COMMISSION IMPLEMENTING REGULATION (EU) 2015/407

of 11 March 2015

approving propan-2-ol as an active substance for use in biocidal products for product-types 1, 2 and 4

(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 active substances to be evaluated with a view to their possible approval for use in biocidal products or inclusion into Annex I to Regulation (EU) No 528/2012. That list includes propan-2-ol.

(2) Propan-2-ol has been evaluated in accordance with Article 90(2) of Regulation (EU) No 528/2012 for use in biocidal products for product-type 1, human hygiene disinfectants, product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, and product-type 4, food and feed area disinfectants, as defined in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 5 November 2012 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ([3]).

(4) The opinions of the European Chemicals Agency were formulated on 18 June 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products used for product-types 1, 2 and 4 and containing propan-2-ol may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC of the European Parliament and of the Council ([4]) provided that certain specifications and conditions relating to its use are satisfied.

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

(7) Since the evaluations did not address nanomaterials, the approvals should not cover such materials in accordance with Article 4(4) of Regulation (EU) No 528/2012.

(8) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing propan-2-ol in materials and articles intended to come into contact directly or indirectly with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([5]). Such materials may require the establishment of specific limits on the migration into food, as referred to in Article 5(1)(e) of Regulation (EC) No 1935/2004. The approval should therefore not cover such use unless the Commission has established such limits or it has been established pursuant to that Regulation that such limits are not necessary.

([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]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

([4]) 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).

([5]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

(9) 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.

(10) 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

Propan-2-ol shall be approved as an active substance for use in biocidal products for product-types 1, 2 and 4, 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, 11 March 2015.

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 (2)
Propan-2-ol	IUPAC Name: 2-Propanol EC No: 200-661-7 CAS No: 67-63-0	99 % w/w	1 July 2016	30 June 2026	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.
					2	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.
					4	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. For biocidal products, authorisations are subject to the following conditions: (1) 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 (3) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (4) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded; (2) biocidal products containing propan-2-ol shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of propan-2-ol into food or it has been established pursuant to that Regulation that such limits are not necessary.

(1) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 8 of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.

(2) For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/environment/chemicals/biocides/index_en.htm

(3) 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).

(4) 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).