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COMMISSION IMPLEMENTING REGULATION (EU) 2026/829

of 10 April 2026

granting a Union authorisation for the single biocidal product 'Bioxal – Soproper' 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 2020, BIOXAL SA submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a single biocidal product named 'Bioxal – Soproper' of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Germany had agreed to evaluate the application. The application was recorded under case number BC-YH062085-30 in the Register for Biocidal Products.

(2) 'Bioxal – Soproper' contains peracetic acid 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-type 2.

(3) On 21 February 2025, 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 25 September 2025, the Agency submitted to the Commission its opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'Bioxal – Soproper' and the final assessment report on the single biocidal product, in accordance with Article 44(3) of Regulation (EU) No 528/2012.

(5) The opinion concludes that 'Bioxal – Soproper' is a single biocidal product within the meaning of Article 3(1), point (r), 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) of that Regulation.

(6) On 10 October 2025, 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 'Bioxal – Soproper'.

(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, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) ECHA opinion of 10 September 2025 on the Union authorisation of the biocidal product 'Bioxal – Soproper' (ECHA/BPC/494/2025), https://echa.europa.eu/opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0035787-0000 is hereby granted to BIOXAL SA for the making available on the market and use of the single biocidal product 'Bioxal – Soproper' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 6 May 2026 until 30 April 2036.

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, 10 April 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Bioxal – Soproper

Product type(s)

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

Authorisation number: EU-0035787-0000

R4BP asset number: EU-0035787-0000

1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	Soproper perform® select Soproper JCE-DSI APS 3.5

1.2. **Authorisation holder**

Name and address of the authorisation holder	Name	BIOXAL SA
	Address	Route des Varennes BP 30072 71103 CEDEX CHALON sur SAONE FR
Authorisation number		EU-0035787-0000
R4BP asset number		EU-0035787-0000
Date of the authorisation		6 May 2026
Expiry date of the authorisation		30 April 2036

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

Name of manufacturer	Bioxal SA
Address of manufacturer	Zone Industrielle Sud Secteur A, Route des Varennes 71100 Chalon sur Saone France
Location of manufacturing sites	Bioxal SA site 1 Zone Industrielle Sud Secteur A, Route des Varennes 71100 Chalon sur Saone France

Name of manufacturer	Schülke & Mayr GmbH
Address of manufacturer	Robert-Koch-Str. 2 22851 Norderstedt Germany
Location of manufacturing sites	Schülke & Mayr GmbH site 1 Robert-Koch-Str. 2 22851 Norderstedt Germany

Name of manufacturer	Entegris Cleaning Process (ECP)
Address of manufacturer	395 Rue Louis Lépine 34000 Montpellier France
Location of manufacturing sites	Entegris Cleaning Process (ECP) site 1 395 Rue Louis Lépine 34000 Montpellier France

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

Active substance	Peracetic acid
Name of manufacturer	Bioxal SA
Address of manufacturer	Zone Industrielle Sud Secteur A Route des Varennes 71100 Chalon sur Saone France
Location of manufacturing sites	Bioxal SA site 1 Zone Industrielle Sud Secteur A Route des Varennes 71100 Chalon sur Saone France

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 (%)
Acetic Acid	Acetic Acid	Non-active substance	64-19-7	200-580-7	20,8 % (w/w)
Hydrogen peroxide	Hydrogen peroxide	Non-active substance	7722-84-1	231-765-0	9,3 % (w/w)
Peracetic acid	Ethaneperoxoic acid	Active substance	79-21-0	201-186-8	3,6 % (w/w)

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

XX – Others: Any other liquid (AL) and Soluble concentrate (SL)

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H272: May intensify fire; oxidiser. H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage. H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled. H410: Very toxic to aquatic life with long lasting effects. EUH071: Corrosive to the respiratory tract.

Precautionary statements	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. P234: Keep only in original packaging. P260: Do not breathe vapour or spray. 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 (e.g. butyl rubber) /protective clothing/eye protection/face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P302+P352: IF ON SKIN: Wash with plenty of water. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. 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. P312: Call a POISON CENTER/doctor if you feel unwell. P321: Specific treatment (see POISON CENTER/doctor/ first aid instructions on this label on this label). P330: Rinse mouth. P362+P364: Take off contaminated clothing and wash it before reuse. P363: Wash contaminated clothing before reuse. P370+P378: In case of fire: Use contents to extinguish. P390: Absorb spillage to prevent material damage. P391: Collect spillage. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents to an approved waste disposal plant. P501: Dispose of container to an approved waste disposal plant.

4. AUTHORISED USE(S)

4.1. **Use description**

Table 1

Use #1-Surface disinfection in industrial areas - spraying (automatically)

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi Common name: viruses Common name: bacterial spores
Field(s) of use	indoor use Disinfection of clean, non-porous surfaces, materials and equipment in systems preventing direct contact of the user with the product (e.g. in tunnels) in industrial areas
Application method(s)	Method: spraying - automatically Detailed description: The biocidal product will be used via an automated dosing system from a closed storage tank, in a way that no direct contact of the user with the product is possible. The handling of these machines is done via a control panel outside of the washing area.
Application rate(s) and frequency	Application Rate: 50 ml/m^2 In-use concentrations and contact times: - bacteria: 0,47 % (v/v), 5 minutes - yeast: 0,47 % (v/v), 15 minutes - fungi: 3,9 % (v/v), 15 minutes - viruses: 2,9 % (v/v), 15 minutes - bacterial spores: 1,0 % (v/v), 5 minutes Number and timing of application: Once per day, max. 1 000 m^2. Application when required.
Category(ies) of users	industrial professional
Pack sizes and packaging material	bottle: 1 l, HDPE (high-density polyethylene), vented cap (HDPE) canister: 5-30 l, HDPE, vented cap (HDPE)

4.1.1. *Use-specific instructions for use*

Prepare the working solution by adding the required quantity of the concentrate into water manually by using a measuring cup/canister pump or automatically by using appropriate dosing equipment. Clean surfaces before using the disinfectant. Spray the working solution automatically. Wet surfaces completely and allow taking effect for the required contact time.

4.1.2. *Use-specific risk mitigation measures*

See section 5.2

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

See section 5.3

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

See section 5.4

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

See section 5.5

4.2. **Use description**

Table 2

Use #2-Surface disinfection in industrial areas - Surface decontamination in isolators with vaporised biocide

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi Common name: bacterial spores
Field(s) of use	indoor use Disinfection of clean, non-porous surfaces, materials and equipment in isolators with a size between 0,25 m^3 and 5 m^3 in industrial areas
Application method(s)	Method: Vaporizing (closed system) Detailed description: -
Application rate(s) and frequency	Application Rate: isolator size between 0,25 and < 4 m^3: vaporization time of 2 hours/m^3 with a product vaporization rate of 70-80 ml/hour isolator size between 4 and 5 m^3: vaporization time of 1,5 hours/m^3 with a product vaporization rate of 63-80 ml/hour. Once per day. Use undiluted.
Category(ies) of users	industrial professional
Pack sizes and packaging material	bottle: 1 l, HDPE, vented cap (HDPE) canister: 5-30 l, HDPE, vented cap (HDPE)

4.2.1. *Use-specific instructions for use*

Clean surfaces before using the disinfectant. Use a constant air flow of 50 litres/minute. Automatically vaporize 70-80 ml/hour undiluted product for isolators between 0,25 m^3 and < 4 m^3 for 2 hours/m^3 and 63-80 ml/hour for isolators between 4 and 5 m^3 for 1,5 hours/m^3. After an aeration time of at least 15 minutes the isolators can be ventilated.

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

4.2.2. *Use-specific risk mitigation measures*

See section 5.2

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 section 5.3

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

See section 5.4

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

See section 5.5

4.3. **Use description**

Table 3

Use #3-Surface disinfection in clean rooms in industrial areas - spraying (automatically)

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi Common name: viruses Common name: bacterial spores
Field(s) of use	indoor use Disinfection of clean non-porous surfaces, materials and equipment in clean rooms in systems preventing direct contact of the user with the product (e.g. in tunnels) in industrial areas
Application method(s)	Method: spraying - (automatically) Detailed description: The biocidal product will be used via an automated dosing system from a closed storage tank, in a way that no direct contact of the user with the product is possible. The handling of these machines is done via a control panel outside of the washing area.
Application rate(s) and frequency	Application Rate: 50 ml/m^2 In-use concentrations and contact times: - bacteria: 0,47 % (v/v), 5 minutes - yeast: 0,47 % (v/v), 15 minutes - fungi: 3,9 % (v/v), 15 minutes - viruses: 2,9 % (v/v), 15 minutes - bacterial spores: 1,0 % (v/v), 5 minutes Number and timing of application: Once per day, max. 1 000 m^2. Application when required.
Category(ies) of users	industrial professional
Pack sizes and packaging material	bottle: 1 l, HDPE, vented cap (HDPE) canister: 5-30 l, HDPE, vented cap (HDPE)

4.3.1. *Use-specific instructions for use*

Prepare the working solution by adding the required quantity of the concentrate into water manually by using a measuring cup/canister pump or automatically by using appropriate dosing equipment. Spray the working solution on the clean surface automatically. Wet surfaces completely and allow taking effect for the required contact time.

4.3.2. *Use-specific risk mitigation measures*

See section 5.2

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

See section 5.3

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

See section 5.4

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

See section 5.5

4.4. **Use description**

Table 4

Use #4-Surface disinfection in clean rooms in industrial areas - Surface decontamination in isolators with vaporised biocide

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Common name: bacteria Common name: yeasts Common name: fungi Common name: bacterial spores
Field(s) of use	indoor use Disinfection of clean non-porous surfaces, materials and equipment in isolators with a size between 0,25 m^3 and 5 m^3 in clean rooms in industrial areas.
Application method(s)	Method: Vaporizing (closed system) Detailed description: -
Application rate(s) and frequency	Application Rate: isolator size between 0,25 and < 4 m^3: vaporization time of 2 hours/m^3 with a product vaporization rate of 70-80 ml/hour isolator size between 4 and 5 m^3: vaporization time of 1,5 hours/m^3 with a product vaporization rate of 63-80 ml/hour Once per day. Use undiluted.
Category(ies) of users	industrial professional
Pack sizes and packaging material	bottle: 1 l, HDPE, vented cap (HDPE) canister: 5-30 l, HDPE, vented cap (HDPE)

4.4.1. *Use-specific instructions for use*

Use a constant air flow of 50 litres/minute. Automatically vaporize 70-80 ml/hour undiluted product for clean isolators between 0,25 m^3 and < 4 m^3 for 2 hours/m^3 and 63-80 ml/hour for clean isolators between 4 and 5 m^3 for 1,5 hours/m^3. After an aeration time of at least 15 minutes the isolators can be ventilated.

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

4.4.2. *Use-specific risk mitigation measures*

See section 5.2

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

See section 5.3

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

See section 5.4

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

See section 5.5

5. GENERAL DIRECTIONS FOR USE ([1])

5.1. **Instructions for use**

For use at room temperature.

Inform the authorisation holder if the treatment is ineffective.

5.2. **Risk mitigation measures**

The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work:

The wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 or equivalent (glove material to be specified by the authorisation holder within the product information) is required.

The use of eye protection (EN166 or equivalent) during handling of the product is mandatory.

Wear a protective coverall, type 6 (meeting the requirements of European Standard EN 13034, or equivalent), during mixing and loading (coverall material to be specified by the authorisation holder within the product information).

Wear chemical protective footwear (EN 13832 or equivalent).

Before using respiratory protective equipment, company-specific instruction must be given on the safe handling and operation of the respiratory protective equipment.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1) (EN 12941 or equivalent, EN 12942 or equivalent), or a half /quarter mask (EN 140 or equivalent) with combination filter gas (EN 14387or equivalent)/ P2 filter (EN 12083 or equivalent), or a full face mask (EN 136 or equivalent) with combination filter gas (EN 14387 or equivalent)/P2 filter (EN 12083 or equivalent) is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).

See section 6 for the full titles of the EN standard and Council Directive.

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

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.

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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor

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.

Information to Healthcare personnel/doctor:

Initiate life support measures if needed, thereafter call a POISON CENTRE.

Antidote: (if any available)

Avoid direct release of the undiluted product to the environment and sewage system.

Large spills: Cover the liquid with absorbent material (Suitable material: inert, non-oxidizing material e.g. sand). Contain in suitable closed containers and collect for disposal.

Clean contaminated surface thoroughly. Flush with water.

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

Residues of the biocidal product must be disposed off in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations. Waste key for the unused product: EWC 160903* (peroxides, e.g. hydrogen peroxide).

Do not empty into drains.

Leave biocidal products in original containers. Do not mix with other wastes. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable.

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

Shelf life: 18 months

Store at temperatures not exceeding 25 °C.

Keep away from heat & direct sunlight.

Keep only in the original container.

6. OTHER INFORMATION

Uses # 2 and #4: For orientation: relative humidity in isolators as tested in EN 17272 for efficacy: 52 – 55 % ± 5 %.

With respect to the 'Category(ies) of user(s)' note: 'Professionals' (including industrial users) means trained professionals if this is required by national legislation.

Please be aware of the European reference value of 0,5 mg/m³ for the active substance peracetic acid (CAS No.: 79-21-0) which was used for the risk assessment for the biocidal product.

Please be aware of the European reference value of 1,25 mg/m³ for the equilibrium partner of the active substance hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for the biocidal product (please be aware that relevant lower national limit values may apply).

Full titles of EN standards and legislation referred to in the summary of product characteristics:

1. EN ISO 374 Protective gloves against dangerous chemicals and micro-organisms.
2. EN 13034 Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)
3. EN 13832 Footwear protecting against chemicals
4. EN 12941 Respiratory protective devices - Powered filtering devices incorporating a helmet or a hood
5. EN 12942 Respiratory protective devices - Power assisted filtering devices incorporating full face masks, half masks or quarter masks
6. EN 140:1998 Respiratory protective devices - Half masks and quarter masks
7. EN 14387 Respiratory protective devices - Gas filter(s) and combined filter(s)
8. EN 12083 Respiratory protective devices - Filters with breathing hoses, (Non-mask mounted filters) – Particle filters, gas filters, and combined filters
9. EN 136 Respiratory protective devices - Full face masks
10. EN 17272: Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities
11. 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)

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