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COMMISSION IMPLEMENTING REGULATION (EU) 2026/2474

of 6 November 2026

granting a Union authorisation for the biocidal product 'Product 3' 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 June 2022, Zimmer Reinigungstechnik 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 Union authorisation of the same product, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named 'Product 3', of product-type 1, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-UG078203-36 in the Register for Biocidal Products. The application referred to the biocidal product family 'ECA Disinfect skin Product family 7' authorised by Commission Implementing Regulation (EU) 2026/750 ([3]), with authorisation number EU-0035043-0000.

(2) The same product 'Product 3' contains active chlorine released from hypochlorous 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 1.

(3) On 2 July 2025, the Agency submitted to the Commission its opinion ([4]) in accordance with Article 6 of Implementing Regulation (EU) No 414/2013, and on 14 July 2025, the draft summary of product characteristics ('SPC') of 'Product 3', in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(4) In the opinion, the Agency concludes that the proposed differences between the same product 'Product 3' and the related reference biocidal product 'ECA Disinfect skin 1000', which is a family member of 'ECA Disinfect skin Product family 7,' 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 'ECA Disinfect skin 1000' and subject to compliance with the draft SPC, the same product 'Product 3' 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 same product 'Product 3'.

([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) 2026/750 of 31 March 2026 granting a Union authorisation for the biocidal product family 'ECA Disinfect skin Product family 7' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2026/750, 1.4.2026, ELI: http://data.europa.eu/eli/reg_impl/2026/750/oj).

([4]) European Chemicals Agency opinion of 2 July 2025 on the Union authorisation of the same biocidal product 'Product 3', 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 'ECA Disinfect skin 1000'.

(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-0035170-0000 is hereby granted to Zimmer Reinigungstechnik GmbH for the making available on the market and use of the same product 'Product 3' in accordance with the summary of the product characteristics set out in the Annex.

The Union authorisation is valid from 29 November 2026 until 31 March 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, 6 November 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Product 3

Product type(s)

PT01: Human hygiene

Authorisation number: EU-0035170-0000

R4BP asset number: EU-0035170-0000

1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	Product 3 DESINFECT HAND & SKIN Plus DESINFECT COMPLETE cleaniq free hands plus cleaniq complete Dialysin Sure Hands + Dialysin Complete SUBTAN RED FORTE lool blue HD + lool yellow CO lool black CC DIASEPT HAND Plus HP DIASEPT COMPLETE CO Die Desinfection HAND&SKIN HS 100 Die Desinfection COMPLETE CO 100 Aseptolyt HD Forte Aseptolyt DES Forte Screen!x HD Plus Screen!x NA Plus LOSANO HD PRO freebee HD pro freebee CO freebee CC Intimity Hand & Skin Pro Intimity Complete Pro Sure Intimity Pro CaCaDes HD Pro Hychlos HD Forte Hychlos Protect Hychlos Complex VERIDES HD Forte VERIDES Protect VERIDES Pure

1.2. **Authorisation holder**

Name and address of the authorisation holder	Name	Zimmer Reinigungstechnik GmbH
	Address	Raiffeisenstraße 6 97265 Hettstadt DE
Authorisation number	EU-0035170-0000	

R4BP asset number	EU-0035170-0000
Date of the authorisation	29 November 2026
Expiry date of the authorisation	31 March 2036

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

Name of manufacturer	Zimmer Reinigungstechnik GmbH
Address of manufacturer	Raiffeisenstr. 6 97265 Hettstadt Germany
Location of manufacturing sites	Zimmer Reinigungstechnik GmbH site 1 Raiffeisenstraße 6 97265 Hettstadt Germany

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

Active substance	Active chlorine released from hypochlorous acid
Name of manufacturer	Zimmer Reinigungstechnik GmbH
Address of manufacturer	Raiffeisenstr. 6 97265 Hettstadt Germany
Location of manufacturing sites	Zimmer Reinigungstechnik GmbH site 1 Raiffeisenstraße 6 97265 Hettstadt Germany

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 (%)
Hypochlorous acid	Hypochlorous acid	Releaser	7790-92-3	232-232-5	0,1 % (w/w)
Active chlorine released from hypochlorous acid	Active chlorine released from hypochlorous acid	Active substance			0,1 % (w/w)

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

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H290: May be corrosive to metals.
Precautionary statements	P390: Absorb spillage to prevent material damage. P234: Keep only in original packaging.

4. AUTHORISED USE(S)

4.1. **Use description**

1.1. **Hand disinfection non-medical (PT1)**

Product type	PT01: Human hygiene
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: Viruses Development stage: no data
Field(s) of use	indoor use
Application method(s)	Method: pouring Detailed description: Pour 3 ml onto clean and dry hands, rub hands thoroughly for 30 seconds. Repeat application.
Application rate(s) and frequency	Application Rate: 2 × 3 ml. The products are ready to use (RTU) Number and timing of application: 3 ml for 30 seconds performed twice. Maximum 25 times per day (professional use). Maximum 10 times per day (non-professional use). Contact time: 2 × 30 seconds. Product must be formulated to pH 4-8.
Category(ies) of users	professional; general public (non-professional)
Pack sizes and packaging material	Bottle and IBC tank: High density polyethylene (HDPE) / polyethylene terephtalate (PET) Sizes: Non-professional users: Bottle: 500 ml; 750 ml; 1 L Professional users: Bottle: 500 ml; 750 ml; 1 L; 2,5 L; 5 L; 7,5 L; 10 L; 20 L. IBC-Tank: 500 L; 600 L; 1 000 L

4.1.1. *Use-specific instructions for use*

Apply 3 ml onto clean and dry hands, and rub hands thoroughly for 30 seconds. Perform twice.

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

5.1. **Instructions for use**

Comply with instructions for use.

5.2. **Risk mitigation measures**

No risk mitigation measures needed.

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

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

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

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

If medical advice is needed, have product container or label at hand.

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

Dispose of content/container in accordance with local/national/international regulations.

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

Shelf life: 18 months.

Must be stored at a temperature of maximum 20 °C.

Protect from frost.

Protect from light.

Keep out of reach of children and non-target animals/pets

6. OTHER INFORMATION

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