COMMISSION IMPLEMENTING REGULATION (EU) 2024/1707

of 19 June 2024

granting a Union authorisation for the biocidal product family 'STERI-PEROX' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 Article 44(5), first subparagraph, thereof,

Whereas:

(1) On 27 January 2017, Veltek Associates Inc. Europe submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'STERI-PEROX' of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-GQ029577-18 in the Register for Biocidal Products.

(2) 'STERI-PEROX' contains hydrogen peroxide 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 for product-type 2.

(3) On 27 February 2023, 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 Agency.

(4) On 2 October 2023, the Agency submitted to the Commission its opinion ([2]), including the draft summary of the biocidal product characteristics ('SPC') of 'STERI-PEROX' 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 'STERI-PEROX' is a biocidal product family within the meaning of Article 3(1), point (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 20 October 2023, 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 'STERI-PEROX'.

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

([1]) OJ L 167, 27.6.2012, p. 1, http://data.europa.eu/eli/reg/2012/528/oj.
([2]) ECHA opinion of 14 September 2023 on the Union authorisation of 'STERI-PEROX' (ECHA/BPC/393/2023), https://echa.europa.eu/opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0031643-0000 is granted to Veltek Associates Inc. Europe for the making available on the market and use of the biocidal product family 'STERI-PEROX' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 10 July 2024 until 30 June 2034.

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, 19 June 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT FAMILY

STERI-PEROX®

Product type(s)

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

Authorisation number EU-0031643-0000

R4BP asset number EU-0031643-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. **Family name**

Name	STERI-PEROX®

1.2. **Product type(s)**

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

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Veltek Associates Inc. Europe
	Address	Rozengaard 1940 8212DT Lelystad NL
Authorisation number		EU-0031643-0000
R4BP asset number		EU-0031643-0000
Date of the authorisation		10 July 2024
Expiry date of the authorisation		30 June 2034

1.4. **Manufacturer(s) of the product**

Name of manufacturer	Veltek Associates, Inc.
Address of manufacturer	15 Lee Blvd. PA19355 Malvern United States (the)
Location of manufacturing sites	15 Lee Blvd. PA19355 Malvern United States (the)

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

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US))
Address of manufacturer	One Commerce Square 2005 Market Street Suite 3200 PA 19103 Philadelphia United States (the)
Location of manufacturing sites	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US)) site 1 PeroxyChem Bayport Plant, 12000 Bay Area Blvd TX 77507 Passadena United States (the)

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 (%)
Hydrogen peroxide		active substance	7722-84-1	231-765-0	6,4 - 6,4 % (w/w)

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

Formulation type(s)	AL Any other liquid XX diverse: Ready to Use Wipe

PART II.

SECOND INFORMATION LEVEL - META SPC(S)

1. **META SPC 1 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC 1 - Wipes

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

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 (%)
Hydrogen peroxide		active substance	7722-84-1	231-765-0	6,4 - 6,4 % (w/w)

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

Formulation type(s)	XX Diverse: Ready to Use Wipe

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1**

Hazard statements	H319: Causes serious eye irritation.
Precautionary statements	P264: Wash face and hands thoroughly after handling. P280: Wear eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice.

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

4.1. **Use description**

Table 1.

1.1 – Industrial use – Wipe - Indoors - Meta SPC 1

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Disinfectant of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Not for use in medical areas. Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical,biopharmaceutical, medical device and diagnostic product manufacturing facilities.

Application method(s)	Method: Wiping Detailed description: -
Application rate(s) and frequency	Application rate: 30,5 cm x 30,5 cm wipe – 32,5 ml per wipe. 7,5 ml is freely available per wipe. 1 wipe = 7,5 ml per m^2 Dilution (%): The product is ready to use. Number and timing of application: Frequency: 3 applications per day. Contact time: 10 minutes Use temperature: room temperature
Category(ies) of users	industrial
Pack sizes and packaging material	Wipe is composed of 100% continuous filament polyester fibre. Pack sizes are detailed below: Sterile (gamma irradiated) or non-sterile Wipes: 12 x 12 inches (30,5 cm x 30,5 cm). 20 wipes per pack. 10 packs per case. Reclosable (peel and seal) low density polyethylene (opaque) bags. 12 x 12 inches (30,5 cm x 30,5 cm). Individual wipe. 100 packs per case. Low density polyethylene (opaque) bags.

4.1.1. *Use-specific instructions*

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 OF THE META SPC 1

5.1. Instructions for use

Apply away from eyes and face. Pre-clean surface before application.

Only use wet wipes. Remove one or two wipes at a time. Wipe article thoroughly to ensure it is visibly wet. Allow surface to remain wet for 10 minutes (bactericidal and yeasticidal uses). Discard wipe after use. Close the package after opening.

5.2. Risk mitigation measures

During application only the user of the product can be present in the room.

During application and for re-entry, the airborne hydrogen peroxide levels may not exceed the AEC inhalation limit of 1,25 mg/m³ (or a lower relevant national reference value). A calibrated sensor shall be used to establish that the airborne hydrogen peroxide levels are not exceeded.

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

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

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

Waste disposal recommendation: Dispose in a safe manner in accordance with local/national regulations. Ecology - waste materials: Avoid release to the environment.

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

Keep container tightly closed. Keep in a cool, well-ventilated place. Reseal package between uses to retain moisture.

Store in original container. Protect from frost. Do not store at temperatures high than 40°C.

Shelf-life = 2 years

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)			STERI-PEROX® 6% WIPE	Market area: EU	
Authorisation number				EU-0031643-0001 1-1	
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		active substance	7722-84-1	231-765-0	6,4

1. **META SPC 2 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 2 identifier**

Identifier	Meta SPC2 - Liquid

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

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 (%)
Hydrogen peroxide		active substance	7722-84-1	231-765-0	6,4 - 6,4 % (w/w)

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

Formulation type(s)	AL Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2**

Hazard statements	H319: Causes serious eye irritation.
Precautionary statements	P264: Wash face and hands thoroughly after handling. P280: Wear eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice.

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

4.1. **Use description**

Table 1.

2.1 - Industrial use – Liquid spraying - Indoors - Meta SPC 2

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Fungi Development stage: no data

Field(s) of use	indoor use Disinfectant of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Not for use in medical areas. Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.
Application method(s)	Method: spraying Detailed description: -
Application rate(s) and frequency	Application rate: 60 ml product per m^2 Dilution (%): The product is ready to use. Number and timing of application: Frequency: 3 applications per day. Contact time: 10 minutes for bacteria and yeasts, 20 minutes for fungi Use temperature: room temperature
Category(ies) of users	industrial
Pack sizes and packaging material	473 ml bottle (sterile only). 946 ml bottle (sterile only). Trigger spray attachment is supplied separately. Packaging materials: **Bottles** Bottles are made of high density polyethylene (opaque). A separate hand sprayer has polypropylene dip tube. The bottle cap is polypropylene, the induction seal is polypropylene. Bottles are provided with a polyethylene sprayer separately within bags, the sprayers are not connected to the bottles and are supplied separately. The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available. Distributors distribute sealed cases, not individual customers.

4.1.1. *Use-specific instructions*

Pre-clean surface before application. Unwrap and apply trigger to bottle. Pre-clean surface before application. Direct the spray onto the surface from a distance of 15-20 cm away. Thoroughly wet surface with product and allow to take effect for a minimum of 10 minutes (bactericidal, yeasticidal uses) and 20 minutes (for fungicidal uses). Allow surface to air dry, or after the required contact time has been achieved, wipe dry with sterilised cloth or wipe, if necessary.

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

4.2. **Use description**

Table 2.

2.2 - Industrial use – Liquid Soaking – Indoors – Meta SPC 2

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Fungi Development stage: no data Scientific name: no data Common name: Bacterial spores Development stage: no data
Field(s) of use	indoor use Disinfectant of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Not for use in medical areas. Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.
Application method(s)	Method: Soaking Detailed description: -
Application rate(s) and frequency	Application rate: - Dilution (%): The product is ready to use. Number and timing of application: Frequency: 3 applications per day Contact time: 10 minutes (bactericidal, yeasticidal), 20 minutes (fungicidal), 60 minutes (sporicidal) Use temperature: room temperature
Category(ies) of users	industrial
Pack sizes and packaging material	**Bottles:** 473 ml bottle (sterile only) 946 ml bottle (sterile only). Bottles are made of high density polyethylene (opaque). The bottle cap is polypropylene, the induction seal is polypropylene. The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available. 3,79 litres (sterile and non-sterile)

	Containers made of high density polyethylene (opaque) with a moulded carrying handle and small screw-capped pouring spout moulded towards the top edge. Polypropylene screw cap with liner covers the pouring opening, the induction seal is polypropylene. All bottle caps are screw caps and able to be re-applied onto the bottle. Distributors distribute sealed cases, not individual containers. The sterile versions are individually double-bagged and bags are heat-sealed shut. Optional quadruple bagging is available. **Drum:** 200 litres (sterile only) High Density polyethylene (opaque). Blow moulded, closed head. Molded integral top ring. Double bagged and shrink wrapped to secure it. For secure dispensing after opening, the 200 litres drum has a 5 centimeter top-mounted polypropylene screw cap having a one-way directional dip tube attached to a length of 0,95 cm Santoprene® 73A FDA rubber tubing to connect to a peristaltic non-product contact dispensing pump of the customer's choice – not supplied. The pump and tubing remain attached and ready for dispensing during the entire use period. There are no fittings for adding material back into the drum.

4.2.1. *Use-specific instructions*

Pre-clean surface before application. immerse item in a basin with product and allow to remain in the basin for a minimum of 10 minutes (bactericidal, yeasticidal uses), 20 minutes (fungicidal uses) or 60 minutes (sporicidal use). After the required contact time has been achieved, allow surface to air dry, or wipe dry with sterilised cloth or wipe, if necessary. Only use dipping bath once.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use

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*

See general directions for use

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

See general directions for use

4.2.5. *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 OF THE META SPC 2**

5.1. **Instructions for use**

Use with adequate ventilation and apply away from eyes and face.

5.2. **Risk mitigation measures**

During application only the user of the product can be present in the room.

During application and for re-entry, the airborne hydrogen peroxide levels may not exceed the AEC inhalation limit of 1,25 mg/m³ (or a lower relevant national reference value). A calibrated sensor shall be used to establish that the airborne hydrogen peroxide levels are not exceeded.

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

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

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

Waste disposal recommendations: Dispose in a safe manner in accordance with local or national regulations. Ecology – waste materials: Avoid release to the environment

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

Keep container tightly closed. Keep in a cool, well-ventilated place. Reseal package between uses to retain moisture. For the liquid discard 60 days after opening
Store in original container. Protect from frost. Do not store at temperatures higher than 40°C.
Shelf-life = 2 years

6. **OTHER INFORMATION**

Trade name: STERI-PEROX® 6%

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)			STERI-PEROX 6%	Market area: EU	
Authorisation number				EU-0031643-0002 1-2	
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		active substance	7722-84-1	231-765-0	6,4