

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/365****of 26 February 2021****approving active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-type 1****(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 <sup>(1)</sup>, and in particular Article 9(1)(a) thereof,

Whereas:

- (1) On 31 July 2007, the competent authority of Slovakia ('the evaluating competent authority') received an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council <sup>(2)</sup>, for the inclusion of the active substance active chlorine released from hypochlorous acid in Annex I to that Directive for use in biocidal products of product-type 1, human hygiene, as defined in Annex V to that Directive, which corresponds to product-type 1 as defined in Annex V to Regulation (EU) No 528/2012.
- (2) On 19 November 2010, the evaluating competent authority submitted the assessment report together with its conclusions to the Commission in accordance with Article 11(2) of Directive 98/8/EC.
- (3) On 16 June 2020, the Biocidal Products Committee adopted the opinion of the European Chemicals Agency <sup>(3)</sup> ('the Agency'), having regard to the conclusions of the evaluating competent authority.
- (4) According to that opinion, biocidal products of product-type 1 using active chlorine released from hypochlorous acid may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.
- (5) Taking into account the opinion of the Agency, it is appropriate to approve active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-type 1 subject to compliance with certain specifications and conditions.
- (6) 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*

Active chlorine released from hypochlorous acid is approved as an active substance for use in biocidal products of product-type 1 subject to the specifications and conditions set out in the Annex.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.<sup>(2)</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).<sup>(3)</sup> Biocidal Products Committee Opinion on the application for approval of the active substance active chlorine released from hypochlorous acid, Product type:1, ECHA/BPC/255 adopted on 16 June 2020.

*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, 26 February 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (%)	Date of approval	Expiry date of approval	Product type	Specific conditions
Active chlorine released from hypochlorous acid	IUPAC name: Hypochlorous acid EC No: 232-232-5 CAS No: 7790-92-3	Specification established for hypochlorous acid (as dry weight min. 90,87 % w/w) releasing active chlorine. Hypochlorous acid is the predominant species at pH 3,0 – 7,4.	1 July 2021	30 June 2031	1	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.