Product Information File

Contec® Sterile 70% Isopropanol

Product Codes

SBT170I
SBC570I

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

Contents

Company Overview

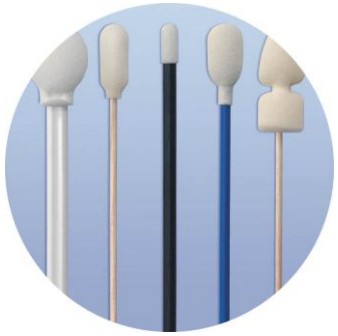
Experienced Industry Leader

Contec® is a leading manufacturer of contamination control cleaning products for critical manufacturing environments. Contec's cleanroom wipes and mops are used in biomedical, pharmaceutical, medical device, microelectronics, optics, semiconductor, data storage, animal lab, automotive OEM, aerospace and other critical industrial applications worldwide. Our flexible manufacturing environment allows us to easily customise products to your specific requirements. Our sales and technical support teams are fully trained to assist you in finding or creating the product that best meets your needs. We are committed to exceeding your requirements and expectations.

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

- **Mopping Systems and Cleaning Tools:** lightweight, easy-to-manoeuvre, wide surface coverage and low operator fatigue
- **Validated Sterile Products:** for critical applications, packaged to minimize waste
- **Pre-saturated Wipes:** ProSat and SATWipes – clean and sanitise with 70% IPA. Effectively remove micro-organisms, and particulate contamination.
- **Knitted and Non-woven Wipes:** - excellent abrasion resistance, compatible with a wide range of chemicals, ideal for application of disinfectants and cleaning solvents
- **Spill Control Products, Sponges, and Swabs**
- **Sterile 70% Alcohols**



Global Manufacturing and Distribution

Contec® operates cleanroom manufacturing facilities and distribution centres in South Carolina, USA, Suzhou, China, and Brittany, 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 USA

Contec China

Contec France

Contec® has established a cleanroom manufacturing facility and distribution centre in Vannes, France, with long term strategic partner Socomore, part of Groupe Méaban. Socomore specialises in the development, manufacture and sale of innovative chemical products for surface treatments and finishing in the global transport industries.

Socomore France

Pre-saturation Cleanroom

DIESTONE DLS SATWIPES

Contec® has teams of technical specialists and sales representatives in North America, Asia and Europe. Our manufacturing facilities and dedicated team members give Contec the ability to provide product and technical support to multinational customers with a global presence.

Regulatory Certificates

ISO certificates:

- Spartanburg, USA, 2011
- Suzhou, China, 2010

ISO 9001:2008 revises the previous ISO 9001:2000 and “specifies requirements for a quality management system where an organization

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

**From the International Organization for Standardization website; www.iso.org.*

Please refer in this section to the copies of Contec’s ISO 9001 certificates which confirm our compliance with this standard.

ZERTIFIKAT • CERTIFICATE • 認証書 • СЕРТИФИКАТ • CERTIFICADO • CERTIFICAT

America

CERTIFICATE

The Certification Body of
TÜV SÜD AMERICA INC.

hereby certifies that

CONTEC

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

(see page 2 for additional locations)

has implemented a Quality Management System in accordance with:

ISO 9001:2008

The scope of this Quality Management System includes:

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

Certificate Expiry Date: October 24, 2014

Certificate Registration No: 950 99 0586

Effective Date: October 25, 2011

Gary W. Minks
VP, Regulatory Affairs

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

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

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Manufacture of cleaning products used in critical environment

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

This certificate is valid from 14 February 2013 until 14 February 2016
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 29 January 2016
Issue 4. Certified since 15 February 2007

Authorised by

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

SGS 9001-8 01 0311

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Product Overview

Contec® Sterile 70% Isopropanol is a blend of completely miscible organic and inorganic solvents capable of dissolving or suspending contaminants allowing them to be removed from critical surfaces.

In applications where volatile organic compound (VOC) levels or solvent storage are of particular concern, **Contec Prosat® *Sterile*™ Pre-saturated Wipes** with 70% Isopropanol should be used.

Contec® Sterile 70% Isopropanol

Contec® Sterile 70% Isopropanol is adapted for use in critical clean environments and recommended for regular, effective, rapid removal of surface residues and contaminants on:

Hard surfaces of cleanrooms, isolators, laminar flow cabinets, Restrictive Access Barrier System (RABS), filling lines

*'The sanitation of clean areas is particularly important. They should be cleaned thoroughly in accordance with a written programme.' **

Gloved hands

Products and equipment before transfer into controlled environments

*'The transfer of materials into and out of the unit is one of the greatest potential sources of contamination.'**

*As standard disinfection procedure, a combination of spraying and wiping should be employed at least once in the transfer process. ***

70% v/v Isopropanol blended with Purified Water
Conforms to the European Pharmacopoeia

FEATURES	BENEFITS
Ready to use with a 2 year shelf life	• Eliminates mixing, filtration, processing and QC expense of in-house production. Allows easy inventory management
Filled in a Grade C (ISO Class 7) Cleanroom, 0.2 micron filtered and gamma irradiated not less than 25 kGy using validated processes	• **Ensures isopropanol, container and packaging are free from particulate contamination and are sterile** *'Disinfectants and detergents used in grades A and B areas should be sterile prior to use'.**
Endotoxin level less than 0.25 EU/ml and residue-free	• **Suitable for use during critical manufacturing processes**
Each bottle is labelled with the batch no. and expiration date. Certificates of analysis, irradiation and sterility (EP method) with each batch	• Assures complete product traceability and provides assurance of product quality
Filled bottles are enclosed in two sealed, protective linear-tear bags	• Enables serial transfer into critical areas and easy opening when wearing cleanroom gloves
Co-extruded flexible inner bag and solid outer bottle with modified trigger create an 'airless' system	• Prevents bottle contents becoming contaminated during use. No requirement to discard unused product during shelf life.
Ergonomic bottles designed in optimised sizes, with lock-caps and no pressurized propellants	• Convenient, comfortable, easy to use, cost effective, secure, economical waste disposal
Spray or jet options dispensing larger size droplets of fast drying isopropanol	• Facilitates process standardisation and optimised production efficiency

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info@contecinc.com
www.contecinc.com

Ordering Information

Part No.	Description	Quantity
SBT170I	Sterile bottle with trigger, 70% isopropanol, 1L	6 x 1L / case
SBC570I	Sterile bottle with cap, 70% isopropanol, 5L	2 x 5L /case

Product Application

Apply directly to the surface ensuring even coverage.
Physically remove contaminants from the surface using an appropriate cleanroom wipe and a recommended wiping technique for optimum contamination control.

*The use of a wiping stage that follows a spraying stage is recommended because any spores that may have been washed away on a surface on spraying can be picked up and removed with the use of a wipe. ***

Contec offers a range of innovative wipes and mopping systems designed for efficient and effective cleaning in controlled environments. See www.contecinc.com or contact your local sales representative for advice and information about the most suitable products and cleaning techniques for your facility.

References

**** Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007:***
Section II, Part 1, Annex 1: Manufacture of Sterile Medicinal Products:

*****Evaluation of Disinfecting Procedures for Aseptic Transfer in Hospital Pharmacy Departments***
MANITA MEHMI,1 LINDSAY J. MARSHALL,1 PETER A. LAMBERT,1 and JULIAN C. SMITH2,
1School of Life and Health Sciences, Aston University, Birmingham, B4 7ET, UK; and 2All Wales Quality Assurance Pharmacist, St Mary's Pharmaceutical Unit (SMPU), Cardiff, CF14 5RA, UK ©PDA, Inc. 2009

CONTEC®

Europe
ZI du Prat - RP 3707
56037 VANNES Cedex
FRANCE
+ 33 297 437 690

info@contecinc.com
www.contecinc.com

N. America
P.O.Box 530
Spartanburg, SC 29304
USA
+ 1-864-503-8333

China
1 Zhujing Road, Weiting Town
Suzhou 215022
CHINA
+ 86-512-6274 4050

Technical Specification
Contec® Sterile 70% Isopropanol

Composition	v/v 70% isopropanol and 30% Purified Water
Odour	Characteristic of isopropanol
Clarity	Clear, colourless
Specific Gravity	0.868 to 0.878
Endotoxin Limit	Less than 0.25 EU/ml
Production	0.2 micron filtered in an ISO Class 7 cleanroom
Packaging	Spray bottle is a co-extruded flexible inner bag and solid outer bottle with modified trigger
	Each bottle is protected with two hermetically sealed linear tear cleanroom bags
Sterility	Gamma irradiated not less than 25kGy

Product Codes

SBT170I	Trigger Spray	6 x 1L
SBC570I	Capped Bottle	2 x 5L

Please refer in this section to Contec's formal declaration confirming that Contec Sterile 70% Isopropanol does not contain any causative agents of Transmissible Spongiform Encephalopathy (TSE).

June 25, 2008

To Whom It May Concern

Subject: 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. 2 – October 2003)

Dear Contec Customer:

Contec certifies that we exclude the presence of any animal or human derived products within our manufacturing processes. This includes raw materials, reagents and cleaning supplies.

Contec is committed to providing you with quality products that meet or 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,

Sincerely,

Genoa Atwood
Quality Manager
Contec, Inc
864-699-8282
gatwood@contecinc.com

Instructions for Use

Contec® Sterile 70% Isopropanol 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 70% Isopropanol 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 70% Isopropanol 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 optimise the physical removal of contaminants from the surface.

See Appendix 1 for information about correct wiping techniques for optimal results.

Materials and their Compatibility

Contec® Sterile 70% Isopropanol is suitable for use on the majority of materials found in cleanroom environments. It is not suitable for use on acrylic surfaces.
In case of doubt it is recommended to test the materials with the product before prolonged contact.

Product Certificates

CONTEC®

CERTIFICAT PRODUIT

Produit:	Contec Sterile 70% Isopropanol
Code Produit:	SBT170I
Description Produit:	v/v 70% Isopropanol et 30% Eau Purifiée
Numéro de Lot:	XXXXXXXXXXoa
Date de Fabrication:	MM/AAAA
Date de Péremption:	MM/AAAA

ANALYSES

Tests:	Spécifications:	Résultats:
Aspect:	Liquide limpide	Conforme
Couleur:	Incolore	Conforme
Filtration:	Filtré à 0.2 microns	Conforme
Endotoxines:	<0.25 EU/ml	Conforme
Densité à 20°C:	0.868 à 0.878	X.XXX

Le fabricant est certifié selon le référentiel ISO 9001 : version 2008. Le produit est réalisé, testé et validé en conformité avec les procédures qualité en vigueur et les spécifications définies dans le cahier des charges.

IRRADIATION

	Spécifications:	Résultats:
Dose Irradiation du dosimètre Routine B (KGy):	Entre XX.X et XX.X	XX.X

Nous certifions que les produits sont irradiés par une exposition à des rayons gamma. La dose d'exposition délivrée est conforme à la Pharmacopée Européenne soit une dose minimum de 25 kGy.

Le Traitement d'Irradiation appliqué est en conformité avec les certifications:

ISO 9001: 2000 Système de Management par la Qualité

ISO 13485: Système de Management par la Qualité – Dispositifs Médicaux

ISO 11137: Stérilisation des produits de santé - Irradiation - exigences relatives à la mise au point, à la validation et au contrôle de routine des procédés de stérilisation.

ISO 14001: Système de Management Environnemental

STERILITE

Résultat Test de Stérilité: Conforme

Méthode utilisée correspondant la méthode décrite dans l'édition actuelle de la Pharmacopée Européenne : § 2.6.1

Nom :	1: HENRY Delphine	2: LE GREVELLEC Yann
Fonction:	1: Assistante Qualité	2: Responsable QHSE
Date :	1: 14/12/2010	2: 14/12/2010
Visa:	1:	2:

For and on behalf of Contec®

SPECIMEN

NORTH AMERICA
Contec, Inc.
P.O. Box 530
Spartanburg, SC 29304 USA
tel: +1-864-503-8333
fax: +1-864-503-8444

EUROPE
Contec, Inc.
ZI du Prat - B.P. 3207
F-56037 VANNES Cedex France
tel: +33 (0)2 97 43 76 90
fax: +33 (0)2 97 43 76 86

ASIA
Contec Cleanroom Technology (Suzhou) Co., Ltd.
1 Zhujing Road, Weiting Town
Suzhou Industrial Park, Suzhou 215022 China
tel: +86 512 6274 4050
fax: +86 512 6274 4051

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

CONTEC®

PRODUCT CERTIFICATE

Product:	Contec Sterile 70% Isopropanol
Product Code:	SBC570I
Product Description:	v/v 70% Isopropanol and 30% EP purified water
Batch Number:	XXXXXXXXX
Manufacture Date:	MM/YEAR
Expiry Date:	MM/YEAR

ANALYSIS

Test:	Specification:	Results:
Colour:	Colourless	Complies
Clarity:	Clear	Complies
Filtration:	Filtered to 0.2 microns	Complies
SG at 20oC:	0.868 to 0.878	Complies

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

IRRADIATION

	Specification:	Results:
Irradiation Dose Routine B (KGy):	Between 40.3 to 67.3	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 European Pharmacopoeia.

Irradiation treatment applied was accordance with:

ISO 9001: Quality Management System

ISO 13485: Quality Management System – Medical Devices

ISO 11137: Sterilisation of Healthcare Products – Requirements for Validation and Routine Control – Radio sterilisation

ISO 14001: Environmental Management System

STERILITY

Sterility test result: Complies

Test method as described in the current edition of the European Pharmacopoeia: § 2.6.1

CONFORMITY

BATCH ☒ CONFORM ☐ NON-CONFORM

Name:	1: HENRY Delphine	2: LE GREVELLEC Yann
Position:	1: QA	2: QM
Date:	1: DD/MM/YEAR	2: DD/MM/YEAR
Authorised Signature:	1:	2:

For and on behalf of Contec®

SPECIMEN

NORTH AMERICA
Contec, Inc.
P.O. Box 530
Spartanburg, SC 29304 USA
tel: +1-864-503-8333
fax: +1-864-503-8444

EUROPE
Contec, Inc.
ZI du Pret - B.P. 3707
F-56037 VANNES Cedex France
tel: +33 (0)2 97 43 76 90
fax. +33 (0)2 97 43 76 98

ASIA
Contec Cleanroom Technology (Suzhou) Co., Ltd.
1 Zhujing Road, Wuting Town
Suzhou Industrial Park, Suzhou 215022 China
tel: +86 512 6274 4050
fax: +86 512 6274 4051

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

MSDS

Material Safety Data Sheets are available in 14 languages; Czech, Danish, Dutch, English, Finnish, French, German, Italian, Norwegian, Polish, Portuguese, Slovenian, Spanish, Swedish.

Please contact your Contec representative for assistance.

SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : CONTEC STERILE 70% ISOPROPANOL

Product code : 43271D.

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

Cleaner

Solvent

Professional uses

Industrial uses

1.3. Details of the supplier of the safety data sheet

Registered company name: CONTEC INC..

Address : PO BOX 350 525 LOCUST GROVE.29304 SC.SPARTANBURG.USA.

Telephone : 1-8645038333. Fax : 1-8645033453.

HealthandSafety@contecinc.com

CONTEC Europe - avenue Paul Duplaix - 56037 VANNES Cedex France - Tel. +33 (0)2 97 43 76 83 - Fax +33 (0)2 97 54 50 26

1.4. Emergency telephone number : +33 (0)1 45 42 59 59.

Association/Organisation : INRS / ORFILA http://www.centres-antipoison.net.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Highly flammable.

Possibility of irritation to the eyes.

Vapors may cause drowsiness and dizziness.

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

Detergent mixture (see section 15).

Mixture for spray application.

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Hazard symbols :

Irritant

Highly flammable

Risk phrase :

R 36	Irritating to eyes.
R 11	Highly flammable.
R 67	Vapours may cause drowsiness and dizziness.

Safety phrase:

S 23	Do not breathe vapour.
S 16	Keep away from sources of ignition - No smoking.
S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 60	This material and its container must be disposed of as hazardous waste.
S 9	Keep container in a well-ventilated place.

2.3. Other hazards

No data available.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

No substances fulfil the criteria set forth in annexe II section A of the REACH regulation (EC) n° 1907/2006.

3.2. Mixtures

Composition :

Identification	Name	Classification	%
INDEX: 603-117-00-0 CAS: 67-63-0 EC: 200-661-7 REACH: 01-2119457558-25	PROPAN-2-OL	GHS02, GHS07, Dgr Xi,F H:225-319-336 R: 11-36-67	50 <= x % < 100

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of exposure by inhalation :

In the event of massive inhalation, remove the person exposed to fresh air. Keep warm and at rest.

In the event of splashes or contact with eyes :

Wash thoroughly with soft, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of swallowing :

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor.

Keep the person exposed at rest. Do not force vomiting.

Seek medical attention, showing the label.

If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show the label.

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

No data available.

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

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Flammable.

Chemical powders, carbon dioxide and other extinguishing gas are suitable for small fires.

5.1. Extinguishing media

Keep packages near the fire cool, to prevent pressurised containers from bursting.

Suitable methods of extinction

In the event of a fire, use :

- sprayed water or water mist
- water with AFFF (Aqueous Film Forming Foam) additive
- halon
- foam
- multipurpose ABC powder
- BC powder
- carbon dioxide (CO2)

Prevent the effluent of fire-fighting measures from entering drains or waterways.

Unsuitable methods of extinction

In the event of a fire, do not use :

- water jet

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO2)

5.3. Advice for firefighters

Fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non fire-fighters

Because of the organic solvents contained in the mixture, eliminate sources of ignition and ventilate the area.

Avoid any contact with the skin and eyes.

For fire-fighters

Fire-fighters will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Ensure that there is adequate ventilation, especially in confined areas.

Fire prevention :

Handle in well-ventilated areas.

Vapours are heavier than air. They can spread along the ground and form mixtures that are explosive with air.

Prevent the formation of flammable or explosive concentrations in air and avoid vapor concentrations higher than the occupational exposure limits.

Prevent the accumulation of electrostatic charges with connections to earth.

The mixture can become electrostatically charged: always earth during decanting operations. Wear antistatic shoes and clothing and floors should be electrically conductive.

Use the mixture in premises free of naked flames or other sources of ignition and ensure that electrical equipment is suitably protected.

Keep packages tightly closed and away from sources of heat, sparks and naked flames.

Do not use tools which may produce sparks. Do not smoke.

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Where the personnel must carry out work in a booth, whether for spraying or otherwise, the ventilation may be inadequate to control particles and solvent vapors in every case.

It is therefore recommended that personnel wear masks with a compressed air supply during spraying operations until the concentration of particles and solvent vapors has fallen below the exposure limits.

Avoid eye contact with this mixture.

Packages which have been opened must be reclosed carefully and stored in an upright position.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Keep the container tightly closed in a dry, well-ventilated place

Keep away from all sources of ignition - do not smoke.

Keep well away from all sources of ignition, heat and direct sunlight

Avoid accumulation of electrostatic charges.

The floor must be impermeable and form a collecting basin so that, in the event of an accidental spillage, the liquid cannot spread beyond this area.

Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits :

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
67-63-0	200 ppm	400 ppm	-	-	-

- Germany - AGW (BAuA - TRGS 900, 21/06/2010) :

CAS	VME :	VME :	Excess	Notes
67-63-0	200 ml/m3	500 mg/m3	2(II)	DFG, Y

- France (INRS - ED984:2007 and French Order of 30/06/2004) :

CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
67-63-0	-	-	400	980	-	84

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Use eye protectors designed to protect against liquid splashes

Before handling, wear safety goggles with protective sides accordance with standard EN166.

In the event of high danger, protect the face with a face shield.

When spraying, wear a face shield in accordance with standard EN166.

Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

Provide eyewash stations in facilities where the product is handled constantly.

- Hand protection

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question: other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Type of gloves recommended :

- Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))

Recommended properties :

- Impervious gloves in accordance with standard EN374

- Body protection

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

Avoid breathing vapours.

If the ventilation is insufficient, wear appropriate breathing apparatus.

When workers are confronted with concentrations that are above occupational exposure limits, they must wear a suitable, approved, respiratory protection device.

Anti-gas and vapour filter(s) (Combined filters) in accordance with standard EN14387 :

- A1 (Brown)

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state:	fluid liquid.

Important health, safety and environmental information

pH of the substance or preparation :	not relevant.
The pH is impossible to measure or its value is not relevant.	
Boiling point/boiling range :	82 °C.
Flash point interval :	not relevant.
Flash point interval :	Flash point < 21°C
Vapour pressure :	not relevant.
Density :	< 1
Water solubility :	Dilutable.
Self-ignition temperature :	not specified.

9.2. Other information

VOC (g/l) :	563

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

When exposed to high temperatures, the mixture can release hazardous decomposition products, such as carbon monoxide and dioxide, fumes and nitrogen oxide.

10.4. Conditions to avoid

Any apparatus likely to produce a flame or to have a metallic surface at high temperature (burners, electric arcs, furnaces etc.) must not be allowed on the premises.

Avoid :

- accumulation of electrostatic charges.
- heating
- heat
- flames and hot surfaces

10.5. Incompatible materials

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO2)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Repeated or prolonged contact with the mixture may cause removal of natural oil from the skin resulting in non-allergic contact dermatitis and absorption through the skin.

May have reversible effects on the eyes, such as eye irritation which is totally reversible by the end of observation at 21 days.

Splashes in the eyes may cause irritation and reversible damage

Narcotic effects may occur, such as drowsiness, narcosis, decreased alertness, loss of reflexes, lack of coordination or dizziness.

Effects may also occur in the form of violent headaches or nausea, judgement disorder, giddiness, irritability, fatigue or memory disturbance.

Substances

No toxicological data available for the substances.

Mixture

No toxicological data available for the mixture.

SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity

Substances

No aquatic toxicity data available for the substances.

Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

Codes of wastes (Decision 2001/573/EC, Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste) :

14 06 03 * other solvents and solvent mixtures

SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2011 - IMDG 2010 - ICAO/IATA 2011).

14.1. UN number

1219

14.2. UN proper shipping name

UN1219=ISOPROPANOL (ISOPROPYL ALCOHOL)

14.3. Transport hazard class(es)

- Classification :

3

14.4. Packing group

II

14.5. Environmental hazards

-

14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	3	F1	II	3	33	1 L	601	E2	2	D/E

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	3	-	II	1 L	F-E,S-D	-	E2

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ

	3	-	II	353	5 L	364	60 L	A180	E2
	3	-	II	Y341	1 L	-	-	A180	E2

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No data available.

SECTION 15 : REGULATORY INFORMATION

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

- Particular provisions :

No data available.

15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Title for H, EUH and R indications mentioned in section 3 :

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
R 11	Highly flammable.
R 36	Irritating to eyes.
R 67	Vapours may cause drowsiness and dizziness.

Abbreviations :

ADR : European agreement concerning the international carriage of dangerous goods by Road.

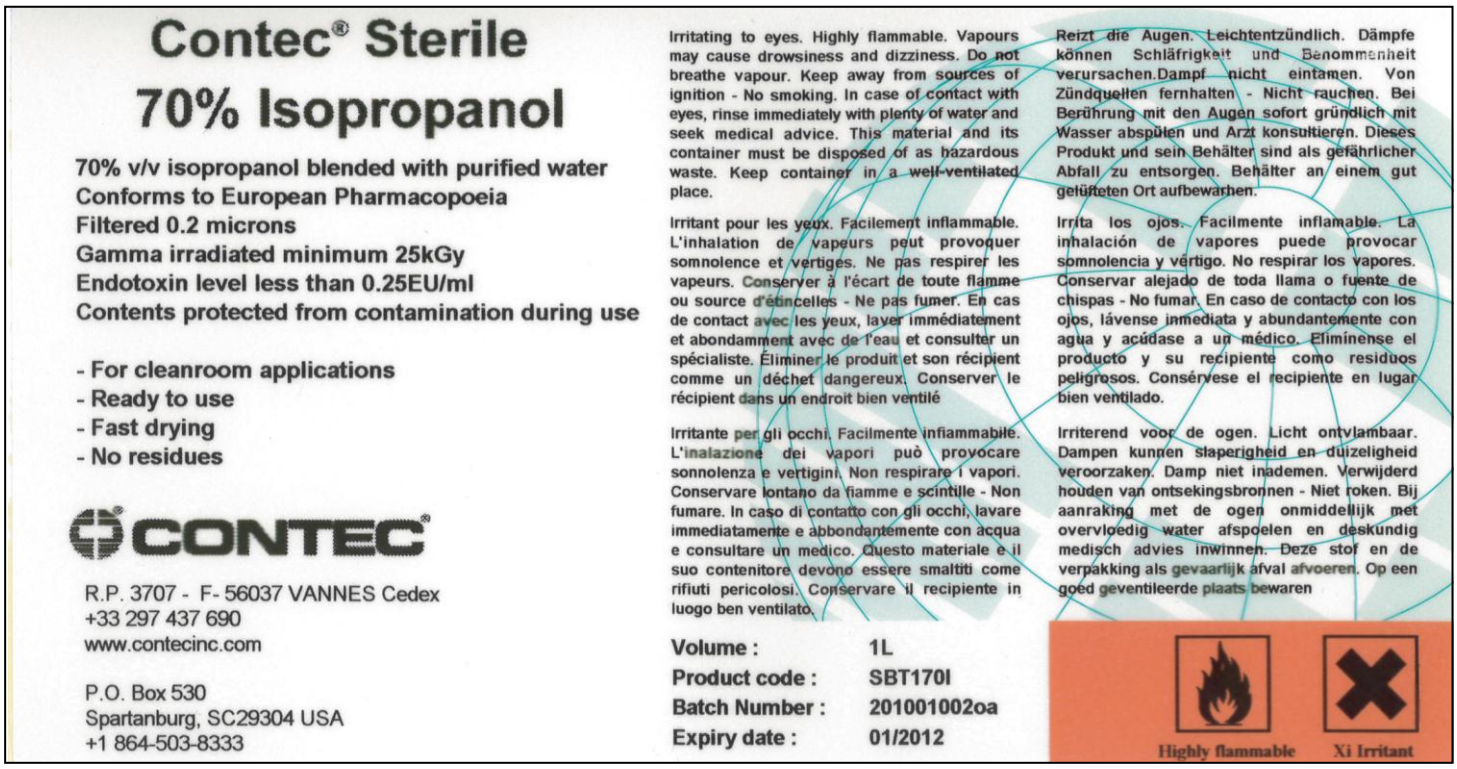
IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

Product Labels



Contec® Sterile 70% Isopropanol

70% v/v isopropanol blended with purified water
Conforms to European Pharmacopoeia
Filtered 0.2 microns
Gamma irradiated minimum 25kGy
Endotoxin level less than 0.25EU/ml
Contents protected from contamination during use

- **For cleanroom applications**
- **Ready to use**
- **Fast drying**
- **No residues**

CONTEC

R.P. 3707 - F- 56037 VANNES Cedex
+33 297 437 690
www.contecinc.com

P.O. Box 530
Spartanburg, SC29304 USA
+1 864-503-8333

Irritating to eyes. Highly flammable. Vapours may cause drowsiness and dizziness. Do not breathe vapour. Keep away from sources of ignition - No smoking. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. This material and its container must be disposed of as hazardous waste. Keep container in a well-ventilated place.

Irritant pour les yeux. Facilement inflammable. L'inhalation de vapeurs peut provoquer somnolence et vertiges. Ne pas respirer les vapeurs. Conserver à l'écart de toute flamme ou source d'étincelles - Ne pas fumer. En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste. Éliminer le produit et son récipient comme un déchet dangereux. Conserver le récipient dans un endroit bien ventilé

Irritante per gli occhi. Facilmente infiammabile. L'inalazione dei vapori può provocare sonnolenza e vertigini. Non respirare i vapori. Conservare lontano da fiamme e scintille - Non fumare. In caso di contatto con gli occhi, lavare immediatamente e abbondantemente con acqua e consultare un medico. Questo materiale e il suo contenitore devono essere smaltiti come rifiuti pericolosi. Conservare il recipiente in luogo ben ventilato.

Reizt die Augen. Leichtentzündlich. Dämpfe können Schläfrigkeit und Benommenheit verursachen.Dampf nicht einatmen. Von Zündquellen fernhalten - Nicht rauchen. Bei Berührung mit den Augen sofort gründlich mit Wasser abspülen und Arzt konsultieren. Dieses Produkt und sein Behälter sind als gefährlicher Abfall zu entsorgen. Behälter an einem gut gelüfteten Ort aufbewahren.

Irrita los ojos. Facilmente inflamable. La inhalación de vapores puede provocar somnolencia y vértigo. No respirar los vapores. Conservar alejado de toda llama o fuente de chispas - No fumar. En caso de contacto con los ojos, lávense inmediata y abundantemente con agua y acúdase a un médico. Elimínense el producto y su recipiente como residuos peligrosos. Consérvese el recipiente en lugar bien ventilado.

Irriterend voor de ogen. Licht ontvlambaar. Dampen kunnen slaperigheid en duizeligheid veroorzaken. Damp niet inademen. Verwijderd houden van ontsekingsbronnen - Niet roken. Bij aanraking met de ogen onmiddellijk met overvloedig water afspoelen en deskundig medisch advies inwinnen. Deze stof en de verpakking als gevaarlijk afval afvoeren. Op een goed geventileerde plaats bewaren

Volume : 1L
Product code : SBT170I
Batch Number : 201001002oa
Expiry date : 01/2012

Certificate of Conformance
This product complies with all Contec, Inc. specifications which are available upon request.

SBT170I

Contec Sterile 70% Isopropanol

70% -v/v isopropanol blended with purified water

Bottle 1L, - Case contents 6 x 1L

Made in France

Lot No : 201001002

Exp. Date : 01/2012
Mfg. Date : 01/2010

CONTEC
www.contecinc.com

R.P. 3707 - F-56037 VANNES Cedex
T. +33 297 437 690
P.O. Box 530 Spartanburg, SC 29304 USA
T. +1-864-503-8333

Certificate of Conformance
This product complies with all Contec, Inc. specifications which are available upon request.

SBT170I

Contec Sterile 70% Isopropanol

70% -v/v isopropanol blended with purified water

Bottle 1L, - Case contents 6 x 1L

Made in France

Lot No : 201001002

Exp. Date : 01/2012
Mfg. Date : 01/2010

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Contec® Sterile 70% Isopropanol

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Conforms to European Pharmacopoeia
Filtered 0.2 microns
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Endotoxin level less than 0.25EU/ml
Contents protected from contamination during use

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- Fast drying
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Volume : 5L
Product code : SBC570I
Batch Number : 201001002oa
Expiry date : 01/2012

Certificate of Conformance
This product complies with all Contec, Inc. specifications which are available upon request.

SBC570I

Contec Sterile 70% Isopropanol

70% -v/v isopropanol blended with purified water

Bottle 5L, - Case contents 2 x 5L

Made in France

Lot No : 201001002

Exp. Date : 01/2012
Mfg. Date : 01/2010

CONTEC

R.P. 3707 - F-56037 VANNES Cedex
T. +33 297 437 690
P.O. Box 530 Spartanburg, SC 29304 USA

Certificate of Conformance
This product complies with all Contec, Inc. specifications which are available upon request.

SBC570I

Contec Sterile 70% Isopropanol

70% -v/v isopropanol blended with purified water

Bottle 5L, - Case contents 2 x 5L

Made in France

Lot No : 201001002

Exp. Date : 01/2012
Mfg. Date : 01/2010

CONTEC

R.P. 3707 - F-56037 VANNES Cedex
T. +33 297 437 690
P.O. Box 530 Spartanburg, SC 29304 USA

Packaging

The **packaging of Contec® Sterile 70% Isopropanol** is designed to minimize the risk of contamination being transferred into the manufacturing area.

Each closed HDPE bottle with the trigger attached is hermetically sealed in two linear tear plastic bags. These LDPE bags are manufactured in a cleanroom class ISO 5 to ensure their cleanliness. The linear tear feature ensures ease of opening when wearing cleanroom gloves.

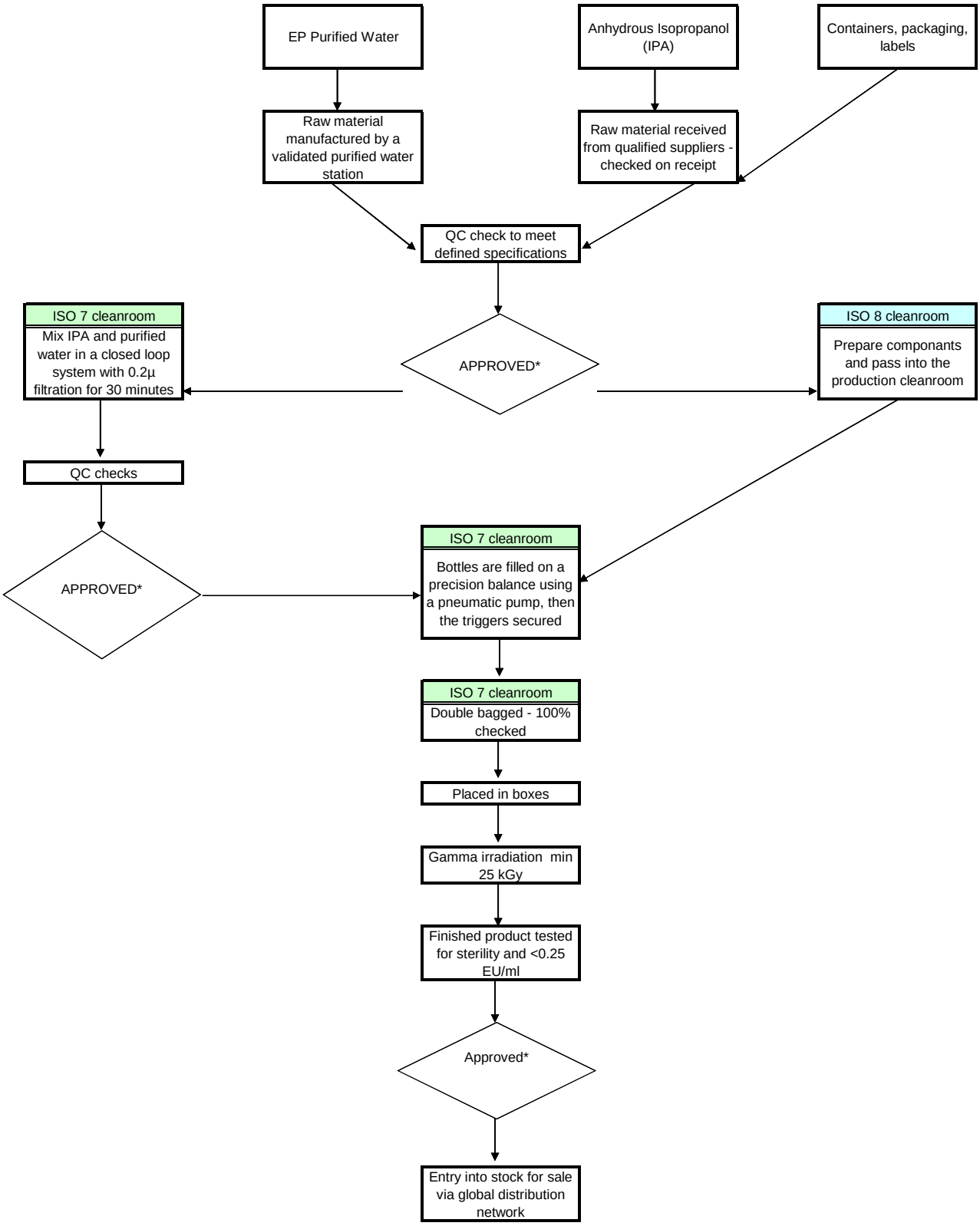
Each case is lined with plastic so the finished products are not in contact with the protective cardboard packaging.

The boxes meet the UN requirements for transport of these products and are labelled to indicate the correct orientation for storage.

Production Process

The manufacturing process has been designed so that **Contec ® Sterile 70% Isopropanol** can be used to treat surfaces in cleanrooms.

Manufacturing Process for Contec® Sterile 70% Isopropanol



* At each step in the process, if a non-conformity is seen, the product is placed in quarantine for investigation then discarded if necessary

Quality Assurance and Quality Control

Contec® is committed to manufacturing high quality contamination control products for use in regulated industries. **Quality assurance** and **quality controls** are essential to achieve this aim and Contec implements continuous improvement plans in line with GMP (Good Manufacturing Practice, EudraLex – Volume 4 Good Manufacturing (GMP) Guidelines).

Validation of Irradiation

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 (kiloGray).

Our service provider Ionisos is responsible for the sterilisation of Contec products, following well defined specifications to achieve performance qualification. The gamma irradiation is conducted at their site in Sable sur Sarthe.

Performance qualification of our products is conducted every two years.

The sterile products 70% Isopropanol and Denatured Ethanol have a similar density and identical packaging, so the performance qualification of these products references a single packaging format (see the performance qualification report below).

Qualification report - 1L bottle: Contec Sterile 70% Isopropanol

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

IONISOS
Traitement par rayonnement gamma

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

Compte rendu de qualification de performance

Client : **SOCOMORE** N° Cde client : **PFO A01 1101 00108**

Référence Produit : **ISOPROPANOL 70% STERILE SIDJI 1L et CONTECT 5L**

24 FEV. 2011

N° Lot produit : 110100110

1. Objet

Une qualification de performance a pour objet de vérifier la répartition des doses dans les charges du client, dans les conditions normales d'exploitation de la cellule concernée du site de Sablé sur Sarthe.
Conformément aux normes ISO 9001, ISO 13485 et ISO 11137 (pour QP 3 runs).

2. Caractéristiques Produit

Type de conditionnement : Cartons (*)

(*) préciser si <autres> :

Hauteur (cm)	Longueur (cm)	Epaisseur (cm)	Poids (kg)	Densité (g/cm3)
184	118	95	587	0.28

Dose minimale demandée : **25.0 kGy** **Dose maximale demandée :** **95.0 kGy**

3. Caractéristiques Installation

Le conteneur d'irradiation est une nacelle présentant 2 niveaux de chargement pour des palettes.
Les capacités utiles des chargement des nacelles par niveau sont les suivantes :
Dimensions: 100 x 120 x 200 cm Poids: 1000 kg maxi
Les palettes hautes et basses d'une nacelle sont permutées, de telle sorte que toutes les palettes réalisent le même nombre de passages en position haute et en positon basse dans les nacelles.
Le dosimètre de routine B est placé sur l'axe B de la palette à 25 cm du bas du produit.
Le dosimètre de routine A est placé sur l'axe A de la palette à 1 cm du bas du produit

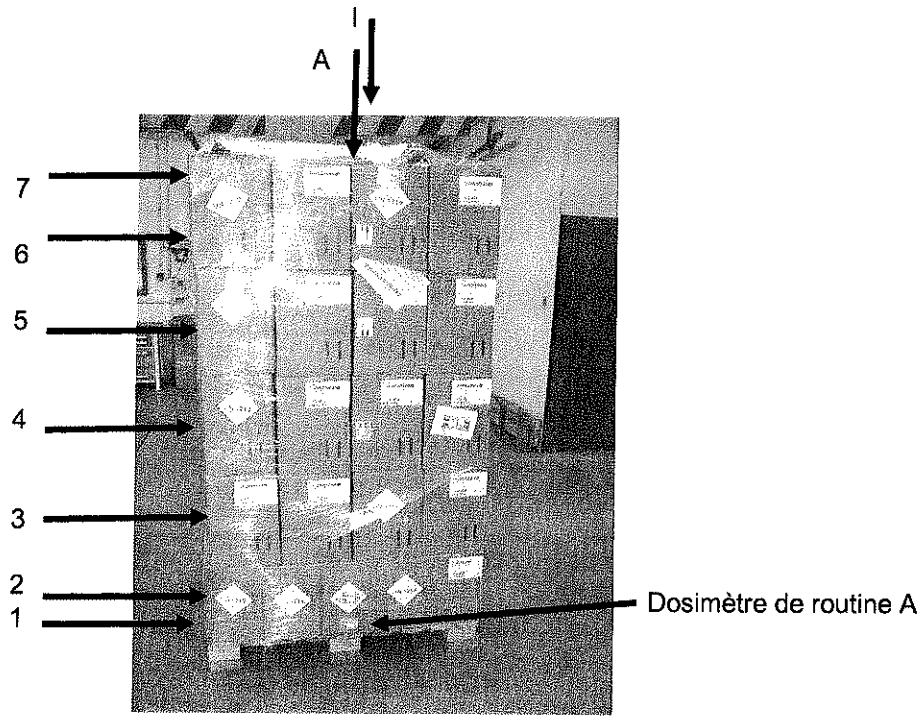
Référence Qualification de l'installation : Qualification de l'installation - Sablé - Rév 1
Configuration de source de référence : CR QO SAB 2011 rév 0

Type de dosimètre utilisés : Red
N° lot de dosimètres : 4034 LE Date d'étalonnage : 23/11/2010

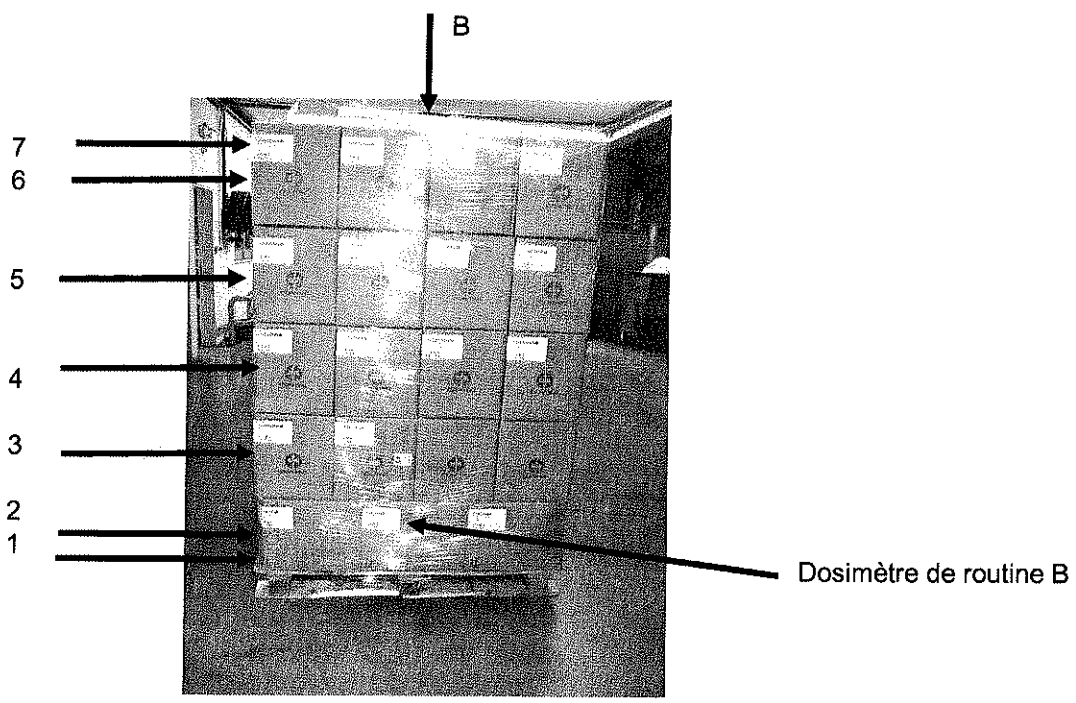
Site de Sablé sur Sarthe
Z.I. de l'Aubrée
72300 Sablé sur Sarthe (France)

4. Schéma de position des colis dans les conteneurs / dosimétrie

Nombre de colis par couche : 15 + 16 Nombre de couches de colis : 1 + 4
Nombre total de colis / palette : 79 Nombre de palettes instrumentées : 1
N° palettes instrumentées : 8565101S - -



FACE A



FACE B

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

5. Traitement

N° Commande Ionisos : 0128565/01
N° Traitement Ionisos : 8565101S
Date(s) de traitement : 25/01/2011
Nombre de tours file 1 : 10 + 10

6. Résultats de la Dosimétrie

Position des dosimètres numérotés de 01 à XX pour chaque axe. 01 étant la position la plus basse puis incrément de 1 pour chaque niveau.

Conteneur n° 1		Conteneur n° 2		Conteneur n° 3		Synthèse	
N° dosimètre	Dose	N° dosimètre	Dose	N° dosimètre	Dose	Position	Moyenne
B137320R	59.4 kGy					Routine B	59.4 kGy
A113665R	43.8 kGy					Routine A	43.8 kGy
8665101S5107R	45.9 kGy					I 07	45.9 kGy
8665101S5106R	38.5 kGy					I 06	38.5 kGy
8665101S5105R	36.5 kGy					I 05	36.5 kGy
8665101S5104R	37.0 kGy					I 04	37.0 kGy
8665101S5103R	33.7 kGy					I 03	33.7 kGy
8665101S5102R	28.2 kGy					I 02	28.2 kGy
8665101S5101R	27.2 kGy					I 01	27.2 kGy
8665101S2107R	61.6 kGy					B 07	61.6 kGy
8665101S2106R	59.4 kGy					B 06	59.4 kGy
8665101S2105R	57.6 kGy					B 05	57.6 kGy
8665101S2104R	59.1 kGy					B 04	59.1 kGy
8665101S2103R	59.1 kGy					B 03	59.1 kGy
8665101S2102R	59.6 kGy					B 02	59.6 kGy
8665101S2101R	61.7 kGy					B 01	61.7 kGy
8665101S1107R	51.6 kGy					A 07	51.6 kGy
8665101S1106R	46.1 kGy					A 06	46.1 kGy
8665101S1105R	42.9 kGy					A 05	42.9 kGy
8665101S1104R	42.2 kGy					A 04	42.2 kGy
8665101S1103R	39.7 kGy					A 03	39.7 kGy
8665101S1102R	42.0 kGy					A 02	42.0 kGy
8665101S1101R	44.6 kGy					A 01	44.6 kGy

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

7. Exploitation des résultats

Dose minimale :	27.2 kGy	**Dose maximale :**	61.7 kGy
Dose Routine B :	59.4 kGy	**Dose Routine A :**	43.8 kGy

Ratio Dose Max /dose Min : 2.270

RmA (Dose RA / Dose Min) : 1.610 RMA (Dose RA / Dose Max) : 0.709

Dose minimale visée en Rx = Dose minimale visée x Rmx

Dose minimale visée en RA = 40.3 kGy

Dose maximale visée en Rx = Dose maximale visée x RMx

Dose maximale visée en RA= 67.3 kGy

Les résultats obtenus servent de base pour définir la fourchette de dose utilisée en routine.

Le visa du client qui approuve le présent rapport, valide les conclusions.

A dater de ce jour et sauf avis contraire de votre part, nous modifions et appliquons les données de traitements selon les instructions déterminées dans le rapport.

Les résultats des lectures sont données avec une incertitude de : 5 %

	Rédacteur	Approbateur
Nom	Aurélie Chaillou	Sébastien DESMONTILS
Fonction	Responsable Qualité	Direction Commerciale
Date	22/02/11	22/02/2011
Visa		

La dernière page de ce rapport doit nous être retournée signée (fax).

IONISOS
Traitement par rayonnement gamma

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

Synthèse Qualification de Performance

Client : **SOCOMORE** N° Cde client : **PFO A01 1101 00108**

Référence Produit : **ISOPROPANOL 70% STERILE SIDJI 1L et CONTECT 5L**

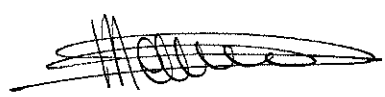
Dose minimale demandée : **25.0 kGy** **Dose maximale demandée :** **95.0 kGy**

N° Traitement Ionisos : 8565101S

Date(s) de traitement : 25/01/2011

Ratio Dose Max /dose Min : 2.270

RmA (Dose RA / Dose Min) :	1.610	**RMA (Dose RA / Dose Max) :**	0.709
Dose minimale visée en RA =	40.3 kGy	**Dose maximale visée en RA=**	67.3 kGy

	Approbation Client
Nom	HENRY Delphine
Fonction	A. Qualité
Date	28/09/2011
Visa	

Les résultats des lectures sont données avec une incertitude de : 5 %

Cette page doit nous être retournée visée, à l'attention du service commercial par fax au n° 02 43 92 03 51

Shelf life Validations

All our sterility tests are conducted and validated by an independent laboratory ACM Pharma, recognised by ANSM as a pharmaceutical manufacturer and acknowledged in published research studies.

Accelerated Aging Studies

Incubation at 37 degrees centigrade: To simulate aging, two bottles of Contec Sterile 70% Isopropanol were stored in an incubator at with the trigger nozzles open.

First test: The contents of the first bottle were tested every two months according to the following criteria: clarity, colour, and specific gravity. This test lasted for one year.
This study confirmed the product is stable over time in extreme storage conditions

Second test: After 43 days incubation he second bottle was sent to a laboratory. The bottle contents were tested for sterility (according to the current version of the European Pharmacopoeia). This second test confirmed that under extreme conditions the sterility of the product is maintained.

Incubation at 25 degrees centigrade: To simulate aging, one bottle of Contec Sterile 70% Isopropanol was stored in an incubator at with the trigger nozzle open.

After 43 days incubation the bottle was sent to a laboratory. The bottle contents were tested for sterility (according to the current version of the European Pharmacopoeia).

After incubation to simulate extreme conditions the product remained sterile.

Shelf life validation during normal storage conditions

6 bottles of Contec Sterile 70% Isopropanol were stored at ambient temperature to determine whether the product is stable and the packaging protects the product. The bottles were stored in their original packaging.

Every 6 months a bottle was sent to the external laboratory. The bottle contents were tested for sterility (according to the current version of the European Pharmacopoeia).

After 24 months in normal storage conditions the product remained sterile.

In-use shelf life validation

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

Every week day the trigger was depressed 5 times to dispense the 70% isopropanol 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. The bottle contents were tested for sterility (according to the current version of the European Pharmacopoeia).

During these conditions of use, the product remained sterile.

Drop Test

The objective of this test is to simulate the fall of a box from a pallet to determine the potential damage caused by the fall of the products.

The box fell from a height of 1.80m with the critical impact point being to the corner of the box.

The test results are satisfactory since the bottles remained undamaged, only the corner of the box was damaged.

Drop Test: 1.80m for 6 x1L bottles

Condition of the containers before the test

Condition of the containers and box after the test

Bouteille n°1 la plus exposée

Intérieur du carton

Fond de la bouteille n°1

Results: The fall of the box did not have any negative impact on the bottles.
The box was slightly damaged.

Appendix 1: Correct Wiping Techniques for Optimal Cleaning

A recent study of different techniques for aseptic transfer of components required in Grade A pharmaceutical environments has shown that; *'Of the different application methods tested, spraying followed by wiping was the most effective, followed closely by wiping alone. Spraying alone was least effective.*[A]

A second study found that; *'Alcohol impregnated wipes performed better at reducing microbial bioburden than the alcohol spray/dry wipe applications.*[B] The use of Contec ProSat Sterile Wipes pre-saturated with 70% isopropanol should be considered to address this point.

References

[A]Evaluation of Disinfecting Procedures for Aseptic Transfer in Hospital Pharmacy Departments
Manita Mehmi,[1] Lindsay J. Marshall,[1] Peter A. Lambert,[1] and Julian C. Smith[2],*

[1] School of Life and Health Sciences, Aston University, Birmingham, B4 7ET, UK; and [2] All Wales Quality Assurance Pharmacist, St Mary's Pharmaceutical Unit (SMPU), Cardiff, CF14 5RA, UK ©PDA, Inc. 2009

[B] Evaluation of alcohol wipes used during aseptic manufacturing
M.N. Panousi [1] , G.J. Williams [1] , S. Girdlestone [2] , S.J. Hiom [2] and J.-Y. Maillard [1]

[1] Welsh School of Pharmacy, Cardiff University, Cardiff, Wales, UK
[2] St Mary Pharmaceutical Unit, Cardiff & Vales NHS Trust, Llanishen, Cardiff, Wales, UK

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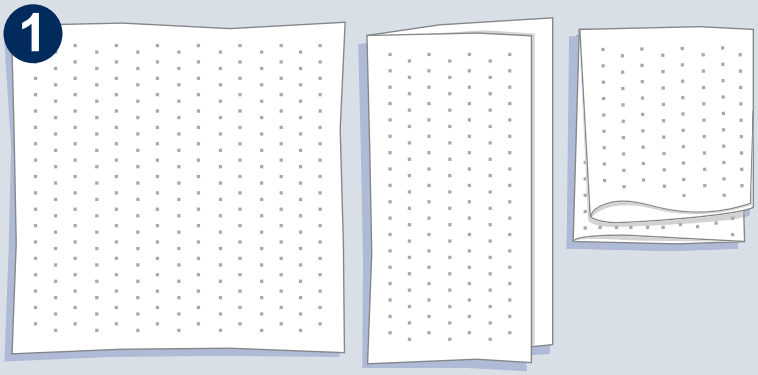
Recommended Wiping Technique

For Cleanroom Contamination Control

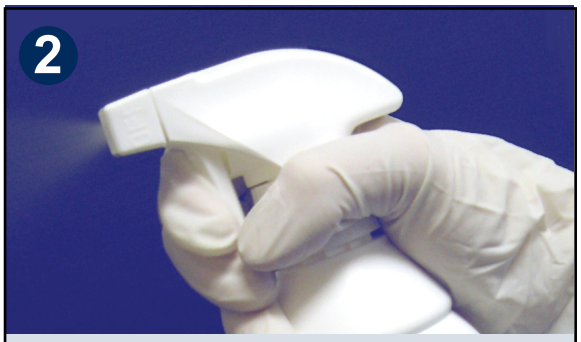
- The physical action of wiping will remove contaminants from the surface to be retained in the wipe.
- Technique is important to prevent the trapped contamination being re-deposited on a surface.
- Wiping the cleanest area before moving to the dirtiest will minimise the risk of transferring contaminants onto critical surfaces.
- These considerations apply to all surfaces both horizontal and vertical.

1



Fold the wipe in half, then in half again, creating a quarter-folded wipe.

2



Apply Contec Sterile 70% Isopropanol to the wipe ensuring uniform saturation.
NOTE: Use of Contec PROSAT Sterile wipes eliminates this step.

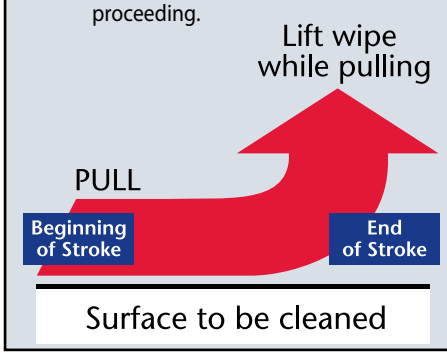
3

Pick up the quarter-folded wipe at the open edge. Grasp the unfolded edges between thumb and forefinger.

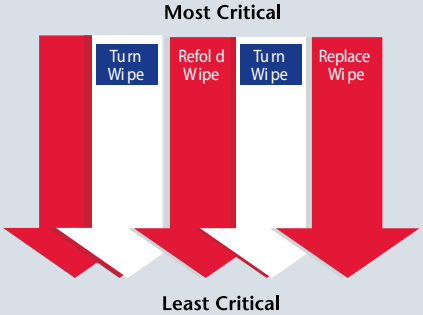
4

When wiping, place equal pressure across the edge of the hand and pull across the surface to be cleaned.

5 Lift the wipe at the end of each stroke so that contamination is removed from the surface. Refold the wipe, exposing a clean surface before proceeding.



6 Wipe in one direction with slightly overlapping strokes, from most critical to least critical areas, lifting the wipe at the end of each stroke.



7 Dispose of used wipes according to site protocol.

Contec offers a range of innovative wipes and mopping systems designed for efficient and effective cleaning in controlled environments. See www.contecinc.com or contact your local sales representative for advice and information about the most suitable products and cleaning techniques for your facility.

EUR004 102909

Asia +86-512-6274 4050
Europe +33 297 437 690
North America +1-864-503-8333
wipers@contecinc.com
www.contecinc.com

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Appendix 2: Considerations When Manufacturing Sterile 70% Isopropanol

It is increasingly common for life-science companies to source commercially manufactured cleaning agents like **Contec® Sterile 70% Isopropanol** rather than continue the traditional practice of manufacturing such products in-house.

Initially it can appear to be more expensive to purchase a commercial product, however it is important to ensure that cost comparisons take into account all the hidden costs of in-house manufacture in addition to the obvious raw materials costs.

Points to evaluate include:

Costs

Purchase of raw materials:

- 99% isopropanol for dilution
- EP purified water
- Bottles, triggers and protective packaging

Technician's time or dedicated staff:

- Clean and maintain the preparation area before and after use
- Sterilize components including bottles, triggers, filters and equipment
- Blend and filter the cleaning agent and integrity test the filter after use
- Lost from performing core activities

QC staff time to create, validate and record:

- Sterilisation protocols for raw materials
- Integrity of the finished blend including sterility testing
- Environmental monitoring of the preparation area

Waste Disposal of:

- Unused raw materials and filters
- Finished product due to short in-use shelf life

Site Considerations

- Space required for storage of raw materials and finished products
- Special storage requirements for bulk containers of flammable liquid
- Production downtime during manufacture of sterile 70% isopropanol or
- Use of a dedicated preparation area and consequent loss of valuable cleanroom production space

Risks

- Health and safety implications for staff handling bulk quantities of flammable materials
- Storage of bulk quantities of flammable materials
- Inadequate efficacy due to incorrect dilution during preparation
- Compromised sterility of sterile 70% isopropanol during preparation or in-use