PRODUCT INFORMATION FILE

Contec® HydroPure

Product Code

SBT16HPW
SBC16HP
SBC56HP
FBT16HP
FBC16HP
FBC56HP

Rev 5 11-12-2019
www.contecinc.com

Contec
Vannes Cedex
France
Tel: +33(0) 2 97 43 76 98

Contec Inc
Spartanburg, SC
United States
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Contec Cleanroom Technology (Suzhou) Co. Ltd
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Contec® HydroPure

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Contents

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Section 1
Company Overview

Contec is a leading manufacturer of contamination control products for critical cleaning in manufacturing environments worldwide. Contec's cleanroom wipes and mops are used in various industries across the globe including biotechnology, pharmaceutical, medical device, healthcare and other critical life science applications.

Experienced

With more than 30 years of experience behind us, we understand the unique cleaning requirements of these highly regulated markets. Our sales and technical support teams are fully trained to assist customers in finding or creating a Contec product that best meets their needs.

Global

Contec has established a cleanroom manufacturing facility and distribution centre in Europe which allows us to locally support our European customers. Contec owns and operates further manufacturing facilities in Spartanburg, USA and Suzhou, China. Contec has a team of technical specialists and sales representatives in Europe, North and South America and Asia. These facilities and dedicated team members give Contec the ability to provide product and technical support to multi-national customers with global needs.

Committed to quality

We recognise our customers as the centre of our organizational structure. Our employees are committed to meeting each customer's specifications and exceeding each customer's expectations. We will achieve this through the periodic review and continuous improvement of all processes in our management system. All manufacturing facilities are certified to ISO 9001:2015 which ensures customers of consistent quality products – from development to delivery. As a vertically integrated manufacturer, Contec controls more of the manufacturing process than any other supplier.

Committed to customers

Let us help solve your cleaning challenges. Product samples, demonstrations and trials are always offered free-of-charge. We have regional technical specialists working with our professional sales staff who will come to your location and recommend the best product and practices for your needs. If necessary, we can develop unique custom solutions to your problems.

Product range

Contec's extensive product line for cleanrooms and critical environments includes:

- **Mopping Systems and Cleaning Tools**
- **Validated Sterile Products**
- **Pre-saturated Wipes**
- **Knitted and Non-woven Wipes**
- **Spill Control Products, Sponges and Swabs**
- **Sterile 70% Alcohols**
- **Sterile Disinfectants**

Global Manufacturing and Distribution

Contec Inc operates cleanroom manufacturing facilities and distribution centres in Ashington, UK, Spartanburg, USA and Suzhou, China. European customers are also supported via customer service and a distribution centre based in Vannes, France. We ensure quality in our finished products through rigorous design and control of our manufacturing processes. Continuous internal testing and annual ISO audits ensure the quality of our processes and products. Contec's plants in Spartanburg and Suzhou carry out the same manufacturing processes meaning that in the event of any disaster manufacturing can switch to the other site.

Contec USA

Contec China

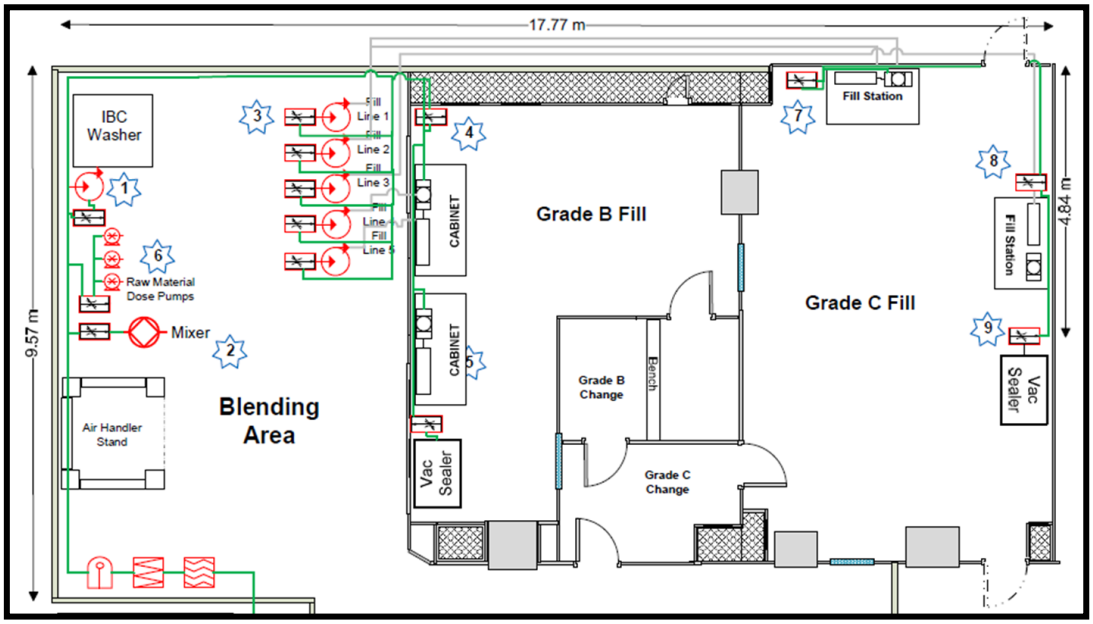
Contec France

Ashington Manufacturing Plant

Contec's bottled disinfectants and European alcohols are filled at Contec's new production facility in Ashington, in the North East England. The facility comprises two GMP cleanrooms; Grade B and Grade C, a purified water plant and a QC laboratory.

The plant has four individual filling heads all operating under Grade A uni-directional air flow. Each filling head and line is dedicated to a single chemistry so there is no potential for cross contamination between one product and another.

Blending is carried out in a dedicated area which is a controlled zone.



Water Plant and QC Laboratory

A mezzanine floor houses the air handling system, the water plant and the QC laboratory.

Blending Area

Blending is carried out in a controlled environment using a calibrated weighing cell.

Staging areas

Grade B cleanroom

Fitted with two Grade A Biological Safety Cabinets; the Grade B cleanroom is used for sterile filling of products which cannot be terminally sterilised ie, Contec *Sterile* ProChlor and CyChlor. Contec *Sterile* HydroPure, Contec Filtered ProChlor and CyChlor are also filled in this room. Entered through a two-stage change room, product transfer is via the Grade C cleanroom.

Grade C cleanroom

Fitted with two Grade A hoods; the Grade C cleanroom is used for filling of all 70% alcohol products and Contec NeutraKlean.

Regulatory Certificates

Contec Inc is EN ISO 9001:2015 accredited. Copies of the most recent certificates which confirm our compliance are in this section. ISO 9001:2015 revises the previous ISO 9001:2008 and "specifies requirements for a quality management system where an organisation:-

- needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
- aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements."

From 1st September 2013, Biocidal Products are regulated in the EU by the EU Biocides Regulation 528/2012 (EU BPR). This replaces the previous Biocidal Products Directive (BPD).

All active substances in Contec's biocides are being supported for assessment in PT2 under the EU BPR review programme.

Contec intends to submit applications for Union Authorisation for all its biocidal product families to ensure continuity of supply throughout the entire EU/EAA.

Biocidal Products Regulation

Biocidal Products manufactured in or imported into the European Union (EU) or European Economic Area (EEA) must be authorised for compliance with the requirements of the EU Biocidal Products Regulation (BPR) and any relevant national legislation before they are placed on the market.

The EU Biocides Regulation (Regulation 528/2012) covers a very diverse group of products, including disinfectants, pest control products and preservatives. It repeals and updates the Biocidal Products Directive 98/8/EEC (the BPD and the supporting UK Biocidal Products Regulations (BPR) from 1 September 2013.

There are two consecutive steps to EU BPR biocidal product authorisation:

1. The active substances must be approved under the appropriate Product Type (PT) for use in the Biocidal Product (BP).

2. Each Biocidal Product consisting of, containing or generating the approved active substance(s) is reviewed for approval under the appropriate Product Type (PT).

The EU BPR includes 22 different Biocidal Product Types covering: disinfectants, preservatives, pest control and specialty biocides such as antifouling products, embalming and taxidermy fluids.

Contec's biocides are all categorised under PT2: disinfectants and algaecides not intended for direct application to humans or animals.

All active substances in Contec's biocides are being supported for assessment in PT2 under the EU BPR review programme. Details can be found in Annex II of the EU BPR Review Regulation (Commission Delegated Regulation EU 1062/2014).

As active substances are approved, they are listed in EU BPR Article 9 Approved List of Active Substances (Union List). Contec will submit EU BPR applications for Union Authorisation approvals of its biocidal products before the active substance approval dates to ensure continuity of supply in the EU/EAA.

From 1 September 2015, a biocidal product can only be made available on the EU market if the active substance supplier or biocidal product supplier is included in list for the appropriate product type found in Article 95 (2) of Regulation (EU) No 528/2012.

Contec and Contec's suppliers of active substances are all listed in the 'Article 95 list' of the Biocidal Products Regulation.

Contec intends to submit applications for Union Authorisation for all its biocidal product families to ensure continuity of supply throughout the entire EU/EAA.

BPR Status of Hydrogen Peroxide products

Biocidal products, which are not going through the authorisation process can no longer be placed on the market from 180 days after the date of approval of the active substance, and they can no longer be used from 365 days after the date of approval. Where the biocidal product contains more than one active substance, the relevant phase- out periods begin on the date of approval of the final active substance to be approved, or not-approved.

Hydrogen peroxide (CAS No. 7722-84-1) was approved as an active substance under the BPR (EU) for product types 1-6 on **1st February 2017.**

If a company did not seek product authorisation for a biocide containing hydrogen peroxide (unless it contained other actives) before 1st Feb 2017 they had until the 31st July 2017 to remove the product from the European market, and until 1st February 2018 to dispose of, or use any remaining stock.

Contec's biocidal product dossier for all Contec HydroPure products containing 6% hydrogen peroxide was submitted before the BPR deadline of 1 February 2017 and is now under evaluation by the MSCA for the UK.

The dossier is expected to enter the BPC process mid-2019.

Contec's Hydrogen Peroxide Case Number is BC-VJ029379-17.

Contec's TSE statement is also detailed below.

CONTEC

June 13, 2017

To: Contec Customers
Ref: Compliance with Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMEA/410/01 Rev. 3)

Dear Customer:

Contec products are manufactured wholly from synthetic materials and do not contain any raw materials produced from or substances derived of animal origin.

Our manufacturing process does not use any ingredient of animal origin, nor do our materials come into contact with animal products during storage and transportation.

Products manufactured by Contec, Inc. are free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE).

Contec is committed to providing you with quality products that meet and exceed your expectations, and we thank you for the opportunity to assist in your cleaning and contamination control product needs.

Please let me know if you have any additional questions or concerns.

Regards,

Nancy Bockstiegel
Contec, Inc.
Quality Manager
Office: 864-699-8227
Email: nbockstiegel@contecinc.com

Contec, Inc.
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web: www.contecinc.com
email: info@contecinc.com

Certificate GB15/93329

The management system of

Contec Cleanroom (UK) Ltd

Unit 6A, Wansbeck Business Park, Rotary Parkway,
Ashington, Northumberland, NE63 8QW, UK

Unit 9 & 10, Wansbeck Business Park, Wansbeck Network Centre,
Rotary Parkway, Ashington, Northumberland, NE63 8QU, UK

Suite 4, Wansbeck Network Centre, Rotary Parkway,
Ashington, Northumberland, NE63 8QZ, UK

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Development and manufacture of disinfectant and cleaning products for critical environments.

This certificate is valid from 07 May 2019 until 01 July 2021
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 5. Certified since 01 July 2015

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 9001 2015 0818

ZERTIFIKAT • CERTIFICATE • 認證證書 • СЕРТИФИКАТ • CERTIFICADO • CERTIFICAT

CERTIFICATE

The Certification Body of
TÜV SÜD AMERICA INC.

hereby certifies that

Contec Inc
525 Locust Grove
Spartanburg, SC 29303 USA
(see page 2-3 for additional locations)

has implemented a Quality Management System
in accordance with:

ISO 9001:2015

The scope of this Quality Management System includes:

The Design, Manufacture, and Distribution of Cleaning Products for use in Aseptic Environments, Cleanrooms, Industrial Surface Preparation, and Professional Cleaning. The Distribution of Products used in Cleanrooms.

Certificate Expiry Date: October 24, 2020

Certificate Registration No: 950 99 0586

Effective Date: September 28, 2018

Reissue Date: July 9, 2019

Mark Alpert
Vice President, Business Assurance

Certificate CN07/00113

The management system of

Contec Cleanroom Technology (Suzhou) Company, Ltd.

No. 17, Longyun Road, Suzhou Industrial Park,
Suzhou City, Jiangsu Province, P.R. China

Unified Social Credit Code 91320594778675949B

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Manufacture of cleaning products used in critical environment

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation

This certificate is valid from 15 February 2019 until 14 February 2022
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 7. Certified since 15 February 2007

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

HC SGS 9001 2015 0118

Section 2
Product Overview – Contec HydroPure

Contec HydroPure is a blend of 6% hydrogen peroxide and water for injection or purified water. Efficacious against bacteria, fungi, moulds, yeasts and spores

Contec HydroPure leaves little to no residue and is available with a guaranteed endotoxin level of less than 0.25 EU/ml making it ideal for use in product contact areas *

Contec HydroPure is available sterile in a 1L trigger spray (with water for injection) or with purified water in a 1L and 5L capped container. A non-sterile version for lower grade rooms is also available. The product is 0.2 µm filtered and filled under Grade A uni-directional flow air and bagged in a Grade B cleanroom.

Provided either double or triple bagged, the product is designed for ease of entry into pharmaceutical cleanrooms. The 1L trigger sprays are fitted with a protective system to protect the contents during use.

Feature	Benefit
Hydrogen peroxide breaks down to water and oxygen	Very low residue so suitable for product contact areas
Available with a guaranteed endotoxin level of less than 0.25 EU/ml	Safe to use in product contact areas
Filtered to 0.2 microns under Grade A airflow in a Grade B cleanroom	Ensures the product is free from contamination particulates
Sporicidal in 15 mins	Sufficient sporicidal activity for a Grade A / B area
Sterile option available	Suitable for Grade A and B areas
Triple / double bagged in linear tear packaging	Each bag is easy to open even when wearing gloves Facilitates transfer disinfection into isolators and RABS
Not classed as corrosive	Can be used safely in all areas of the cleanroom

Ordering Information

Part No.	Description	Packaging
* SBT16HPW	Contec *Sterile* HydroPure 1L Trigger Spray	6 x 1L
SBC16HP	Contec *Sterile* HydroPure 1L Capped	6 x 1L
* SBC56HP	Contec *Sterile* HydroPure 5L Capped	2 x 5L
FBT16HP	Contec HydroPure 1L Trigger Spray	6 x 1L
FBC16HP	Contec HydroPure 1L Capped	6 x 1L
FBC56HP	Contec HydroPure 5L Capped	2 x 5L

Product Specification – Sterile HydroPure 1L Trigger Spray

Product Name	Contec *Sterile* HydroPure
Product Description	Sterile 6% Stabilised Hydrogen Peroxide in water for injection
Product Code	SBT16HPW 1L Trigger Spray x 6
Product Specification	
Colour	Colourless
Clarity	Clear
Endotoxin	Less than 0.25 EU/ml
Specific Gravity @ 20°C	1.021 to 1.025
% H_2O_2	6% - 6.9% H_2O_2
Production	Filtered to 0.2 micron under Grade A uni-directional airflow in a Grade B cleanroom.
Packaging	Adjustable trigger spray on PP bottle with inner Surlyn layer (protected trigger spray system) Triple packed in polyethylene linear tear packaging 6 bottles per double walled cardboard box
Sterility	Sterile filtered into pre-irradiated containers.
Shelf Life	Unopened: 2 years from date of manufacture In-use: 6 months from date of opening

Product Specification – Sterile HydroPure 1L capped

Product Name	Contec *Sterile* HydroPure
Product Description	Sterile 6% Stabilised Hydrogen Peroxide in purified water
Product Code	SBC16HP 1L Capped x 6
Product Specification	
Colour	Colourless
Clarity	Clear
Specific Gravity @ 20°C	1.021 to 1.025
% H_2O_2	6% - 6.9% H_2O_2
Production	Filtered to 0.2 micron under Grade A uni-directional airflow in a Grade B cleanroom.
Packaging	Tamper evident cap on HDPE bottle Double packed in polyethylene linear tear packaging 6 bottles per double walled cardboard box
Sterility	Sterile filled into pre-irradiated containers.
Shelf Life	Unopened: 2 years from date of manufacture

Product Specification – Sterile HydroPure 5L capped

Product Name	Contec *Sterile* HydroPure
Product Description	Sterile 6% Stabilised Hydrogen Peroxide in purified water
Product Code	SBC56HP 5L Capped x 2
Product Specification	
Colour	Colourless
Clarity	Clear
Endotoxin	Less than 0.25 EU/ml
Specific Gravity @ 20°C	1.021 to 1.025
% H_2O_2	6% - 6.9% H_2O_2
Production	Filtered to 0.2 micron under Grade A uni-directional airflow in a Grade B cleanroom.
Packaging 5L	Tamper evident cap on HDPE bottle Double packed in polyethylene linear tear packaging 2 bottles per double walled cardboard box
Sterility	Sterile filled into pre-irradiated containers.
Shelf Life	Unopened: 2 years from date of manufacture

Product Specification – Contec HydroPure 1L and 5L

Product Name		Contec HydroPure
Product Description		6% Stabilised Hydrogen Peroxide in purified water
Product Code		FBT16HP 1L Trigger Spray x 6 FBC16HP 1L Capped x 6 FBC56HP 5L Capped x 2
Product Specification		
	Colour	Colourless
	Clarity	Clear
	Specific Gravity @ 20°C	1.021 to 1.025
	% H_2O_2	6% - 6.9% H_2O_2
	Production	Filtered to 0.2 micron under Grade A uni-directional airflow in a Grade B cleanroom.
	Packaging 1L	Adjustable trigger spray on PP bottle with inner Surlyn layer (protected trigger spray system) Trigger spray is a protected system Double packed in polyethylene linear tear packaging 6 bottles per double walled cardboard box
	Packaging 5L	Tamper evident cap on HDPE bottle Double packed in polyethylene linear tear packaging 2 bottles per double walled cardboard box
	Shelf Life	Unopened: 2 year from date of manufacture In-use 1L: 6 months from date of opening

Use biocides safely. Always read the label and product information before use.

Section 3
Product Certificates

Contec HydroPure is provided with the following batch specific documentation. All certificates are controlled within Contec's quality system and subject to written change control.

CONTEC

PRODUCT CERTIFICATE

Product:	Contec Sterile HydroPure
Product Code:	SBT16HPW
Product Description:	Sterile 6% Stabilised Hydrogen Peroxide in water for injection (EP) 1L Trigger Spray
Batch Number:	
Manufacture Date:	MON / YYYY
Expiry Date:	MON / YYYY

ANALYSIS

Test	Specification	Results
Colour:	Colourless	
Clarity:	Clear	
Filtration:	Filtered to 0.2 microns	
Endotoxins:	<0.25 EU/ml	
SG at 20°C:	1.021 – 1.025	
Concentration of H_2O_2:	6.0% - 6.9%	

Manufactured product via a Quality System certified to ISO 9001:2015, tested in accordance with documented quality procedures and approved when required specifications are met.

STERILITY

Sterility test number:	xxxxxxxxxx
Sterility test result:	No evidence of microbial growth

Test method as described in the current edition of the European Pharmacopoeia.

Name:	1: John Gray	2: Lee Rodgers
Position:	1: Quality Manager	2: QC Supervisor
Date:	1:	2:
Authorised Signature: For and on behalf of Contec Inc	1:	2:

COA07 Rev 6

Manufactured by: Contec Cleanroom (UK) Ltd, Unit 6A Wansbeck Business Park, Ashington, UK

America Contec Inc, P.O.Box 530, Spartanburg SC, USA

Europe Contec Inc, Zi du Pret RP 3707, 56037 VANNES, France

China Contec Cleanroom Technology (Suzhou) Co. Ltd, No. 17 Longyun Road, Suzhou 215024, China

www.contecinc.com

CONTEC

PRODUCT CERTIFICATE

Product:	Contec Sterile HydroPure
Product Code:	SBC16HP
Product Description:	Sterile 6% Stabilised Hydrogen Peroxide in purified water (EP) 1L Capped
Batch Number:	
Manufacture Date:	MON / YYYY
Expiry Date:	MON / YYYY

ANALYSIS

Test	Specification	Results
Colour:	Colourless	
Clarity:	Clear	
Filtration:	Filtered to 0.2 microns	
SG at 20°C:	1.021 – 1.025	
Concentration of H_2O_2:	6.0% - 6.9%	

Manufactured product via a Quality System certified to ISO 9001:2015, tested in accordance with documented quality procedures and approved when required specifications are met.

STERILITY

Sterility test number:	xxxxxxxxxx
Sterility test result:	No evidence of microbial growth

Test method as described in the current edition of the European Pharmacopoeia.

Name:	1: John Gray	2: Lee Rodgers
Position:	1: Quality Manager	2: QC Supervisor
Date:	1:	2:
Authorised Signature:	1:	2:

For and on behalf of Contec Inc

Manufactured by:
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CONTEC

PRODUCT CERTIFICATE

Product:	Contec Sterile HydroPure
Product Code:	SBC56HP
Product Description:	Sterile 6% Stabilised Hydrogen Peroxide in purified water (EP) 5L Capped
Batch Number:	
Manufacture Date:	MON / YYYY
Expiry Date:	MON / YYYY

ANALYSIS

Test	Specification	Results
Colour:	Colourless	
Clarity:	Clear	
Filtration:	Filtered to 0.2 microns	
Endotoxins:	<0.25 EU/ml	
SG at 20°C:	1.021 – 1.025	
Concentration of H_2O_2:	6.0% - 6.9%	

Manufactured product via a Quality System certified to ISO 9001:2015, tested in accordance with documented quality procedures and approved when required specifications are met.

STERILITY

Sterility test number:	xxxxxxxxxx
Sterility test result:	No evidence of microbial growth

Test method as described in the current edition of the European Pharmacopoeia.

Name:		1: John Gray	2: Lee Rodgers
Position:		1: Quality Manager	2: QC Supervisor
Date:	1:		2:
Authorised Signature:	1:		2:

For and on behalf of Contec Inc

Manufactured by:
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CONTEC

PRODUCT CERTIFICATE

Product:	Contec HydroPure
Product Code:	FBT16HP
Product Description:	Filtered 6% Stabilised Hydrogen Peroxide in purified water (EP) 1L Trigger Spray
Batch Number:	
Manufacture Date:	MON / YYYY
Expiry Date:	MON / YYYY

ANALYSIS

Test	Specification	Results
Colour:	Colourless	
Clarity:	Clear	
Filtration:	Filtered to 0.2 microns	
SG at 20°C:	1.021 – 1.025	
Concentration of H_2O_2:	6.0% - 6.9%	

Manufactured product via Quality Systems certified to ISO 9001:2015, tested in accordance with documented quality procedures and approved when required specifications are met.

Name:	1: Lee Rodgers	2: John Gray
Position:	1: Snr. Quality Technician	2: Quality Manager
Date:	1:	2:
Authorised Signature: For and on behalf of Contec Inc	1:	2:

Manufactured by:
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PRODUCT CERTIFICATE

Product:	Contec HydroPure
Product Code:	FBC16HP
Product Description:	Filtered 6% Stabilised Hydrogen Peroxide in purified water (EP) 1L Capped
Batch Number:	
Manufacture Date:	MON / YYYY
Expiry Date:	MON / YYYY

ANALYSIS

Test	Specification	Results
Colour:	Colourless	
Clarity:	Clear	
Filtration:	Filtered to 0.2 microns	
SG at 20°C:	1.021 – 1.025	
Concentration of H_2O_2:	6.0% - 6.9%	

Manufactured product via Quality Systems certified to ISO 9001:2015, tested in accordance with documented quality procedures and approved when required specifications are met.

Name:	1: Lee Rodgers	2: John Gray
Position:	1: Snr. Quality Technician	2: Quality Manager
Date:	1:	2:
Authorised Signature: For and on behalf of Contec Inc	1:	2:

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CONTEC

PRODUCT CERTIFICATE

Product:	Contec HydroPure
Product Code:	FBC56HP
Product Description:	Filtered 6% Stabilised Hydrogen Peroxide in purified water (EP) 5L Capped
Batch Number:	
Manufacture Date:	MON / YYYY
Expiry Date:	MON / YYYY

ANALYSIS

Test	Specification	Results
Colour:	Colourless	
Clarity:	Clear	
Filtration:	Filtered to 0.2 microns	
SG at 20°C:	1.021 – 1.025	
Concentration of H_2O_2:	6.0% - 6.9%	

Manufactured product via Quality Systems certified to ISO 9001:2015, tested in accordance with documented quality procedures and approved when required specifications are met.

Name:	1: Lee Rodgers	2: John Gray
Position:	1: Snr. Quality Technician	2: Quality Manager
Date:	1:	2:
Authorised Signature: For and on behalf of Contec Inc	1:	2:

Manufactured by:
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Section 4
Instructions for Use

Contec HydroPure is a ready to use product and does not require dilution.

When transferring the bottles to the point of use, remove each packaging layer as the environment becomes more critical. Contec HydroPure is triple bagged or double bagged to facilitate to the ease of transfer into product contact areas.

Apply Contec HydroPure to an appropriate Contec cleanroom wipe or mop. Ensure the wipe or mop is sufficiently and uniformly saturated before wiping the surface to be cleaned. Leave for required contact time before wiping to dry. Wiping will also optimise the physical removal of contaminants from the surface.

Contec HydroPure will break down to water and oxygen on a surface leaving no residue, however Contec HydroPure should not be left wet on a surface longer than the contact time required. Best practice suggests disinfectants are wiped to dry and removed after the contact time.

Storage conditions

Contec HydroPure must be stored in the original packaging. Do not freeze. Store below 40^0 C.

Section 5
Product Labels

Each of Contec's disinfectant products is labelled to aid with easy identification of the active ingredients. The labels meet the requirements of the new legislation for labelling of chemicals: The Classification, Labelling and Packaging of Substances and Mixtures Regulation (CLP), Regulation (EC) No 1272/2008 which is the EU implementation of the UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which came into force in Jan 2009.

CLP replaces the Dangerous Substances Directive 67/548/EEC and the Dangerous Preparations Directive 1999/45/EC.

Each active ingredient is colour coded. The roundel carries the colour representing the active ingredient and either a green or blue dot to signify whether the product is sterile or filtered. Dark blue signifies a filtered product and green signifies a sterile product.

Each master label has its own code and revision level for control purposes. Labels are controlled under the quality system and change control.

The labels are manufactured from alcohol resistant material and inks so are suitable for wipe down with alcohol for disinfection purposes. Each new batch of labels is tested before use.

This product is currently being manufactured under deviation and the gamma irradiation claim on the product label has been replaced with sterile fill.

Contec *Sterile* HydroPure 1L

EN 100ml contains 6ml hydrogen peroxide in Water for Injection. Warning Causes serious eye irritation. Do not breathe vapours. IF IN EYES: rinse cautiously with water for several minutes. Get medical advice/attention. Dispose of contents/container to hazardous waste. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent: 6 ml de peroxyde d'hydrogène avec de l'eau pour préparation injectable. Attention Provoque une sévère irritation des yeux. Eviter de respirer les vapeurs. EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Iter un médecin. Éliminer le contenu/récipient aux déchets dangereux. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 6 ml Wasserstoffperoxid in Wasser für Injektionen. Achtung Verursacht schwere Augenreizung. Dampf nicht einatmen. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztlichen Rat einholen / ärztliche Hilfe hinzuziehen. Dieser Stoff und/oder sein Behälter sind als gefährlicher Abfall zu entsorgen. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 6 ml peróxide de hidrógeno en agua para inyección. Atención Provoca irritación ocular grave. No respirar los vapores. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulte a un médico. Eliminar el contenido o el recipiente en residuos peligrosos. Almacenar a temperaturas no superiores a 40°C. No congele.

I 100 ml, contiene 6ml di perossido d'idrogeno in acqua per iniezione. Attenzione Provoca grave irritazione oculare. Non respirare i vapori. IN CASO DI CONTATTO CON GLI OCCHI: Sciacquare accuratamente per parecchi minuti. Consultare un medico. Smaltire il prodotto/ recipiente di rifiuti pericolosi. Conservare in luogo fresco a temperature non superiori a 40°C. Non congelare.

RO 100 ml contine 6 ml peroxid de hidrogen in Apa pentru Preparate Injectabile. Atenţie Provoacă o iritaţie gravă a ochilor. Nu inspiraţi vapori. ÎN CAZ DE CONTACT CU OCHII: Clătiţi cu atenţie cu apă timp de mai multe minute. Consultaţi medicul. Aruncaţi conţinutul/recipientul la deşeurile periculoase. A se depozita la temperaturi care nu depăşesc 40°C. A nu se congela.

FI 100 ml sisältää 6 ml vetyperoksidia WFI-vedessä. Varoitus Ärsyttää voimakkaasti silmiä. Varo höyryn hengittämistä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävitä sisältö/pakkaus vaarallisin jätteisiin. Varastoi alle 40°C lämpötilassa. Ei saa jäätyä.

DA 100ml indeholdende 6ml hydrogen peroxid i injektionsvand. Advarsel Forårsager alvorlig øjenirritation. Indånd ikke damp. VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Søg lægehjælp. Indholdet/containeren bortskaffes som farligt affald Opbevares ved en temperatur, som ikke overstiger 40°C. Må ikke nedfryses.

SV 100ml innehåller 6ml väteperoxid i injektionsvatten. Varning Orsakar allvarlig ögonirritation. Andas inte ångor. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkarvård. Detta material och dess behållare skall tas om hand som farligt avfall. Förvaras vid högst 40°C. Får ej frysas.

Supplier
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Emergency telephone Chemtrec® +1-703-527-3887
Biocide Registration Numbers: Irish: 97485 German: N-53320 French: 30910

STERILE

CONTEC HYDROPURE

STERILE 6% STABILISED HYDROGEN PEROXIDE

- Ready to use, hard surface sporicidal disinfectant solution containing 6% stabilised hydrogen peroxide blended with water for injection (EP).
- Suitable for use on clean hard surfaces. Ensure complete wetting of area. For optimum results wipe dry after contact time. Close nozzle after use.
- Manufactured in a Grade C cleanroom and filtered to 0.2 microns.
- Gamma irradiated to at least 25 kGy.
- Endotoxin levels of less than 0.25 EU/ml.
- Contact times:

Bacteria	5 mins	EN1276
Fungi	15 mins	EN1650
Spores	15 mins	EN13704
Spores	15 mins	EN13697

- For professional use only.

001 of 500 LA3037/02

1 LITRE Product Code **SBT16HPW**

CONTEC
www.contecinc.com

Contec *Sterile* HydroPure 1L Capped

EN 100ml contains 6ml hydrogen peroxide in purified water. Warning Causes serious eye irritation. Do not breathe vapours. IF IN EYES: rinse cautiously with water for several minutes. Get medical advice/attention. Dispose of contents/container to hazardous waste. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent: 6 ml de peroxyde d'hydrogène dans de l'eau purifiée. Attention Provoque une sévère irritation des yeux. Éviter de respirer les vapeurs. EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Iter un médecin. Éliminer le contenu/ récipient aux dèchets dangereux. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 6 ml Wasserstoffperoxid in gereinigtem Wasser. Achtung Verursacht schwere Augenreizung. Dampf nicht einatmen. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztlichen Rat einholen / ärztliche Hilfe hinzuziehen. Dieser Stoff und/oder sein Behälter sind als gefährlicher Abfall zu entsorgen. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 6 ml peróxide de hidrógeno en agua purificada. Atención Provoca irritación ocular grave. No respirar los vapores. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulte a un médico. Eliminar el contenido o el recipiente en residuos peligrosos. Almacenar a temperaturas no superiores a 40°C. No congele.

I 100 ml, contiene 6ml di perossido d'idrogeno in acqua purificata. Attenzione Provoca grave irritazione oculare. Non respirare i vapori. IN CASO DI CONTATTO CON GLI OCCHI : Sciacquare accuratamente per parecchi minuti. Consultare un medico. Smaltire il prodotto/ recipiente di rifiuti pericolosi. Conservare in luogo fresco a temperature non superiori a 40°C. Non congelare.

RO 100 ml contine 6 ml peroxid de hidrogen in apa purificata. Atenie Provoacă o iritaţie gravă a ochilor. Nu inspiraţi vapori. ÎN CAZ DE CONTACT CU OCHII: Clătiţi cu atenţie cu apă timp de mai multe minute. Consultaţi medicul. Aruncaţi conţinutul/ recipientul la deşeurile periculoase. A se depozita la temperaturi care nu depăşesc 40°C. A nu se congela.

FI 100 ml sisältää 6 ml vetyperoksidia puhdistetussa vedessä. Varoitus Ärsyttää voimakkaasti silmiä. Varo höyryn hengittämistä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävitä sisältö/pakkaus vaarallisiin jätteisiin. Varastoi alle 40°C lämpötilassa. Ei saa jäätyä.

DA 100ml indeholdende 6ml hydrogen peroxid i ultra rent vand. Advarsel Forårsager alvorlig øjenirritation. Indånd ikke damp. VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Søg lægehjælp. Indholdet/containeren bortskaffes som farligt affald Opbevares ved en temperatur, som ikke overstiger 40°C. Må ikke nedfryses.

SV 100ml innehåller 6ml väteperoxid i ultrarent vatten. Varning Orsakar allvarlig ögonirritation. Andas inte ångor. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkarvård. Detta material och dess behållare skall tas om hand som farligt avfall. Förvaras vid högst 40°C. Får ej frysas.

Supplier

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Biocide Registration Numbers: Irish: 97485 German: N-53320 French: 30910
Manufactured in the UK by Contec Cleanroom (UK) Ltd

STERILE

CONTEC HYDROPURE

STERILE 6% STABILISED HYDROGEN PEROXIDE

- Ready to use, hard surface sporicidal disinfectant solution containing 6% stabilised hydrogen peroxide blended with purified water (EP).
- Apply to clean, hard surfaces. Ensure complete wetting of area. For optimum results wipe dry after contact time.
- Sterile filtered to 0.2 microns in a Grade B cleanroom.
- Contact times:

Bacteria	5 mins	EN1276
Fungi	15 mins	EN1650
Spores	15 mins	EN13704
Spores	15 mins	EN13697

- For professional use only.

0001 of 1000 LAB117/01

1 LITRE

Product Code **SBC16HP**

CONTEC
www.contecinc.com

Contec *Sterile* HydroPure 5L

EN 100ml contains 6ml hydrogen peroxide in Water for Injection. Warning Causes serious eye irritation. Do not breathe vapours. IF IN EYES: rinse cautiously with water for several minutes. Get medical advice/attention. Dispose of contents/container to hazardous waste. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent: 6 ml de peroxyde d'hydrogène avec de l'eau pour préparation injectable. Attention Provoque une sévère irritation des yeux. Éviter de respirer les vapeurs. EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Iter un médecin. Éliminer le contenu/récipient aux déchets dangereux. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 6 ml Wasserstoffperoxid in Wasser für Injektionen. Achtung Verursacht schwere Augenreizung. Dampf nicht einatmen. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztlichen Rat einholen / ärztliche Hilfe hinzuziehen. Dieser Stoff und/ oder sein Behälter sind als gefährlicher Abfall zu entsorgen. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 6 ml peróxide de hidrógeno en agua para inyección. Atención Provoca irritación ocular grave. No respirar los vapores. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulte a un médico. Eliminar el contenido o el recipiente en residuos peligrosos. Almacenar a temperaturas no superiores a 40°C. No congele.

I 100 ml, contiene 6ml di perossido d'idrogeno in acqua per iniezione. Attenzione Provoca grave irritazione oculare. Non respirare i vapori. IN CASO DI CONTATTO CON GLI OCCHI : Sciacquare accuratamente per parecchi minuti. Consultare un medico. Smaltire il prodotto/ recipiente di rifiuti pericolosi. Conservare in luogo fresco a temperature non superiori a 40°C. Non congelare.

RO 100 ml contine 6 ml peroxid de hidrogen in Apa pentru Preparate Injectabile. Atenție Provoacă o iritație gravă a ochilor. Nu inspirați vapori. ÎN CAZ DE CONTACT CU OCHII: Clătiți cu atenție cu apă timp de mai multe minute. Consultați medicul. Aruncați conținutul/recipientul la deșeurile periculoase. A se depozita la temperaturi care nu depășesc 40°C. A nu se congela.

FI 100 ml sisältää 6 ml vetyperoksidia WFI-vedessä. Varoitus Ärsyttää voimakkaasti silmiä. Varo höyryn hengittämistä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävitä sisältö/pakkaus vaarallisiin jätteisiin. Varastoi alle 40°C lämpötilassa. Ei saa jäätyä.

DA 100ml indeholdende 6ml hydrogen peroxid i injektionsvand. Advarsel Forårsager alvorlig øjenirritation. Indånd ikke damp. VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Søg lægehjælp. Indholdet/containeren bortskaffes som farligt affald Opbevares ved en temperatur, som ikke overstiger 40°C. Må ikke nedfryses.

SV 100ml innehåller 6ml väteperoxid i injektionsvatten. Varning Orsakar allvarlig ögonirritation. Andas inte ångor. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkarvård. Detta material och dess behållare skall tas om hand som farligt avfall. Förvaras vid högst 40°C. Får ej frysas.

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Biocide Registration Numbers: Irish: 97485 German: N-53320 French: 30910
Manufactured in the UK by Contec Cleanroom (UK) Ltd

STERILE

CONTEC HYDROPURE

STERILE 6% STABILISED HYDROGEN PEROXIDE

- Ready to use, hard surface sporicidal disinfectant solution containing 6% stabilised hydrogen peroxide blended with purified water.
- Suitable for use on clean hard surfaces. Ensure complete wetting of area. For optimum results wipe dry after contact time.
- Manufactured in a Grade C cleanroom and filtered to 0.2 microns.
- Contact times:

Bacteria	5 mins	EN1276
Fungi	15 mins	EN1650
Spores	15 mins	EN13704
Spores	15 mins	EN13697

- For professional use only.

0001 of 1000 LAB039/02

5 LITRE

Product Code **SBC56HP**

CONTEC
www.contecinc.com

Contec HydroPure 1L

EN 100ml contains 6ml hydrogen peroxide in purified water. Warning Causes serious eye irritation. Do not breathe vapours. IF IN EYES: rinse cautiously with water for several minutes. Get medical advice/attention. Dispose of contents/container to hazardous waste. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent: 6 ml de peroxyde d'hydrogène dans de l'eau purifiée. Attention Provoque une sévère irritation des yeux. Éviter de respirer les vapeurs. EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Iter un médecin. Éliminer le contenu/ récipient aux dèchets dangereux. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 6 ml Wasserstoffperoxid in gereinigtem Wasser. Achtung Verursacht schwere Augenreizung. Dampf nicht einatmen. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztlichen Rat einholen / ärztliche Hilfe hinzuziehen. Dieser Stoff und/oder sein Behälter sind als gefährlicher Abfall zu entsorgen. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 6 ml peróxide de hidrógeno en agua purificada. Atención Provoca irritación ocular grave. No respirar los vapores. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulte a un médico. Eliminar el contenido o el recipiente en residuos peligrosos. Almacenar a temperaturas no superiores a 40°C. No congele.

I 100 ml, contiene 6ml di perossido d'idrogeno in acqua purificata. Attenzione Provoca grave irritazione oculare. Non respirare i vapori. IN CASO DI CONTATTO CON GLI OCCHI : Sciacquare accuratamente per parecchi minuti. Consultare un medico. Smaltire il prodotto/ recipiente di rifiuti pericolosi. Conservare in luogo fresco a temperature non superiori a 40°C. Non congelare.

RO 100 ml contine 6 ml peroxid de hidrogen in apa purificata. Atenie Provoacă o iritaţie gravă a ochilor. Nu inspiraţi vapori. ÎN CAZ DE CONTACT CU OCHII: Clătiţi cu atenţie cu apă timp de mai multe minute. Consultaţi medicul. Aruncaţi conţinutul/ recipientul la deşeurile periculoase. A se depozita la temperaturi care nu depăşesc 40°C. A nu se congela.

FI 100 ml sisältää 6 ml vetyperoksidia puhdistetussa vedessä. Varoitus Ärsyttää voimakkaasti silmiä. Varo höyryn hengittämistä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävitä sisältö/pakkaus vaarallisiin jätteisiin. Varastoi alle 40°C lämpötilassa. Ei saa jäätyä.

DA 100ml indeholdende 6ml hydrogen peroxid i ultra rent vand. Advarsel Forårsager alvorlig øjenirritation. Indånd ikke damp. VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Søg lægehjælp. Indholdet/containeren bortskaffes som farligt affald Opbevares ved en temperatur, som ikke overstiger 40°C. Må ikke nedfryses.

SV 100ml innehåller 6ml väteperoxid i ultrarent vatten. Varning Orsakar allvarlig ögonirritation. Andas inte ångor. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkarvård. Detta material och dess behållare skall tas om hand som farligt avfall. Förvaras vid högst 40°C. Får ej frysas.

Supplier

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Biocide Registration Numbers: Irish: 97485 German: N-53320 French: 30910
Manufactured in the UK by Contec Cleanroom (UK) Ltd

NON STERILE

CONTEC HYDROPURE

FILTERED 6% STABILISED HYDROGEN PEROXIDE

- Ready to use, hard surface sporicidal disinfectant solution containing 6% stabilised hydrogen peroxide blended with purified water.
- Suitable for use on clean hard surfaces. Ensure complete wetting of area. For optimum results wipe dry after contact time. Close nozzle after use.
- Manufactured in a Grade B cleanroom and filtered to 0.2 microns.
- Contact times:

Bacteria	5 mins	EN1276
Fungi	15 mins	EN1650
Spores	15 mins	EN13704
Spores	15 mins	EN13697

- For professional use only.

0001 of 1000 LAB060/02

1 LITRE

Product Code **FBT16HP**

CONTEC
www.contecinc.com

Contec HydroPure 1L Capped

EN 100ml contains 6ml hydrogen peroxide in purified water. Warning Causes serious eye irritation. Do not breathe vapours. IF IN EYES: rinse cautiously with water for several minutes. Get medical advice/attention. Dispose of contents/container to hazardous waste. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent: 6 ml de peroxyde d'hydrogène dans de l'eau purifiée. Attention Provoque une sévère irritation des yeux. Éviter de respirer les vapeurs. EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Iter un médecin. Éliminer le contenu/ récipient aux dèchets dangereux. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 6 ml Wasserstoffperoxid in gereinigtem Wasser. Achtung Verursacht schwere Augenreizung. Dampf nicht einatmen. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztlichen Rat einholen / ärztliche Hilfe hinzuziehen. Dieser Stoff und/oder sein Behälter sind als gefährlicher Abfall zu entsorgen. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 6 ml peróxide de hidrógeno en agua purificada. Atención Provoca irritación ocular grave. No respirar los vapores. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulte a un médico. Eliminar el contenido o el recipiente en residuos peligrosos. Almacenar a temperaturas no superiores a 40°C. No congele.

I 100 ml, contiene 6ml di perossido d'idrogeno in acqua purificata. Attenzione Provoca grave irritazione oculare. Non respirare i vapori. IN CASO DI CONTATTO CON GLI OCCHI : Sciacquare accuratamente per parecchi minuti. Consultare un medico. Smaltire il prodotto/ recipiente di rifiuti pericolosi. Conservare in luogo fresco a temperature non superiori a 40°C. Non congelare.

RO 100 ml contine 6 ml peroxid de hidrogen în apa purificata. Atenie Provoacă o iritaţie gravă a ochilor. Nu inspiraţi vapori. ÎN CAZ DE CONTACT CU OCHII: Clătiţi cu atenţie cu apă timp de mai multe minute. Consultaţi medicul. Aruncaţi conţinutul/ recipientul la deşeurile periculoase. A se depozita la temperaturi care nu depăşesc 40°C. A nu se congela.

FI 100 ml sisältää 6 ml vetyperoksidia puhdistetussa vedessä. Varoitus Ärsyttää voimakkaasti silmiä. Varo höyryn hengittämistä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävitä sisältö/pakkaus vaarallisiin jätteisiin. Varastoi alle 40°C lämpötilassa. Ei saa jäätyä.

DA 100ml indeholdende 6ml hydrogen peroxid i ultra rent vand. Advarsel Forårsager alvorlig øjenirritation. Indånd ikke damp. VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Søg lægehjælp. Indholdet/containeren bortskaffes som farligt affald Opbevares ved en temperatur, som ikke overstiger 40°C. Må ikke nedfryses.

SV 100ml innehåller 6ml väteperoxid i ultrarent vatten. Varning Orsakar allvarlig ögonirritation. Andas inte ångor. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkarvård. Detta material och dess behållare skall tas om hand som farligt avfall. Förvaras vid högst 40°C. Får ej frysas.

Supplier
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Biocide Registration Numbers: Irish: 97485 German N-53320 French: 30910
Manufactured in the UK by Contec Cleanroom (UK) Ltd

NON STERILE

CONTEC HYDROPURE

FILTERED 6% STABILISED HYDROGEN PEROXIDE

- Ready to use, hard surface sporicidal disinfectant solution containing 6% stabilised hydrogen peroxide blended with purified water.
- Suitable for use on clean hard surfaces. Ensure complete wetting of area. For optimum results wipe dry after contact time.
- Manufactured in a Grade B cleanroom and filtered to 0.2 microns.
- Contact times:

Bacteria	5 mins	EN1276
Fungi	15 mins	EN1650
Spores	15 mins	EN13704
Spores	15 mins	EN13697

- For professional use only.

0001 of 1000 LAB118/01

1 LITRE

Product Code **FBC16HP**

CONTEC
www.contecinc.com

Contec HydroPure 5L

EN 100ml contains 6ml hydrogen peroxide in purified water. Warning Causes serious eye irritation. Do not breathe vapours. IF IN EYES: rinse cautiously with water for several minutes. Get medical advice/attention. Dispose of contents/container to hazardous waste. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent: 6 ml de peroxyde d'hydrogène dans de l'eau purifiée. Attention Provoque une sévère irritation des yeux. Éviter de respirer les vapeurs. EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Iter un médecin. Éliminer le contenu/ récipient aux déchets dangereux. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 6 ml Wasserstoffperoxid in gereinigtem Wasser. Achtung Verursacht schwere Augenreizung. Dampf nicht einatmen. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztlichen Rat einholen / ärztliche Hilfe hinzuziehen. Dieser Stoff und/ oder sein Behälter sind als gefährlicher Abfall zu entsorgen. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 6 ml peróxide de hidrógeno en agua purificada. Atención Provoca irritación ocular grave. No respirar los vapores. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulte a un médico. Eliminar el contenido o el recipiente en residuos peligrosos. Almacenar a temperaturas no superiores a 40°C. No congele.

I 100 ml, contiene 6ml di perossido d'idrogeno in acqua purificata. Attenzione Provoca grave irritazione oculare. Non respirare i vapori. IN CASO DI CONTATTO CON GLI OCCHI : Sciacquare accuratamente per parecchi minuti. Consultare un medico. Smaltire il prodotto/ recipiente di rifiuti pericolosi. Conservare in luogo fresco a temperature non superiori a 40°C. Non congelare.

RO 100 ml contine 6 ml peroxid de hidrogen in apa purificata. Atenie Provoacă o iritatie gravă a ochilor. Nu inspirați vapori. ÎN CAZ DE CONTACT CU OCHII: Clătiți cu atenție cu apă timp de mai multe minute. Consultați medicul. Aruncați conținutul/ recipientul la deșeurile periculoase. A se depozita la temperaturi care nu depășesc 40°C. A nu se congela.

FI 100 ml sisältää 6 ml vetyperoksidia puhdistetussa vedessä. Varoitus Ärsyttää voimakkaasti silmiä. Varo höyryn hengittämistä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävitä sisältö/pakkaus vaarallisiin jätteisiin. Varastoi alle 40°C lämpötilassa. Ei saa jäätyä.

DA 100ml indeholdende 6ml hydrogen peroxid i ultra rent vand. Advarsel Forårsager alvorlig øjenirritation. Indånd ikke damp. VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Søg lægehjælp. Indholdet/ containeren bortskaffes som farligt affald Opbevares ved en temperatur, som ikke overstiger 40°C. Må ikke nedfryses.

SV 100ml innehåller 6ml väteperoxid i ultrarent vatten. Varning Orsakar allvarlig ögonirritation. Andas inte ångor. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkarvård. Detta material och dess behållare skall tas om hand som farligt avfall.Förvaras vid högst 40°C. Får ej frysas.

Supplier
Contec
P.O. Box 530, Spartanburg,
SC 29304, USA
Tel +1 864 503 8333

Authorisation Holder
Contec Europe
R.P. 3707, F-56037,
VANNES, France
Tel +33 297 437 690

Emergency telephone Chemtrec® +1-703-527-3887
Biocide Registration Numbers: Irish: 97485 German: N-53320 French: 30910
Manufactured in the UK by Contec Cleanroom (UK) Ltd

NON STERILE

CONTEC HYDROPURE

FILTERED 6% STABILISED HYDROGEN PEROXIDE

- Ready to use, hard surface sporicidal disinfectant solution containing 6% stabilised hydrogen peroxide blended with purified water.
- Suitable for use on clean hard surfaces. Ensure complete wetting of area. For optimum results wipe dry after contact time.
- Manufactured in a Grade B cleanroom and filtered to 0.2 microns.
- Contact times:

Bacteria	5 mins	EN1276
Fungi	15 mins	EN1650
Spores	15 mins	EN13704
Spores	15 mins	EN13697

- For professional use only.

001 of 400 LAB061/02

5 LITRE

Product Code **FBC56HP**

CONTEC
www.contecinc.com

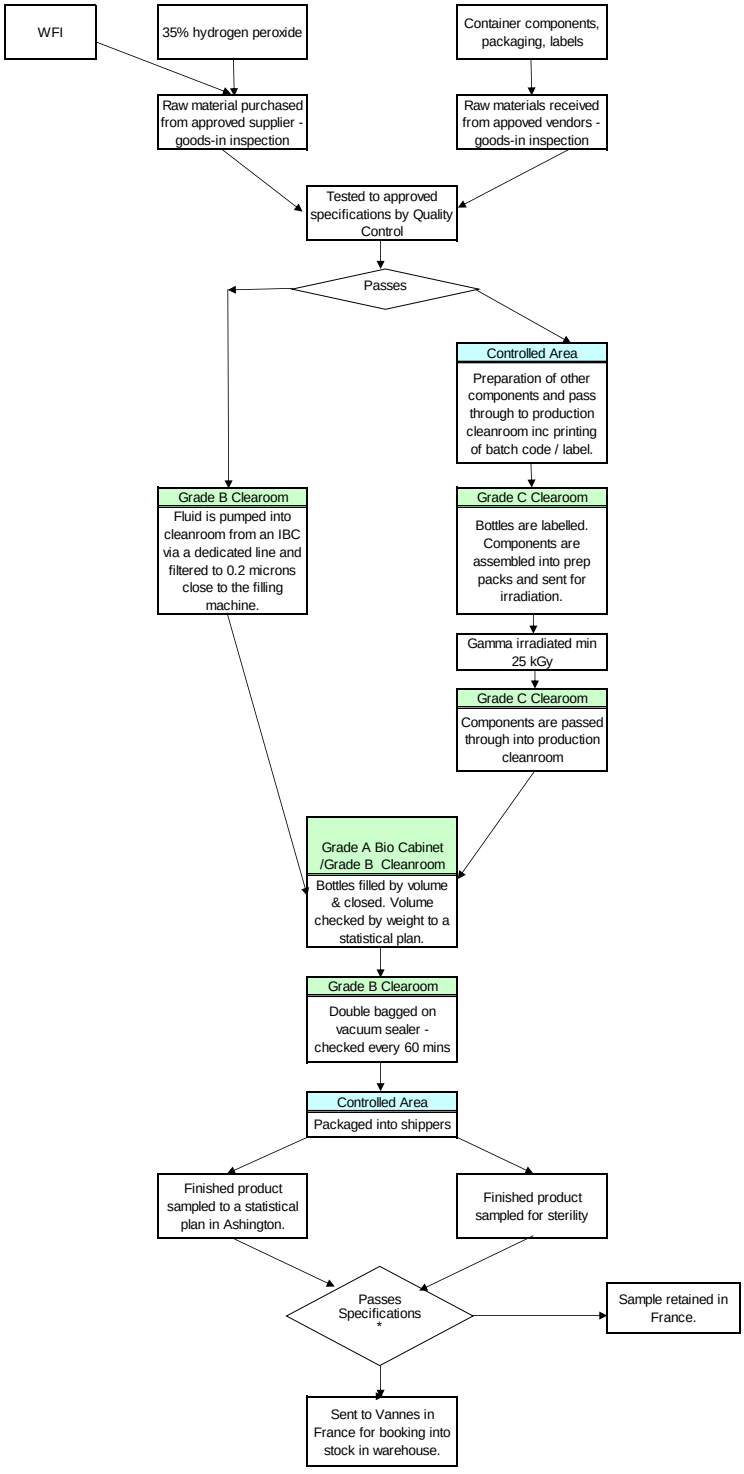
Section 6
Production Process

Contec HydroPure is filtered to 0.2 micron under Grade A uni-directional airflow in a biological safety cabinet. The cabinet is sited in a Grade B cleanroom. Contec Sterile HydroPure is sterile filtered into pre-irradiated containers.

CONTEC®

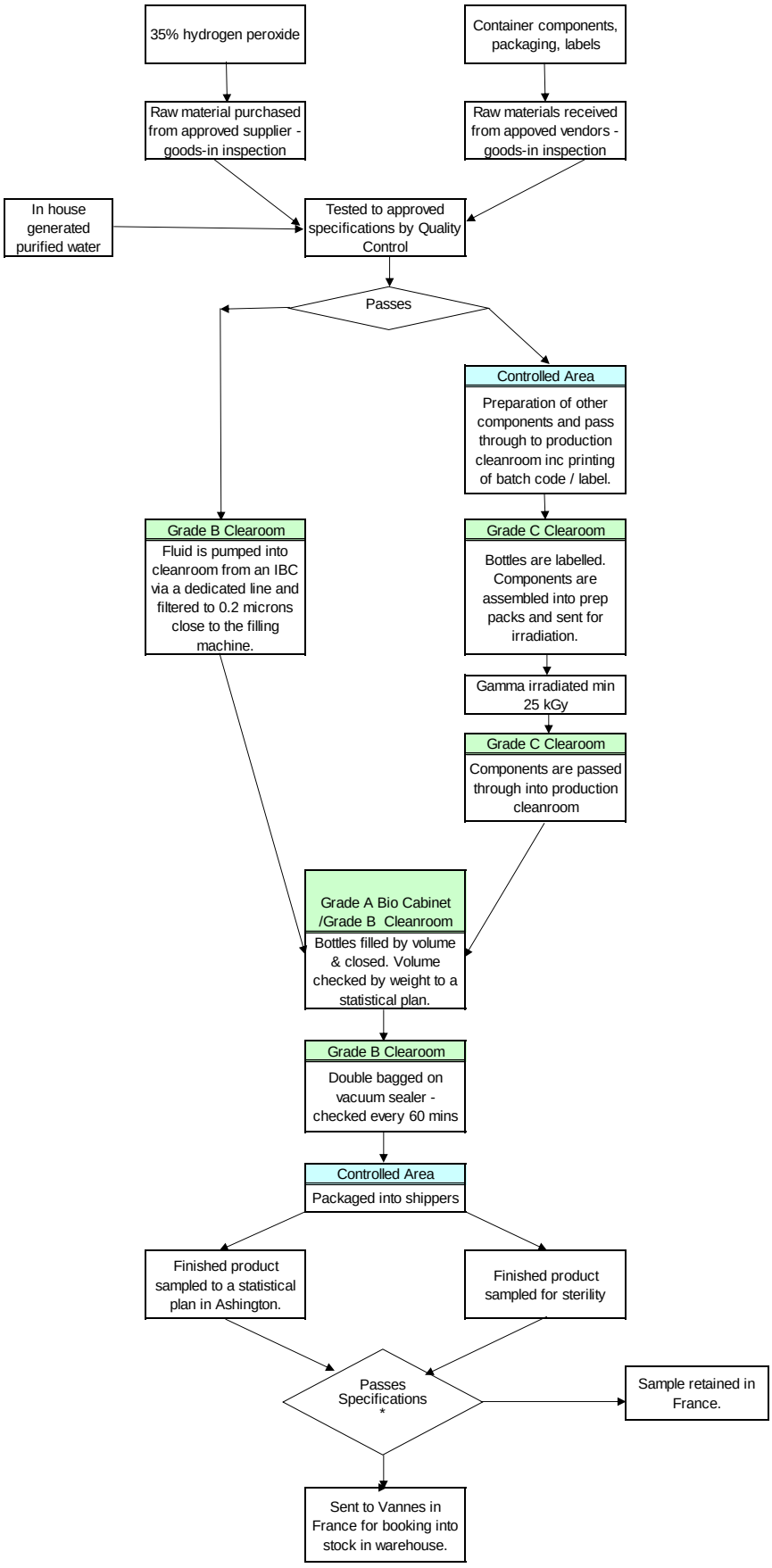
Rev 3 Deviation Sept 16

Production Process Flow Chart Contec® *Sterile* HydroPure



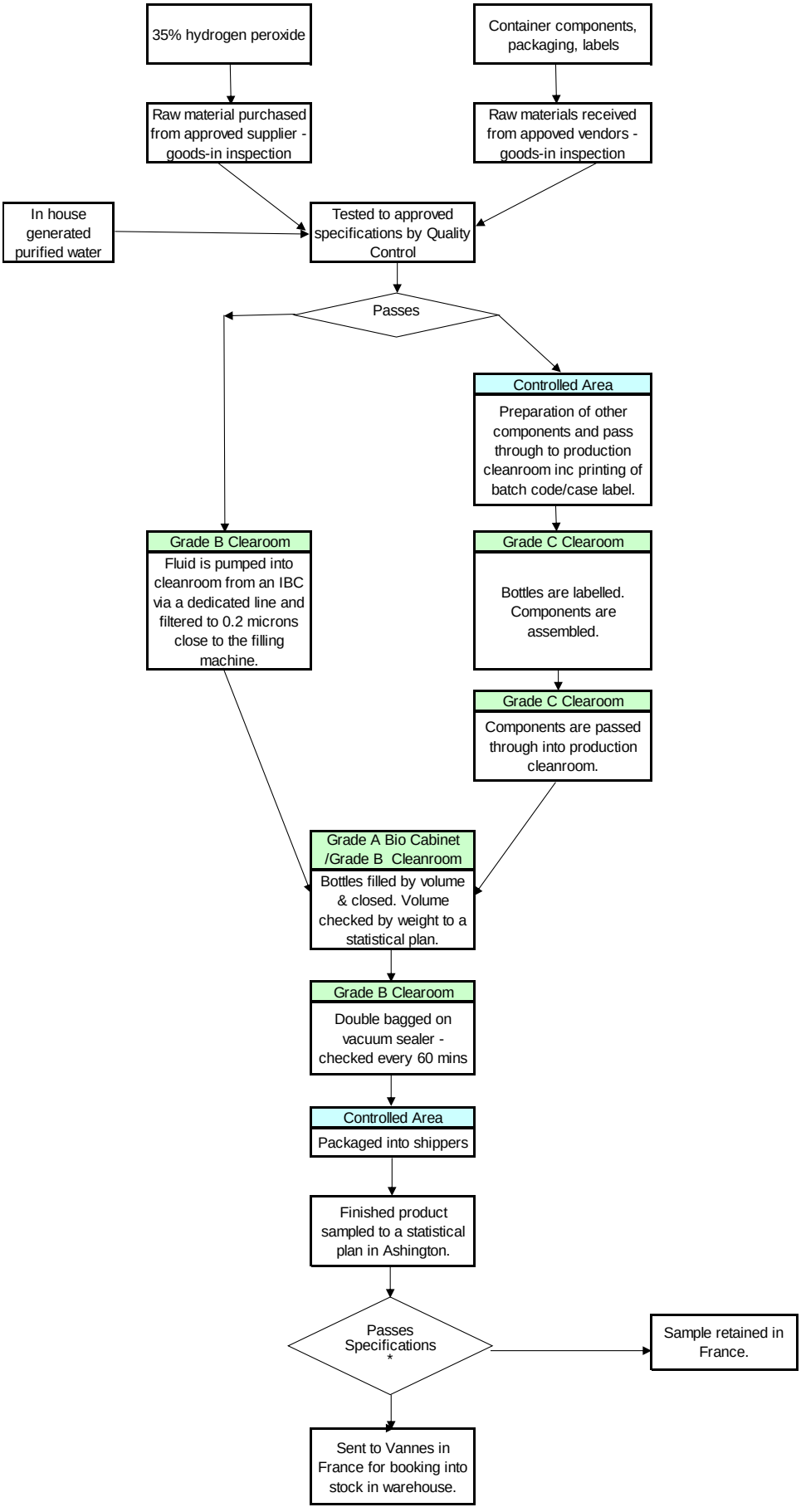
* Should there be a QC failure at any point in the production process, the product is quarantined for investigation and disposal

Production Process Flow Chart Contec® *Sterile* HydroPure 5L



* Should there be a QC failure at any point in the production process, the product is quarantined for investigation and disposal

Production Process Flow Chart Contec HydroPure 1 and 5L



* Should there be a QC failure at any point in the production process, the product is quarantined for investigation and disposal

Section 7
SDS

Additional languages are available please contact your local representative for copies.

SAFETY DATA SHEET

CONTEC STERILE HYDROPURE 1L AND 5L

Compilation date: 09/03/2015

Revision date: 18/06/2015

Revision No: 2

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: CONTEC STERILE HYDROPURE 1L AND 5L

Product code: SBT16HPW / SBC56HP

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of substance / mixture: PC8: Biocidal products (e.g. Disinfectants, pest control). Biocidal Product PT-02

1.3. Details of the supplier of the safety data sheet

Company name: Contec Inc.
525 Locust Grove
Spartanburg
South Carolina
29303
USA

Tel: +33 (0) 2 97 43 76 90

Email: sds@contecinc.com

1.4. Emergency telephone number

Emergency tel: +1 703 527 3887 (24 hours)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: Eye Irrit. 2: H319

Most important adverse effects: Causes serious eye irritation.

2.2. Label elements

Label elements:

Hazard statements: H319: Causes serious eye irritation.

Signal words: Warning

Hazard pictograms: GHS07: Exclamation mark

Precautionary statements: P280: Wear protective gloves/protective clothing/eye protection/face protection.
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+313: If eye irritation persists: Get medical attention.

[cont...]

2.3. Other hazards

Other hazards: Irritating to eyes. Irritating to skin. Irritating to respiratory system.

PBT: This product is not identified as a PBT/vPvB substance.

Section 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients:

HYDROGEN PEROXIDE SOLUTION

EINECS	CAS	PBT / WEL	CLP Classification	Percent
231-765-0	7722-84-1	-	Ox. Liq. 1: H271; Acute Tox. 4: H332; Acute Tox. 4: H302; Skin Corr. 1A: H314	1-10%

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Remove all contaminated clothes and footwear immediately unless stuck to skin. Wash immediately with plenty of soap and water. Get medical attention if irritation develops or persists.

Eye contact: Bathe the eye with running water for 15 minutes. Consult a doctor.

Ingestion: Do not induce vomiting. Wash out mouth with water. Consult a doctor.

Inhalation: Remove casualty from exposure ensuring one's own safety whilst doing so. If unconscious, check for breathing and apply artificial respiration if necessary. Consult a doctor.

4.2. Most important symptoms and effects, both acute and delayed

Skin contact: There may be irritation and redness at the site of contact.

Eye contact: There may be irritation and redness. The eyes may water profusely.

Ingestion: There may be soreness and redness of the mouth and throat.

Inhalation: There may be irritation of the throat with a feeling of tightness in the chest. Exposure may cause coughing or wheezing.

Delayed / immediate effects: Immediate effects can be expected after short-term exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Eye bathing equipment should be available on the premises.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Alcohol or polymer foam. Dry chemical powder. Use water spray to cool containers.

[cont...]

5.2. Special hazards arising from the substance or mixture

Exposure hazards: In combustion emits toxic fumes.

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details. If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Turn leaking containers leak-side up to prevent the escape of liquid.

6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers. Contain the spillage using bunding.

6.3. Methods and material for containment and cleaning up

Clean-up procedures: Absorb into dry earth or sand. Transfer to a closable, labelled salvage container for disposal by an appropriate method.

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Avoid direct contact with the substance. Ensure there is sufficient ventilation of the area.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a cool, well ventilated area. Keep container tightly closed. Keep away from direct sunlight. Do not freeze. Store below 40°C.

7.3. Specific end use(s)

Specific end use(s): PC8: Biocidal products (e.g. Disinfectants, pest control).

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: **Respirable dust**

State	8 hour TWA	15 min. STEL	8 hour TWA	15 min. STEL
UK	1ppm	2ppm	-	-

[cont...]

Hazardous ingredients:

HYDROGEN PEROXIDE SOLUTION...100%

Workplace exposure limits: **Respirable dust**

State	8 hour TWA	15 min. STEL	8 hour TWA	15 min. STEL
UK	1.4 mg/m3	2.8 mg/m3	-	-

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Ensure there is sufficient ventilation of the area.

Respiratory protection: Use an EN149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hand protection: Nitrile gloves. Rubber gloves.

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: Protective clothing. Ensure safety shower is to hand.

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Liquid

Colour: Colourless

Odour: Characteristic odour

Boiling point/range°C: No data available.

Melting point/range°C: No data available.

Flammability limits %: lower: Not applicable.

upper: Not applicable.

Flash point°C: Not applicable.

Part.coeff. n-octanol/water: No data available.

Autoflammability°C: No data available.

Vapour pressure: No data available.

Relative density: 1.021 - 1.023

pH: Not applicable.

VOC g/l: No data available.

9.2. Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

Decomposition may occur on exposure to conditions or materials listed below.

[cont...]

10.4. Conditions to avoid

Conditions to avoid: Heat. Flames. Sources of ignition.

10.5. Incompatible materials

Materials to avoid: Strong oxidising agents. Strong acids.

10.6. Hazardous decomposition products

Haz. decomp. products: In combustion emits toxic fumes.

Section 11: Toxicological information

11.1. Information on toxicological effects

Hazardous ingredients:

HYDROGEN PEROXIDE SOLUTION...100%

ORL	MUS	LD50	2	gm/kg
ORL	RAT	LD50	376	mg/kg
SKN	RAT	LD50	4060	mg/kg

Relevant hazards for substance:

Hazard	Route	Basis
Serious eye damage/irritation	OPT	Hazardous: calculated

Symptoms / routes of exposure

Skin contact: There may be irritation and redness at the site of contact.

Eye contact: There may be irritation and redness. The eyes may water profusely.

Ingestion: There may be soreness and redness of the mouth and throat.

Inhalation: There may be irritation of the throat with a feeling of tightness in the chest. Exposure may cause coughing or wheezing.

Delayed / immediate effects: Immediate effects can be expected after short-term exposure.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: No data available.

12.3. Bioaccumulative potential

Bioaccumulative potential: No data available.

12.4. Mobility in soil

Mobility: No data available.

[cont...]

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

12.6. Other adverse effects

Other adverse effects: No data available.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Transfer to a suitable container and arrange for collection by specialised disposal company.

Disposal of packaging: Dispose of in a regulated landfill site or other method for hazardous or toxic wastes.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

Transport class: This product does not require a classification for transport.

Section 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Specific regulations: Not applicable.

15.2. Chemical Safety Assessment

Section 16: Other information

Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

* indicates text in the SDS which has changed since the last revision.

Phrases used in s.2 and s.3: H271: May cause fire or explosion; strong oxidiser.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H319: Causes serious eye irritation.

H332: Harmful if inhaled.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

SAFETY DATA SHEET

CONTEC STERILE & FILTERED CAPPED HYDROPURE 1L

Compilation date: 20/03/2018

Revision No: 1

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: CONTEC STERILE & FILTERED CAPPED HYDROPURE 1L

Product code: SBC16HP / FBC16HP

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of substance / mixture: PC8: Biocidal products (e.g. Disinfectants, pest control). Biocidal Product PT-02

1.3. Details of the supplier of the safety data sheet

Company name: Contec Inc.
525 Locust Grove
Spartanburg
South Carolina
29303
USA

Tel: +33 (0) 2 97 43 76 98

Email: sds@contecinc.com

1.4. Emergency telephone number

Emergency tel: +1 703 527 3887 (24 hours)

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: Eye Irrit. 2: H319

Most important adverse effects: Causes serious eye irritation.

2.2. Label elements

Label elements:

Hazard statements: H319: Causes serious eye irritation.

Hazard pictograms: GHS07: Exclamation mark

Signal words: Warning

Precautionary statements: P280: Wear protective gloves/protective clothing/eye protection/face protection.
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+313: If eye irritation persists: Get medical attention.

[cont...]

2.3. Other hazards

Other hazards: Irritating to eyes. Irritating to skin. Irritating to respiratory system.

PBT: This product is not identified as a PBT/vPvB substance.

Section 3: Composition/information on ingredients

3.1. Substances

Chemical identity: CONTEC STERILE & FILTERED CAPPED HYDROPURE 1L

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Remove all contaminated clothes and footwear immediately unless stuck to skin. Wash immediately with plenty of soap and water. Get medical attention if irritation develops or persists.

Eye contact: Bathe the eye with running water for 15 minutes. Consult a doctor.

Ingestion: Do not induce vomiting. Wash out mouth with water. Consult a doctor.

Inhalation: Remove casualty from exposure ensuring one's own safety whilst doing so. If unconscious, check for breathing and apply artificial respiration if necessary. Consult a doctor.

4.2. Most important symptoms and effects, both acute and delayed

Skin contact: There may be irritation and redness at the site of contact.

Eye contact: There may be irritation and redness. The eyes may water profusely.

Ingestion: There may be soreness and redness of the mouth and throat.

Inhalation: There may be irritation of the throat with a feeling of tightness in the chest. Exposure may cause coughing or wheezing.

Delayed / immediate effects: Immediate effects can be expected after short-term exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Eye bathing equipment should be available on the premises.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Alcohol or polymer foam. Dry chemical powder. Use water spray to cool containers.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: In combustion emits toxic fumes.

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

Section 6: Accidental release measures

[cont...]

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details. If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Turn leaking containers leak-side up to prevent the escape of liquid.

6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers. Contain the spillage using bunding.

6.3. Methods and material for containment and cleaning up

Clean-up procedures: Absorb into dry earth or sand. Transfer to a closable, labelled salvage container for disposal by an appropriate method.

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Avoid direct contact with the substance. Ensure there is sufficient ventilation of the area.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a cool, well ventilated area. Keep container tightly closed. Keep away from direct sunlight. Do not freeze. Store below 40°C.

7.3. Specific end use(s)

Specific end use(s): PC8: Biocidal products (e.g. Disinfectants, pest control).

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: No data available.

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

Engineering measures: Ensure there is sufficient ventilation of the area.

Respiratory protection: Use an EN149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hand protection: Nitrile gloves. Rubber gloves.

Eye protection: Safety glasses. Ensure eye bath is to hand.

Skin protection: Protective clothing. Ensure safety shower is to hand.

[cont...]

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Liquid

Colour: Colourless

Odour: Characteristic odour

Boiling point/range°C: No data available.

Melting point/range°C: No data available.

Flammability limits %: lower: Not applicable.

upper: Not applicable.

Flash point°C: Not applicable.

Part.coeff. n-octanol/water: No data available.

Autoflammability°C: No data available.

Vapour pressure: No data available.

Relative density: 1.021 - 1.023

pH: Not applicable.

VOC g/l: No data available.

9.2. Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

Decomposition may occur on exposure to conditions or materials listed below.

10.4. Conditions to avoid

Conditions to avoid: Heat. Flames. Sources of ignition.

10.5. Incompatible materials

Materials to avoid: Strong oxidising agents. Strong acids.

10.6. Hazardous decomposition products

Haz. decomp. products: In combustion emits toxic fumes.

Section 11: Toxicological information

11.1. Information on toxicological effects

Relevant hazards for product:

Hazard	Route	Basis

[cont...]

Serious eye damage/irritation	OPT	Hazardous: calculated

Symptoms / routes of exposure

Skin contact: There may be irritation and redness at the site of contact.

Eye contact: There may be irritation and redness. The eyes may water profusely.

Ingestion: There may be soreness and redness of the mouth and throat.

Inhalation: There may be irritation of the throat with a feeling of tightness in the chest. Exposure may cause coughing or wheezing.

Delayed / immediate effects: Immediate effects can be expected after short-term exposure.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: No data available.

12.3. Bioaccumulative potential

Bioaccumulative potential: No data available.

12.4. Mobility in soil

Mobility: No data available.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT/vPvB substance.

12.6. Other adverse effects

Other adverse effects: No data available.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Transfer to a suitable container and arrange for collection by specialised disposal company.

Disposal of packaging: Dispose of in a regulated landfill site or other method for hazardous or toxic wastes.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

Transport class: This product does not require a classification for transport.

Section 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Specific regulations: Not applicable.

[cont...]

15.2. Chemical Safety Assessment

Section 16: Other information

Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 2015/830.

* indicates text in the SDS which has changed since the last revision.

Phrases used in s.2 and s.3: H319: Causes serious eye irritation.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

Section 8
Efficacy

Disinfectant efficacy in Europe can easily be tested and compared in a laboratory environment using a series of EN tests. CEN technical committee 309 has developed a series of tests for the testing of disinfectants suitable for use in industrial areas. It must be noted that they are not specifically designed for the testing of cleanroom disinfectants and even the clean conditions test involves using a small amount of interfering substance.

The EN tests include a mixture of surface and suspension tests:-

Phase 1:	Screening by basic suspension tests
Phase 2:	Step 1 Extended suspension tests for defined applications
	Step 2 Evaluation in "practice mimicking" conditions
Phase 3:	Field Tests (*not yet developed*)

Phase 1 testing does not specify any contact time or involve and interfering substances. These tests tend to be used by disinfectant manufacturers to show initial activity during the development process.

Phase 2 Step 1 tests are suspension tests for bacteria, fungi, yeasts, viruses and spores with specified organisms, contact times and interfering substance added. Phase 2 Step 2 testing is a surface test, whereby the organism under test is dried onto a disc and the disinfectant added for a specified contact time. The test is specified for bacteria, fungi and yeasts but can be adapted for spores.

Contec HydroPure Efficacy

Contec HydroPure has been tested according to the following tests:

BS EN 1276:1997
Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

BS EN1650:2008 +A1:2013
Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

BS EN 13704:2002
Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.

BS EN 14476:2005 +A1:2006
Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.

BS EN 13697:2015
Chemical Disinfectants and Antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.

Neutraliser

The neutraliser suitable for use with Contec HydroPure is:

Lecithin	3g / l
Tween 80	30g / l
L-histidine	1g / l
Saponin	30g / l
Phosphate buffer	0.35g / l
Sodium Thiosulphate	5g / l

Standard EN Tests Parameters

Test	Organisms	Contact Time	Log reduction
EN1276	E. *hirae*	5 mins	Log 5
	E. *coli*	5 mins	Log 5
	P. *aeruginosa*	5 mins	Log 5
	S. *aureus*	5 mins	Log 5
EN1650	C. *albicans*	15 mins	Log 4
	A. *niger (brasiliensis*	15 mins	Log4
EN14476	Poliovirus	60 mins	Log 4
	Adenovirus	60 mins	Log 4
EN13704	B. *subtilis*	60 mins	Log 3
EN13697	E. *hirae*	5 mins	Log 4
	E. *coli*	5 mins	Log 4
	P. *aeruginosa*	5 mins	Log 4
	S. *aureus*	5 mins	Log 4
	C. *albicans*	15 mins	Log 3
	A. *brasiliensis*	15 mins	Log 3

In addition to the specific test organisms, other organisms were also tested.

Test	Organisms	Contact Time	Log reduction
EN13697	*B.cepacia*	5 mins	Log 5
EN13697	B. *subtilis*	60 mins	Log 2*

HydroPure Efficacy Results Production Batch

Batch No: 130400238 / 130400239 / 130400240

Test Lab: FDAS Laboratories Nottingham UK

EN1276 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 5	> 5.0	5 mins	PASS	Dilution neutralisation
E.*hirae*	Log 5	> 5.0	5 mins	PASS	Dilution neutralisation
E.*coli*	Log 5	> 5.0	5 mins	PASS	Dilution neutralisation
P.*aeruginosa*	Log 5	> 5.0	5 mins	PASS	Dilution neutralisation

EN1650 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
A.*brasiliensis*	Log 4	> 4.0	15 mins	PASS	Dilution neutralisation
C.*albicans*	Log 4	> 4.0	15 mins	PASS	Dilution neutralisation

EN13704 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
B.*subtilis*	Log 3	> 3.0	15 mins	PASS	Dilution neutralisation

EN13697 – clean conditions / stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
B.*subtilis*	Log 2*	>4.0	15 mins	PASS	Dilution neutralisation

Batch No: 130400238

Test Lab: FDAS Laboratories Nottingham UK

EN13697 – clean conditions / stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 4	> 7.12	5 mins	PASS	Dilution neutralisation
P.*aeruginosa*	Log 4	> 6.81	5 mins	PASS	Dilution neutralisation
A.*brasiliensis*	Log 3	4.12	15 mins	PASS	Dilution neutralisation
B.*subtilis*	Log 2*	3.5	15 mins	PASS	Dilution neutralisation

Batch No: 170300592

Test Lab: MGS Labs, UK

EN13697 – clean conditions / stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 4	> 5.80	5 mins	PASS	Dilution neutralisation
P.*aeruginosa*	Log 4	> 5.64	5 mins	PASS	Dilution neutralisation
E.coli	Log 4	> 5.20	5 mins	PASS	Dilution neutralisation
E.hirae	Log 4	> 5.49	5 mins	PASS	Dilution neutralisation
A.*brasiliensis*	Log 3	>4.97	15 mins	PASS	Dilution neutralisation
C.albicans	Log 3	>4.29	*15 mins*	*PASS*	Dilution neutralisation
B.*subtilis*	Log 2*	>2.70	15 mins	PASS	Dilution neutralisation

Batch No: 180500830

Test Lab: MGS Labs, UK

EN13697 – stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
B.cepacia	Log 5 (clean)	> 4.85	5 mins	PASS	Dilution neutralisation
B.cepacia	Log 5 (dirty)	4.00	5 mins	PASS	Dilution neutralisation

Batch No: 171000714

Test Lab: MGS Labs, UK

EN1650 – 5 mins contact time

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
C.*albicans*	Log 4	> 4.32	5 mins	PASS	Dilution neutralisation

EN13697 – 5 mins contact time

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
C.*albicans*	Log 3	> 4.23	5 mins	PASS	Dilution neutralisation

Batch No: 150100223

Test Lab: Virnext Lab, Lyon, France.

EN14476 – dirty conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
Poliovirus	Log 4	5.4	15 mins	PASS	Dilution neutralisation
Adenovirus	Log 4	4.7	15 mins	PASS	Dilution neutralisation

Standard tests R and D trials

Test House – ALS Labs, Ely, UK

EN1276 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 5	> 5.0	5 mins	PASS	Dilution neutralisation
P.*aeruginosa*	Log 5	> 5.0	5 mins	PASS	Dilution neutralisation

Test House – ALS Labs, Ely, UK

EN1650 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
A.*niger (brasiliensis*)	Log 4	>4.8	15 mins	PASS	Dilution neutralisation

Test House – A Chris Seldom Laboratories, UK

EN13704 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
B.*subtilis*	Log 3	> 3.0	15 mins	PASS	Dilution neutralisation

Conclusion

Tests carried out against the standard EN tests for qualification of disinfectants has shown that Contec *Sterile* HydroPure is a suitable cleanroom sporicide effective in clean conditions against :

Bacteria	5 mins
Yeasts	5 mins
Fungi	15 mins
Moulds	15 mins
Spores	15 mins
Viruses	15 mins

Mode of Action

Hydrogen peroxide belongs to the group of oxidising disinfectants. Hydrogen peroxide reacts very fast. It will than disintegrate into hydrogen and water, without the formation of byproducts and his increases the amount of oxygen in water.

It is believed that hydrogen peroxide works by inflicting multiple cell damage to cells and removal of protein, ending in cell death. It produces destructive hydroxyl-free radicals that can attack membrane lipids, DNA and essential cell components.

Section 9
Compatibility

The compatibility of Contec HydroPure with both cleanroom materials and other chemicals was analysed.

Cleanroom Materials

Contec HydroPure is not classed as corrosive towards surfaces so is suitable for use on the majority of materials found in cleanroom environments. It is an oxidiser however.

However, all fluids used in cleanrooms, including water for injection can cause damage if they are used inappropriately. The main cause of corrosion in cleanrooms is disinfectants which have been left wet because they have got into areas which cannot be wiped dry. Always apply disinfectants with a wipe or a mop so the application is controlled and fluid cannot run into areas that are not appropriate or reachable. Best practice suggests that disinfectants should be wiped to dry and removed after the contact time.

In case of doubt it is recommended to test the materials with the product before prolonged contact.

Corrosion Testing

Evaluation of compatibility of Contec HydroPure against a variety of cleanroom materials

Summary

The investigation was carried out to check the compatibility of Contec HydroPure when used on common cleanroom materials. Several different methods of applying Contec HydroPure to the materials were investigated as part of the test work. Compatibility will be determined via the visual condition of the material post-test and the weight of material post-test. Full details of the test and results can be seen in Technical report TN1702 in Section 13.

Test Methods

All samples surfaces were cleaned by spraying with Contec Denatured Ethanol and wiping down with a dry polyester wipe prior to weighing. All samples were tested in triplicate with the exception of the aluminium plinth, vinyl flooring, PVC and polycarbonate samples which were tested in duplicate.

Spray and spray/wipe method

Twice every working day each sample was sprayed 3 times from a distance of approx. 30cm away from the sample with Contec HydroPure.

Spray samples - The disinfectant was left to dry on the surface

Wipe samples – After 10 minutes' contact time the surfaces were wiped dry using a dry polyester cellulose wipe

The above testing was carried out for a duration of 4 weeks. All samples were then visually examined and re-weighed.

As a blank control Deionised water was run on 1 x sample of each material. Contec HydroPure assay – 6.36% Hydrogen Peroxide.

Materials used

316 grade passivated stainless steel -
304 grade stainless steel –
Polyester Powder coated galvanised steel
HPL Compact
Cast aluminium powder coated polyester
Silicone gasket
Vinyl flooring
PVC
Polycarbonate

Results

Summary

All spray and wipe tests show no material incompatibility.

Spray only Grade 304 stainless steel showed a lot of surface oxidation.

Polyester powder coated galvanised steel samples show blistering. The blistering on the surface of the powder coated galvanised steel was unexpected but highly visible on all samples tested. Even at 2 weeks blistering of the powder coated galvanised steel was very visible

The change in the weight of the silicone gasket will likely be due to some water absorption

Hydrogen peroxide solutions leave little to no residue on surface, but it is an oxidiser. From the results obtained it is clear that an application method incorporating spray and wipe-to-dry is best on all materials as no visible issues were reported using this method over a 4-week period. All materials tested displayed no issues. There were a few minor increases in weight of several of the materials but this was very minimal and can even be related to the accuracy of the pre and post weighing's.

In contrast, continuous spraying on the materials had a more negative result on some of the materials tested. The majority of materials were ok, however the 304 stainless steel showed a lot of water staining and oxidation to the surface. The powder coated galvanised steel was also adversely affected by HydroPure displaying blistering of the coated surface within 2 weeks of testing. It should be noted that the 304 stainless steel was also water stained and corroded when deionised water was sprayed on the surface and left.

The overall conclusion is that Contec HydroPure is compatible with all the above materials. Care would be needed when using on 304 stainless steel surfaces as any scratches to the surface could result in visible oxidation forming over time.

The blistering effect noted on the powder coated galvanised steel means this surface would require HydroPure to be wiped dry after its required contact time to prevent any damage to the coating.

A spray and wipe-to-dry application technique would help to eliminate any potential issues on all surfaces.

Corrosion Testing – Stainless Steel

In order to test HydroPure's compatibility with one of the most common materials in a cleanroom, the product was tested on stainless steel.

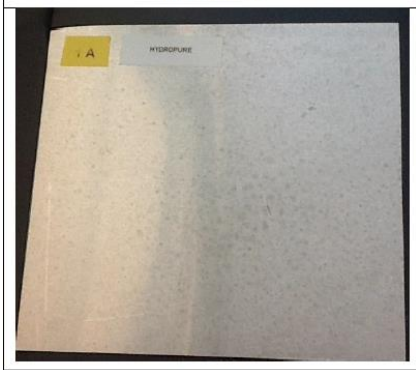
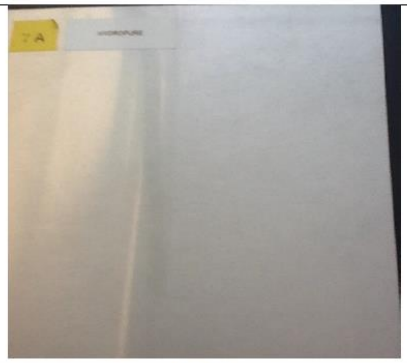
Method

Using a trigger spray Contec *Sterile* HydroPure was sprayed onto a stainless steel table every week for 6 weeks. Three different methods were used. As a comparison deionised water was also sprayed by the same methods.

1) Sprayed to cover the surface suitable for disinfection and left wet – 3A and 3B
2) Sprayed, left for 1 min contact time and wiped to dry – 6A and 6B
3) Sprayed, left for 1 min contact time, wiped dry and then wiped with 70% IPA – 9A and 9B

Results

Contec HydroPure

Leave Wet	Spray & Wipe & Dry	Spray , Wipe & Dry & IPA Wipe
		
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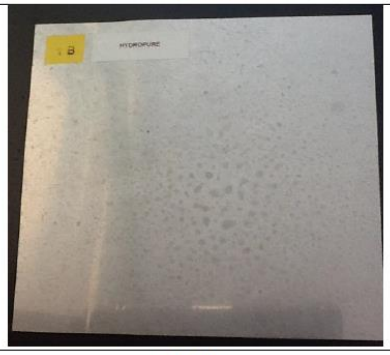
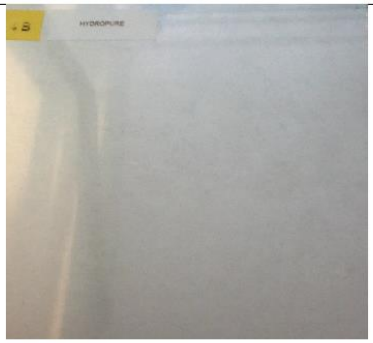
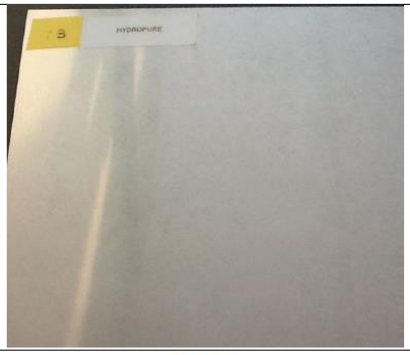
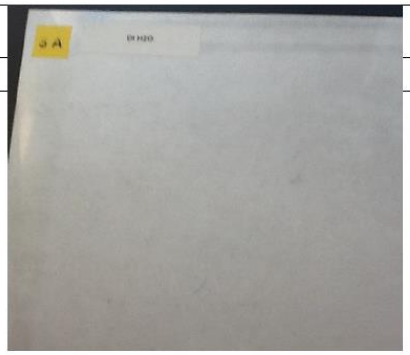
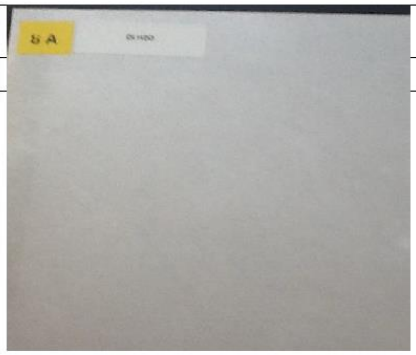
		
Ref 1B	Ref 4B	Ref 7B

Deionised Water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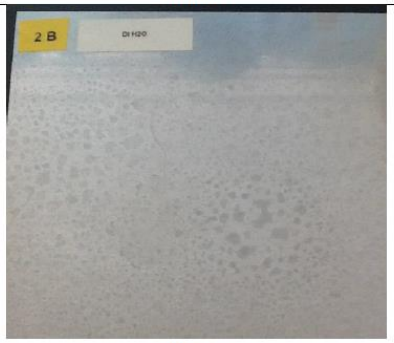
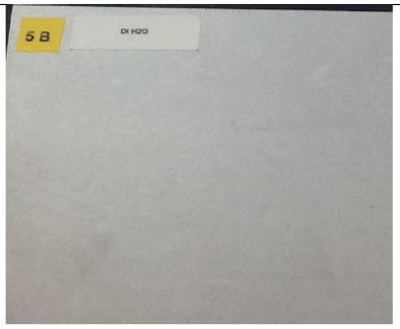
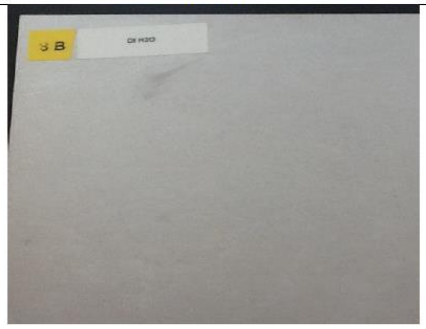
		
Ref 2B	Ref 5B	Ref 8B

As can be seen from the photos there is no difference to the surface from using Contec HydroPure to using water. The marks on picture 1A/B and 2A/B are water staining. This water staining was eliminated if a wiping phase was introduced.

Compatibility with other Contec disinfectants

Although not critical if a regime of disinfect and wipe to dry is used it is interesting to note if there are any interactions between different Contec disinfectants. In order to establish what would happen if two chemicals were inadvertently mixed we took a 50:50 mix of all of our products and noted the reaction.

Method

A 50:50 mix of each product was shaken together in a test tube. The original pH of each fluid was noted and the starting temperature of the fluids. The pH, temperature after mixing and any visual reaction were noted & recorded

Starting temperature 24.4^{o}C

Initial pH of each fluid

Contec ProChlor	pH 3.7
Contec HydroPure	pH 4.2
Contec 70% IPA	pH 6.8
Contec 70% Denatured Ethanol	pH 5.9
Contec NeutraKlean	pH 7.1

Results

	ProChlor	HydroPure	NeutraKlean	70% IPA	70% DE
ProChlor		pH 3.18 Temp 24.9 °C (+0.5°C) Fizzing / bubbles produced	pH 6.12 Temp 24.4 °C (no change) No visual change	pH 4.56 Temp 30.1 °C (+5.7°C) No visual change	pH 4.56 Temp 28.8 °C (+5.4°C) No visual change
HydroPure	pH 3.18 Temp 24.9 °C (+0.5°C) Fizzing / bubbles produced		pH 6.84 Temp 24.4 °C (no change) No visual change	pH 4.56 Temp 29.1 °C (+4.7°C) No visual change	pH 4.79 Temp 29.8 °C (+5.4°C) No visual change
NeutraKlean	pH 6.12 Temp 24.4 °C (no change) No visual change	pH 6.84 Temp 24.4 °C (no change) No visual change		pH 7.85 Temp 29.9 °C (+5.5°C) No visual change	pH 7.53 Temp 30.0 °C (+5.6°C) No visual change

Conclusion

As can be seen from the results there is no significant reaction when HydroPure is mixed in large quantities with other Contec disinfectants. Mixing with Contec ProChlor (hypochlorous acid) did result in effervescence and a small exothermic reaction - care should be taken if using these two products together to ensure surfaces are wiped dry after use.

If adding HydroPure to a vessel that has been used for Contec ProChlor , ensure that the vessel has been emptied and rinsed thoroughly.

Conclusion

Contec *Sterile* HydroPure is extremely low residue making it especially suitable for product contact areas.

The chemical reaction taking place is:

$$2H_2O_2 \rightarrow 2H_2O+O_2$$

So the hydrogen peroxide breaks down to water and oxygen leaving no residue on the surface. This also helps with its compatibility with cleanroom materials. However, Contec HydroPure is an oxidiser so as could be seen when tested on the different cleanroom materials, care does need to be takem.

The overall conclusion is that Contec HydroPure is compatible with a wide range of cleanroom materials. Care would be needed when using on 304 stainless steel surfaces as any scratches to the surface could result in visible oxidation forming over time.

The blistering effect noted on the powder coated galvanised steel means this surface would require HydroPure to be wiped dry after its required contact time to prevent any damage to the coating.

A spray and wipe-to-dry application technique would help to eliminate any potential issues on all surfaces.

Section 10
Residue Analysis

A residue left by a disinfectant can be detrimental to the ongoing disinfection of the facility and also lead to sticky floors, staining or even potential corrosion. As Contec HydroPure is 6% Hydrogen Peroxide it leaves virtually no reside on a surface. At a surface level H_20_2 breaks down to water and oxygen. In order to prove this a simple test was carried out using the EP residue on evaporation.

Residue on evaporation

The European Pharmacopoeia has a residue on evaporation test which was used to test HydroPure.

Method

1) Evaporate 100 ml of test substance to dryness in a water bath and dry at 100 - 105°C for 1 hour
2) Weigh container after drying and subtract weight of the original container

Results

Test House ALS Labs, Ely, UK – Sterile HydroPure

Test	Residue from 100ml
Sample 1	4ppm

Filtered HydroPure

Test	Residue from 100ml
Sample 1	7ppm

Conclusion

Contec HydroPure leaves virtually no residue on a surface, the residue that is left can be easily removed. A result of 4ppm compares very favourable to other disinfectants such as quaternary ammonium compounds and hypochlorites which leave significantly more residue. As a comparison alcohol solutions must leave less than 25ppm per 100ml on a residue on evaporation test.

Product	Residue on Evaporation/ppm
Quat/Biguanide Liquid	6,106
Quat / Chlorine Dioxide Liquid	20,595
Amphoteric Surfactant Liquid	62,213
Quat / Biguanide Liquid	5,256
Amphoterics / Biguanide Liquid	5,948

The chemical reaction taking place is:

$$2H_2O_2 \rightarrow 2H_2O+O_2$$

Hydrogen peroxide breaks down to water and oxygen leaving no residue on the surface.

Section 11
Sterility Validation

Contec *Sterile* HydroPure is currently being manufactured under deviation as a sterile fill product into pre-irradiated components.

All component parts, bottles, bags, labels, triggers and caps are gamma irradiated at no less than 25kGy prior to being passed into a Grade B cleanroom.

Performance qualification is a key step in the production of sterile products or raw materials. It confirms the irradiation dose distribution across the pallet to ensure all products receive the required minimum dose of 25kGy.

Synergy Health in the UK is validation for the sterilisation of Contec's prep pack products, following well defined specifications to achieve performance qualification. The gamma irradiation is conducted at Synergy's Daventry plant.

The current performance qualifications of the raw materials used in the manufacture of Contec HydroPure are detailed below. Performance qualifications are carried out on families of product, this product family is for preparation of raw materials for subsequent aseptic processing.

The results serve as a basis for defining the dose range used in routine processing to ensure consistent sterility of the product.

Certificates of sterility and endotoxin testing are also included in this section from an independent laboratory showing that the initial production trial of HydroPure, sterile filled into pre-irradiated containers, rendered the product sterile and with endotoxin levels below 0.25 EU/ml.

Contec HydroPure is not provided sterile but is 0.2 micron filtered under Grade A air in a Grade B cleanroom.

VAL062

Performance Qualification Daventry Gamma
Record of Amendment

Date Issued: 28-Oct-15
Report Reference: 4781 Rev 01
Customer: Contec Cleanroom UK Ltd
Product Description: Suction Pump~~SBC16HPW~~ SBT16HPW & 02Nov16.

Amendment Details Date: 28-Oct-15

New report.

Amendment Justification

Not applicable.

Amended Item Specification Number: 1107914

Signatures
Approved:

Site Quality Manager

02Nov16.

Validation Ref: 4781
Performance Qualification Daventry **Rev 01**

Customer: **Contec Cleanroom UK Ltd**

Product Description: **SBC16HPW-Prep Packs**

Valid From: **28-Oct-16** Expires: **27-Oct-21**

Introduction

This report outlines the distribution of absorbed dose across the product detailed above, establishing routine processing parameters to enable Synergy Health AST to irradiate the products within the agreed processing specification using a Co60 Gamma irradiation. The placement of the dosimeters to assess the min and max dose has been determined during the Operational Qualification

Objective

The objective of this report is to determine the location of dose extremes, i.e minimum dose zone (the lowest dose absorbed by the product) and the maximum dose zone (the highest dose absorbed). To characterise dose distribution within the product, and thus determine the relationship ratio of D_{Ref}/D_{Min} and $D_{Ref}/D_{Max.}$ To define cycle parameters for routine processing

Conclusion

The delivered dose in the product presentation illustrated on pages 4-5 achieves the requested dose specification of 25.0 kGy minimum dose and 95.0 kGy maximum dose. In order to meet this specification during routine processing the recorded dose at D_{Ref} must be between **26.1** kGy and **88.7** kGy. This incorporates an estimation of uncertainty associated with the measurement system.

Authorisation

Position	Signature	Date
Plant Manager		31 Oct 2016
Daventry Quality Manager		01 Nov 2016

Note:
It is the responsibility of the customer to routinely provide product in the presentation and orientation outlined in this report

This performance qualification validates the delivery of radiation doses only. Validation of the sterilisation effect and radiation induced material effects, if any, are not addressed by this qualification.

Methodology

Qualification data is obtained by placing Harwell Perspex dosimeters in a defined pattern throughout a Synergy Health AST Irradiation container loaded with product.

The performance qualification is conducted in triplicate with the dosimeters placed throughout the product to assess both the dose distribution and determine the variability of the absorbed dose measurements, when processed under the same processing conditions.

Following processing the relationship between $\overline{D_{ref}} / \overline{D_{min}}$ and $\overline{D_{ref}} / \overline{D_{max}}$ are calculated to determine an acceptable D_{Ref} processing range.

D_{Ref} processing range is calculated by multiplying the R_{min} by the Customer minimum specification and the R_{max} by the Customer maximum specification. During routine processing if the D_{Ref} value falls within this range then processing is deemed as meeting the required specification:

D_{Ref} Minimum = Expected value of R_{min} x Minimum Dose Required
D_{Ref} Maximum = Expected value of R_{max} x Maximum Dose Required

Uncertainty

The specification for D_{Ref} incorporates an estimation of the uncertainty associated with the measurement system. Uncertainty has been calculated using the method outlined in ASTM E 2303. This method provides a confidence level of 95%.

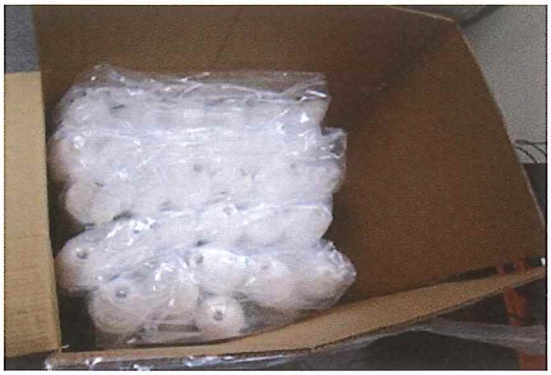
Definitions

D_{Ref} - Reference Dose
D_{Min} - Minimum Dose
D_{Max} - Maximum Dose
R_{min} - D_{Ref}/D_{Min} ratio
R_{max} - D_{Ref}/D_{Max} ratio
CV% - Coefficient of Variance
Co60 - Cobalt 60

Product Detail

Customer Name: **Contec Cleanroom UK Ltd**
Product Desciption **SBC16HPW-Prep Packs** Expiry Date **27-Oct-21**

Layout Of Shipper Contents



Dosimetry Placement

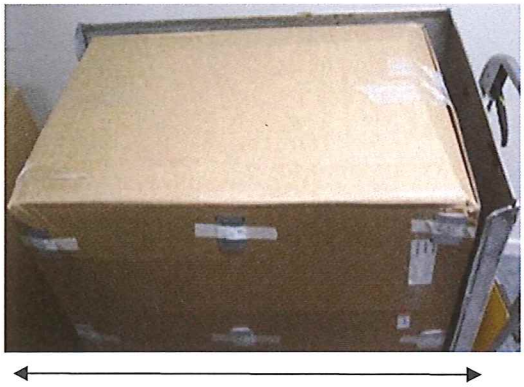
Product Detail

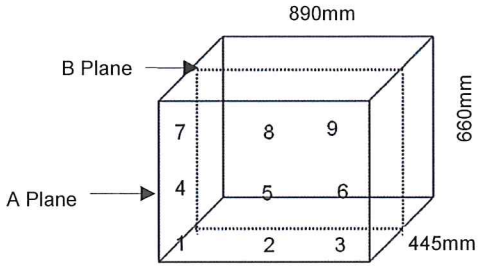
Customer Name: **Contec Cleanroom UK Ltd**

Product Description: **SBC16HPW-Prep Packs** Expiry Date **27-Oct-21**

Number Per Container: **1** Number Per Shipper: **8**

Irradiation Container





Approved By: **Date:** 31 Oct 2016.

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
D_{ref} Position 1A	32.3	32.4	32.4	**32.4**	**0.06**	**0.18**	0.01
2A	33.2	34.3	33.4	33.6	0.59	1.74	0.69
3A	32.4	32.2	32.3	32.3	0.10	0.31	0.02
4A	33.1	32.8	32.7	32.9	0.21	0.63	0.09
5A	34.9	34.9	34.1	34.6	0.46	1.33	0.43
6A	32.8	32.8	33.1	32.9	0.17	0.53	0.06
7A	32.4	32.7	32.7	32.6	0.17	0.53	0.06
8A	34.5	34.5	33.3	34.1	0.69	2.03	0.96
9A	33.2	32.8	33.4	33.1	0.31	0.92	0.19
1B	31.2	31.1	31.0	31.1	0.10	0.32	0.02
2B	31.1	32.5	30.9	31.5	0.87	2.77	1.52
3B	30.4	32.0	30.8	31.1	0.83	2.68	1.39
4B	32.1	32.3	32.2	32.2	0.10	0.31	0.02
5B	32.7	32.8	32.6	32.7	0.10	0.31	0.02
6B	31.9	32.0	31.6	31.8	0.21	0.65	0.09
7B	31.7	32.8	31.4	32.0	0.74	2.31	1.09
8B	32.2	32.6	31.9	32.2	0.35	1.09	0.25
9B	32.4	31.3	31.5	31.7	0.59	1.85	0.69

Pooled variance ($s^2_{overall}$)	**0.21**	**D_{Ref} release criteria**	
Minimum detectable difference (б)	**0.63**	D_{Ref} Minimum	**26.1**
Mean Minimum dose (D_{Min})	**31.1**	D_{Ref} Maximum	**88.7**
Mean Maximum dose (D_{Max})	**34.6**		
Expected value of R_{min}	**1.0421**		
Expected value of R_{max}	**0.9344**		

Product Detail

Customer Name: **Contec Cleanroom UK Ltd**
A/C No: **126485** Report Ref.: **4781**
Issue Date: **28-Oct-16** Expiry Date: **27-Oct-21**

Product Description: SBC16HPW-Prep Packs

Type of package: **Carton**
No of Packages/Irradiation Container: **1**
No of Packages/Shipper: **8**

Dimensions of Package (mm): **830** x **640** x **460**
Weight of Package (kg): **14.40** Density (gcm^3): **0.06**

Plant Batch No: **S11705132-1-1**

Current Co60 Loading (Mc_i): **3.12**

Standard Plant Dwell Time (sec): **81**

Dwell Time (sec): **75**

Dose Range Specification (kGy): **25.0** Min. **95.0** Max.

Number of passes **1**

Synergy Processing Instruction

Guide Plant Dwell Time Range: **0.75** Min **2.54** Max

D_{Ref} Minimum **26.1**
D_{Ref} Maximum **88.7**

Ratio's

Synergy (1/Rmin) **0.9596**
Synergy (1/Rmax) **1.0702**

Comments

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON
insight creating advantage

Contec Cleanroom (UK) Ltd
Wansbeck Business Park
Rotary Park
Ashington
NE63 8QW

FAO: Simon Csaba, John Gray

Report of Tests on:	Sterile Contec Hydropure		
Sample Description:	SBT16HPW/NSA026- Beg		
Lucideon Sample Number:	(163567)-24204		
Lucideon Report Number:	(163567)-24204/MFEP	**Issue Number:**	1
Date Logged:	08-Aug-2016	**Order Number:**	N/A
Date Reported:	31-Aug-2016	**Date(s) of Test(s):**	09-Aug-2016 to 23-Aug-2016

Sterility Testing

Membrane Filtration EP

Test Results:

Result: Pass

End of Test Report

31 Aug 16

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PHARMACEUTICAL ANALYSIS REPORT

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FAO: Simon Csaba, John Gray

Report of Tests on:	Sterile Contec Hydropure		
Sample Description:	SBT16HPW/NSA026- End		
Lucideon Sample Number:	(163567)-24205		
Lucideon Report Number:	(163567)-24205/MFEP	**Issue Number:**	1
Date Logged:	08-Aug-2016	**Order Number:**	N/A
Date Reported:	31-Aug-2016	**Date(s) of Test(s):**	09-Aug-2016 **to** 23-Aug-2016

Sterility Testing

Membrane Filtration EP

Test Results:

Result: Pass

End of Test Report

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PHARMACEUTICAL ANALYSIS REPORT

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FAO: Simon Csaba, John Gray

Report of Tests on:	Sterile Contec Hydropure		
Sample Description:	SBT16HPW/NSA026		
Lucideon Sample Number:	(163567)-24206		
Lucideon Report Number:	(163567)-24206/ETEP	**Issue Number:**	1
Date Logged:	08-Aug-2016	**Order Number:**	N/A
Date Reported:	31-Aug-2016	**Date(s) of Test(s):**	09-Aug-2016 **to** 09-Aug-2016

Endotoxin Test (EP)

2.6.14 Bacterial Endotoxins - Method C - Turbidimetric Kinetic Method

Test Results:

Result: Pass (<0.05EU/ml)

End of Test Report

07 Sep 16.
(PNS - Accredited)
EMP.

31 Aug 16

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PHARMACEUTICAL ANALYSIS REPORT

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FAO: Simon Csaba

Report of Tests on:	Contec Sterile 5L Hydropure		
Sample Description:	SBC56HP/NSA026		
Lucideon Sample Number:	(163623)-24591		
Lucideon Report Number:	(163623)-24591/ETEP	**Issue Number:**	1
Date Logged:	10-Aug-2016	**Order Number:**	N/A
Date Reported:	12-Aug-2016	**Date(s) of Test(s):**	12-Aug-2016 **to** 12-Aug-2016

Endotoxin Test (EP)

2.6.14 Bacterial Endotoxins - Method C - Turbidimetric Kinetic Method

Test Results:

Result: Pass (<0.025EU/ml)

End of Test Report

14/Aug/16.

(5L FROM IRRADIATED PACK-COVERS.)

12 Aug 16

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PHARMACEUTICAL ANALYSIS REPORT

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FAO: Simon Csaba

Report of Tests on:	Contec Sterile 5L Hydropure		
Sample Description:	SBC56HP/NSA026		
Lucideon Sample Number:	(163623)-24590		
Lucideon Report Number:	(163623)-24590/MFEP	**Issue Number:**	1
Date Logged:	10-Aug-2016	**Order Number:**	N/A
Date Reported:	31-Aug-2016	**Date(s) of Test(s):**	12-Aug-2016 **to** 26-Aug-2016

Sterility Testing
Membrane Filtration EP

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

End of Test Report

02Sep16.

31 Aug 16

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Section 12
Shelf Life Validation

Shelf life validation for cleanroom disinfectants is separated into 2 parts, validation of the unopened shelf life and also validation of the time the product remains efficacious and sterile during normal use; the in-use shelf life.

Contec HydroPure has an un-opened shelf life of 24 months from date of manufacture. Contec HydroPure 1L trigger spray has an in-use shelf life of 6 months. The 5L capped product unless additional validation work has been carried out by the customer should be used up within a daily session.

Currently Contec *Sterile* HydroPure is being manufactured under deviation, by sterile filtration into pre-irradiated containers. As the terminal irradiation of HydroPure in the bottles was deemed to be more aggressive on the product, the shelf life work has been carried over for both the sterile fill product and the filtered product.

Initial studies were based on accelerated aging studies. The product was also put on ambient testing and results will be announced at key intervals.

To support the BPR submission, work was also carried out an independent laboratory; Eurofins Biolab in Italy. Their accelerated testing looked at appearance of the test item and packaging, relative density and an assay of the active ingredient, hydrogen peroxide. A summary of their testing is attached.

Unopened Shelf Life Validation

Accelerated aging studies

In order to assess new products for shelf life testing accelerated aging needs to be carried out. Contec Sterile HydroPure samples were stored at 40^0C ± 2^oC for 24 weeks which equates to a shelf life of 24 months at ambient temperature. This is based on the EMEA "Guidelines on Stability Testing". Ambient shelf life testing was also carried out in parallel.

To assess the product at end of shelf the product was retested against its release specification and a representative sample of efficacy tests were also carried out. The samples were also checked visually for any signs of bottle degradation or leakage.

Contec *Sterile* HydroPure Production trial 1L

Three initial batches were produced and a sample from each tested. The samples were put on both accelerated and ambient shelf life testing.

Production samples of Contec *Sterile* HydroPure 1L

Batch Code		**Actual irradiation dosage**	
1.	130400238	1.	47.4kGy
2.	130400239	2.	48.4kGy
3.	130400240	3.	48.4kGy

The starting specification of the samples non irradiated was:-

Test	Specification	Result
Specific Gravity @20^{0}C	1.021 to 1.023	1.022
pH	2.5 – 4.5	4.10
Percentage H_20_2	6% - 6.9%	6.9%
Colour	Colourless	Colourless
Odour	None	None

Results

From R and D trials we know that there is a small effect on the pH and percentage of hydrogen peroxide available after irradiation so the post irradiation specification was also checked.

Chemical results post irradiation

Sample	pH	% H_2O_2	Colour	Odour	S.G
Batch 238	3.92	6.87%	Colourless	None	1.022
Batch 239	3.89	6.87%	Colourless	None	1.022
Batch 240	3.94	6.91%	Colourless	None	1.022

Chemical results after 24 weeks storage at 40^{0}C

Sample	pH	% H_2O_2	Colour	Odour	S.G
Batch 130400238 - 1	3.43	6.12%	Colourless	None	1.022
Batch 130400238 – 2	3.51	6.12%	Colourless	None	1.022
Batch 130400238 – 3	3.55	6.12%	Colourless	None	1.022
Batch 130400239– 1	3.44	6.29%	Colourless	None	1.022
Batch 130400239 – 2	3.48	6.29%	Colourless	None	1.022
Batch 130400239 – 3	3.44	6.29%	Colourless	None	1.022
Batch 130400240 – 1	3.48	6.12%	Colourless	None	1.022
Batch 130400240 – 2	3.52	6.12%	Colourless	None	1.022
Batch 130400240 – 3	3.52	6.12%	Colourless	None	1.022

Chemical results after 24 months storage at ambient temperature

Sample	pH	% H_2O_2	Colour	Odour	S.G
Batch 130400238 - 1	3.55	6.29%	Colourless	None	1.022
Batch 130400238 – 2	3.51	6.29%	Colourless	None	1.022
Batch 130400238 – 3	3.52	6.29%	Colourless	None	1.022
Batch 130400239– 1	3.51	6.29%	Colourless	None	1.022
Batch 130400239 – 2	3.48	6.29%	Colourless	None	1.022
Batch 130400239 – 3	3.49	6.29%	Colourless	None	1.022
Batch 130400240 – 1	3.50	6.19%	Colourless	None	1.022
Batch 130400240 – 2	3.47	6.12%	Colourless	None	1.022
Batch 130400240 – 3	3.49	6.19%	Colourless	None	1.022

Contec *Sterile* HydroPure Production trial 5L

Three initial batches were produced and a sample from each tested. The samples were put on both accelerated and ambient shelf life testing.

Production samples of Contec *Sterile* HydroPure 5L

Batch Code		**Actual irradiation dosage**	
2.	150200234	1.	44.9kGy
2.	150400247	2.	44.0kGy
3.	150700264	3.	60.0kGy

The starting specification of the samples non irradiated was:-

Test	Specification	Result Batch 1	Result Batch 2	Result Batch 3
Specific Gravity @20^{0}C	1.021 to 1.023	1.021	1.023	1.023
pH	2.5 – 4.5			
Percentage H_20_2	6% - 6.9%	6.6%	6.8%	6.74%
Colour	Colourless	Colourless	Colourless	Colourless
Odour	None	None	None	None

Results

From R and D trials we know that there is a small effect on the pH and percentage of hydrogen peroxide available after irradiation so the post irradiation specification was also checked.

Chemical results post irradiation

Sample	pH	% H_2O_2	Colour	Odour	S.G
Batch 150200234	3.91	6.56%	Colourless	None	1.021
Batch 150400247	3.83	6.73%	Colourless	None	1.023
Batch 150700264	3.98	6.74%	Colourless	None	1.023

Chemical results after 24 weeks storage at 40^0C

Sample	pH	% H_2O_2	Colour	Odour	S.G
Batch 150200234 - 1	3.55	6.29%	Colourless	None	1.021
Batch 150200234– 2	3.63	6.29%	Colourless	None	1.021
Batch 150200234 – 3	3.54	6.29%	Colourless	None	1.021
Batch 150400247– 1	3.42	6.40%	Colourless	None	1.023
Batch 150400247 – 2	3.39	6.40%	Colourless	None	1.023
Batch 150400247– 3	3.42	6.34%	Colourless	None	1.023
Batch 150700264 – 1	3.48	6.29%	Colourless	None	1.023
Batch 150700264– 2	3.53	6.34%	Colourless	None	1.023
Batch 150700264 – 3	3.51	6.29%	Colourless	None	1.023

Chemical results after 24 months storage at ambient temperature

Sample	pH	% H_2O_2	Colour	Odour	S.G
Batch 150200234 - 1	3.47	6.20%	Colourless	None	1.021
Batch 150200234– 2	3.44	6.20%	Colourless	None	1.021
Batch 150200234 – 3	3.51	6.20%	Colourless	None	1.021
Batch 150400247– 1	3.41	6.20%	Colourless	None	1.023
Batch 150400247 – 2	3.47	6.12%	Colourless	None	1.023
Batch 150400247– 3	3.42	6.20%	Colourless	None	1.023
Batch 150700264 – 1	3.39	6.12%	Colourless	None	1.023
Batch 150700264– 2	3.35	6.12%	Colourless	None	1.023
Batch 150700264 – 3	3.39	6.08%	Colourless	None	1.023

Accelerated testing at Eurofins Biolab, Italy.

The study was planned applying storage conditions (CIPAC method MT 46.3) at 30^{0}C for 18 weeks. Storage conditions were applied on a single batch in its original packaging. The parameters which were assessed to indicate item stability, were the appearance of the test item and packaging, relative density and an assay of the active ingredient, hydrogen peroxide.

RESULTS

Summary results obtained on the test item "Contec HydroPure SBT16HPW" are reported below.

SAMPLING DATE			T0	T18 WEEKS
TESTS	METHOD	SPECIFIC	September 15th, 2016 Analysis: September 20th, 2016	January 18th, 2017 Analysis: January 20th-23rd, 2017
Appearance of the test item	Visual	No variation from initial	The test item consists of a colorless transparent liquid.	No variation from initial
Appearance of the packaging	Visual	No variation from initial	The packaging is a blank plastic bottle closed by a spray trigger. The bottle is contained in three sealed transparent plastic bag.	No variation from initial
Relative density	CIPAC MT 3	-	1.022	1.022
Content of hydrogen peroxide active ingredient (%w/w)	S-2016-03142AM-MdP	6.7 %w/w (theoretical value)	6.34 %w/w	6.23 %w/w (98.3% of T0)

Efficacy testing

One of the key items to check is that the efficacy of the product has not been affected over the shelf life period. The chemical testing showed all chemical parameters had remained within specification but full EN testing of efficacy was also carried out. The results below show the efficacy testing on both 1L accelerated and ambient samples.

Accelerated testing

Test House – FDAS Labs, Nottingham, UK

EN1276 – clean conditions

All three batches passed EN1276 with a result greater than Log 5.

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 5	> 5.0	5 mins	PASS	Dilution neutralisation
E.*hirae*	Log 5	> 5.0	5 mins	PASS	Dilution neutralisation
E.*coli*	Log 5	> 5.0	5 mins	PASS	Dilution neutralisation
P.*aeruginosa*	Log 5	> 5.0	5 mins	PASS	Dilution neutralisation

EN1650 – clean conditions

All three batches passed EN1650 with a result greater than Log 4.

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
A.*niger* (brasiliensis)	Log 4	> 4.0	15 mins	PASS	Dilution neutralisation
C.*albicans*	Log 4	>4.8	15 mins	PASS	Dilution neutralisation

EN13704 – clean conditions

All three batches passed EN13704 with a result greater than Log 3.

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
B.*subtilis*	Log 3	> 3.0	15 mins	PASS	Dilution neutralisation

EN13697 – clean conditions / stainless steel

All three batches passed EN1370 with a result greater than Log 3.

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
B.*subtilis*	Log 2*	>4.0	15 mins	PASS	Dilution neutralisation

* There is no provision in EN13697 for testing of spore forming bacteria, however, a log 2 reduction of spores would be a suitable requirement as this follows a log 1 reduction from the suspension test requirements that is applied to bacteria and fungi.

Ambient testing – 24 months

Test Lab: MGS Labs, UK

EN13697 – clean conditions / stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 4	> 5.71	5 mins	PASS	Dilution neutralisation
P.*aeruginosa*	Log 4	> 5.76	5 mins	PASS	Dilution neutralisation
E.coli	Log 4	> 5.60	5 mins	PASS	Dilution neutralisation
E.hirae	Log 4	> 5.54	5 mins	PASS	Dilution neutralisation
A.*brasiliensis*	Log 3	>4.97	15 mins	PASS	Dilution neutralisation
C.albicans	Log 3	>4.75	*15 mins*	*PASS*	Dilution neutralisation
B.*subtilis*	Log 2*	>3.85	15 mins	PASS	Dilution neutralisation

In-Use Shelf Life Validation

Due to fact that standard trigger spray bottles pull return air into the sterile fluid many cleanroom trigger spray systems work as a closed system where the return air cannot enter the fluid. This is usually achieved with an integral bag inside the bottle. The return air is unable to enter the bag which holds the sterile fluid, returning through holes in the bottom of the bottle to stop the bottle collapsing.

Contec use a “bag-in-bottle” system for their sterile trigger sprays. As the system is the same for all sterile bottles the test work was carried out on an IPA solution which has the least effect on spores if any were to potentially get pulled into the bottle.

Method

A bottle of Contec Sterile 70% Isopropanol was stored in a general chemistry laboratory with the trigger nozzle open at all times.

Every day for the working week, the trigger was depressed 5 times to dispense the alcohol and the bottle was weighed before and after. The first weighing of the bottle determined the initial weight. Once the bottle became 30% of the initial weight the trigger nozzle was closed and the bottle was sent to an external laboratory. This was after 6 months of use. The bottle contents were tested for sterility (according to the current version of the European Pharmacopoeia).

Results

The 70% Isopropanol had remained sterile.

Conclusion

Contec HydroPure in a 1L trigger spray and in a 5L capped container is stable and remains efficacious over a 24 month period as demonstrated in the above accelerated and ambient testing.

The percentage of hydrogen peroxide which is key to the product remaining efficacious remains in specification. Full EN efficacy testing after both accelerated and ambient testing shows the product has the same efficacy at end of shelf life as the original samples which were tested.

Contec HydroPure can be given a 2 year shelf life. Contec HydroPure 1L trigger spray has an in-use shelf life of 6 months.

Section 13
Technical Reports

The following technical reports include further test work carried out on Contec HydroPure.

TN1702 Rev 1 October 2017

Evaluation of compatibility of Contec HydroPure against a variety of cleanroom materials

TN1703 Rev 1 November 2017

Evaluation of compatibility of Contec HydroPure against a variety of cleanroom gloves using EN 374-3 test for chemical permeability.

CONTEC INC

TECHNICAL NOTE TN1702

REV 1

October 2017

Evaluation of compatibility of Contec HydroPure against a variety of cleanroom materials

Summary

The investigation was carried out to check the compatibility of Contec HydroPure when used on common cleanroom materials. Several different methods of applying Contec HydropUre to the materials were investigated as part of the test work. Compatibility will be determined via the visual condition of the material post-test and the weight of material post-test.

Test Methods

All samples surfaces were cleaned by spraying with Contec Denatured Ethanol and wiping down with a dry polyester wipe prior to weighing. All samples were tested in triplicate with the exception of the aluminium plinth, vinyl flooring, PVC and polycarbonate samples which were tested in duplicate.

Spray and spray/wipe method

Twice every working day each sample was sprayed 3 times from a distance of approx. 30cm away from the sample with Contec HydroPure.

Spray samples - The disinfectant was left to dry on the surface

Wipe samples – After 10 minutes' contact time the surfaces were wiped dry using a dry polyester cellulose wipe

The above testing was carried out for a duration of 4 weeks. All samples were then visually examined and re-weighed.

As a blank control Deionised water was run on 1 x sample of each material. Contec HydroPure assay – 6.36% Hydrogen Peroxide

Materials used

Sterile 1L Contec HydroPure Batch: 160400391

316 grade passivated stainless steel -10 x 10cm squares & 5 x 2.5cm coupons

304 grade stainless steel -10 x 10cm squares & 5 x 2.5cm coupons

Polyester Powder coated galvanised steel (0.6mm thickness)- 10 x 10cm squares & 5 x 2.5cm coupons

HPL Compact - 10 x 10cm squares & 5 x 2.5cm coupons

Aluminium Plinth, cast aluminium powder coated polyester 25µm thickness – 11 x 14.5cm

Silicone gasket – 10 x 10cm

Vinyl flooring 1 x 1cm

PVC – 1 x 1cm

Polycarbonate – 1 x 1cm

Results

Summary

All spray and wipe tests show no material incompatibility.

Spray only Grade 304 stainless steel showed a lot of surface oxidation.

Polyester powder coated galvanised steel samples show blistering. The blistering on the surface of the powder coated galvanised steel was unexpected but highly visible on all samples tested. Even at 2 weeks blistering of the powder coated galvanised steel was very visible

The change in the weight of the silicone gasket will likely be due to some water absorption

.

Spray Test Results

Material	Pre-weight/g	Post-weight/g	Weight Change/g	Comments on Final Visible Condition
316 s/s A	116.30	116.30	0	Good condition, no damage
316 s/s B	116.54	116.54	0	Good condition, no damage
316 s/s C	116.13	116.13	0	Good condition, no damage
304 s/s A	62.67	62.68	+0.01	Poor condition visible oxidation to surface
304 s/s B	62.87	62.87	0	Poor condition visible oxidation to surface
304 s/s C	62.88	62.88	0	Poor condition visible oxidation to surface
Gal Steel A	47.42	47.43	+0.01	Poor Condition, visible blistering to the surface
Gal Steel B	47.90	47.91	+0.01	Poor Condition, visible blistering to the surface
Gal steel C	47.60	47.60	0	Poor Condition, visible blistering to the surface
HPL A	57.14	57.16	+0.02	Good condition, no damage
HPL B	57.16	57.18	+0.02	Good condition, no damage
HPL C	57.15	57.18	+0.03	Good condition, no damage
Al. Plinth A	72.77	72.77	0	Good condition, no damage
Al. Plinth B	72.66	72.66	0	Good condition, no damage
Silic. Gasket A	3.46	3.46	0	Good Condition
Silic. Gasket B	3.44	3.44	0	Good Condition
Vinyl A	0.73	0.73	0	Good Condition
Vinyl B	0.75	0.75	0	Good Condition
PVC A	1.81	1.81	0	Good condition, no damage
PVC B	1.81	1.81	0	Good condition, no damage
Polycarb. A	0.50	0.50	0	Good condition, no damage
Polycarb. B	0.50	0.50	0	Good condition, no damage
316 Control	116.50	116.58	+0.08	Good Condition visible water marks on surface
304 Control	62.63	62.64	+0.01	Poor condition water marks and oxidation visible
Gal St. control	47.54	47.57	+0.03	Good Condition
HPL control	57.11	57.15	+0.04	Good Condition
Plinth control	72.68	72.70	+0.02	Good Condition
Gasket control	3.41	3.42	+0.01	Good Condition
Vinyl control	0.76	0.78	+0.02	Good Condition
PVC control	1.81	1.81	0	Good Condition
Poly. control	0.51	0.51	0	Good Condition

Spray & Wipe Test

Material	Pre-weight/g	Post-weight/g	Weight Change/g	Comments on Final Visible Condition
316 s/s A	115.43	115.43	0	Good condition no surface issues noted
316 s/s B	115.92	115.93	+0.01	Good condition no surface issues noted
316 s/s C	116.65	116.65	0	Good condition no surface issues noted
304 s/s A	62.76	62.76	0	Good condition no surface issues noted
304 s/s B	62.87	62.87	0	Good condition no surface issues noted
304 s/s C	62.64	62.64	0	Good condition no surface issues noted
Gal Steel A	47.30	47.30	0	Good condition no surface issues noted
Gal Steel B	47.47	47.48	+0.01	Good condition no surface issues noted
Gal steel C	47.41	47.42	+0.01	Good condition no surface issues noted
HPL A	57.28	57.28	0	Good condition no surface issues noted
HPL B	57.28	57.29	+0.01	Good condition no surface issues noted
HPL C	57.21	57.21	0	Good condition no surface issues noted
Al. Plinth A	72.83	72.84	0	Good condition no surface issues noted
Al. Plinth B	72.86	72.86	0	Good condition no surface issues noted
Silic. Gasket A	3.49	3.52	+0.03	Good condition no surface issues noted
Silic. Gasket B	3.41	3.45	+0.04	Good condition no surface issues noted
Vinyl A	0.72	0.72	0	Good condition no surface issues noted
Vinyl B	0.73	0.73	0	Good condition no surface issues noted
PVC A	1.83	1.83	0	Good condition no surface issues noted
PVC B	1.80	1.80	0	Good condition no surface issues noted
Polycarb. A	0.49	0.49	0	Good condition no surface issues noted
Polycarb. B	0.49	0.49	0	Good condition no surface issues noted
316 Control	116.42	116.42	0	Good condition no surface issues noted
304 Control	63.03	63.03	0	Good condition no surface issues noted
Gal St. control	47.72	47.72	0	Good condition no surface issues noted
HPL control	57.30	57.30	0	Good condition no surface issues noted
Plinth control	72.18	72.18	0	Good condition no surface issues noted
Gasket control	3.40	3.40	0	Good condition no surface issues noted
Vinyl control	0.79	0.79	0	Good condition no surface issues noted
PVC control	1.83	1.83	0	Good condition no surface issues noted
Poly. control	0.53	0.53	0	Good condition no surface issues noted

Conclusion

Hydrogen peroxide solutions leave little to no residue on surface, but it is an oxidiser.

From the results obtained it is clear that an application method incorporating spray and wipe-to-dry is best on all materials as no visible issues were reported using this method over a 4-week period. All materials tested displayed no issues. There were a few minor increases in weight of several of the materials but this was very minimal and can even be related to the accuracy of the pre and post weighing's.

In contrast, continuous spraying on the materials had a more negative result on some of the materials tested. The majority of materials were ok, however the 304 stainless steel showed a lot of water staining and oxidation to the surface. The powder coated galvanised steel was also adversely affected by HydroPure displaying blistering of the coated surface within 2 weeks of testing. It should be noted that the 304 stainless steel was also water stained and corroded when deionised water was sprayed on the surface and left.

The overall conclusion is that Contec HydroPure is compatible with all the above materials. Care would be needed when using on 304 stainless steel surfaces as any scratches to the surface could result in visible oxidation forming over time.

The blistering effect noted on the powder coated galvanised steel means this surface would require HydroPure to be wiped dry after its required contact time to prevent any damage to the coating.

A spray and wipe-to-dry application technique would help to eliminate any potential issues on all surfaces.

CONTEC INC

TECHNICAL NOTE TN1703

REV 1

November 2017

Evaluation of compatibility of Contec HydroPure against a variety of cleanroom gloves using EN 374-3 test for chemical permeability.

Summary

Testing was carried out using Contec HydroPure and three commonly available cleanroom gloves. Three different types of gloves were tested, nitrile, latex and polychloroprene.

Testing was carried out for two reasons; to show compatibility of HydroPure with standard cleanroom gloves and also to show which gloves are suitable for use with HydroPure in terms of Personal Protective Equipment (PPE).

All three types of glove material are commonly used in life science cleanrooms. The gloves were kindly supplied by Nitritex Ltd, UK.

Test Methods

The test method used was EN 374-3:2003. Gloves giving protection from chemicals and micro-organisms – Part 3: Determination of resistance to permeation by chemicals.

Test Laboratory

Satra Technology, Kettering, UK

Materials used

Contec Sterile HydroPure SBT16HPW

Bioclean Excell Sterile Nitrile Gloves

Bioclean Advance Sterile Latex Gloves

Bioclean P Zero Sterile Polychloroprene Gloves

Results

Test Report CHM0247988/1628/EN-B **Date 16/09/16**

Bioclean Excell Sterile Nitrile Gloves

Chemical	Min detectable permeation rate	Procedure	Mean thickness	Breakthrough tIme *	Observations
Contec HydroPure	0.02 µg/(min.cm^2)	CAT-025	0.16	>480 mins	No change
Contec HydroPure	0.02 µg/(min.cm^2)	CAT-025	0.16	>480 mins	No change
Contec HydroPure	0.02 µg/(min.cm^2)	CAT-025	0.15	>480 mins	No change

* Based on detection of Hydrogen Peroxide (CAS no 7722-84-1)

Test Report CHM0247988/1628/EN-A **Date 16/09/16**

Bioclean Advance Sterile Latex Gloves

Chemical	Min detectable permeation rate	Procedure	Mean thickness	Breakthrough tIme *	Observations
Contec HydroPure	0.02 µg/(min.cm^2)	CAT-025	0.21	>480 mins	No change
Contec HydroPure	0.02 µg/(min.cm^2)	CAT-025	0.21	>480 mins	No change
Contec HydroPure	0.02 µg/(min.cm^2)	CAT-025	0.21	>480 mins	No change

* Based on detection of Hydrogen Peroxide (CAS no 7722-84-1)

Test Report CHM0247988/1628/EN-C **Date 16/09/16**

Bioclean P-Zero Sterile Polychloroprene Gloves

Chemical	Min detectable permeation rate	Procedure	Mean thickness	Breakthrough tIme *	Observations
Contec HydroPure	0.02 µg/(min.cm^2)	CAT-025	0.16	>480 mins	No change
Contec HydroPure	0.02 µg/(min.cm^2)	CAT-025	0.17	>480 mins	No change
Contec HydroPure	0.02 µg/(min.cm^2)	CAT-025	0.15	>480 mins	No change

* Based on detection of Hydrogen Peroxide (CAS no 7722-84-1)

Conclusion

The permeation test results show that latex, nitrile and polychloroprene gloves are all suitable for use when handling Contec HydroPure in a cleanroom environment. Tested against EN374-3 there was no breakthrough of HydroPure through the glove for up to 8 hours.

This test work can also be used in infer that as the HydroPure doesn't break through the gloves over an 8 hour period, the gloves are compatible with HydroPure and are not broken down. There was no visible change in the gloves after the gloves had been in permanent contact with the fluid for the duration of the test.