COMMISSION IMPLEMENTING REGULATION (EU) 2017/1273

of 14 July 2017

approving active chlorine released from sodium hypochlorite as an existing active substance for use in biocidal products of product-types 1, 2, 3, 4 and 5

(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 the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes active chlorine released from sodium hypochlorite (hereafter referred to as 'sodium hypochlorite').

(2) Sodium hypochlorite has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council ([3]) for use in products of product-type 1, human hygiene biocidal products, product-type 2, private area and public health area disinfectants and other biocidal products, product-type 3, veterinary hygiene biocidal products, product-type 4, food and feed area disinfectants, and product-type 5, drinking water disinfectants, as defined in Annex V to that Directive, which correspond respectively to product-types 1, 2, 3, 4 and 5 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Italy was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 17 May 2010.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 14 December 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 1, 2, 3, 4 and 5 containing sodium hypochlorite may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning its use are complied with.

(6) It is therefore appropriate to approve sodium hypochlorite for use in biocidal products of product-types 1, 2, 3, 4 and 5, subject to compliance with certain specifications and conditions.

(7) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(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.

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) 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).

HAS ADOPTED THIS REGULATION:

Article 1

Active chlorine released from sodium hypochlorite is approved as an active substance for use in biocidal products of product-types 1, 2, 3, 4 and 5, subject to the specifications and conditions set out in the Annex.

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, 14 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
Active chlorine released from sodium hypochlorite (hereafter referred to as 'sodium hypochlorite').	IUPAC Name: Sodium hypochlorite EC No: 231-668-3 CAS No: 7681-52-9	Minimum purity of the releaser sodium hypochlorite: aqueous solution with an active chlorine concentration ≤ 180 g/kg (i.e. ≤ 18 % w/w).	1 January 2019	31 December 2028	1	The authorisations of biocidal products are subject to the following condition: The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.
					2	The authorisations of biocidal products are subject to the following conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. (2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: (a) professional users and non-professional users; (b) surface water and sediment for disinfection of sewage / waste water in the effluent stream of the sewage treatment plant (post-chlorination).
					3	The authorisations of biocidal products are subject to the following conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. (2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users and non-professional users. (3) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (2) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (3) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
					4	The authorisations of biocidal products are subject to the following conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. (2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users. (3) For products that may lead to residues in food or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					5	The authorisations of biocidal products are subject to the following conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. (2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users. (3) For products that may lead to residues in food or feed, the need to set new or to amend existing (MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

(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.

(2) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

(3) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).