Contec® Sterile IPA

Product Code

SBT0570IW
SBT170IW
SBC570I

CONTEC

Europe - France
RP 3707 - 56037 VANNES Cedex
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www.contecinc.com

Contec® Sterile IPA

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SBT170IW
SBC570I

Contents

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 twenty five 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

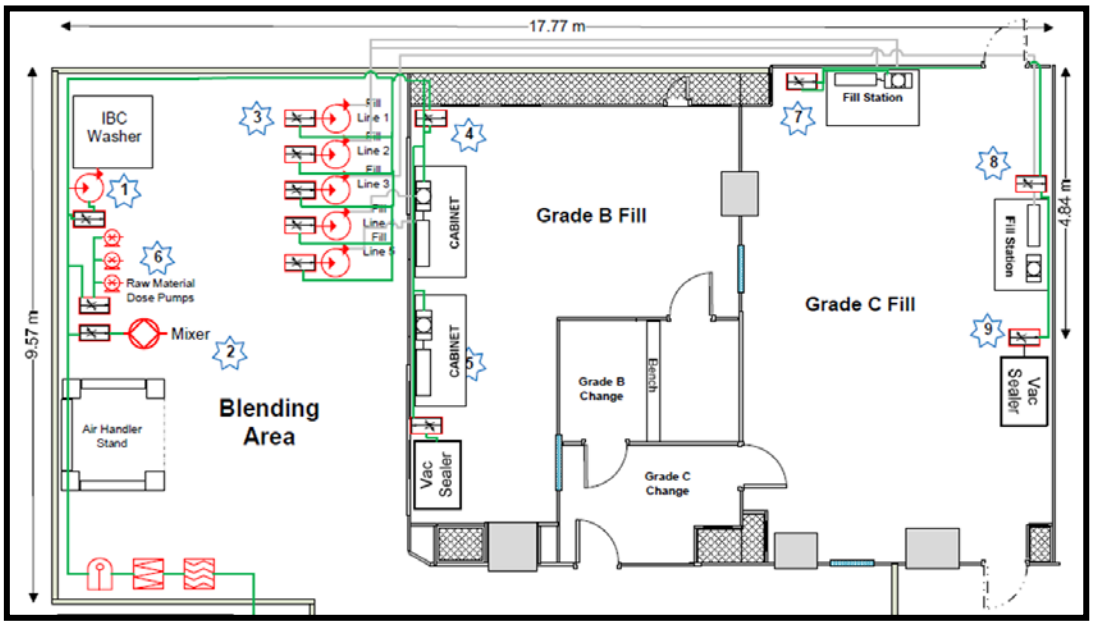
Contec France

Ashington Manufacturing Plant

Contec's bottled disinfectants and European alcohols are filled at Contec's new production facility in Ashington, in 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 including Contec *Sterile* ProChlor. Contec *Sterile* HydroPure and non sterile Contec ProChlor 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 9001:2008 accredited. Copies of the most recent certificates which confirm our compliance are in this section. ISO 9001:2008 revises the previous ISO 9001:2000 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). 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's dossier for all products containing 70% IPA (propan-2-ol) was submitted before the BPR deadline 1st July 2016 and is now under review by the Member State Competent Authority (MSCA) for the UK before continuing to the Biocidal Products Committee (BPC) for ECHA.

July 19, 2016

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. 4)

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,

Champagne Inthavongsa
Contec, Inc.
Sr. Quality Supervisor
Office: 864-699-8271
Email: cinthavongsa@contecinc.com

Contec, Inc.
P.O. Box 530
Spartanburg, SC 29304

tel: +1-864-503-8333
toll free: 1-800-289-5762
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 15, Bolam Business Park, Bassington Drive,
Cramlington, Northumberland, NE23 8AL, UK

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Manufacture of disinfectant and cleaning products for critical environments.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 01 July 2015 until 01 July 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 18 May 2018
Issue 1. Certified since 01 July 2015

Authorised by

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

SGS 9001-8 01 0614

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UKAS MANAGEMENT SYSTEMS
0005

This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at http://www.sgs.com/en/Our-Company/Certified-Client-Directories/Certified-Client-Directories.aspx. Any 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.

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

America

CERTIFICATE

The Certification Body of
TÜV SÜD AMERICA INC.

hereby certifies that

CONTEC
Contec, Inc.
525 Locust Grove
Spartanburg, SC 29303 USA

(see page 2 for additional locations)

has implemented a Quality Management System in accordance with:

ISO 9001:2008

The scope of this Quality Management System includes:

Design, Manufacture and Distribution of Textile and Pre-Saturated Products for use in the Semiconductor, Microelectronics, Pharmaceutical, Medical Device and other Clean Room Environments. Design, Manufacture and Distribution of Specialty Products used in Industrial Surface Preparation Applications for Aerospace and other Industries. Design, Manufacture and Distribution of Surface Preparation and Surface Finishing Products used in Automotive Assembly Plants and the Automotive Aftermarket. The Distribution of Products used in Clean Rooms.

Certificate Expiry Date: October 24, 2017

Certificate Registration No: 950 99 0586

Effective Date: October 25, 2014

Gary W. Minks
VP, Regulatory Affairs

ANAB ACCREDITED

TÜV SÜD AMERICA INC • 10 Centennial Drive • Peabody, MA 01960 USA • www.TUVamerica.com TÜV®

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

Organization Code 77867594-9

has been assessed and certified as meeting the requirements of

ISO 9001:2008

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 9001:2008 requirements may be obtained by consulting the organization

This certificate is valid from 15 February 2016 until 15 September 2018
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 5. Certified since 15 February 2007

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
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

UKAS MANAGEMENT SYSTEMS
0005

SGS 9001-8 01 0614

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Section 2
Product Overview – Contec *Sterile* IPA

Contec *Sterile* IPA is blend of 70% v/v Isopropanol with 30% water for injection or purified water.

The alcohol blend is 0.2 micron filtered, filled and bagged in a Grade C (ISO Class 7) cleanroom. This clean manufacture coupled with the water for injection or purified water means the alcohol blend is guaranteed to have an endotoxin level of less than 0.25EU / ml.

Contec sterile alcohol is provided sterile by gamma irradiated using a validated process at no less than 25 kGy.

Supplied as 0.5L or 1L trigger sprays fitted with a protected system, which ensures sterility throughout use, or 5L capped container for larger areas.

Feature	Benefit
Guaranteed endotoxin levels of <0.25EU/ml	Suitable for use in product contact areas
GMP manufactured under Grade A air flow in a Grade C cleanroom	Ensures the alcohol, container and packaging are free from contamination and particulates
Alcohol “flashes off”	Completely residue free
Trigger spray and “bag in bottle” protected system	Prevents bottle contents from becoming contaminated during use
	Bottles can be completely emptied eliminating wastage so no need to discard unused product during shelf life
Trigger spray can be set to jet or spray	Large droplet size reduces the risk of inhalation and provides good surface coverage
Double/triple bagged packed in linear tear packaging	Each bag is easy to open even when wearing gloves
	Facilitates transfer disinfection into cleanroom
Sterile via gamma irradiation	Suitable for use in Grade A and B cleanrooms

Part No.	Name	Description	Packaging
SBT0570IW	Contec *Sterile* IPA	Sterile 70% IPA in water for injection 0.5L Trigger Spray	8 x 0.5L
SBT170IW	Contec *Sterile* IPA	Sterile 70% IPA in water for injection 1L Trigger Spray	6 x 1L
SBC570I	Contec *Sterile* IPA	Sterile 70% IPA in purified water 5L Capped	2 x 5L

Product Specification 0.5L and 1L Trigger Spray

Product Name		Contec *Sterile* IPA
Product Description		Sterile 70% Isopropanol in water for injection
Product Code		SBT0570IW 0.5L Trigger Spray x 8 SBT170IW 1L Trigger Spray x 6
Product Specification		
	Colour	Colourless
	Clarity	Clear
	Specific Gravity @ 20°C	0.868 to 0.878
	Endotoxin level	Less than 0.25 EU/ml
	Production	0.2 micron filtered under Grade A airflow in a Grade C cleanroom
	Packaging	Adjustable trigger spray on HDPE bottle (protected trigger spray system) Triple packed in polyethylene linear tear packaging 0.5L 8 bottles per double walled cardboard box 1L 6 bottles per double walled cardboard box
	Sterility	Sterilised by gamma irradiation at no less than 25 kGy
	Shelf Life	Unopened: 3 years from date of manufacture In-use: 6 months

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

Product Specification 5L Capped

Product Name		Contec *Sterile* IPA
Product Description		Sterile 70% IPA in purified water (EP)
Product Code		SBC570I 5L Capped x 2
Product Specification		
	Colour	Colourless
	Clarity	Clear
	Specific Gravity @ 20°C	0.868 to 0.878
	Endotoxin level	Less than 0.25 EU/ml
	Sterility	Gamma irradiated at no less than 25 kGy
	Production	0.2 micron filtered in a Grade C cleanroom
	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: 3 years from date of manufacture

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

Section 3
Product Certificates

Contec® ***Sterile*** **IPA** 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 IPA
Product Code:	SBT0570IW
Product Description:	Sterile 70% Isopropanol in water for injection 0.5L Trigger Spray
Batch Number:	
Manufacture Date:	MON / YYYY
Expiry Date:	MON / YYYY

ANALYSIS

Test	Specification	Results
Colour:	Colourless	
Clarity:	Clear	
Filtration:	Filtered to 0.2 microns	
Endotoxins:	<0.25 EU/ml	
SG at 20°C:	0.868 to 0.878	

Manufactured product via a Quality System certified to ISO 9001:2008, tested in accordance with documented quality procedures and approved when required specifications are met.

IRRADIATION

Irradiation certificate number:	xxxxxxxxxxx	
Irradiation Dose (kGy):	> 25 kGy	> xx.x

We certify that the notified goods have undergone irradiation by exposure to γ (Gamma) irradiation with an exposure of not less than 25 kGy to conform to the European Pharmacopoeia.

Irradiation treatment applied was accordance with:

ISO 9001:2008	Quality Management System
ISO 13485:2012	Quality Management System – Medical Devices
ISO 11137:2006	Sterilisation of Healthcare Products – Requirements for Validation & Routine Control – Radio-sterilisation

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: Declan O'Connor
Position:	1: Quality Manager	2: QC Supervisor
Date:	1:	2:
Authorised Signature:	1:	2:

For and on behalf of Contec Inc

COA31 Rev 1

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

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

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

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

www.contecinc.com infoeu@contecinc.com

PRODUCT CERTIFICATE

Product:	Contec Sterile IPA
Product Code:	SBT170IW
Product Description:	Sterile 70% Isopropanol in water for injection 1L Trigger Spray
Batch Number:	
Manufacture Date:	MON / YYYY
Expiry Date:	MON / YYYY

ANALYSIS

Test	Specification	Results
Colour:	Colourless	
Clarity:	Clear	
Filtration:	Filtered to 0.2 microns	
Endotoxins:	<0.25 EU/ml	
SG at 20°C:	0.868 to 0.878	

Manufactured product via a Quality System certified to ISO 9001:2008, tested in accordance with documented quality procedures and approved when required specifications are met.

IRRADIATION

Irradiation certificate number:	xxxxxxxxxxx	
Irradiation Dose (kGy):	> 25 kGy	> xx.x

We certify that the notified goods have undergone irradiation by exposure to γ (Gamma) irradiation with an exposure of not less than 25 kGy to conform to the European Pharmacopoeia.

Irradiation treatment applied was accordance with:

ISO 9001:2008	Quality Management System
ISO 13485:2012	Quality Management System – Medical Devices
ISO 11137:2006	Sterilisation of Healthcare Products – Requirements for Validation & Routine Control – Radio-sterilisation

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: Simon Csaba
Position:	1: Quality Manager	2: QC Supervisor
Date:	1:	2:
Authorised Signature:	1:	2:

For and on behalf of Contec Inc

COA13 Rev 3

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

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

Europe
Contec Inc
ZI du Prat RP 3707
56037 VANNES
France

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

www.contecinc.com
infoeu@contecinc.com

PRODUCT CERTIFICATE

Product:	Contec Sterile IPA
Product Code:	SBC570I
Product Description:	Sterile 70% Isopropanol in purified water (EP) 5L Capped
Batch Number:	
Manufacture Date:	MON / YYYY
Expiry Date:	MON / YYYY

ANALYSIS

Test	Specification	Results
Colour:	Colourless	
Clarity:	Clear	
Filtration:	Filtered to 0.2 microns	
Endotoxins:	<0.25 EU/ml	
SG at 20°C:	0.868 to 0.878	

Manufactured product via a Quality System certified to ISO 9001:2008, tested in accordance with documented quality procedures and approved when required specifications are met.

IRRADIATION

Irradiation certificate number:	xxxxxxxxxxx	
Irradiation Dose (kGy):	> 25 kGy	> xx.x

We certify that the notified goods have undergone irradiation by exposure to γ (Gamma) irradiation with an exposure of not less than 25 kGy to conform to the European Pharmacopoeia.

Irradiation treatment applied was accordance with:

ISO 9001:2008	Quality Management System
ISO 13485:2012	Quality Management System – Medical Devices
ISO 11137:2006	Sterilisation of Healthcare Products – Requirements for Validation & Routine Control – Radio-sterilisation

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: Neil Simpson	2: Simon Csaba
Position:	1: Quality Manager	2: QC Supervisor
Date:	1:	2:
Authorised Signature:	1:	2:

For and on behalf of Contec Inc

COA014 Rev 2

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

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

Europe
Contec Inc
Zi du Prat RP 3707
56037 VANNES
France

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

www.contecinc.com
infoeu@contecinc.com

Section 4
Instructions for Use

Contec® *Sterile* IPA 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 *Sterile* IPA 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.

Alternatively apply Contec *Sterile* IPA directly to the surface. Ensure the surface is uniformly covered with the solvent then wipe to dry with a Contec sterile cleanroom wipe or mop. Wiping will also optimise the physical removal of contaminants from the surface.

Storage Conditions

Contec *Sterile* IPA must be stored in the original packaging. Do not freeze. Store below 40°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.

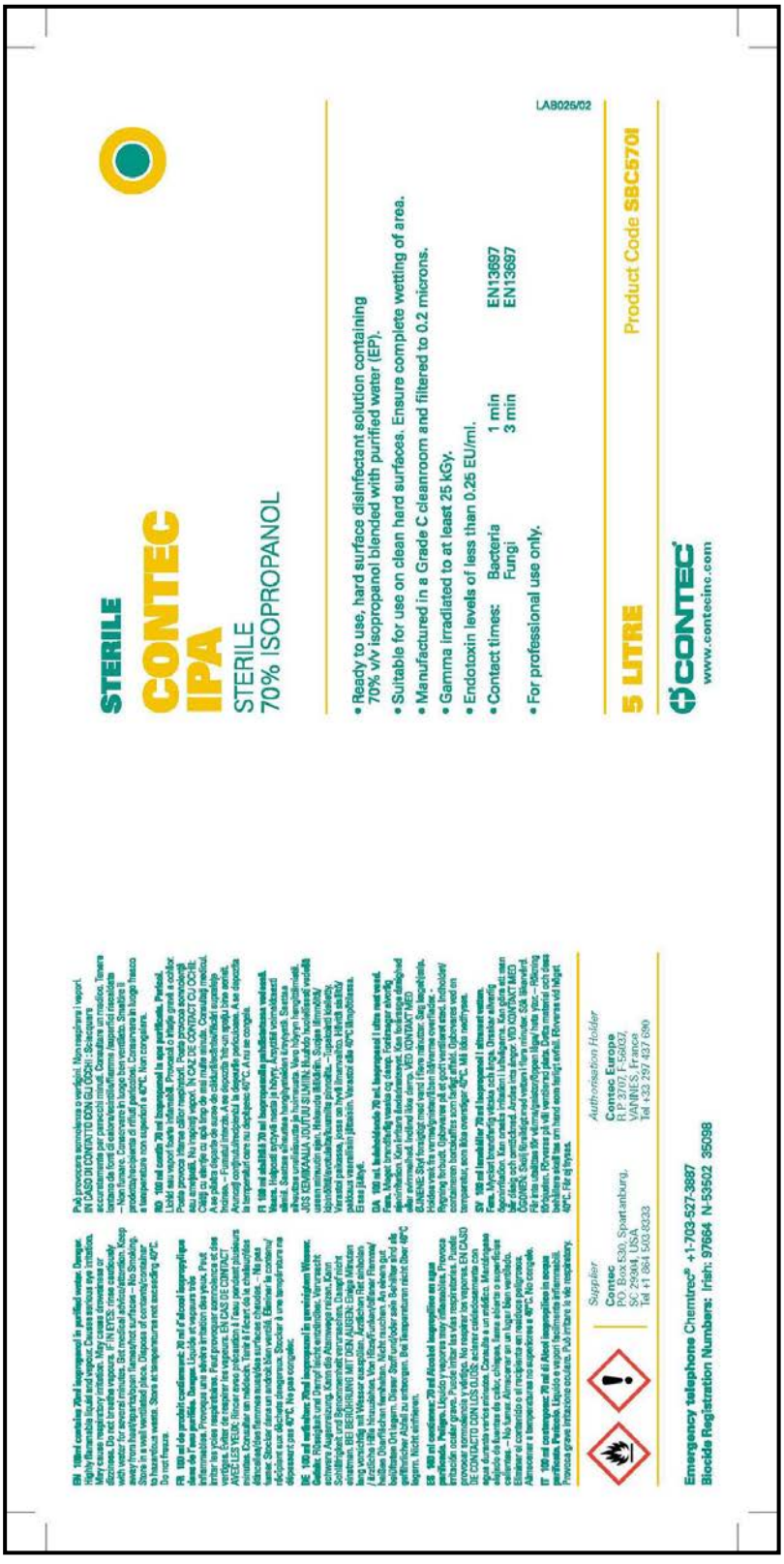
Each active ingredient is colour coded. The roundel carries the colour representing the active ingredient and either a green or blue dot to signify whether the product is sterile or filtered. Dark blue signifies a filtered product and green signifies a sterile product.

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* IPA with water for injection 0.5L

Contec *Sterile* IPA with water for injection 1L

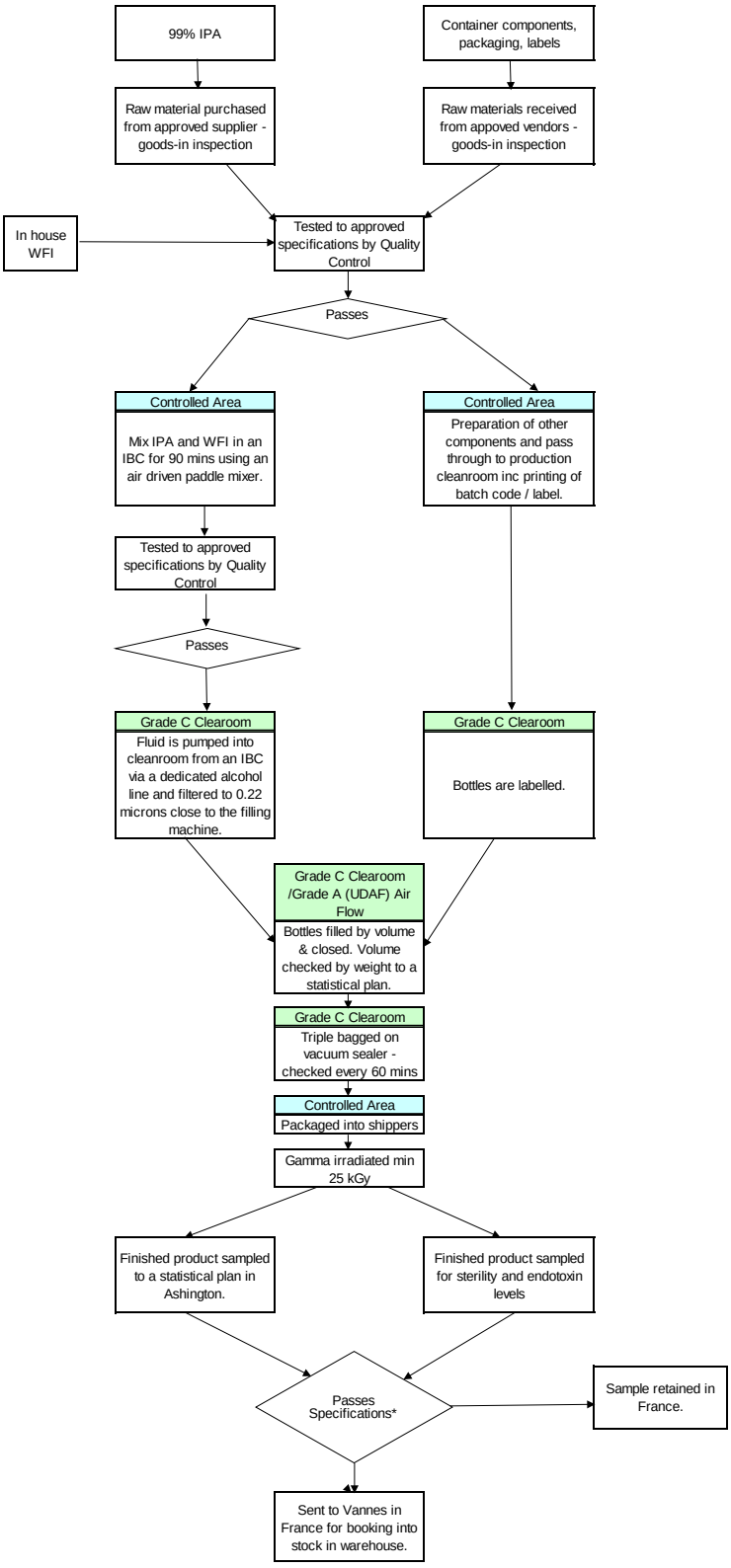


Contec *Sterile* IPA with purified water 5L

Section 6
Production Process

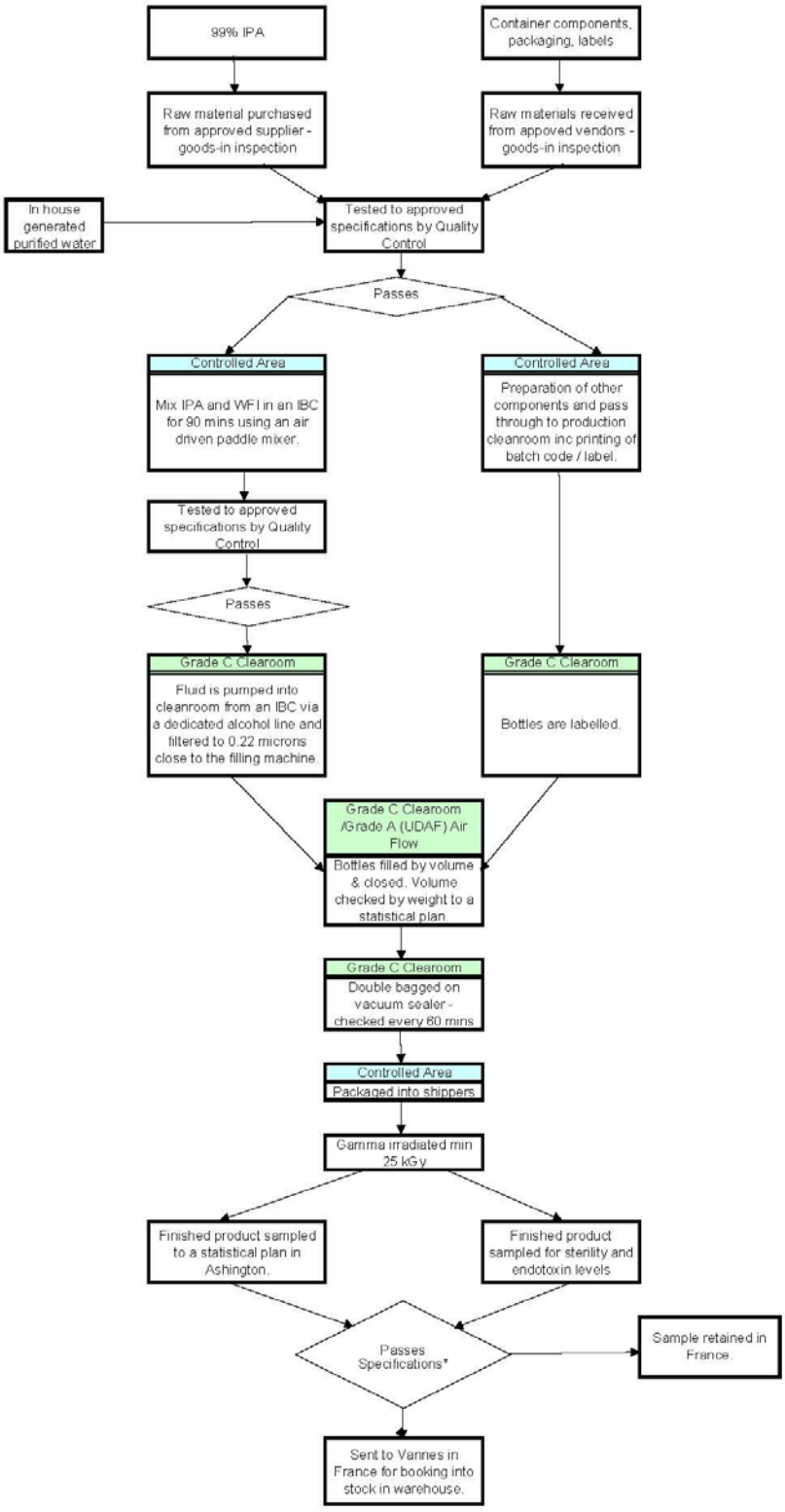
Contec *Sterile* IPA is filtered to 0.2 micron under Grade A airflow in a Grade C cleanroom, before gamma irradiation at no less than 25 kGy

Production Process Flow Chart Contec® 70% Sterile IPA with WFI



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

Production Process Flow Chart Contec® 70% Sterile IPA



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

Section 7
SDS

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

SAFETY DATA SHEET

CONTEC STERILE 70% IPA WITH WFI 500mL AND 1L

Compilation date: 02/08/2015

Revision date: 25/04/2016

Revision No: 3

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

1.1. Product identifier

Product name: CONTEC STERILE 70% IPA WITH WFI 500mL and 1L

Product code: SBT0570IW / SBT170IW

Synonyms: PROPAN-2-OL

ISOPROPANOL

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). PC35: Washing and cleaning products (including solvent based products).

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: Flam. Liq. 2: H225; Eye Irrit. 2: H319; STOT SE 3: H336; STOT SE 3: H335

Most important adverse effects: Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. May cause respiratory irritation.

2.2. Label elements

Label elements:

Hazard statements: H225: Highly flammable liquid and vapour.

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness.

H335: May cause respiratory irritation.

Signal words: Danger

Hazard pictograms: GHS02: Flame

GHS07: Exclamation mark

[cont...]

Precautionary statements: P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P243: Take precautionary measures against static discharge.

P370+378: In case of fire: Use dry chemical, carbon dioxide to extinguish.

P280: Wear protective gloves, protective clothing and eye protection.

P261: Avoid breathing mist/vapours/spray.

P403+233: Store in a well-ventilated place. Keep container tightly closed.

P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+313: If eye irritation persists: Get medical advice/attention.

P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304+341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312: Call a POISON CENTER/doctor//if you feel unwell.

2.3. Other hazards

Other hazards: Highly flammable. Irritating to eyes. Irritating to respiratory system. May cause sensitisation by skin contact. May cause sensitisation by inhalation.

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

Section 3: Composition/information on ingredients

3.2. Mixtures

Non-classified ingredients:

PROPAN-2-OL

EINECS	CAS	CHIP Classification	CLP Classification	Percent
200-661-7	67-63-0	-	Flam. Liq. 2: H225; Eye Irrit. 2: H319; STOT SE 3: H336	50-70%

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Remove all contaminated clothes and footwear immediately unless stuck to skin. Drench the affected skin with running water for 10 minutes or longer if substance is still on skin. Get medical attention if irritation develops or persists.

Eye contact: Bathe the eye with running water for 15 minutes. Remove contact lenses, if present and easy to do so. If eye irritation persists, get medical advice/attention.

Ingestion: Do not induce vomiting. Consult a doctor.

[cont...]

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

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

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: Alcohol resistant foam. Carbon dioxide. Dry chemical powder. Water fog. Water spray.

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: Evacuate the area immediately. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Eliminate all sources of ignition.

6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers.

6.3. Methods and material for containment and cleaning up

Clean-up procedures: Absorb into dry earth or sand. Do not use equipment in clean-up procedure which may produce sparks. 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. Avoid the formation or spread of mists in the air. Earth any equipment used in handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in a cool, well ventilated area. Keep away from sources of ignition. Keep container tightly closed. Keep away from direct sunlight. Prevent the build up of electrostatic charge in the immediate area. Avoid incompatible materials and conditions - see section 10 of SDS. Do not freeze. Store below 40°C.

Suitable packaging: Must only be kept in original packaging.

[cont...]

7.3. Specific end use(s)

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

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: **Respirable dust**

State	8 hour TWA	15 min. STEL	8 hour TWA	15 min. STEL
UK	400ppm	500ppm	-	-

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

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

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

Hand protection: Neoprene gloves. Rubber gloves. PVC gloves. Nitrile gloves.

Eye protection: Tightly fitting safety goggles. Face-shield. Ensure eye bath is to hand.

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

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Liquid

Colour: Colourless

Odour: Alcoholic

Boiling point/range°C: 82-89

Melting point/range°C: No data available.

Flammability limits %: lower: 2

upper: 12

Flash point°C: 21

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

Autoflammability°C: 399

Vapour pressure: 43.0hpa @ 20deg C

Relative density: No data available.

pH: 5-6

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.

[cont...]

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.

10.4. Conditions to avoid

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

10.5. Incompatible materials

Materials to avoid: Strong acids. Strong oxidising agents. Halogens.

10.6. Hazardous decomposition products

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

Section 11: Toxicological information

11.1. Information on toxicological effects

Relevant hazards for substance:

Hazard	Route	Basis
Serious eye damage/irritation	OPT	Hazardous: calculated
STOT-single exposure	INH	Hazardous: calculated

Symptoms / routes of exposure

Section 12: Ecological information

12.1. Toxicity

Ecotoxicity values:

Species	Test	Value	Units
DAPHNIA	96H LC50	10000000	µg/l

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: Readily absorbed into soil.

12.5. Results of PBT and vPvB assessment

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

[cont...]

12.6. Other adverse effects

Other adverse effects: No data available.

Section 13: Disposal considerations

13.1. Waste treatment methods

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

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

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

Section 14: Transport information

14.1. UN number

UN number: UN1219

14.2. UN proper shipping name

Shipping name: Isopropanol Solution
(PROPAN-2-OL; WATER)

14.3. Transport hazard class(es)

Transport class: 3

14.4. Packing group

Packing group: II

14.5. Environmental hazards

Environmentally hazardous: No **Marine pollutant:** No

14.6. Special precautions for user

Special precautions: No special precautions.

Section 15: Regulatory information

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

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: H225: Highly flammable liquid and vapour.

H319: Causes serious eye irritation.

[cont...]

H335: May cause respiratory irritation.

H336: May cause drowsiness or dizziness.

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

SAFETY DATA SHEET

CONTEC STERILE 70% IPA 1L AND 5L

Compilation date: 09/03/2015

Revision date: 15/12/2015

Revision No: 4

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

1.1. Product identifier

Product name: CONTEC STERILE 70% IPA 1L AND 5L

Product code: SBT170I / SBC570I

Synonyms: PROPAN-2-OL

ISOPROPANOL

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). PC35: Washing and cleaning products (including solvent based products).

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: Flam. Liq. 2: H225; Eye Irrit. 2: H319; STOT SE 3: H336; STOT SE 3: H335

Most important adverse effects: Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. May cause respiratory irritation.

2.2. Label elements

Label elements:

Hazard statements: H225: Highly flammable liquid and vapour.

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness.

H335: May cause respiratory irritation.

Signal words: Danger

Hazard pictograms: GHS02: Flame

GHS07: Exclamation mark

[cont...]

Precautionary statements: P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P243: Take precautionary measures against static discharge.

P370+378: In case of fire: Use dry chemical, carbon dioxide to extinguish.

P280: Wear protective gloves, protective clothing and eye protection.

P261: Avoid breathing mist/vapours/spray.

P403+233: Store in a well-ventilated place. Keep container tightly closed.

P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+313: If eye irritation persists: Get medical advice/attention.

P303+361+353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304+341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312: Call a POISON CENTER/doctor//if you feel unwell.

2.3. Other hazards

Other hazards: Highly flammable. Irritating to eyes. Irritating to respiratory system. May cause sensitisation by skin contact. May cause sensitisation by inhalation.

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

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Ingestion: Do not induce vomiting. Consult a doctor.

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Flash point°C: 21

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Autoflammability°C: 399

Vapour pressure: 43.0hpa @ 20deg C

Relative density: No data available.

pH: 5-6

VOC g/l: No data available.

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Shipping name: Isopropanol Solution
(PROPAN-2-OL; WATER)

14.3. Transport hazard class(es)

Transport class: 3

14.4. Packing group

Packing group: II

14.5. Environmental hazards

Environmentally hazardous: No **Marine pollutant:** No

14.6. Special precautions for user

Special precautions: No special precautions.

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Section 16: Other information

Other information

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

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[cont...]

H335: May cause respiratory irritation.

H336: May cause drowsiness or dizziness.

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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.

Isopropanol Efficacy

The efficacy of 70% alcohol is well documented. As confirmation Contec *Sterile* IPA 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
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 13697:2001
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 IPA 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	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
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 most facilities alcohol is used for transfer disinfection at short contact times. So, the standard EN surface test EN13697 for bacteria and fungi were carried out at 1 and 3 min contact times.

Contec *Sterile* IPA Efficacy Results Production Batch

EN1276 – clean conditions

Test Lab: Medsa Research, Bridgend, UK

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

EN1650 – clean conditions

Test Lab: ALS Labs, Ely, UK

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

Test House – FDAS, Nottingham, UK

EN13697 – clean conditions / stainless steel

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus*	Log 4	>5.3	1 min	PASS	Dilution neutralisation
E.*hirae*	Log 4	>4.58	1 min	PASS	Dilution neutralisation
E.*coli*	Log 4	>5.78	1 min	PASS	Dilution neutralisation
P.*aeruginosa*	Log 4	>5.75	1 min	PASS	Dilution neutralisation
A.*niger (brasiliensis*)	Log 3	>4.62	3 mins	PASS	Dilution neutralisation
C.*albicans*	Log 3	>5.77	3 mins	PASS	Dilution neutralisation

Conclusion

Alcohols have rapid bactericidal activity against non-sporulating bacteria. As they evaporate at room temperature, they leave no residue and are an ideal broad spectrum disinfectant with efficacy against both gram positive and gram negative bacteria and fungi.

Tests carried out against the standard EN tests for qualification of disinfectants confirms that Contec *Sterile* IPA 70% meets those criteria. The tests were carried out at the standard contact times for the tests in question of 5 mins for bacteria and 15 mins for fungi. Additional work was carried out to validate a shorter contact time and tests against the standard surface test for bacteria and fungi showed activity in 1 min for bacteria and 3 mins for fungi.

Mode of Action

The presence of water is crucial for effectiveness of alcohol as a disinfectant. The most effective concentration is between 50% and 80%. Increasing the concentration to 90% however, does increase the virucidal efficacy of alcohol.

The mode of action of alcohol is two-fold, the ability to denature proteins within the cell and affect the cell membrane of the micro-organism.

Proteins are essential to the function and growth of all living organisms and are involved in all of the necessary functions for life. Alcohols act to change the configuration of these proteins and as such prevent them from performing their specific functions.

Alcohols also work by attacking the cell membrane resulting in cytoplasm leakage and cell lysis. They have the capacity to dissolve lipids which has lytic effect on the membrane of cells. All bacteria employ a bi-lipid phosphoglycerol based membrane structure within cell walls. 70% alcohol solutions lower the surface tension of the cell membrane which allows extracellular water present in the surrounding environment to pass via osmosis through the membrane resulting in bacterial lysis.

Section 9
Materials and their Compatibility

As IPA quickly evaporates off a surface at room temperature there are no reported problems with metals used in cleanrooms such as stainless steel and aluminium. 70% IPA solution is compatible with PVC.

However, alcohol solutions can remove the plasticisers from acrylics over time making them go brittle and potentially crack. Care should be taken with materials such as polypropylene, acrylics and polycarbonates, this tend to be used for windows and screens on isolators and RABS's.

This effect can be minimized by always applying the alcohol solution in a controlled manner such as on a wipe or mop and ensuring it can always evaporate.

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.

One of the significant advantages of alcohol as a disinfectant is the lack of residue that is left behind on a surface, making it especially suitable for product contact areas.

Test work was carried out using a simple residue on evaporation test to show how little residue is left on a surface. The work was carried out on Contec *Sterile* IPA with purified water which will give a representative result for Contec *Sterile* IPA with water for injection.

The EP description for 100% IPA states that it should have a residue on evaporation of less than 20ppm per 100ml.

Residue on evaporation

The European Pharmacopoeia has a residue on evaporation test which was used to test Contec *Sterile* IPA.

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

The sample tested, production batch 110900290 had a residue per 100ml of 0 ppm.

Conclusion

Contec *Sterile* IPA leaves very little to no residue on a surface. The result of 0ppm is within specification for IPA (EP).

Section 11
Irradiation Validation

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

In order to shorten leadtimes and maintain flexibility Contec have validated two irradiation providers. Ionisos in France and Synergy Health in the UK are responsible for the sterilisation of Contec products, following well defined specifications to achieve performance qualification. The gamma irradiation at Ionisos is conducted at their site in Sable sur Sarthe and at Synergy's Daventry plant.

Performance qualification of our products is conducted on routine basis. The current performance qualifications are detailed below. Irradiation validations are carried out on product families with the same density, so the validation is carried out on 1L trigger spray alcohol products and 5L capped alcohol products.

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

IONISOS
Traitement par rayonnement gamma

Site de Sablé sur Sarthe
Z.I. de l'Aubrée
72300 Sablé sur Sarthe (France)

Performance qualification report

Customer : **CONTEC CLEANROOM** Customer order: **36**

Product Reference : **STERILE 70% ALCOHOL**
pallet 1
N° batch Customer : 140200174 /
140400180

1. Subject

The performance qualification has the objective of determining the dose distribution inside the parcels of the customer, under normal exploitation conditions of the gamma cell of Sablé's site.
In accordance with standards ISO 9001, ISO 13485 and 11137 (for PQ 3 runs).

2. Product Specifications

Packaging : Boxes (*)

(*) Specify if <other> :

Lenght (cm)	Thickness (cm)	Height (cm)	Weight (kg)	Density (g/cm3)
104	103	176	533	0,28

Aimed minimum dose : **25,0 kGy** **Aimed maximum dose :** **95,0 kGy**

3. Plant specifications

The irradiation container is a tote with 2 levels of loading pallet:
The useful dimensions of irradiation containers are :
Dimensions: 100 x 120 x 200 cm. Weight: 1000 kg max.
The upper and lower pallets of the totes are swapped, so all pallets receive the same number of passes in the upper and in the lower positions.
The dosimeter routine B is placed on the B axis at 25 cm from the bottom of the product.
The dosimeter routine A is placed on the A axis at 1 cm from the bottom of the product.

Installation Qualification reference : Qualification de l'installation - Sablé - Rév 1
Configuration of source : QO Sablé janvier 2014 rev 0

Type of dosimeters used : Red
Dosimeters batch : 4034 ML Calibration date : 10/09/2013

CONTEC
Europe - France
RP 3707 - 56037 VANNES Cedex
+33 297 437 690 - info@contecinc.com
www.contecinc.com

Site de Sablé sur Sarthe
Z.I. de l'Aubrée
72300 Sablé sur Sarthe (France)

4. Containers loading pattern and dosimetry

Number of parcel by layer :	16	Number of layer parcel :	5
Total parcel number / Pallet :	80	Number of pallets instrumented :	1
Instrumented pallets :	1402126S-01 - -		

product orientation in the boxes

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Z.I. de l'Aubrée
72300 Sablé sur Sarthe (France)

5. Treatment

Ionisos Order : 1402126S
Ionisos treatment batch : 14T02089S
Treatment date : 30/04/2014
Number of laps line 1: 9 + 9

6. Dosimetry results

Position dosimeters numbered from 01 to XX for each axis. 01 being the lowest position and then increment by 1 for each level.

Container n° 1		Container n° 2		Container n° 3		Synthesis	
N° Dosimeter	Dose	N° Dosimeter	Dose	N° Dosimeter	Dose	Position	Average
B214991R	53,7 kGy					Routine B	53,7 kGy
A203438R	40,0 kGy					Routine A	40,0 kGy
1402126S0115111R	32,0 kGy					I 11	32,0 kGy
1402126S0115110R	29,8 kGy					I 10	29,8 kGy
1402126S0115109R	27,9 kGy					I 09	27,9 kGy
1402126S0115108R	27,3 kGy					I 08	27,3 kGy
1402126S0115107R	27,9 kGy					I 07	27,9 kGy
1402126S0115106R	27,4 kGy					I 06	27,4 kGy
1402126S0115105R	27,8 kGy					I 05	27,8 kGy
1402126S0115104R	28,2 kGy					I 04	28,2 kGy
1402126S0115103R	28,3 kGy					I 03	28,3 kGy
1402126S0115102R	28,2 kGy					I 02	28,2 kGy
1402126S0115101R	30,1 kGy					I 01	30,1 kGy
1402126S0112111R	52,8 kGy					B 11	52,8 kGy
1402126S0112110R	53,2 kGy					B 10	53,2 kGy
1402126S0112109R	53,9 kGy					B 09	53,9 kGy
1402126S0112108R	50,8 kGy					B 08	50,8 kGy
1402126S0112107R	50,9 kGy					B 07	50,9 kGy
1402126S0112106R	51,4 kGy					B 06	51,4 kGy
1402126S0112105R	54,5 kGy					B 05	54,5 kGy
1402126S0112104R	50,5 kGy					B 04	50,5 kGy
1402126S0112103R	50,1 kGy					B 03	50,1 kGy
1402126S0112102R	53,6 kGy					B 02	53,6 kGy
1402126S0112101R	53,7 kGy					B 01	53,7 kGy
1402126S0111111R	41,5 kGy					A 11	41,5 kGy
1402126S0111110R	40,0 kGy					A 10	40,0 kGy
1402126S0111109R	38,6 kGy					A 09	38,6 kGy
1402126S0111108R	38,3 kGy					A 08	38,3 kGy
1402126S0111107R	37,5 kGy					A 07	37,5 kGy
1402126S0111106R	37,7 kGy					A 06	37,7 kGy
1402126S0111105R	37,3 kGy					A 05	37,3 kGy
1402126S0111104R	37,5 kGy					A 04	37,5 kGy
1402126S0111103R	38,3 kGy					A 03	38,3 kGy
1402126S0111102R	38,3 kGy					A 02	38,3 kGy
1402126S0111101R	40,0 kGy					A 01	40,0 kGy

Site de Sablé sur Sarthe
Z.I. de l'Aubrée
72300 Sablé sur Sarthe (France)

7. Operating results

Minimum dose :	27,3 kGy	**Maximum dose :**	54,5 kGy
Routine B Dose :	53,7 kGy	**Routine A Dose :**	40,0 kGy

Ratio Max dose / Min dose : 2,000

RmA (Dose Min / Dose RA) : 0,682 RMA (Dose Max / Dose RA) : 1,363

Minimum Rx dose required = Minimum dose required / Rmx

Minimum RA dose required = 36,7 kGy

Maximum Rx dose required = Maximum dose required / RMx

Maximum RA dose required = 69,6 kGy

The results provide the basis to define the dose range used routinely.

The visa of the client approves the report's findings.

From that day, without other instruction from you, we modify and apply data processing according to the instructions specified in the report.

The dosimetric results are given with an uncertainty of : 5,1 %

	Editor	Approver
Name	Coralie VAUCEL	Amaury Du BOULLAY
Function	Quality assistant	Business management
Date	19/05/2014	19/05/2014
Visa		

The last page of this report must be re-turned signed (fax)

Validation Ref: 0.4201
Performance Qualification Daventry **Rev 01**

Customer: **Contec Cleanroom (UK) Ltd**

Product Description: **Sterile 70% Alcohol**

Valid From: **28-Jul-14** Expires: **27-Jul-19**

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 **30.7** kGy and **83.3** kGy. This incorporates an estimation of uncertainty associated with the measurement system.

Authorisation

Position	Signature	Date
Plant Manager		28/07/14
Daventry Quality Manager		30 Jul 14

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

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Product Detail

Customer Name:	**Contec Cleanroom (UK) Ltd**		
Product Desciption	**Sterile 70% Alcohol**	Expiry Date	**27-Jul-19**

Layout Of Shipper Contents

Dosimetry Placement

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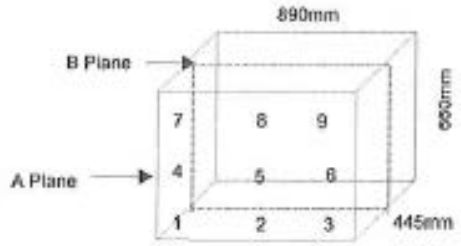
Product Detail

Customer Name: **Contec Cleanroom (UK) Ltd**

Product Description: **Sterile 70% Alcohol** Expiry Date **27-Jul-19**

Number Per Container: **6** Number Per Shipper: **1**

Irradiation Container



Approved By: **Date:** 22/07/16

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Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
D_{ref} Position 1A	36.1	36.0	36.3	36.1	0.15	0.42	0.05
2A	37.4	36.2	37.2	36.9	0.64	1.74	0.83
3A	36.1	35.8	36.7	36.2	0.46	1.27	0.42
4A	36.9	36.3	36.4	36.5	0.32	0.88	0.21
5A	39.0	38.3	39.2	38.8	0.47	1.22	0.45
6A	36.9	36.7	37.5	37.0	0.42	1.12	0.35
7A	39.5	39.1	38.2	38.9	0.67	1.71	0.89
8A	42.0	40.8	40.7	41.2	0.72	1.76	1.05
9A	39.5	38.5	39.4	39.1	0.55	1.41	0.61
1B	30.3	29.7	30.5	30.2	0.42	1.38	0.35
2B	29.2	30.0	29.3	29.5	0.44	1.48	0.38
3B	31.6	30.2	31.1	31.0	0.71	2.29	1.01
4B	30.8	31.9	32.5	31.7	0.86	2.72	1.49
5B	31.4	31.4	32.0	31.6	0.35	1.10	0.24
6B	32.8	32.3	31.9	32.3	0.45	1.39	0.41
7B	35.8	36.3	36.7	36.3	0.45	1.24	0.41
8B	36.7	37.2	37.1	37.0	0.26	0.72	0.14
9B	36.9	36.9	36.6	36.8	0.17	0.47	0.06

Pooled variance ($s^2_{overall}$)	0.26	D_{Ref} release criteria	
Minimum detectable difference (δ)	0.70	D_{Ref} Minimum	30.7
Mean Minimum dose (D_{Min})	29.5	D_{Ref} Maximum	83.3
Mean Maximum dose (D_{Max})	41.2		
Expected value of R_{min}	1.2252		
Expected value of R_{max}	0.8776		

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Product Detail

Customer Name: **Contec Cleanroom (UK) Ltd**
A/C No: **126485** Report Ref.: **0.4201**
Issue Date: **28-Jul-14** Expiry Date: **27-Jul-19**

Product Description: Sterile 70% Alcohol

Type of package: **Carton**
No of Packages/Irradiation Container: **6**
No of Packages/Shipper: **1**

Dimensions of Package (mm): **320** x **290** x **230**
Weight of Package (kg): **6.22** Density (gcm^3): **0.29**

Plant Batch No: **S11205457-1-1**

Current Co60 Loading (Mc_i): **3.04**

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

Dwell Time (sec): **106**

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

Number of passes 1

Synergy Processing Instruction

Guide Plant Dwell Time Range: **1.10** Min **2.98** Max

$D_{1,Ref}$ Minimum **30.7**
D_{Ref} Maximum **83.3**

Ratio's

Synergy (1/Rmin) **0.8162**
Synergy (1/Rmax) **1.1395**

Comments

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IONISOS
Traitement par rayonnement gamma

Site de Sablé sur Sarthe
Z.I. de l'Aubrée
72300 Sablé sur Sarthe (France)

Performance qualification report

Customer : **CONTEC CLEANROOM** Customer order: **63**

Product Reference : **5L STERILE 70% ALCOHOL**
pallet 1

N° batch Customer : 140500186

1. Subject

The performance qualification has the objective of determining the dose distribution inside the parcels of the customer, under normal exploitation conditions of the gamma cell of Sablé's site.
In accordance with standards ISO 9001, ISO 13485 and 11137 (for PQ 3 runs).

2. Product Specifications

Packaging : Boxes (*)

(*) Specify if <other> :

Lenght (cm)	Thickness (cm)	Height (cm)	Weight (kg)	Density (g/cm3)
117	100	100	455	0,39

Aimed minimum dose : **25,0 kGy** **Aimed maximum dose :** **95,0 kGy**

3. Plant specifications

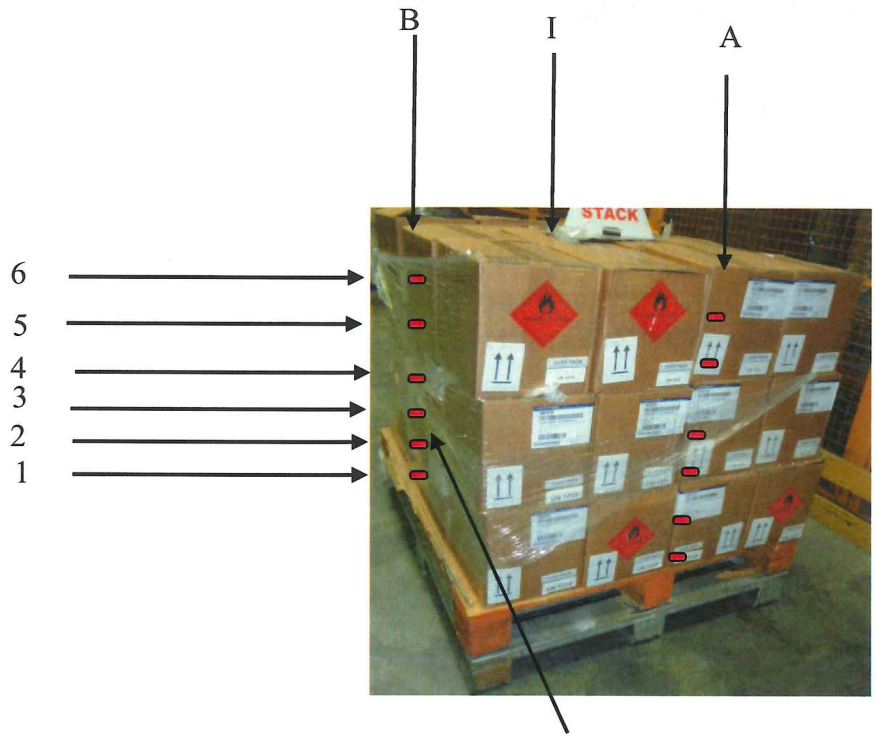
The irradiation container is a tote with 2 levels of loading pallet:
The useful dimensions of irradiation containers are :
Dimensions: 100 x 120 x 200 cm. Weight: 1000 kg max.
The upper and lower pallets of the totes are swapped, so all pallets receive the same number of passes in the upper and in the lower positions.
The dosimeter routine B is placed on the B axis at 25 cm from the bottom of the product.
The dosimeter routine A is placed on the A axis at 1 cm from the bottom of the product.

Installation Qualification reference : Qualification de l'installation - Sablé - Rév 1
Configuration of source : QO Sablé janvier 2014 rev 1

Type of dosimeters used : Red
Dosimeters batch : 4034 ML Calibration date : 10/09/2013

4. Containers loading pattern and dosimetry

Number of parcel by layer :	15	Number of layer parcel :	3
Total parcel number / Pallet :	45	Number of pallets instrumented :	1
Instrumented pallets :	1402672S-01 - 1402672U-01 -		



Routine control point B

product orientation in the boxes

Site de Sablé sur Sarthe
Z.I. de l'Aubrée
72300 Sablé sur Sarthe (France)

5. Treatment

Ionisos Order : 1402672S
Ionisos treatment batch : 14T02748S - 14T02858S -
Treatment date : 11/06/2014 19/06/2014
Number of laps line 1: 7 + 7 3 + 3

6. Dosimetry results

Position dosimeters numbered from 01 to XX for each axis. 01 being the lowest position and then increment by 1 for each level.

Container n° 1		Container n° 2		Container n° 3		Synthesis	
N° Dosimeter	Dose	N° Dosimeter	Dose	N° Dosimeter	Dose	Position	Average
B218097R	56,1 kGy					Routine B	56,1 kGy
A200866R	39,9 kGy					Routine A	39,9 kGy
1402672S0115106R	41,0 kGy					I 06	41,0 kGy
1402672S0115105R	32,0 kGy					I 05	32,0 kGy
1402672S0115104R	28,5 kGy					I 04	28,5 kGy
1402672S0115103R	29,0 kGy					I 03	29,0 kGy
1402672S0115102R	27,5 kGy					I 02	27,5 kGy
1402672S0115101R	31,7 kGy					I 01	31,7 kGy
1402672S0112106R	57,5 kGy					B 06	57,5 kGy
1402672S0112105R	55,1 kGy					B 05	55,1 kGy
1402672S0112104R	53,3 kGy					B 04	53,3 kGy
1402672S0112103R	54,9 kGy					B 03	54,9 kGy
1402672S0112102R	57,7 kGy					B 02	57,7 kGy
1402672S0112101R	56,6 kGy					B 01	56,6 kGy
1402672S0111106R	43,9 kGy					A 06	43,9 kGy
1402672S0111105R	39,7 kGy					A 05	39,7 kGy
1402672S0111104R	37,2 kGy					A 04	37,2 kGy
1402672S0111103R	36,9 kGy					A 03	36,9 kGy
1402672S0111102R	37,4 kGy					A 02	37,4 kGy
1402672S0111101R	40,9 kGy					A 01	40,9 kGy

Site de Sablé sur Sarthe
Z.I. de l'Aubrée
72300 Sablé sur Sarthe (France)

7. Operating results

Minimum dose :	27,5 kGy	**Maximum dose :**	57,7 kGy
Routine B Dose :	56,1 kGy	**Routine A Dose :**	39,9 kGy

Ratio Max dose / Min dose :	2,098		
RmB (Dose Min / Dose RB) :	0,490	RMB (Dose Max / Dose RB) :	1,029
RmA (Dose Min / Dose RA) :	0,689	RMA (Dose Max / Dose RA) :	1,446

Minimum Rx dose required = Minimum dose required / Rmx

Minimum RB dose required =	51,1 kGy	Minimum RA dose required =	36,3 kGy

Maximum Rx dose required = Maximum dose required / RMx

Maximum RB dose required =	92,3 kGy	Maximum RA dose required =	65,6 kGy

The results provide the basis to define the dose range used routinely.

The visa of the client approves the report's findings.

From that day, without other instruction from you, we modify and apply data processing according to the instructions specified in the report.

The dosimetric results are given with an uncertainty of : 5,1 %

	Editor	Approver
Name	Aurélie CHAILLOU	Amaury Du BOULLAY
Function	Quality Manager	Business management
Date	25/06/14	25/06/2014
Visa		

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IONISOS
Traitement par rayonnement gamma

Site de Sablé sur Sarthe
Z.I. de l'Aubrée
72300 Sablé sur Sarthe (France)

Performance Qualification Synthesis

Customer : **CONTEC CLEANROOM** Customer order: **63**

Product Reference : **5L STERILE 70% ALCOHOL**

Aimed minimum dose : **25,0 kGy** **Aimed maximum dose :** **95,0 kGy**

Ionisos treatment batch : 14T02748S - 14T02858S -

Treatment date : 11/06/2014 19/06/2014

Ratio Max dose / Min dose : 2,098

RmB (Dose Min / Dose RB) :	0,490	**RMB (Dose Max / Dose RB) :**	1,029
Minimum RB dose required =	51,1 kGy	**Maximum RB dose required =**	92,3 kGy
RmA (Dose Min / Dose RA) :	0,689	**RMA (Dose Max / Dose RA) :**	1,446
Minimum RA dose required =	36,3 kGy	**Maximum RA dose required =**	65,6 kGy

	Customer Approval
Name	NEIL SIMSON
Function	QUALITY MANAGER
Date	25 June 14
Visa	N. Simson

The dosimetric results are given with an uncertainty of : 5,1 %

This page must be signed and sent back to the attention of the commercial service fax N° 33 (0)2 43 92 03 51

VAL 25

Performance Qualification Daventry Gamma
Record of Amendment

Date Issued: 18-Nov-14
Report Reference: 0.4267 **Rev 01**
Customer: Contec Cleanroom (UK) Ltd
Product Description: 70% 5L Sterile Alcohol

Amendment Details **Date:** 18-Nov-14

New report

Amendment Justification

Not applicable.

Amended Item Specification Number: 1077948

Signatures
Approved:

Site Quality Manager

26 Nov 14

Customer: **Contec Cleanroom (UK) Ltd**

Product Description: **70% 5L Sterile Alcohol**

Valid From: **18-Nov-14** Expires: **17-Nov-19**

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 **34.9** kGy and **88.5** kGy. This incorporates an estimation of uncertainty associated with the measurement system.

Authorisation

Position	Signature	Date
Plant Manager		18 Nov 14
Daventry Quality Manager		19 Nov 14

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.

NS 05 Jan 15

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 **70% 5L Sterile Alcohol** Expiry Date **17-Nov-19**

Layout Of Shipper Contents

Dosimetry Placement

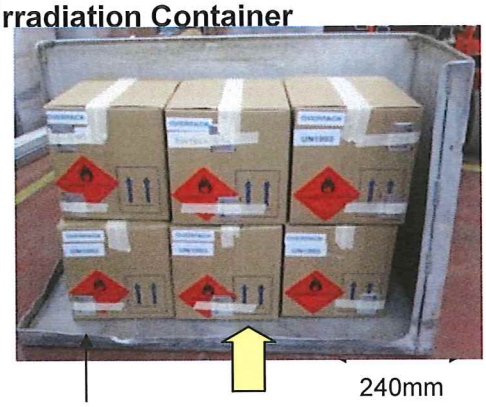
Product Detail

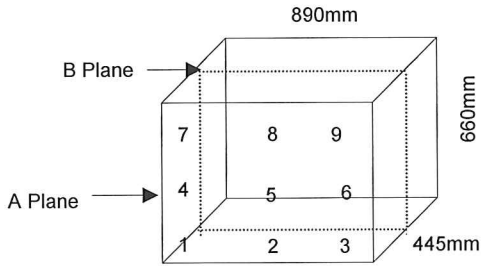
Customer Name: **Contec Cleanroom (UK) Ltd**

Product Description: **70% 5L Sterile Alcohol** Expiry Date **17-Nov-19**

Number Per Container: **6** Number Per Shipper: **2**

Irradiation Container





Approved By: **Date:** 18 Nov 14

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
D_{ref} Position 1A	34.1	36.1	35.2	**35.1**	**1.00**	**2.85**	2.01
2A	33.3	35.6	35.5	34.8	1.30	3.74	3.38
3A	36.9	34.9	35.7	35.8	1.01	2.81	2.03
4A	34.8	36.5	35.4	35.6	0.86	2.42	1.49
5A	36.6	36.0	36.0	36.2	0.35	0.96	0.24
6A	38.8	35.0	36.9	36.9	1.90	5.15	7.22
7A	38.3	37.4	37.3	37.7	0.55	1.46	0.61
8A	35.5	37.8	39.0	37.4	1.78	4.75	6.33
9A	38.8	36.2	37.9	37.6	1.32	3.51	3.49
1B	25.0	27.4	26.5	26.3	1.21	4.61	2.94
2B	24.9	25.0	25.8	25.2	0.49	1.95	0.49
3B	26.8	25.5	26.3	26.2	0.66	2.50	0.86
4B	26.8	28.8	27.3	27.6	1.04	3.77	2.17
5B	26.5	26.9	26.9	26.8	0.23	0.86	0.11
6B	29.5	26.6	28.6	28.2	1.48	5.26	4.41
7B	26.7	30.3	27.9	28.3	1.83	6.48	6.72
8B	27.1	27.1	30.1	28.1	1.73	6.16	6.00
9B	29.9	28.0	29.7	29.2	1.04	3.58	2.18

Pooled variance ($s^2_{overall}$)	**1.46**
Minimum detectable difference (б)	**1.67**
Mean Minimum dose (D_{Min})	**25.2**
Mean Maximum dose (D_{Max})	**37.7**
Expected value of R_{min}	**1.3955**
Expected value of R_{max}	**0.9318**

D_{Ref} release criteria

D_{Ref} Minimum	**34.9**
D_{Ref} Maximum	**88.5**

Validation Ref: 0.4267
Performance Qualification Daventry **Rev 01**

Product Detail

Customer Name: **Contec Cleanroom (UK) Ltd**
A/C No: **126485** Report Ref.: **0.4267**
Issue Date: **18-Nov-14** Expiry Date: **17-Nov-19**

Product Description: 70% 5L Sterile Alcohol

Type of package: **Carton**
No of Packages/Irradiation Container: **6**
No of Packages/Shipper: **2**

Dimensions of Package (mm): **310** x **280** x **240**
Weight of Package (kg): **9.80** Density (gcm^3): **0.47**

Plant Batch No: **S11275576-1-1**

Current Co60 Loading (Mc_i): **2.91**

Standard Plant Dwell Time (sec): **86**

Dwell Time (sec): **109**

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

Number of passes 2

Synergy Processing Instruction

Guide Plant Dwell Time Range: **1.26** Min **3.13** Max

D_{Ref} Minimum **34.9**
D_{Ref} Maximum **88.5**

Ratio's

Synergy (1/Rmin) **0.7166**
Synergy (1/Rmax) **1.0732**

Comments

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 *Sterile* IPA has an un-opened shelf life of 3 years from date of manufacture. Contec *Sterile* IPA has an in-use shelf life of 6 months.

Unopened Shelf Life Validation

A retained sample of current production was taken which was already past the 3 year time point. The second sample was not yet at 3 years ambient shelf life so was aged at 40^0C ± 2^oC to take it past the 3 year time point on accelerated testing. Each week at 40^0C ± 2^oC equates to a month of ambient testing as described in EMEA "Guidelines on Stability Testing". This batch was stored in an incubator for the required time.

Sample	Batch	Expiry Date	No of weeks accelerated to equate to 3 years shelf life
1L Sterile IPA	2010010094OA	Jan 2012	0 weeks already 3 years old
1L Sterile IPA	110600067	June 2013	15 weeks

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.

The release specification of Contec *Sterile* IPA is:-

Test	Specification
Specific Gravity @20^0C	0.868 to 0.878
Colour	Colourless
Clarity	Clear

Results – chemical specification

1L Contec Sterile IPA Batch 2010010094OA already at 3 years ambient

Test	Specification	Result
Specific Gravity @20^{0}C	0.868 to 0.878	0.872
Colour	Colourless	Colourless
Clarity	Clear	Clear

1L Contec Sterile IPA Batch 110600067 21 months ambient 15 weeks accelerated

Test	Specification	Result
Specific Gravity @20^{0}C	0.868 to 0.878	0.872
Colour	Colourless	Colourless
Clarity	Clear	Clear

Results – sterility

One of the samples after accelerated to 3 years shelf life was sent to ACM Pharma for sterility testing according to Ph Eur. 7th edition 7.7 Ch 2.6.1.

The sample passed sterility testing.

Rapport d'essais No 0000142556.0 is available on request.

Results - 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.

Test House – ALS Labs, Ely, UK

EN1276 – clean conditions

Both batches passed EN1276 with a result greater than Log 5.

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
S.*aureus* – sample 1	Log 5	> 5.2	5 mins	PASS	Dilution neutralisation
S.*aureus* – sample 2	Log 5	> 5.2	5 mins	PASS	Dilution neutralisation
P.*aeruginosa* - 1	Log 5	> 5.1	5 mins	PASS	Dilution neutralisation
P.*aeruginosa* - 2	Log 5	> 5.1	5 mins	PASS	Dilution neutralisation

EN1650 – clean conditions

Both batches passed EN1650 with a result greater than Log 4.

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
A.*niger* – sample 1 *(brasiliensis)*	Log 4	> 4.0	15 mins	PASS	Dilution neutralisation
A.niger – sample 2 *(brasiliensis)*	Log 4	>4.8	15 mins	PASS	Dilution neutralisation

In-Use Shelf Life Validation

Due to fact that standard trigger spray bottles pull return air into the sterile fluid many cleanroom trigger spray systems work as a 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

Contec *Sterile* IPA is stable and remains efficacious over a 3 year period as demonstrated in the above ambient and accelerated testing.

The packaging keeps the product sterile over the shelf life period.

Full EN efficacy testing shows the product has the same efficacy at end of shelf life as the original samples which were tested.

Contec *Sterile* IPA can be given a 3 year shelf life. Contec *Sterile* IPA has an in-use shelf life of 6 months.