

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1763**of 25 November 2020****approving formaldehyde as an existing active substance for use in biocidal products of product-types 2 and 3****(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 formaldehyde.
- (2) Formaldehyde has been evaluated for use in biocidal products of product-type 2, private area and public health area disinfectants and other biocidal products, and product-type 3, veterinary hygiene biocidal products, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ⁽³⁾, which correspond respectively to product-types 2 and 3 as described in Annex V to Regulation (EU) No 528/2012.
- (3) The evaluating competent authority of Germany submitted the assessment reports together with its conclusions to the Commission on 29 July 2013.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency ⁽⁴⁾ (the 'Agency') were adopted on 10 December 2019 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) It can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC.
- (6) According to the opinions of the Agency, biocidal products of product-types 2 and 3 containing formaldehyde may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.
- (7) It is therefore appropriate to approve formaldehyde for use in biocidal products of product-types 2 and 3, subject to compliance with certain specifications and conditions.
- (8) The opinions of the Agency conclude that formaldehyde meets the criteria for classification as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁵⁾.
- (9) Since formaldehyde should be approved under the terms of Directive 98/8/EC, taking into account that property, the period of approval should be considerably shorter than 10 years, in accordance with the latest practice established under that Directive. In addition, since formaldehyde has benefitted from the transitional period provided for in Article 89 of Regulation (EU) No 528/2012 since 14 May 2000 and has been under peer review since 29 July 2013,

⁽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⁾ Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Formaldehyde, Product type: 2, ECHA/BPC/232/2019, adopted on 10 December 2019; Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Formaldehyde, Product type: 3, ECHA/BPC/233/2019, adopted on 10 December 2019.

⁽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).

and with the view to examine at Union level as soon as possible in the context of a potential renewal of approval whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied for formaldehyde, the period of approval should be three years.

- (10) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities of the Member States should evaluate whether the conditions of Article 5(2) of that Regulation can be satisfied in their territories in order to decide whether a biocidal product containing formaldehyde can be authorised.
- (11) For the purposes of Article 23 of Regulation (EU) No 528/2012, formaldehyde meets the conditions laid down in point (a) of Article 10(1) of that Regulation and should therefore be considered a candidate for substitution. The competent authorities of the Member States should therefore perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing formaldehyde.
- (12) Since, as concluded by the Agency, formaldehyde meets the criteria for classification as carcinogen category 1B and as skin sensitiser category 1 in accordance with Annex I to Regulation (EC) No 1272/2008, treated articles treated with or incorporating formaldehyde should be appropriately labelled when placed on the market.
- (13) This Regulation does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC ⁽⁶⁾ and 98/24/EC ⁽⁷⁾, and Directive 2004/37/EC of the European Parliament and of the Council ⁽⁸⁾.
- (14) 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.
- (15) 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

Formaldehyde is approved as an active substance for use in biocidal products of product-types 2 and 3, 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, 25 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁶⁾ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

⁽⁷⁾ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

⁽⁸⁾ Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

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
Formaldehyde	IUPAC Name: Methanal EC No: 200-001-8 CAS No: 50-00-0	25–55,5 % formaldehyde in aqueous solution (minimum purity 87,5 % w/w with regard to formaldehyde)	1 February 2022	31 January 2025	2	<p>Formaldehyde is considered a candidate for substitution in accordance with point (a) of Article 10(1) of Regulation (EU) No 528/2012.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> 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. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: <ol style="list-style-type: none"> professional users for products used for disinfection by mopping and wiping of surfaces; secondary exposure of the general public and children; the aquatic environment for products used for room disinfection by fumigation in epidemic cases. <p>The placing on the market of treated articles is subject to the following condition that the person responsible for the placing on the market of a treated article treated with or incorporating formaldehyde 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.</p>
					3	<p>Formaldehyde is considered a candidate for substitution in accordance with point (a) of Article 10(1) of Regulation (EU) No 528/2012.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> 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. In addition, pursuant to point 10

					<p>of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.</p> <p>2. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.</p> <p>3. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:</p> <ul style="list-style-type: none"> (i) professional users for products used for disinfection by spraying of animal housing and of vehicles in epidemic cases; (ii) secondary exposure of the general public; (iii) surface water, sediment, soil and groundwater following use of products for disinfection of vehicles and disinfection of animal's feet by bathing or dipping. <p>4. For products that may lead to residues in food or feed, it shall be verified whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended 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⁾, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.</p> <p>The placing on the market of treated articles is subject to the condition that the person responsible for the placing on the market of a treated article treated with or incorporating formaldehyde 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.</p>
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⁽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).