## **COMMISSION IMPLEMENTING REGULATION (EU) 2021/364**

#### of 26 February 2021

approving active chlorine generated from sodium chloride by electrolysis 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 (1), 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 ('), for the inclusion of the active substance active chlorine generated from sodium chloride by electrolysis 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 (3) ('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 generated from sodium chloride by electrolysis 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 generated from sodium chloride by electrolysis 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 generated from sodium chloride by electrolysis 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>(\*)</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>(\*)</sup> Biocidal Products Committee Opinion on the application for approval of the active substance active chlorine generated from sodium chloride by electrolysis, Product type:1, ECHA/BPC/250 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 EN

| Common Name   | IUPAC Name<br>Identification Numbers   | Minimum degree of purity of the active substance (')  | Date of approval       | Expiry date of approval  | Product<br>type | Specific conditions  |
|---|--|---|------------------------|--------------------------|-----------------|--|
| Active chlorine generated from sodium chloride by electrolysis EC No: not CAS No: n Precursor: IUPAC Nat Chloride EC No 231 CAS No 70 | UPAC name: not applicable EC No: not applicable CAS No: not applicable Precursor: IUPAC Name: Sodium Chloride EC No 231-598-3 CAS No 7647-14-5 | The specifications for active chlorine generated from sodium chloride by electrolysis in situ are dependent on the precursor sodium chloride which must comply with purity requirements of one of the following standards: NFBrand, EN 973 A, EN 973 B, EN 14805 Type 1, EN 14805 Type 2, EN 16401 Type 1, EN 16401 Type 2, CODEX STAN 16401 Type 2, CODEX STAN 150-1985 or European Pharmacopoeia 9.0. | 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 requirement  | s for the precursor indicated ir   | (1) The purity requirements for the precursor indicated in this column are those provided in the application for the approval of the active substance evaluated   | on for the approval of | the active substance eva | ıluated.        |  |