



PRODUCT INFORMATION FILE

Contec® CyChlor

Product Codes

SBT100CC
SBC100CC
SBC500CC
FBT100CC
FBC100CC
FBC500CC

Rev 4 09-12-2019
www.contecinc.com



Contec® CyChlor

SBT100CC
SBC100CC
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FBT100CC
FBC100CC
FBC500CC

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Rev 4 09-12-2019
www.contecinc.com

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 9001:2008 which ensures customers of consistent quality products – from development to delivery. As a vertically integrated manufacturer, Contec controls more of the manufacturing process than any other supplier.

Committed to customers

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

Product range

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

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

Global Manufacturing and Distribution

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



Contec USA



Contec China



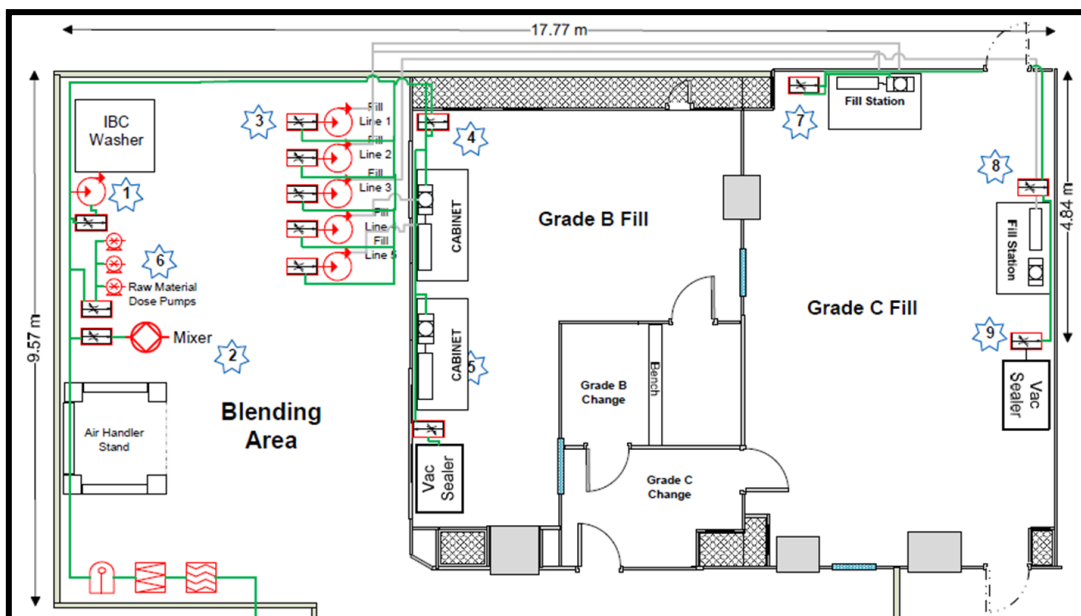
Contec France

Ashington Manufacturing Plant

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

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

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



Water Plant and QC Laboratory

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



Blending Area

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



Staging areas



Grade B cleanroom

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



Grade C cleanroom

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



Regulatory Certificates

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

- needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
- aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.” From 1st September 2013, Biocidal Products are regulated in the EU by the EU Biocides Regulation 528/2012 (EU BPR). This replaces the previous Biocidal Products Directive (BPD).

Biocidal Products Regulation

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

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

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

1. The active substances must be approved under the appropriate Product Type (PT) for use in the Biocidal Product (BP).
2. Each Biocidal Product consisting of, containing or generating the approved active substance(s) is reviewed for approval under the appropriate Product Type (PT).

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

Contec’s biocides are all categorised under PT2: disinfectants and algacides 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/EEA.

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's TSE statement is also detailed below.



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 (EMA/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,

A handwritten signature in cursive script that reads "Nancy Bockstiegel".

Nancy Bockstiegel
Contec, Inc.
Quality Manager
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Email: nbockstiegel@contecinc.com

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web: www.contecinc.com
email: info@contecinc.com

SGS

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
Rosemore Business Park, Ellesmere Port, Cheshire CH65 3EN UK
T +44 (0)151 350-6606 F +44 (0)151 350-6600 www.sgs.com

HC SGS 9001 2015 0316

Page 1 of 1



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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
Mark Alpert
Vice President, Business Assurance
Page 1 of 3





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

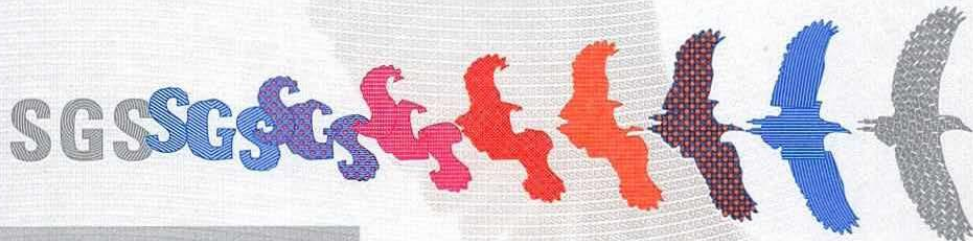
The certification information can be verified on the web site of Certification and Accreditation
Administration of the People's Republic of China www.cnca.gov.cn



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HC SGS 9001 2015 0118

Page 1 of 1



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unauthorized alteration, forgery or falsification of the content or appearance of
this document is unlawful and offenders may be prosecuted to the fullest extent
of the law.

Section 2

Product Overview – Contec CyChlor

Contec CyChlor is a new broad spectrum disinfectant designed for every day use and rotation with Contec ProChlor or Contec HydroPure.

A blend of hypochlorous acid in purified water, Contec CyChlor is provided ready-to-use and is efficacious against bacteria and yeasts in 3 mins.

Contec CyChlor 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 5L capped containers for when larger volumes are required.



Feature

Broad spectrum efficacy in 3 mins

Filtered to 0.2 microns and filled in a Grade A environment

Sterile version available

Contains no quaternary ammonium or surfactant

No hazard classification

Trigger spray can be set to jet or spray

Double bagged packed in linear tear packaging

Not classed as corrosive

Benefit

Fast acting so saves time spent on decontamination

Ensures the product is free from contamination and particulates

Suitable for Grade A and B cleanrooms

Very low residue, saving time on residue removal

Good operator acceptability as no strong odour
Only basic PPE required and no special disposal required

Large droplet size reduces the risk of inhalation and provides good surface coverage

Each bag is easy to open even when wearing gloves
Facilitates transfer disinfection into cleanroom

Can be used safely in all areas of the cleanroom

Part No.	Description		Packaging
SBT100CC	Contec <i>Sterile</i> CyChlor	1L Trigger Spray	6 x 1L
SBC100CC	Contec <i>Sterile</i> CyChlor	1L Capped	6 x 1L
SBC500CC	Contec <i>Sterile</i> CyChlor	5L Capped	2 x 5L
FBT100CC	Contec CyChlor	1L Trigger Spray	6 x 1L
FBC100CC	Contec CyChlor	1L Capped	6 x 1L
FBC502CC	Contec CyChlor	5L Capped	2 x 5L

Section 3

Product Specification – Sterile CyChlor

Product Name	Contec <i>Sterile</i> CyChlor
Product Description	Sterile Stabilised Hypochlorous Acid in purified water (EP)
Product Code	SBT100CC 1L Trigger Spray x 6 SBC100CC 1L Capped x 6 SBC502CC 5L Capped x 2
Product Specification	
Colour	Colourless
Clarity	Clear
Specific Gravity @ 20°C	0.990 – 1.010
Available chlorine	> 300ppm
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: 12 months from date of manufacture In-use: 24 weeks from date of opening

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

Product Specification – Filtered CyChlor

Product Name	Contec CyChlor
Product Description	Filtered Stabilised Hypochlorous Acid in purified water (EP)
Product Code	FBT100CC 1L Trigger Spray x 6 FBC100CC 1L Capped x 6 FBC502PC 5L Capped x 2
Product Specification	
Colour	Colourless
Clarity	Clear
Specific Gravity @ 20°C	0.990 – 1.010
Available chlorine	> 300ppm
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: 12 months from date of manufacture In-use: 24 weeks for date of opening

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

Section 4

Product Certificates

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



PRODUCT CERTIFICATE

Product: Contec Sterile CyChlor

Product Code: SBT100CC

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:	>300ppm	
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: xxxxxxxxxxx

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.

00004 Rev 2

Manufactured by:
Contec Cleanroom (UK) Ltd
Unit 5A Warwick Business Park
Ardington
UK

America
Contec Inc.
P.O. Box 150
Sparksburg MD
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Europe
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96037 VANVES
France

China
Contec Cleanroom Technology (Shanghai) Co. Ltd
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Suzhou 215004
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china@contecdna.com



PRODUCT CERTIFICATE

Product: Contec Sterile CyChlor
Product Code: SBT100CC
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:	>300ppm	
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: xxxxxxxxxxxx
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

COM4 Rev 2

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China
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PRODUCT CERTIFICATE

Product: Contec Sterile CyChlor
Product Code: SBC500CC
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:	>300ppm	
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: xxxxxxxxxxxx
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.

COMS Rev 2

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China
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Suzhou 215024
China

www.contedinc.com
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PRODUCT CERTIFICATE

Product: Contec CyChlor
Product Code: FBT100CC
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:	>300ppm	
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:
Authorized Signature:	1:	2:

For and on behalf of Contec, Inc

COA#7 Rev 2

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PRODUCT CERTIFICATE

Product: Contec CyChlor
Product Code: FBC100CC
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:	> 300ppm	
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:	1:	2:

For and on behalf of Contec Inc

COA49 Rev 2

Manufactured by:
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info@contecltd.com



PRODUCT CERTIFICATE

Product: Contec CyChlor
Product Code: FBC500CC
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:	>300ppm	
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: 1: 2:

For and on behalf of Contec Inc

COACH Rev 2

Manufactured by:
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Unit 5A Westwick Business Park
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Section 5

Instructions for Use

Contec CyChlor 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 CyChlor 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 CyChlor will leave a small residue on a surface which is free rinsing and easily removed with either alcohol or water, if removed immediately. If CyChlor 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 CyChlor must be stored in the original packaging. Do not freeze. Store below 40^oC.

Section 6

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.



STERILE

CONTEC CYCHLOR

STERILE STABILISED
HYPOCHLOROUS ACID

EN 100ml contains 0.06ml 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 CyChlor can be disposed of via a foul drain. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent: 0,06 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. Eliminer comme tout déchet industriel ordinaire. Le rejet de petites quantités de CyChlor à l'égout est toléré. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 0,06 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 CyChlor können als normales Schmutzwasser entleert werden. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 0,06 ml de hipoclorito de calcio en agua purificada. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulta a un médico. Eliminar como los residuos industriales normales. Se pueden eliminar pequeñas cantidades de CyChlor mediante un desagüe. Almacenar a temperaturas no superiores a 40°C. No congeles.

I 100 ml contengono: 0,06 ml di ipoclorito di calcio in acqua purificata. IN CASO DI CONTATTO CON GLI OCCHI: Sciacquare accuratamente per parecchi minuti. Consultare un medico. Disporre nel modo utilizzato per normali rifiuti industriali. Piccole quantità di CyChlor possono essere smaltite tramite uno scarico fango. Conservare in luogo fresco a temperature non superiori a 40°C. Non congelare.

RO 100 ml contin 0,06 ml hipoclorit de calciu in apa purificata. IN CAZ DE CONTACT CU OCHII: Clătiți cu atenție cu apă timp de mai multe minute. A se elimina asemenea deeurilor industriale normale. Cantități mici de CyChlor 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: 0,06 ml kalsiumhypokloriittia puhdistetussa vedessä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävitetään kuten normaali teollisuusjäte. Pieniä määriä CyChlor:ia voidaan hävittää huuruveden kautta. Varasto alle 40°C lämpötilassa. Ei saa jäättyä.

DA 100 ml indeholder: 0,06 ml calcium hypochlorit i ultra rent vand. VED KONTAKT MED ØJENE: Skyl forsigtigt med vand i flere minutter. Sørg lækavård. Bortskaffes som normalt, industrielt affald. Små mængder CyChlor kan bortskaffes via et dårligt afløb. Opbevaras ved en temperatur, som ikke overstiger 40°C. Må ikke nedfrysas.

SV 100 ml innehåller: 0,06 ml kalciumhypoklorit i ultrarent vatten. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkavård. Omhändertagas som industriavfall. Små mängder CyChlor kan kasseras via ett orogelbundet avlopp. Förvaras vid högst 40°C. Får ej frysas.

- 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.
- Sterile filtered to 0.22 microns in a Grade B cleanroom.

• Contact times: Bacteria 3 mins EN13697
Yeast 3 mins EN13697

- For professional use only.

1 LITRE

Product Code **SBT100CC**

CONTEC
www.contecinc.com

Authorisation Holder

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

Supplier

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Emergency telephone Chemtreac® +1-703-527-3887

Bioicide Registration Number: German: N-75408

Manufactured in the UK by Contec Cleanroom (UK) Ltd



STERILE

CONTEC CYCHLOR

**STERILE STABILISED
HYPOCHLOROUS ACID**

001 of 1000 LAB110/01

EN 100ml contains 0.06ml 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 CyChlor can be disposed of via a foul drain. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contenant 0,06 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. Eliminer comme tout déchet industriel ordinaire. Le rejet de petites quantités de CyChlor à l'égout est toléré. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthält 0,06 ml Calciumhypochlorit in gereinigtem Wasser. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztlichen Rat einholen / ärztliche Hilfe. Wie normalen Industrierfall entsorgen. Kleine Mengen an CyChlor können als normales Schmutzwasser entsorgt werden. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contiene 0,06 ml de hipoclorito de calcio 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 CyChlor mediante un desagüe. Almacenar a temperatura no superiores a 40°C. No congelar.

I 100 ml contengono 0,06 ml di ipoclorito di calcio in acqua purificata. IN CASO DI CONTATTO CON GLI OCCHI : Sciacquare accuratamente per parecchi minuti. Consultare un medico. Disporre nel modo utilizzato per normali rifiuti industriali. Piccole quantità di CyChlor possono essere smaltite tramite uno scarico fatis. Conservare in luogo fresco a temperature non superiori a 40°C. Non congelare.

RO 100 ml conține 0,06 ml hipoclorit de calciu în apă purificată. 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 CyChlor pot fi eliminate printr-un canal de scurgere. A se depozita la temperatură care nu depășește 40°C. A nu se congela.

FI 100 ml sisältää 0,06 ml kalsiumhypokloriittia puhdistetussa vedessä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Heikkuudu lääkäriin. Hävittäin koton normaali teollisuusjätke. Pieniä määriä CyChloria voidaan hävittää huuruvuodon kautta. Varasto alle 40°C lämpötilassa. Et saa jäättyä.

DA 100 ml indeholder 0,06 ml kalcium hypochlorit i ultra rent vand. VED KONTAKT MED ØJENENE: Skyl forsigtigt med vand i flere minutter. Søg lægehjælp. Bortskaffes som normalt, industrielt affald. Små mængder CyChlor kan bortskaffes via et dæknigt afløb. Opbevarer ved en temperatur, som ikke overstiger 40°C. IKKE ikke nedfryses.

SV 100 ml innehåller 0,06 ml kalciumhypoklorit i ultrarent vatten. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkare. Omhändertagas som industriavfall. Små mängder CyChlor kan kasseras via ett oregelbundet avlopp. Förvaras vid högst 40°C. Får ej frysas.

Supplier

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Authorisation Holder

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1 LITRE

Product Code SBC100CC

CONTEC
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Emergency telephone Chemtrec® +1-703-527-3887
Biocide Registration Number: German: N-75408
Manufactured in the UK by Contec Cleanroom (UK) Ltd



STERILE

CONTEC CYCHLOR

STERILE STABILISED HYPOCHLOROUS ACID

001 of 500 LAB111/01

RO 100 ml contin 0.06 ml hipoclorit de calciu in apa purificata. IN CAZ DE CONTACT CU OCHI: Clătiți cu abiaște și apă timp de mai multe minute. A se elimina asemenea obiectelor industriale normale. Cantități mici de CyChlor pot fi eliminate printr-un canal de scurgere. A se depozita la temperatură care nu depășească 40°C. A nu se congela.

FI 100 ml sisältää: 0.06 ml kalsiumhypokloriittia puhdistetussa vedessä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhto huollillisesti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävittäkään kutan normaaliin teroitusajalle. Pieniä määriä CyChloria voidaan hävittää huuvuveden kautta. Varastoi alle 40°C lämpötilassa. Ei saa jäättyä.

DA 100 ml indeholder 0.06 ml kalcium hypochlorit i ultra rent vand. VED KONTAKT MED ØJNE: Skyl forsigtigt med vand i flere minutter. Sørg jævnligt for Bortskaffelse som normalt, indtørret erfar. Små mængder CyChlor kan bortskaffes via et dærligt afløb. Opbevarer ved en temperatur, som ikke overstiger 40°C. Må ikke nedfryses.

SV 100 ml innehåller 0.06 ml kalciumhypoklorit i ultrarent vatten. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkare. Omhändertagas som industravfall. Små mängder CyChlor kan kasseras via ett orgelbundet avlopp. Förvaras vid högst 40°C. Får ej frysas.

EN 100ml contains 0.06ml 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 CyChlor can be disposed of via a foul drain. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent 0.06 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. La rejet de petites quantités de CyChlor à l'égout est toléré. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 0.06 ml Calciumhypochlorit in gereinigtem Wasser. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztechen Rat einholen / ärztliche Hilfe. Wie normalen Industriabfall entsorgen. Kleine Mengen an CyChlor können als normales Schmutzwasser entsorgt werden. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 0.06 ml de hipoclorito de calcio en agua purificada. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulta a un médico. Eliminar como los residuos industriales normales. Se pueden eliminar pequeñas cantidades de CyChlor mediante un desagüe. Almacenar a temperaturas no superiores a 40°C. No congelar.

I 100 ml contengono: 0.06 ml di ipoclorito di calcio in acqua purificata. IN CASO DI CONTATTO CON GLI OCCHI: Sciacquare accuratamente per parecchi minuti. Consultare un medico. Disporre nel modo utilizzato per normali rifiuti industriali. Piccole quantità di CyChlor possono essere smaltite tramite uno scarico fello. Conservare in luogo fresco a temperatura non superiori a 40°C. Non congelare.

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Authorisation Holder

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Biocide Registration Number: German: N-75408

Manufactured in the UK by Contec Cleanroom (UK) Ltd

5 LITRE

Product Code SBC500CC



- 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 3 mins EN13697
Yeast 3 mins EN13697
- For professional use only.



NON STERILE

**CONTEC
CYCHLOR**

**FILTERED STABILISED
HYPOCHLOROUS ACID**

001 of 1000 LAB112/01

- 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 3 mins EN13697
Yeast 3 mins EN13697
- For professional use only.

1 LITRE

Product Code **FBT100CC**

CONTEC
www.contecinc.com

EN 100ml contains 0.06ml 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 CyChlor can be disposed of via a foul drain. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent: 0,06 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 quantités de CyChlor à l'égoût est toléré. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 0,06 ml Calciumhypochlorit in gereinigtem Wasser. BEI BERÜHRUNG MIT DEN AUGEN: Einige Minuten lang vorsichtig mit Wasser ausspülen. Ärztlichen Rat einholen / ärztliche Hilfe. Wie normalen Industriebfall entsorgen. Kleine Mengen an CyChlor können als normales Schmutzwasser entleert werden. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 0,06 ml de hipoclorito de calcio en agua purificada. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulta a un médico. Eliminar como los residuos industriales normales. Se pueden eliminar pequeñas cantidades de CyChlor mediante un desagüe. Almacenar a temperaturas no superiores a 40°C. No congelar.

I 100 ml contengono: 0,06 ml di ipoclorito di calcio in acqua purificata. IN CASO DI CONTATTO CON GLI OCCHI: Sciacquare accuratamente per parecchi minuti. Consultare un medico. Disporre nel modo utilizzato per normali rifiuti industriali. Piccole quantità di CyChlor possono essere smaltite tramite uno scarico fatiso. Conservare in luogo fresco a temperature non superiori a 40°C. Non congelare.

RO 100 ml contin 0,06 ml hipoclorit de calciu in apa purificata. IN CAZ DE CONTACT CU OCHII: Clătiți cu atenție cu apă limă de mai multe minute. A se elimina asemenea deeurilor industriale normale. Cantități mici de CyChlor pot fi eliminate printr-un canal de scurgere. A se deponiza la temperaturi care nu depășesc 40°C. A nu se congela.

FI 100 ml sisältää: 0,06 ml kalsiumhypokloriittia puhdistetussa vedessä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huulellisasti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävittäen kuten normaali teollisuustähte. Pieniä määriä CyChloria voidaan hävittää huuroveden kautta. Varastoi alle 40°C lämpötilassa. Ei saa jäättyä.

DA 100 ml indeholder 0,06 ml calcium hypochlorit i ultra rent vand. VED KONTAKT MED ØJNE: Skyf forsigtigt med vand i flere minutter. Søg lægehjælp. Bortskaffes som normalt. Industrielt affald. Små mængder CyChlor kan bortskaffes via et dæknigt afløb. Opbevaras ved en temperatur, som ikke overstiger 40°C. Må ikke nedfryses.

SV 100 ml innehåller 0,06 ml kalciumhypoklorit i ultrarent vatten. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkarevård. Omhändertagas som industrifall. Små mängder CyChlor kan kaseras via ett oregelbundet avlopp. Förvaras vid högst 40°C. Får ej frysas.

Supplier

Contec
P.O. Box 530, Spartanburg,
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Authorisation Holder

Contec Europe
R.P. 3707, F-56037,
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Emergency telephone Chemtrec® +1-703-527-3887
Biocide Registration Number: German: N-75408
Manufactured in the UK by Contec Cleanroom (UK) Ltd



NON STERILE

CONTEC CYCHLOR

FILTERED STABILISED HYPOCHLOROUS ACID

001 of 1000 LAB113/01

EN 100ml contains 0.06ml 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 CyChlor can be disposed of via a foul drain. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contiennent 0,06 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. Eliminer comme tout déchet industriel ordinaire. Le rejet de petites quantités de CyChlor à l'égout est toléré. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthalten: 0,06 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 CyChlor können als normales Schmutzwasser entsorgt werden. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 0,06 ml de hipoclorito de calcio en agua purificada. EN CASO DE CONTACTO CON LOS OJOS: aclarar cuidadosamente con agua durante varios minutos. Consulta a un médico. Eliminar como los residuos industriales normales. Se pueden eliminar pequeñas cantidades de CyChlor mediante un desagüe. Almacenar a temperaturas no superiores a 40°C. No congeal.

I 100 ml contengono: 0,06 ml di ipoclorito di calcio in acqua purificata. IN CASO DI CONTATTO CON GLI OCCHI: Sciacquare accuratamente per parecchi minuti. Consultare un medico. Disporre nel modo utilizzato per normali rifiuti industriali. Piccole quantità di CyChlor possono essere smaltite tramite uno scarico fatiso. Conservare in luogo fresco a temperatura non superiori a 40°C. Non congelare.

RO 100 ml contin 0,06 ml hipoclorit de calciu in apa purificata. IN CAZ DE CONTACT CU OCII: Clătiți cu atenție cu apă limpede mai multe minute. A se elimina asemenea deșeurilor industriale normale. Cantități mici de CyChlor 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: 0,06 ml kalsiumhypokloriittia puhdistetussa vedessä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huolellisesti vedellä usean minuutin ajan. Hakeudu lääkäriin. Hävitätään kuten normaali teollisuusjätke. Pieniä määriä CyChloria voidaan hävittää huuruveden kautta. Varastoi alla 40°C lämpötilassa. Ei saa jäättyä.

DA 100 ml. indeholder: 0,06 ml. kalcium hypochlorit i ultra rent vand. VED KONTAKT MED ØJNENE: Sky forsigtigt med vand i flere minutter. Søg lægehjælp. Bortskaffes som normalt, industrielt affald. Små mængder CyChlor kan bortskaffes via et dærfrit afløb. Opbevares ved en temperatur, som ikke overstiger 40°C. Må ikke nedfrysas.

SV 100 ml innehåller 0,06 ml kalciumhypoklorit i ultrarent vatten. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkarvård. Omhändertagas som industriavfall. Små mängder CyChlor kan kasseras via ett oregebandat avlopp. Förvaras vid högst 40°C. Får ej frysas.

• 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.

• Filtered to 0.22 microns in a Grade B cleanroom.

• Contact times: Bacteria 3 mins
Yeast 3 mins

• For professional use only.

EN13697
EN13697

1 LITRE

Product Code FBC100CC

CONTEC
www.contecinc.com

Supplier

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Biocide Registration Number: German: N-75408

Manufactured in the UK by Contec Cleanroom (UK) Ltd

EN 100ml contains 0.05ml 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 CyChlor can be disposed of via a foul drain. Store at temperatures not exceeding 40°C. Do not freeze.

FR 100 ml de produit contenant 0,05 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. Eliminer comme tout déchet industriel ordinaire. Le rejet de petites quantités de CyChlor à l'épuration est toléré. Stocker à une température ne dépassant pas 40°C. Ne pas congeler.

DE 100 ml enthält: 0,05 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 CyChlor können als normales Schmutzwasser entsorgt werden. Bei Temperaturen nicht über 40°C lagern. Nicht einfrieren.

ES 100 ml contienen: 0,05 ml de hipoclorito de calcio 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 CyChlor mediante un desagüe. Almacenar a temperaturas no superiores a 40°C. No congelar.

I 100 ml contains: 0,05 ml di ipoclorito di calcio in acqua purificata. IN CASO DI CONTATTO CON GLI OCCHI: Sciacquare accuratamente per parecchi minuti. Consultare un medico. Disporre nel modo utilizzato per normali rifiuti industriali. Piccole quantità di CyChlor possono essere smaltite tramite uno scarico fango. Conservare in luogo fresco a temperatura non superiori a 40°C. Non congelare.

RO 100 ml conțin 0,05 ml hipoclorit de calciu în apă purificată. ÎN CAZ DE CONTACT CU OCHI: Clătiți cu atenție cu apă timp de mai multe minute. A se elimina deșeurile deșeurilor industriale normale. Cantități mici de CyChlor pot fi eliminate printr-un canal de scurgere. A se depozita la temperatură care nu depășesc 40°C. A nu se congela.

FI 100 ml sisältää 0,05 ml kalsiumhypokloriittia puhdistetussa vedessä. JOS KEMIKAALIA JOUTUU SILMIIN: Huuhdo huuhdellaaksesi vedellä useita minuuttia ajan, hakeudu lääkärin. Hävittäkään kuten normaali teollisuusjätettä. Pieniä määriä CyChloria voidaan hävittää huuvuveden kautta. Varastoi alle 40°C lämpötilassa. Ei saa jäätelyä.

DA 100 ml indeholdende 0,05 ml kalciumhypochlorit i ultra rent vand. VED KONTAKT MED ØJNE: Skyl forsigtigt med vand i flere minutter. Sørg lægehjælp. Børnskaffes som normalt, indstøbt af fald. Små mængder CyChlor kan bortskaffes via et dækket afløb. Opbevares ved en temperatur, som ikke overstiger 40°C. Må ikke nedfryses.

SV 100 ml innehåller 0,05 ml kalsiumhypoklorit i ultrarent vatten. VID KONTAKT MED ÖGONEN: Skölj försiktigt med vatten i flera minuter. Sök läkare. Omhändertagas som industrifäll. Små mängder CyChlor kan kasseras via ett oregelbundet avlopp. Förvaras vid högst 40°C. Får ej frysas.



NON STERILE CONTEC CYCHLOR 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.
- Filtered to 0.22 microns in a Grade B cleanroom.
- Contact times: Bacteria 3 mins
Yeast 3 mins
- For professional use only.

001 of 500 LAB114/01

5 LITRE

Product Code **FBC500CC**

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Emergency telephone Chemtrecc® +1-703-527-3887

Biocide Registration Number: German: N-75408

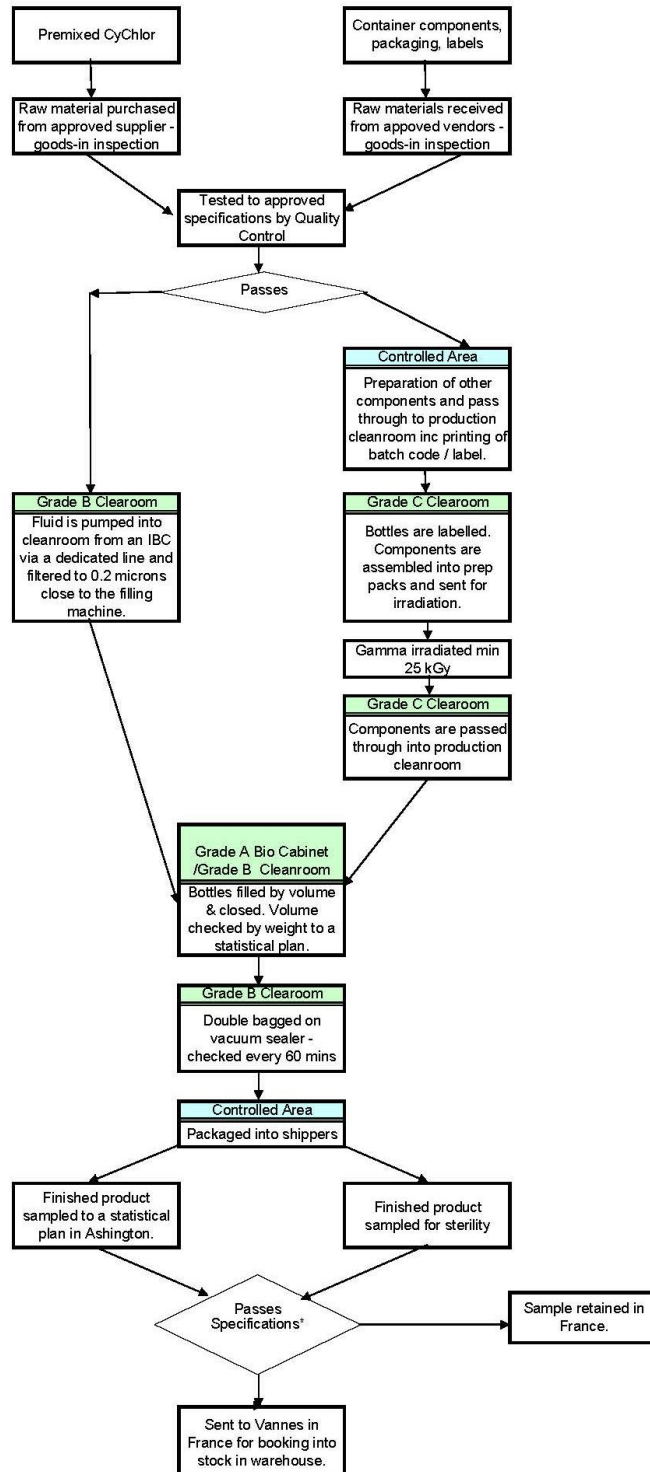
Manufactured in the UK by Contec Cleanroom (UK) Ltd

Section 7

Production Process – Sterile CyChlor

Contec *Sterile* CyChlor 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* CyChlor

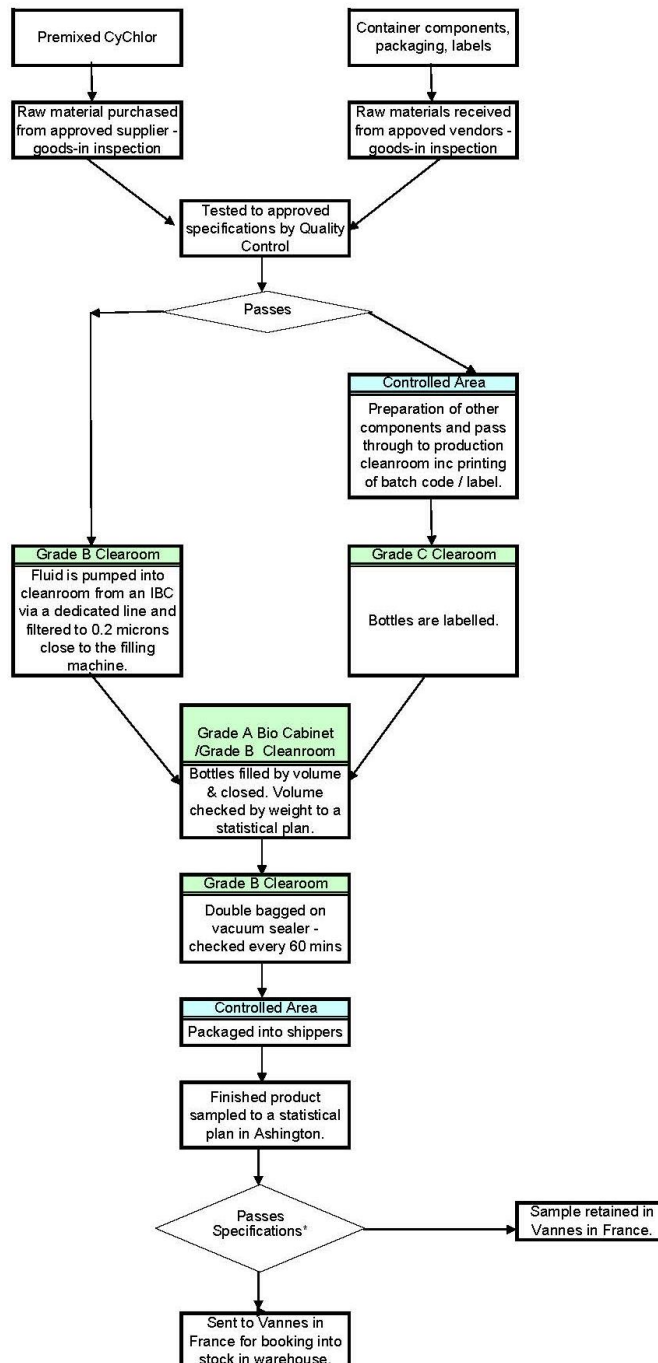


* Should there be a QC failure at any point in the production process, the product is quarantined for investigation and disposal

Production Process – Filtered CyChlor

Contec CyChlor 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 CyChlor



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

Section 8

SDS

Included in this section is the SDS for Contec Sterile 1L Trigger and 5L Capped product. The SDSs for the other product codes are exactly the same and can be found on the Contec website www.contecinc.com. Additional languages are available on the website or please contact your local representative for copies.

Personal Protective Equipment

Even though Contec CyChlor 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 CyChlor has an odour which may build up over time when used continuously. Good ventilation in the area in which CyChlor is being used will prevent this build up.

There are no exposure limits for Contec CyChlor, 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.

Hand Protection

Nitrile or latex gloves should be worn when handling CyChlor. Section 10 shows there is no breakthrough of Contec ProChlor through nitrile or latex gloves for up to 4 hours, as Contec ProChlor is a higher concentration of hypochlorous acid than Contec CyChlor this work can be carried over.

Eye Protection

Safety glasses should be worn.

Skin Protection

Protective clothing such as a lab coat should be worn.



SAFETY DATA SHEET
CONTEC STERILE CYCHLOR 1L AND 5L

Page: 1
Compilation date: 08/01/2018
Revision date: 15/06/2018
Revision No: 2

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

1.1. Product identifier

Product name: CONTEC STERILE CYCHLOR 1L AND 5L
Product code: SBT100CC SBC500CC

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

Use of substance / mixture: Biocidal Product PT-02

1.3. Details of the supplier of the safety data sheet

Company name: Contec Inc.
525 Locust Grove
Spartanburg
South Carolina
29303
USA
Tel: +33 (0) 2 97 43 76 98
Email: sds@contecinc.com

1.4. Emergency telephone number

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

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: This product has no classification under CLP.

2.2. Label elements

Label elements: This product has no label elements.

2.3. Other hazards

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

Section 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients:

SAFETY DATA SHEET
CONTEC STERILE CYCHLOR 1L AND 5L

Page: 2

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%

Non-classified ingredients:

WATER

EINECS	CAS	PBT / WEL	CLP Classification	Percent
-	7732-18-5	-	-	>90%

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.

Ingestion: Wash out mouth with water.

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

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 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.

[cont...]

SAFETY DATA SHEET
CONTEC STERILE CYCHLOR 1L AND 5L

Page: 3

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

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

6.4. Reference to other sections

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

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: Ensure there is sufficient ventilation of the area.

7.2. Conditions for safe storage, including any incompatibilities

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

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: Respiratory protection not required.

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: Perceptible odour

Solubility in water: Miscible

Boiling point/range°C: No data available.

Melting point/range°C: No data available.

Flammability limits %: lower: Not applicable.

[cont...]

SAFETY DATA SHEET
CONTEC STERILE CYCHLOR 1L AND 5L

Page: 4

Flash point°C: Not applicable.	upper: Not applicable.
Autoflammability°C: No data available.	Part.coeff. n-octanol/water: No data available.
Relative density: No data available.	Vapour pressure: No data available.
VOC g/l: No data available.	pH: 4

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: Direct sunlight. Heat.

10.5. Incompatible materials

Materials to avoid: Not applicable.

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
-----	-----	------	-----------

Excluded hazards for substance:

Hazard	Route	Basis
Acute toxicity (ac. tox. 4)	-	No hazard: calculated
Acute toxicity (ac. tox. 3)	-	No hazard: calculated
Acute toxicity (ac. tox. 2)	-	No hazard: calculated

[cont...]

SAFETY DATA SHEET
CONTEC STERILE CYCHLOR 1L AND 5L

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Acute toxicity (ac. tox. 1)	-	No hazard: calculated
Skin corrosion/irritation	-	No hazard: calculated
Serious eye damage/irritation	-	No hazard: calculated
Respiratory/skin sensitisation	-	No hazard: calculated
Germ cell mutagenicity	-	No hazard: calculated
Carcinogenicity	-	No hazard: calculated
Reproductive toxicity	-	No hazard: calculated
STOT-single exposure	-	No hazard: calculated
STOT-repeated exposure	-	No hazard: calculated
Aspiration hazard	-	No hazard: calculated

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 data available.

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values: No data available.

12.2. Persistence and degradability

Persistence and degradability: No data available.

12.3. Bioaccumulative potential

Bioaccumulative potential: No 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: Small quantities may be disposed of via a foul drain. 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.

[cont...]

SAFETY DATA SHEET
CONTEC STERILE CYCHLOR 1L AND 5L

Page: 6

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

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

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.

Section 9

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 any 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.

Contec CyChlor Efficacy

Contec CyChlor 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 13697:2015

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

Neutraliser

The neutraliser suitable for use with Contec CyChlor is:

Lecithin	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	<i>E. hirae</i>	5 mins	Log 5
	<i>E. coli</i>	5 mins	Log 5
	<i>P. aeruginosa</i>	5 mins	Log 5
	<i>S. aureus</i>	5 mins	Log 5
EN1650	<i>C. albicans</i>	15 mins	Log 4
	<i>A. Brasiliensis (niger)</i>	15 mins	Log4
EN13697	<i>E. hirae</i>	5 mins	Log 4
	<i>E. coli</i>	5 mins	Log 4
	<i>P. aeruginosa</i>	5 mins	Log 4
	<i>S. aureus</i>	5 mins	Log 4
	<i>C. albicans</i>	15 mins	Log 3
	<i>A. Brasiliensis (niger)</i>	15 mins	Log 3

CyChlor Efficacy Results Pre - Production Batch

Test Lab: MGS Laboratories Reading UK

EN13697 – clean conditions / stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
<i>S.aureus</i>	Log 4	>5.54	1 min	PASS	Dilution neutralisation
<i>E.hirae</i>	Log 4	>5.43	1 min	PASS	Dilution neutralisation
<i>E.coli</i>	Log 4	>5.12	1 min	PASS	Dilution neutralisation
<i>P.aeruginosa</i>	Log 4	>5.48	3 mins	PASS	Dilution neutralisation
<i>C.albicans</i>	Log 3	3.12	1 min	PASS	Dilution neutralisation

Further test work was carried out on production samples at the end of shelf life.

CyChlor Efficacy Results Production Batch

Test Lab: MGS Laboratories, UK

EN1276 – clean conditions (after 24 weeks storage at 40°C)

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
<i>S.aureus</i>	Log 5	> 5.34	3 mins	PASS	Dilution neutralisation
<i>E.hirae</i>	Log 5	> 5.26	3 mins	PASS	Dilution neutralisation
<i>E.coli</i>	Log 5	> 5.30	3 mins	PASS	Dilution neutralisation
<i>P.aeruginosa</i>	Log 5	> 5.24	3 mins	PASS	Dilution neutralisation

EN1650 – clean conditions (after 24 weeks storage at 40°C)

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
<i>C.albicans</i>	Log 4	> 4.12	3 mins	PASS	Dilution neutralisation

EN13697 – clean conditions / stainless steel (after 12 weeks storage at 40°C)

Test Lab: MGS Laboratories Reading UK

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
<i>S.aureus</i>	Log 4	4.00	3 mins	PASS	Dilution neutralisation
<i>E.hirae</i>	Log 4	5.43	3 mins	PASS	Dilution neutralisation
<i>E.coli</i>	Log 4	>5.16	3 mins	PASS	Dilution neutralisation
<i>P.aeruginosa</i>	Log 4	>5.65	3 mins	PASS	Dilution neutralisation
<i>C.albicans</i>	Log 3	4.36	3 mins	PASS	Dilution neutralisation

Conclusion

Tests carried out against the standard EN tests for qualification of disinfectants has shown that Contec CyChlor is a fast-acting broad spectrum disinfectant, effective in 3 minutes against **bacteria and yeasts**.

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.

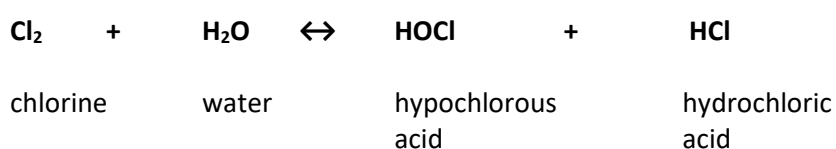
For each of the mechanisms described above the effectiveness of each disinfecting agent is a function of both its rate of diffusion through the cell wall and its reactivity with the cell wall, proteins and nucleic acid.

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 at penetrating the organisms cell wall. It also reacts more rapidly than other chlorine based disinfectants to oxidation reactions with organic matter, ie the critical components of microbial cells.

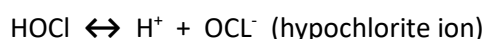
Conversely, the hypochlorite ion is a relatively poor disinfectant because of its inability to diffuse through the cell wall. Since it is negatively charged it is electrostatically repelled from the cell walls which are also negatively charged. It is much larger in size than an HOCl molecule so it also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

Chlorine chemistry

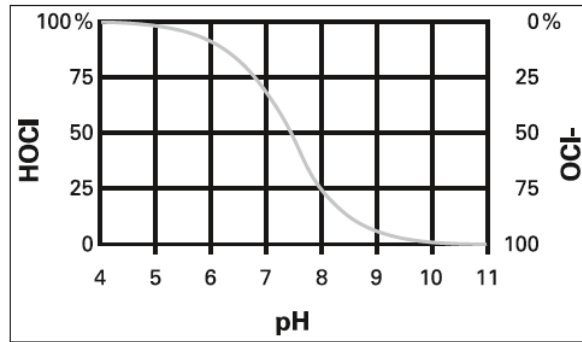
Chlorine is added to water in one of three forms: elemental chlorine (chlorine gas), sodium hypochlorite solution or calcium hypochlorite powder (high-test hypochlorite). Chlorine gas reacts rapidly with water to form two compounds - hypochlorous acid (HOCl) and hydrochloric acid (HCl).



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



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 Cl₂.



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.

Section 10

Compatibility

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

Cleanroom Materials

Contec CyChlor 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 CyChlor against a variety of cleanroom materials

Summary

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

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 3 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 CyChlor assay – 673ppm / pH 4.40

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 apart from the silicone gasket showed surface salt residue build up and an increase of the weight of the material from the start. On all samples the surface salt could be removed with IPA.

316 stainless steel – removed salt but some deposits left behind.

With the exception of the aluminium and silicone gasket, after the salt had been removed, water staining could still be seen.

The changes in weight noted is likely due to the deposit of salt on the surface of the materials over the duration of the test whilst using Contec CyChlor, salt deposits were visible on all the large square samples. Water staining was also noticeable on the water controls.

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

Spray and wipe dry

All samples showed no increase in weight.

All samples showed no build up of salt.

All samples showed no water staining.

Conclusion

It is already known that Contec CyChlor 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 3-week period.

In contrast continuous spraying on the materials resulted in different results. The salt was visibly present from even after a week on the stainless steel samples although after the 3 weeks this salt residue could be still be removed from all surfaces using IPA.

The overall conclusion is that Contec CyChlor is compatible with all the above materials if used for the stated contact time. If sprayed onto the surface and not removed immediately a salt will form on the surface which can be removed if wiped with IPA after 3 weeks. A best practice routine of apply and wipe dry eliminated any potential salt build up or water staining.

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. Contec ProChlor is a higher concentration solution than CyChlor so the work can be carried over.

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

Sterile Nitrile Gloves Test Report CP261114A/HK

Date 15/12/14

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)

Sterile Latex Gloves Test Reports CP261114B/HK

Date 15/12/14

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 & discoloured

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

Sterile Polychloroprene Gloves Test Reports CP261114C/HK

Date 15/12/14

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 to 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.

This conclusion can also be carried over to Contec CyChlor which is the same formulation at a lower concentration.

Section 11

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 CyChlor is 99% purified water and leaves a very low level of residue on a surface.

Any residue which is left is free rinsing and can be easily removed with either water or alcohol. Contec CyChlor 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 CyChlor.

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	1,484ppm
Sample 2	1,492ppm
Sample 3	1,512ppm
Sample 4	1,407ppm
Average	1,474ppm

The average residue on evaporation for 100ml CyChlor was 1,474ppm.

Conclusion

Contec CyChlor will leave a small residue on a surface which is free rinsing and easily removed with either alcohol or water, if removed immediately. If CyChlor 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.

A result of 1,474ppm 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 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 CyChlor has an un-opened shelf life of 12 months from date of manufacture. Contec CyChlor has an in-use shelf life of 6 months.

Originally shelf work was carried out using accelerated testing on trial samples. The work was carried out on the sterile product which can be carried over to the filtered product.

R and D and production trial samples have also been put on ambient testing, when available the data will be added to the file.

Unopened Shelf Life Validation

Accelerated shelf life studies

In order to assess new products for shelf life testing accelerated aging needs to be carried out. The product was stored at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 12 weeks which equates to a shelf life of 12 months at ambient temperature. This is based on the EMEA "Guidelines on Stability Testing".

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.

R and D Testing

Product Code SBT100CC / SBC500CC Batch S1072

Three trial samples of 1L trigger spray and 5L capped product were put on accelerated shelf life testing for both 1L and 5L product. The storage temperature was maintained at 40°C . The bottles remained closed for the duration of the test.

The starting specification of the sample was:-

Test	Specification	Result 1L	Result 5L
Specific Gravity @20°C	0.990 – 1.010	0.999	1.000
pH	3.0 – 6.0	4.40	4.40
Available chlorine	>300ppm	673ppm	673ppm
Colour	Colourless	Colourless	Colourless
Odour	Slight chlorine	Slight chlorine	Slight chlorine

Chemical results after 12 weeks storage at 40°C – 1L product

Sample	pH	Available Cl ₂ ppm	Colour	Odour	S.G
Bottle 1	3.31	390	Colourless	Chlorine	0.999
Bottle 2	3.29	390	Colourless	Chlorine	0.999
Bottle 3	3.29	390	Colourless	Chlorine	0.999

Chemical results after 12 weeks storage at 40°C – 5L product

Sample	pH	Available Cl ₂ ppm	Colour	Odour	S.G
Bottle 1	3.31	464	Colourless	Chlorine	1.000
Bottle 2	3.29	464	Colourless	Chlorine	1.000
Bottle 3	3.29	464	Colourless	Chlorine	1.000

Efficacy testing

One of the key items to check is that the efficacy of the product has not been affected over the shelf life period. The chemical testing showed all chemical parameters had remained within specification but full EN testing of efficacy was also carried out.

EN1276 – clean conditions after 24 weeks at 40°C

Test Lab: MGS Laboratories UK

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
<i>S.aureus</i>	Log 5	> 5.34	3 mins	PASS	Dilution neutralisation
<i>E.hirae</i>	Log 5	> 5.26	3 mins	PASS	Dilution neutralisation
<i>E.coli</i>	Log 5	> 5.30	3 mins	PASS	Dilution neutralisation
<i>P.aeruginosa</i>	Log 5	> 5.24	3 mins	PASS	Dilution neutralisation

EN1650 – clean conditions after 24 weeks at 40°C

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
<i>C.albicans</i>	Log 4	> 4.12	3 mins	PASS	Dilution neutralisation

EN13697 – clean conditions / stainless steel after 24 weeks at 40°C

Test Lab: MGS Laboratories UK

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
<i>S.aureus</i>	Log 4	>5.94	3 mins	PASS	Dilution neutralisation
<i>E.hirae</i>	Log 4	>5.88	3 mins	PASS	Dilution neutralisation
<i>E.coli</i>	Log 4	>5.30	3 mins	PASS	Dilution neutralisation
<i>P.aeruginosa</i>	Log 4	>5.63	3 mins	PASS	Dilution neutralisation
<i>C.albicans</i>	Log 3	4.28	3 mins	PASS	Dilution neutralisation

In-use Shelf Life Validation

Due to fact that standard trigger spray bottles pull return air into the sterile fluid many cleanroom trigger spray systems work as a 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 their sterile trigger sprays. As the system is the same for all sterile bottles the test work was carried out on an IPA solution which has the least effect on spores if any were to potentially get pulled into the bottle.

Method

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

Every day for the working week, the trigger was depressed 5 times to dispense the alcohol and the bottle was weighed before and after. The first weighing of the bottle determined the initial weight.

Once the bottle became 30% of the initial weight the trigger nozzle was closed and the bottle was sent to an external laboratory. This was after 6 months of use. The bottle contents were tested for sterility (according to the current version of the European Pharmacopoeia).

Results

The 70% Isopropanol had remained sterile.

Conclusion

Unopened shelf life

Contec CyChlor can be given an un-opened shelf life of 12 months.

It is stable and remains efficacious over a 12 month period as demonstrated by 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 efficacious with a contact time of 3 mins.

Efficacy testing carried out on product which had been on accelerated aging passed against all required organisms against EN13697 surface test in 3 min. This show there has been no degradation in efficacy at the end of shelf life.

In-use shelf life

Contec CyChlor 1L trigger sprays can be given an in-use shelf life of 6 months. It is unlikely that a product would be in-use for any longer than this in a cleanroom environment.

Contec CyChlor 1L trigger sprays use the same system as the Contec Sterile IPA 1L which was tested to show the product remained sterile in use over a 6 month period.