Commission Implementing Regulation (EU) 2015/1759 of 28 September 2015 approving glutaraldehyde as an existing active substance for use in biocidal products for product-types 2, 3, 4, 6, 11 and 12 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1759

of 28 September 2015

approving glutaraldehyde as an existing active substance for use in biocidal products for product-types 2, 3, 4, 6, 11 and 12

(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.

(2) That list includes glutaraldehyde.

(3) Glutaraldehyde 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 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, product-type 6, in-can preservatives, product-type 11, preservatives for liquid-cooling and processing systems, and product-type 12, slimicides, as defined in Annex V to that Directive, which correspond respectively to product-types 2, 3, 4, 6, 11 and 12 as defined in Annex V to Regulation (EU) No 528/2012.

(4) Finland was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 30 March 2011 and 31 January 2013 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007[(4)].

(5) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 1 October 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(6) According to those opinions, biocidal products used for product-types 2, 3, 4, 6, 11 and 12 and containing glutaraldehyde may be expected to satisfy the requirements of

Article 5 of Directive 98/8/EC, provided that certain conditions concerning its use are complied with.

(7) It is therefore appropriate to approve glutaraldehyde for use in biocidal products for product-types 2, 3, 4, 6, 11 and 12 subject to compliance with the specific conditions in the Annex.

(8) The opinions conclude that glutaraldehyde meets the criteria for classification as a respiratory sensitiser as defined in point 3.4.1.1 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[5].

(9) Since, pursuant to Article 90(2) of Regulation (EU) No 528/2012, substances for which the Member States' evaluation has been completed by 1 September 2013 should be approved in accordance with Directive 98/8/EC, the period of approval should be 10 years, in accordance with the practice established under that Directive.

(10) For the purposes of Article 23 of Regulation (EU) No 528/2012 however, glutaraldehyde meets the conditions of Article 10(1)(b) of that Regulation and should therefore be considered a candidate for substitution.

(11) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing glutaraldehyde 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[6]. 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.

(12) Since glutaraldehyde meets the criteria for classification as respiratory sensitiser, and as skin sensitiser sub-category 1A as defined in Annex I to Regulation (EC) No 1272/2008, treated articles treated with or incorporating glutaraldehyde should be appropriately labelled when placed on the market.

(13) 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.

(14) 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

Glutaraldehyde is approved as an active substance for use in biocidal products for product-types 2, 3, 4, 6, 11 and 12, 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, 28 September 2015.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC NameIdentification Numbers	Minimum degree of purity of the active substance[a]	Date of approval	Expiry date of approval	Product type	Specific conditions
Glutaraldehyde	IUPAC Name: 1,5-pentanedial EC No: 203-856-5 CAS No: 111-30-8	950 g/kg dry weight (95 %)	1 October 2016	30 September 2026	2	Glutaraldehyde is considered a candidate for substitution in accordance with Article 10(1)(b) of Regulation (EU) No 528/2012. 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. The authorisations of biocidal products are subject

						to the following conditions. (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) In view of the risks to professional users, products cannot be applied by wiping

						unless it can be demonstrated that risks can be reduced to an acceptable level. The placing on the market of treated articles is subject to the following condition. The person responsible for the placing on the market of a treated article treated with or incorporating glutaraldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					3	Glutaraldehyde is

						considered a candidate for substitution in accordance with Article 10(1)(b) of Regulation (EU) No 528/2012. 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. The authorisations of biocidal products are subject to the following conditions. (1) For industrial or professional users, safe operational

							procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.
						(2)	Application by fogging shall be restricted to trained professionals.
						(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[b] or Regulation (EC) No 396/2005 of the European Parliament and of the Council[c] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable

						MRLs are not exceeded. The placing on the market of treated articles is subject to the following condition. The person responsible for the placing on the market of a treated article treated with or incorporating glutaraldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					4	Glutaraldehyde is considered a candidate for substitution in accordance with Article 10(1)(b) of Regulation

						(EU) No 528/2012. 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. The authorisations of biocidal products are subject to the following conditions. (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Products

							shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.
						(2)	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 or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
						(3)	Products 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 glutaraldehyde into food or it has been established pursuant to that Regulation that such limits are not necessary. The placing on the market of treated articles is subject to the following condition. The person responsible for the

						placing on the market of a treated article treated with or incorporating glutaraldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					6	Glutaraldehyde is considered a candidate for substitution in accordance with Article 10(1)(b) of Regulation (EU) No 528/2012. 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. The authorisations of biocidal products are subject to the following conditions. (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level

							by other means.
						(2)	In view of the risks to human health, products intended for non-professional users shall not contain glutaraldehyde at a concentration triggering classification as skin sensitiser, unless exposure can be reduced to an acceptable level by other means than the wearing of personal protective equipment.
						(3)	In view of the risks

						to the environment, products shall not be authorised for preservation of drilling and cementing fluids unless it can be demonstrated that risks can be reduced to an acceptable level.
						The placing on the market of treated articles is subject to the following conditions.
						(1) Mixtures treated with or incorporating glutaraldehyde shall not contain glutaraldehyde at a concentration triggering classification

							as skin sensitiser, unless exposure can be reduced to an acceptable level by other means than the wearing of personal protective equipment.
						(2)	The person responsible for the placing on the market of a treated article treated with or incorporating glutaraldehyde shall ensure that the label of that treated article provides the information listed

						in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					11	Glutaraldehyde is considered a candidate for substitution in accordance with Article 10(1)(b) of Regulation (EU) No 528/2012. 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.

						The authorisations of biocidal products are subject to the following conditions. (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) In view of the risks to the soil and

							surface water, products shall not be authorised for use in small open recirculating cooling systems, unless it can be demonstrated that risks can be reduced to an acceptable level.
						(3)	In view of the risks to the environment, products shall not be authorised for preservation of hydrotesting water unless it can be demonstrated that

						risks can be reduced to an acceptable level. The placing on the market of treated articles is subject to the following condition. The person responsible for the placing on the market of a treated article treated with or incorporating glutaraldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					12	Glutaraldehyde is considered a candidate for substitution in accordance

						with Article 10(1)(b) of Regulation (EU) No 528/2012. 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. The authorisations of biocidal products are subject to the following conditions. (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall

							be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.
						(2)	In view of the risks to the environment, products shall not be authorised for use in pulp or paper mills which are not connected to a wastewater treatment plant unless

						it can be demonstrated that risks can be reduced to an acceptable level. The placing on the market of treated articles is subject to the following condition. The person responsible for the placing on the market of a treated article treated with or incorporating glutaraldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

a 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 16(2) of Directive 98/8/EC. 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.

b	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).
c	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).

(**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).

(**4**) 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).

(**5**) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(**6**) 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).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1759.