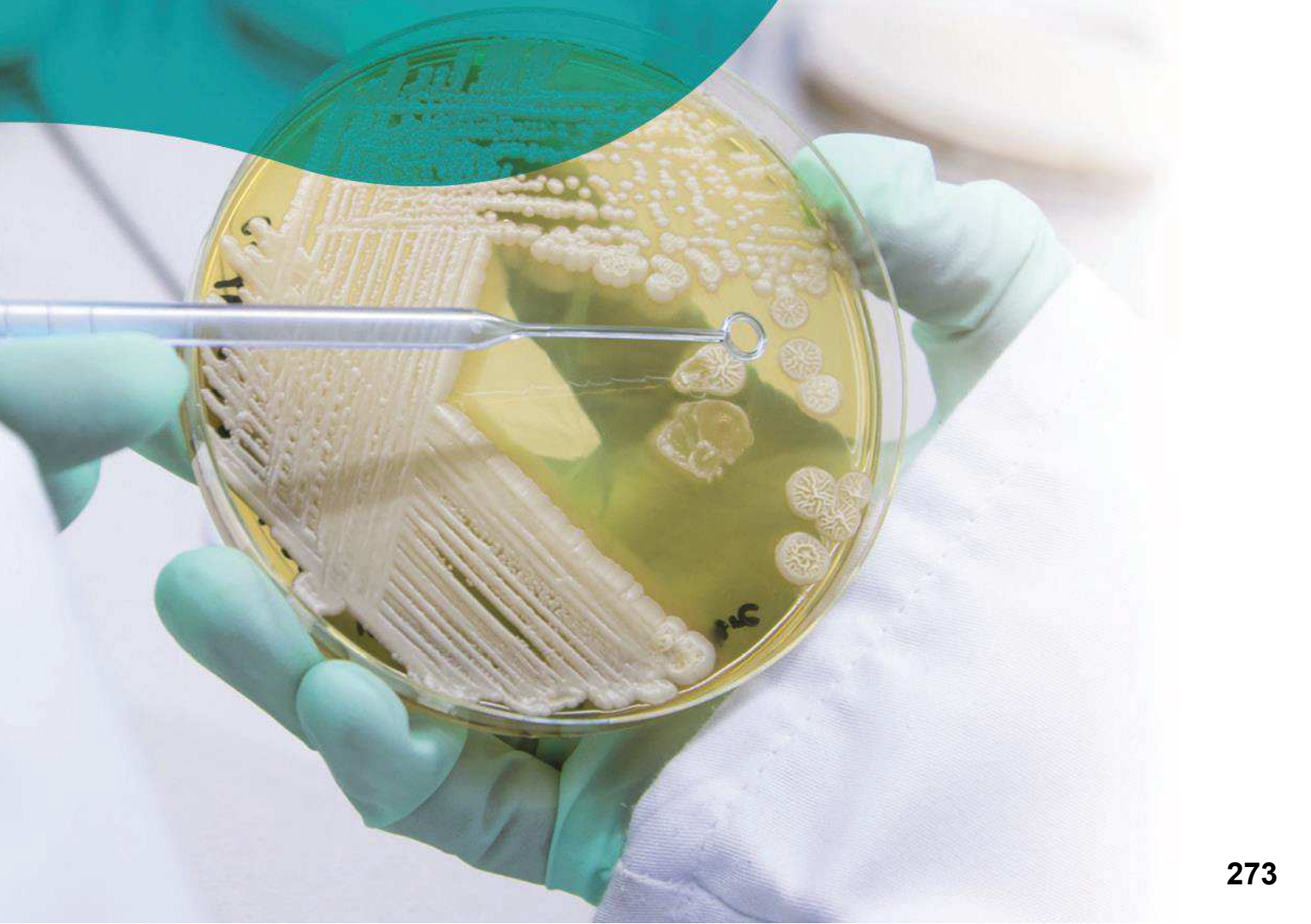

Test Report No.: VX-TR-23-0503
Copy No.: 1

DETERMINATION OF THE SPORICIDAL ACTIVITY (EN 17126) OF F3307

Lab No.:	VX-268-22-0011
Sample Name:	F3307
Method:	EN 17126:2018 (E) Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area – Test method and requirements (phase 2, step 1)
Client:	Sodel 190 rue René Barthélemy 14100 Lisieux France
Sample Receipt Date:	07 November 2022
Report Date:	14 February 2023

Kuala Lumpur, 14 February 2023

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Materials and Method

Quantitative suspension test for the evaluation of sporicidal activity of chemical in the medical area according to EN 17126:2018 (E)

1. Testing laboratory identification

Viroxy Sdn. Bhd.
6th Floor, Menara RKT
50300 Kuala Lumpur
Malaysia

2. Sample identification

2.1	Batch no.:	0209E036221028Z
2.2	Product appearance:	Clear, bluish solution
2.3	Manufacturer:	Sodel 190 rue René Barthélemy 14100 Lisieux France
2.4	Active substances:	0.54 % Orthophthalaldehyde
2.5	Sample receipt date:	07 November 2022
2.7	Storage conditions:	Room temperature
2.8	Product diluent:	Distilled water

3. Experimental conditions

3.1	Testing period:	26 January 2023
3.2	Test organism(s):	*Clostridium difficile* NCTC 13366
3.3	Concentration / contact time:	0.10 % / 15 and 30 minutes 70.00 % / 15 and 30 minutes 80.00 % / 15 and 30 minutes
3.4	Loading:	0.30 g/L bovine albumin solution
3.5	Test temperature:	20 °C ± 1 °C
3.6	Counting method:	Pour plate
3.7	Incubation period:	5 days, 36 °C ± 1 °C

4. Test method and its validation

4.1	Testing method:	Dilution-neutralization

4.2 Inactivation combination: 30.00 g/L Tween 80
20.00 g/L Sodium thiosulphate
3.00 g/L Lecithin
0.25 g/L Catalase
in tryptone soya broth

The results of validation tests A, B, and C proved the viability of the method in all cases.

5. Test results

The results are stated in Tables A and B.

6. Conclusion

F3307 did not show the required microbial reduction of ≥4.0 $\log_{10}$ against test strain(s) *Clostridium difficile* NCTC 13366 in accordance with EN 17126:2018 (E) at 0.10 % concentration(s) after 15 and 30 minutes under the stated conditions. According to the simple acceptance decision rule†, there is a minimal risk of false rejection.

F3307 showed the required microbial reduction of ≥4.0 $\log_{10}$ against test strain(s) *Clostridium difficile* NCTC 13366 in accordance with EN 17126:2018 (E) at 70.00 % and 80.00 % concentration(s) after 15 and 30 minutes under the stated conditions. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance.

Kuala Lumpur, 14 February 2023

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7. Note

Sporicidal activity – the capability of a product to produce a reduction in the number of viable spores belonging to reference strains under defined conditions by at least 4 orders (10^4).

$R = N_0/N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Table A: Evaluation of the sporicidal activity of F3307 on test strain(s) according to EN 17126

Product: F3307
Loading: 0.30 g/L bovine albumin solution

Test strain: *Clostridium difficile* NCTC 13366

N	V_{C1}	V_{C2}	Test suspension, N
10^{-5}	>330	>330	N: 4.05×10^7 N_0: 4.05×10^6 lg N_0: **6.61**
10^{-6}	40	41	

Test concentration (%) / contact time (min)	Dilution	V_{C1}	V_{C2}	Test procedure, N_a $N_a = \bar{x} \times 10$
0.10 / 15	10^0	>330	>330	N_a: $>3.30 \times 10^4$ lg N_a: **>4.52** lg R: **<2.09**
	10^{-1}	>330	>330	
0.10 / 30	10^0	>330	>330	N_a: $>3.30 \times 10^4$ lg N_a: **>4.52** lg R: **<2.09**
	10^{-1}	>330	>330	
70.00 / 15	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>4.46**
	10^{-1}	<14	<14	
70.00 / 30	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>4.46**
	10^{-1}	<14	<14	
80.00 / 15	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>4.46**
	10^{-1}	<14	<14	
80.00 / 30	10^0	<14	<14	N_a: $<1.40 \times 10^2$ lg N_a: **<2.15** lg R: **>4.46**
	10^{-1}	<14	<14	

Table B: Control tests and method validation for Table A

Test strain	Validation suspension	Validation of experimental conditions	Neutralizer toxicity or filtration control	Method validation control
C. difficile NCTC 13366	N_{V0}: 1.18 x 10^2 N_{VB}: 1.16 x 10^2	A: 1.14 x 10^2	B: 1.27 x 10^2	C: 9.15 x 10^1

Note

cfu: Colony forming units

V_C: Number of cfu counted per 1.0 ml sample

$\bar{x}$: Average V_{C1} and V_{C2} values

N: Number of cfu per ml in the test suspension

N_0: Number of cfu per ml at the beginning of the contact time

N_{V0}: Number of cfu per ml in the mixtures A, B, and C at the beginning of the contact time

N_a: Number of survivors per ml in the test mixture at the end of the contact time and before neutralization

A: Number of cfu per ml in the experimental conditions control

B: Number of cfu per ml in the neutralizer toxicity or filtration control

C: Number of cfu per ml in the dilution-neutralization or membrane filtration method validation

Table C: Summary of the log reductions of the quantitative suspension test according to EN 17126

Test strain	Test concentration (%) / contact time (min)	Log reduction	Percentage reduction (%)	Associated risk†
C. difficile NCTC 13366	0.10 / 15	**<2.09 ± 0.04**	**<99**	Minimal risk of false rejection
	0.10 / 30	**<2.09 ± 0.04**	**<99**	Minimal risk of false rejection
	70.00 / 15	**>4.46 ± 0.04**	**>99.99**	Minimal risk of false acceptance
	70.00 / 30	**>4.46 ± 0.04**	**>99.99**	Minimal risk of false acceptance
	80.00 / 15	**>4.46 ± 0.04**	**>99.99**	Minimal risk of false acceptance
	80.00 / 30	**>4.46 ± 0.04**	**>99.99**	Minimal risk of false acceptance

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Sodel
190 rue René Barthélemy
14100 Lisieux
France

Efficacy of F3307 against *Clostridium difficile* NCTC 13366 in a quantitative suspension test at 20 ˚C according to EN 17126:2018 (E) under clean condition

EXPERT OPINION*

This expert opinion is based on the test report VX-TR-23-0503 dated 14 February 2023.

The sporicidal activity of the disinfectant F3307 of Sodel against *Clostridium difficile* NCTC 13366 was investigated by a quantitative suspension test according to EN 17126:2018 (E) under clean condition (0.30 g/L bovine albumin solution).

According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having sporicidal activity if the number of viable spores is reduced by ≥4 $\log_{10}$ (inactivation ≥99.99 %) within the recommended exposure period.

F3307 was examined at 20 ˚C at the concentration(s) of 0.10%, 70.00 % and 80.00 % for the exposure time(s) of 15 and 30 minutes against *Clostridium difficile* NCTC 13366. After the exposure time(s), the spore reduction exceeded 4 $\log_{10}$-steps in all assays except for 0.10 %. According to the simple acceptance decision rule†, there is a minimal risk of false acceptance for 70.00 % and 80.00 % and a minimal risk of false rejection for 0.10 %. Therefore, a sporicidal activity against *Clostridium difficile* NCTC 13366 was measured as follows:

Clean condition	70.00 %	15 and 30 minutes
Clean condition	80.00 %	15 and 30 minutes

Kuala Lumpur, 14 February 2023

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* Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

† The decision rule applied is simple acceptance rule with no guard band and up to 50 % risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

Appendix 1

QAU CERTIFICATE*

The results stated in test report VX-TR-23-0503 dated 14 February 2023 were compared to the raw data of the tests and checked for correct transfer. No deviations were detected.

Kuala Lumpur, 14 February 2023

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Appendix 2 Raw data

Test Method	EN 17126:2018				
Product	F3307			**Batch No.**	0209E036221028Z
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0011
Test Organism	*Clostridium difficile NCTC 13366*				
Interfering Substance	0.30 g/L bovine albumin solution				
Test Temperature (°C)	20		**Incubation Temperature (°C)**		36
Neutralizer or Rinsing Liquid	30.0 g/L Tween 80, 20.0 g/L Sodium thiosulphate, 3.00 g/L Lecithin, 0.25g/L Catalase in Tryptone soya broth				
Inactivation Method	Dilution-neutralization			**Plating Method**	Pour plate
Test Date	26/01/2023	**Analyzed By**	EZA	**Verified By**	PCH

Test and Validation Suspension

	N	V_{C1}	V_{C2}		
Test Suspension (N)				$\bar{x}_{wm}$ = N = 4.05E+07	N_0 = N/10
	10^{-5}	>330	>330	lg N_0 = 6.61	6.17 ≤ lg N_0 ≤ 6.70
	10^{-6}	40	41	Pass?	**Yes**

	V_{C1}	V_{C2}		
Validation Suspension (N_V)			N_{V0} = 118.0	N_{V0} = N_V/10
	112	124	30 ≤ N_{V0} ≤ 160	Pass? **Yes**
Validation Suspension (N_{VB})	V_{C1}	V_{C2}	N_{V0} = 115.5	N_{V0} = N_{VB}/1000
	115	116	30 ≤ N_{V0} ≤ 160	Pass? **Yes**

Validation and Control Procedures

	V_{C1}	V_{C2}		
Experimental Conditions Control (A)			A = 113.5	Pass? **Yes**
	121	106	A ≥ 0.5 x Nv/10	
Neutralizer Toxicity or Filtration Control (B)	V_{C1}	V_{C2}	B = 126.5	Pass? **Yes**
	119	134	B ≥ 0.5 x N_{VB}/1000 or Nv/10	
Method Validation (C)	V_{C1}	V_{C2}	C = 91.5	Pass? **Yes**
Concentration: 80 %	97	86	C ≥ 0.5 x Nv/10	

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg N_0 - lg Na
0.10 %	15	10^0	>330	>330	>3.30E+04	>4.52	<2.09
		10^{-1}	>330	>330			
		10^{-2}	-	-			
		10^{-3}	-	-			
0.10 %	30	10^0	>330	>330	>3.30E+04	>4.52	<2.09
		10^{-1}	>330	>330			
		10^{-2}	-	-			
		10^{-3}	-	-			
		10^0					
		10^{-1}					
		10^{-2}					
		10^{-3}					

Raw Data of Colony Count

	N $^{-5}$	N $^{-6}$	N_V	N_{VB}	A	B	C
V_{C1}	>330	40	112	115	121	119	97
V_{C2}	>330	41	124	116	106	134	86

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
0.10 %	15	>330	>330	>330	>330	-	-	-	-
0.10 %	30	>330	>330	>330	>330	-	-	-	-

Appendix 2 Raw data

Test Method	EN 17126:2018				
Product	F3307			**Batch No.**	0209E036221028Z
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0011
Test Organism	*Clostridium difficile NCTC 13366*				
Interfering Substance	0.30 g/L bovine albumin solution				
Test Temperature (°C)	20	**Incubation Temperature (°C)**		36	
Neutralizer or Rinsing Liquid	30.0 g/L Tween 80, 20.0 g/L Sodium thiosulphate, 3.00 g/L Lecithin, 0.25g/L Catalase in Tryptone soya broth				
Inactivation Method	Dilution-neutralization			**Plating Method**	Pour plate
Test Date	26/01/2023	**Analyzed By**	EZA	**Verified By**	PCH

Test and Validation Suspension

	N	V_{C1}	V_{C2}		
Test Suspension (N)				$\bar{x}_{wm}$ = N = 4.05E+07	N_0 = N/10
	10^{-5}	>330	>330	lg N_0 = 6.61	6.17 ≤ lg N_0 ≤ 6.70
	10^{-6}	40	41	Pass?	**Yes**

	V_{C1}	V_{C2}		
Validation Suspension (N_V)			N_{V0} = 118.0	N_{V0} = N_V/10
	112	124	30 ≤ N_{V0} ≤ 160	Pass? **Yes**
Validation Suspension (N_{VB})	V_{C1}	V_{C2}	N_{V0} = 115.5	N_{V0} = N_{VB}/1000
	115	116	30 ≤ N_{V0} ≤ 160	Pass? **Yes**

Validation and Control Procedures

	V_{C1}	V_{C2}		
Experimental Conditions Control (A)			A = 113.5	Pass? **Yes**
	121	106	A ≥ 0.5 x Nv/10	
Neutralizer Toxicity or Filtration Control (B)	V_{C1}	V_{C2}	B = 126.5	Pass? **Yes**
	119	134	B ≥ 0.5 x N_{VB}/1000 or Nv/10	
Method Validation (C)	V_{C1}	V_{C2}	C = 91.5	Pass? **Yes**
Concentration: 80 %	97	86	C ≥ 0.5 x Nv/10	

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg N_0 - lg Na
70 %	15	10^0	<14	<14	<1.40E+02	<2.15	>4.46
		10^{-1}	<14	<14			
		10^{-2}	-	-			
		10^{-3}	-	-			
70 %	30	10^0	<14	<14	<1.40E+02	<2.15	>4.46
		10^{-1}	<14	<14			
		10^{-2}	-	-			
		10^{-3}	-	-			
		10^0					
		10^{-1}					
		10^{-2}					
		10^{-3}					

Raw Data of Colony Count

	N^{-5}	N^{-6}	N_V	N_{VB}	A	B	C
V_{C1}	>330	40	112	115	121	119	97
V_{C2}	>330	41	124	116	106	134	86

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
70 %	15	0	0	0	0	-	-	-	-
70 %	30	0	0	0	0	-	-	-	-

Appendix 2 Raw data

Test Method	EN 17126:2018				
Product	F3307			**Batch No.**	0209E036221028Z
Product Diluent	Distilled water			**Lab No.**	VX-268-22-0011
Test Organism	*Clostridium difficile NCTC 13366*				
Interfering Substance	0.30 g/L bovine albumin solution				
Test Temperature (°C)	20		**Incubation Temperature (°C)**		36
Neutralizer or Rinsing Liquid	30.0 g/L Tween 80, 20.0 g/L Sodium thiosulphate, 3.00 g/L Lecithin, 0.25g/L Catalase in Tryptone soya broth				
Inactivation Method	Dilution-neutralization			**Plating Method**	Pour plate
Test Date	26/01/2023	**Analyzed By**	EZA	**Verified By**	PCH

Test and Validation Suspension

	N	V_{C1}	V_{C2}		
Test Suspension (N)				$\bar{x}_{wm}$ = N = 4.05E+07	N_0 = N/10
	10^{-5}	>330	>330	lg N_0 = 6.61	6.17 ≤ lg N_0 ≤ 6.70
	10^{-6}	40	41	Pass?	**Yes**

	V_{C1}	V_{C2}		
Validation Suspension (N_V)			N_{V0} = 118.0	N_{V0} = N_V/10
	112	124	30 ≤ N_{V0} ≤ 160	Pass? **Yes**
Validation Suspension (N_{VB})	V_{C1}	V_{C2}	N_{V0} = 115.5	N_{V0} = N_{VB}/1000
	115	116	30 ≤ N_{V0} ≤ 160	Pass? **Yes**

Validation and Control Procedures

	V_{C1}	V_{C2}		
Experimental Conditions Control (A)			A = 113.5	Pass? **Yes**
	121	106	A ≥ 0.5 x Nv/10	
Neutralizer Toxicity or Filtration Control (B)	V_{C1}	V_{C2}	B = 126.5	Pass? **Yes**
	119	134	B ≥ 0.5 x N_{VB}/1000 or Nv/10	
Method Validation (C)	V_{C1}	V_{C2}	C = 91.5	Pass? **Yes**
Concentration: 80 %	97	86	C ≥ 0.5 x Nv/10	

Test Procedure

Product Concentration	Contact Time (minutes)	Dilution	V_{C1}	V_{C2}	Na = $\bar{x}$ or $\bar{x}_{wm}$ x 10	lg Na	lg R = lg N_0 - lg Na
80 %	15	10^0	<14	<14	<1.40E+02	<2.15	>4.46
		10^{-1}	<14	<14			
		10^{-2}	-	-			
		10^{-3}	-	-			
80 %	30	10^0	<14	<14	<1.40E+02	<2.15	>4.46
		10^{-1}	<14	<14			
		10^{-2}	-	-			
		10^{-3}	-	-			
		10^0					
		10^{-1}					
		10^{-2}					
		10^{-3}					

Raw Data of Colony Count

	N $^{-5}$	N $^{-6}$	N_V	N_{VB}	A	B	C
V_{C1}	>330	40	112	115	121	119	97
V_{C2}	>330	41	124	116	106	134	86

Product Concentration	Contact Time (minutes)	Na^0		Na^{-1}		Na^{-2}		Na^{-3}	
		V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}	V_{C1}	V_{C2}
80 %	15	0	0	0	0	-	-	-	-
80 %	30	0	0	0	0	-	-	-	-

Note

cfu: Colony forming units.

V_C: Number of cfu counted per 1.0 ml sample.

$\bar{x}$: Average V_{C1} and V_{C2} values

N: Number of cfu per ml in the test suspension

N_0: Number of cfu per ml at the beginning of the contact time

N_{V0}: Number of cfu per ml in the mixtures A, B, and C at the beginning of the contact time

N_a: Number of survivors per ml in the test mixture at the end of the contact time and before neutralization

A: Number of cfu per ml in the experimental conditions control

B: Number of cfu per ml in the neutralizer toxicity or filtration control

C: Number of cfu per ml in the dilution-neutralization or membrane filtration method validation

Appendix 3 Summary of test description

1. Materials and reagents

1.1 Tryptone Soya Agar (TSA, Oxoid, catalogue no. CM0131)

1.2 Tryptone, pancreatic digest of casein (Oxoid, catalogue no. LP0042)

1.3 D-Glucose (R&M Chemicals, catalogue no. G/0500)

1.4 Meat extract (HiMedia, catalogue no. RM002)

1.5 Manganese (II) sulphate monohydrate ($MnSO_4 \cdot H_2O$, Merck, catalogue no. 1.05941.0250)

1.6 Agar (Oxoid, catalogue no. LP0011B)

1.7 Sodium chloride (Merck, catalogue no. 1.06404.0500)

1.8 Magnesium chloride ($MgCl_2$, Acros Organics, catalogue no. AC223211000)

1.9 Calcium chloride ($CaCl_2$, R&M Chemicals, catalogue no. 9924-00)

1.10 Sodium bicarbonate ($NaHCO_3$, Fisher Chemical, catalogue no. 10152780)

1.11 Bovine albumin fraction V (Merck, catalogue no. 1.12018.0100)

1.12 Neutralizer or rinsing liquid.

1.12.1 Tween 80 (Fisher Chemical, catalogue no. 10498800)

1.12.2 Lecithin (Nacalai Tesque, catalogue no. 20335-65)

1.12.3 Sodium Thiosulphate (R&M Chemicals, catalogue no. 6722-00)

1.12.4 Catalase from bovine liver (Sigma-Aldrich, catalogue no. C9322)

1.12.5 Tryptone Soya Broth (TSB, Oxoid, catalogue no. CM0129)

2. Apparatus and glassware

2.1 Autoclave (TOMY, model SX500)

2.2 Water baths (Memmert, model WNB 29)

2.3 Incubator (Binder, model BD 260)

2.4 pH-meter (Ohaus, model 3100 Meter with ST310)

2.5 Vortex® mixer (Biosan model Biosan V-1 Plus)

2.6 Petri dishes (Wanpow Plastic)

3. Test procedure

3.1 Test Na – Determination of sporicidal concentrations

3.1.1 Pipette 1.0 ml of interfering substance into a tube.

3.1.2 Add 1.0 ml of the test suspension.

3.1.3 Start the stopwatch immediately, mix and place the tube in a water bath controlled at the chosen test temperature θ for 2 minutes ± 10 seconds.

3.1.4 At the end of this time, add 8.0 ml of the product test solution.

3.1.5 Restart the stopwatch at the beginning of the addition.

3.1.6 Mix and place the tube in a water bath controlled at θ for the chosen contact time *t*.

3.1.7 Just before the end of *t*, mix again.

3.1.8 For dilution-neutralization method:

3.1.8.1 At the end of *t*, take 1.0 ml sample of the test mixture Na and transfer into a tube containing 8.0 ml neutralizer and 1.0 ml water.

3.1.8.2 Mix and place in a water bath controlled at 20 °C ± 1 °C.

3.1.8.3 After a neutralization time of 5 minutes ± 10 seconds, mix and immediately take a sample of 1.0 ml of the neutralized test mixture Na (containing neutralizer, product test solution, interfering substance, and test suspension) in duplicate and inoculate using the pour plate technique. Additionally, prepare 10^{-1} and 10^{-2} dilution of the text mixture Na.

3.1.8.4 When using the pour plate technique, pipette each 1.0 ml sample into separate Petri dishes and add 12 to 15 ml of melted TSA, cooled to 45 °C ± 1 °C.

3.1.9 For membrane filtration method:

3.1.9.1 At the end of *t*, pipette two samples of 0.1 ml of the text mixture and transfer each sample into a separate membrane filtration apparatus equipped with a membrane and containing 50 ml of rinsing liquid.

3.1.9.2 Filter immediately. The time required for transfer and filtration should not exceed 1 minute.

3.1.9.3 Rinse with at least 150 ml but not more than 500 ml of rinsing liquid. Filter and rinse with 50 ml of water and transfer the membranes to the surface of two separate TSA plates.

3.1.10 Incubate the plates for 20 to 24 hours at 36 °C ± 1 °C.

3.1.11 Note the exact number of colonies for each plate but record >330 for any counts higher than 330 and determine the V_C-values. On membranes, the upper limit is 165.

3.1.12 Perform the procedure using the other product test solutions at the same time.

3.1.13 Perform the procedure applying the other obligatory and – if appropriate – other additional experimental conditions.

3.2 Experimental conditions control A – Validation of the selected experimental conditions and/or verification of the absence of any lethal effect in the test conditions

3.2.1 Pipette 1.0 ml of interfering substance into a tube.

3.2.2 Add 1.0 ml of the validation suspension.

3.2.3 Start the stopwatch immediately, mix, and place the tube in a water bath controlled at θ for 2 minutes ± 10 seconds.

3.2.4 At the end of this time, add 8.0 ml of hard water. In the case of ready-to-use products: water instead of hard water.

3.2.5 Restart the stopwatch at the beginning of the addition.

3.2.6 Mix and place the tube in a water bath controlled at θ for t.

3.2.7 Just before the end of t, mix again.

3.2.8 For dilution-neutralization method:

3.2.8.1 At the end of t, take a sample of 1.0 ml of this mixture A in duplicate and inoculate using the pour plate technique.

3.2.9 For membrane filtration method:

3.2.9.1 At the end of t, take a sample of 1.0 ml of this mixture A in duplicate and transfer into two separate membrane filtration apparatus equipped with a membrane and containing 50 ml of rinsing liquid.

3.2.9.2 Filter and rinse with 50 ml of water and transfer the membranes to the surface of two separate TSA plates.

3.2.10 Calculate the numbers of cfu/ml in the validation mixture A.

3.2.11 Verify according to Section 3.5.

3.3 Neutralizer control B – Verification of the absence of toxicity of the neutralizer or the filtration procedure

3.3.1 For dilution-neutralization method:

3.3.1.1 Pipette 9.0 ml of the neutralizer used in the test.

3.3.1.2 Add 1.0 ml of the validation suspension.

3.3.1.3 Start the stopwatch at the beginning of the addition and mix.

3.3.1.4 Place the tube in a water bath controlled at 20 °C ± 1 °C for 5 minutes ± 10 seconds.

3.3.1.5 Just before the end of this time, mix.

3.3.1.6 At the end of this time, take a sample of 1.0 ml of this mixture B in duplicate and inoculate using the pour plate technique.

3.3.2 For membrane filtration method:

3.3.2.1 Take a sample of 0.1 ml of the validation suspension and transfer into two separate membrane filtration apparatus equipped with a membrane and containing 50 ml of rinsing liquid.

3.3.2.2 Filter and rinse with 50 ml of water and transfer the membranes to the surface of two separate TSA plates.

3.3.3 Calculate the numbers of cfu/ml in the validation mixture B.

3.3.4 Verify according to Section 3.5.

3.4 Method validation C – Dilution-neutralization or membrane filtration validation

3.4.1 Pipette 1.0 ml of interfering substance into a tube.

3.4.2 Add 1.0 ml of the water.

3.4.3 Start the stopwatch, add 8.0 ml of the product test solution only of the highest concentration used in the test.

3.4.4 Mix and place the tube in a water bath controlled at θ for t.

3.4.5 Just before the end of t, mix again.

3.4.6 For dilution-neutralization method:

3.4.6.1 At the end of t, transfer 1.0 ml of the mixture into a tube containing 8.0 ml of neutralizer.

3.4.6.2 Restart the stopwatch at the beginning of the addition.

3.4.6.3 Mix and place the tube in a water bath controlled at 20 °C ± 1 °C for 5 minutes ± 10 seconds.

3.4.6.4 Add 1.0 ml of the validation suspension.

3.4.6.5 Start the stopwatch at the beginning of the addition and mix.

3.4.6.6 Place the tube in a water bath controlled at 20 °C ± 1 °C for 30 minutes ± 1 minute.

3.4.6.7 Just before the end of this time, mix again.

3.4.6.8 At the end of this time, take a sample of 1.0 ml of the mixture C in duplicate and inoculate using the pour plate technique.

3.4.7 For membrane filtration method:

3.4.7.1 At the end of *t*, take a sample of 0.1 ml of the mixture in duplicate and transfer into two separate membrane filtration apparatus equipped with a membrane and containing 50 ml of rinsing liquid.

3.4.7.2 Filter and rinse the membranes with at least 150 ml and not more than 500 ml per 50 ml or 100 ml measure of rinsing liquid.

3.4.7.3 Cover the membranes with 50 ml of rinsing liquid and add 0.1 ml of the validation suspension.

3.4.7.4 Filter and rinse with 50 ml of water and transfer the membranes to the surface of two separate TSA plates.

3.4.8 Calculate the numbers of cfu/ml in the validation mixture C.

3.4.9 Verify according to Section 3.5.

3.5 Basic limits

3.5.1 N is between 1.5×10^7 and 5.0×10^7 ($7.17 \leq \lg N \leq 7.70$)

3.5.2 N_0 is between 1.5×10^6 and 5.0×10^6 ($6.17 \leq \lg N_0 \leq 6.70$)

3.5.3 N_{V0} is between 30 and 160 (3.0×10^1 and 1.6×10^2)

3.5.4 N_V is between 3.0×10^2 and 1.6×10^3

3.5.5 A, B, C are equal to or greater than $0.5 \times N_{V0}$

3.5.6 Control of weighted mean counts: quotient is not lower than 5 and not higher than 15

4. Literature

4.1 EN 17126:2018 (E): Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area – Test method and requirements (phase 2, step 1)

4.2 EN 14885:2018 (E): Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics

4.3 EN 12353:2013 (E): Chemical disinfectants and antiseptics – Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity

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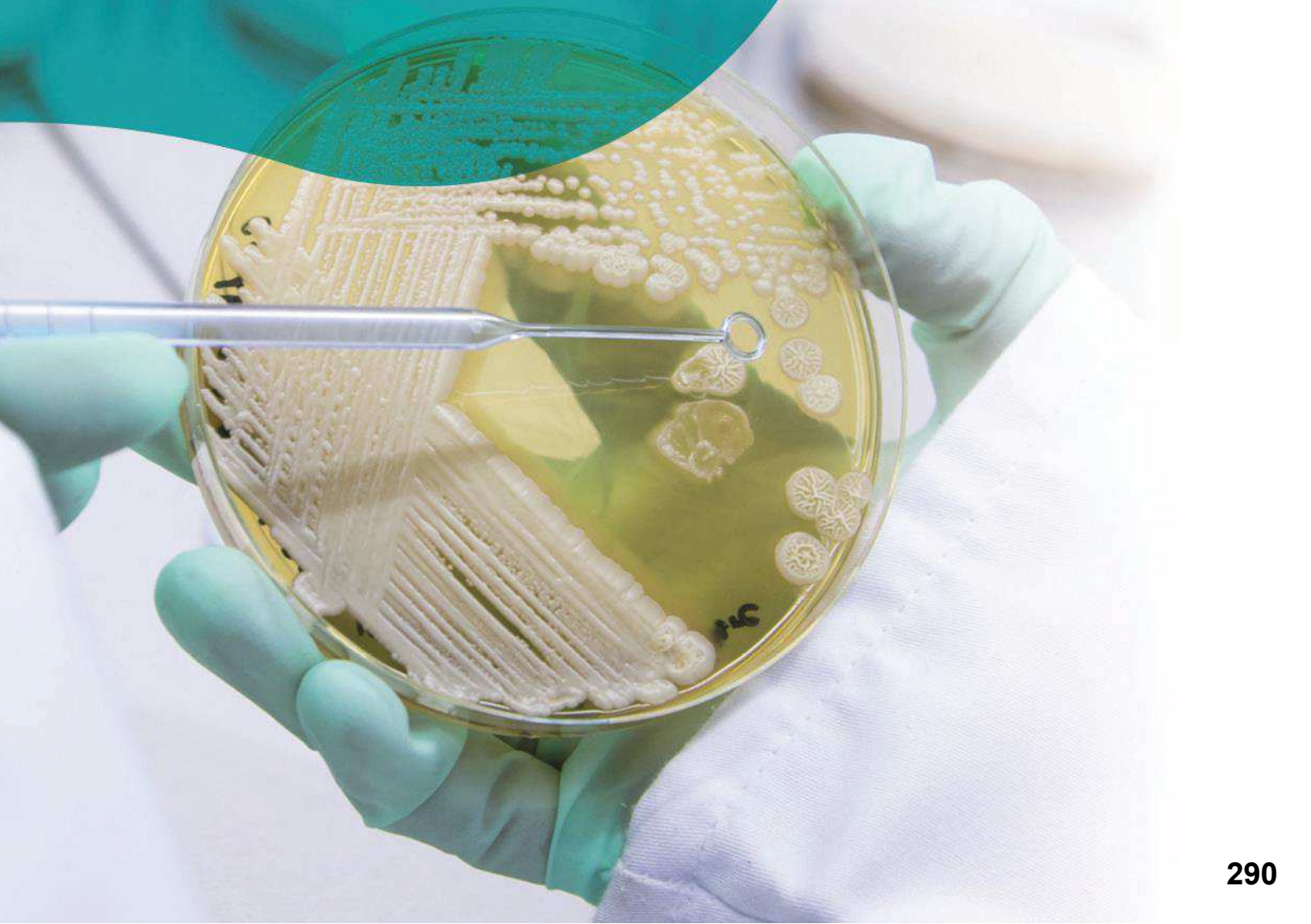

TEST REPORT

DETERMINATION OF THE SPORICIDAL ACTIVITY OF THE F3307 PRODUCT ACCORDING TO THE EN 17126 STANDARD

Delivered to: **Ms HORGNIES**

For: **SODEL**
190 RUE BARTHELEMY
14 100 LISIEUX
FRANCE

Date of request: 04/28/2022

Study references: #137D57-2022-02

SPORICIDAL TESTS:

According to the European standards EN 17126 (December 2018) – Chemical disinfectants and antiseptics - Quantitative suspension tests for the evaluation of sporicidal activity of disinfectants used in medical area (phase 2, step 1).

Tests using the F3307 product against the strains *Bacillus cereus,* and *Bacillus subtilis*.

This test report includes 9 pages.

Study completion date: 07/18/2022

Stephanie MOROT – BIZOT
PhD in Microbiology
Study Director

SUMMARY

Editor	**Supervisor**
Ms Emilie CANTREL, laboratory technician	Mrs Stephanie MOROT-BIZOT, Director
	

1 PERFORMING LABORATORY

APEX BIOSOLUTIONS
3, RUE DE LA TERRE ROUGE
ESPACE INDUSTRIEL DE BEAUPRE
25220 ROCHE LEZ BEAUPRE
FRANCE

2 PRODUCT IDENTITY

Reference	Batch N°
F3307	0209E036211116A

Expiration date: 01/17/2024

Manufacturer: SODEL

Manufacturing date: 01/18/2022

Storage conditions: as recommended by the manufacturer.

Active substances: Ortho-phtalaldéhyde 0.54%

Appearence of the product: liquid, blue

Diluent recommended by the manufacturer: none, ready-to-use product

Date of receipt: 02/22/2022

Date of the study: from 02/16/2022 to 06/17/2022

3 EXPERIMENTAL CONDITIONS

Final concentrations of the product: 80,0% - 70,0% - 0,01%

Appearance of the product and its dilutions: clear

Method: dilution-neutralization

Exposure time: 90 min

Temperature using during the assays: 20°C ± 1°C

Diluent used for the assays: distilled water

Diluent used for the bacterial suspensions: sterile trypton salt solution

Bacterial strains: *Bacillus cereus* CIP 105151 batch 6210 and *Bacillus subtilis subsp. Spizizenii ref 52.62 batch n° 17510 (ATCC 6633)*

Media and growth conditions: TSA (Trypton Soy Agar)

Organic soil load: clean conditions, BSA 0,3 g/L

Product stability: limpid solution with organic soil load

Stop solution: saponin (30 g/L), polysorbate 80 (30 g/L) and egg yolk (5 mL/L)

Editor	**Supervisor**
Ms Emilie CANTREL, laboratory technician	Mrs Stephanie MOROT-BIZOT, Director
	

4 CONCLUSIONS

According to the EN 17126 standard (December 2018), the F3307 product:

- **Demonstrated a sporicidal activity on the reference strains *Bacillus cereus* and *Bacillus subtilis*, when used at the concentration of 80.0%, for 90 min of contact time, at 20°C, in clean conditions (0,3 g/L bovine albumin)**

5 VALIDATIONS AND RESULTS SHEETS

Attached below.

- *Bacillus cereus*, **R = 4,26** for 90 min of contact time
- *Bacillus subtilis*, **R = 4,32** for 90 min of contact time

For all result sheets:

Methodology:
- 30 UFC/ml < Nv0 < 160 UFC/ml
- $1{,}5.10^7$ UFC/ml < N < 5.10^7 UFC/ml
- 6,17 ≤ lg N0 ≤ 6,70
- A ≥ 0,5 x Nv0
- B ≥ 0,5 x Nv0
- C ≥ 0,5 x Nv0

Legend:

Na = average of the number of cfu counted on Vc1 and Vc2
Log N = logarithm of the number of cfu of the microbial test suspension
Log R = logarithmic reduction obtained (log R = log N0 – log Na)
VC = value counted per Petri dish

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6 RESULTS SHEET- TRIAL *Bacillus cereus* 90 min

TEST STRAIN	Suspension of validation (Nv0)		Validation A		Validation B		Validation C	
Bacillus cereus	112	106	84	88	80	76	73	68
	$\bar{X}$	**109,0**	$\bar{X}$	**86,0**	$\bar{X}$	**78,0**	$\bar{X}$	**70,5**
	30 ≤ Nv0 ≤ 160 ?		A ≥ 0,5 * Nv0 ?		B ≥ 0,5 * Nv0 ?		C ≥ 0,5 * Nv0 ?	
	× yes □ no		× yes □ no		× yes □ no		× yes □ no	

TEST STRAIN	Trial suspension			TRIAL		80,00%	TRIAL		70,00%	TRIAL		0,01%
Bacillus cereus	1.10^{-5}	251	252	Vc			Vc			Vc		
	1.10^{-6}	29	27	1.10^{0}	12	9	1.10^{0}	46	41	1.10^{0}	>330	>330
	N	$2,54.10^{7}$		1.10^{-1}	1	1	1.10^{-1}	4	6	1.10^{-1}	48	44
	Log N0	**6,40**		Na	105,00		Na	435,00		Na	4600,00	
	6,17 ≤ lg N0 ≤ 6,70 ?			Log Na	2,02		Log Na	2,64		Log Na	3,66	
	× yes □ no			Lg R = logN0-logNa		**4,38**	Lg R = logN0-logNa		**3,76**	Lg R = logN0-logNa		**2,74**

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7 RESULTS SHEET- TRIAL *Bacillus subtilis* 90 min

TEST STRAIN	Suspension of validation (Nv0)		Validation A		Validation B		Validation C	
Bacillus subtilis	78	83	72	75	63	69	66	66
	$\bar{x}$	**80,5**	$\bar{x}$	**73,5**	$\bar{x}$	**66,0**	$\bar{x}$	**66,0**
	30 ≤ Nv0 ≤ 160 ?		A ≥ 0,5 * Nv0 ?		B ≥ 0,5 * Nv0 ?		C ≥ 0,5 * Nv0 ?	
	× yes □ no		× yes □ no		× yes □ no		× yes □ no	

TEST STRAIN	Trial suspension			TRIAL		80,00%	TRIAL		70,00%	TRIAL		0,01%
Bacillus subtilis	1.10^{-5}	239	247	Vc			Vc			Vc		
	1.10^{-6}	30	28	1.10^{0}	17	19	1.10^{0}	55	47	1.10^{0}	>330	>330
	N	$2,47.10^{7}$		1.10^{-1}	3	2	1.10^{-1}	6	5	1.10^{-1}	60	72
	Log N0	**6,39**		Na	180,00		Na	510,00		Na	6600,00	
	6,17 ≤ lg N0 ≤ 6,70 ?			Log Na	2,26		Log Na	2,71		Log Na	3,82	
	× yes □ no			Lg R = logN0-logNa		**4,13**	Lg R = logN0-logNa		**3,68**	Lg R = logN0-logNa		**2,57**

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8 RESULTS SHEET- REPETITION *Bacillus cereus* 90 min

TEST STRAIN	Suspension of validation (Nv0)		Validation A		Validation B		Validation C	
Bacillus cereus	91	100	95	98	85	91	79	82
	$\bar{X}$	**95,5**	$\bar{X}$	**96,5**	$\bar{X}$	**88,0**	$\bar{X}$	**80,5**
	30 ≤ Nv0 ≤ 160 ?		A ≥ 0,5 * Nv0 ?		B ≥ 0,5 * Nv0 ?		C ≥ 0,5 * Nv0 ?	
	× yes □ no		× yes □ no		× yes □ no		× yes □ no	

TEST STRAIN	Trial suspension			TRIAL		80,00%	TRIAL		70,00%	TRIAL		0,01%
Bacillus cereus	1.10^{-5}	218	236	Vc			Vc			Vc		
	1.10^{-6}	22	27	1.10^{0}	18	15	1.10^{0}	51	46	1.10^{0}	>330	>330
	N	$2,29.10^{7}$		1.10^{-1}	2	2	1.10^{-1}	9	5	1.10^{-1}	51	50
	Log N0	**6,36**		Na	165,00		Na	485,00		Na	5050,00	
	6,17 ≤ lg N0 ≤ 6,70 ?			Log Na	2,22		Log Na	2,69		Log Na	3,70	
	× yes □ no			Lg R = logN0-logNa		**4,14**	Lg R = logN0-logNa		**3,67**	Lg R = logN0-logNa		**2,66**

Editor	**Supervisor**
Ms Emilie CANTREL, laboratory technician	Mrs Stephanie MOROT-BIZOT, Director
	

9 RESULTS SHEET- REPETITION *Bacillus subtilis* 90 min

TEST STRAIN	Suspension of validation (Nv0)		Validation A		Validation B		Validation C	
Bacillus subtilis	88	81	72	77	76	64	63	60
	$\bar{x}$	**84,5**	$\bar{x}$	**74,5**	$\bar{x}$	**70,0**	$\bar{x}$	**61,5**
	30 ≤ Nv0 ≤ 160 ?		A ≥ 0,5 * Nv0 ?		B ≥ 0,5 * Nv0 ?		C ≥ 0,5 * Nv0 ?	
	× yes □ no		× yes □ no		× yes □ no		× yes □ no	

TEST STRAIN	Trial suspension		TRIAL		80,00%	TRIAL		70,00%	TRIAL		0,01%
Bacillus subtilis	1.10^{-5}	209	227	Vc			Vc			Vc		
	1.10^{-6}	23	23	1.10^{0}	6	8	1.10^{0}	61	53	1.10^{0}	>330	>330
	N	$2,19.10^{7}$		1.10^{-1}	1	1	1.10^{-1}	7	7	1.10^{-1}	77	69
	Log N0	**6,34**		Na	70,00		Na	570,00		Na	7300,00	
	6,17 ≤ lg N0 ≤ 6,70 ?			Log Na	1,85		Log Na	2,76		Log Na	3,86	
	× yes □ no			Lg R = logN0-logNa		**4,49**	Lg R = logN0-logNa		**3,58**	Lg R = logN0-logNa		**2,48**

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10 TECHNICAL APPENDIX

Media:

TSA (Trypton Soy Agar), Dominique Dutscher, ref. n° 777410, batch n° 809295

ORGANIC SOIL LOAD:

Bovine serum albumin powder, Dominique Dutscher, ref. 871001, batch D1304039

Diluent

Trypton-Sel Solution (TS)

Ingredients in grams per litre of distilled water:

- Trypton, Dominique Dutscher, ref. 1612, batch n ° 091229----------1,00 g/l
- Sodium chloride, Dominique Dutscher, ref. n° 19032391, batch n° 808211----------8,50 g/l

pH after autoclaving at 25 °C: 7.0 ± 0.2

Stop solution

Ingredients per liter of distilled water:

- Tween 80, Sigma Aldrich, ref 59924, batch BCBJ6978V---------- 10 g/L
- Egg yolk, ---------- 3 g/L

HARD WATER

Solution A: -MgCl2 anhydrous, ref. M8266, batch n° 108K0068, SIGMA ALDRICH

- CaCl2 Anhydrous, Ref. C1016, batch n° 059K0030, SIGMA ALDRICH

Solution B: - NaHCO3, Ref. S6014, batch n°059K0052, SIGMA ALDRICH

pH after filtration: 7.0 ± 0.2 at 25 °C

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Productos sanitarios regulados por el Reglamento UE 2017/745

A RELLENAR POR EL SOLICITANTE

Categoría del (de los) producto(s): exeol OPA: Desinfectante de alto nivel. Solución lista para usar a base de ortoftalaldehído para la desinfección final por inmersión de productos sanitarios reutilizables, invasivos y no invasivos, sensibles al calor, semicríticos y críticos, previamente limpiados.

Número de páginas adjuntas: No aplicable

IUD-ID de base: 326824F3307-01WX

Número de certificado CE (organismo notificado): No aplicable

Chambre de commerce et d'industrie de région Paris Ile-de-France
Vu exclusivement pour certification matérielle de la signature de
M.
(seen exclusively to certify the above signature)
Pour le président, le fabricant

El nombre del (de los) producto(s) aparece en la(s) declaración(es) CE de conformidad del fabricante o del representante autorizado

Clase de producto(s) sanitario(s): I☐ Ir☐ Is☐ Im☐ IIa☐ IIb☒ III☐

Nombre y dirección del fabricante o del representante autorizado:
Sodel - 190 rue René Barthélemy - 14100 Lisieux

Timothy BAILLIE
Expert Traducteur
près la Cour d'Appel de Besançon
ANGLAIS, FRANÇAIS, ESPAGNOL, PORTUGAIS
N° ne varietur S/2107050 Date 03 JUIL. 2024

Nombre y dirección del centro de producción (facultativo):
Sodel - 190 rue René Barthélemy - 14100 Lisieux

Yo, la abajo firmante **Marlène HORGNIES**, **PRRC**, certifico que las informaciones susodichas son correctas y que los productos sanitarios que figuran en la declaración CE de conformidad son marcados CE bajo mi responsabilidad en virtud de la directiva n.° 93/42/CEE y cumplen con las exigencias esenciales de salud y de seguridad.

Fecha: 18/12/2023 Firma: (Firma ilegible)

PARTE RESERVADA A LA CCI PARÍS ILE-DE-FRANCE

Los productos sanitarios marcados CE de conformidad con el reglamento UE 2017/745 pueden ser comercializados en Francia y en otros Estados miembros de la Unión Europea y partes del acuerdo sobre el Espacio económico europeo, y ser exportados hacia los países terceros. Este certificado de libre venta es válido con sujeción al mantenimiento, por el fabricante de los productos sanitarios en cuestión, de una declaración de conformidad UE (producto(s) sanitario(s) de clase I), acompañada en su caso, de los certificados necesarios expedidos por un organismo notificado (producto(s) sanitario(s) de clase Is, Im, IIa, IIb, III). Este certificado de libre venta sólo puede utilizarse para la exportación fuera de la Unión Europea.

[Nota: PARÍS EL 12.01.24]

CCI PARÍS ILE-DE-FRANCE
DGA - CCI Internacional París Ile-de-France
Servicio de CLV
9, rue Coquillère
75001 PARÍS

[Sello: CÁMARA DE COMERCIO Y DE INDUSTRIA DE REGIÓN PARÍS ILE-DE-FRANCE
REPÚBLICA FRANCESA]

El responsable del Departamento de Facilitación del Comercio Exterior
CCI PARÍS ILE-DE-FRANCE

[Sello: **CCI PARÍS ILE-DE-FRANCE INTERNACIONAL**
(Firma ilegible)
Por el presidente, Dieynaba SOW-DIAGNE]

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

COLOMBIE

1. *République française*

Le présent acte public

2. a été signé par... **Brice BAILLY**

3. agissant en qualité de... **Attaché**

4. est revêtu du sceau/timbre de... **Chambre de Commerce et d'Industrie de Paris**

Attesté

5. à Paris

6. le... 04 JUIL. 2024

7. *par le Procureur général près la Cour d'appel de Paris*

8. sous n° 74/C

9. Sceau : Signature : SYLVIE SCHLANGER AVOCAT GENERAL

COUR D'APPEL DE PARIS

COUR D'APPEL DF PARIS

"L'Apostille confirme seulement l'authenticité de la signature, du sceau ou timbre sur le document. Elle ne signifie pas que le contenu du document est correct ou que la République française approuve son contenu"

CCI PARIS ILE-DE-FRANCE INTERNATIONAL

REPUBLIQUE FRANCAISE

Direction Générale Adjointe - CCI International Paris Île-de-France
Département des Facilitations du Commerce Extérieur
Service CLV

Certificat de Libre Vente pour l'exportation vers les pays non membres de l'Union européenne

Free sale certificate for exportation to the non-EC Member States

Dispositifs médicaux relevant du règlement UE 2017/745

Medical devices covered by Regulation EU 2017/745

PARTIE A COMPLETER PAR LE DEMANDEUR

Section to be completed by the applicant

Catégorie du (des) dispositif(s) : exeol OPA : Désinfectant de haut niveau. Solution prête à l'emploi à base d'orthophtalaldéhyde pour la désinfection finale par immersion des dispositifs médicaux thermosensibles semi-critiques et critiques réutilisables invasifs et non-invasifs préalablement nettoyés

Device(s) category: exeol OPA: High level disinfectant. Ready-to-use solution orthophtalaldehyde based solution for final disinfection by immersion of pre-cleaned semi-critical and critical heat-sensitive invasive and non-invasive reusable medical devices.

Nombre de page en annexe : NA
Page in annex : NA

IUD-ID de base / *Basic UDI-DI :* ***326824F3307-01WX***

Numéro de certificat CE (Organisme notifié) */ CE certificate number (notified body): NA*

La désignation du (des) dispositif(s) apparaît sur la(les) déclaration(s) CE de conformité du fabricant ou du mandataire
The name of the device(s) appears on the EC declaration(s) of conformity of the manufacturer or the authorized representative

Classe du (des) dispositif(s) medical(aux): *Class of the medical device(s):* I☐ Ir☐ Is☐ Im☐ IIa☐ IIb☒ III☐

Nom et adresse du fabricant ou du mandataire :
Name and address of the manufacturer or the authorized representative:
Sodel – 190 rue René Barthélemy – 14100 Lisieux

Nom et adresse du site de production (facultatif) :
Name and address of Production site (optional):
Sodel – 190 rue René Barthélemy – 14100 Lisieux

Timothy BAILLIE
Expert Traducteur
près la Cour d'Appel de Besançon
ANGLAIS, FRANÇAIS, ESPAGNOL, PORTUGAIS
N° ne varietur 5/240705o Date 03 JUIL. 2024

Je soussigné **Marlène HORGNIES, PRRC,** certifie que les informations mentionnées ci-dessus sont exactes et que les dispositifs médicaux figurant sur la déclaration CE de conformité sont marqués CE sous ma responsabilité au titre de la directive n°93/42/CEE et répondent aux exigences essentielles de santé et de sécurité.

I the undersigned ***Marlène HORGNIES, PRRC,*** *declare that the information above-mentioned is correct and the medical devices on the EC declaration of conformity are CE marked under my responsibility within the meaning of the European directive n°93/42/EEC and fulfil the essential requirements of health and safety.*

Date :18/12/2023

Signature :

PARTIE RESERVEE A LA CCI PARIS ILE-DE-FRANCE
Section reserved for the administration

Les dispositifs médicaux marqués CE en conformité avec règlement UE 2017/745 peuvent être mis sur le marché en France et dans les autres Etats membres de l'Union européenne et parties à l'accord sur L'Espace économique européen, et être exportés vers les pays tiers. Ce certificat de libre vente est valide à concurrence du maintien, par le fabricant des dispositifs médicaux concernés, d'une déclaration de conformité UE (DM de classe I), accompagnée le cas échéant, des certificats UE nécessaires délivrés par un organisme notifié (DM de classe Ir, Is, Im, IIa, IIb, III).
Ce certificat de libre vente est utilisable uniquement à des fins d'exportation hors Union européenne.

12.01

DGA - CCI International Paris Ile-de-France
Service des CLV
9, rue Coquillière
75001 PARIS

CCI PARIS ILE-DE-FRANCE INTERNATIONAL

Pour le président, Dieynaba SOW-DIAGNE

The medical devices CE marked in conformity with the Regulation EU 2017/745 can be placed on the French market and in the other Member states of the European Union and part of the European Free Trade Association, and be exported in the non-EC Member States. This certificate is valid until the maintenance, by the manufacturer of the concerned devices, of a declaration of conformity EU (Class I MD) together with when appropriate, the certificates EU delivered by a notified body (Class Is, Ir, Im, IIa, IIb, III MD). This free sale certificate can only be used for exportation outside European Union.

Declaración de conformidad UE

La abajo firmante, Marlène HORGNIES, persona responsable de velar que se cumpla la normativa sobre los dispositivos médicos (PRRC), declara que el dispositivo médico descrito a continuación:

- cumple las disposiciones que le conciernen de conformidad con el anexo IX, capítulos I y III del Reglamento (UE) 2017/745, con evaluación de la documentación técnica "DTCE_RD0209_018-m2" elaborada conforme a los anexos II y III del Reglamento,
- cumple los requisitos generales de seguridad y funcionamiento del anexo I del Reglamento (UE) 2017/745 que le son aplicables.

Tipo de producto		Solución desinfectante para dispositivos médicos invasivos y no invasivos.	
Nombre del producto		Desinfectante de alto nivel.	
Nombre comercial		**exeol OPA**	
Código(s) del artículo(s)	**Envase(s) unitario(s)**	EXS0095	Bidón 5L
IUD-ID de base		326824F3307-01WX	
Finalidad		Solución lista para usar a base de orto-ftalaldehído para la desinfección final por inmersión de dispositivos médicos termosensibles invasivos y no invasivos reutilizables, semicríticos y críticos, previamente limpiados.	
Clase de riesgo	**Regla (anexo VIII)**	Clase IIb	Regla 16
Nombre del organismo notificado	**N.º de identificación**	GMED - 1, Rue Gaston Boissier - 75015 PARÍS	0459
Sistema de gestión de la calidad certificado por GMED según NF EN ISO 13485: 2016		Certificado n° 35009 rev.3 - Fecha de caducidad: martes, 19 de noviembre de 2024	
Marcado CE		Certificado UE n.º 39301 rev.1 - Fecha de caducidad: martes, 16 de mayo de 2028	

La presente declaración de conformidad de la UE se emite bajo la exclusiva responsabilidad de Sodel SAS, 190 rue René Barthélemy- 14100 Lisieux (Francia), registrada en EUDAMED con el SRN: **FR-MF-000000367** como fabricante.

Lisieux, 2023-11-22

Marlène HORGNIES

PRRC

Sodel – 190 rue René Barthélemy, 14100 Lisieux, France – Tél. : + 33 (0)2 31 31 10 50 – Fax : + 33 (0)2 31 31 80 60 – www.exeol.fr
S.A.S au capital de 352 350€ - RCS Lisieux 627 150 105 00070 – TVA Intra. : FR12 627 150 105 – APE 2041Z – Code emballeur : 14366B

RISK MANAGEMENT FILE

Generic / Product

Générique A1 PAE

exeol OPA

DGR_F3307_036-m1

References:
Regulation (EU) 2017/745
EN ISO 13485: 2016
EN ISO 14971: 2019 / A11: 2021
ISO TR 24971: 2020
XP S 99-223: 2020
PM6.08 Product risk management

RISK-MANAGEMENT PLAN AND RISK/BENEFIT RATIO

According to EN ISO 14971: 2019 / A11: 2021 (chapter 4.4) and ISO/TR 24971: 2020 (chapter 4.4, Annex C)

Review and changes to updates

m	Date	Origin	Manager	Description
-	2022-02-16	New product	Marlène Horgnies	Creation
-	2022-11-29	Changes to form	Marlène Horgnies	Update to the Post-Market Surveillance procedure reference (PM6.04 instead of PM4.2). Form reference changed following the reallocation of Risk Management to PM06: FM6.16 v1 (formerly FM4.28 v3). Signature box and change tracking added.
1	2024-02-04	Round 1 - GMED assessment	Mehdi AIT MALAK	Intended use updated to specify use exclusively on semi-critical and critical medical devices

Scope of planned activities relating to risk and benefit/risk management

Regulatory requirements	Information		Date of update
Description	Ready-to-use orthophthalaldehyde based solution for final disinfection by immersion of pre-cleaned semi-critical and critical heat-sensitive invasive and non-invasive reuseable medical devices (class IIb)		2024-02-04
Device identification	F3307 / RD0209E36	Trade names of the devices concerned: - exeol santé range: **exeol OPA** - OBL distributors: none to date	2022-02-16
Lifecycle phases concerned	Initial product risk analysis:	Intended use & reasonably foreseeable misuse + Identification of safety-related characteristics + Design lifecycle phase Begun before the device is first put on the market (during R&D)	2022-02-16
	Product risk analysis:	Lifecycle phases: Design + Production + Storage + Transport + Use + Disposal Completes the initial risk analysis for acceptance of the first placing on the market of the devices, and is updated according to the post-marketing data for the devices => Updated information shown in orange in the product characteristics and risk analysis	2022-02-16
Interaction with the usability engineering file	Lifecycle phases:	Storage + Transport + Use + Disposal Begun before devices are placed on the market for the first time (during R&D) or after they have been placed on the market in the case of UOUPs (User Interface of Unknown Provenance) + Takes into account risk control measures based on safety related information (I) => Information shown by purple lines/cells (like this line)	2022-02-16

Allocation of responsibilities and authority

Lifecycle phase	Function groups	Function of representatives	First and last names of representatives	Date of update
Design	Technical aspects	R&D	Christophe Renard (Manager) Dominique Durand (Manager) Gaëtan Rauwel (Director)	2022-02-17
		Marketing	Claire Brasseur (Director)	2022-02-17
	Regulatory Affairs	MD Regulatory Affairs	Marlène Horgnies (Director) Séverine Huvet (Officer)	2022-05-11
	Naive	Quality control	Joséphine Richiardi (Technician)	2022-02-17
Production	Technical aspects	Production		
		Packaging	Morgane Ballester (Manager)	2022-03-07
		Quality control	Joséphine Richiardi (Technician)	2022-03-07
	Methods	Maintenance		
		R&D / Manufacturing	Christophe Renard (Manager) Dominique Durand (Manager) François Duchatelle (Manager)	2022-03-07
		Quality control	Joséphine Richiardi (Technician)	2022-03-07
	Regulatory Affairs /Naïve	MD Regulatory Affairs / Marketing	Marlène Horgnies (Director) Séverine Huvet (Officer)	2022-05-11
Storage	Technical aspects	Logistics	Mathieu Leonard (Manager)	2022-03-14
		Infrastructure / Manufacturing	François Duchatelle (Manager)	2022-03-14
	Regulatory Affairs	MD Regulatory Affairs	Marlène Horgnies (Director) Séverine Huvet (Officer)	2022-05-11
	Naive	Export sales		
Transport	Technical aspects	Logistics	Mathieu Leonard (Manager)	2022-03-14
		Infrastructure / Manufacturing	François Duchatelle (Manager)	2022-03-14
	Regulatory Affairs	MD Regulatory Affairs	Marlène Horgnies (Director) Séverine Huvet (Officer)	2022-05-11
	Naive	Export sales		
Use	Technical aspects	Sales	Yann Costard (Director) Pierre-François Lebart (Manager)	2022-03-14
		Marketing		
	Regulatory Affairs	MD Regulatory Affairs	Marlène Horgnies (Director) Séverine Huvet (Officer)	2022-05-11
	Naive	R&D	Gaétan Rauwel	2022-03-14
Disposal	Technical aspects	Logistics	Mathieu Leonard (Manager)	2022-03-14
		Infrastructure / Manufacturing	François Duchatelle (Manager)	2022-03-14
	Regulatory Affairs	MD Regulatory Affairs	Marlène Horgnies (Director) Séverine Huvet (Officer)	2022-05-11
	Naive	Export sales		

RISK-MANAGEMENT PLAN AND RISK/BENEFIT RATIO

According to EN ISO 14971: 2019 / A11: 2021 (chapter 4.4) and ISO/TR 24971: 2020 (chapter 4.4, Annex C)

Requirements for reviewing risk management activities

Risk control

Lifecycle phase	Pre-market frequency	Post-market frequency	Date of update
Design	Twice a month	See Procedure PM6.04 current version: Post-market surveillance	2022-02-16
Production	Weekly from design transfer		2022-02-16
Storage	Annual		2022-02-16
Transport	Annual		2022-02-16
Use	Twice a month		2022-02-16
Disposal	Annual		2022-02-16

Verification activities

Date of update: 2022-02-16

Verification concerning implementation of risk management measures
This verification is carried out as and when risk measures are put in place, based on the frequency set out above
Verification concerning the effectiveness of risk management measures
This verification is carried out during post-market surveillance and monitoring of the quality management system (quality indicators, internal audits, etc.)

Risk acceptability criteria

Date of update: 2022-02-16

Factors	Sodel policy	Risk acceptability criteria	Assessment
Regulatory requirements	The risk acceptability criteria for each device must take into account the regulatory requirements applicable in the regions where the medical device is to be marketed	Application of the applicable standard ISO 14971 (version 2021) + reduction of risks as far as possible (1) + no intolerable residual risk before the assessment of the Benefit/Risk ratio (1) + maximum 10% undesirable residual risk for the patient and/or user (2) + positive Benefit/Risk ratio (1) + assessment of new risks resulting from the combination of residual risks (2) (1) Criteria for individual risks (2) Criteria for overall risk (including individual risks)	Results of the risk analysis: - Risk analysis, assessment and control - Identification and distribution of residual risks - Analysis of combined residual risks
Applicable standards	The risk acceptability criteria for each device must take into account the relevant national and/or international standards applicable to the medical device and the risk management process	Using the standards listed in Annex O.4 of the DT CE to implement risk control measures	Proof of application of standards (Annex O.4 - List of standards and documents applied)
State of the art	The risk acceptability criteria for each device must take into account the generally accepted state of the art, based on national and/or international standards, best practices relating to the technology, the results of recognised scientific studies, publications by the authorities, and other information relating to similar medical devices and other comparable products	Monitoring: evaluation of literature on safety and performance (at least equivalent to products on the market) => validation of safety and performance claims => benefits with regard to the literature	Clinical and biological evaluation file (literature evaluation report, trial results, etc.)
Stakeholder concerns	The risk acceptability criteria for each device should take into account the concerns of stakeholders, for example, those conveyed directly by users, practitioners, patients or regulators, or indirectly through press reports, social media or patient forums.	Monitoring of stakeholder concerns (at least equivalent to products on the market) => updating of safety and performance claims => benefits with regard to stakeholder communication	Post-market surveillance file (evaluation report on stakeholder communications)

RISK-MANAGEMENT PLAN AND RISK/BENEFIT RATIO

According to EN ISO 14971: 2019 / A11: 2021 (chapter 4.4) and ISO/TR 24971: 2020 (chapter 4.4, Annex C)

Assessment criteria

Individual risk assessment criteria

Date of update: 2022-12-10

See procedure PM6.08 - Managing product risk for the Medical Device (MD)

Frequency	Definition of risk levels	F_i or F
Unlikely	The chances of this happening are very small. Unlikely to occur during the lifetime of the medical device.	**1**
Rare	Could occur, but rarely. Could occur a few times during the lifetime of the medical device.	**2**
Possible	Likely to occur frequently. Likely to occur several times during the lifetime of the medical device.	**3**
Frequent	Likely to occur almost systematically. Could occur each time the medical device is used.	**4**

Severity	Damage for the user or a third party, and the environment (disposal phase) */ Damage for the patient*	G_i or G
Minor - Discomfort	Fleeting effect: Whitening of the skin, Appearance of slight redness, Cough. Non-hazardous for the environment / Biodegradable. */ Temporary discomfort (slight pain)*	**1**
Significant - Sickness / Injury	Temporary effect: Discomfort caused by vapours, skin or eye irritation. Minor damage to fauna and flora (H412) */ Superficial injury or infection not requiring hospitalisation owing to a damaged or soiled instrument*	**2**
Major - Slight / temporary disability	Average long-term effect: Burns or corrosion leaving scars, temporary eye damage. Temporary reduction in fauna or flora (H411, low biodegradability). */ Injury or infection requiring hospitalisation, Performance of a new medical procedure, Temporary irritation or corrosion*	**4**
Critical - Permanent disability / Death	Permanent effect: Loss of sight, loss of mobility. Total destruction of fauna or flora (H410, non-biodegradable) */ Permanent treatment following healthcare-associated infection (nosocomial), death*	**6**

Note: For risks common to all products in the Sodel range, the level of risk severity G_i and G will be based on the Worst case for the range whatever its purpose.
Identification of risks based on Worst case: levels Gi and G will be shown in bold.

Risk Estimate (C_i and C) = Frequency * Severity		Severity of damage			
		Minor - Discomfort	Significant - Sickness / Injury	Major - Slight / temporary disability	Critical - Permanent disability / Death
Frequency	Unlikely	1	2	4	6
	Rare	2	4	8	12
	Possible	3	6	12	18
	Frequent	4	8	16	24

Individual Risk Assessment	Level of risk
≤ 2	**Negligible level of risk**
3 to 4	**Tolerable level of risk** (to be monitored as part of post-market surveillance)
6 to 12	**Undesirable level of risk** (to be monitored as part of post-market surveillance, but no more than 10% based on the criteria above)
≥ 16	**Unacceptable level of risk**

RISK-MANAGEMENT PLAN AND RISK/BENEFIT RATIO

According to EN ISO 14971: 2019 / A11: 2021 (chapter 4.4) and ISO/TR 24971: 2020 (chapter 4.4, Annex C)

Criteria for estimating individual benefit

Date of update: 2022-12-10

See procedure PM6.08 - Managing product risk for the Medical Device (MD)

Frequency	Appearance of benefit	F_b
Unlikely	The chances of this happening are very small. Unlikely to occur during the lifetime of the medical device.	1
Rare	Could occur, but rarely. Could occur a few times during the lifetime of the medical device.	2
Possible	Likely to occur frequently. Likely to occur several times during the lifetime of the medical device.	3
Frequent	Likely to occur almost systematically. Could occur each time the medical device is used.	4

Scale	Positive impact	I_b
Unexpected / Very low	Inadequate cleaning and disinfection before reusing the reusable medical device	1
Desirable / Moderate	Quality of cleaning and disinfection comparable to a control (water) before reusing the reusable medical device	2
Preferable / High	Optimised quality of the obligatory cleaning and disinfection before reusing the reusable medical device	4
Essential / Maximum	Obligatory cleaning and disinfection before reusing the reusable medical device	6

Estimated Benefit (B) = Frequency * Scale		Scale of the positive impact			
		Very low / Negligible	Desirable / Average	Preferable / High	Essential / Maximum
Frequency	Unlikely	1	2	4	6
	Rare	2	4	8	12
	Possible	3	6	12	18
	Frequent	4	8	16	24

Level of the positive impact	
≤ 2	No benefit
3 to 4	Little benefit
6 to 12	Acceptable benefit
≥ 16	High benefit

The colour code in the table above is provided for purposes of information to show the mirror effect with the level described in the risk estimate. No interpretation of the colour code is applied.
The Benefit is considered "Acceptable" if the estimated Benefit is ≥ 6, taking into account the severity of the residual risk.

Acceptance criteria for the individual benefit/risk ratio

Date of update: 2022-02-16

Estimated Benefit (B) / Residual Risk (C) ratio	
Acceptable if B/C > 1	
≤ 1	Unfavourable ratio
> 1	Acceptable ratio

If the Benefit/Risk ratio is greater than 1, then the Residual Risk is accepted.
If the Benefit/Risk Ratio is less than or equal to 1, then risk control needs to be reviewed.

Examination of risk management (9)

Date of update: 2022-08-18

See procedure PM6.08 - Managing product risk for the Medical Device (MD)

Method(s) for obtaining appropriate production and post-production information

Date of update: 2022-08-18

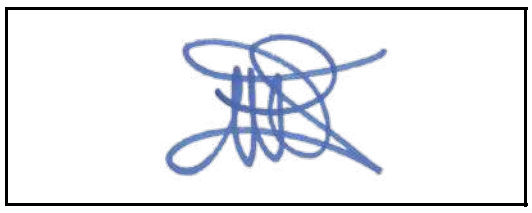
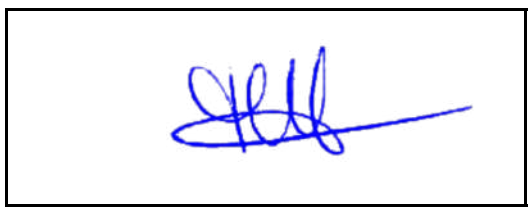
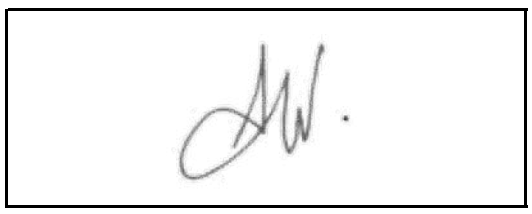
See procedures PM6.08 - Managing product risk for the Medical Device (MD) and PM6.04 - Post-market surveillance

RISK-MANAGEMENT PLAN AND RISK/BENEFIT RATIO

According to EN ISO 14971: 2019 / A11: 2021 (chapter 4.4) and ISO/TR 24971: 2020 (chapter 4.4, Annex C)

Validation of the Risk Management Plan

Date: **2024-02-04**

Written by:	Séverine Huvet *MD Regulatory Affairs Officer*	
Checked by:	Marlène Horgnies *MD Regulatory Affairs and Microbiology Director*	
Checked by:	Annick Nguyen *Quality Director*	
Approved by:	Gaëtan Rauwel *Director of Scientific Affairs and Product Strategy*	

RISK ANALYSIS

RISK ANALYSIS, ASSESSMENT AND CONTROL

Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
				Estimation								Final estimation of residual risk					Estimation of benefit							
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	F_i	G_i	$(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	F	G	(F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	F_b	I_b	$(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
PHASE 1: DESIGN OF THE DEVICE																								
A. Biological hazards																								
a. Biological contamination of the MD treated	1.A.a.01	No reasonably foreseeable event identified																						
B. Chemical hazards																								
a. Device hazardous to human health	1.B.a.02	Specification of substances not known or not included in the raw materials (MP)	Presence of unknown impurities in the MP in contact with the operator, user and/or patient	Irritation / corrosion / toxic: operator, user and patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Choice of raw materials, taking account of substance quality 2- Raw materials inspected on reception 3- Biological assessment of the product	1- Formulation sheet (FM4.82) F3307 approved (2022-09-01) 2- Raw material inspection record based on form FR5.01 3- Biological assessment report RPBIOL2022_F3307_03 approved (2022-09-01)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2022-12-15
									P	1- Supply of personal protective equipment (PPE) for operators	1/2- FDS_exeol OPA_3307-112-1_1.3_FR_20220831 approved													None	2023-07-17
									I	1- Information on the label (ETQ) + Instructions for Use (NU): Rinse thoroughly using sterile or filtered water (0.2µm) before reuse	1- ETQEXS0095 (FRR-01 and FRV-01) et NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	1.B.a.03	Primary packaging weakened by a substance in the formula	Packaging leak	Irritation / corrosion / toxic: user / third party	2	1	2 ; 1 = 2	Negligible risk	C	1- Choice of packaging, ADR approved 2- Compatibility of container/contents	1- / 2- Results of VV_RD0209_m1 (2023-08-01) (FM4.31 v2) approved		1	1	1 ; 1 = 1	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	24,0	Acceptable	None	2023-08-02
									P	-	-													None	
									I	1- Information on labels (ETQ): Precautionary statements in accordance with the CLP Regulation	1- / 2- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	1.B.a.04	Incompatibility label (glue) / container / formula	High temperatures => labels peel off => Container with no label => Incorrect product or expired product used => contaminated MD	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Scheduling the approval of pilot batches: studies on stability in accelerated and real-life conditions	1- Manufacturing process approval report: Reports QO CONDI-630 - version C (2023-03-22) and QO CONDI-710 - version C (2023-03-22)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
									P	-	-													None	
									I	1- Information on labels (ETQ): Symbol for storage conditions (in accordance with ISO 15223-1): 5°C- 25°C	1- / 2- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	1.B.a.05	Primary packaging does not provide a good grip	Handle difficult to hold => container dropped when transferring the product into the tank => contact with user	Irritation / corrosion / toxic: user	1	1	1 ; 1 = 1	Negligible risk	C	1- Selection of standard containers used by Sodel and available on the market 2- Usability tests	1- CDC LOTPILQOOPA F3307 2X5L (2022-03-25) 2- Usability engineering report RDDIAU2022_F3313_01 (2022-06-13)		1	1	1 ; 1 = 1	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	24,0	Acceptable	None	
									P	-	-													None	
									I	1- Information on labels (ETQ): Precautionary statements in accordance with the CLP Regulation	1- / 2- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	1.B.a.06	Non-resistant primary packaging/box combination	Stacked too high: containers/boxes pushed out of shape => leakage of containers => contact with the user/third party	Irritation / corrosion / toxic: user / third party	1	1	1 ; 1 = 1	Negligible risk	C	1- Choice of packaging/boxes 2- Validation of ADR approval of the combination stoppered container/box	1- Results of VV_RD0209_m1 (2023-08-01) (FM4.31 v2) approved 2- Approval certificate 2x5L: n°8705 Index 1 of 08/10/2019 + Extension 006 Index 0 of 09/07/2021 Approval certificate 4x5L: n°7999 Index 2 of 24/05/2018 + Extension 007 Index 0 of 11/05/2021		1	1	1 ; 1 = 1	Negligible risk	See mix classification	- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	24,0	Acceptable	None	2024-02-09
									P	-	-													None	
									I	1- Information on the label (ETQ): Precautionary statements in accordance with the CLP Regulation	1- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28

RISK ANALYSIS

RISK ANALYSIS, ASSESSMENT AND CONTROL

Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures *=> to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
	1.B.a.07	No specific marking on the boxes	Boxes stored upside down with a risk of leakage	Irritation / corrosion / toxic: contact with user/ third party	3	1	3 ; 1 = 3	Tolerable risk (to be monitored)	C	1- Definition of specifications for mandatory information on box packaging	1- Box print approval 2x5L: CA0047 n°2021103_0 of 21/05/2021, Box print approval 4x5L: CA0048 n°2021102_0 of 21/05/2021 approved		2	1	2 ; 1 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	2022-12-15
									P	1- Inspection of incoming packaging (PR2.1)	1- Registration by the reception desk on the Delivery Note (BL): quantity + reference, reconciliation with the Purchase Order (BC) + comparison with the print approval + Approval of the Box Inspection report for the box approved by the HSE department => *Procedure currently being updated*													None	
									I	1- Educating operators to check for the presence of markings (arrows) in accordance with MR3.38	1- Recording of workstation training, including the position of the box for each batch packed: Print/label (FR3.17)													None	
	1.B.a.09	- Characteristics of personal protective equipment (PPE) not communicated to the operator - Incorrect PPE characteristics communicated to the operator (user of the raw material (MP))	Direct contact with the product: using gloves made of latex rather than nitrile => contact with the operator	Irritation / corrosion / toxic: operator	4	**4**	4 ; 4 = 16	Unacceptable risk	C	1- Replacement of all latex gloves by nitrile gloves	1- Currently under way for all products, mandatory for exeol GTA 2%		2	**2**	2 ; 2 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-													None	
									I	1- Information in nomenclature X3: NITRILE GLOVES MUST BE WORN	1- MODOP nomenclature F3307 (2022-10-25) approved following transfer (pilot batches)													None	2024-02-09
b. Device hazardous to human health	1.B.b.01	No reasonably foreseeable event identified																							
C. Physical hazards																								
a. Temperature, humidity, sunlight	1.C.a.01	No reasonably foreseeable event identified																						
b. Injury to humans	1.C.b.01	No reasonably foreseeable event identified																						2022-11-02
D. Immunological hazards																								
E. Hazards associated with performance																								
a. Insufficient device performance	1.E.a.01	Deviation from design specifications in terms of regulations and standards : Performance not achieved for the intended use	Failure to take account of a change to the standard version or failure to take account of a harmonised standard => Insufficient product performance	Contamination: MD / patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Definition of mandatory disinfection standards to be claimed as an MD providing a high level of disinfection: - bactericidal: EN 13727 (P2E1) and EN 14561 (P2E2) - yeasticidal/fungicidal: EN 13624 (P2E1) and EN 14562 (P2E2) - virucidal: EN 14476 (P2E1) and EN 17111 (P2E2) - tuberculocidal/mycobactericidal: EN 14348 (P2E1) and EN 14563 (P2E2) - sporicidal: EN 17126 (P2E1) 2- Planning of tests in accordance with the mandatory disinfection standards to be claimed as an MD providing a high level of disinfection as described above 3- Monitoring of standards and participation in AFNOR Commission T72Q - Disinfection and antiseptics	1- List of applicable and claimed standards (Annex O.4 of the DT CE) 2- Result VV_RD0209_m1 (2023-08-01) (FM4.31 v2) - Microbiology test reports 3- Form FM4.21 - Regulatory monitoring completed		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-08-01
									P	-	-													None	
									I	1- Information in the Instructions for Use (NU): List of disinfection tests carried out, specifying the name of the standard and its version, as well as the test conditions and conclusion	1- NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	1.E.a.02	Deviation from design specifications in terms of marketing: Not proving commercial claims	Performance claims not proved by design tests => Insufficient level of performance	Contamination: MD / patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Drafting of FM4-31 - Verification / Approval with Design Specification FM4.02 + Test scheduling 2- Validation of technical and commercial documents (FT, ETQ, NU, PRT, etc.) based on test results 3- Justification for performance claims in clinical assessment	1- Results of VV_RD0209_m1 (2023-08-01) and CDC RD0209 (02/09/2022) approved 2- Marketing documents approved 3- Clinical Assessment Report RPCLIN2022_F3307_03 (Ind. 03 - 2023-10-16) approved		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2024-02-09
									P	-	-													None	
									I	-	-													None	
	1.E.a.03	Deviation from design specifications from an organoleptic and/or physico-chemical standpoint	Not meeting CDC requirements (depending on user habits): appearance of bath when used, fragrance not appreciated => over-consumption of product	Renewing baths more often	3	1	3 ; 1 = 3	Tolerable risk (to be monitored)	C	1- Drafting of FM4-31 - Verification /Approval with Design Specifications FM4.02	1- Result of VV_RD0209_m1 (2023-08-01) and CDC RD0209 (02/09/2022) approved		2	1	2 ; 1 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	2023-08-02
									P	-	-													None	
									I	-	-													None	

RISK ANALYSIS

RISK ANALYSIS, ASSESSMENT AND CONTROL

Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation			Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures *=> to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk			Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit			Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
				F_i	G_i	$(F_i ; G_i) = C_i$						F	G	(F ; G) = C				F_b	I_b	$(F_b ; I_b) = B$				
	1.E.a.04	Deviation from design specifications concerning the logistics / supply chain	Failure to take into account the specific storage/transport requirements of the various countries in which the product is to be marketed => Loss of product performance in the supply chain	Contamination: MD / patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Planning of stability studies at different temperatures (FM4.44) 2- Contract with the distributors who are responsible for transport after shipments clear French customs	1- Stability protocol/report RSTAB2022084_TEMPS_REEL_F3307_m1 (2023-12-20), RSTAB2022084_F3307_ACCELEREE (2023-05-23) et protocole de stabilité PSTAB2022084_F3307_v1 (2022-12-14) approved 2- RAQ signed by the distributors		1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	-	-													None	
								I	1- Information on the label (ETQ): Symbol for storage conditions (in accordance with ISO 15223-1): 5°C- 25°C	1- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	1.E.a.05	- Reaction between one or more co-formulants or impurities and the active substance	Active substance not effective or less effective - => Failure to meet performance requirements	Contamination: MD / patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Choice of raw materials (MP), taking account of incompatibilities during formulation 2- Stability studies showing changes in physico-chemical characteristics and appearance 3- Planning of tests in accordance with standards of antimicrobial efficacy 4- Approval of industrial transfer	1- RD0209 design book in Orchidée 2- / 3- Result of VV_RD0209_m1 (2023-08-01) (FM4.31 v2) approved 4- Industrial transfer report / approval in progress: R-QP 2023 - Version A (2023-03-3)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-08-02
								P	1- Systematic verification of production batches based on physico-chemical, antimicrobial and visual specifications	1- Specifications: BA/CC approved													None	
								I	-	-													None	
b. Loss of performance in treated MD	1.E.b.01	No reasonably foreseeable event identified																						
c. Errors in use	1.E.c.01	- Incomprehensible information on the label - Information on the label illegible or not sufficiently legible	Incorrect use of the product	Contamination: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Usability tests 2- Use of pictograms to simplify recommendations and/or for illiterate users	1-/ 2- Usability engineering report RPDIAU2022_F3313_01 (2022-06-13)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2022-08-18
								P	1- Customer test sheet to check understanding of information on the labels and the protocols for use	1- Template and completed customer test form *(pending market launch)*													None	
								I	1- Information in the Instructions for Use (NU): If you have any doubts about how to use the product, please contact the sales department 2- Information in the Instructions for Use (NU): Definition of symbols used in documentation	1- NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
F. Hazards associated with quality processes																								
a. Quality Management System	1.F.a.01	Design changes: specific claim added for a country, for example	Non-recognition of methods and tests carried out in accordance with European standards	Registration impossible in the country	3	1	3 ; 1 = 3	Tolerable risk (to be monitored)	C	1- Regulatory watch by country to define specific requirements 2- Planning of specific tests described in the design CDC FM4.02	1- Form FM4.21 - Regulatory monitoring completed 2- Product VV results		2	1	2 ; 1 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	
								P	-	-													None	
								I	-	-													None	
	1.F.a.02	- Material unsuitable for printing symbols - Labelling requirements not taken into account	Failure to use symbols set out in ISO 15223-1: - No symbols for batch number and expiry date - No instructions for use and/or instructions for use not dated => Using the device after the expiry date or without knowing the associated risks	Regulatory non-compliance	2	2	2 ; 2 = 4	Tolerable risk (to be monitored)	C	1- Standards watch on standard EN 15223-1 2- Decision to indicate/print: - the batch number and expiry date in DATA MATRIX format directly on the label + symbols set out in standard EN 15223-1 3- Approval of translations of ETQ, NU, PRT, FT, etc. (technical and sales documentation) if the symbols cannot be included	1- Form FM4.21 - Regulatory monitoring completed 2- Response to point 23.2 of the EGSP 3- Using symbols + definition in the NU of all languages		2	2	2 ; 2 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	-	-													None	
								I	1- Information in the Instructions for Use (NU): Definition of symbols used in documentation	1- NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	1.F.a.03	Non-compliance with point 23 of the EGSP concerning labelling and the instructions for use	Missing safety and performance information	Regulatory non-compliance	2	**2**	2 ; 2 = 4	Tolerable risk (to be monitored)	C	1- ETQ and NU check lists to be completed on Calenco	1- Check list approved + Part V of the DT CE approved		1	**2**	1 ; 2 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	
								P	-	-													None	
								I	1- Creation of label (ETQ)	1- ETQEXS0095 (FRR-01 and FRV-01) approved													None	2023-07-28
b. Traceability	1.F.b.01	No reasonably foreseeable event identified																						2022-11-02

RISK ANALYSIS

RISK ANALYSIS, ASSESSMENT AND CONTROL

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Identifying hazards and hazardous situations				Initial risk assessment				Risk control															
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures *=> to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
PHASE 2: PRODUCTION OF THE DEVICE																							
A. Biological hazards																							
a. Biological contamination of the MD treated	2.A.a.01	Change of control settings for each batch (packaging)	Filter added with removal / reinstallation of spacers (chambers) => contact with the product => Product contamination	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Creating control settings	1- Control settings by product family: approval in progress		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	2- Microbiological quality control of each batch	1- Approved batch files												None	
									I	-	-												None	
	2.A.a.02	Water quality not controlled in manufacturing: hardness / conductivity	Random specification of water quality => Non-compliant / not meeting required level of performance	Infection: patient	3	4	3 ; 4 = 12	Undesirable risk	C	1- Control of the water line = Water loop 2- Approval of the manufacturing process (QI/ QO) with the current system (without water loop)	1- Water loop implementation plan in progress: Change control (CC); approval in progress 2- Manufacturing process approval report: QI WATER reports version A (2022-03-14) / QO WATER version A approved (2022-05-02)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
									P	1- Batch control: Microbiological and organoleptic characteristics	1- Approved batch files												None	
									I	-	-												None	
	2.A.a.03	- Quality of raw materials (MP) received not compliant with specifications - Using polluted or contaminated MP - Using out-of-date MP - Unclear link with the manufacturer of an MP on receipt of the BA	Manufacturing a batch with non-compliant or out-of-date MP => Product non-compliant / not meeting the required level of performance	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Implementing inspections of incoming MP: Verification of references and quantities + sampling for inspection (MR2.01) + verification of CoA compliance (PR5.1) + verification of the presence of information concerning the manufacturer (Annex O.1 of the DT CE) 2- Follow-up of MP expiring in 1 month at least: MP checks to determine the actions to be implemented (MR5.12) 3- Changing the status of expired MP to "not available" => impossible to initiate a production order (OF) as the MP will not be available	1- Inspections recorded on the Delivery Note (BL), the Check Sheet and the CoA 2- Recorded in the Monitoring Table + table analysed once a month to determine the actions to be taken 3- Computer procedure to show that the production order cannot be created: MR5.09		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	1- Release of batches with verification of the batch file (procedure, etc.)	1- Files concerning batches approved for release												None	
									I	1- Industrial transfer: Informing staff and raising awareness of the need to check MP compliance	1- Manufacturing process approval report: QO report Tank 15 - version A (2022-02-22) and QO Tank 16 - version A (2022-02-22)												None	2023-07-17
	2.A.a.04	- Incorrect tightening adjustment - Tightening equipment does not measure torque => no on-line torque check - Insufficient maintenance of tightening equipment => tightening incorrectly adjusted during packaging	Cap not correctly closed: not tight enough => product contamination	Infection: patient	3	**4**	3 ; 4 = 12	Undesirable risk	C	1- Installation of a torque spanner to check tightening of the 5-litre container => torque achieved 2- Order in progress for a tool to improve manoeuvrability and measure with a torque meter	1- / 2- Indication of torque approval in the document accompanying the Tracking Form		2	**4**	2 ; 4 = 8	Undesirable risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	3,0	Acceptable	None	
									P	1- Microbiological inspection of each batch	1- Approved batch files												None	
									I	-	-												None	
	2.A.a.05	Containers open on the conveyor belt during packaging	Poor air quality with contamination of packaging (resistant germs) => Contamination of the product	Infection: patient	1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Procedure put in place to clear the conveyor belts in the evening 2- Determining the need to set a limit during the day (stopping the line during breaks/maintenance/rinsing time)	1- / 2- Operating procedure MR3.22 v2 (2022-10-11) - Belt clearance approved		1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2022-12-15
									P	-	-												None	
									I	-	-												None	
B. Chemical hazards																							
a. Device hazardous to human health	2.B.a.01	Change of control settings for each batch (packaging)	Filter added with removal / reinstallation of spacers (chambers) => contact with the product	Irritation / Corrosion : packaging operator	3	**4**	3 ; 4 = 12	Undesirable risk	C	1- Creating control settings	1- Control settings by product family: approval in progress		2	**4**	2 ; 4 = 8	Undesirable risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	3,0	Acceptable	None	
									P	1- Supply of appropriate personal protective equipment (PPE) for operators	1- FDS_exeol OPA_3307-112-1_1.3_FR_20220831 approved												None	2023-07-17
									I	1- Information on labels (ETQ): Precautionary statements in accordance with the CLP Regulation	1- ETQEXS0095 (FRR-01 and FRV-01) approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28

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RISK ANALYSIS, ASSESSMENT AND CONTROL

Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
	2.B.a.02	Loose cap / spray	The bottles fall over on the packaging line	Irritation / Corrosion : packaging operator	3	4	3 ; 4 = 12	Undesirable risk	C	1- Test reference to check correct closure (MS1.01 v1_2019-08-21) 2- Quality control on receipt of packaging (caps) 3- Preventive maintenance of closure tools to be implemented 4- Creation of control settings	1- Test records (FS1.01 v2_2019-08-23) 2- Recorded on reception on the Delivery Note (BL): quantity + reference, with reconciliation of the Purchase Order (BC) => *Procedure currently being updated* 3- Implementation of the preventive maintenance plan for the Machine + line (FS6.01 v1 and FS06.02 v1) 4- Control range by product family: approval in progress		2	4	2 ; 4 = 8	Undesirable risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	3,0	Acceptable	None	2022-12-15
								P	1- Supply of appropriate personal protective equipment (PPE) for packaging operators	1- FDS_exeol OPA_3307-112-1_1.3_FR_20220831 approved													None	2023-07-17
								I	1- Information on labels (ETQ): Precautionary statements in accordance with the CLP Regulation	1- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	2.B.a.03	Product sampling for batch quality control	Product splashes or spills: opening of tap or valve	Irritation / Corrosion=> packaging operator	3	4	3 ; 4 = 12	Undesirable risk	C	1- Installation of a tap on tanks 15 and 16 (reserved for MD) for easier sampling	1- Service order n° 595 of 11/03/2022		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	1- Supply of appropriate personal protective equipment (PPE) for packaging operators	1- FDS_exeol OPA_3307-112-1_1.3_FR_20220831 approved													None	2023-07-17
								I	-	-													None	
	2.B.a.04	Quality control sample from the batch to be transported to the laboratory	Sample bottle falling before reaching the laboratory: stairs, jostling, etc.	Irritation / Corrosion : Quality control operator	2	4	2 ; 4 = 8	Undesirable risk	C	1- Introduction of closed sampling jars + transport basket	1- Implementation in December 2021 (health, safety working conditions action plan put in place by the CSE (social and economic committee))		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	Supply of appropriate personal protective equipment for quality control operators	-													None	
								I	-	-													None	
	2.B.a.05	Filling machine jams: the door closes on the bottle or the bottle falls	Product spillage on the packaging line => contact with the packaging operator	Irritation / Corrosion : packaging operator	3	4	3 ; 4 = 12	Undesirable risk	C	1- Preventive maintenance to be introduced for closure tools on the packaging lines 2- Creation of control settings	1- Approved maintenance forms (FS6.01 v1 and FS6.02 v1) 2- Range by product family:approval under way by packaging line		2	4	2 ; 4 = 8	Undesirable risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	3,0	Acceptable	None	2022-12-15
								P	1- Supply of appropriate personal protective equipment (PPE) for packaging operators	-													None	
								I	1- Information on labels (ETQ): Precautionary statements in accordance with the CLP Regulation	1- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	2.B.a.06	Failure to wear personal protective equipment (PPE) when manufacturing the product	Contact with the raw materials for a greater or lesser period of time	Irritation / Corrosion : manufacture operator	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Selection of the MP with the most suitable characteristics on the market	1- Listing form for new raw material (FM4.30 v4)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-28
								P	1- Supply of appropriate personal protective equipment (PPE): nitrile gloves + respiratory mask + overalls + safety goggles + ...	1- MODOP nomenclature F3307 of 25 Oct. 2022 + MODOP nomenclature F3330 of 10 March 2022 (dye)													None	2023-01-09
								I	-	-													None	

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Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
	2.B.a.07 Failure to wear personal protective equipment (PPE) when manufacturing or packaging the product	Contact with the product for a greater or lesser period of time: a few seconds to several minutes e.g. valve drainage	Irritation / Corrosion : manufacturing / packaging operator/	2	4	2 ; 4 = 8	Undesirable risk	C	1- Replacement of all latex gloves by nitrile gloves	1- Implementation for all products, mandatory for exeol GTA 2%		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	1- Implementation of an extraction system 2 - Supply of appropriate personal protective equipment (PPE): nitrile gloves + respiratory mask + overalls + safety goggles, etc.	1- Implementation in progress (launch August 2022) for the production platform + lines 630 and 710 2- Indication on MODOP nomenclature F3307 of 25 Oct. 2022: NITRILE GLOVES MANDATORY"											None	2022-12-15
								I	-	-													None	
	2.B.a.08 Non-compliant or damaged primary packaging: incorrect weight or material, poor sealing or poor material distribution, for example	Primary packaging leak	Irritation / corrosion: operator	3	4	3 ; 4 = 12	Undesirable risk	C	1- Inspection of incoming packaging (PR2.01 v2_2023-01-13)	1- Recorded on reception on the Delivery Note (BL): quantity + reference, with reconciliation of the Purchase Order (BC)		3	4	3 ; 4 = 12	Undesirable risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	2,0	Acceptable	None	2023-07-17
								P	1- Supply of appropriate personal protective equipment (PPE)	-													None	
								I	-	-													None	
	2.B.a.09 Damaged box: punctured, dented or not glued down	Non-resistant box or box with loss of resistance => dropped or dropped + splashing	Irritation / corrosion: operator	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Inspection of incoming packaging (PR2.01 v2_2023-01-13)	1- Recorded on reception on the Delivery Note (BL): quantity + reference, with reconciliation of the Purchase Order (BC)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
								P	1- Supply of appropriate personal protective equipment (PPE)	-													None	
								I	-	-													None	
	2.B.a.10 Box not compliant with specifications: specific marking, thickness, size, etc.	Damage during storage: pallet dented => containers crushed with risk of leakage	Irritation / corrosion: operator	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Inspection of incoming packaging (PR2.01 v2_2023-01-13)	1- Registration by the reception desk on the Delivery Note (BL): quantity + reference, reconciliation with the Purchase Order (BC) + comparison with the print approval + Approval of the Box Inspection report for the box approved by the HSE department		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
								P	-	-													None	
								I	-	-													None	
	2.B.a.11 - Incorporation of raw materials during manufacture - packaging line enclosed but no exhaust system	Fumes breathed in by manufacturing and/or packaging operators	Irritation / corrosion: operator	4	4	4 ; 4 = 16	Unacceptable risk	C	1- Select tanks 15 and 16 for production, since they are fitted with lids	1- MODOP nomenclature for X3: indication "Production only in tanks 15 or 16"		4	1	4 ; 1 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	1- Implementation of a mobile extraction system 2 - Supply of appropriate personal protective equipment (PPE): nitrile gloves + respiratory mask + overalls + safety goggles, etc.	1- Implementation for production platform + lines 630 and 710 2- Indication on MODOP nomenclature F3307 of 25 Oct. 2022: NITRILE GLOVES MANDATORY"											None	2022-12-15
								I	-	-													None	
	2.B.a.12 -Incorrect adjustment of closing force on a weakened container => immediate leak / Incorrect adjustment of closing force on a container => leak over time from the cap	Caps pressed down too hard on the containers: => container neck pushed out of shape => leakage	Irritation / corrosion: operator / third party	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Creating control settings	1- Settings by product family: approval in progress		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	1- Leak test for each batch (FR5.35 v1_2022-10-31): 1 - Box positioned on its side for the duration of packaging => result recorded on the documents accompanying the tracking sheet	1- Approved batch files											None	2023-02-14
								I	-	-													None	
	2.B.a.13 - Incorrect tightening adjustment /sealing - Tightening equipment does not measure torque => no on-line torque check - Sealing settings not controlled - Insufficient maintenance of tightening /sealing equipment => tightening /sealing incorrectly adjusted during packaging	Cap not correctly closed: not tight enough / Poor sealing of the flowpack or doses => Leak	Irritation / corrosion: operator	3	4	3 ; 4 = 12	Undesirable risk	C	1- Installation of a torque spanner to check tightening of the 5-litre container => torque achieved 2- Order in progress for a tool to improve manoeuvrability and measure with a torque meter	1- / 2- Indication of torque approval in the document accompanying the Tracking Form		2	4	2 ; 4 = 8	Undesirable risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	3,0	Acceptable	None	
								P	1- Leak test for each batch (FR5.35 v1_2022-10-31) for packaging at Sodel	1- Approved batch files											None	2023-02-14
								I	-	-													None	
b. Device hazardous to human health	2.B.b.01 No reasonably foreseeable event identified																							

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Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
C. Physical hazards																								
a. Temperature, humidity, sunlight	2.C.a.01	Plant environment: temperature variation from 15°C to 40°C depending on the season	The density of the water varies according to the temperature => impact on the volume meter => varying quantity of water used in the production process => product non-compliant => does not contain enough of the Active Substance (AS)	Infection: patient	2	**4**	2 ; 4 = 8	Undesirable risk	C	1- Calibration of volume meters	1- Calibration scheduled every 6 months: company service report		1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	1- Physico-chemical inspection of batches (FR5.35 v1_2022-10-31)	1- Approved batch files													None	2023-02-14
								I	-	-													None	
b. Injury to humans	2.C.b.01	Damaged box: punctured, dented or not glued down	Non-resistant box or box with loss of resistance => dropped or dropped + splashing	Physical injury to the operator	1	2	1 ; 2 = 2	Negligible risk	C	1- Combination box + 5L containers: combined BVT approval => drop test (in accordance with Transport of Hazardous Goods requirements)	1- Approval certificate 2x5L: n°8705 Index 1 of 08/10/2019 + Extension 006 Index 0 of 09/07/2021 Approval certificate 4x5L: n°7999 Index 2 of 24/05/2018 + Extension 007 Index 0 of 11/05/2021		1	2	1 ; 2 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	2022-12-15
									2- Inspection of incoming packaging (PR2.1)	2- Registration by the reception desk on the Delivery Note (BL): quantity + reference, reconciliation with the Purchase Order (BC) + comparison with the print approval + Approval of the Box Inspection report for the box approved by the HSE department => *Procedure currently being updated*													None	
								P	1- Supply of appropriate personal protective equipment (PPE)	-												None	
								I	-	-													None	
D. Immunological hazards																								
a. Allergenic device	2.D.a.01	No reasonably foreseeable event identified																						
E. Hazards associated with performance																								
a. Insufficient device performance	2.E.a.01	No reasonably foreseeable event identified																						
b. Loss of performance in treated MD	2.E.b.01	No reasonably foreseeable event identified																						
c. Errors in use	2.E.c.01	No reasonably foreseeable event identified																						2022-11-02
F. Hazards associated with quality processes																								
a. Quality Management System	2.F.a.01	Non-homogeneity of the formula: non-compliance with the specific requirements of the incorporation protocol (successive additions, sprinkling, etc.)	Production order incorrectly completed(nomenclature) => Product non-compliant / not meeting the required level of performance	Infection: patient	3	**4**	3 ; 4 = 12	Undesirable risk	C	1- Industrial transfer: production of pilot batches for approval of the OF (QP) 2- Follow-up of deviations over time (waiver request) to adjust the OF or specifications as appropriate 3- Approval of nomenclature registration in X3	1- Manufacturing process approval report RV 042 (2022-06-08) 2- Changes recorded in the OF and on the form for recording change calculations (FM5.41) + Plans to monitor adjustments every 15 days, to provide feedback to R&D 3- MODOP nomenclature F3307 of 25 Oct. 2022 + MODOP nomenclature F3330 of 3 Jan. 2023 (dye)		1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-01-09
								P	-	-													None	
								I	-	-													None	
	2.F.a.02	Non-homogeneity of the formula: non-compliance with the specific requirements of the incorporation protocol (order of MP, agitation time, successive additions, sprinkling, etc.)	Failure to comply with OF = => Product non-compliant / not meeting the required level of performance	Infection: patient	3	**4**	3 ; 4 = 12	Undesirable risk	C	-	-		1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	1- Microbiological, physico-chemical and organoleptic batch control	1- Approved batch files													None	
								I	1- Industrial transfer: raising awareness/training staff in the new nomenclature	1- Manufacturing process approval report: QO report Tank 15 - version A (2022-02-22) and QO Tank 16 - version A (2022-02-22)													None	2023-07-17
	2.F.a.03	Slow process for dissolving the powder (specific to OPA and other powders): The dose should be incorporated in 5 stages and agitated for 30 min.or 30 minutes => no indication of incorporation	Varying the quantity of OPA	Product non-compliant / not meeting the required level of performance => patient infection	2	4	2 ; 4 = 8	Undesirable risk	C	1- Production nomenclature with batch control stages during manufacture and packaging	1- Manufacturing process approval report: QO report Tank 15 - version A (2022-02-22) and QO Tank 16 - version A (2022-02-22)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
								P	1- Microbiological, physico-chemical and organoleptic batch control	1- Approved batch files (MR3.17)													None	

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Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
								I	-	-													None	
2.F.a.04	Non-compliance with the OF	- Non-compliance with order of incorporation - Non-compliance with mixing time between each incorporation and/or after all incorporations - Wrong MP used - Incorporation of the wrong quantity of MP- Using a non-approved tank: tanks 15 and 16 obligatory => Product not compliant / not meeting the required level of performance	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Consideration to be given to setting up a system for scanning the output of raw materials (MP)	1- To be planned with the modernisation of the production system		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	1- Batch release with verification of the batch file (FR5.35 v1 2022-10-31))	1- Files concerning batches approved for release													None	2023-02-14
								I	1- Industrial transfer: raising awareness/training staff to comply with OFs	1- Manufacturing process approval report: QO report Tank 15 - version A (08/06/2022) and QO Tank 16 - version A (08/06/2022)													None	2023-07-17
2.F.a.05	- Inadequate or non-existent cleaning of the production line - Contamination of the production tool: microbial or particulate development	Product contamination	Infection: patient / user	3	4	3 ; 4 = 12	Undesirable risk	C	1- Implementing and approving the cleaning and disinfection process between 2 batches 2- Recording the implementation of cleaning/disinfection processes	1- Approval report for cleaning process: R QN - Version B (2023-02-20) 2- Cleaning recorded on FR3.17 and disinfection on FR3.27 in the batch file for the batch manufactured after cleaning and/or disinfection		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
								P	1- Microbiological batch inspection	1- Files concerning batches approved for release													None	
								I	-	-													None	
2.F.a.06	Product manufacture before or after a formula with amine	Product staining => Loss of performance	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Implementing and approving the cleaning and disinfection process between 2 batches 2- Recording the implementation of cleaning/disinfection processes	1- Approval report for cleaning process: Report QN - Version B (2023-02-20) 2- Cleaning recorded on FR3.17 and disinfection on FR3.27 in the batch file for the batch manufactured after cleaning and/or disinfection		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
								P	-	-													None	
								I	-	-													None	
2.F.a.07	Product manufacture before or after a formula with enzyme	Formation of deposits (flocculation)	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Implementing and approving the cleaning and disinfection process between 2 batches 2- Recording the implementation of cleaning/disinfection processes	1- Approval report for cleaning process: Report QN - Version B (2023-02-20) 2- Cleaning recorded on FR3.17 and disinfection on FR3.27 in the batch file for the batch manufactured after cleaning and/or disinfection		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
								P	-	-													None	
								I	-	-													None	
2.F.a.08	Environmental pollution => no lid on some tanks	Dust, pests, etc. => Contaminated formula	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Selection of closed tanks for manufacturing these products (tanks 15 and 16) 2- Assessment of the need to install strainers (protection from large pieces of debris)	1- Manufacturing process approval report: Reports QO Tank 15 - version A (2022-06-08) and QO Tank 16 - version A (2022-06-08) 2- As the solution is filtered during packaging, strainers are not required		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
								P	1- Microbiological, physico-chemical and organoleptic inspection of the batch produced	1- Files concerning batches approved for release													None	
								I	-	-													None	
2.F.a.09	Missing or illegible regulatory information on the label	Incorrect printer settings => Using a non-compliant product	Infection: patient	3	**4**	3 ; 4 = 12	Undesirable risk	C	1- Printer settings	1- DBTECH training on Code Soft software for printer settings: 25 and 26 January 2023		1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
								P	1- Control of printing (overprinting) on the line: batch number + expiry date checked at batch start-up on the first bottle and first box + verification of each pallet for the batch number	1- Inspection records in FR3.17 v7 (2023-01-23)												None	2023-07-17
								I	-	-													None	
2.F.a.11	Different expiry dates on the UDI and "hourglass" symbol	Mistake in entering dates in the two fields of the Soft Code software => Using a product that has expired	Infection: patient	2	**4**	2 ; 4 = 8	Undesirable risk	C	1- Setting up a link between X3 and Code soft so that information arrives automatically and not manually as it does now	1- Planned following DBTECH training		1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	1- Inspection during batch release (FR5.35 v1_2022-10-31)	1- Approved batch files													None	2022-12-15
								I	-	-													None	

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Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures *=> to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
	2.F.a.12	Non-homogeneity of the product in the dead zone	Sampling of dead zones in the valve: a zone where the concentration of the Active Substance (AS) is low => Non-compliant product	Infection: patient	3	4	3 ; 4 = 12	Undesirable risk	C	1- Setting up valve drainage	1- Operating procedure MR3.14 v4 (2023-01-16) for the commissioning of a packaging line		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	Contact with the operator during valve drainage => 2.B.a.07	2023-07-17
									P	1- Physico-chemical checks on the tank and packaging line	1- Inspections recorded in the table dedicated to the formula + printed in BA/CC (FR5.05 v4) + approval of specifications in the batch file												None	2023-07-17
									I	-	-												None	
	2.F.a.13	Non-homogeneity of the product in the dead zone	Sampling of dead zones in the valve: a zone where the concentration of hazardous substances (AS) is high => Non-compliant product	Irritation / corrosion: patient	3	4	3 ; 4 = 12	Undesirable risk	C	1- Setting up valve drainage	1- Operating procedure MR3.14 v4 (2023-01-16) for the commissioning of a packaging line		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	Contact with the operator during valve drainage => 2.B.a.07	2023-07-17
									P	1- Physico-chemical checks on the tank and packaging line	1- Inspections recorded in the table dedicated to the formula + printed in BA/CC (FR5.05 v4) + approval of specifications in the batch file												None	2023-07-17
									I	-	-												None	
	2.F.a.14	Insufficient agitation: low rotation	Non-homogeneity of the product in the manufacturing tank: does not contain a sufficient quantity of the Active Substance (AS) => Product not compliant	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Manufacturing process approval	1- Manufacturing process approval report: QO report Tank 15 - version A (08/06/2022) and QO Tank 16 - version A (08/06/2022)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
									P	1- Physico-chemical checks on the tank	1- Inspections recorded in the table dedicated to the formula + printed in BA/CC (FR5.05 v4) + approval of specifications in the batch file												None	
									I	-	-												None	
	2.F.a.15	Insufficient agitation: low rotation	Non-homogeneity of the product in the manufacturing tank: contains too many hazardous substances => Product not compliant	Irritation / corrosion: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Manufacturing process approval	1- Manufacturing process approval report: QO report Tank 15 - version A (08/06/2022) and QO Tank 16 - version A (08/06/2022)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
									P	1- Physico-chemical checks on the tank	1- Inspections recorded in the table dedicated to the formula + printed in BA/CC (FR5.05 v4) + approval of specifications in the batch file												None	2023-02-14
									I	-	-												None	
	2.F.a.16	Several people are involved in the manufacture of a tank	Putting the same Raw Material (MP) into the tank several times => Product not compliant / not meeting the required level of performance	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Production procedure with batch control stages during manufacture and packaging	Operating procedure MR3.17 v3 (2022-12-13) - Inspection to be carried out on FP liquids		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	1- Microbiological, physico-chemical and organoleptic batch control	1- Batch files												None	
									I	-	-												None	
	2.F.a.17	Tank connection error: wrong product packaged in labelled container	Using a non-efficient product that does not correspond to the labelling => Product not compliant / not meeting the required level of performance	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Registration of the connection tank by the operator 2- Installation of an automated record of the number of the tank to be connected = AZLAC traceability 3- Identification of connections and clamps used for connections with the tank	1- Approved batch files 2- AZLAC software: approval in progress 3- Registration in MR3.44 v2 (2022-10-05)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-												None	
									I	1- Information on the OF of the production tank	1- Information on MODOP nomenclature F3307 of 25 Oct. 2022 + MODOP nomenclature F3330 of 3 Jan. 2023 (dye): "Manufacturing only in tank number 15 or 16"												None	2023-01-09
	2.F.a.19	Non-compliant weighing/measuring equipment	Incorrect quantity of raw material incorporated / containers filled with incorrect quantity of solution	Product non-compliant / not meeting the required level of performance => patient infection	2	4	2 ; 4 = 8	Undesirable risk	C	1- Planning periodic checks and calibration of measurement equipment	1- Recording inspections in the OPTIMU software		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-												None	
									I	-	-												None	
b. Traceability	2.F.b.01	No reasonably foreseeable event identified																						2022-11-02

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Identifying hazards and hazardous situations				Initial risk assessment				Risk control															
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
PHASE 3: STORAGE AND TRANSPORT OF THE DEVICE																							
A. Biological hazards																							
a. Biological contamination of the MD treated	3.A.a.01	No reasonably foreseeable event identified																					
B. Chemical hazards																							
a. Device hazardous to human health	3.B.a.01	- Unsuitable storage conditions - Non-compliance with storage and transport conditions: stacking - Non-resistant combination of primary packaging and box	High pressure when stacking => damaged container => product leakage	Irritation / corrosion: operator / third party	2	**2**	2 ; 2 = 4	Tolerable risk (to be monitored)	C	1- Choice of box / 5L container combination, approved for hazardous materials with drop tests, compatibility with hazardous materials, etc. 2- CACES training for forklift drivers and internal authorisation	1- Approval certificate 2x5L : n°8705 Index 1 of 08/10/2019 + Extension 006 Index 0 of 09/07/2021 Approval certificate 4x5L: n°7999 Index 2 of 24/05/2018 + Extension 007 Index 0 of 11/05/2021 2- Training certificates + internal authorisation in employee files		2	**2**	2 ; 2 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	1- Clothing + safety footwear (PPE) required and provided	1- Job description in personnel files													None	
									I	1- Information on labels (ETQ): Precautionary statements in accordance with the CLP Regulation	1- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
b. Device hazardous to human health	3.B.b.01	Product not ADR classified, so not considered as hazardous for the driver during transport	Accident with product spillage => no associated transport documents => no information for the fire fighters	Harmful to organisms (H412)	1	2	1 ; 2 = 2	Negligible risk	C	1- Choice of ADR-approved box and 5L container, even if the product is not subject to ADR	1- Approval certificate 2x5L: n°8705 Index 1 of 08/10/2019 + Extension 006 Index 0 of 09/07/2021 Approval certificate 4x5L: n°7999 Index 2 of 24/05/2018 + Extension 007 Index 0 of 11/05/2021		1	2	1 ; 2 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	2022-12-15
									P	1- FDS communicated to the shipper to inform fire fighters	1- Acknowledgement and read receipt of emails sent to the shipper													None	
									I	1- Information on labels (ETQ): Precautionary statements in accordance with the CLP Regulation	1- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
C. Physical hazards																							
a. Temperature, humidity, sunlight	3.C.a.01	Humidity: Incompatibility box / label (glue) / container / formula	Using an incorrect product or an out-of-date product because: - Illegible information - Label peeling off - Box squashed => MD contaminated	Infection: patient	1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Approval of manufacturing processes 2- Choice of appropriate glue for the label of the 5L container 3- Choice of appropriate ink/printer/label 4- Accelerated stability study at 40°C 5- Container/box approval tests taking account of humidity parameters	1- Manufacturing process approval report: Reports QO CONDI-630 - version C (2023-03-22) and QO CONDI-710 - version C (2023-03-22) 2- / 3- Specifications for labels and printing technique 4- Stability report RSTAB2022084_F3307_ACCELERATED (2023-05-23) 5- Certificate of approval 2x5L : n°8705 Index 1 of 08/10/2019 + Extension 006 Index 0 of 09/07/2021 Approval certificate 4x5L: n°7999 Index 2 of 24/05/2018 + Extension 007 Index 0 of 11/05/2021 and box inspection report for approved box: COBB index (humidity)		1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-08-02
									P	-	-													None	
									I	-	-													None	
b. Injury to humans	3.C.b.01	- Unsuitable storage conditions - Non-compliance with storage and transport conditions: handling - Non-resistant combination of primary packaging and box e.g.: ADR - Approval)	Incorrect handling => damaged boxes => boxes falling on the picker / shipper	Superficial injury: picker / shipper	3	**2**	3 ; 2 = 6	Undesirable risk	C	1- Shrink-wrapping the pallet + Checking the first pallet 2- Organisation of logistics (WMS) to leave pallets that are not shrink-wrapped on the floor after picking => kept in the picking area until the pallet is empty	1- OF F3307 approved: MODOP nomenclature 25 Oct. 2022 2- WMS settings: in the picking area, pallets that are not shrink wrapped are left on the floor		2	**2**	2 ; 2 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-17
									P	1- Wearing safety shoes is compulsory	1- Job description in personnel files													None	
									I	-	-													None	
	3.C.b.02	- Stacking of 2 pallets or more - High stacking pressure: pallet	Pallet collapses and boxes on top fall off	Injury requiring hospital admission: picker / shipper	3	**4**	3 ; 4 = 12	Undesirable risk	C	1- No stacking of 2 pallets: single location in storage (WMS)	1- WMS configuration + Rack design		2	**2**	2 ; 2 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-													None	
									I	1- Implementation of a "Do not stack" pictogram on the film round the pallet	1 - To be planned													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	

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RISK ANALYSIS, ASSESSMENT AND CONTROL

Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
Hazards	Reasonably foreseeable events		Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
D. Immunological hazards																								
a. Allergenic device	3.D.a.01	No reasonably foreseeable event identified																						
E. Hazards associated with performance																								
a. Insufficient device performance	3.E.a.01	Duration of exposure to extreme temperatures above or below those recommended	Using the product without realising that it has not been correctly stored or transported => Unstable formula => Loss of performance	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Accelerated stability study at 40°C => no phase change or crystallisation observed 2- Provide test strips for checking the solution on first and subsequent uses	1- Stability study report RSTAB2022084_F3307_ACCELERATED (2023-05-23) 2- Test strip approval report RPEXCE2022006 (2022-08-30)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-08-02
									P	-	-													None	
									I	1- Information on labels (ETQ): Symbol for storage conditions (in accordance with ISO 15223-1): 5°C-25°C 2- Description in the distributors' QAR of storage and transport conditions, since the global export distributor is responsible for transport	1- ETQEXS0095 (FRR-01 and FRV-01) approved 2- Distributor QAR signed												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-17
	3.E.a.02	- Delivery of a product set to expire in the near future: less than 6 months (on reception at the customer's premises) - Failure to take into account the expiry date of the product indicated on the label/packaging	Using an expired product => Loss of performance	Infection: patient	3	4	3 ; 4 = 12	Undesirable risk	C	1- Study of shelf-life stability 2- WMS: ban on deliveries 6 months ahead + transport times recorded by customer	1- Stability study report RSTAB2022084_F3307_ACCELERATED (2023-05-23) 2- WMS configuration: Registration of tests now being integrated into the QMS		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-08-02
									P	1- Manufacturing to order for private labels	1- Distributor sales contract													None	
									I	1- Expiry date indicated on the pallet/box/bottle label and on the Delivery Note (BL) 2- Explanation of how to read the traceability code (Datamatrix) in the Regulatory Information section of the Instructions for Use (NU) 3- Information on the labels (ETQ) and the Instructions for Use (NU): Before use, check the expiry date on the label	1- Approved batch files 2- / 3- ETQEXS0095 (FRR-01 and FRV-01) and NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	3.E.a.03	Containers rubbing together in the box => Overprinted information disappears: traceability	Using an out-of-date product in the absence of traceability data => Loss of performance	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Choice of label compatible with the ink: ink adhering to the label 2- Implementation of tests to confirm the behaviour of the ink on all types of label	1- Label specifications 2- Planning of tests in progress: purchase of test equipment		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-														None	
									I	1- Information in the Instructions for Use (NU): If the label is damaged, set the container aside from the rest and inform the sales representative.	1- NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	3.E.a.04	Plant environment: temperature variation from 15°C to 40°C depending on the season	Using the product without realising that it has not been correctly stored or transported => Loss of performance	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Design of the storage building with concrete walls and roof insulation => little variation in temperature 2- Contractualisation of storage and transport conditions with our distributors	2- Contracts with our distributors		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	1- Recording and monitoring the temperature of stock: setting thresholds of alert if recommended temperatures are exceeded	1- Temperatures with warning thresholds recorded in OCEAVIEW (MM5.16 v1 2023-01-16)												None	2023-02-14
									I	1- Information on the ETQ: Symbol for storage conditions (in accordance with ISO 15223-1): 5°C- 25°C	1- NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	3.E.a.05	Failure to manage the storage /handling conditions of raw materials (MP): failure to comply with requirements in terms of temperature, humidity, light/dark conditions, etc.	Loss of MP compliance during storage and/or handling at Sodel => Non-compliant product	Risk: patient / user	2	4	2 ; 4 = 8	Undesirable risk	C	1- Physico-chemical and organoleptic inspection of batches of semi-finished products => identification of a non-compliant MP 2- Checks to ensure that MP can be stored in the conditions defined by suppliers	1- Approved batch files 2- New MP referencing form (FM4.30 v2_2022-01-14): indication of MP storage conditions and location		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-													None	
									I	-	-													None	
b. Loss of performance in treated MD	3.E.b.01	No reasonably foreseeable event identified																						
c. Errors in use	3.E.c.01	No reasonably foreseeable event identified																						2022-11-02
F. Hazards associated with quality processes																								
a. Quality Management System	3.F.a.01	No reasonably foreseeable event identified																						
b. Traceability	3.F.b.01	No reasonably foreseeable event identified																						

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Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
				Estimation								Final estimation of residual risk						Estimation of benefit						
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	F_i	G_i	$(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures *=> to be assessed after auditing and after CE marking is obtained*	F	G	(F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	F_b	I_b	$(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
PHASE 4: USE OF THE DEVICE																								
A. Biological hazards																								
a. Biological contamination of the MD treated	4.A.a.01	- Use by unskilled personnel - Use by non-professionals	- Failure to follow instructions for use - Non-compliance with good disinfection practices (guides and documents issued by health authorities) => MD not disinfected or insufficiently disinfected	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Sales to professionals only 2- Support for users available for first use 3- Availability of protocols and technical data sheets drafted by Sodel	1- SIRET (company identification number) requested to open an account 2- User support form 3- Documentation approval		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-												None	
									I	1- Indication on the label (ETQ) and instructions for use (NU), as well as on the technical data sheet (FT) and the protocol for use (PRT): instructions for use	1- ETQEXS0095 (FRR-01 and FRV-01) + NU-EXEOL OPA-FR-02 + FT-EXEOL OPA-FR-02 + PRT-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.A.a.02	- Use by people not "supported" by Sodel on first use - Insufficient support during product application - Temporary workers or workforce with high turnover	- Failure to follow instructions for use - Change of product or instructions for use while maintaining the habits associated with the old product => MD not disinfected or insufficiently disinfected	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- User support available on first use => request for justification if support not provided 2- Sales staff trained/aware of how to offer support	1- Template for the support sheet: "Product training sheet" + Support sheets produced 2- Registration sheet for sales staff training: "Attendance sheet FS2.32		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-												None	
									I	1- Indication on the label (ETQ) and instructions for use (NU), as well as on the technical data sheet (FT) and the protocol for use (PRT): instructions for use	1- ETQEXS0095 (FRR-01 and FRV-01) + NU-EXEOL OPA-FR-02 + FT-EXEOL OPA-FR-02 + PRT-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.A.a.03	Diluting the product in water when using	Disinfection of the MD with a solution that is partially or non-effective: lower minimum effective concentration => MD not disinfected /insufficiently disinfected	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Compliance with standards of 80% - 70% suspension 2- Implementing test strips to check the AS concentration of baths => based on 80% "dilution"	1- Standard reports 2- Test strip approval report RPEXCE2022006 (30/08/2022)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-												None	
									I	1- Information on the intended use of the product on the label (ETQ) and in the Instructions for Use (NU): - Ready-to use solution. -Before use, check the validity of the bath with the test strips exeol strips OPA	1- ETQEXS0095 (FRR-01 and FRV-01) + NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.A.a.04	Using the product on medical devices that have not been cleaned beforehand	Dirt becomes ingrained because aldehydes and alcohol are fixatives => MD insufficiently cleaned and disinfected	Infection: patient	2	**4**	2 ; 4 = 8	Undesirable risk	C	1- User support available on first use => request for justification if support not provided 2- Sales staff trained in how to offer this support	1- Template for the support sheet: "Product training sheet + Support sheets produced		1	**4**	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	1- Monitoring the marketing of detergents and disinfectants in establishments	1- PSUR report (to be planned)												None	
									I	1- Information on the label (ETQ): Is used undiluted on a previously cleaned and rinsed surface	1- ETQEXS0095 (FRR-01 and FRV-01) approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.A.a.05	- Using in a washer-disinfector or power scrubber or in an IWD*** with recycling of the disinfection solution	- Diluted solution - Impossible to set contact time => MD insufficiently disinfected	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	-	-		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-												None	
									I	1- Information on the label (ETQ): pictogram for "manual soaking" 2 - Information in the Instructions for Use (NU): Do not use in a washer disinfector	1- ETQEXS0095 (FRR-01 and FRV-01) approved 2- NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.A.a.06	Using for final disinfection of heat-resistant medical devices	Using the product on surgical instruments that need to be sterilised (non-heat sensitive) and that therefore should not be disinfected with a high-level or intermediate level disinfectant	MD not sterilised, but disinfected	1	1	1 ; 1 = 1	Negligible risk	C	1- High-level microbiological tests: bactericidal, fungicidal, virucidal, mycobactericidal and sporicidal characteristics	1- Standards reports		1	1	1 ; 1 = 1	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	24,0	Acceptable	None	
									P	-	-												None	
									I	1- Information in the NU: Do not use on MD that require sterilisation (non-heat sensitive)	1- NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28

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Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
	4.A.a.09	Product streaks on labels (ETQ)	Important information deleted on the ETQ => Incorrect use of the product => Incorrect disinfection	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Label resistance tests 2- Approval of the supplier and the characteristics of resistant labels	1- Tests planned: test equipment ordered 2- Test reports pending to determine whether we need to change suppliers		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	-	-													None	
								I	1- Information in the Instructions for Use (NU): If the label is damaged, set the container aside from the rest and inform the sales representative.	1- NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.A.a.10	Not using the right quantity of product: MD not fully immersed and hollow bodies non-irrigated	Using a non- or partially disinfected MD	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	-	-		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	-	-													None	
								I	1- Information on the label (ETQ): Open and disassemble the medical devices and place them in the solution, ensuring that they are completely immersed. Ensure that channels are irrigated as appropriate	1- ETQEXS0095 (FRR-01 and FRV-01) approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
B. Chemical hazards																								
a. Device hazardous to human health	4.B.a.01	- Use by unskilled personnel - Use by non-professionals	Failure to wear PPE	Irritation of the user / Sensitisation of the user	1	1	1 ; 1 = 1	Negligible risk	C	1- Sale to professionals only 2- Support for users available for first use 3- Availability of protocols and technical data sheets drafted by Sodel => no PPE required according to the CLP classification of the finished product	1- SIRET (company identification number) requested to open an account 2- User support template 3- Documentation approval		1	1	1 ; 1 = 1	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	24,0	Acceptable	None	
								P	-	-													None	
								I	1- Indication on the label (ETQ) and instructions for use (NU), as well as on the technical data sheet (FT) and the protocol for use (PRT): - FOR PROFESSIONAL USE ONLY - instructions for use - Use long-sleeved gloves 2- Information in the Safety Data Sheet (FDS): The use of protective gloves is not mandatory. If your protocols recommend wearing them, use appropriate chemical-resistant gloves in accordance with EN 374 standard.	FDS_exeol OPA_3307-112-1_1.3_FR_20220831 + ETQEXS0095 (FRR-01 and FRV-01) + NU-EXEOL OPA-FR-02 + FT-EXEOL OPA-FR-02 + PRT-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.B.a.02	The user dips their hands into the solution to retrieve the medical devices before rinsing them with unsuitable gloves or without gloves	Contact with the product on each use lasting between a few seconds and a few minutes	Colouring of proteins, and therefore of the hands	3	1	3 ; 1 = 3	Tolerable risk (to be monitored)	C	1- Permeation tests of nitrile / latex gloves	1- Test report RPPERM2022_F3307_003 approved		3	1	3 ; 1 = 3	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	8,0	Acceptable	None	
								P	-	-													None	
								I	1- Information on the Safety Data Sheet (FDS), the label (ETQ) and in the Instructions for Use (NU): Use long-sleeved gloves	1- FDS_exeol OPA_3307-112-1_1.3_FR_20220831 + ETQEXS0095 (FRR-01 and FRV-01) + NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.B.a.07	- Non-ergonomic position of the 5L or 2L container when pouring the contents into the tank - "Throwing" MD into the bath	Splashing during transfer or when immersing MDs	Irritation / corrosion: user****	2	1	2 ; 1 = 2	Negligible risk	C	1- Usability test 2- Commercial support available when the product is installed in the plant, with an explanation of how to position the container during transfer if the user is unfamiliar with it	1- Usability engineering report RPDIAU2022_F3313_01 (2022-06-13) 2- Support sheet		2	1	2 ; 1 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	
								P	-	-													None	
								I	1- Information in the Protocol for Use (PRT): diagram showing how to fill the tank with the container at an angle	1- PRT-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.B.a.08	Container cap difficult to open by hand	Container spills on opening	Irritation / corrosion of the user	1	1	1 ; 1 = 1	Negligible risk	C	1- Usability test	1- Usability engineering report RPDIAU_F3313_01 (2022-06-13)		1	1	1 ; 1 = 1	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	24,0	Acceptable	None	
								P	-	-													None	
								I	1- Information on the label (ETQ): When using for the first time, remove the tamper-proof ring before unscrewing the cap.	1- ETQEXS0095 (FRR-01 and FRV-01)approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28

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Identifying hazards and hazardous situations					Initial risk assessment				Risk control															
Hazards	Reasonably foreseeable events		Hazardous situations	Damage	Estimation			Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk			Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit			Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
					F_i	G_i	$(F_i ; G_i) = C_i$						F	G	(F ; G) = C				F_b	I_b	$(F_b ; I_b) = B$				
	4.B.a.09	Using on patients	Use as an antiseptic on a wound	Irritation / corrosion: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	-	-		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-													None	
									I	1- Information in the Instructions for Use (NU): Do not use directly on the patient	1- NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
b. Device hazardous to human health	4.B.b.01	No reasonably foreseeable event identified																						
C. Physical hazards																								
a. Temperature, humidity, sunlight	4.C.a.01	Using in premises where the environment is not controlled	Solution evaporates in an environment with an uncontrolled temperature (too hot) => Loss of performance	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Solution stability at 54°C for 8 weeks 2- Test strips approved to check bath stability	1- Stability report RSTAB2022084_F3307_ACCELEREE (2023-05-23) approved 2- Test strip approval report RPEXCE2022006 (2022-08-30)		2	2	2 ; 2 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-08-02
									P	-	-													None	
									I	1- Information on the label (ETQ) and the Instructions for Use (NU): - Symbol for storage conditions (in accordance with ISO 15223-1): 5°C- 25°C- Use only outdoors or in a well-ventilated area. - Regularly check the validity of the bath using the test strips exeol strips OPA. - Cover the tank	1- ETQEXS0095 (FRR-01 and FRV-01) and NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
b. Injury to humans	4.C.b.01	Using on materials identified as non-compatible	Using a damaged MD	Injury and/or infection: patient	1	2	1 ; 2 = 2	Negligible risk	C	1- Literature review to identify non-compatible materials 2- Electrochemical tests to determine the corrosive power of the product	1- Literature review report 2- Electrochemistry report RPELEC2022_F3307_006 (2022-04-28)		1	2	1 ; 2 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	
									P	-	-													None	
									I	1- Information in the Instructions for Use (NU): List of (compatible and) non-compatible materials, with reference to tests	1- NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
D. Immunological hazards																								
a. Allergenic device	4.D.a.01	- Inadequate rinsing / negligent rinsing - Endoscope channels not drained: product in channel lighting	Residues present on the MD => Invasive contact with disinfection residues in the event of insufficient rinsing	Allergic shock => patient temporarily admitted to hospital	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Review of the literature in the biological assessment	1- Biological assessment report RPBIOL2022_F3307_03 (2022-09-01)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-													None	
									I	1- Information on the label (ETQ): Rinse thoroughly	1- / 2- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
E. Hazards associated with performance																								
a. Insufficient device performance	4.E.a.01	Using in a washer disinfector or power scrubber or in an IWD with recycling of the disinfection solution	Appearance of foam => Poorly irrigated endoscope: MD not disinfected or insufficiently disinfected + washer error	Repeat the treatment	1	1	1 ; 1 = 1	Negligible risk	C	1- Planning of foam tests	1- Test report: FM4.73 - v1 Report RPMOUS2022_F3307_002(2022-05-03)		1	1	1 ; 1 = 1	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	24,0	Acceptable	None	
									P	-	-													None	
									I	1- Information on the label (ETQ): pictogram for "manual soaking"+ in the intended use: "for final disinfection by immersion of invasive and non-invasive reusable medical devices 2- Information in the Instructions for Use (NU): Do not use in a washer disinfector	1- ETQEXS0095 (FRR-01 and FRV-01) approved 2- NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
			Use at temperatures above 20°C	Beneficial effect on antimicrobial efficacy	1	1	1 ; 1 = 1	Negligible risk	C	-	-		1	1	1 ; 1 = 1	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	24,0	Acceptable	None	
									P	-	-													None	
									I	1- Information on the label (ETQ): "20°C" in disinfectant properties (ETQ)	1- ETQEXS0095 (FRR-01 and FRV-01) approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28

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Identifying hazards and hazardous situations				Initial risk assessment				Risk control																
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation			Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures *=> to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk			Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit			Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
				F_i	G_i	$(F_i ; G_i) = C_i$						F	G	(F ; G) = C				F_b	I_b	$(F_b ; I_b) = B$				
	4.E.a.02	- Inadequate rinsing of an enzyme- and/or amine-based detergent used prior to disinfection	Using poor quality intermediate rinse water => Staining of MD: identification of biofilm	MD not used because the damage will be identified before use	2	1	2 ; 1 = 2	Negligible risk	C	-	-		2	1	2 ; 1 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	
								P	-	-													None	
								I	1- Information in the Instructions for Use (NU): Do not use the retreated medical device if deposits are visible, but contact the sales department	1- NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.E.a.05	Not closing the container after use	Product evaporates if the container is left open => Loss of performance	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	-	-		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	1- Checks using test strips on each use in compliance with current French regulations	1- Test strips approval report RPEXCE2022006 (2022-08-30)													None	
								I	1- Information in the instructions on the label of the 5L container (ETQ) and in the Instructions for Use (NU): Close the container after use	1- ETQEXS0095 (FRR-01 and FRV-01) + NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.E.a.06	- Not checking or not sufficiently checking the stability of the bath with the test strips over the period of use (7 days / 30 days) - Instructions for using the strip not known or not followed - Incorrect interpretation of the test strip reading - Not changing the bath when the strip indicates that the bath is no longer usable	Disinfecting the MD with a non-effective product => MD not disinfected	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Validation of bath stability using a method based on NFT 72-901 2- Validation of test strips and their instructions for use 3- Checks to ensure understanding of the instructions for using the test strips	1- Test report RPBAIN2022_F3307_002 (2022-08-30) => stability for 14 days 2- ETQEXS0095 (FRR-01 and FRV-01) approved + Test strip approval report RPEXCE2022006 (2022-08-30)) 3- Test strip customer test sheet		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-28
								P	-	-													None	
								I	1- Information on the label (ETQ) and the Instructions for Use (NU): Regularly check the validity of the bath using the test strips 2- Information on how to use the test strips on the test strip tube 3- Information in the Protocol for Use (PRT): how to use the test strip	1- ETQEXS0095 (FRR-01 and FRV-01) + NU-EXEOL OPA-FR-02 approved 2- ETQAC0176-01 approved 3- PRT-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.E.a.07	- Incorrect storage of the test strip - Using an expired or faulty test strip - User cannot distinguish between the colours: cannot read the strip	Using the bath when the test strip shows that the bath can no longer be used => MD not disinfected	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Validation of test strips and their instructions for use 2- Non-specific storage conditions: 0°C - 40°C 3- Check understanding of how to use the test strips	1- ETQEXS0095 (FRR-01 and FRV-01) approved + Test strip approval report RPEXCE2022006 (2022-08-30) 2- Specifications from test strip suppliers 3- Test strip customer test sheet		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	2023-07-28
								P	-	-													None	
								I	1- Information on the test strip tube - instructions for use - storage symbol (in compliance with ISO 15223-1): 0°C - 40°C 2- Information in the Protocol for Use (PRT): how to use the test strips	1- ETQEXS0095 (FRR-01 and FRV-01) approved 2- PRT-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.E.a.08	- Using a test strip not specific to the product - Time limit exceeded for reading the test strip based on instructions for use - Continuing to use the bath after 7 days (or 30 days outside France) of use: the test strip shows that the bath is still stable	Systematically positive results on the test strip, even though the bath is not stable =>MD not disinfected	Infection: patient	2	4	2 ; 4 = 8	Undesirable risk	C	1- Supply of test strips to check the concentration of active substance (AS) in the product	1- Test strip approval report RPEXCE2022006 (2022-08-30), with checks to ensure that the test strips do not react with co-formulants in the solution		2	4	2 ; 4 = 8	Undesirable risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	3,0	Acceptable	None	
								P	-	-													None	
								I	1- Information in the Protocol for Use (PRT): instructions for use of the test strips, specifying the colours of compliant and non-compliant test strips 2- Information in the Instructions for Use (NU): sales reference of the test strips	1- PRT-EXEOL OPA-FR-02 approved 2- NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.E.a.09	Failure to take into account the expiry date of the product indicated on the label/packaging	Using an expired product => Non-disinfectant	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Usability test: Checking that information is easily accessible	1- Usability engineering report RPDIAU2022_F3313_01 (2022-06-13)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
								P	-	-													None	
								I	1- Information in the DataMatrix and next to the hourglass symbol (ISO 15223-1) on the label (ETQ): expiry date 2- Information in "Precautions" on the label (ETQ): Before use, check the expiry date on the label 3- Information in the Instructions for Use (NU): Explanation of how to read traceability (Datamatrix)	1- and 2- ETQEXS0095 (FRR-01 and FRV-01) approved 3- NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28

RISK ANALYSIS

RISK ANALYSIS, ASSESSMENT AND CONTROL

Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations					Initial risk assessment				Risk control																				
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation			Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk			Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit			Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
				F_i	G_i	$(F_i ; G_i) = C_i$						F	G	(F ; G) = C				F_b	I_b	$(F_b ; I_b) = B$				
	4.E.a.10	Transferring the product to different packaging when using	- Mixing the product with residues from another product - Non-compatibility between container and contents - Loss of traceability => Inefficient product	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	-	-		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-														None	
									I	1- Information in the Instructions for Use (NU): Keep the recipient tightly closed with the original packaging and labelling 2- Information on the label (ETQ): Do not mix with other products	1- NU-EXEOL OPA-FR-02 approved 2- ETQEXS0095 (FRR-01 and FRV-01)approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.E.a.11	Keeping the container open	- Spillage of the container - Evaporation (odour) => Inefficient product	Infection: patient	1	4	1 ; 4 = 4	Tolerable risk (to be monitored)	C	1- Usability test: understanding the instructions for use	1- Usability engineering report RPDIAU2022_F3313_01 (2022-06-13)		1	4	1 ; 4 = 4	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	6,0	Acceptable	None	
									P	-	-														None	
									I	1- Information in the Instructions for Use (NU) and label (ETQ) Close the container after use	1- ETQEXS0095 (FRR-01 and FRV-01) and NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	4.E.a.12	Using dirty tanks => dirt becomes ingrained with aldehydes	Tank not rinsed after use => Loss of active substance (AS) content, adhering to the soiling of the tank	Infection: patient	1	2	1 ; 2 = 2	Negligible risk	C	-	-		1	2	1 ; 2 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	
									P	1- Checking the stability of the bath with a test strip	1- ETQEXS0095 (FRR-01 and FRV-01) approved												None	2023-07-28
									I	1- Information in the Instructions for Use (NU): the tanks must be cleaned and rinsed thoroughly	1- NU-EXEOL OPA-FR-02 approved												Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
b. Loss of performance in treated MD	4.E.b.01	Contact times too long and/or repeated too often	Using a damaged MD: - opacification of optical components (deposits on endoscope lenses) - discolouration of endoscope markings - embrittlement of the rubber around the plastic: endoscope sheaths - damage to the suction systems for dental units - non-functional rotating instruments	MD not used because the damage will be identified before use					C	No action taken as no damage identified								- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs						None	
									P	No action taken as no damage identified	-												None	
									I	No action taken as no damage identified	-												None	
c. Errors in use	4.E.c.01	No reasonably foreseeable event identified																								2022-11-02
F. Hazards associated with quality processes																													
a. Traceability	4.F.a.01	No reasonably foreseeable event identified																											
b. Quality Management System	4.F.b.01	No reasonably foreseeable event identified																								2022-11-02

RISK ANALYSIS

RISK ANALYSIS, ASSESSMENT AND CONTROL

Based on standard NF EN ISO 14971: 2019 / A11: 2021 (chapters 5.4 and Annex C/ 5.5/ 6/ 7) and ISO/TR 24971: 2020 (chapters 5.4 and Annex F / 5.5 / 6 / 7 and Annex D)

Identifying hazards and hazardous situations				Initial risk assessment				Risk control															
Hazards	Reasonably foreseeable events	Hazardous situations	Damage	Estimation F_i	Estimation G_i	Estimation $(F_i ; G_i) = C_i$	Initial risk assessment	Option	Implementation of risk control measures	Verification concerning implementation of risk control measures	Verification of the effectiveness of risk control measures => *to be assessed after auditing and after CE marking is obtained*	Final estimation of residual risk F	Final estimation of residual risk G	Final estimation of residual risk (F ; G) = C	Residual risk assessment	Identified residual risk	Identification of the benefit based on the severity of the damage of the residual risk	Estimation of benefit F_b	Estimation of benefit I_b	Estimation of benefit $(F_b ; I_b) = B$	Risk/benefit ratio	Acceptance of residual risk in accordance with the R / B ratio	Risks arising from risk control measures	Date of modification
PHASE 5: DISPOSAL OF THE DEVICE																								
A. Biological hazards																								
a. Biological contamination of the MD treated	5.A.a.01	No reasonably foreseeable event identified																						
B. Chemical hazards																								
a. Device hazardous to human health	5.B.a.01	Rinsing the container and disposing of it as non-hazardous waste - Failure to place the container in the right waste bin (hazardous)	Disposing of packaging as non-hazardous waste, when in fact it is hazardous => if the product is rinsed, the residue will be less hazardous than the initial solution	Danger to the health of a third party (waste management)	3	1	3 ; 1 = 3	Tolerable risk (to be monitored)	C	1- REP DEIC regulations to be implemented by 2025 at the latest, for better management and information on packaging waste	1- Implementation planning: pending official requirements		3	1	3 ; 1 = 3	Tolerable risk (to be monitored)		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	8,0	Acceptable	None	
									P	-	-													None	
									I	1- Information in the Instructions for Use (NU): Empty the recipient completely without rinsing it.	1- NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
b. Device hazardous to human health	5.B.b.01	Lack of knowledge of disposal methods	Directly disposing of the product in the environment	Harmful to the environment (H412)	1	2	1 ; 2 = 2	Negligible risk	C	-	-		1	2	1 ; 2 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	
									P	-	-													None	
									I	1- Information on the Safety Data Sheet (FDS), the label (ETQ) and in the Instructions for Use (NU): methods of product disposal	1- FDS_exeol OPA_3307-112-1_1.3_FR_20220831, ETQEXS0095 (FRR-01 et FRV-01) and NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
	5.B.b.02	Emptying the rest of the container into the sink	Establishment not connected to a WWTP => pollution of waterways and stormwater networks	Harmful to the environment (H412)	1	2	1 ; 2 = 2	Negligible risk	C	-	-		1	2	1 ; 2 = 2	Negligible risk		- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs	4	6	4 ; 6 = 24	12,0	Acceptable	None	
									P	-	-													None	
									I	1- Information in the Instructions for Use (NU): method of effluent disposal	1- NU-EXEOL OPA-FR-02 approved													Information not taken into account => equivalent to the same risk as 1.E.c.01 Incomprehensible information	2023-07-28
C. Physical hazards																								
a. Temperature, humidity, sunlight	5.C.a.01	No reasonably foreseeable event identified																						
b. Injury to humans	5.C.b.01	No reasonably foreseeable event identified																						2022-11-02
D. Immunological hazards																								
a. Allergenic device	5.D.a.01	No reasonably foreseeable event identified																						
E. Hazards associated with performance																								
a. Insufficient device performance	5.E.a.01	No reasonably foreseeable event identified																						
b. Loss of performance in treated MD	5.E.b.01	No reasonably foreseeable event identified																						
c. Errors in use	5.E.c.01	No reasonably foreseeable event identified																						2022-11-02
F. Hazards associated with quality processes																								
a. Quality Management System	5.F.a.01	No reasonably foreseeable event identified																						2022-11-02
b. Traceability	5.F.b.01	No reasonably foreseeable event identified																						2022-11-02

RISK MANAGEMENT REPORT

According to EN ISO 14971: 2019 / A11: 2021 (chapter 9)

Review and changes to updates

m.	Date	Origin	Manager	Description
-	2022-09-02	New product	Marlène Horgnies	Creation and signature
-	2023-08-04	Form modification	Séverine Huvet	Changes to risk analysis, assessment and control taken into account Change of form reference following the reallocation of Risk Management to PM06: FM6.16 v1 (formerly FM4.28 v3) Modifications tracker added
1	2024-02-23	Round 1 - GMED assessment	Mehdi AIT MALAK	Intended use updated to specify use exclusively on semi-critical and critical medical devices

Scope of planned activities relating to risk and benefit/risk management

Regulatory requirements		Information
Description		Ready-to-use orthophthalaldehyde based solution for final disinfection by immersion of pre-cleaned semi-critical and critical heat-sensitive invasive and non-invasive reuseable medical devices (class IIb)
Device identification	F3307 / RD0209E36	Trade names of the devices concerned: - exeol santé range: **exeol OPA** - OBL distributors: none to date
Lifecycle phases concerned	Initial product risk analysis:	Intended use & reasonably foreseeable misuse + Identification of safety-related characteristics + Design lifecycle phase Begun before the device is first put on the market (during R&D)
	Product risk analysis:	Lifecycle phases: Design + Production + Storage + Transport + Use + Disposal Completes the initial risk analysis for acceptance of the first placing on the market of the devices, and is updated according to the post-marketing data for the devices => Updated information shown in orange in the product characteristics and risk analysis
Interaction with the usability engineering file	Lifecycle phases:	Storage + Transport + Use + Disposal Begun before devices are placed on the market for the first time (during R&D) or after they have been placed on the market in the case of UOUPs (User Interface of Unknown Provenance) + Takes into account risk control measures based on safety related information (I) => Information shown by purple lines/cells (like this line)

Risk Management File deliverables

Risk Management Plan and Risk-Benefit Ratio

Risk analysis, including:

- Intended use & Reasonably foreseeable misuse
- Identification of safety-related features
- Identifying hazards and hazardous situations
- Initial risk assessment
- Risk control
- Assessment of overall residual risk

Risk management report

RISK MANAGEMENT REPORT

According to EN ISO 14971: 2019 / A11: 2021 (chapter 9)

Assessment criteria

Individual risk assessment criteria

See procedure PM6.08 - Managing product risk

Frequency	Definition of risk levels	F_i or F
Unlikely	The chances of this happening are very small. Unlikely to occur during the lifetime of the medical device.	**1**
Rare	Could occur, but rarely. Could occur a few times during the lifetime of the medical device.	**2**
Possible	Likely to occur frequently. Likely to occur several times during the lifetime of the medical device.	**3**
Frequent	Likely to occur almost systematically. Could occur each time the medical device is used.	**4**

Severity	Damage for the user or a third party, and the environment (disposal phase) */ Damage for the patient*	G_i or G
Minor - Discomfort	Fleeting effect: Whitening of the skin, Appearance of slight redness, Cough. Non-hazardous for the environment / Biodegradable. */ Temporary discomfort (slight pain)*	**1**
Significant - Sickness / Injury	Temporary effect: Discomfort caused by vapours, skin or eye irritation. Minor damage to fauna and flora (H412) */ Superficial injury or infection not requiring hospitalisation owing to a damaged or soiled instrument*	**2**
Major - Slight / temporary disability	Average long-term effect: Burns or corrosion leaving scars, temporary eye damage. Temporary reduction in fauna or flora (H411, low biodegradability). */ Injury or infection requiring hospitalisation, Performance of a new medical procedure, Temporary irritation or corrosion*	**4**
Critical - Permanent disability / Death	Permanent effect: Loss of sight, loss of mobility. Total destruction of fauna or flora (H410, non-biodegradable) */ Permanent treatment following healthcare-associated infection (nosocomial), death*	**6**

Note: For risks common to all products in the Sodel range, the level of risk severity G_i and G will be based on the Worst case for the range whatever its purpose.
Identification of risks based on Worst case: levels Gi and G will be shown in bold.

Risk Estimate (C_i and C) = Frequency * Severity		Severity of damage			
		Minor - Discomfort	Significant - Sickness / Injury	Major - Slight / temporary disability	Critical - Permanent disability / Death
Frequency	Unlikely	1	2	4	6
	Rare	2	4	8	12
	Possible	3	6	12	18
	Frequent	4	8	16	24

Individual Risk Assessment	Level of risk
≤ 2	**Negligible level of risk**
3 to 4	**Tolerable level of risk** (to be monitored as part of post-market surveillance)
6 to 12	**Undesirable level of risk** (to be monitored as part of post-market surveillance, but no more than 10% based on the criteria above)
≥ 16	**Unacceptable level of risk**

RISK MANAGEMENT REPORT

According to EN ISO 14971: 2019 / A11: 2021 (chapter 9)

Criteria for estimating individual benefit

See procedure PM6.08 - Managing product risk

Frequency	Appearance of benefit	F_b
Unlikely	The chances of this happening are very small. Unlikely to occur during the lifetime of the medical device.	1
Rare	Could occur, but rarely. Could occur a few times during the lifetime of the medical device.	2
Possible	Likely to occur frequently. Likely to occur several times during the lifetime of the medical device.	3
Frequent	Likely to occur almost systematically. Could occur each time the medical device is used.	4

Scale	Positive impact	I_b
Unexpected / Very low	Inadequate cleaning and disinfection before reusing the reusable medical device	1
Desirable / Moderate	Quality of cleaning and disinfection comparable to a control (water) before reusing the reusable medical device	2
Preferable / High	Optimised quality of the obligatory cleaning and disinfection before reusing the reusable medical device	4
Essential / Maximum	Obligatory cleaning and disinfection before reusing the reusable medical device	6

Estimated Benefit (B) = Frequency * Scale		Scale of the positive impact			
		Very low / Negligible	Desirable / Average	Preferable / High	Essential / Maximum
Frequency	Unlikely	1	2	4	6
	Rare	2	4	8	12
	Possible	3	6	12	18
	Frequent	4	8	16	24

Level of the positive impact	
≤ 2	No benefit
3 to 4	Little benefit
6 to 12	Acceptable benefit
≥ 16	High benefit

The colour code in the table above is provided for purposes of information to show the mirror effect with the level described in the risk estimate. No interpretation of the colour code is applied.
The Benefit is considered "Acceptable" if the estimated Benefit is ≥ 6, taking into account the severity of the residual risk.

Acceptance criteria for the individual benefit/risk ratio

Estimated Benefit (B) / Residual Risk (C) ratio	
Acceptable if B/C > 1	
≤ 1	Unfavourable ratio
> 1	Acceptable ratio

If the Benefit/Risk ratio is greater than 1, then the Residual Risk is accepted.
If the Benefit/Risk Ratio is less than or equal to 1, then risk control needs to be reviewed.

RISK MANAGEMENT REPORT

According to EN ISO 14971: 2019 / A11: 2021 (chapter 9)

Examination of risk management

Enforcement of the Risk Management Plan

This report summarizes the elements of the Risk Management File following the previously defined risk management plan.

Global residual risk

Summary	Estimation before risk control	Estimation after risk control	Breakdown of risks after risk control	
Negligible risk	16	20	21,5%	92,5%
Tolerable risk (to be monitored)	32	66	71,0%	
Undesirable risk	43	7	7,5%	
Intolerable risk	2	0	0,0%	
Total	**93**	**93**		

The distribution of residual risks identified as "undesirable" above is presented below according to the categories "Patient", "User", "Operator" and "Environment":

Event	"Undesirable" residual risk	Associated damage:			
		Patient	User	Operator	Environment
2.A.a.04	RR2.4	X			
2.B.a.01	RR2.6			X	
2.B.a.02	RR2.7			X	
2.B.a.05	RR2.10			X	
2.B.a.08	RR2.13			X	
2.B.a.13	RR2.18			X	
4.E.a.08	RR4.18	X			
		2	0	5	0
Unwanted RR Number / Number Risks identified:		2,2%		5,4%	

ANALYSIS Overall residual risk	86 residual risks of the 93 risks identified for the system (92.5%) are at an "acceptable" or "tolerable" level. 7 residual risks (7.5%) are at the "undesirable" level: 2 are associated with a patient/user risk (2.2%) and 5 are associated with an operator risk at Sodel (5.4%). In accordance with what was established in the risk management plan, the rate of undesirable residual risks being less than 10% for the patient/user, the overall residual risk is accepted.

Risk/benefit ratio

Claimed clinical (indirect) benefits:	- Prevent healthcare-associated infection rates and in particular the main disabling nosocomial infections - Use reusable medical devices after reprocessing in complete safety, in order to reduce readmissions into hospital and the associated costs
Probability of occurrence of benefit:	Could occur each time the medical device is used. (4)

ANALYSIS Risk/benefit ratio	In accordance with what was established in the Risk Management Plan, the analysis of the individual and overall benefit/risk ratio is positive (8.1 on average).

Combined residual risks

ANALYSIS Combined residual risks	The 73 residual risks were combined. No new risks were identified in the analysis of the combined residual risks.

Application of methods

The methods proposed in Risk Management have been applied. The information collected will be analyzed periodically.

RISK MANAGEMENT REPORT

According to EN ISO 14971: 2019 / A11: 2021 (chapter 9)

Conclusion

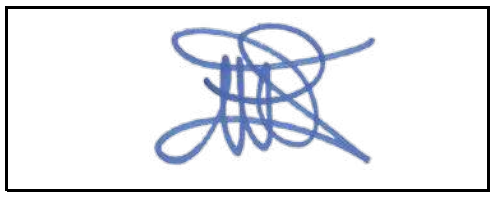
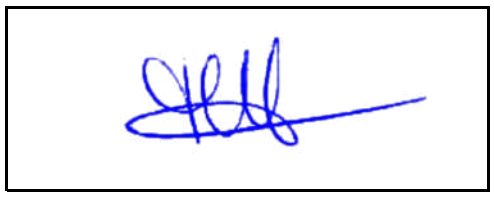
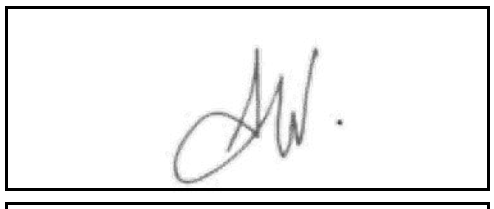
According to the Risk Management Policy defined in the Risk Management Plan:

- The management process was implemented according to the ISO 14971 standard: 2019 / A11: 2021
- Risks have been reduced as much as possible.
- No intolerable residual risk before estimation of the Benefit/Risk ratio is identified.
- After risk control measures and before analysis of the Benefit / Risk ratio, there remains less than 10% (2.2%) of residual risks considered "undesirable" for the patient and/or user.
- The individual and overall Benefit/Risk ratio is systematically positive (8.1 on average) .
- The combination of residual risks did not give rise to new risks.

The overall residual risk and the Benefit/Risk Ratio of exeol OPA are accepted.

Validation of the Risk Management Report

Date: **2024-02-26**

Editor :	Séverine Huvet *MD Regulatory Affairs Officer*	
Checked by:	Marlène HORGNIES *Regulatory Affairs and Microbiology Director* *Person Responsible for Regulatoy Compliance*	
Checked by:	Annick NGUYEN *Quality Director* *Alternate Person Responsible for Regulatoy Compliance*	
Approved by:	Gaëtan Rauwel *Scientific Director & Products Strategy*