



COMMISSION IMPLEMENTING REGULATION (EU) 2019/2076
of 29 November 2019
granting a Union authorisation for the biocidal product family
‘Contec IPA Product Family’
(Text with EEA relevance)

Article 1

A Union authorisation with authorisation number EU-0020460-0000 is granted to Contec Europe for the making available on the market and use of the biocidal product family ‘Contec IPA Product Family’, subject to compliance with the terms and conditions set out in Annex I and in accordance with the summary of the biocidal product characteristics set out in Annex II.

The Union authorisation is valid from 26 December 2019 until 30 November 2029.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

▼B

ANNEX I

TERMS AND CONDITIONS (EU-0020460-0000)

The authorisation holder shall conduct a long-term storage test at ambient temperature for wipes in their commercial packaging.

By 31 July 2021 the authorisation holder shall submit the results of the test to the Agency.

▼ **M2***ANNEX II***Summary of product characteristics for a biocidal product family**

Contec IPA Product Family

Product type(s)

PT02: Disinfectants and algacides not intended for direct application to humans or animals

PT04: Food and feed area

Authorisation number EU-0020460-0000**R4BP asset number** EU-0020460-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	Contec IPA Product Family
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1.2. Product type(s)

Product type(s)	PT02: Disinfectants and algacides not intended for direct application to humans or animals PT04: Food and feed area
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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	
<i>R4BP asset number</i>	EU-0020460-0000	
Date of the authorisation	26 December 2019	
Expiry date of the authorisation	30 November 2029	

1.4. Manufacturer(s) of the product

Name of manufacturer	Contec Inc.
Address of manufacturer	525 Locust Grove SC 29303 Spartanburg United States (the)
Location of manufacturing sites	Contec Inc. site 1 525 Locust Grove SC 29303 Spartanburg United States (the)

▼ M2

Name of manufacturer	Contec Cleanroom Technology (Suzhou) Co., Ltd. China
Address of manufacturer	17 Longyun Road, Suzhou Industrial Park 215024 Suzhou China
Location of manufacturing sites	Contec Cleanroom Technology (Suzhou) Co., Ltd. China site 1 17 Longyun Road, Suzhou Industrial Park 215024 Suzhou China

Name of manufacturer	Contec Cleanroom (UK) Ltd
Address of manufacturer	Unit 6A, Wansbeck Business Park, Rotary Parkway NE63 8QW Ashington, Northumberland United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Contec Cleanroom (UK) Ltd site 1 Unit 6A, Wansbeck Business Park, Rotary Parkway NE63 8QW Ashington, Northumberland United Kingdom of Great Britain and Northern Ireland (the)

Name of manufacturer	Flexible Medical Packaging
Address of manufacturer	Unit 8 Hightown, White Cross Industrial Estate LA1 4XS Lancaster, Lancashire United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Flexible Medical Packaging site 1 Unit 8 Hightown, White Cross Industrial Estate LA1 4XS Lancaster, Lancashire United Kingdom of Great Britain and Northern Ireland (the)

Name of manufacturer	VWR International BVBA
Address of manufacturer	Researchpark Haasrode 2020, Geldenaaksebaan 464 B-3001 Leuven Belgium
Location of manufacturing sites	VWR International BVBA site 1 Researchpark Haasrode 2020, Geldenaaksebaan 464 B-3001 Leuven Belgium

▼ **M2**1.5. **Manufacturer(s) of the active substance(s)**

Active substance	propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Messeallee 11 45131 Essen Germany
Location of manufacturing sites	Brenntag GmbH site 1 Haven 3222, Vondelingenweg 601 3196 KK Vondelingenplaat Netherlands (the)

Active substance	propan-2-ol
Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Römerstraße 733 47443 Moers Germany
Location of manufacturing sites	INEOS Solvents Germany GmbH site 1 Römerstraße 733 47443 Moers Germany

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 % (w/w)

2.2. **Type(s) of formulation**

Formulation type(s)	AL (any other liquid) – RTU wipe AL (any other liquid) - RTU solution/trigger spray
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PART II

SECOND INFORMATION LEVEL - META SPC(S)

1. **META SPC 1 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC: Contec IPA Liquid Products
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1.2. **Suffix to the authorisation number**

Number	1-1
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▼ **M2**1.3. **Product type(s)**

Product type(s)	PT02: Disinfectants and algacides not intended for direct application to humans or animals PT04: Food and feed area
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2. **META SPC 1 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

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 % (w/w)

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation type(s)	AL (any other liquid) - RTU solution/trigger spray
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1**

Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed. P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P271: Use only outdoors or in a well-ventilated area.

▼ **M2**

	<p>P280: Wear eye protection.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P312: Call a Poison centre if you feel unwell.</p> <p>P337+P313: If eye irritation persists: Get medical advice.</p> <p>P370+P378: In case of fire: Use alcohol resistant foam to extinguish.</p> <p>P403+P235: Store in a well-ventilated place. Keep cool.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents/ container in accordance with local regulations.</p>
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4. **AUTHORISED USE(S) OF THE META SPC**4.1. **Use description***Table 1***Professional use**

Product type	<p>PT02: Disinfectants and algaecides not intended for direct application to humans or animals</p> <p>PT04: Food and feed area</p>
Where relevant, an exact description of the authorised use	<p>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.”</p> <p>Acceptable use temperature: room temperature (20±2°C)</p>

▼ **M2**

Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: -</p> <p>Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage: -</p> <p>Scientific name: Yeast Common name: Yeasts Development stage: -</p>
Field(s) of use	indoor use
Application method(s)	<p>Method: Spraying and wiping</p> <p>Detailed description: -</p>
Application rate(s) and frequency	<p>Application rate: 50 ml product per m² of surface.</p> <p>Number and timing of application: Wiping: 1 minute contact time for bacteria and mycobacteria 3 minutes contact time for yeast</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>High-density polyethylene (HDPE) trigger spray bottle – 0,5 litre – 1 litre</p> <p>HDPE capped refill bottle - 1 litre, 2 litres and 5 litres</p>

4.1.1. *Use-specific instructions*

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

▼ M2**5. GENERAL DIRECTIONS FOR USE OF THE META SPC 1****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.

▼ M2

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 1

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

Trade name(s)		Contec IPA	Market area: EU			
		Contec Sterile IPA	Market area: EU			
		Ipasept	Market area: EU			
Authorisation number		EU-0020460-0001 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 % (w/w)	

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC: Contec IPA Wipes
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▼ **M2**1.2. **Suffix to the authorisation number**

Number	1-2
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1.3. **Product type(s)**

Product type(s)	PT02: Disinfectants and algaecides not intended for direct application to humans or animals PT04: Food and feed area
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2. **META SPC 2 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 2**

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 % (w/w)

2.2. **Type(s) of formulation of the meta SPC 2**

Formulation type(s)	AL (any other liquid) – RTU wipe
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2**

Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

▼ **M2**

	<p>P233: Keep container tightly closed.</p> <p>P261: Avoid breathing vapours.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P280: Wear eye protection.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P312: Call a POISON CENTER if you feel unwell.</p> <p>P337+P313: If eye irritation persists: Get medical advice.</p> <p>P370+P378: In case of fire: Use alcohol resistant foam to extinguish.</p> <p>P403+P235: Store in a well-ventilated place. Keep cool.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to container in accordance with local regulations.</p>
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4. **AUTHORISED USE(S) OF THE META SPC**4.1. **Use description***Table 1***Professional use**

Product type	<p>PT02: Disinfectants and algaecides not intended for direct application to humans or animals</p> <p>PT04: Food and feed area</p>
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▼ M2

Where relevant, an exact description of the authorised use	<p>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.”</p> <p>Acceptable use temperature: room temperature (20±2°C)</p>
Target organism(s) (including development stage)	<p>Scientific name: Bacteria Common name: Bacteria Development stage: -</p> <p>Scientific name: Mycobacteriaceae Common name: Mycobacteria Development stage: -</p> <p>Scientific name: Yeast Common name: Yeasts Development stage: -</p>
Field(s) of use	indoor use
Application method(s)	<p>Method: Wiping</p> <p>Detailed description:</p> <p>-</p>
Application rate(s) and frequency	<p>Application rate:</p> <p>-</p> <p>Number and timing of application:</p> <p>1 minute contact time for bacteria and mycobacteria</p> <p>3 minutes contact time for yeast</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>Impregnated 100 % polypropylene wipes in:</p> <ul style="list-style-type: none"> — 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 <p>Impregnated 100 % polyester wipes in:</p> <ul style="list-style-type: none"> — HDPE canister with HDPE cap – 100 wipes (2,25 L) — PET/PE packet sealed with PET/PE flow wrap – 20 wipes

▼ **M2**

	<p>Impregnated 100 % knitted polyester wipes in:</p> <ul style="list-style-type: none"> — PET/PE packet sealed with PET/PE flow wrap – 8, 10, 20, 30 or 50 wipes <p>Impregnated 55 % cellulose / 45% polyester wipes in:</p> <ul style="list-style-type: none"> — 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 <p>Impregnated 50 % rayon / 50% polyester wipes in:</p> <ul style="list-style-type: none"> — HDPE canister with HDPE cap - 700 wipes (11,4 L)
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4.1.1. *Use-specific instructions*

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 2**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

▼ M2**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

▼ **M2****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.

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 2**7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)		PROSAT EasyReach	Market area: EU		
		PROSAT Sterile EasyReach	Market area: EU		
		PROSAT Wipes	Market area: EU		
		PROSAT Sterile Wipes	Market area: EU		
		SATWipes Wipes	Market area: EU		
		SATWipes Sterile Wipes	Market area: EU		
		Cleanroom wipes, presaturated Spec-Wipe	Market area: EU		
Authorisation number		EU-0020460-0002 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 % (w/w)