

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/1425**  
**of 8 October 2020**  
**granting a Union authorisation for the biocidal product family ‘PeridoxRTU 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 <sup>(1)</sup>, and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 26 September 2017, Contec Europe submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named ‘PeridoxRTU Product Family’ of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Belgium had agreed to evaluate the application. The application was recorded under case number BC-HT057172-25 in the Register for Biocidal Products.
- (2) ‘PeridoxRTU Product Family’ contains peracetic acid, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.
- (3) On 27 August 2019, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 7 April 2020, the Agency submitted to the Commission an opinion <sup>(2)</sup>, including the draft summary of the biocidal product characteristics (‘SPC’) of ‘PeridoxRTU Product Family’ and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘PeridoxRTU Product Family’ is a ‘biocidal product family’ within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 27 April 2020, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘PeridoxRTU Product Family’.
- (8) 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*

A Union authorisation with authorisation number EU-0023658-0000 is granted to Contec Europe for the making available on the market and use of the biocidal product family ‘PeridoxRTU Product Family’ in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 29 October 2020 until 30 September 2030.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> ECHA opinion of 5 March 2020 on the Union authorisation of ‘PeridoxRTU Product Family’ (ECHA/BPC/247/2020), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>.

*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, 8 October 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

**Summary of product characteristics for a biocidal product family**

## PeridoxRTU Product Family

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

Authorisation number: EU-0023658-0000

R4BP asset number: EU-0023658-0000

## PART I

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

Name	PeridoxRTU Product Family
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**1.2. Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
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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, 56 000 Vannes, France
Authorisation number	EU-0023658-0000	
R4BP asset number	EU-0023658-0000	
Date of the authorisation	29 October 2020	
Expiry date of the authorisation	30 September 2030	

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

Name of manufacturer	Enviro Tech Chemical Services, Inc.
Address of manufacturer	500 Winmoore Way, CA 95 358 Modesto United States
Location of manufacturing sites	500 Winmoore Way, CA 95 358 Modesto United States 724 Phillips Rd 411, AR 72 342 Helena United States

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

Active substance	Peracetic acid
Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1, 9721 Weißenstein Austria
Location of manufacturing sites	Industriestraße 1, 9721 Weißenstein Austria

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
Peracetic acid		Active Substance	79-21-0	201-186-8	0,23	0,23
Hydrogen Peroxide	Hydrogen Peroxide	Non-active Substance	7722-84-1	231-765-0	4,4	4,4
Acetic Acid	Acetic Acid	Non-active Substance	64-19-7	200-580-7	5,0	5,0

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

Formulation(s)	AL – Any other liquid
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## 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 PeridoxRTU
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1.2. **Suffix to the authorisation number**

Number	1-1
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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 (Disinfectants)
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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 (%)	
					Min	Max
Peracetic acid		Active Substance	79-21-0	201-186-8	0,23	0,23
Hydrogen Peroxide	Hydrogen Peroxide	Non-active Substance	7722-84-1	231-765-0	4,4	4,4
Acetic Acid	Acetic Acid	Non-active Substance	64-19-7	200-580-7	5,0	5,0

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

Formulation(s)	AL – Any other liquid
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## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes severe skin burns and eye damage. May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Do not breathe vapours. Do not breathe spray. Keep only in original packaging. Wash hands thoroughly after handling. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. 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. Immediately call a POISON CENTRE or doctor/physician. Specific treatment (see information on this label). Wash contaminated clothing before reuse. Absorb spillage to prevent material damage. Store locked up. Dispose of contents to in accordance with local/regional/national/international regulations (to be specified). Dispose of container to in accordance with local/regional/national/international regulations (to be specified).

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

## 4.1. Use description

**Table 1. Use # 1 – Application by trigger spray onto a suitable cleanroom wipe and use of the wipe to distribute the liquid on the surface**

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Fungi

	Yeast Bacterial spores
Field(s) of use	Indoor Surface disinfection of clean, hard non-porous surfaces in cleanrooms not associated with food or feed areas, by spraying onto a suitable cleanroom wipe and using the wipe to distribute the liquid on the surface.
Application method(s)	Spraying Spray onto a suitable cleanroom wipe and use the wipe to distribute the liquid on the surface. Uniform distribution of the biocidal product should be ensured.
Application rate(s) and frequency	50,0 mL/m <sup>2</sup> – Ready-to-use product Ensure the surface is uniformly covered with the product and leave for the required contact time. Contact time for bacteria – 2-minutes. Contact time for fungi, yeasts and bacterial spores – 3-minutes.
Category(ies) of users	Professional
Pack sizes and packaging material	900 ml High density polyethylene (HDPE) bottle, delivered with a poly propylene screw cap which is replaced with the poly propylene trigger.

#### 4.1.1. Use-specific instructions for use

For use only on visibly clean surfaces. Cleaning prior to disinfection is required. Physically remove contaminants from the surface before disinfection using a suitable cleanroom wipe and a recommended wiping technique for optimum contamination control.

Spray directly onto a suitable cleanroom wipe. Use a wipe to distribute the liquid on the surface.

Ensure the surface is uniformly covered with the product and leave for the required contact time indicated to kill bacteria, fungi, yeast and bacterial spores.

Do not apply more than 50 ml/m<sup>2</sup>.

Leave for required contact time and wipe to dry afterwards.

For use at room temperature (20 ± 2 °C).

Suitable cleanroom wipe materials should be used in order to minimise interaction with the product.

Used wipes must be disposed in a closed container.

#### 4.1.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information)

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

A ventilation rate of at least 20/hr is mandatory when handling the product.

The product must only be applied for disinfection of small surfaces.

#### 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

Inhalation: Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Maintain an open airway. Loosen tight clothing such as collar, tie or belt. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention. Place unconscious person on their side in the recovery position and ensure breathing can take place.

**Skin contact:** It is important to remove the substance from the skin immediately. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes and get medical attention. Chemical burns must be treated by a physician.

**Eye contact:** Rinse immediately with plenty of water. Do not rub eye. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes and get medical attention.

**Ingestion:** Rinse mouth thoroughly with water. Give a few small glasses of water or milk to drink. Stop if the affected person feels sick as vomiting may be dangerous. Never give anything by mouth to an unconscious person. Place unconscious person on their side in the recovery position and ensure breathing can take place. Keep affected person under observation. Get medical attention if symptoms are severe or persist.

**Indication of any immediate medical attention and special treatment needed:** Treat symptomatically.

**Environmental precautions:** Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. Spills or discharge to natural waterways is likely to kill aquatic organisms.

**Personal precautions, protective equipment and emergency procedures in case of accidental release measures:** Evacuate area.

Keep upwind of spill. Ventilate area of leak or spill. Only trained and properly protected personnel may be involved in clean-up operations. Use appropriate safety equipment.

**Methods and materials for containment and cleaning up:** Avoid making contact with spilled material. When cleaning up a spill always wear the appropriate protective equipment, including respiratory protection, gloves and protective clothing. A self-contained breathing apparatus or respirator and absorbents may be necessary, depending on the size of the spill and the adequacy of ventilation.

**Small spills:** Wear the correct protective equipment and cover the liquid with absorbent material. Collect and seal the material and the dirt that has absorbed the spilled material in polyethylene bags and place in a drum for transit to an approved disposal site. Rinse away the remaining spilled material with water to reduce odour and discharge the rinsate into a municipal or industrial sewer, not into a natural waterway.

**Large spills:** In case of nasal and respiratory irritation, vacate the room immediately. Personnel cleaning up should be trained and equipped with a self-contained breathing apparatus, or an officially approved or certified full-face respirator equipped with an organic vapour cartridge, gloves, and clothing impervious, including rubber boots or shoe protection.

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

This biocidal product, when being disposed of in its unused and uncontaminated state should be treated as a hazardous waste according to Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3). Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste.

Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment.

High-temperature incineration is an acceptable practice.

Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

Store in a cool, well ventilated area.

Keep this product in the original container tightly closed.

Container must be stored and transported in an upright position to prevent spilling the contents.

Keep away from direct sunlight.

Do not freeze.

Store below 30 °C.

The shelf-life is 12 months (unopened).

## 4.2. Use description

**Table 2. Use # 2 – Application by pouring into a container and then using a suitable cleanroom mop/wipe to apply the liquid on the surface**

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Fungi Yeast Bacterial spores
Field(s) of use	Indoor Surface disinfection of clean, hard non-porous surfaces in cleanrooms not associated with food or feed areas, by pouring into a container and then applying the liquid on the surface with a suitable cleanroom mop/wipe.
Application method(s)	Pouring Pour into a container and then apply with a suitable cleanroom mop/wipe.
Application rate(s) and frequency	50,0 mL/m <sup>2</sup> – Ready-to-use product Ensure the surface is uniformly covered with the product and leave for the required contact time. Contact time for bacteria – 2-minutes. Contact time for fungi, yeasts and bacterial spores – 3-minutes.
Category(ies) of users	Professional
Pack sizes and packaging material	3 750 ml HDPE bottle with a poly propylene screw cap 900 ml HDPE bottle, delivered with a poly propylene screw cap which is replaced with the poly propylene push/pull cap

## 4.2.1. Use-specific instructions for use

For use only on visibly clean surfaces. Cleaning prior to disinfection is required. Physically remove contaminants from the surface before disinfection using a suitable cleanroom mop/wipe and a recommended wiping technique for optimum contamination control.

Pour the product into a container and then mop onto the surface.

Ensure the surface is uniformly covered with the product and leave for the required contact time indicated to kill bacteria, fungi, yeast and bacterial spores. Do not apply more than 50 ml/m<sup>2</sup>.

Leave for required contact time and wipe to dry afterwards. For use at room temperature (20 ± 2 °C).

Suitable cleanroom wipe and mop materials should be used in order to minimise interaction with the product.

Used wipes must be disposed in a closed container.

#### 4.2.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information).

A protective overall which is impermeable for the biocidal product shall be worn (overall material to be specified by the authorisation holder within the product information).

Application of technical or engineering controls to remove airborne residues is mandatory (e.g. room ventilation or local exhaust ventilation (LEV)) during product application. A minimum ventilation rate of 100 air change per hour is mandatory.

Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before operatives are permitted to enter into treated areas after surface disinfection. Where necessary, a waiting restriction of sufficient duration must be set to allow time for the removal of airborne residues.

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

**Inhalation:** Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Maintain an open airway. Loosen tight clothing such as collar, tie or belt. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention. Place unconscious person on their side in the recovery position and ensure breathing can take place.

**Skin contact:** It is important to remove the substance from the skin immediately. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes and get medical attention. Chemical burns must be treated by a physician.

**Eye contact:** Rinse immediately with plenty of water. Do not rub eye. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes and get medical attention.

**Ingestion:** Rinse mouth thoroughly with water. Give a few small glasses of water or milk to drink. Stop if the affected person feels sick as vomiting may be dangerous. Never give anything by mouth to an unconscious person. Place unconscious person on their side in the recovery position and ensure breathing can take place. Keep affected person under observation. Get medical attention if symptoms are severe or persist.

Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

**Environmental precautions:** Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. Spills or discharge to natural waterways is likely to kill aquatic organisms.

**Personal precautions, protective equipment and emergency procedures in case of accidental release measures:** Evacuate area.

Keep upwind of spill. Ventilate area of leak or spill. Only trained and properly protected personnel may be involved in clean-up operations. Use appropriate safety equipment.

**Methods and materials for containment and cleaning up:** Avoid making contact with spilled material. When cleaning up a spill always wear the appropriate protective equipment, including respiratory protection, gloves and protective clothing. A self-contained breathing apparatus or respirator and absorbents may be necessary, depending on the size of the spill and the adequacy of ventilation.

**Small spills:** Wear the correct protective equipment and cover the liquid with absorbent material. Collect and seal the material and the dirt that has absorbed the spilled material in polyethylene bags and place in a drum for transit to an approved disposal site. Rinse away the remaining spilled material with water to reduce odour and discharge the rinsate into a municipal or industrial sewer, not into a natural waterway.

Large spills: In case of nasal and respiratory irritation, vacate the room immediately. Personnel cleaning up should be trained and equipped with a self-contained breathing apparatus, or an officially approved or certified full-face respirator equipped with an organic vapour cartridge, gloves, and clothing impervious, including rubber boots or shoe protection.

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

This biocidal product, when being disposed of in its unused and uncontaminated state should be treated as a hazardous waste according to Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3). Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste.

Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment.

High-temperature incineration is an acceptable practice.

Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

Store in a cool, well ventilated area.

Keep this product in the original container tightly closed.

Container must be stored and transported in an upright position to prevent spilling the contents.

Keep away from direct sunlight.

Do not freeze.

Store below 30 °C.

The shelf-life is 12 months (unopened).

5. **GENERAL DIRECTIONS FOR USE <sup>(1)</sup> OF THE META SPC 1**

5.1. **Instructions for use**

See Use-specific instructions for use.

5.2. **Risk mitigation measures**

See Use-specific risk mitigation measures.

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

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

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

See, where specific to the use, the instructions for safe disposal of the product and its packaging.

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

See, where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage.

<sup>(1)</sup> 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.

## 6. OTHER INFORMATION

## 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 Sterile PeridoxRTU			
Authorisation number	EU-0023658-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	0,23
Hydrogen Peroxide	Hydrogen Peroxide	Non-active Substance	7722-84-1	231-765-0	4,4
Acetic Acid	Acetic Acid	Non-active Substance	64-19-7	200-580-7	5,0

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

Trade name(s)		Contec PeridoxRTU			
Authorisation number	EU-0023658-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	0,23
Hydrogen Peroxide	Hydrogen Peroxide	Non-active Substance	7722-84-1	231-765-0	4,4
Acetic Acid	Acetic Acid	Non-active Substance	64-19-7	200-580-7	5,0