COMMISSION IMPLEMENTING REGULATION (EU) 2023/1454

of 13 July 2023

granting a Union authorisation for the single biocidal product 'WESSOCLEAN GOLD LINE' 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 28 September 2017, WESSO AG 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 single biocidal product named 'WESSOCLEAN GOLD LINE' of product-types 3 and 4, 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-QN034236-29 in the Register for Biocidal Products.

(2) 'WESSOCLEAN GOLD LINE' 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-types 3 and 4.

(3) On 9 March 2022, 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 14 October 2022, the Agency submitted to the Commission its opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'WESSOCLEAN GOLD LINE' 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 'WESSOCLEAN GOLD LINE' 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 28 October 2022, 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.

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

([2]) ECHA opinion of 28 September 2022 on the Union authorisation of the single biocidal product 'WESSOCLEAN GOLD LINE' (ECHA/BPC/359/2022), https://echa.europa.eu/opinions-on-union-authorisation.

(7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'WESSOCLEAN GOLD LINE'.

(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-0029720-0000 is granted to WESSO AG for the making available on the market and use of the single biocidal product 'WESSOCLEAN GOLD LINE' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 3 August 2023 to 31 July 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, 13 July 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

WESSOCLEAN GOLD LINE

Product type 3 - Veterinary hygiene (Disinfectants)

Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0029720-0000

R4BP asset number: EU-0029720-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	WESSOCLEAN GOLD LINE WESSOCLEAN AGRO PROTECT

1.2. Authorisation holder

Name and address of the authorisation holder	Name	WESSO AG
	Address	Wacholderweg 6, 90518 Altdorf b. Nürnberg Germany
Authorisation number	EU-0029720-0000	
R4BP asset number	EU-0029720-0000	
Date of the authorisation	3 August 2023	
Expiry date of the authorisation	31 July 2033	

1.3. Manufacturer(s) of the product

Name of manufacturer	WESSO AG
Address of manufacturer	Wacholderweg 6, 90518 Altdorf b. Nürnberg Germany
Location of manufacturing sites	Wacholderweg 6, 90518 Altdorf b. Nürnberg Germany

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

Active substance	Peracetic acid
Name of manufacturer	Evonik Resource Efficiency GmbH
Address of manufacturer	Postfach 1345, 63403 Hanau Germany
Location of manufacturing sites	Evonik Peroxid GmbH, Industriestraße 11, 9721 Weissenstein Austria

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 (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	0,03
ethanol		Non-active substance	64-17-5	200-578-6	1,61
propan-2-ol		Non-active substance	67-63-0	200-661-7	2,52
hydrogen peroxide		Non-active substance	7722-84-1	231-765-0	3,15
acetic acid		Non-active substance	64-19-7	200-580-7	0,06
sulphuric acid		Non-active substance	7664-93-9	231-639-5	0,01

2.2. Type of formulation

AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	May be corrosive to metals. Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Wash hands thoroughly after handling. Avoid release to the environment. Wear eye protection. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice. Absorb spillage to prevent material damage. Dispose of contents to an approved waste disposal plant in accordance with national regulations. Dispose of container to an approved waste disposal plant in accordance with national regulations.

4. **AUTHORISED USE(S)**

4.1. **Use description**

Table 1

Use # 1 – Use 1 – Disinfection of hatching eggs at room temperature in the sluice

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage: - Scientific name: yeast Common name: Yeasts Development stage: - Scientific name: fungi Common name: Fungi Development stage: -
Field(s) of use	Indoor Hatcheries (sluice), disinfection of hatching eggs
Application method(s)	Method: Closed system: cold fogging Detailed description: -
Application rate(s) and frequency	Application Rate: Application rate: 1 litre undiluted product per 15 m^3 (= 0,067 litre/m^3) room air; median droplet size ≤ 15 µm Dilution (%): undiluted Number and timing of application: Disinfecting after each refilling of the disinfection chamber with eggs.
Category(ies) of users	Professional
Pack sizes and packaging material	— 1 litre bottle (Polyethylene - PE) — 20 litre can (High density polyethylene - HDPE) — 220 litre drum (HDPE) — 1 000 litre Intermediate Bulk Container (IBC) (PE)

4.1.1. *Use-specific instructions for use*

1) 1 litre product per 15 m^3 (= 0,067 litre/m^3) must be distributed for a period of at least 30 minutes. The contact time starts when the required total volume of product (see application rate) is nebulized.

For bactericidal, yeasticidal and fungicidal efficacy, let the product take effect at 20 °C for 60 minutes contact time. Afterwards, the air in the chamber should be replaced by means of an exhaust system.

2) The product is a ready-to-use solution.

3) Disinfection after each refilling of the disinfection chamber with eggs.

4) Only for use in dry enclosures of 4 -150 m^3.

5) Biological validation shall be performed by the user of the biocidal products for each room setup (including for example, hatching eggs, equipment) to be disinfected by fogging (or in a suitable 'standard' room in a facility, if applicable) with the devices to be used for the disinfection process, after which a protocol for disinfection processes in these rooms can be made and used thereafter.

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

Use # 2 – Use 2 – Disinfection of hatching eggs at 36 °C in the hatcher

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage: - Scientific name: yeast Common name: Yeasts Development stage: - Scientific name: fungi Common name: Fungi Development stage: -
Field(s) of use	Indoor Hatcheries (hatcher), disinfection of hatching eggs
Application method(s)	Method: Closed system: cold fogging Detailed description: -
Application rate(s) and frequency	Application Rate: Application rate: 1 litre undiluted product per 15 m^3 (= 0,067 litre/m^3) room air; median droplet size ≤ 15 µm Dilution (%): undiluted Number and timing of application: Disinfecting after each refilling of the disinfection chamber with eggs.

Category(ies) of users	Professional
Pack sizes and packaging material	— 1 l bottle (PE) — 20 litre can (HDPE) — 220 litre drum (HDPE) — 1 000 litre IBC container (PE)

4.2.1. *Use-specific instructions for use*

1) 1 litre product per 15 m^3 (= 0,067 litre/m^3) must be distributed for a period of at least 30 minutes. The contact time starts when the required total volume of product (see application rate) is nebulized.

For bactericidal, yeasticidal and fungicidal efficacy, let the product take effect at 36 °C for 60 minutes contact time. Afterwards, the air in the chamber should be replaced by means of an exhaust system.

2) The product is a ready-to-use solution.

3) Disinfection after each refilling of the disinfection chamber with eggs.

4) Only for use in dry enclosures of 4 -150 m^3.

5) Biological validation shall be performed by the user of the biocidal products for each room setup (including for example, hatching eggs, equipment) to be disinfected by fogging (or in a suitable 'standard' room in a facility, if applicable) with the devices to be used for the disinfection process, after which a protocol for disinfection processes in these rooms can be made and used thereafter.

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

4.3. **Use description**

Table 3

Use # 3 – Use 3 – Disinfection of surfaces in the vegetable, fruit and plants packaging industry by airborne diffusion

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: bacteria Common name: Bacteria Development stage: - Scientific name: yeast

	Common name: Yeasts Development stage: - Scientific name: fungi Common name: Fungi Development stage: -
Field(s) of use	Indoor Non-porous surfaces of transport and storage equipment for potatoes, fruits, vegetables and plants without direct contact to potatoes, fruits, vegetables or plants.
Application method(s)	Method: Closed system: cold fogging Detailed description: -
Application rate(s) and frequency	Application Rate: 40 ml product per 1 m^3 (0,04 litre/m^3) room air; median droplet size ≤ 15 µm Dilution (%): undiluted Number and timing of application: Disinfecting before placing new items in the packaging line.
Category(ies) of users	Professional
Pack sizes and packaging material	1 litre bottle (PE) 20 litre can (HDPE) 220 litre drum (HDPE) 1 000 litre IBC container (PE)

4.3.1. *Use-specific instructions for use*

1) 40 ml ready-to-use product per 1 m^3 room air (0,04 litre/m^3) is distributed for a period of at least 30 minutes. The contact time starts when the required total volume of product (see application rate) is nebulized.

   For bactericidal, yeasticidal and fungicidal efficacy let the product take effect at room temperature for 30 minutes contact time. Afterwards, the room should be intensively aerated.

2) The product is a ready-to-use solution that must not be diluted with water.

3) Disinfecting before placing new items in the packaging line.

4) Only for use in dry enclosures of 3 – 5 m^3.

5) Biological validation shall be performed by the user of the biocidal products for each installation to be used for disinfection by fogging (or in a suitable 'standard' installation in a facility, if applicable) with the devices to be used for the disinfection process, after which a protocol for disinfection in these installations can be made and used thereafter.

4.3.2. *Use-specific risk mitigation measures*

See general directions for use

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 general directions for use

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

See general directions for use

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

See general directions for use

5. **GENERAL DIRECTIONS FOR USE** ([1])

5.1. **Instructions for use**

For loading the product:

The product may only be transferred/loaded with automatic pumps.

5.2. **Risk mitigation measures**

For loading the product:

1) Use of eye protection consistent with European standard EN ISO16321 or equivalent during handling of the product. See Section 6 for the full title of the EN standard.

For application of the product:

1) Application of the product is only permitted in closed, airtight disinfection systems. Workers must not be present during the disinfection process. No workers are allowed in the disinfection chamber during application.

2) The disinfection shall only be started from outside of the disinfection chamber to avoid contact with the disinfectant.

3) The chamber must remain hermetically sealed during disinfection and re-entry must be prevented. It shall be indicated that a disinfection process is running.

4) After application, the chamber must be completely ventilated by a technical ventilation system.

5) Re-entry is only permitted once the product has dried from all surfaces and the air concentrations of peracetic acid and hydrogen peroxide have dropped below their respective reference values (AECs). To ensure sufficient ventilation, either a disinfection system with sensors indicating when the relevant concentrations have dropped below the reference values shall be used, or the required duration of the technical ventilation shall be established by measurement with suitable measurement equipment for each technical installation and after any change in relevant boundary conditions.

For repair or maintenance of dosing pumps:

1) Prior to carrying out repair or maintenance of the pumps, existing product residues must be largely removed by flushing the pumps.

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

First aid

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

2) 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.

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

4) 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.

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

Environment

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

6) Large spills: cover the liquid with absorbent material. Contain and collect for disposal.

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

1) Residues of the biocidal product must be disposed of in accordance with Directive 2008/98/EC of the European Parliament and of the Council and the European Waste Catalogue (EWC) as well as national and regional regulations.

2) Do not empty into drains.

3) Dispose of contents and container to an authorised waste collection point.

4) Leave biocidal products in original containers. Do not mix with other wastes.

5) When totally empty, containers are recyclable.

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

1) Shelf life: 12 months.

2) Protect from frost.

3) Store at temperatures below 30 °C.

6. **OTHER INFORMATION**

1) Please be aware of the EU 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 this product.

2) Please be aware of the EU reference value of 1,25 mg/m³ for the substance of concern hydrogen peroxide (CAS No: 7722-84-1) which was used for the risk assessment for this product.

3) Please be aware of the EU reference value of 17,9 mg/kg bw/d for the substance of concern propan-2-ol (CAS No: 67-63-0) which was used for the risk assessment for this product.

4) For orientation: relative humidity as tested in adapted EN 17272 for efficacy: 33 - 53 %.

The full titles of the EN standards referenced in this section and in Sections 5.2 'Risk mitigation measures'and 5.4 'Instructions for safe disposal of the product and its packaging' are:

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.

EN ISO16321 - Eye and face protection for occupational use

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).