II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1322

of 3 August 2021

amending Implementing Regulation (EU) 2019/2076 to make administrative changes to the Union authorisation of the biocidal product family 'Contec IPA Product Family'

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular the first subparagraph of Article 44(5) and Article 50(2) thereof,

Whereas:

(1) On 29 November 2019, Commission Implementing Regulation (EU) 2019/2076 ([2]) granted a Union authorisation with authorisation number EU-0020460-0000 to Contec Europe for the making available on the market and use of the biocidal product family 'Contec IPA Product Family'.

(2) On 5 February 2020, Contec Europe submitted a notification to the European Chemicals Agency ('the Agency'), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 ([3]), regarding the administrative changes to the Union authorisation for the biocidal product family 'Contec IPA Product Family' as referred to in Section 1 of Title 1 of the Annex to that Regulation.

(3) Contec Europe proposed the revision of the list of product trade names, including the changes in the trade names and the removal of the trade names of the individual products in the meta SPCs 1 and 2, of the summary of the product characteristics for the biocidal product family 'Contec IPA Product Family' as set out in Annex II to Implementing Regulation (EU) 2019/2076. The notification was recorded under the case number BC-GC057245-55 in the Register for Biocidal Products.

(4) On 6 March 2020, the Agency submitted an opinion ([4]) on the proposed changes to the Commission, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013. The opinion concludes that the amendments to the existing authorisation sought by the authorisation holder fall under Article 50(3)(a) of Regulation (EU) No 528/2012, and that after the implementation of the changes the conditions of Article 19 of that Regulation are still met. On the same date, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics in all the official languages of the Union in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Implementing Regulation (EU) 2019/2076 of 29 November 2019 granting a Union authorisation for the biocidal product family 'Contec IPA Product Family' (OJ L 316, 6.12.2019, p. 19).

([3]) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

([4]) ECHA opinion of 2 March 2020 on the administrative change of the Union authorisation of the biocidal product family 'Contec IPA Product Family', https://echa.europa.eu/documents/10162/22836226/opinion_for_ua_admin_change_bc-gc057245-55_en.pdf/b848e01c-b8bb-41ac-4dff-650cbfd33ff9

(5) The Commission concurs with the opinion of the Agency and therefore considers it appropriate to amend the Union authorisation of the biocidal product family 'Contec IPA Product Family'.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Implementing Regulation (EU) 2019/2076 is replaced by the text in the Annex to this Regulation.

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.

Done at Brussels, 3 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

'ANNEX II

Summary of product characteristics for a biocidal product family

Contec IPA Product Family

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0020460-0000

R4BP asset number: EU-0020460-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Contec IPA Product Family

1.2. **Product type(s)**

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	Zl Du Prat, Avenue Paul Duplaix, 56000, Vannes, France
Authorisation number	EU-0020460-0000	
R4BP asset number	EU-0020460-0000	
Date of the authorisation	26 December 2019	
Expiry date of the authorisation	30 November 2029	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	Contec Inc.
Address of manufacturer	525 Locust Grove, SC 29303 Spartanburg United States
Location of manufacturing sites	525 Locust Grove, SC 29303 Spartanburg United States

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	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
Location of manufacturing sites	Unit 6A, Wansbeck Business Park, Rotary Parkway, NE63 8QW Ashington, Northumberland United Kingdom

Name of manufacturer	Flexible Medical Packaging
Address of 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	Propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of 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 (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,9	62,9

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

Formulation(s)	AL (any other liquid) – RTU solution/trigger spray AL (any other liquid) – RTU wipe

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 1 identifier**

Identifier	Contec IPA Liquid Products

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

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 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 (%)	
					Min	Max
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 1**

Formulation(s)	AL (any other liquid) – RTU solution/trigger spray

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

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/container in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. **Use description**

Table 1

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	
Target organism(s) (including development stage)	Bacteria Mycobacteria Yeasts
Field(s) of use	Indoor 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)
Application method(s)	Spraying and wiping
Application rate(s) and frequency	50 ml product per m^2 of surface. Wiping: 1 minute contact time for bacteria and myobacteria 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 L – 1 L HDPE capped refill bottle – 5 L

4.1.1. *Use-specific instructions for use*

See general directions for use

4.1.2. *Use-specific risk mitigation measures*

See general directions for use

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 general directions for use

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

See general directions for use

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

See general directions for use

5. GENERAL DIRECTIONS FOR USE [1] 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, diarrhoea and haemorrhagic gastritis.

Pulmonary aspiration hazard may induce pneumonitis, hypotension and hypoglycaemia.

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.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

Take the individual to a healthcare centre 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 CENTRE □ [INSERT LOCAL NUMBER HERE].

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 Contec Sterile IPA				
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

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	Contec IPA Wipes

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

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 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 (%)	
					Min	Max
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 2**

Formulation(s)	AL (any other liquid) – RTU wipe

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

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/container in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. **Use description**

Table 2

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	-
Target organism(s) (including development stage)	Bacteria Mycobacteria Yeasts
Field(s) of use	Indoor 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)
Application method(s)	Wiping
Application rate(s) and frequency	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 L 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 general directions for use

4.1.2. *Use-specific risk mitigation measures*

See general directions for use

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 general directions for use

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

See general directions for use

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

See general directions for use

5. GENERAL DIRECTIONS FOR USE ([2]) 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"

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, diarrhoea and haemorrhagic gastritis.

Pulmonary aspiration hazard may induce pneumonitis, hypotension and hypoglycaemia.

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 centre 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.

([2]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

Ipecac use is contraindicated.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTRE □ [INSERT LOCAL NUMBER HERE].

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/m^3 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 PROSAT Sterile EasyReach PROSAT Wipes PROSAT Sterile Wipes SATWipes Wipes SATWipes Sterile Wipes Cleanroom wipes, presaturated Spec-Wipe				
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’