PRODUCT INFORMATION FILE

Contec® ProChlor

Product Code

SBT102PC
SBC102PC
SBC502PC
FBT102PC
FBC102PC
FBC502PC

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

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Contec® ProChlor

SBT102PC
SBC102PC
SBC502PC
FBT102PC
FBC102PC
FBC502PC

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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

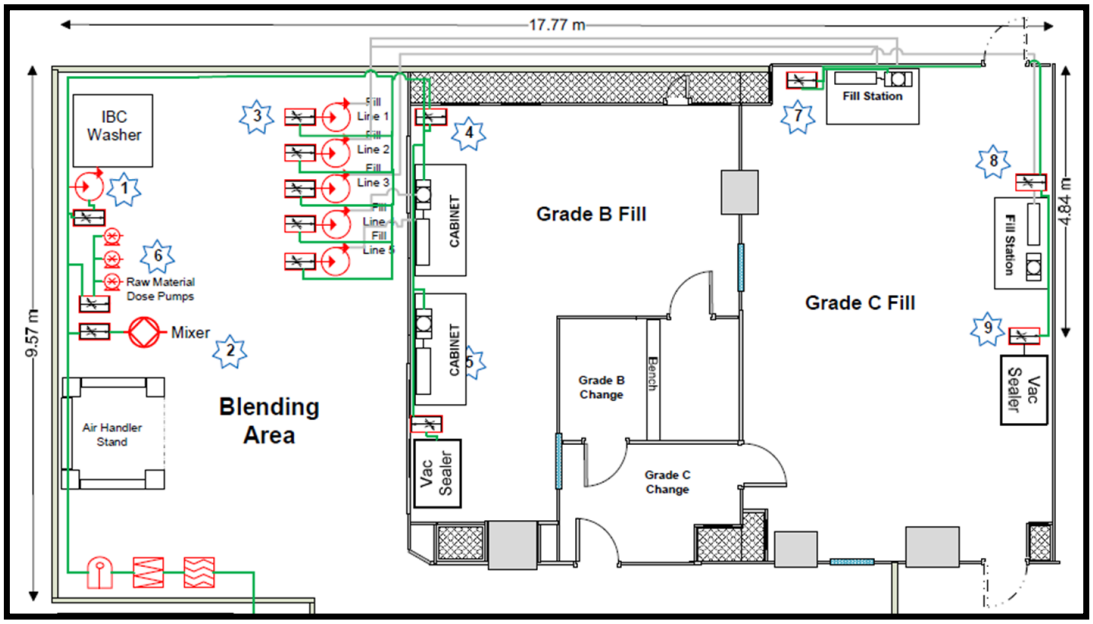
Contec France

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."

Biocidal Products Regulation

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 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 active chlorine 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.

Active chlorine generated from calcium hypochlorite (CAS No. 7778-54-3) was approved as an active substance under the BPR (EU) for product types 2 in December 2016**.**

If a company did not seek product authorisation for a biocide containing calcium hypochlorite (unless it contained other actives) before 1st Jan 2019 they had/have until the 31st July 2019 to remove the product from the European market, and until 1st February 2020 to dispose of, or use any remaining stock.

Contec's biocidal product dossier for Contec ProChlor was submitted before the BPR deadline of 1 January 2019 and is now under review by the MSCA for the Netherlands [Contec Calcium Hypochlorite Product Family Case number: BC-LY047116-11].

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

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fax: +1-864-503-8333

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

Page 1 of 1

CONTEC

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

America

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

CONTEC

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 ProChlor

Contec ProChlor is a revolutionary new sporicide achieving a 100% kill against spores in under 1 min.

A blend of hypochlorous acid in EP purified water, Contec ProChlor is provided ready to use and is efficacious against bacteria, fungi, moulds, yeasts, viruses and spores.

Contec ProChlor is 0.2 micron filtered, and filled in a Grade A environment. The sterile product is filled into pre-irradiated components.

Provided double bagged, the product is designed for ease of entry into pharmaceutical cleanrooms. Supplied as either trigger sprays for small areas or 1L and 5L capped containers for when larger volumes are required.

Feature	Benefit
Log 6 kill against Bacillus *subtilis* in 60 secs	Fast acting so saves time spent on decontamination
Filtered to 0.2 microns in a Grade B cleanroom	Ensures the product is free from contamination and particulates
Sterile version available	Suitable for Grade A and B cleanrooms
Contains no quaternary ammonium or surfactant	Very low residue, saving time on residue removal
No hazard classification	Good operator acceptability as no strong odour
	Only basic PPE required and no special disposal required
Trigger spray can be set to jet or spray	Large droplet size reduces the risk of inhalation and provides good surface coverage
Double bagged packed in linear tear packaging	Each bag is easy to open even when wearing gloves
	Facilitates transfer disinfection into cleanroom
Not classed as corrosive	Can be used safely in all areas of the cleanroom

Part No.	Description	Packaging
SBT102PC	Contec *Sterile* ProChlor 1L Trigger Spray	6 x 1L
SBC102PC	Contec *Sterile* ProChlor 1L Caped	6 x 1L
SBC502PC	Contec *Sterile* ProChlor 5L Capped	2 x 5L
FBT102PC	Contec ProChlor 1L Trigger Spray	6 x 1L
FBC102PC	Contec ProChlor 1L Capped	6 x 1L
FBC502PC	Contec ProChlor 5L Capped	2 x 5L

Product Specification – Sterile ProChlor

Product Name		Contec *Sterile* ProChlor
Product Description		Sterile Stabilised Hypochlorous Acid in purified water (EP)
Product Code		SBT102PC 1L Trigger Spray x 6 SBC102PC 1L Capped x 6 SBC502PC 5L Capped x 2
Product Specification		
	Colour	Colourless
	Clarity	Clear
	Specific Gravity @ 20°C	1.021 to 1.025
	Available chlorine	> 1000ppm
	pH @ 20°C	3.0 – 6.0
	Production	Filtered to 0.2 micron under Grade A uni-directional airflow in a Grade B cleanroom.
	Sterility	All components irradiated at no less than 25 kGy. Sterile filtered to 0.2 micron under aseptic conditions.
	Packaging 1L	Trigger Spray: Adjustable trigger spray on HDPE bottle Capped: Cap on HDPE bottle Double packed in polyethylene linear tear bags 6 bottles per double walled cardboard box
	Packaging 5L	Tamper evident cap on HDPE bottle Double packed in polyethylene linear tear bags 2 bottles per double walled cardboard box
	Shelf Life	Unopened: 2 years from date of manufacture In-use: 6 months from date of opening

Product Specification – Filtered ProChlor

Product Name		Contec ProChlor
Product Description		Stabilised Hypochlorous Acid in purified water (EP)
Product Code		FBT102PC 1L Trigger Spray x 6 FBC102PC 1L Capped x 6 FBC502PC 5L Capped x 2
Product Specification		
	Colour	Colourless
	Clarity	Clear
	Specific Gravity @ 20°C	1.021 to 1.025
	Available chlorine	> 1000ppm
	pH @ 20°C	3.0 – 6.0
	Production	Filtered to 0.2 micron under Grade A uni-directional airflow in a Grade B cleanroom.
	Packaging 1L	Trigger Spray: Adjustable trigger spray on HDPE bottle Capped: Cap on HDPE bottle Double packed in polyethylene linear tear bags 6 bottles per double walled cardboard box
	Packaging 5L	Tamper evident cap on HDPE bottle Double packed in polyethylene linear tear bags 2 bottles per double walled cardboard box
	Shelf Life	Unopened: 2 years from date of manufacture In-use: 6 months from date of opening

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

Section 3
Product Certificates

Contec ProChlor 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 ProChlor
Product Code:	SBT102PC
Product Description:	Sterile Stabilised Hypochlorous Acid in purified water 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:	0.990 – 1.010	
Available chlorine:	>1000ppm	
pH at 20°C :	3.0 – 6.0	

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

COA09 Rev 4

Manufactured by:
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Contec Cleanroom Technology (Suzhou) Co. Ltd
No. 17 Longyun Road
Suzhou 215024
China

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infoeu@contecinc.com

PRODUCT CERTIFICATE

Product:	Contec Sterile ProChlor
Product Code:	SBC102PC
Product Description:	Sterile Stabilised Hypochlorous Acid in purified water 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:	0.990 – 1.010	
Available chlorine:	>1000ppm	
pH at 20°C :	3.0 – 6.0	

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

COA50 Rev 2

Manufactured by:
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PRODUCT CERTIFICATE

Product:	Contec ProChlor
Product Code:	SBC502PC
Product Description:	Sterile Stabilised Hypochlorous Acid 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:	0.990 – 1.010	
Available chlorine:	>1000ppm	
pH at 20°C :	3.0 – 6.0	

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

COA10 Rev 4

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PRODUCT CERTIFICATE

Product:	Contec ProChlor
Product Code:	FBT102PC
Product Description:	Filtered Stabilised Hypochlorous Acid 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:	0.990 – 1.010	
Available chlorine:	>1000ppm	
pH at 20°C :	3.0 – 6.0	

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.

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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PRODUCT CERTIFICATE

Product:	Contec ProChlor
Product Code:	FBC102PC
Product Description:	Filtered Stabilised Hypochlorous Acid 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:	0.990 – 1.010	
Available chlorine:	>1000ppm	
pH at 20°C :	3.0 – 6.0	

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:

COA51 Rev 2

Manufactured by:
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PRODUCT CERTIFICATE

Product:	Contec ProChlor
Product Code:	FBC502PC
Product Description:	Filtered Stabilised Hypochlorous Acid 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:	0.990 – 1.010	
Available chlorine:	>1000ppm	
pH at 20°C :	3.0 – 6.0	

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.

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:

COA12 Rev 6

Manufactured by:
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Section 4
Instructions for Use

Contec® ProChlor 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.

Apply Contec ProChlor to a Contec sterile 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 ProChlor will leave a small residue on a surface which is free rinsing and easily removed with either alcohol or water, if removed immediately. If ProChlor is routinely allowed to dry onto a surface without removal over an extended time, (approximately 3 weeks) it will become more difficult to remove. Best practice suggests disinfectants are wiped to dry and removed after the contact time.

Storage conditions

Contec ProChlor 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.

Contec *Sterile* ProChlor Trigger Spray 1L

Contec *Sterile* ProChlor Capped 1L

EN 100ml contains 0.2ml calcium hypochlorite in purified water. IF IN EYES: rinse cautiously with water for several minutes. Get medical advice/attention. Dispose of as normal industrial waste. Small quantities of ProChlor can be disposed of via a foul drain. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent: 0,2 ml d' hypochlorite de calcium dans de l'eau purifiée. EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Consulter un médecin. Éliminer comme tout déchet industriel ordinaire. Le rejet de petites quantité de Prochlor à l'égout est toléré. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 0,2 ml Calciumhypochlorit in gereinigtem Wasser. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztlichen Rat einholen / ärztliche Hilfe. Wie normalen Industrieabfall entsorgen. Kleine Mengen an ProChlor können als normales Schmutzwasser entleert werden. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 0,2 ml de hipoclorito de calico en agua purificada. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulte a un médico. Eliminar como los residuos industriales normales. Se pueden eliminar pequeñas cantidades de ProChlor mediante un desagüe. Almacenar a temperaturas no superiores a 40°C. No congeal.

I 100 ml contengono: 0,2 ml di ipoclorito di calcio in acqua purificata. IN CASO DI CONTATTO CON GLI OCCHI : Sciacquare accuratamente per parecchi minuti. Consultare un medico. Disporne nel modo utilizzato per normali rifiuti industriali. Piccole quantità di ProChlor possono essere smaltite tramite uno scarico fallo. Conservare in luogo fresco a temperature non superiori a 40°C. Non congelare.

RO 100 ml contin 0,2 ml hipoclorit de calciu in apa purificata. ÎN CAZ DE CONTACT CU OCHII: Clătiți cu atenție cu apă timp de mai multe minute. A se elimina asemenea deșeurilor industriale normale. Cantități mici de ProChlor pot fi eliminate printr-un canal de scurgere. A se depozita la temperaturi care nu depășesc 40°C. A nu se congela.

FI 100 ml sisältää: 0,2 ml kalsiumhypokloriittia puhdistetussa vedessä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävitetään kuten normaali teollisuusjäte. Pieniä määriä ProChloria voidaan hävittää huuruveden kautta. Varastoi alle 40°C lämpötilassa. Ei saa jäätyä.

DA 100 ml. indeholdende 0,2 ml. kalcium hypochlorit i ultra rent vand. VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Søg lægehjælp. Bortskaffes som normalt, industrielt affald. Små mængder ProChlor kan bortskaffes via et dårligt afløb. Opbevares ved en temperatur, som ikke overstiger 40°C. Må ikke nedfryses.

SV 100 ml innehåller 0,2 ml kalciumhypoklorit i ultrarent vatten. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkarvård. Omhändertages som industriavfall. Små mängder ProChlor kan kasseras via ett oregelbundet avlopp. Förvaras vid högst 40°C. Får ej frysas.

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

Authorisation Holder
Contec Europe
R.P. 3707, F-56037,
VANNES, France
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Emergency telephone Chemtrec® +1-703-527-3887
Biocide Registration Numbers: Irish: 97486 German: N-53321 French: 30920
Manufactured in the UK by Contec Cleanroom (UK) Ltd

STERILE

CONTEC PROCHLOR

STERILE STABILISED HYPOCHLOROUS ACID

- Ready to use, hard surface disinfectant solution containing stabilised hypochlorous acid.
- Suitable for use on clean hard surfaces. Ensure complete wetting of area. For optimum results wipe dry after contact time.
- Sterile filtered to 0.22 microns in a Grade B cleanroom.
- Contact times:

Bacteria	1 min	EN1276 / EN13697
Fungi	1 min	EN1650 / EN13697
Spores	1 min	EN13704 / EN13697

- For professional use only.

0001 of 1000 LAB115/01

1 LITRE

Product Code **SBC102PC**

CONTEC
www.contecinc.com

Contec *Sterile* ProChlor 5L

Contec ProChlor Trigger Spray 1L

EN 100ml contains 0.2ml calcium hypochlorite in purified water. 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: 0,2 ml d' hypochlorite de calcium dans de l'eau purifiée. EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Consulter 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: 0,2 ml Calciumhypochlorit in gereinigtem Wasser. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztlichen Rat einholen / ärztliche Hilfe. 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: 0,2 ml de hipoclorito de calico en agua purificada. 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 congeal.

I 100 ml contengono: 0,2 ml di ipoclorito di calcio in acqua purificata. 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 contin 0,2 ml hipoclorit de calciu in apa purificata. ÎN CAZ DE CONTACT CU OCHII: Clătiți cu atenție cu apă timp de mai multe minute. Aruncați conținutul/recipientul la deșeurile periculoase. A se depozita la temperaturi care nu depășesc 40°C. A nu se congela.

FI 100 ml sisältää: 0,2 ml kalsiumhypokloriittia puhdistetussa vedessä. 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.

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Supplier
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Authorisation Holder
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Emergency telephone Chemtrec® +1-703-527-3887
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Manufactured in the UK by Contec Cleanroom (UK) Ltd

NON STERILE

CONTEC PROCHLOR

FILTERED STABILISED HYPOCHLOROUS ACID

- Ready to use, hard surface disinfectant solution containing stabilised hypochlorous acid.
- Suitable for use on clean hard surfaces. Ensure complete wetting of area. For optimum results wipe dry after contact time. Close nozzle after use.
- Filtered to 0.22 microns in a Grade B cleanroom.
- Contact times:

Bacteria	1 min	EN1276 / EN13697
Fungi	1 min	EN1650 / EN13697
Spores	1 min	EN13704 / EN13697

- For professional use only.

0001 of 8000 LAB001/04

1 LITRE

Product Code **FBT102PC**

CONTEC
www.contecinc.com

Contec ProChlor Capped 1L

EN 100ml contains 0.2ml calcium hypochlorite in purified water. IF IN EYES: rinse cautiously with water for several minutes. Get medical advice/attention. Dispose of as normal industrial waste. Small quantities of ProChlor can be disposed of via a foul drain. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent: 0,2 ml d' hypochlorite de calcium dans de l'eau purifiée. EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Consulter un médecin. Éliminer comme tout déchet industriel ordinaire. Le rejet de petites quantité de Prochlor à l'égout est toléré. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

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NON STERILE

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- Suitable for use on clean hard surfaces. Ensure complete wetting of area. For optimum results wipe dry after contact time.
- Filtered to 0.22 microns in a Grade B cleanroom.
- Contact times:

Bacteria	1 min	EN1276 / EN13697
Fungi	1 min	EN1650 / EN13697
Spores	1 min	EN13704 / EN13697

- For professional use only.

0001 of 1000 LAB116/01

1 LITRE

Product Code **FBC102PC**

CONTEC
www.contecinc.com

Contec ProChlor 5L

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NON STERILE

CONTEC PROCHLOR

FILTERED STABILISED
HYPOCHLOROUS ACID

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- Suitable for use on clean hard surfaces. Ensure complete wetting of area. For optimum results wipe dry after contact time.
- Filtered to 0.22 microns in a Grade B cleanroom.
- Contact times:

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Fungi	1 min	EN1650 / EN13697
Spores	1 min	EN13704 / EN13697

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001 of 1000 LAB002/04

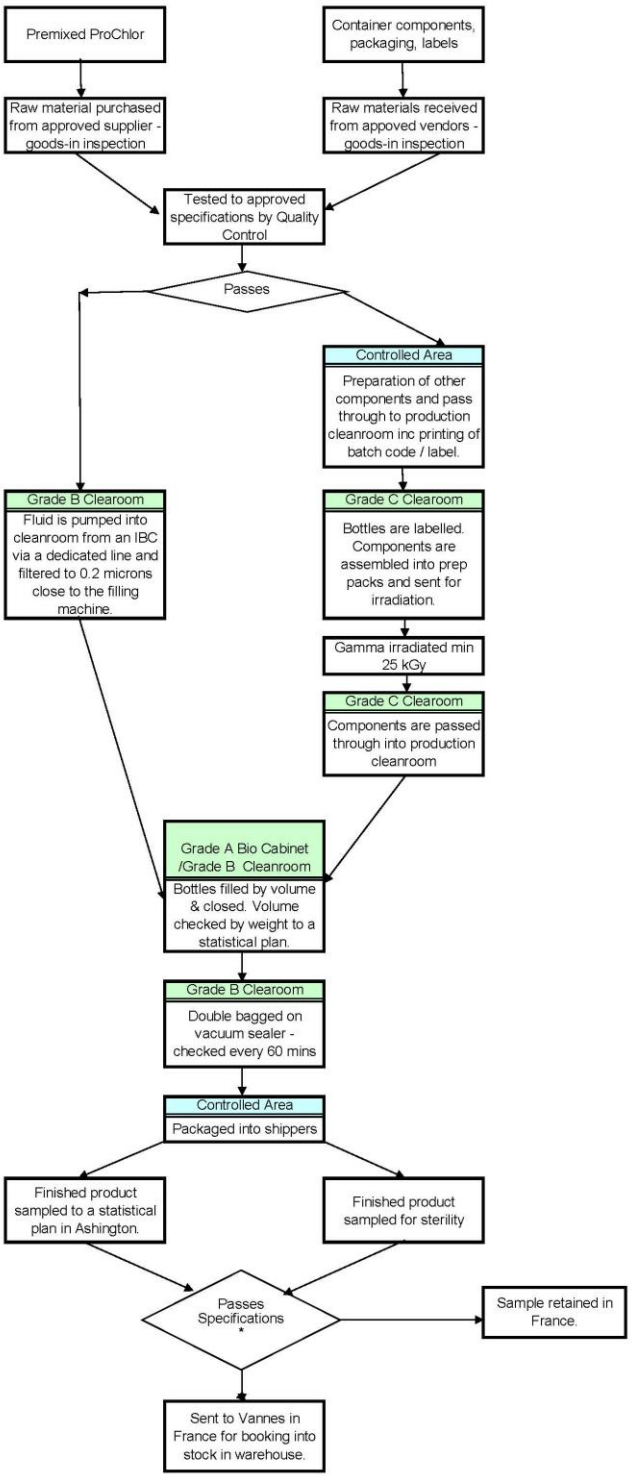
5 LITRE Product Code **FBC502PC**

CONTEC
www.contecinc.com

Section 6
Production Process – Sterile ProChlor

Contec *Sterile* ProChlor is sterile filtered to 0.2 micron under Grade A laminar airflow in a biological safety cabinet. The cabinet is sited in a Grade B cleanroom. All components have been irradiated at no less than 25 kGy.

Production Process Flow Chart Contec® *Sterile* ProChlor

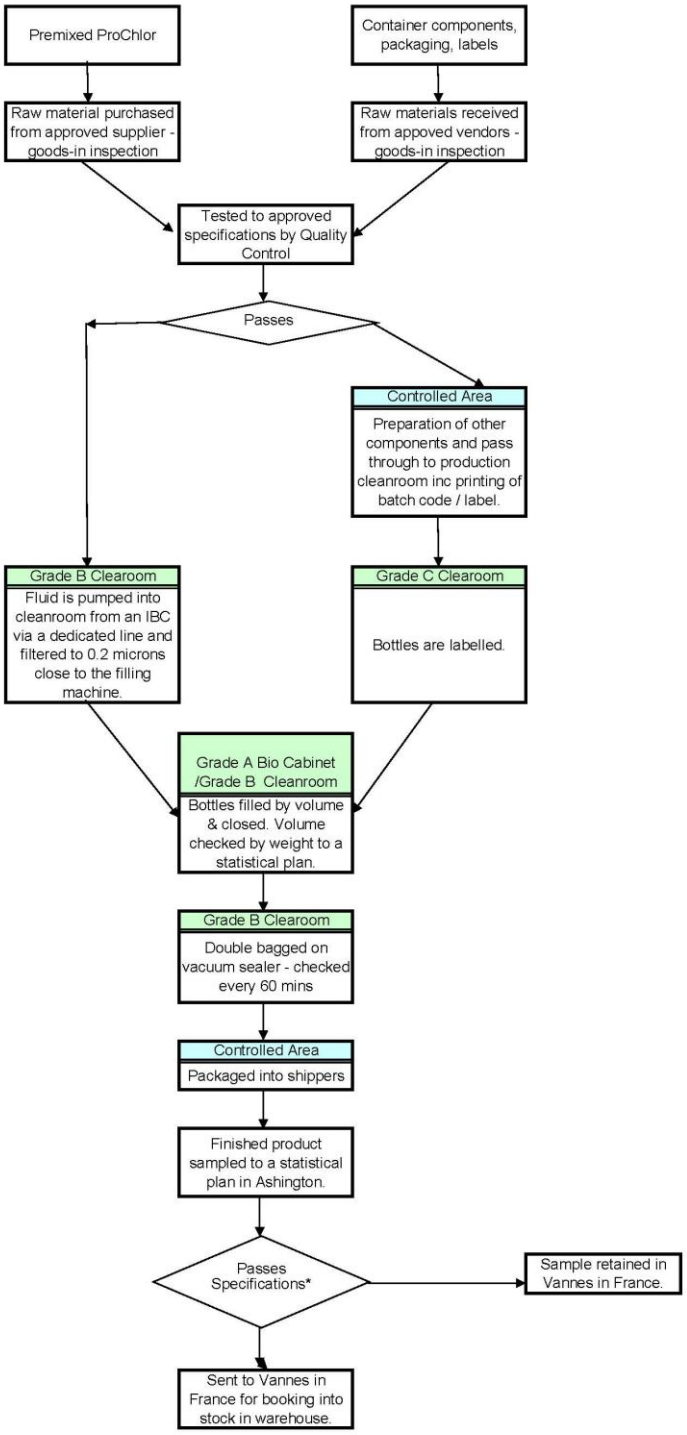


* Should there be a QC failure at any point in the production process, the product is quarantined for investigation and disposal

Production Process – Filtered ProChlor

Contec ProChlor is filtered to 0.2 micron under Grade A laminar airflow in a biological safety cabinet. The cabinet is sited in a Grade B cleanroom.

Production Process Flow Chart Contec® ProChlor



* 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.

Personal Protective Equipment

Even though Contec ProChlor has been classified with no specific hazard under the CLP guidelines, the SDS suggests the wearing of basic PPE.

Respiratory Protection

As with all disinfectants Contec ProChlor has an odour which may build up over time when used continuously. Good ventilation in the area in which ProChlor is being used will prevent this build up.

There are no exposure limits for Contec ProChlor, however if any personnel experience irritation or other symptoms an EN149 respirator can be worn. This may also be useful if the smell of the disinfectant is a particular problem for a user.

EN149 approved respirators

Disposable Particulate Respirators (Filtering Facepieces) approved to EN149:2001+A1:2009 are designed to reduce the wearer's exposure to airborne particles. Filtering Facepieces (FFP) offer protection in three classes against respirable dust, aerosols, smoke, and fine particles during work. This kind of facepiece is also known as particle-filtering half mask or fine particle mask and they are divided into the protection classes FFP1, FFP2 and FFP3. A respirator mask covers mouth and nose and is constructed of various filter materials and the mask itself, which is manufactured of rubber or silicon. Disposable particulate respirators require a fit test.

Odour-stopping versions are equipped with an additional activated carbon layer, which filters out nuisance odours and unpleasant smells.

Protective respiratory masks complying with EN149:2001 may be classified into one of three categories, depending on their filter efficiency under laboratory conditions:

Classification

FFP1	Total inward leakage 22%	Filtering Efficiency 78%
FFP2	Total inward leakage 8%	Filtering Efficiency 92%
FFP3	Total inward leakage 2%	Filtering Efficiency 98%

This means that an FFP3 Respirator Mask would filter out at least 98% of the airborne respirable particles, whereas an FFP1 Respirator Mask would filter out at least 78% of the respirable particles. FFP3 Respirator Masks are therefore most efficient in filtering out fine particles including viruses, mould spores & asbestos.

Hand Protection

Nitrile or latex gloves should be worn when handling ProChlor. Section 13 contains a technical report that shows there is no breakthrough of Contec ProChlor through nitrile or latex gloves for up to 4 hours.

Eye Protection

Safety glasses should be worn.

Skin Protection

Protective clothing such as a lab coat should be worn.

SAFETY DATA SHEET

CONTEC STERILE PROCHLOR 1 AND 5L

Compilation date: 09/03/2015

Revision date: 29/03/2017

Revision No: 6

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

1.1. Product identifier

Product name: CONTEC STERILE PROCHLOR 1 AND 5L

Product code: SBT102PC / SBC502PC

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: This product has no classification under CLP.

2.2. Label elements

Label elements: This product has no label elements.

2.3. Other hazards

Other hazards: May cause sensitisation by inhalation. May cause sensitisation by skin contact. Harmful if swallowed. Irritating to eyes.

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

Section 3: Composition/information on ingredients

3.2. Mixtures

[cont...]

Hazardous ingredients:

CALCIUM HYPOCHLORITE

EINECS	CAS	PBT / WEL	CLP Classification	Percent
231-908-7	7778-54-3	-	Ox. Sol. 2: H272; Acute Tox. 4: H302; Skin Corr. 1B: H314; Aquatic Acute 1: H400; -: EUH031	0.200%

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Wash immediately with plenty of soap and water.

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

Ingestion: Wash out mouth with water.

Inhalation: Move to fresh air in case of accidental inhalation of vapours. Consult a doctor.

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

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

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

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

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Dry chemical powder. Alcohol or polymer foam. 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

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details. 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.

[cont...]

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: 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 sources of ignition. Keep away from direct sunlight. Do not freeze. Store below 40°C.

Suitable packaging: Must only be kept in original packaging.

7.3. Specific end use(s)

Specific end use(s): No data available.

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 irritation or other sypmtoms are experienced.

Hand protection: Nitrile gloves. Rubber gloves.

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

Skin protection: Protective clothing.

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: No data available.

[cont...]

pH: 4

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. Sources of ignition. Flames.

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:

CALCIUM HYPOCHLORITE

ORL	RAT	LD50	850	mg/kg

Toxicity values: No data available.

Symptoms / routes of exposure

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

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

[cont...]

12.2. Persistence and degradability

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4. Mobility in soil

Mobility: Soluble in water.

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: Negligible ecotoxicity.

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Deposit into or on to land (e.g. landfill, etc.)

Disposal of packaging: Dispose of as normal industrial waste.

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 2015/830.

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

Phrases used in s.2 and s.3: EUH031: Contact with acids liberates toxic gas.

H272: May intensify fire; oxidiser.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H400: Very toxic to aquatic life.

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 PROCHLOR 1L AND 5L

Compilation date: 03/09/2015

Revision date: 21/12/2015

Revision No: 4

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

1.1. Product identifier

Product name: CONTEC PROCHLOR 1L AND 5L

Product code: FBT102PC / FBC502PC

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: This product has no classification under CLP.

2.2. Label elements

Label elements: This product has no label elements.

2.3. Other hazards

Other hazards: May cause sensitisation by inhalation. May cause sensitisation by skin contact. Harmful if swallowed. Irritating to eyes.

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

Section 3: Composition/information on ingredients

3.2. Mixtures

[cont...]

Hazardous ingredients:

CALCIUM HYPOCHLORITE

EINECS	CAS	PBT / WEL	CLP Classification	Percent
231-908-7	7778-54-3	-	Ox. Sol. 2: H272; Acute Tox. 4: H302; Skin Corr. 1B: H314; Aquatic Acute 1: H400; -: EUH031	<1%

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Wash immediately with plenty of soap and water.

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

Ingestion: Wash out mouth with water.

Inhalation: Move to fresh air in case of accidental inhalation of vapours. Consult a doctor.

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

Skin contact: No data available.

Eye contact: No data available.

Ingestion: No data available.

Inhalation: No data available.

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

Immediate / special treatment: Not applicable.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Dry chemical powder. Alcohol or polymer foam. 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

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details. 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.

[cont...]

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: 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 sources of ignition. Keep away from direct sunlight. Do not freeze. Store below 40°C.

Suitable packaging: Must only be kept in original packaging.

7.3. Specific end use(s)

Specific end use(s): No data available.

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 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.

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: No data available.

[cont...]

pH: 4

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. Sources of ignition. Flames.

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:

CALCIUM HYPOCHLORITE

ORL	RAT	LD50	850	mg/kg

Toxicity values: No data available.

Symptoms / routes of exposure

Skin contact: No data available.

Eye contact: No data available.

Ingestion: No data available.

Inhalation: No data available.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

[cont...]

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: Deposit into or on to land (e.g. landfill, etc.)

Disposal of packaging: Dispose of as normal industrial waste.

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: EUH031: Contact with acids liberates toxic gas.

H272: May intensify fire; oxidiser.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H400: Very toxic to aquatic life.

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 ProChlor Efficacy

Contec Prochlor 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 13697:2001
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 ProChlor is:

Lecitin	3g / l
Polysorbate 80	30g / l
L-histidine	1g / l
Saponin	30g / l
Phosphate buffer	0.35g / 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. *niger (brasiliensis*)	15 mins	Log 3

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

Test	Organisms	Contact Time	Log reduction
EN13704	C. *sporogenes*	1 min	Log 3
	C. *difficile*	1 min	Log 3
	B. *pumilis*	1 min	Log 3
	B. *cereus*	1 min	Log 3
	P. glucanolyticus (isolate)	1 min	Log 3
EN14476	Parvo virus (mouse)	1 min	Log 4
	Norovirus (mouse)	1 min	Log 4
EN13697	B. *subtilis*	1 min	Log 2*

ProChlor Efficacy Results Production Batch

Batch No: 11152

Test Lab: MGS Laboratories Reading UK

EN1276 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 5	> 5.0	60 secs	PASS	Dilution neutralisation
E.*hirae*	Log 5	> 5.0	60 secs	PASS	Dilution neutralisation
E.*coli*	Log 5	> 5.0	60 secs	PASS	Dilution neutralisation
P.*aeruginosa*	Log 5	> 5.0	60 secs	PASS	Dilution neutralisation

EN1650 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
A.niger *(brasiliensis)*	Log 4	> 4.0	60 secs	PASS	Dilution neutralisation
C.*albicans*	Log 4	> 4.0	60 secs	PASS	Dilution neutralisation

EN13704 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
B.*subtilis*	Log 3	> 3.54	60 secs	PASS	Dilution neutralisation

Test House – ALS Labs, Ely, UK / MGS Labs, Poyle, UK

EN13697 – clean conditions / stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 4	>5.9	60 secs	PASS	Dilution neutralisation
E.*hirae*	Log 4	>5.9	60 secs	PASS	Dilution neutralisation
E.*coli*	Log 4	>5.5	60 secs	PASS	Dilution neutralisation
P.*aeruginosa*	Log 4	>5.6	60 secs	PASS	Dilution neutralisation
A.*niger (brasiliensis*)	Log 3	>3.7	60 secs	PASS	Dilution neutralisation
C.*albicans*	Log 3	>4.6	60 secs	PASS	Dilution neutralisation
B.*subtilis*	Log 2*	2.3	60 secs	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.

Additional tests production batch

Batch No 140800194

EN13697– clean conditions/stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
*P. Brevicompactum**	Log 3	> 3,3	3 mins	PASS	Dilution neutralisation
P.chrysogenum	Log 3	> 3.7	60 secs	PASS	Dilution neutralisation

EN13697 – clean conditions / stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
B.*cereus*	Log 2*	2.3	60 secs	PASS	Dilution neutralisation
B.*pumilis*	Log 2*	2.3	60 secs	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.

EN13697 – clean conditions

Further test work was carried out using *bacillus subtilis* on a variety of commonly found cleanroom surfaces: glass, PVC, laminated plastic and vinyl.

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
B.*subtilis* - glass	Log 2*	>3.9	60 secs	PASS	Dilution neutralisation
B.*subtilis* - PVC	Log 2*	>3.8	60 secs	PASS	Dilution neutralisation
B.*subtilis* - laminate	Log 2*	>3.8	60 secs	PASS	Dilution neutralisation
B.*subtilis* - vinyl	Log 2*	>3.8	60 secs	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.

Standard tests R and D trials

Test House – MGS Labs, Poyle, UK

EN1650 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
A.*niger (brasiliensis)*	Log 4	>4.19	60 secs	PASS	Dilution neutralisation

Test House – FDAS Labs, Nottingham, UK

EN13704 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
B.*subtilis*	Log 3	> 6.0	60 secs	PASS	Dilution neutralisation

EN13697 – clean conditions

Test House – ALS Labs, Ely, UK

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
A.*niger (brasiliensis)*	Log 3	> 6.0	60 secs	PASS	Dilution neutralisation
B.*subtilis*	Log 2*	> 6.0	60 secs	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.

Additional tests R and D trials

Test House – ALS Labs, Ely, UK / MGS Labs, Poyle, UK

EN13704 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
C. *sporogenes*	Log 3	> 6.0	60 secs	PASS	Dilution neutralisation
C. *difficile*	Log 3	> 6.0	60 secs	PASS	Dilution neutralisation
B.*pumilis*	Log 3	> 3.88	60 secs	PASS	Dilution neutralisation
P. *glucanolyticus* *	Log 3	>3.12	60 secs	PASS	Dilution neutralisation
B.*cereus*	Log 3	> 3.24	60 secs	PASS	Dilution neutralisation

*House isolate

EN13697 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
A.*niger (brasiliensis)*	Log 4	>6.0	60 secs	PASS	Dilution neutralisation
B.*subtilis*	Log 2*	>6.0	60 secs	PASS	Dilution neutralisation

Third Party Independent Test Work

EN1276 – clean conditions

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 5	> 7.0	60 secs	PASS	Dilution neutralisation
E.*hirae*	Log 5	> 7.0	60 secs	PASS	Dilution neutralisation
E.*coli*	Log 5	> 7.0	60 secs	PASS	Dilution neutralisation
P.*aeruginosa*	Log 5	> 7.0	60 secs	PASS	Dilution neutralisation

EN14476 – clean conditions

Test Lab: Eurofins BioLab, Vimodrome, Italy and Virnext Lab, Lyon, France.

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
Poliovirus	Log 4	4.33	30 secs	PASS	Dilution neutralisation
Adenovirus	Log 4	4.67	30 secs	PASS	Dilution neutralisation
Parvovirus MVM (mouse)	Log 4	>4.0	60 secs	PASS	Dilution neutralisation
Norovirus MNV-1 (mouse)	Log 4	>4.0	60 secs	PASS	Dilution neutralisation

Conclusion

Tests carried out against the standard EN tests for qualification of disinfectants has shown that Contec ProChlor is a powerful disinfectant, effective in 1 minute or less against :

Bacteria

Fungi

Moulds

Viruses

Spores.

Surface test work includes a log 6 kill against Bacillus *subtilis* and Aspergillus *brasiliensis* on stainless steel in 1 min.

Mode of Action

Many studies have explored the mechanism of chlorine disinfection and although it is not possible to precisely explain how each particular chlorine species works, current theory believes that inactivation occurs by means of one or more of the following mechanisms; inactivation of the key enzymes, disruption of nucleic acids rendering them non-functional, and oxidative damage to cell walls or other vital cell components.
For each of the mechanisms described above the effectiveness of each disinfecting agent is a function of both its rate of diffusion through the cell wall and it reactivity with the cell wall, proteins and nucleic acid.

Hypochlorous acid (HOCL) is the most effective disinfectant in the chlorine family available in dilute solution. It is suggested that HOCL is 80 to 120 times more efficacious than sodium hypochlorite. Because HOCL is neutrally charged and has a relatively low molecular weight it is better than the other chlorine based disinfectants to penetrate the cell walls. It also reacts more rapidly than other chlorine based disinfectants to oxidation reactions with organic matter, ie the critical components of microbial cells.

Conversely, the hypochlorite ion is a relatively poor disinfectant because of its inability to diffuse through the cell wall. Since it is negatively charged it is electrostatically repelled from the cell walls which are also negatively charged. It is much larger in size than an HOCL molecule so it also diffuses more slowly due to its larger size.

Chlorine chemistry

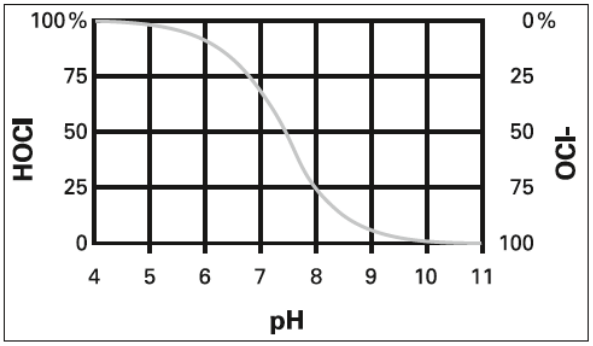
Chlorine is added to water in one of three forms: elemental chlorine (chlorine gas), sodium hypochlorite solution or calcium hypochlorite powder (high-test hypochlorite). Chlorine gas reacts rapidly with water to form two compounds - hypochlorous acid (HOCl) and hydrochloric acid (HCl).

Cl_2	+	H_2O	↔	HOCl	+	HCl
chlorine		water		hypochlorous acid		hydrochloric acid

Hypochlorous acid (HOCl) is a weak acid that further dissociates into the hypochlorite ion (OCl-) and hydrogen ion according to the following equation:

$HOCl \leftrightarrow H^+ + OCL^-$ (hypochlorite ion)

These three species exist in an equilibrium which is both pH and temperature dependent, the sum of these is referred to as the total available chlorine. At 25 °C and a pH of 7.5, half of the total chlorine is present as HOCl and the other half as OCl^-. The dissociated hypochlorite ion (OCl^-) predominates at higher pH values, above 7.5 pH, whilst the undissociated hypochlorous acid (HOCl) predominates at lower pH values. At pH 5, nearly all the chlorine is present as HOCl, while a pH value of 10 drives nearly all the chlorine to be present as OCl^-. Fig 1. At low pH and high chlorine concentrations the hydrolysis is not complete and a significant fraction remains in the form of molecular chlorine Cl_2.



In a sodium hypochlorite solution which normally has a pH of 11 -13, all available chlorine is in a form of hypochlorite ions (OCl-) which as previously discussed is far less efficacious than hypochlorous acid.

Without highly specific test equipment it is not easy to qualify in what format the active chlorine is present. However, ProChlor has been checked using UV-VIS spectroscopy.

Quantification of Hypochlorous acid vs hypochlorite ion concentration using UV-VIS spectroscopy.

Two samples of Contec ProChlor were sent to Oxford Materials Characterisation Service at Oxford University. The hypochlorous and hypochlorite content was estimated by curve fitting the recorded UV-vis spectrum.

An Aglinet Cary 5000 UV-vis-NIR spectrometer was used to obtain the absorption spectrum of the solution over the range 175 – 800 nm at 1 nm data interval. 10 mm UV grade silica cuvettes were used. Water was used in the reference cuvette with the solution in the sample cuvette.

Hypochlorite vs hypochlorous

In aqueous solution the un-ionised hypochlorous acid species and hypochlorite ion are in equilibrium as shown below:

$$HClO_{(aq)} \leftrightarrow H^+_{(aq)} + ClO^-_{(aq)}$$

The equilibrium constant (pK) for this dissociation is 7.25. The hypochlorite ion (ClO-) is characterized by an absorption at ca. 290 nm whilst the hypochlorous species produces a peak at 235 nm. From the absorption peaks in the UV-vis spectrum of the solution the absorptions at the specified wavelengths were measured and the concentration of each species calculated from the Beer-Lambert law of absportion using the referenced extinction coefficients.

Matching the peaks on the spectra gave approximate concentrations of 1496ppm hypochlorous acid and only a small ppm, 134ppm hypochlorite ions.

Chloramine production

Chloramines are formed from the reaction of chlorine and ammonia. The mixture that results may contain monochloramine (NH_2Cl), dichloramine ($NHCl_2$), or nitrogen trichloride (NCl_3). In aqueous solutions with pH 7.0 to 8.5, HOCl reacts rapidly with ammonia to form inorganic chloramines in a series of competing reactions.

This reaction can be found most commonly in swimming pool disinfection when chloramines are formed by the reaction of the free chlorine with organic substances produced by bathers. It is the production of chloramines which is more irritating to eyes.

In a cleanroom in the absence of any organic soiling and therefore ammonia there is no potential for the formation of the undesirable by-product, chloramine.

Section 9
Compatibility

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

Cleanroom Materials

Contec ProChlor has no associated hazard so is not classed as corrosive towards surfaces so is suitable for use on the majority of materials found in cleanroom environments.

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 ProChlor against a variety of cleanroom materials

Summary

The investigation was carried out to check the compatibility of Contec ProChlor when used on common cleanroom materials. Several different methods of applying Contec ProChlor 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 TN1701 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 ProChlor.

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 ProChlor assay – 2200ppm / pH 4.23

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 the spray and wipe tests showed no material incompatibility.

Spray only – All samples showed surface salt residue build up and an increase of the weight of the material from the start. All samples except 304 grade Stainless steel surface salt could be removed with IPA.

Grade 304 stainless steel showed a lot of surface oxidation and salt residue could not be removed using IPA.

Vinyl flooring and Polycarbonate samples displayed white bleaching effect but this did not show any change to physical characteristics (no embrittlement, cracking loss of flexibility).

The changes in weight noted in the table below is likely due to the deposit of salt on the surface of the materials over the duration of the test whilst using Contec ProChlor, salt deposits were visible on all the large square samples. Additions in weight were also noted with the water controls. On the 304 stainless steel sample the salt residue could not be removed using IPA. Oxidation on the 304 samples could be where there are small scratches and/or marks to the s/s surface. All other samples showing salt residue this could be removed using IPA.

At 3 weeks the visible salt could be removed from all samples using IPA.

Conclusion

It is already known that Contec ProChlor if left to dry on a surface, will dry to form a calcium salt. Over time this salt can become insoluble and difficult to remove with water and/or Isopropanol. From the results obtained it is clear that an application method which incorporates spray and wipe to dry is best for all materials as no visible issues were reported using this method over a 4-week period.

All materials tested displayed none of the issues that were noted when spraying but not removing the ProChlor. There were a few minor increases in weight of several of the materials but this was very minimal and not due to any visible presence of calcium salt, so not likely to be due to a build-up on the surface.

In contrast continuous spraying on the materials resulted in very different results. The salt was visibly present from approximately the middle of week 2, although up until week 3 this salt residue could be removed from all surfaces using IPA.

From week 3 onwards this residue could not be removed from the 304 grade stainless steel material. This material also displayed the worst visual results with oxidation spots occurring in many areas on the test surface, although this is likely to have developed on areas of the test surface that were already scratched or damaged. The fact that the water control also showed oxidation spots in this test could prove this point. On the remaining surfaces the calcium salt was removed from the surface at the end of the 4-week test period using IPA.

The overall conclusion is that Contec ProChlor is compatible with all the above materials if used for the stated contact time and then removed or wiped to dry.

Corrosion Testing

Previous work was carried out on stainless steel as one of the most common materials in a cleanroom. To test the compatibility of ProChlor on stainless steel, the following spray and wipe work was carried out.

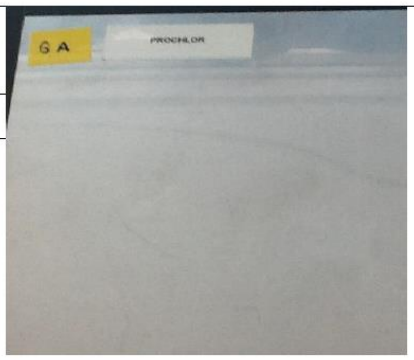
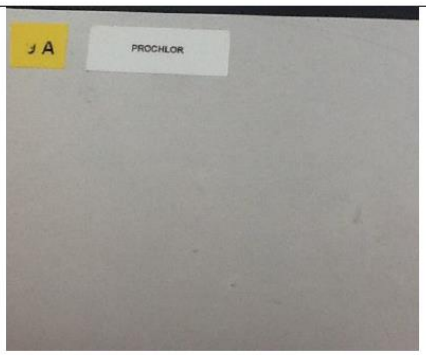
Method

Using a trigger spray Contec ProChlor 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 ProChlor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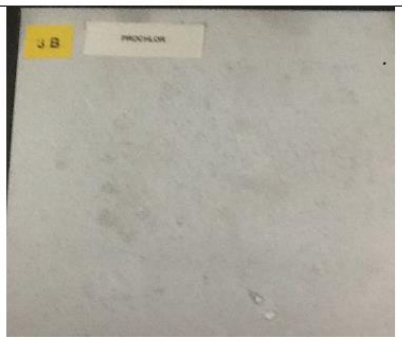
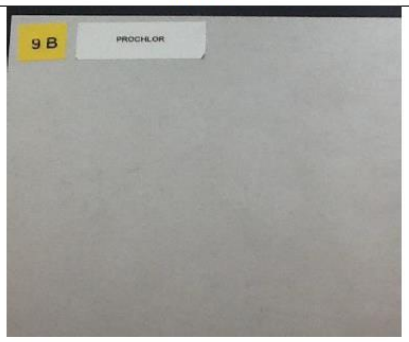
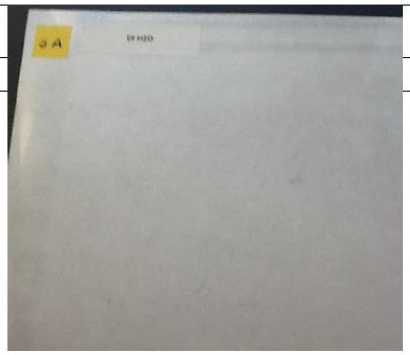
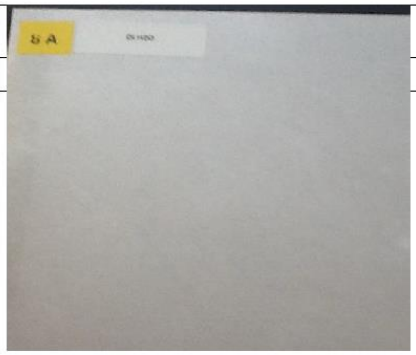
		
Ref 3B	Ref 6B	Ref 9B

Deionised Water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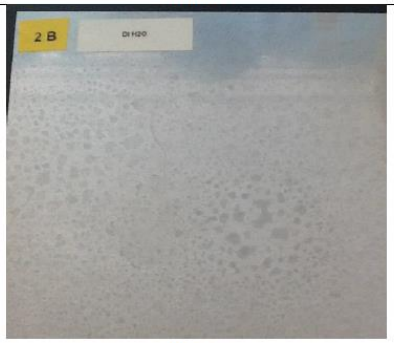
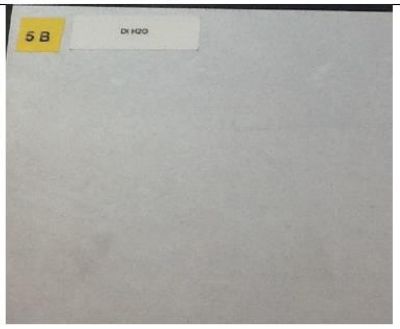
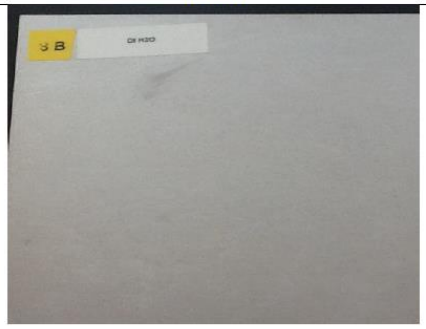
		
Ref 2B	Ref 5B	Ref 8B

As can be seen from the photos there is no difference to the surface from using Contec ProChlor to using water. The marks on picture 2A/B and 3A/B are water staining. This water staining was eliminated if a wiping phase was introduced.

Conclusion

Contec ProChlor is hypochlorous acid at a very low concentration, 2000ppm. The amount of residue left on the surface is approximately 1000ppm (see section 11 for details). The removal of a disinfectant residue is best practice as it prevents any potential problems with subsequent disinfection.

Over the time of the trial there was no difference to the surface between using Contec ProChlor and deionised water.

If used correctly Contec ProChlor is compatible with 304 stainless steel.

Corrosion testing – analysis at a microscopic level of the effect of ProChlor on the surface roughness of stainless steel.

White light interferometry (WLI) is an optical metrology technique and provides measurement of the physical characteristics of a material surface including:-

- Microtopography
- Form and texture
- Surface roughness
- Dimensional metrology
- Transparent film thickness

WLI was used to demonstrate whether the product has a measurable corrosive effect on the surface roughness or topography of a stainless steel surface as compared an untreated control sample of the same surface.

Test House Lucideon Ltd, Stoke-on-Trent, UK

A control sample which had received no treatment and three samples of 304 stainless steel which had been treated with Contec Prochlor over a four week period with five treatment cycles per week using various exposure times have been analysed by white light interferometry (WLI) to determine any effects of the treatments on the surface topography and roughness of the samples.

Method

Contec Prochlor Batch No 11152

Sample 1 - Surface sprayed and left for a contact time of 1 minute before wiping. This was done every day for 4 weeks.

Sample 2 - Surface sprayed and left for a contact time of 15 minutes before wiping. This was done every day for 4 weeks.

Sample 3 - Surface sprayed and left with no wiping. This was done every day for 4 weeks.

Results

All the samples showed very similar levels of surface roughness (Sa ~ 0.24 µm and S10 z ~ 5 µm) with similar amounts of surface pitting which was no greater than that seen on the control sample.

No statistically significant difference (using Student T test, two tailed, unequal variance) was found between the surface roughness results of the control sample and the results of any of the treated samples.

There is no evidence of any corrosive action by any of the treatments applied on the surface topography or roughness of the stainless steel.

Conclusion

As there was no evidence of corrosion after 4 weeks of treatment with Contec ProChlor it was decided to extend the test period and repeat the study.

Method

Contec Prochlor Batch No 11152

Sample 1 - Surface sprayed and left for a contact time of 1 minute before wiping. This was done every day for 4 weeks.

Sample 2 - Surface sprayed and left for a contact time of 15 minutes before wiping. This was done every day for 4 weeks.

Sample 3 - Surface sprayed and left with no wiping. This was done every day for 4 weeks.

Results

All the samples showed very similar levels of surface roughness (Sa ~ 0.24 µm and S10 z ~ 5 µm) with similar amounts of surface pitting which was no greater than that seen on the control sample.

No statistically significant difference (using Student T test, two tailed, unequal variance) was found between the surface roughness results of the control sample and the results of any of the treated samples.

There is no evidence of any corrosive action by any of the treatments applied on the surface topography or roughness of the stainless steel.

Conclusion

As there was no evidence of corrosion after 4 weeks of treatment with Contec ProChlor it was decided to extend the test period and repeat the study.

Spray and wipe testing

Further testing was carried out on some 304 stainless, polysulphonate and polycarbonate, all of which are materials commonly found on equipment in cleanrooms.

Method

The samples were sprayed with Contec ProChlor on a routine basis for a three month period. One side of each sample of material was sprayed, the contact time left for one minute and then wiped dry. This is in accordance with the instructions for use for ProChlor.

The second side was sprayed and the fluid left in contact for 20 – 30 mins before wiping dry.

Results

There was no visible degradation of any sample.

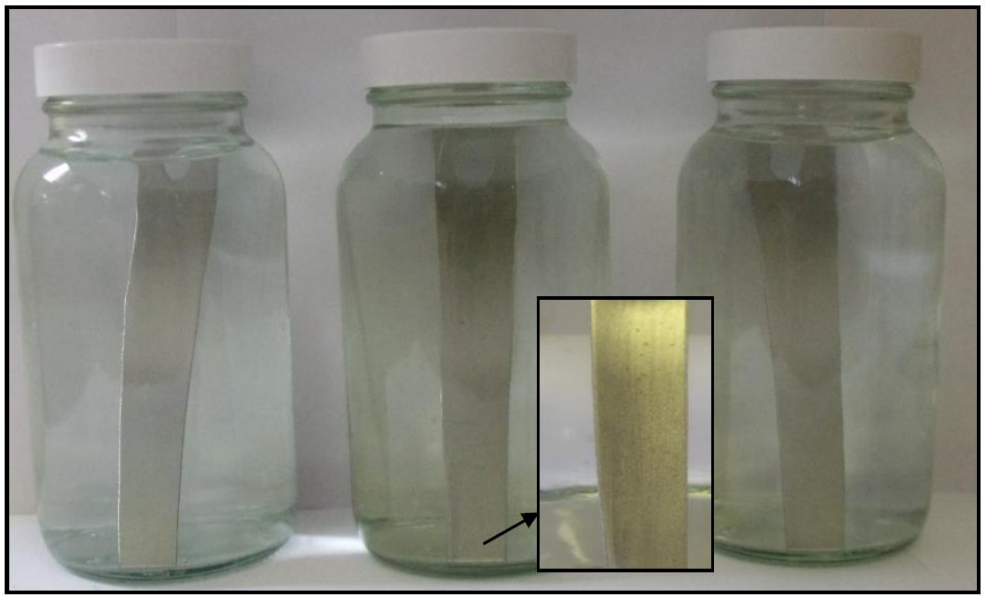
Third party testing

Some immersion corrosion work was also carried out by a third party on a 5000ppm solution of hypochlorous acid. This is over twice the concentration of Contec ProChlor.

Method

Standard coupons of 4cm x 0.5cm 304 and 316 stainless steel were immersed in 5000ppm hypochlorous acid for 8 weeks. Metal coupons were also immersed in 5000ppm sodium hypochlorite and deionised water as a comparison.

Results - 304 stainless steel



5000ppm hypochlorous 5000ppm sodium hypochlorite deionised water

After 8 weeks the coupons were checked. There was no noticeable effect to the stainless steel which had been immersed in hypochlorous acid and deionised water but there were the start of corrosion spots on the stainless steel immersed in sodium hypochlorite. This supports the results that Contec obtained.

Results - 316 stainless steel

After 8 weeks the coupons were checked. There was no noticeable detrimental effect to the 316 stainless steel which had been immersed in any of the solutions.

Contec cleanroom use

Contec ProChlor is used routinely in our own cleanrooms in Ashington. Contec ProChlor is used on the walls, floors and ceilings of a Grade C cleanroom. The cleanroom consists of vinyl flooring and laminate wall panels. It is also used on stainless steel tables, polycarbonate screens and ancillary items.

Contec ProChlor is used daily on all surfaces, sprayed or mopped onto the surface, left for 1 minute and then wiped dry.

We have seen no visible changes to any of the surfaces in the cleanroom.

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°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 ProChlor is mixed in large quantities with other Contec disinfectants. Mixing with Contec HydroPure (6% hydrogen peroxide) 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 ProChlor to a vessel that has been used for Contec HydroPure, ensure that the vessel has been emptied and rinsed thoroughly.

Conclusion

Contec ProChlor is hypochlorous acid at a very low concentration, 2000ppm. The amount of residue left on the surface is approximately 1000ppm (see section 11 for details). The residue is a calcium salt.

All test work that we have carried out so far has shown no detrimental effect on any of the surfaces it has been used on, if used for the stated contact time and then removed or wiped to dry.

However, over time the calcium salt can become insoluble and difficult to remove with water and/or Isopropanol. From the results obtained it is clear that an application method which incorporates spray and wipe to dry is best for all materials as no visible issues were reported using this method over a 4-week period.

In contrast, continuous spraying on the materials resulted in very different results. The salt was visibly present after one to two weeks although up until week 3 this salt residue could be removed from all surfaces using IPA.

The overall conclusion is that Contec ProChlor is compatible with all the above materials if used for the stated contact time and then removed or wiped to dry.

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.

Contec ProChlor is 98% purified water and leaves a very low level of residue on a surface. Any residue which is left is free rinising and can be easily removed with either water or alcohol.

Contec ProChlor is based on calcium hypochlorite and any residue remaining will be a calcium salt.

Test work was carried out using a simple residue on evaporation test to show how little residue is left on a surface.

Residue on evaporation

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

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

Test	Residue from 100ml
Sample 1	719ppm
Sample 2	1,001ppm
Sample 3	1,634ppm
Average	1,118ppm

Conclusion

Contec ProChlor leaves very little residue on a surface, the residue that is left can be easily removed. An average result of 1118ppm compares favourably to other disinfectants such as quaternary ammonium compounds and hypochlorites which leave significantly more residue.

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

Section 11
Sterility Validation

Contec *Sterile* ProChlor cannot be irradiated in its final container as the hypochlorous acid is not stable through gamma irradiation.

In order to create a sterile product the hypochlorous acid is sterile filled 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 ProChlor 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.

The certificate of sterility is also included in this section from an independent laboratory showing that the production process of sterile filling into pre-irradiated containers renders the product sterile.

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

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PHARMACEUTICAL ANALYSIS REPORT

Description:	Validation of Sterility Testing
Test Method:	Sterility Validation
Lucideon Sample Number:	(15263)-4152
Sample Description:	1L Contec Prochlor
Lucideon Report Number:	(15263)-4152/Ste
Issue Number:	1
Client:	Contec Cleanroom (UK) Ltd Wansbeck Business Park Rotary Park Ashington NE63 8QW
For the Attention of:	Mr Neil Simpson
Date Logged:	21-Jan-2015
Date of Tests:	26-Jan-2015 to 29-Jan-2015
Report Date:	23-Feb-2015
Purchase Order No.:	None
Work Location:	Lucideon UK

Mrs Jan Pearson
Pharmaceutical Microbiologist

Miss Victoria Belcher
Pharmaceutical Quality Manager

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Reg. England 1960455

Description	Customer Reference	Lucideon Sample No.
Sample 7 - 1L Contec Prochlor	Batch No. 140800194	(15263)-4152

AIM OF WORK

Validation of test product: 1L Contec Prochlor, for suitability for Sterility Testing.

SUMMARY

The Sterility Test is considered an acceptable method for assessing the sterility of this product: 1L Contec Prochlor when tested using the validated procedure described in this report. This validation outcome is based on the results generated using one container from one batch of product only.

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		Pages
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SUMMARY		3
1	INTRODUCTION	5
2	EXPERIMENTAL	5
3	PROCEDURE	6
4	RESULTS	7
5	CONCLUSION	7

1 INTRODUCTION

The Sterility Test is applied to products that are required to be sterile. The purpose of the validation process is to determine any inhibition of microbial growth due to the presence of the product and thereto develop a method to satisfactorily eliminate said activity for the purposes of the test.

Validation of test product: 1L Contec Prochlor for suitability for Sterility Testing was performed by the pharmaceutical laboratories of Lucideon Limited on behalf of Contec Cleanroom Ltd.

Successful completion of this validation will enable the pharmaceutical laboratories of Lucideon Limited to perform routine sterility testing of 1L Contec Prochlor.

2 EXPERIMENTAL

The validation undertaken was based on the current European Pharmacopoeia methodology; 2.6.1 Sterility - Membrane Filtration.

This validation used one container from one batch of product only.

3 PROCEDURE

A 1L Contec Prochlor container was aseptically opened and 100 ml (10%) of product was transferred to each of the two filters of a Steritest kit (TZHVSL210).

The filters were each rinsed with 150ml Fluid D and 350ml Fluid A (500ml rinse in total per filter); the final portion of Fluid A for each filter being inoculated with low numbers (not more than 100cfu) of one of the microorganisms as specified below in Table 1.

Tryptone Soya Broth (TSB) and Fluid Thioglycollate (FT) medium were transferred onto the relevant filters as specified below in Table 1.

The above process was repeated for the remaining organisms.

Positive controls were carried out in the absence of product.

The vessels were incubated at the temperatures as specified in Table 1 for not exceeding 5 days.

The containers were examined daily for signs of growth.

TABLE 1

Microorganism	Medium	Incubation Temperature (°C)
C. albicans (ATCC 10231)	TSB	20 - 25°C
A. brasiliensis (ATCC16404)		
B. subtilis (ATCC 6633)		
P. aeruginosa (ATCC 9027)	FT	30 - 35°C
S. aureus (ATCC 6538)		
C. sporogenes (ATCC 11437)		

4 RESULTS

Sample Description: Sample 7 - 1L Contec Prochlor, BN: 140800194 (Lab. Ref. (15263)-4152).

Microorganism	Validation Results
C. albicans (ATCC 10231)	Growth observed day 3
A. brasiliensis (ATCC16404)	Growth observed day 3
B. subtilis (ATCC 6633)	Growth observed day 2
P. aeruginosa (ATCC 9027)	Growth observed day 2
S. aureus (ATCC 6538)	Growth observed day 1
C. sporogenes (ATCC 11437)	Growth observed day 1

Positive controls satisfactory; growth of all organisms observed within 3 days.

5 CONCLUSION

The Sterility Test is an acceptable method for this product; 1L Contec Prochlor, when performed as validated above.

This validation outcome is based on the results generated using one container from one batch of product only.

Customer: **Contec Cleanroom UK Ltd**

Product Description: **1L Prochlor Prep Packs**

Valid From: **04-Jul-16** Expires: **03-Jul-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 45.0 kGy maximum dose. In order to meet this specification during routine processing the recorded dose at D_{Ref} must be between **26.2** kGy and **41.5** kGy. This incorporates an estimation of uncertainty associated with the measurement system.

Authorisation

Position	Signature	Date
Plant Manager		05/07/16
Daventry Quality Manager		05-Jul-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

Product Detail

Customer Name: **Contec Cleanroom UK Ltd**
Product Desciption **1L Prochlor Prep Packs** Expiry Date **03-Jul-21**

Layout Of Shipper Contents

Dosimetry Placement

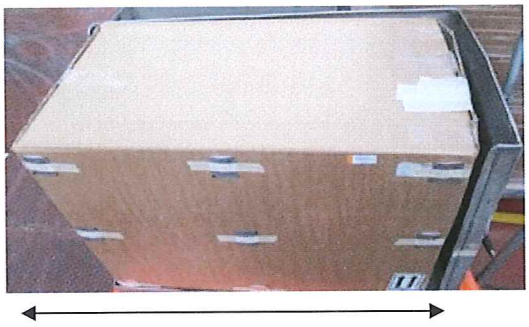
Product Detail

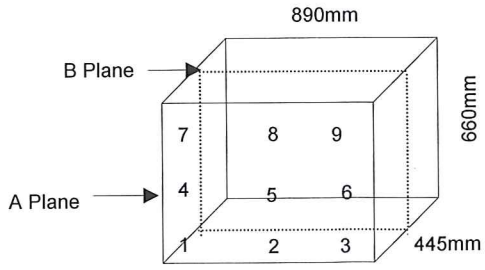
Customer Name: **Contec Cleanroom UK Ltd**

Product Description: **1L Prochlor Prep Packs** Expiry Date **03-Jul-21**

Number Per Container: **1** Number Per Shipper: **4**

Irradiation Container





Approved By: **Date:** 05 July 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	30.9	31.4	31.0	**31.1**	**0.26**	**0.85**	0.14
2A	32.2	32.0	32.3	32.2	0.15	0.47	0.05
3A	32.0	30.5	30.3	30.9	0.93	3.00	1.73
4A	31.5	31.9	32.0	31.8	0.26	0.83	0.14
5A	33.5	33.5	34.0	33.7	0.29	0.86	0.17
6A	32.0	32.3	32.1	32.1	0.15	0.48	0.05
7A	31.3	31.7	31.9	31.6	0.31	0.97	0.19
8A	32.8	33.3	33.0	33.0	0.25	0.76	0.13
9A	31.9	32.1	31.4	31.8	0.36	1.13	0.26
1B	30.5	31.2	29.8	30.5	0.70	2.30	0.98
2B	30.7	31.1	30.3	30.7	0.40	1.30	0.32
3B	30.0	29.6	29.5	29.7	0.26	0.89	0.14
4B	31.8	31.8	31.6	31.7	0.12	0.36	0.03
5B	31.9	32.1	31.6	31.9	0.25	0.79	0.13
6B	30.9	31.2	30.5	30.9	0.35	1.14	0.25
7B	31.2	31.3	31.7	31.4	0.26	0.84	0.14
8B	31.2	31.8	32.1	31.7	0.46	1.45	0.42
9B	30.9	31.2	31.2	31.1	0.17	0.56	0.06

Pooled variance ($s^2_{overall}$)	**0.15**	**D_{Ref} release criteria**	
Minimum detectable difference (б)	**0.53**	D_{Ref} Minimum	**26.2**
Mean Minimum dose (D_{Min})	**29.7**	D_{Ref} Maximum	**41.5**
Mean Maximum dose (D_{Max})	**33.7**		
Expected value of R_{min}	**1.0473**		
Expected value of R_{max}	**0.9236**		

Product Detail

Customer Name: **Contec Cleanroom UK Ltd**
A/C No: **126485** Report Ref.: **4688**
Issue Date: **04-Jul-16** Expiry Date: **03-Jul-21**

Product Description: 1L Prochlor Prep Packs

Type of package: **Carton**
No of Packages/Irradiation Container: **1**
No of Packages/Shipper: **4**

Dimensions of Package (mm): **820** x **640** x **450**
Weight of Package (kg): **11.30** Density (gcm^3): **0.05**

Plant Batch No: **S11637241-1-1**

Current Co60 Loading (Mc_i): **2.92**

Standard Plant Dwell Time (sec): **87**

Dwell Time (sec): **79**

Dose Range Specification (kGy): **25.0** Min. **45.0** Max.

Number of passes 1

Synergy Processing Instruction

Guide Plant Dwell Time Range: **0.76** Min **1.21** Max

D_{Ref} Minimum **26.2**
D_{Ref} Maximum **41.5**

Ratio's

Synergy (1/Rmin) **0.9548**
Synergy (1/Rmax) **1.0827**

Comments

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Certificate of Irradiation

Date Issued: 01-Jul-2016

UK33S11637241-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
EN ISO 9001:2008 Quality Management System
EN ISO 13485:2012 Quality System - Medical Devices

Contec Cleanroom UK Ltd
Unit 6A
Wansbeck Business Park
Ashington
NE63 8GW
UNITED KINGDOM

Order Information

Account Number:	126485
Synergy Health Sales Part Reference:	1105225
Customer Reference Number:	1065
Product Description:	1L PROCHLOR PREP PACKS 25-45kGy TRIPLE VALIDATION
Quantity Received:	14
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	160400382, 4 plts
Other Process Details:	Actual min dose: 29.5kGy Actual max dose: 34.0kGy

Irradiation Data

Date and Time of Irradiation:	01-Jul-2016 11:38

Irradiation Release Authorised By Synergy Health plc

Validation Ref: 4794
Performance Qualification Daventry **Rev 01**

Customer: **Contec Cleanroom UK Ltd**

Product Description: **5L Prep Packs**

Valid From: **15-Nov-16** Expires: **14-Nov-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 **26.2** kGy and **87.9** kGy. This incorporates an estimation of uncertainty associated with the measurement system.

Authorisation

Position	Signature	Date
Plant Manager		05 Dec 2016
Daventry Quality Manager		05 DEC 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 **5L Prep Packs** Expiry Date **14-Nov-21**

Layout Of Shipper Contents

Dosimetry Placement

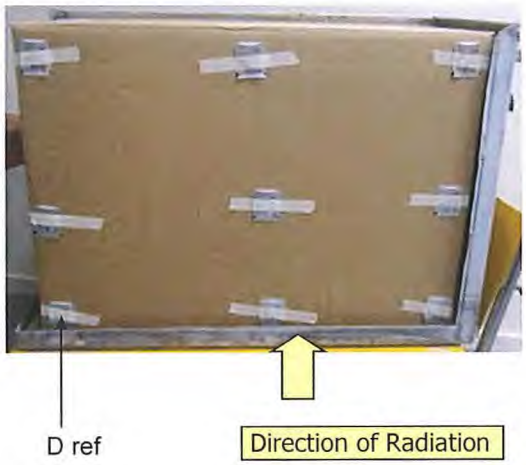
Product Detail

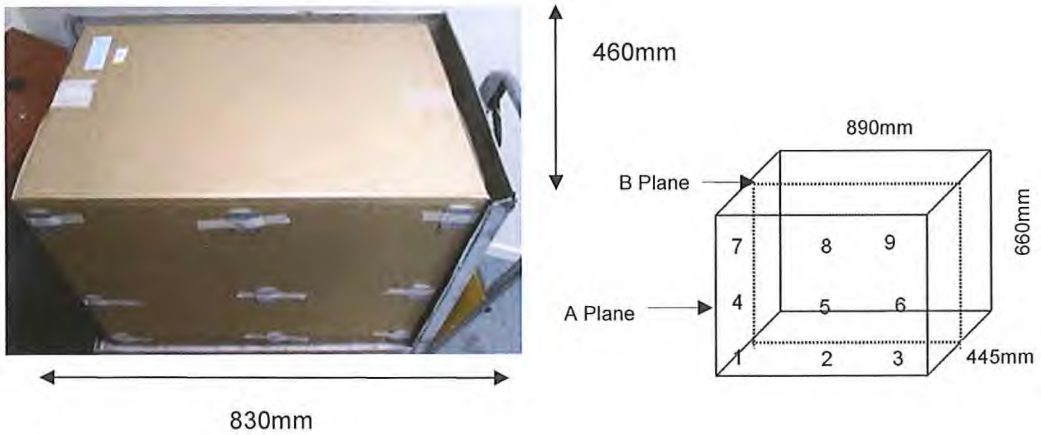
Customer Name: **Contec Cleanroom UK Ltd**

Product Description: **5L Prep Packs** Expiry Date **14-Nov-21**

Number Per Container: **1** Number Per Shipper: **5**

Irradiation Container





Approved By: **Date:** 05/12/16

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
D_{ref} Position 1A	32.2	31.7	32.2	**32.0**	**0.29**	**0.90**	0.17
2A	34.2	32.9	33.3	33.5	0.67	1.99	0.89
3A	32.8	32.3	32.5	32.5	0.25	0.77	0.13
4A	33.5	32.9	32.9	33.1	0.35	1.05	0.24
5A	34.5	34.8	34.5	34.6	0.17	0.50	0.06
6A	32.7	33.2	32.9	32.9	0.25	0.76	0.13
7A	33.8	32.2	32.9	33.0	0.80	2.43	1.29
8A	35.5	34.5	33.5	34.5	1.00	2.90	2.00
9A	33.2	33.2	32.8	33.1	0.23	0.70	0.11
1B	31.2	30.1	30.5	30.6	0.56	1.82	0.62
2B	30.5	30.4	31.6	30.8	0.67	2.16	0.89
3B	30.5	30.6	31.0	30.7	0.26	0.86	0.14
4B	33.4	32.0	32.2	32.5	0.76	2.33	1.15
5B	34.2	33.0	32.9	33.4	0.72	2.17	1.05
6B	32.5	32.5	32.6	32.5	0.06	0.18	0.01
7B	33.5	31.8	32.2	32.5	0.89	2.73	1.58
8B	33.7	32.9	32.3	33.0	0.70	2.13	0.99
9B	33.3	32.5	31.9	32.6	0.70	2.16	0.99

Pooled variance ($s^2_{overall}$)	**0.34**
Minimum detectable difference (б)	**0.81**
Mean Minimum dose (D_{Min})	**30.6**
Mean Maximum dose (D_{Max})	**34.6**
Expected value of R_{min}	**1.0472**
Expected value of R_{max}	**0.9256**

D_{Ref} release criteria	
D_{Ref} Minimum	**26.2**
D_{Ref} Maximum	**87.9**

Product Detail

Customer Name: **Contec Cleanroom UK Ltd**
A/C No: **126485** Report Ref.: **4794**
Issue Date: **15-Nov-16** Expiry Date: **14-Nov-21**

Product Description: 5L Prep Packs

Type of package: **Carton**
No of Packages/Irradiation Container: **1**
No of Packages/Shipper: **5**

Dimensions of Package (mm): **830** x **640** x **460**
Weight of Package (kg): **8.70** Density (gcm^3): **0.04**

Plant Batch No: **S11727286-1-1**

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

Standard Plant Dwell Time (sec): **82**

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 **2.49** Max

$D_{.Ref}$ Minimum **26.2**
D_{Ref} Maximum **87.9**

Ratio's

Synergy (1/Rmin) **0.9549**
Synergy (1/Rmax) **1.0804**

Comments

VAL005

4620549

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Certificate of Irradiation

Date Issued: 11-Nov-2016 UK33S11727286-1-1

This is to certify that AST Daventry Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
EN ISO 9001:2008 Quality Management System
EN ISO 13485:2012 Quality System - Medical Devices

Contec Cleanroom UK Ltd
Unit 6A
Wansbeck Business Park
Ashington
NE63 8GW
UNITED KINGDOM

Order Information

Account Number:	126485
Synergy Health Sales Part Reference:	1108547
Customer Reference Number:	1396
Product Description:	5L PREP PACK - NEW TRIPLE VAL
Quantity Received:	10
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	95.0
Customer Unit Lot/Batch Number:	161000499, 2 plts **NEW TRIPLE VALIDATION**
Other Process Details:	Actual min dose: 30.1kGy Actual max dose: 35.5kGy

Irradiation Data

Date and Time of Irradiation:	10-Nov-2016 22:15

Irradiation Release Authorised By Synergy Health plc

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 ProChlor has an un-opened shelf life of 2 years from date of manufacture. Contec ProChlor has an in-use shelf life of 24 weeks.

Originally shelf work was carried out using accelerated testing on trial samples. Data is now available for the ambient trials carried out on the first production batches manufactured.

Unopened Shelf Life Validation

Ambient shelf life studies

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.

Production Testing

Product Code SBT102PC Batch 140800194 1L trigger spray

Three samples from production were put on ambient shelf life testing for both 1L and 5L product. The storage temperature was maintained at 25°C.

The starting specification of the sample was:-

Test	Specification	Result
Specific Gravity @20^{0}C	1.002 – 1.008	1.002
pH	2.5 – 4.5	3.68
Available chlorine	>1000ppm	2233ppm
Colour	Colourless	Colourless
Odour	Slight chlorine	Slight chlorine

Chemical results after 24 months storage at 25^{0}C – 1L product

Sample	pH	Available Cl_2 ppm	Colour	Odour	S.G
Bottle 1	3.23	1420	Colourless	Chlorine	1.002
Bottle 2	3.28	1407	Colourless	Chlorine	1.002
Bottle 3	2.25	1506	Colourless	Chlorine	1.002

Product Code SBC502PC Batch: 141000203 5L capped

The starting specification of the sample was:-

Test	Specification	Result
Specific Gravity @20^{0}C	1.002 – 1.008	1.000
pH	2.5 – 4.5	3.71
Available chlorine	>1000ppm	2300ppm
Colour	Colourless	Colourless
Odour	Slight chlorine	Slight chlorine

Chemical results after 24 months storage at 25^{0}C – 1L product

Sample	pH	Available Cl_2 ppm	Colour	Odour	S.G
Bottle 1	3.30	1559	Colourless	Chlorine	1.000
Bottle 2	3.33	1489	Colourless	Chlorine	1.000
Bottle 3	3.29	1559	Colourless	Chlorine	1.000

Efficacy testing

The lowest ppm available chlorine that was measured during testing was 1170ppm when the product had been sprayed daily over an 18 week period whilst being stored at accelerated temperature. Efficacy testing was performed on a 1000ppm sample using EN13704 against spores as a representative test that the product is still efficacious at the end of shelf life.

Test House – ALS Labs, Ely, UK / MGS Labs, Poyle, UK

EN13704 – clean conditions

Organism	Pass Criteria	Contact Time	Test Results Log Reduction 2000ppm	Test Results Log Reduction 1000ppm
B.*subtilis*	Log 3	60 secs	> 6.0	>6.0
B.*pumilis*	Log 3	60 secs	> 3.88	>3.33
P. *glucanolyticus* *	Log 3	60 secs	>3.12	>3.0
B.*cereus*	Log 3	60 secs	> 3.24	>3.67

Efficacy after 20 weeks accelerated testing

Efficacy testing was also carried out on the production samples stored at 40^0C for 20 weeks. Testing was carried out against EN13697 surface test for bacteria, fungi, yeasts and also spores. A log 2 reduction in spores was accepted as the pass criteria.

Test House – FDAS Labs, Nottingham, UK
EN13697 – clean conditions / stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 4	4.7	60 secs	PASS	Dilution neutralisation
E.*hirae*	Log 4	4.2	60 secs	PASS	Dilution neutralisation
E.*coli*	Log 4	4.2	60 secs	PASS	Dilution neutralisation
P.*aeruginosa*	Log 4	4.2	60 secs	PASS	Dilution neutralisation
A.*niger* (*brasiliensis*)	Log 3	3.3	60 secs	TBA	TBA
C.*albicans*	Log 3	3.4	60 secs	PASS	Dilution neutralisation
B.*subtilis*	Log 2*	3.4	60 secs	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 protected 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 the rest of their sterile trigger sprays. However, Contec ProChlor does not use this protected system due to compatibility issues between the “bag” material and the product.

Contec ProChlor packaging has been developed using a standard HDPE bottle (no “bag-in-bottle”) and a standard trigger spray, meaning air is introduced into the bottle each time the sprayer is used.

However, as Contec ProChlor has demonstrated rapid efficacy against all contamination including bacterial spores it was likely that fluid was self-sterilising. Any contamination drawn into the bottle would be killed by the fluid itself within 1 min. In order to validate this, a standard in-use shelf life test was carried out to show the fluid itself was sufficient to keep the fluid sterile during use.

The system was also positively challenged by introducing a known number of spores into the bottle, neutralising after 1 min to ensure if the bottle was contaminate ProChlor would kill any spores.

In-use shelf life method

6 bottles of Contec ProChlor were tested in a Grade C cleanroom and 6 bottles were tested in an unclassified environment (Ashington QC Lab).

When the test was started no Sterile ProChlor was available as it had not yet been manufactured. As the fluid is self-sterilising the test was performed on Contec Filtered ProChlor. The results from this test will be valid for both Contec Sterile ProChlor and Contec Filtered ProChlor

Labelled 1 – 6 the bottles were not removed from the environment during the duration of the test, only removed at the end of the required test period.

Every working day each bottle was sprayed 10 times removing approx.50ml of product per week.

After 6 weeks one 1L bottle from each area to be sent for sterility testing
After 12 weeks 3 x 1L bottles from each area were sent for sterility testing
After 24 weeks the remaining 2 x 1L bottles from each area were sent for sterility testing

Product tested Contec Filtered ProChlor FBT102PC Batch: 11152

Results

After 6 weeks 1 bottle from each location was sent for sterility testing to Stockton QC laboratory. Sterility testing was carried out according to Ph. Eur. 7th edition add. 7.7 Ch. 2.6.1.

Bottle	Absence of micro-organisms	Test No	Pass
Sample 3 – C Room	Yes	CON82391	Yes
Sample 6 – QC Lab	Yes	CON82390	Yes

After 12 weeks 3 bottles from each location was sent for sterility testing to Stockton QC laboratory. Sterility testing was carried out according to Ph. Eur. 7th edition add. 7.7 Ch. 2.6.1.

Bottle	Absence of micro-organisms	Test No	Pass
Sample 1 – C Room	Yes	CON83859	Yes
Sample 2 – C Room	Yes	CON83860	Yes
Sample 6 – C Room	Yes	CON83861	Yes
Sample 1 – QC Lab	Yes	CON83856	Yes
Sample 2 – QC Lab	Yes	CON83857	Yes
Sample 3 – QC Lab	Yes	CON83858	Yes

To ensure there was no detrimental effect on the product as well as sterility, the chemical specification was also checked.

Sample	pH	Available Cl_2 ppm	Colour	Odour
Specification	3.00 – 6.00	>1000ppm	Colourless	Chlorine
Sample 1	3.33	1701ppm	Colourless	Chlorine

After 24 weeks 2 bottles from each location was sent for sterility testing to Stockton QC laboratory. Sterility testing was carried out according to Ph. Eur. 7th edition add. 7.7 Ch. 2.6.1.

Bottle	Absence of micro-organisms	Test No	Pass
Sample 4 – C Room	Yes	CON86310	Yes
Sample 5 – C Room	Yes	CON86311	Yes
Sample 4 – QC Lab	Yes	CON86312	Yes
Sample 5 – QC Lab	Yes	CON86313	Yes

To ensure there was no detrimental effect on the product as well as sterility, the chemical specification was also checked.

Sample	pH	Available Cl_2 ppm	Colour	Odour
Specification	3.00 – 6.00	>1000ppm	Colourless	Chlorine
Sample 1	3.21	1560ppm	Colourless	Chlorine

Environmental Monitoring Results

In order to ensure there was potential contamination in the rooms which could be “sucked” back into the bottle we also carried out environmental monitoring using settle plates and contact plates in the two rooms the bottles were tested in.

Location	Weekly Av (CFU)	Bacteria	Yeast	Fungi
Cleanroom	4	YES	NO	NO
Quality Lab	72	YES	YES	YES

Positive control – MGS Labs, Poyle, UK

Method

A sample of 1L ProChlor from production batch 150700310 was contaminated with 10^7 *Bacillus cereus* spores. *B cereus* spores were chosen as it is generally accepted that they are one of the hardest spore forming bacillus to kill.

After 1 min the product was neutralised and enumerated.

Result

No growth was detected when the product was enumerated.

Conclusion

Unopened shelf life

Contec ProChlor can be given an un-opened shelf life of 24 months.

It is stable and remains efficacious over a 24 month period as demonstrated in the above testing.

The pH which is key to the product remaining efficacious as hypochlorous acid remains in specification.

Efficacy testing showed the product was still sporicidal at 1000ppm with a contact time of 1 min. Efficacy testing carried out on the actual aged product also passed against all standard organisms against EN13697 surface test in 1 min. This show there has been no degradation in efficacy at the end of shelf life.

In-use shelf life

Contec ProChlor can be given an in-use shelf life of 24 weeks. It is unlikely that a product would be in-use for any longer than this in a cleanroom environment.

After a 24 week in-use period, samples that have been used both within a controlled Grade C cleanroom and an unclassified location within the quality laboratory have shown an absence of micro-organisms when sterility tested and therefore it can be validated that Contec ProChlor has a 24 week in-use shelf life once opened. These results will be the same for Contec *Sterile* ProChlor which has additionally been filled into sterile components.

A positive control was carried out which demonstrated that even if the product was grossly contaminated with bacillus spores after one minute there was no growth of micro-organisms, showing that the ProChlor had killed all potential contamination. The contamination introduced into the fluid was at levels far exceeding those that would be found in a cleanroom environment.

Chemical testing was also carried out at the same time and confirmed that there is no detrimental effect on the products chemical stability over a 24 week period of in-use testing.

Section 13
Technical Reports

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

TN1501 Rev 1 October 2015

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

TN1701 Rev 1 October 2017

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

CONTEC INC

TECHNICAL NOTE TN1501

REV 1

October 2015

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

Summary

Testing was carried out using Contec ProChlor 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 ProChlor with standard cleanroom gloves and also to show which gloves are suitable for use with ProChlor 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

Respirex Testing Laboratory, Hull, UK

Materials used

Contec Sterile ProChlor SBT102PC Lot No 140800194

Bioclean Indigo Sterile Nitrile Gloves

Bioclean Advance Sterile Latex Gloves

Bioclean Fusion Sterile Polychloroprene Gloves

Results

Test Report CP261114A/HK Date 15/12/14

Sterile Nitrile Gloves

Chemical	Min detectable permeation rate	Procedure	Mean thickness	Breakthrough tIme *	Observations
Contec ProChlor	0.02 µg/(min.cm^2)	CP30	0.13	>480 mins	Swollen & discoloured
Contec ProChlor	0.02 µg/(min.cm^2)	CP30	0.13	>480 mins	Swollen & discoloured
Contec ProChlor	0.02 µg/(min.cm^2)	CP30	0.12	>480 mins	Swollen and discoloured

* Based on detection of Hypochlorous Acid (CAS no 7790-92-3)

Test Reports CP261114B/HK Date 15/12/14

Sterile Latex Gloves

Chemical	Min detectable permeation rate	Procedure	Mean thickness	Breakthrough tIme *	Observations
Contec ProChlor	0.02 µg/(min.cm^2)	CP30	0.17	>480 mins	Swollen & discoloured
Contec ProChlor	0.02 µg/(min.cm^2)	CP30	0.18	>480 mins	Swollen & discoloured
Contec ProChlor	0.02 µg/(min.cm^2)	CP30	0.19	>480 mins	Swollen and discoloured

* Based on detection of Hypochlorous Acid (CAS no 7790-92-3)

Test Reports CP261114C/HK **Date 15/12/14**

Sterile Polychloroprene Gloves

Chemical	Min detectable permeation rate	Procedure	Mean thickness	Breakthrough tIme *	Observations
Contec ProChlor	0.02 µg/(min.cm^2)	CP30	0.11	>480 mins	Swollen & discoloured
Contec ProChlor	0.02 µg/(min.cm^2)	CP30	0.11	>480 mins	Swollen & discoloured
Contec ProChlor	0.02 µg/(min.cm^2)	CP30	0.11	>480 mins	Swollen and discoloured

* Based on detection of Hypochlorous Acid (CAS no 7790-92-3)

Conclusion

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

This test work can also be used in infer that as the ProChlor doesn't break through the gloves over an 8 hour period, the gloves are compatible with ProChlor and are not broken down. There was some discolouration of the gloves but this was after the gloves had been in permanent contact with the fluid for the duration of the test. In use it is unlikely that ProChlor would be in contact with the gloves for this length of time.

CONTEC INC

TECHNICAL NOTE TN1701

REV 1

October 2017

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

Summary

The investigation was carried out to check the compatibility of Contec ProChlor when used on common cleanroom materials. Several different methods of applying Contec ProChlor 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 ProChlor.

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 ProChlor assay – 2200ppm / pH 4.23

Materials used

Sterile 1L Contec ProChlor Batch: 170200586

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, casted 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 the spray and wipe tests showed no material incompatibility.

Spray only – All samples showed surface salt residue build up and an increase of the weight of the material from the start. All samples except 304 grade Stainless steel surface salt could be removed with IPA.

Grade 304 stainless steel showed a lot of surface oxidation and salt residue could not be removed using IPA.

Vinyl flooring and Polycarbonate samples displayed white bleaching effect but this did not show any change to physical characteristics (no embrittlement, cracking loss of flexibility).

The changes in weight noted in the table below is likely due to the deposit of salt on the surface of the materials over the duration of the test whilst using Contec ProChlor, salt deposits were visible on all the large square samples. Additions in weight were also noted with the water controls. On the 304 stainless steel sample the salt residue could not be removed using IPA. Oxidation on the 304 samples could be where there are small scratches and/or marks to the s/s surface. All other samples showing salt residue this could be removed using IPA.

At 3 weeks the visible salt could be removed from all samples using IPA.

Spray Test Results

Material	Pre-weight/g	Post-weight/g	Weight Change/g	Comments on Final Visible Condition
316 s/s A	116.40	116.41	+0.01	Good condition, some surface salt but no damage
316 s/s B	116.45	116.50	+0.05	Good condition, some surface salt but no damage
316 s/s C	116.47	116.52	+0.05	Good condition, some surface salt but no damage
304 s/s A	62.78	62.79	+0.01	Poor condition visible salt and oxidation to surface
304 s/s B	62.70	62.71	+0.01	Poor condition visible salt and oxidation to surface
304 s/s C	62.90	62.92	+0.02	Poor condition visible salt and oxidation to surface
Gal Steel A	47.45	47.47	+0.02	Good condition, some surface salt but no damage
Gal Steel B	47.62	47.64	+0.02	Good condition, some surface salt but no damage
Gal steel C	47.47	47.50	+0.03	Good condition, some surface salt but no damage
HPL A	56.98	57.03	+0.05	Good condition, some surface salt but no damage
HPL B	56.92	56.97	+0.05	Good condition, some surface salt but no damage
HPL C	57.00	57.06	+0.06	Good condition, some surface salt but no damage
Al. Plinth A	72.75	72.76	+0.01	Good condition, some surface salt but no damage
Al. Plinth B	72.79	72.81	+0.04	Good condition, some surface salt but no damage
Silic. Gasket A	3.43	3.34	0	Good Condition
Silic. Gasket B	3.46	3.47	+0.01	Good Condition
Vinyl A	0.75	0.77	+0.02	Good Condition
Vinyl B	0.75	0.76	+0.01	Good Condition
PVC A	1.79	1.79	0	Good condition, some surface salt but no damage
PVC B	1.82	1.82	0	Good condition, some surface salt but no damage
Polycarb. A	0.51	0.51	0	Good condition, some surface salt but no damage
Polycarb. B	0.52	0.52	0	Good condition, some surface salt but 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	116.58	116.58	0	Good Condition no surface issues noted
316 s/s B	116.34	116.34	0	Good Condition no surface issues noted
316 s/s C	116.20	116.21	0	Good Condition no surface issues noted
304 s/s A	62.81	62.81	0	Good Condition no surface issues noted
304 s/s B	62.83	62.83	0	Good Condition no surface issues noted
304 s/s C	62.84	62.84	0	Good Condition no surface issues noted
Gal Steel A	47.32	47.33	+0.01	Good Condition no surface issues noted
Gal Steel B	47.57	47.58	+0.01	Good Condition no surface issues noted
Gal steel C	47.45	47.47	+0.02	Good Condition no surface issues noted
HPL A	57.10	57.11	+0.01	Good Condition no surface issues noted
HPL B	57.10	57.11	+0.01	Good Condition no surface issues noted
HPL C	57.16	57.17	+0.01	Good Condition no surface issues noted
Al. Plinth A	72.79	72.80	+0.01	Good Condition no surface issues noted
Al. Plinth B	72.77	72.78	+0.01	Good Condition no surface issues noted
Silic. Gasket A	3.44	3.44	0	Good Condition no surface issues noted
Silic. Gasket B	3.44	3.44	0	Good Condition no surface issues noted
Vinyl A	0.76	0.76	0	Good Condition no surface issues noted
Vinyl B	0.76	0.76	0	Good Condition no surface issues noted
PVC A	1.80	1.80	0	Good Condition no surface issues noted
PVC B	1.81	1.81	0	Good Condition no surface issues noted
Polycarb. A	0.50	0.50	0	Good Condition no surface issues noted
Polycarb. B	0.51	0.51	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

It is already known that Contec ProChlor if left to dry on a surface, will dry to form a calcium salt. Over time this salt can become insoluble and difficult to remove with water and/or Isopropanol

From the results obtained it is clear that an application method which incorporates spray and wipe to dry is best for all materials as no visible issues were reported using this method over a 4-week period.

All materials tested displayed none of the issues that were noted when spraying but not removing the ProChlor. There were a few minor increases in weight of several of the materials but this was very minimal and not due to any visible presence of calcium salt, so not likely to be due to a build-up on the surface.

In contrast continuous spraying on the materials resulted in very different results. The salt was visibly present from approximately the middle of week 2, although up until week 3 this salt residue could be removed from all surfaces using IPA.

From week 3 onwards this residue could not be removed from the 304 grade stainless steel material. This material also displayed the worst visual results with oxidation spots occurring in many areas on the test surface, although this is likely to have developed on areas of the test surface that were already scratched or damaged. The fact that the water control also showed oxidation spots in this test could prove this point.

On the remaining surfaces the calcium salt was removed from the surface at the end of the 4-week test period using IPA.

The overall conclusion is that Contec ProChlor is compatible with all the above materials if used for the stated contact time and then removed or wiped to dry.