



2026/2042

14.9.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/2042

of 11 September 2026

granting a Union authorisation for the biocidal product ‘OXTERIL® 350 VHP’ 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 30 September 2025, Evonik Operations GmbH submitted an application to the European Chemicals Agency (‘the Agency’) in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ⁽²⁾ for a Union authorisation of the same biocidal product, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named ‘OXTERIL® 350 VHP’, of product-types 2 and 4, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-RG110491-49 in the Register for Biocidal Products. The application referred to the biocidal product family ‘Evonik’s Hydrogen Peroxide Product Family’ authorised by Commission Implementing Regulation (EU) 2023/2183 ⁽³⁾, with authorisation number EU-0028964-0000.
- (2) The biocidal product ‘OXTERIL® 350 VHP’ contains hydrogen peroxide as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2 and 4.
- (3) On 29 October 2025, the Agency submitted to the Commission its opinion ⁽⁴⁾ in accordance with Article 6 of Implementing Regulation (EU) No 414/2013, and the draft summary of product characteristics (‘SPC’) of ‘OXTERIL® 350 VHP’, in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (4) In its opinion, the Agency concludes that the proposed differences between the biocidal product ‘OXTERIL® 350 VHP’ and the related reference biocidal product family ‘Evonik’s Hydrogen Peroxide Product Family’ are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ⁽⁵⁾, and that based on the assessment of the related reference biocidal product family ‘Evonik’s Hydrogen Peroxide Product Family’ and subject to compliance with the draft SPC, the biocidal product ‘OXTERIL® 350 VHP’ meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.
- (5) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product ‘OXTERIL® 350 VHP’.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

⁽²⁾ Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/414/oj).

⁽³⁾ Commission Implementing Regulation (EU) 2023/2183 of 18 October 2023 granting a Union authorisation for the biocidal product family Evonik’s Hydrogen Peroxide Product Family in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council. (OJ L, 2023/2183, 19.10.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2183/oj).

⁽⁴⁾ European Chemicals Agency opinion of 29 October 2025 on the Union authorisation of the same single biocidal product ‘OXTERIL® 350 VHP’, <https://echa.europa.eu/opinions-on-union-authorisation>.

⁽⁵⁾ 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, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

- (6) The expiry date of the authorisation should be aligned with the expiry date of the authorisation of the related reference biocidal product family 'Evonik's Hydrogen Peroxide Product Family'.
- (7) 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-0035928-0000 is hereby granted to Evonik Operations GmbH for the making available on the market and use of the biocidal product 'OXTERIL® 350 VHP' in accordance with the summary of the product characteristics set out in the Annex.

The Union authorisation is valid from 4 October 2026 until 31 October 2033.

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, 11 September 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

OXTERIL® 350 VHP

Product type(s)

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

PT04: Food and feed area

Authorisation number: EU-0035928-0000**R4BP asset number:** EU-0035928-0000

1. ADMINISTRATIVE INFORMATION

1.1. **Trade name(s) of the product**

Trade name(s)	OXTERIL® 350 VHP Amira Hydrogen Peroxide
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1.2. **Authorisation holder**

Name and address of the authorisation holder	Name	Evonik Operations GmbH
	Address	Rellinghauser Straße 1 - 11 45128 Essen DE
Authorisation number	EU-0035928-0000	
R4BP asset number	EU-0035928-0000	
Date of the authorisation	04.10.2026	
Expiry date of the authorisation	31.10.2033	

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

Name of manufacturer	Evonik Antwerpen NV
Address of manufacturer	Tijsmanstunnel West 2040 Antwerpen Belgium
Location of manufacturing sites	Evonik Antwerpen NV - Site 1 Tijsmanstunnel West 2040 Antwerpen Belgium
Name of manufacturer	Evonik Operations GmbH
Address of manufacturer	Rellinghauser Straße 1-11 45128 Essen Germany
Location of manufacturing sites	Evonik Operations GmbH - Site 1 Untere Kanalstr. 3 79618 Rheinfelden Germany

Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1 9721 Weißenstein Austria
Location of manufacturing sites	Evonik Peroxid GmbH Industriestraße 1 9721 Weißenstein Austria

Name of manufacturer	Evonik Peroxide Netherlands BV
Address of manufacturer	Hettenheuvelweg 37 /39 1101 BM Amsterdam Netherlands
Location of manufacturing sites	Evonik Peroxide Netherlands BV - Site 1 Oosterhorn 14 9936 HD Farmsum Netherlands

Name of manufacturer	Evonik España y Portugal SA
Address of manufacturer	Afuera s/n 50784 La Zaida Spain
Location of manufacturing sites	Evonik España y Portugal SA C/ Afueras s/n. 50784 La Zaida Spain

Name of manufacturer	abcr GmbH
Address of manufacturer	Im Schleht 10 76187 Karlsruhe Germany
Location of manufacturing sites	abcr GmbH Site 1 Im Schleht 10 76187 Karlsruhe Germany

Name of manufacturer	Amira Srl
Address of manufacturer	Via Vecchia Milanese 12 20844 Triuggio (MB) Italy
Location of manufacturing sites	Amira Srl Site 1 Via Vecchia Milanese 12 20844 Triuggio (MB) Italy

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

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Antwerpen NV
Address of manufacturer	Tijlmanstunnel West 2040 Antwerpen Belgium
Location of manufacturing sites	Evonik Antwerpen NV Tijlmanstunnel West 2040 Antwerpen Belgium

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Operations GmbH
Address of manufacturer	Rellinghauser Straße 1-11 45128 Essen Germany
Location of manufacturing sites	Evonik Operations GmbH Untere Kanalstr. 3 79618 Rheinfelden Germany

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1 9721 Weißenstein Austria
Location of manufacturing sites	Evonik Peroxid GmbH Industriestraße 1 9721 Weißenstein Austria

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxide Netherlands BV
Address of manufacturer	Hettenheuvelweg 37 /39 1101 BM Amsterdam Netherlands
Location of manufacturing sites	Evonik Peroxide Netherlands BV Oosterhorn 14 9936 HD Farmsum Netherlands

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik España y Portugal SA
Address of manufacturer	Afuera s/n 50784 La Zaida Spain
Location of manufacturing sites	Evonik España y Portugal SA C/ Afueras s/n. 50784 La Zaida Spain

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 % (w/w)

2.2. Type(s) of formulation

SL Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects. H272: May intensify fire; oxidiser.
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Precautionary statements	P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P280: Wear protective gloves / eye protection / face protection.. P301+P312: IF SWALLOWED: Call a POISON CENTER / doctor / physician if you feel unwell. P330: Rinse mouth. P302+P352: IF ON SKIN: Wash with plenty of water/ soap. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/ doctor/physician if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER / doctor. P332+P313: If skin irritation occurs: Get medical advice. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents / in accordance with local requirements. P501: Dispose of container / in accordance with local requirements. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220: Keep away from clothing or other combustible materials. P370+P378: In case of fire: Use water to extinguish.
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4. AUTHORISED USE(S)

4.1. Use description

Table 1

Surface disinfection by vaporised hydrogen peroxide (VHP) process

Product type	PT02: Disinfectants and algicides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: bacteria Development stage: - Common name: yeasts Development stage: -
Field(s) of use	indoor use Disinfection of dry surfaces and equipment in hospital rooms, laboratories and other enclosed spaces, which do not come in contact with food and feed.

Application method(s)	Method: Vaporisation Detailed description: Automated disinfection with Vaporised Hydrogen Peroxide, generated with the aid of a VHP generator. Main specifications of a VHP generator: Diffusion principle: vaporisation, disinfection with gaseous hydrogen peroxide. Room Volume: 30–150 m ³ . Product concentration: 3 120 mg/m ³ . Relative humidity: 40–80 %. Temperature: room temperature.
Application rate(s) and frequency	Application Rate: The ready to use product should be applied in a hydrogen peroxide concentration of 1 092 mg/m ³ (780 ppm) by the VHP generator. not applicable Number and timing of application: Contact time: at least 4 hours Frequency: daily /if required Maximum 3 times per day
Category(ies) of users	professional
Pack sizes and packaging material	High density polyethylene (HDPE) bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20 m ³

4.1.1.1. Use-specific instructions for use

The area to disinfect is prepared for decontamination by removing standing liquid and by wiping down any visible dirt. Clean the area before disinfection. Cupboard doors should be opened, surfaces should be dried and wet areas (such as sinks) should be disinfected with suitable alternative products.

Specially trained professionals replace the cap of the sealed packaging with a special cap that has a degassing valve and a fast connector. The fast connector is connected to a pipe that connects to the VHP generator. Seal the enclosed space or room and make sure that access to the vapour-treated area is denied during the whole procedure.

Room volume ranging from 30 m³ to 150 m³.

Diffusion speed can vary from 1,5 to 20 g product /minute.

Starting temperature of 20 °C, ± 2 °C.

Relative humidity between 40 and 80 %.

During the disinfection cycle the VHP generator adjusts the hydrogen peroxide concentration up to the effective levels of 1 092 mg/m³ (780 ppm) and keeps it at this level for at least 4 hours. Concentration of hydrogen peroxide is monitored during the disinfection. After disinfection the aeration of the sealed area is required to reduce the concentration of hydrogen peroxide below 1,25 mg/m³ or a lower relevant national reference value before entering the area. This step can be quick but can also last several hours resulting in a total decontamination cycle of 5–8 hours.

The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable 'standard room', if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter.

In the event that there are methods available for chemically monitoring the active substance in the air or on surfaces, chemical validation should be performed besides biological validation, for example with test strips or with a device that measures ppm hydrogen peroxide in the air.

When it concerns a 'standard room' for which a protocol is available, the validation may be limited to only a chemical validation.

4.1.2. Use-specific risk mitigation measures

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal products, chemical resistant gloves classified under European Standard EN 374 or equivalent, face shield and Respiratory Protective Equipment (RPE) (Assigned Protection Factor (APF) = 10) during mixing and loading. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

No access to the treated area is permitted during treatment. During aeration and before permitting re-entry to the treated area it should be checked that the concentration of hydrogen peroxide is below 1,25 mg/m³ or a lower relevant national reference value, using for example test strips. During the operation of the VHP generator or in the event of malfunctions, entry to the room is only possible if wearing chemical protective suits and RPE (APF=10), when the concentration of hydrogen peroxide is at or below 12,5 mg/m³. Observe label instructions.

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

No use specific 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

No use specific 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

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See General directions for use.

4.2. Use description

Table 2

Surface disinfection by vaporised hydrogen peroxide (VHP) process

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: bacteria Development stage: - Common name: yeasts Development stage: -
Field(s) of use	indoor use Disinfection of dry surfaces in food and feed areas and other enclosed spaces.
Application method(s)	Method: Vaporisation Detailed description: Automated disinfection with Vaporised Hydrogen Peroxide, generated with the aid of a VHP generator. Main specifications of a VHP generator: Diffusion principle: vaporisation, disinfection with gaseous hydrogen peroxide. Room Volume 30–150 m ³ . Product concentration: 3 120 mg/m ³ . Relative humidity: 40–80 %. Temperature: room temperature.

Application rate(s) and frequency	Application Rate: The ready to use product should be applied in a hydrogen peroxide concentration of 1 092 mg/m ³ (780 ppm) by the VHP generator Number and timing of application: Contact time: at least 4 hours Frequency: daily /if required Maximum 3 times per day
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20 m ³

4.2.1. *Use-specific instructions for use*

The area to disinfect is prepared for decontamination by removing standing liquid and by wiping down any visible dirt. Clean the area before disinfection. Cupboard doors should be opened, surfaces should be dried and wet areas (such as sinks) should be disinfected with suitable alternative products.

Specially trained professionals replace the cap of the sealed packaging with a special cap that has a degassing valve and a fast connector. The fast connector is connected to a pipe that connects to the VHP generator. Seal the enclosed space or room and make sure that access to the vapour-treated area is denied during the whole procedure.

Room volume ranging from 30 m³ to 150 m³.

Diffusion speed can vary from 1,5 to 20 g product /minute.

Starting temperature of 20 °C, ± 2 °C.

Relative humidity between 40 and 80 %.

During the disinfection cycle the VHP generator adjusts the hydrogen peroxide concentration up to the effective levels of 1 092 mg/m³ (780 ppm) and keeps it at this level for at least 4 hours. Concentration of hydrogen peroxide is monitored during the disinfection. After disinfection the aeration of the sealed area is required to reduce the concentration of hydrogen peroxide below 1,25 mg/m³ or a lower relevant national reference value before entering the area. This step can be quick but can also last several hours resulting in a total decontamination cycle of 5–8 hours.

The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable 'standard room', if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter. In the event that there are methods available for chemically monitoring the active substance in the air or on surfaces, chemical validation should be performed besides biological validation, for example with test strips or with a device that measures ppm hydrogen peroxide in the air.

When it concerns a 'standard room' for which a protocol is available, the validation may be limited to only a chemical validation.

4.2.2. *Use-specific risk mitigation measures*

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal products, chemical resistant gloves classified under European Standard EN 374 or equivalent, face shield and RPE (APF = 10) during mixing and loading. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

No access to the treated area is permitted during treatment. During aeration and before permitting re-entry to the treated area it should be checked that the concentration of hydrogen peroxide is below 1,25 mg/m³ or a lower relevant national reference value, using for example test strips. During the operation of the VHP generator or in the event of malfunctions entry to the room is only possible by wearing chemical protective suits and RPE (APF=10), when the concentration of hydrogen peroxide is at or below 12,5 mg/m³. Observe label instructions.

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*

No use specific 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*

No use specific 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*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾

5.1. **Instructions for use**

See use specific instructions for each use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures for each use.

Observe label instructions.

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

First aid instructions

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

Accidental release measures

Large spillage: Collect product in suitable containers (for example made of plastic) using appropriate equipment (for example liquid pump) for disposal. Never return spills in original containers for re-use. Keep away from flammable and incompatible substances. Rinse away any residue with plenty of water. Dispose of absorbed material in accordance with the applicable environmental regulations.

Small spillage: Dilute product with lots of water and rinse away or absorb with liquid-binding material (for example diatomaceous earth or universal binder). Pick up mechanically and collect in suitable containers. Clean contaminated surface thoroughly. Pack and label wastes like the product. Do not detach label from the delivery containers prior to disposal.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer depending on local requirements.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**Advice on protection against fire and explosion:**

Store away from direct sunlight and heat sources.

Store away from sources of ignition - No smoking.

Store away from flammable substances.

Store away from incompatible substances.

Storage:

Temperature requirement- during storage maximum 40 °C and protect from frost.

Store in clean, dry and well-ventilated places.

Transport and store container in upright position only.

Always close container tightly after removal of product.

Avoid leakage and residues of the product on the containers.

Advice on common storage:

Do not store together with alkalis, reductants, metallic salts (risk of decomposition).

Do not store together with organic solvents (risk of explosion).

Shelf-life:

24 months

6. OTHER INFORMATION

The full titles of the EN standards referenced in the 'Use-specific mitigation measures' sections are:

EN 16321 – Eye and face protection for occupational users

EN 374 – Protective gloves against chemicals and micro-organisms

The Council Directive referenced in the 'Use-specific mitigation measures' sections is: Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998 [RMJ1], p.11, ELI: <http://data.europa.eu/eli/dir/1998/24/oj>).

(¹) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.