

Summary of product characteristics for a biocidal product family

Family name: Contec IPA Product Family

Product type(s): PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: EU-0020460-0000

R4BP 3 asset reference number: IS-0021979-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Contec IPA Product Family

1.2. Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

1.3. Authorisation holder

Name and address of the
authorisation holder

Name	Contec Europe
Address	ZI Du Prat Avenue Paul Duplaix 56000 Vannes France

Authorisation number

EU-0020460-0000

R4BP 3 asset reference
number

IS-0021979-0000

Date of the authorisation

26/12/2019

Expiry date of the
authorisation

30/11/2029

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

Contec Inc.

Address of the manufacturer

525 Locust Grove SC 29303 Spartanburg United States

Location of manufacturing sites

525 Locust Grove SC 29303 Spartanburg United States

Name of the manufacturer	Contec Cleanroom Technology (Suzhou) Co., Ltd. China
Address of the manufacturer	17 Longyun Road, Suzhou Industrial Park 215024 Suzhou China
Location of manufacturing sites	17 Longyun Road, Suzhou Industrial Park 215024 Suzhou China

Name of the manufacturer	Contec Cleanroom (UK) Ltd
Address of the manufacturer	Unit 6A, Wansbeck Business Park, Rotary Parkway NE63 8QW Ashington, Northumberland United Kingdom
Location of manufacturing sites	Unit 6A, Wansbeck Business Park, Rotary Parkway NE63 8QW Ashington, Northumberland United Kingdom

Name of the manufacturer	Flexible Medical Packaging
Address of the manufacturer	Unit 8 Hightown, White Cross Industrial Estate LA1 4XS Lancaster, Lancashire United Kingdom
Location of manufacturing sites	Unit 8 Hightown, White Cross Industrial Estate LA1 4XS Lancaster, Lancashire United Kingdom

1.5. Manufacturer(s) of the active substance(s)

Active substance	1355 - Propan-2-ol
Name of the manufacturer	Brenntag GmbH
Address of the manufacturer	Messeallee 11 45131 Essen Germany
Location of manufacturing sites	Haven 3222, Vondelingenweg 601 3196 KK Vondelingenplaat Netherlands

2. Product family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9 - 62,9

2.2. Type(s) of formulation

AL (any other liquid) - RTU solution/trigger spray

AL (any other liquid) – RTU wipe

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

Contec IPA Liquid Products

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9 - 62,9

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL (any other liquid) - RTU solution/trigger spray

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Highly flammable liquid and vapour.
 Causes serious eye irritation.
 May cause drowsiness or dizziness.
 Repeated exposure may cause skin dryness or cracking.

Precautionary statements

If medical advice is needed, have product container or label at hand.
 Keep out of reach of children.
 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.
 Keep container tightly closed.
 Avoid breathing vapours.
 Wash hands thoroughly after handling.
 Use only outdoors or in a well-ventilated area.
 Wear eye protection.
 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 Call a Poison centre if you feel unwell.
 If eye irritation persists: Get medical advice.
 In case of fire: Use alcohol resistant foam to extinguish.
 Store in a well-ventilated place. Keep cool.

Store locked up.

Dispose of contents to /container in accordance with local regulations.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Professional use

Product type

PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

Disinfectant for use against bacteria, mycobacteria and yeast on hard, non-porous surfaces in cleanrooms for biotechnology, pharmaceutical, manufacture of medical devices, healthcare industries and other critical life science applications and in industrial food and feed preparation areas."

Acceptable use temperature: room temperature (20±2°C)

Target organism(s) (including development stage)

Scientific name: Bacteria
Common name: Bacteria
Development stage: -

Scientific name: Mycobacteriaceae
Common name: Mycobacteria
Development stage: -

Scientific name: Yeast
Common name: Yeasts
Development stage: -

Field(s) of use

Indoor

Application method(s)

Method: Spraying and wiping
Detailed description:

-

Application rate(s) and frequencies

Application Rate: 50 ml product per m² of surface.

Dilution (%):

Number and timing of application:

Wiping: 1 minute contact time for bacteria and mycobacteria
3 minutes contact time for yeast

Category(ies) of users

Professional

Pack sizes and packaging material

High-density polyethylene (HDPE) trigger spray bottle – 0.5 – 1L
HDPE capped refill bottle - 5L

4.1.1 Use-specific instructions for use

See section 5.1

4.1.2 Use-specific risk mitigation measures

See section 5.2

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 5.3

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 5.4

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 5.5

5. General directions for use of the meta SPC

5.1. Instructions for use

Use at room temperature. For visibly soiled surfaces, cleaning prior to disinfection is required.
Wiping: Apply/Spray product to a suitable quality cleanroom wipe. Ensure the wipe is sufficiently and uniformly saturated before wiping the surface to be disinfected.
Ensure the surface is uniformly covered with the product then wipe to dry with a sterile cleanroom wipe.
Contact times: Wiping 1 minute for bacteria and mycobacteria 3 minutes for yeast.
Used wipes must be disposed of in a closed container.

5.2. Risk mitigation measures

Wash hands and exposed skin before meals and after use.
Avoid contact with eyes
For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect adverse effects:

Headache, vertigo, hallucinations, respiratory depression, CNS depression or coma.

Severe irritation of the eyes and or ocular damage.

Nausea, vomiting, diarrhea and hemorrhagic gastritis.

Pulmonary aspiration hazard may induce pneumonitis, hypotension and hypoglycemia.

First aid measures:

Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.

Eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention

Skin contact; wash affected area with plenty of water and soap, No scrubbing.

In case of ingestion; Do NOT induce vomiting and never give anything by mouth to an impaired or unconscious individual; if the individual is unconscious place individual in left sideways (recovery) position with the head lowered and the knees bent.

Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.

Take the individual to a healthcare center and bring packaging or label whenever possible.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

Monitor vital signs and provide symptomatic and supportive treatment.

Evaluate endoscopic procedure in case of ingestion.

Monitor glycaemia and ketones.

Ipecac use is contraindicated.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER 111.

5.4. Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with local regulations.
Do not re-use empty container for any other purpose.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a cool, dry, well-ventilated place in original container.
Keep away from sources of ignition.
Keep away from direct sunlight.
Keep container tightly closed.
Shelf-life: 2 years

6. Other information

The product contains propan-2-ol (CAS No: 67-63-0), for which an European reference value of 129.28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Contec IPA	Market area: IS
	Contec Sterile IPA	Market area: IS
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	IS-0021979-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9

1. Meta SPC administrative information

1.1. Meta SPC identifier

Contec IPA Wipes

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9 - 62,9

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL (any other liquid) – RTU wipe

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Highly flammable liquid and vapour.
Causes serious eye irritation.
May cause drowsiness or dizziness.
Repeated exposure may cause skin dryness or cracking.

Precautionary statements

If medical advice is needed, have product container or label at hand.
Keep out of reach of children.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.
Keep container tightly closed.
Avoid breathing vapours.
Wash hands thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Wear eye protection.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Call a POISON CENTER if you feel unwell.
If eye irritation persists: Get medical advice.
In case of fire: Use alcohol resistant foam to extinguish.
Store in a well-ventilated place. Keep cool.
Store locked up.
Dispose of contents to /container in accordance with local regulations.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Professional use

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfectant for use against bacteria, mycobacteria and yeast on hard, non-porous surfaces in cleanrooms for biotechnology, pharmaceutical, manufacture of medical devices, healthcare industries and other critical life science applications and in industrial food and feed preparation areas." Acceptable use temperature: room temperature (20±2°C)
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: - Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage: - Scientific name: Yeast Common name: Yeasts Development stage: -
Field(s) of use	Indoor
Application method(s)	Method: Wiping Detailed description: -
Application rate(s) and frequencies	Application Rate: - Dilution (%): Number and timing of application: 1 minute contact time for bacteria and mycobacteria 3 minutes contact time for yeast
Category(ies) of users	Professional
Pack sizes and packaging material	Impregnated 100 % polypropylene wipes in: - HDPE canister with HDPE cap – 150 wipes (1.7 or 2.15 L) - Polyethylene terephthalate (PET)/polyethylene (PE) packet sealed with PET/PE flow wrap – 30, 40 or 50 wipes Impregnated 100 % polyester wipes in: - HDPE canister with HDPE cap – 100 wipes (2.25 L)

- PET/PE packet sealed with PET/PE flow wrap – 20 wipes
- Impregnated 100 % knitted polyester wipes in:
- PET/PE packet sealed with PET/PE flow wrap – 8, 10, 20, 30 or 50 wipes
- Impregnated 55 % cellulose / 45% polyester wipes in:
- HDPE canister with HDPE cap – 100 wipes (2.25 L)
 - PET/PE packet sealed with PET/PE flow wrap – 24, 30, 50 or 75 wipes
- Impregnated 50 % rayon / 50% polyester wipes in:
- HDPE canister with HDPE cap - 700 wipes (11.4 L)

4.1.1 Use-specific instructions for use

See section 5.1

4.1.2 Use-specific risk mitigation measures

See section 5.2

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 5.3

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 5.4

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 5.5

5. General directions for use of the meta SPC

5.1. Instructions for use

For soiled surfaces, cleaning prior to disinfection is required.
Ensure the surface is uniformly covered with the product, allow to act for a contact time of 1 minute for bactericidal and mycobactericidal action and 3 minutes for yeasticidal action.

5.2. Risk mitigation measures

Wash hands and exposed skin before meals and after use.
Avoid contact with eyes
For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory e.g. room ventilation or LEV

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect adverse effects:
Headache, vertigo, hallucinations, respiratory depression, CNS depression or coma.
Severe irritation of the eyes and or ocular damage.
Nausea, vomiting, diarrhea and hemorrhagic gastritis.
Pulmonary aspiration hazard may induce pneumonitis, hypotension and hypoglycemia.
First aid measures:
Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.
Eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention
Skin contact; wash affected area with plenty of water and soap, No scrubbing.
In case of ingestion; Do NOT induce vomiting and never give anything by mouth to an impaired or unconscious individual; if the individual is unconscious place individual in left sideways (recovery) position with the head lowered and the knees bent.
Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.
Take the individual to a healthcare center and bring packaging or label whenever possible.
NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!
Advice for medical and healthcare personnel:
Monitor vital signs and provide symptomatic and supportive treatment.
Evaluate endoscopic procedure in case of ingestion.
Monitor glycaemia and ketones.

Ipecac use is contraindicated.
WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER 111

5.4. Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with local regulations.
Do not re-use empty container for any other purpose.
Used wipes must be disposed in a closed container
Dispose of used wipes by dry waste to landfill

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Store in a cool, dry, well-ventilated place in original container.
Keep away from sources of ignition.
Keep away from direct sunlight.
Keep container tightly closed.
Shelf-life: 2 years

6. Other information

Polypropylene, polyester, kitted polyester, 55 % cellulose / 45 % polyester or 50 % rayon / 50 % polyester wipes, 34-240 gsm, containing 5 - 38 ml product (2.75 - 20.9 g propan-2-ol)

The product contains propan-2-ol (CAS No: 67-63-0), for which an European reference value of 129.28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

Hazard Statements and Precautionary statements:

H225: Mjög eldfimur vökvi

H319: Veldur alvarlegri augnertingu

H336: Getur valdið sljóleika eða svima

P101: Ef leita þarf til læknis skal hafa ílát eða merkimiða tiltæk

P102: Geymist þar sem börn ná ekki til

P210: Haldið frá hitagjöfum, heitum flötum, neistagjöfum, opnum eldi og öðrum íkveikjuvöldum. Reykingar bannaðar.

P233: Ílát skal vera lukt.

P261: Gætið þess að anda ekki inn úða.

P264: Þvoið hendur vandlega eftir meðhöndlun.

P271: Notið eingöngu utandyra eða í vel loftræstu rými.

P280: Notið augnhlífur.

P303+P361+P353: BERIST EFNID Á HÚÐ (eða hár): Farið strax úr fötum sem óhreinkast af efninu. Skolið húðina með vatni.

P304+P340: EFTIR INNÖNDUN: Flytjið viðkomandi í ferskt loft og látið hann hvílast í stellingu sem léttir öndun.

P312: Hringið í EITRUNARMÍÐSTÖÐ (s. 5432222/112) ef lasleika verður vart.

P337+P313: Ef augnerting er viðvarandi: Leitið læknis.

P370+P378: Ef eldur kemur upp: Notið áfengisþolna froðu til að slökkva eldinn.

P403+ P235: Geymist á vel loftræstum stað. Geymist á köldum stað.

P405: Geymist á læstum stað.

P501: Fargið innihaldi/íláti á viðeigandi hátt.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)		
	PROSAT EasyReach	Market area: IS
	PROSAT Sterile EasyReach	Market area: IS
	PROSAT Wipes	Market area: IS
	PROSAT Sterile Wipes	Market area: IS
	SATWipes Wipes	Market area: IS
	SATWipes Sterile Wipes	Market area: IS
	Cleanroom wipes, presaturated Spec-Wipe	Market area: IS
Authorisation number (R4BP 3 asset reference number - National Authorisation)	IS-0021979-0002 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9
