PRODUCT INFORMATION FILE

Contec® Sterile IPA

Product Codes

Product Code

SBT0570IW
SBT170IW
SBC570I

Rev 8 11-011-2019
www.contecinc.com/eu

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

Contec Inc
Spartanburg, SC
United States
Tel: +1 (864) 503-8333

Contec Cleanroom Technology (Suzhou) Co. Ltd
Suzhou
China
Tel: +86-512-6274 4050

Contec® Sterile IPA

SBT0570IW
SBT170IW
SBC570I

Contents

Rev 8 11-11-2019
www.contecinc.com/eu

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

Contec Inc
Spartanburg, SC
United States
Tel: +1 (864) 503-8333

Contec Cleanroom Technology (Suzhou) Co. Ltd
Suzhou
China
Tel: +86-512-6274 4050

Section 1
Company Overview

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

Experienced

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

Global

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

Committed to quality

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

Committed to customers

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

Product range

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

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

Global Manufacturing and Distribution

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

Contec USA

Contec China

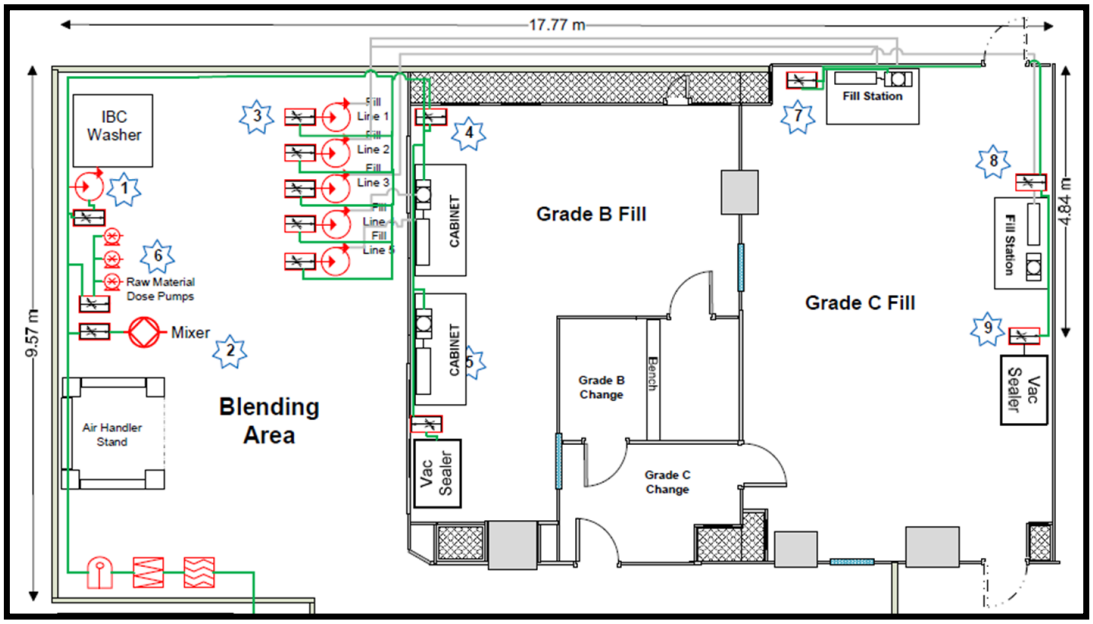
Contec France

Ashington Manufacturing Plant

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

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

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



Water Plant and QC Laboratory

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

Blending Area

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

Staging areas

Grade B cleanroom

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

Grade C cleanroom

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

Regulatory Certificates

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

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

Biocidal Products Regulation

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

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

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

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

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

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

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

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

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

Contec and Contec's suppliers of active substances are all listed in the 'Article 95 list' of the Biocidal Products Regulation. Contec intends to submit applications for Union Authorisation for all its biocidal product families to ensure continuity of supply throughout the entire EU/EEA.

Current deadlines for cleanroom active ingredients

For common disinfectant actives used in cleanrooms, such as IPA, PAA, hypochlorites and hydrogen peroxide, the actives have already been approved and the deadlines for submission of product authorisation dossiers have passed.

After the phase-out periods, any products for which a dossier was not submitted by the relevant deadline must remain off the EU market until authorisation is granted.

Deadline for products containing:

Propan-2-ol (70% IPA)	1st July 2016
Glutaraldehyde	1st October 2016
Hydrogen peroxide	1st February 2017
Peracetic acid	1st October 2017
Active chlorine or containing sodium hypochlorite	1stJanuary 2019.
Propan-1-ol	1st May 2019
PHMB	1st November 2019

Current BPR Status of Contec's 70% IPA products.

Contec 70% IPA, PROSATS with 70% IPA, SATWIPEs with 70% IPA

Contec's EU BPR product dossier for all products containing 70% IPA has received **Union Authorisation** from the ECHA Biocidal Products Committee.

All Contec's IPA products including presaturated wipes are authorised for sale in all EU countries.

The Authorisation Number for the product family is EU-0020460-0000.

Summary of product characteristics for a biocidal product family

Contec IPA Product Family

Product type 2 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0020460-0000

R4BP asset number: EU-0020460-0000

This will be visible on ECHA's website towards the end of 2019.

Contec's TSE statement is also detailed below.

CONTEC

June 13, 2017

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

Dear Customer:

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

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

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

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

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

Regards,

Nancy Bockstiegel

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

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

tel: +1-864-503-0333
toll free: 1-800-289-5762
fax: +1-864-503-0333

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

Certificate GB15/93329

The management system of

Contec Cleanroom (UK) Ltd

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

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

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

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

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

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

Authorised by

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

HC SGS 9001 2015 0818

Page 1 of 1

UKAS MANAGEMENT SYSTEMS
0005

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

America

CERTIFICATE

The Certification Body of
TÜV SÜD AMERICA INC.

hereby certifies that

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

has implemented a Quality Management System in accordance with:

ISO 9001:2015

The scope of this Quality Management System includes:

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

Certificate Expiry Date: October 24, 2020

Certificate Registration No: 950 99 0586

Effective Date: September 28, 2018

Reissue Date: July 9, 2019

Mark Alpert
Vice President, Business Assurance

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

UCB_F_12.03 2012-02

Certificate CN07/00113

The management system of

Contec Cleanroom Technology (Suzhou) Company, Ltd.

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

Unified Social Credit Code 91320594778675949B

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Manufacture of cleaning products used in critical environment

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

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

Authorised by

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

HC SGS 9001 2015 0118

Page 1 of 1

UKAS MANAGEMENT SYSTEMS
0005

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 9001:2015 or ISO 13485*, tested in accordance with documented quality procedures and approved when required specifications are met. (*as required by site of manufacture.)

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 13485:2016	Quality Management System – Medical Devices
ISO 11137:2015	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: Lee Rodgers	2: John Gray
Position:	1: Snr. Quality Technician	2: Quality Manager
Date:	1:	2:
Authorised Signature: For and on behalf of Contec Inc	1:	2:

COA31 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

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 9001:2015 or ISO 13485*, tested in accordance with documented quality procedures and approved when required specifications are met. (*as required by site of manufacture).

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 13485:2016	Quality Management System – Medical Devices
ISO 11137:2015	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: Lee Rodgers	2: John Gray
Position:	1: Snr. Quality Technician	2: Quality Manager
Date:	1:	2:
Authorised Signature: For and on behalf of Contec Inc	1:	2:

COA13 Rev 4

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

America
Contec Inc
P.O.Box 530
Spartenburg 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 9001:2015 or ISO 13485*, tested in accordance with documented quality procedures and approved when required specifications are met. (*as required by site of manufacture).

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 13485:2016	Quality Management System – Medical Devices
ISO 11137:2015	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: 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

COA014 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

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

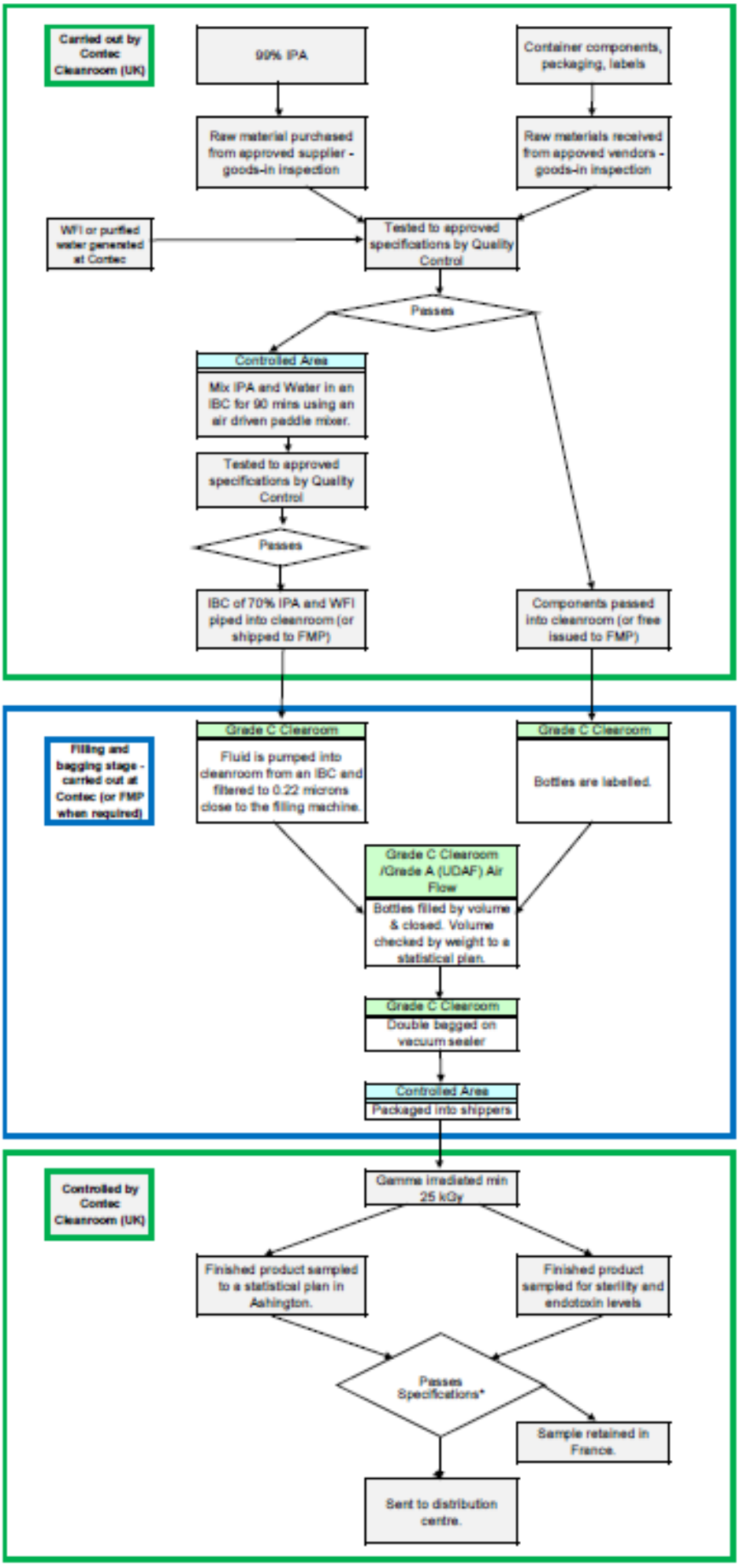
Contec *Sterile* IPA with water for injection 1L

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



* 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: 13/03/2019

Revision No: 5

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

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

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.

Hazard pictograms: GHS02: Flame

GHS07: Exclamation mark

[cont...]

Signal words: Danger

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

P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water .

P243: Take action to prevent static discharges.

P370+P378: In case of fire: Use media other than water to extinguish.

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

P261: Avoid breathing mist/vapours/spray.

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313: If eye irritation persists: Get medical advice/attention.

P304+P341: IF INHALED: if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312: Call 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	PBT / WEL	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.

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

[cont...]

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	-	-

Non-classified ingredients:

PROPAN-2-OL

Workplace exposure limits: **Respirable dust**

State	8 hour TWA	15 min. STEL	8 hour TWA	15 min. STEL
UK	999 mg/m3	1250 mg/m3	-	-

DNEL/PNEC Values

DNEL / PNEC No data available.

8.2. Exposure controls

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

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

Hand protection: 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: 20.5

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.

[cont...]

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.

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

Non-classified ingredients:

PROPAN-2-OL

IVN	RAT	LD50	1088	mg/kg
ORL	MUS	LD50	3600	mg/kg
ORL	RAT	LD50	5045	mg/kg
SCU	MUS	LDLO	6	gm/kg

Relevant hazards for product:

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

Symptoms / routes of exposure

Section 12: Ecological information

12.1. Toxicity

[cont...]

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.

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

[cont...]

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 2015/830.

* 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.

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 5L

Compilation date: 09/03/2015

Revision date: 13/03/2019

Revision No: 6

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

1.1. Product identifier

Product name: CONTEC STERILE 70% IPA 5L

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

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

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.

Hazard pictograms: GHS02: Flame

GHS07: Exclamation mark

[cont...]

Signal words: Danger

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

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

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.

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 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	PBT / WEL	CLP Classification	Percent
200-661-7	67-63-0	-	Flam. Liq. 2: H225; Eye Irrit. 2: H319; STOT SE 3: H336	70.000%

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.

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

[cont...]

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: 20.5

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

Non-classified ingredients:

PROPAN-2-OL

IVN	RAT	LD50	1088	mg/kg
ORL	MUS	LD50	3600	mg/kg
ORL	RAT	LD50	5045	mg/kg
SCU	MUS	LDLO	6	gm/kg

Relevant hazards for product:

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

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
Acute toxicity (ac. tox. 1)	-	No hazard: calculated
Skin corrosion/irritation	-	No hazard: calculated
Respiratory/skin sensitisation	-	No hazard: calculated
Germ cell mutagenicity	-	No hazard: calculated
Carcinogenicity	-	No hazard: calculated

[cont...]

Reproductive toxicity	-	No hazard: calculated
STOT-repeated exposure	-	No hazard: calculated
Aspiration hazard	-	No hazard: 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.

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 (ISOPROPYL ALCOHOL)
(PROPAN-2-OL; WATER)

[cont...]

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.

Tunnel code: D/E

Transport category: 2

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 2015/830.

* 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.

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.

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. Synergy Health and Sterigenics in the UK are responsible for the sterilisation of Contec products, following well defined specifications to achieve performance qualification. The gamma irradiation at Sterigenics is conducted at their site near Chesterfield and at Synergy's Daventry plant.

Performance qualification of our products is conducted on routine basis. The current performance qualifications for Synergy Health are detailed below. Validation work is still being carried out at Sterigenics. Irradiation validations are carried out on product families with the same density, so the validation is carried out on 0.5L and 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

NM Performance Qualification Daventry Gamma
Record of Amendment

Date Issued: 12-Sep-16
Report Reference: 4738 **Rev 01**
Customer: Contec Cleanroom UK Ltd
Product Description: 0.5L Alcohol Sterile 70% Alcohol

Amendment Details **Date:** 12-Sep-16

New report.

Amendment Justification

Not Applicable

Amended Item Specification Number: 1107941

Signatures

Approved:
QA Officer / ~~Quality Manager~~

21SEP16.

Customer: **Contec Cleanroom UK Ltd**

Product Description: **0.5L Alcohol Sterile 70% Alcohol**

Valid From: **12-Sep-16** Expires: **11-Sep-21**

Synergy Ref No. **S11681642-1-1**

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 Co60 Gamma irradiation.

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

Methodology

Qualification data is obtained by placing Harwell Red 4034PMMA dosimeters in a defined pattern throughout an Synergy Health - AST tote loaded with product.
Following processing the relationship between D_{Ref}/D_{Min} and D_{Ref}/D_{Max} are calculated to determine an acceptable D_{Ref} processing range.

Conclusion

The delivered dose in the product presentation illustrated on page 4 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 **28.0** kGy and **85.4** kGy.

Authorisation

Position	Signature	Date
Plant Manager		19 Sept 2016
Quality Manager		19 SEP 2016

Note:
It is the responsibility of the customer to routinely provide product in the presentation and orientation outlined in this report.
This performance qualification validates the delivery of radiation doses only. Validation of the sterilisation effect and radiation induced material effects, if any, are not addressed by this qualification.

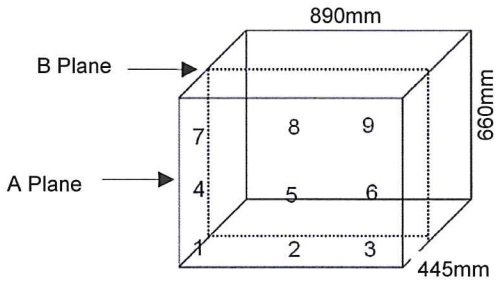
Customer Name: **Contec Cleanroom UK Ltd**

Type of Package: **Carton**

Product Description: **0.5L Alcohol Sterile 70% Alc** Valid From: **12-Sep-16**

Fit Per Tub: **4** Expiry Date: **11-Sep-21**

This performance qualification relates only to the above product loaded in the configuration outlined below.



Authorised By:	Signature	Date
Approved by		19 Sept 2016

Product Detail

Customer Name: **Contec Cleanroom UK Ltd**
Customer Batch/Lot No: **160700447**

A/C No: **126485** Report Ref.: **4738**
Valid From: **12-Sep-16** Expiry Date: **11-Sep-21**

Product Description: **0.5L Alcohol Sterile 70% Alcohol**
Type of package: **Carton**
No of Packages/Irradiation Container: **4**

Dimensions of Package (mm): **395** x **320** x **200**
Weight of Package (kg): **4.8** Density (g/cm^3): **0.19**

Plant Batch No: **S11681642-1-1** Current Cobalt Loading (Mc$_i$): **2.89**
Standard Plant Dwell Time (sec): **80** Dwell Time (sec): **83**

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

Comments

Dosimeter Readings

Position	Qualification Results	
1A	33.7	R*
2A	34.6	
3A	33.4	
4A	34.8	
5A	37.1	
6A	34.6	
7A	35.4	
8A	37.5	
9A	35.8	
1B	30.6	
2B	30.1	
3B	30.3	
4B	32.6	
5B	32.8	
6B	32.0	
7B	35.3	
8B	31.6	
9B	34.9	

Dosimetry Results Summary

D_{Min}	**30.1**
D_{Max}	**37.5**
D_{Ref}	**33.7**

Definitions
D_{Ref}- Reference Dose
D_{Min}- Minimum Dose
D_{Max}- Maximum Dose

D_{ref} (Routine Release Criteria)

D_{ref} **Minimum**	**28.0**
D_{ref} **Maximum**	**85.4**

Ratio's

D_{ref}:D_{min}	**0.8932**
D_{ref}:D_{max}	**1.1128**

** R denotes D_{Ref} Position*

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

Product Detail

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

Layout Of Shipper Contents

Dosimetry Placement

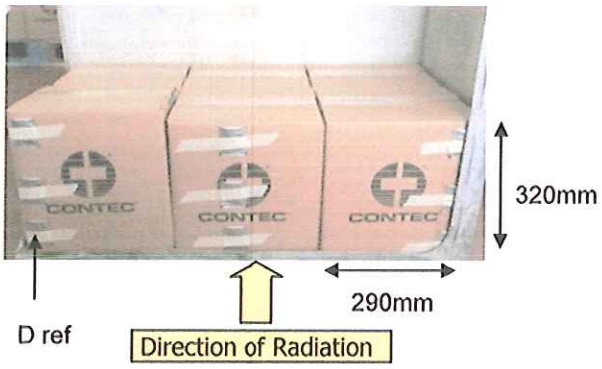
Product Detail

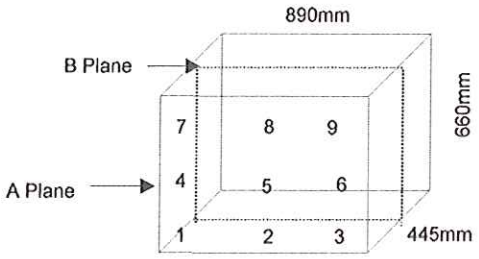
Customer Name: **Contec Cleanroom (UK) Ltd**

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

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

Irradiation Container





Approved By: Date: 28/07/16

Analysis for the Calculation of Release Specification Incorporating Uncertainties

Position	PQ1	PQ2	PQ3	Mean	Stdev	CV	Sum of Squared Differences
D_{ref} Position 1A	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 (б) **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**

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

$D_{i\,Ref}$ Minimum **30.7**
D_{Ref} Maximum **83.3**

Ratio's
Synergy (1/Rmin) **0.8162**
Synergy (1/Rmax) **1.1395**

Comments

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.

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

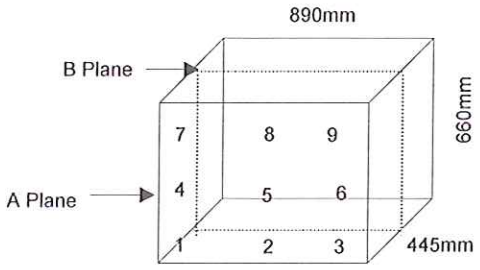
Product Detail

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**

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

Report Title

Performance Qualification dose mapping for Contec's 1L IPA and DE disinfectants.

Technical Leader	Issue date	Facility
Dr. Bart Croonenborghs Technical Director Irradiation	29 May 2019	Sterigenics Markham Vale

Customer, Name and Address	Customer Contact
Contec Cleanroom (UK) Unit 6A Wansbeck Business Park Rotary Parkway Ashington NE63 8QW, UK	John Gray Quality Manager Contec Cleanroom (UK) jgray@contecinc.com

PQ DOSE MAP NUMBER 302_CON

Prepared by:

Digitally signed by Bart Croonenborghs
DN: cn=Bart Croonenborghs, o=Sterigenics, ou=Sterigenics, email=bcroonenborghs@eu.sterigenics.com, c=BE
Date: 2019.06.11 08:48:57 +02'00'

Dr. Bart Croonenborghs
Technical Director Irradiation
Sterigenics

Date

Reviewed / Approved by:

Quality Assurance

Digitally signed by Steven Whelan
DN: cn=Steven Whelan, o=Sterigenics UK, ou=Quality Assurance, email=Swhelan@sterigenics.com, c=GB
Date: 2019.06.11 08:48:19 +01'00'

Steven Whelan
Quality Assurance Manager
Sterigenics Markham Vale

Date

Operations

Digitally signed by rtaylor@sterigenics.com
DN: cn=rtaylor@sterigenics.com
Date: 2019.06.11 10:09:09 +01'00'

Rafael Taylor
General Manager
Sterigenics Markham Vale

Date

Customer

11 JUN 19

JOHN GRAY
QUALITY MANAGER
CONTEC CLEANROOM UK.

Date

Customer

Date

TABLE OF CONTENTS

REVISION HISTORY

Revision 0: 29 May 2019

1. SCOPE

To provide results and conclusions from the Performance Qualification (PQ) dose map study that has been performed in accordance with protocol PR-MV-2019-008r0 to establish a process specification for routine irradiation of Contec Cleanroom (customer) 1L IPA and DE disinfectants (product) in the JS10000 irradiator at Sterigenics Markham Vale, UK. PQ dose map number 302_CON was associated with the study.

In summary, all the acceptance criteria defined in the study protocol were met. The irradiation process was shown to be reproducible across the monitored irradiation containers, a sufficiently tight uniformity of dose was obtained, measured doses were well within the specification of 25 kGy to 95 kGy; and for the start of routine irradiation a normalized cycle time as well as a method for dose monitoring were established.

2. REFERENCE DOCUMENTS

[1.] ISO/ASTM 51261:2013, *Practice for calibration of routine dosimetry systems for radiation processing.*

[2.] ISO/ASTM 51275:2013, *Standard practice for use of a radiochromic film dosimetry system.*

[3.] EN ISO 11137-1:2018, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*

[4.] EN ISO 11137-2:2015, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.*

[5.] EN ISO 11137-3:2017, *Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects of development, validation and routine control.*

[6.] PR-MV-2019-008r0, *Performance Qualification dose mapping for Contec's 1L IPA and DE disinfectants (protocol)*

[7.] FR-MV-2018-001, *Major OQ report for 4pass irradiation processes at Markham Vale JS10000.*

[8.] FWT-060 Dosimetry Calibration Cary100 Summary Record, Batch 1147 (Markham Vale)

3. CHANGES AND DEVIATIONS TO PROTOCOL PR-MV-2019-008r0

No changes were made and no deviations occurred.

4. DEFINITIONS

Performance Qualification Dose Map Grid – A 3-dimensional dosimeter grid used for dose distribution and magnitude characterization studies in conjunction with performance qualification or re-qualification. The PQ dose map grid is shown in Figure 1.

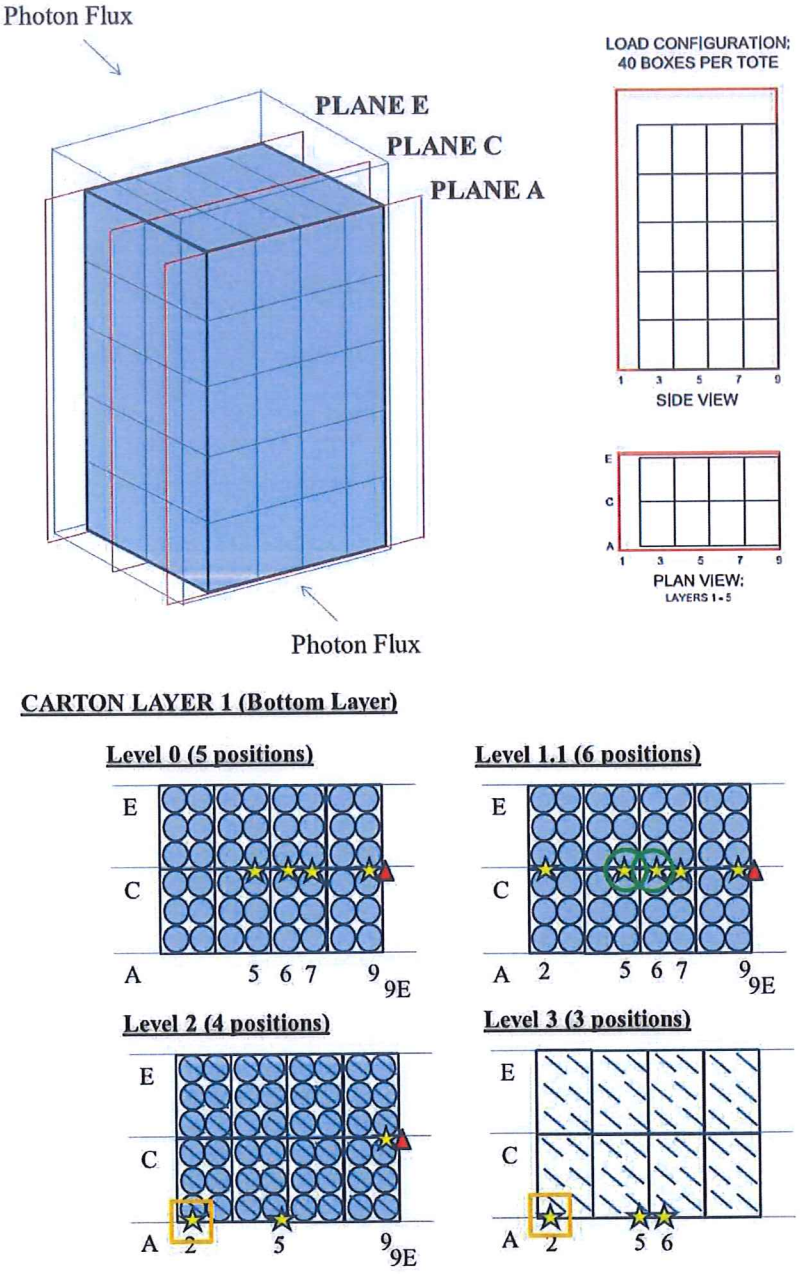
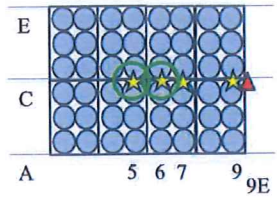


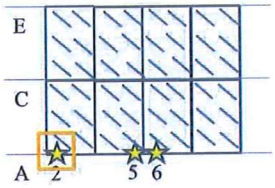
Figure 1: PQ dose map grid. Filled part of a bottle and a trigger spray closure are visualized through a filled circle and a diagonal line, respectively. The meaning of the circles and rectangles is explained in section 7.1.

CARTON LAYER 2

Level 4.3 (5 positions)

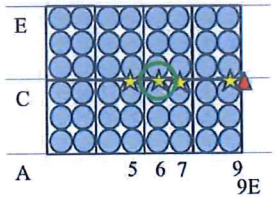


Level 6 (3 positions)

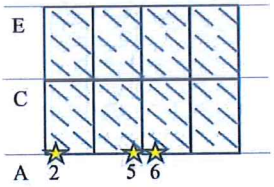


CARTON LAYER 3

Level 7.5 (5 positions)

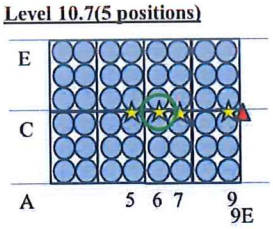


Level 9 (3 positions)



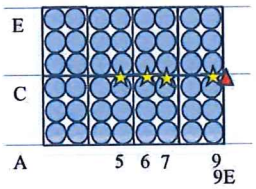
CARTON LAYER 4

Level 10.7(5 positions)

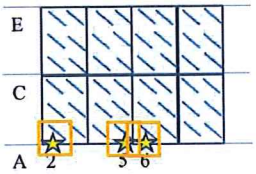


CARTON LAYER 5 (Top Layer)

Level 13.9 (5 positions)



Level 15 (3 positions)



Level T (3 positions)

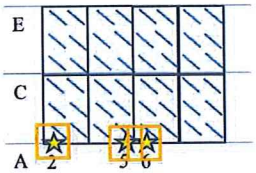


Figure 1 (cont.): PQ dose map grid. Filled part of a bottle and a trigger spray closure are visualized through a filled circle and a diagonal line, respectively. The meaning of the circles and rectangles is explained in section 7.1.

A dosimeter position is uniquely identified using a xyz coordinate:

X= height or level, expressed as a multiple of 10 cm and with T being the top of the configuration
Y= Vertical Plane, A – C or E
Z= Column, 2 – 5 – 6 – 7 – 9 or 9E. The latter corresponds to the red triangles in Figure 1.

Dose Uniformity Ratio (DUR) – Ratio of the maximum to the minimum dose in an irradiation container.

Point of Reference – A dosimeter monitoring location that has a known relationship to the minimum dose and/or maximum dose zone of the product load in an irradiation container.
The ratio factors AFmin and AFmax are the values used for the estimation of the minimum and the maximum dose absorbed by the product load in the irradiation container from the dose measured at the point of reference,

Dose at point of reference (kGy) × AFmin = Minimum dose (kGy)
Dose at point of reference (kGy) × AFmax = Maximum dose (kGy).

5. MATERIALS / EQUIPMENT

Provided by Sterigenics

- FWT60 pouched dosimeters from calibrated Batch 1147, approved lot 471143.
- Qualified and Calibrated CARY 100 spectrophotometers: Agilent technologies, MY18200002 and MY18190003
- Calibrated thickness gauges, serial numbers 81040085 and 81040075
- Calibrated scale
- Calibrated ruler

Provided by customer

- 120 cartons, each holding 6 units of disinfectant.

6. RESULTS

All dosimeters and PQ dose map products were placed as defined in the study protocol, reference Appendix 1. Irradiation was performed on 22 May 2019 under Work Order 2440309 with a normalized cycle time of 1650 seconds at 1 MCi. Leading and trailing material of the 3 irradiation containers with the customer's cartons were 17 alternating irradiation containers with the Markham Vale medium and high density homogeneous material for Operational Qualification studies (bulk density approx. 0.15 g/cm^3 and 0.46 g/cm^3, respectively), as specified in Figure 6 of the protocol.

Raw dosimeter results, calibration reports and process records are retained at Sterigenics Markham Vale. Dosimeter results were provided to the customer's contact person via e-mail and are tabulated in Appendix 2. Sterigenics Markham Vale Quality Assurance Manager verified all the data transcription to be correct.

All conditions stipulated in the protocol as well as all facility procedures were followed, and the whole dataset is considered suitable for analysis.

7. ANALYSIS & DISCUSSION

7.1) Dose magnitude and distribution [9.3.1 a) in EN ISO 11137-1:2018]

The minimum and the maximum dose zone in the specified product load configuration were identified using the Sterigenics t-test tool. Results are presented in Appendix 3, with a visual representation through circles and squares in Figure 1.

The absolute minimum dose position was found at position 1.1C6, which is at the height corresponding to the middle of the filled part of the lowest carton in the vertical centre plane (Plane C) and in column 6 (lateral centre of the configuration). Several monitored positions were found to be on at least 95% confidence level equivalent to the absolute minimum position. They were all in the C5 or C6 columns and included the lower 4 layers of cartons. None of the positions monitored at Level 0 or column C9E was found to be within the minimum dose zone. Monitored positions that were within the minimum dose zone are identified by the green circles in Figure 1.

The maximum dose zone – i.e. absolute maximum dose position or on at least 95% confidence level equivalent to it – was found to mainly include positions for the upper layer of cartons (levels 15 and Top), with the absolute maximum obtained at position TA5. Monitored positions that were within the maximum dose zone are represented by the orange rectangles in Figure 1.

7.2) Reproducibility of dose magnitude and distribution [9.3.5 in EN ISO 11137-1:2018]

The coefficient of variation (CV) for each dosimeter position is presented in the right column of the Table in Appendix 2. Average and extreme of the CV were 3.3% and 7.1%, respectively. The average CV was nearly double the precision of the FWT60 dosimetry system (1.6% at 95% confidence level, reference 8), and indicates a substantial degree of variability introduced by the variation of the dosimeter position (assuming the product variability does not substantially contribute to the observed variation).

The obtained equivalence limits from the analysis with the Sterigenics t-test tool were greater than those of 1.7% to 3.1% that were obtained in OQ studies of homogeneous materials up to a bulk density of 0.46 g/cm^3 [7].

The degree of variability in dose measurements was expected and taken into account in selection of the PQ dose map grid, with multiple positions that would nominally be rendering equivalent dose measurements. As an outcome, the CV for the absolute minimum and maximum dose magnitude for the customer product in an irradiation container was found to be low (0.8% and 2.1% for minimum and maximum dose magnitude, respectively).

The tight spread of minimum and maximum dose results from irradiation container to irradiation container demonstrates the reproducibility of the dose delivery process within the irradiation of this study, and will be used for assessing process capability in section 7.4.

7.3) Routine process monitoring [9.3.1 b) in EN ISO 11137-1:2018]

The minimum and the maximum dose for the product load in an irradiation container can be measured directly at positions 1.1C6 and TA5, respectively (AFmin = 1, AFmax = 1).

Both were found to be absolute dose positions (minimum or maximum) in the PQ dose map study.

The recommended monitoring frequency during routine irradiation is every 18 irradiation containers of the load configuration (and including first and last), so that 2 monitored irradiation containers are in the irradiator at all times – of which 1 resides adjacent to the source racks.

When product is irradiated as in this PQ dose mapping and dose measurements at positions 1.1C6 and TA5 are within 25 kGy and 95 kGy (both values included) the product specification of 25 kGy to 95 kGy will be met.

7.4) Process' capability assessment

A normalized cycle time of 1650 seconds for a source activity of 1 MCi was used for the PQ dose mapping study. Actual cycle time was corrected for source activity at the time of irradiation. An overall dose range of 32.0 kGy – 55.0 kGy was measured, reference Appendix 2. All values were well within the customer's product specification of 25 kGy – 95 kGy.

Using a t-distribution model (n=3)* an assessment was made of the interval of the minimum and maximum dose that 95% of the PQ dose map population encloses. Results are shown in Table 1.

	Min. Dose (kGy)	Max. Dose (kGy)
Lower bound of interval	31.1	49.2
Upper bound of interval	33.3	59.0

Table 1: Calculation of the lower (upper) bound of the interval of minimum (maximum) doses enclosed by 95% of the PQ dose map population.

There is no concern for the process of the PQ dose mapping to respect the dose specification of 25 kGy – 95 kGy on a routine basis.

Other normalized cycle times could be used for routine irradiation without comprising process capability, and allowing inclusion of other products into the processing category. Routine monitoring data will be used to refine the process capability assessment and together with OQ data can determine the possibility for such inclusion.

*(Measured Sample average ± 4.303 × sample standard deviation);
4.303 is the one-tail t-distribution critical value t(0.025,2)

8. CONCLUSIONS

A Performance Qualification dose map study was performed to establish a process in the Markham Vale JS10000 irradiator for irradiation of Contec Cleanroom (customer) 1L IPA and DE disinfectants (product). All objectives and acceptance criteria stipulated in the study protocol PR-MV-2019-008 revision 0 were met. PQ dose map number 302_CON was associated with the study.

40 cartons will be placed per irradiation container according to the configuration shown in Figure 1. Irradiation of any other configuration is not covered in or by this PQ dose map study, and the method of handling partially filled irradiation containers has to be agreed upon before commencing routine irradiation.

A normalized cycle time of 1650 seconds at a source activity of 1 MCi can be used for routine irradiation of the customer's product reference. Other normalized cycle times could be used without comprising process capability.

Routine monitoring data will be used to refine the process capability assessment, and to possibly allow inclusion of other products into the processing category.

Routine dosimetric monitoring will consist of direct monitoring of minimum and maximum dose in the monitored irradiation container at positions 1.1C6 and TA5, using the facility specific monitoring frequency of every 18 irradiation containers of the load configuration (and including the first and the last).

APPENDIX 1: Completed appendices of the protocol - Page 1 of 3

Dosimeter placement and retrieval form

Work Order					Irradiation Date	Page
2440309					23 MAY 19	1 of 1
PQ dose map container number	Correct dosimeter placement (Yes)	Performed by (initials & date)	Reviewed by (initials & date)	Confirm retrieved from correct position (Yes / No – If No add comment)	Performed by (initials & date)	Reviewed by (initials & date)
18	YES	MV 22MAY19	RT 23May19	YES	J.A 29May19	AW 24MAY19
19	YES	BC 22 MAY 19	MV 22MAY19	YES	J.A 29 May 19	AW 24MAY19
20	YES	BC 22 MAY 19	MV 22MAY19	YES	J.A 29 May 19	AW 24 MAY 19

APPENDIX 1: Completed appendices of the protocol - Page 2 of 3

Product placement and retrieval form

Work Order	Irradiation Date	Page
2440309	23 May 19	1 of 1

PQ dose map container number	Confirm product placed correct (Yes)	Performed by (initials & date)	Reviewed by (initials & date)	Confirm product retrieved from correct position (Yes / No – If No add comment)	Performed by (initials & date)	Reviewed by (initials & date)
18	YES	AW 22 MAY 19	J.A 22 May 19	YES	J.A 22 May 19	AW 22 MAY 19
19	YES	AW 22 MAY 19	J.A 22 May 19	YES	J.A 22 May 19	AW 22 MAY 19
20	YES	AW 22 MAY 19.	J.A 22 May 19	YES	J.A 22 May 19	AW 22 MAY 19

APPENDIX 1: Completed appendices of the protocol - Page 3 of 3

Work Order	Irradiation Date	Page
2440309	22MAH2019	1 of 1

All dosimeter from same approved shipping lot	(Yes) / No	Shipping Lot Number: 47-11-43
Cycle time	1800	
Irradiation Sequence (Figure 6) correct	(Yes) / No	
Process Interruptions	Yes / (No) If Yes, describe below	
	Interruption description / actions taken / assessment of effect: NONE	
Spectrophotometer	Serial Number, Calibration date, Valid until: MH18200002 21JUL19 MH18190003 29AUG19	
Thickness gauge	Serial Number, Calibration date, Valid until: 81040085 & 81040075 DAILY VERIFICATION PERFORMED ON ALL READ DAYS.	
Deficiencies	NONE	
Completed by (sign & date)		28MAH19
Reviewed by (sign & date)		28 MAY 19

APPENDIX 2: Tabulated dose measurements - Page 1 of 2

		Dose (kGy) at position in container			Avg.	
	Position	18	19	20	(kGy)	CV
CARTON LAYER1 (BOTTOM)	0C5	38.0	38.1	37.4	37.8	1.0%
	0C6	38.1	37.7	37.4	37.7	0.9%
	0C7	38.0	37.8	37.0	37.6	1.4%
	0C9	39.1	37.7	36.5	37.8	3.4%
	0C9E	38.5	37.5	35.3	37.1	4.4%
	1.1C2	37.6	37.3	35.3	36.7	3.4%
	1.1C5	32.6	33.6	34.1	33.4	2.3%
	1.1C6	32.8	32.1	32.0	32.3	1.3%
	1.1C7	33.2	34.9	33.4	33.8	2.7%
	1.1C9	36.9	34.8	32.7	34.8	6.0%
	1.1C9E	38.5	38.0	35.0	37.2	5.1%
	2A2	51.0	50.2	49.6	50.3	1.4%
	2A5	51.0	47.6	49.8	49.5	3.5%
	2C9	37.8	35.7	34.2	35.9	5.0%
	2C9E	38.4	37.8	35.2	37.1	4.6%
	3A2	51.8	50.7	51.2	51.2	1.1%
	3A5	50.2	48.4	51.2	49.9	2.8%
	3A6	50.0	47.7	49.3	49.0	2.4%
CARTON LAYER2	4.3C5	33.3	33.5	34.0	33.6	1.1%
	4.3C6	33.2	33.5	32.3	33.0	1.9%
	4.3C7	34.2	34.4	33.3	34.0	1.7%
	4.3C9	37.1	37.4	33.2	35.9	6.5%
	4.3C9E	38.3	38.8	35.6	35.9	6.5%
	6A2	52.3	49.1	49.8	37.6	4.6%
	6A5	50.6	48.2	50.1	49.6	2.6%
	6A6	49.0	47.7	48.5	48.4	1.4%
CARTON LAYER3	7.5C5	33.8	34.7	33.7	34.1	1.6%
	7.5C6	33.3	33.6	33.6	33.5	0.5%
	7.5C7	36.4	32.8	33.1	34.1	5.9%
	7.5C9	36.8	35.5	33.2	35.2	5.2%
	7.5C9E	38.9	38.4	35.0	37.4	5.7%
	9A2	50.5	47.3	49.4	49.1	3.3%
	9A5	49.2	46.7	49.0	48.3	2.9%
	9A6	50.0	46.8	48.9	48.6	3.3%

Max CV	7.1%
Min CV	0.5%
Avg CV	3.3%

APPENDIX 2: Tabulated dose measurements - Page 2 of 2

		Dose (kGy) at position in container			Avg.		
	Position	18	19	20	(kGy)	CV	
CARTON LAYER4	10.7C5	34.2	33.3	34.2	33.9	1.5%	
	10.7C6	32.5	34.1	32.4	33.0	2.9%	
	10.7C7	35.6	33.3	34.8	34.6	3.4%	
	10.7C9	37.0	36.2	32.6	35.3	6.6%	
	10.7C9E	39.8	37.6	35.4	37.6	5.9%	
CARTON LAYER5 (TOP)	13.9C5	35.6	35.2	36.0	35.6	1.1%	
	13.9C6	34.9	34.2	35.5	34.9	1.9%	
	13.9C7	38.2	36.7	36.7	37.2	2.3%	
	13.9C9	39.3	37.1	34.1	36.8	7.1%	
	13.9C9E	40.8	39.3	36.8	39.0	5.2%	
	15A2	52.2	51.3	50.9	51.5	1.3%	
	15A5	52.0	49.3	54.9	52.1	5.4%	
	15A6	51.1	49.7	55.0	51.9	5.3%	
	TA2	52.8	52.8	50.6	52.1	2.4%	
	TA5	54.4	51.4	51.0	52.3	3.6%	
	TA6	52.2	51.4	52.0	51.9	0.8%	Stdev. (kGy)
	Min. (kGy)	32.5	32.1	32.0	32.2	0.8%	0.2646
	Max. (kGy)	54.4	52.8	55.0	54.1	2.1%	1.1372
	DUR	1.67	1.64	1.72	1.68	2.4%	

APPENDIX 3: Dose distribution analysis using t-test tool - Page 1 of 1

Markham Vale
Locations of Minima and Maxima
PR-MV-2019-008
Contec 1L IPA / DE

t-Test Template, version 3

Number of Positions = 33
Uniformity = 1.62
Equivalence Limits
Minimum 4.02%
Maximum 3.82%

Minimum Positions

Min (kGy)	Equiv (kGy)	Outlier (T =)
32.3	33.6	1.822
1.1C6	4.3C6	1.1C7
	10.7C6	10.7C5
	1.1C5	4.3C7
	7.5C6	7.5C5
	4.3C5	7.5C7
		10.7C7
		1.1C9
		13.9C6
		7.5C9
		10.7C9

Maximum Positions

Max (kGy)	Equiv (kGy)	Outlier (T =)
52.3	50.3	2.110
TA5	6A2	9A5
	2A2	6A6
	3A2	9A6
	15A2	3A6
	TA6	9A2
	15A6	2A5
	TA2	6A5
	15A5	3A5

Digitally signed by Bart Coonenborghs
DN: cn=Bart Coonenborghs, o=Sterigenics, ou=Sterigenics, email=bcoonenborghs@eu.sterigenics.com, c=BE
Date: 2019.05.29 09:38:08 +02'00'

Manual Data Entry Made By: Date:

Results Reviewed By: Date: 05 June 2019

Sterigenics.
A Sotera Health company

Certificate of Processing

STERIGENICS Seymour Link Road Woodthorpe Mastin Moor
TEL FAX www.sterigenics.com

R55480102

06/11/2019 10:09:58 GMT

Customer Name:	CONTEC CLEANROOM GBP UK ASHINGTON	Processing Facility:	Markham Vale	Work Order #	2440309
P.O.#	99837			Sales Order #	2236554
25 - 95 kGy		Gamma Irradiation		Irradiation Date/Time:	05/23/2019 08:19:06 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	120	BX	SBT170IW	IPA 70% with WFI	N/A	PR-MV-2019-008
	Dose Map		302_0018	HI: TBD LO: TBD		
	120	**BX**	**Total**			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-------Signed By------- User	Date /Time
450.00	Minimum Dose	25.0 kGy Reason Code Test	95.0 kGy	32.0 KGY	Pass	EBROWN EMMA BROWN	05/28/2019 08:18:32 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	95.0 kGy	55.0 KGY	Pass	EBROWN EMMA BROWN	05/28/2019 08:18:48 GMT

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: STEVEN WHELAN
Reason: Work Order Completions
Date: 06/11/2019 10:07:27 GMT

Section 12
Shelf Life Validation

Shelf life validation for cleanroom disinfectants is separated into 2 parts, validation of the unopened shelf life and 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 $40^0C \pm 2^oC$ to take it past the 3 year time point on accelerated testing. Each week at $40^0C \pm 2^oC$ 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.