Official Journal
of the European Union

EN
L series

2026/336

17.2.2026

COMMISSION IMPLEMENTING DECISION (EU) 2026/336

of 13 February 2026

postponing the expiry date of the approval of permethrin for use in biocidal products of product-types 8 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Permethrin was approved as an active substance for use in biocidal products of product-types 8 and 18 by Commission Implementing Regulation (EU) No 1090/2014 ([2]) subject to the conditions set out in the Annex to that Regulation.

(2) The approval of permethrin for use in biocidal products of product-types 8 and 18 ('the approval') is to expire on 30 April 2026. On 18 October 2024, two applications were submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of permethrin for use in biocidal products of product-types 8 and 18 ('the applications').

(3) On 5 December 2024, the evaluating competent authority of Ireland informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the applications was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(6) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the applications. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the Agency of its opinions and the time needed for the Commission to decide whether to renew the approval of permethrin for use in biocidal products of product-types 8 and 18, the expiry date should be postponed to 31 October 2028.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([2]) Commission Implementing Regulation (EU) No 1090/2014 of 16 October 2014 approving permethrin as an existing active substance for use in biocidal products for product-types 8 and 18 (OJ L 299, 17.10.2014, p. 10, ELI: http://data.europa.eu/eli/reg_impl/2014/1090/oj).

(7) After the postponement of the expiry date of the approval, permethrin remains approved for use in biocidal products of product-types 8 and 18 subject to the conditions set out in the Annex to Implementing Regulation (EU) No 1090/2014,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of permethrin for use in biocidal products of product-types 8 and 18 set out in the Annex to Implementing Regulation (EU) No 1090/2014 is postponed to 31 October 2028.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 13 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

Official Journal
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2026/337

17.2.2026

COMMISSION IMPLEMENTING DECISION (EU) 2026/337

of 13 February 2026

postponing the expiry date of the approval of alpha-cypermethrin for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Alpha-cypermethrin was approved as an active substance for use in biocidal products of product-type 18 by Commission Implementing Regulation (EU) 2015/405 ([2]) subject to the conditions set out in the Annex to that Regulation.

(2) The approval of alpha-cypermethrin for use in biocidal products of product-type 18 ('the approval') is to expire on 30 June 2026. On 12 December 2024, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of alpha-cypermethrin for use in biocidal products of product-type 18 ('the application').

(3) On 7 April 2025, the evaluating competent authority of Belgium informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(6) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the Agency of its opinion and the time needed for the Commission to decide whether to renew the approval of alpha-cypermethrin for use in biocidal products of product-type 18, the expiry date should be postponed to 31 December 2028.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) Commission Implementing Regulation (EU) 2015/405 of 11 March 2015 approving alpha-cypermethrin as an active substance for use in biocidal products for product-type 18 (OJ L 67, 12.3.2015, p. 9, ELI: http://data.europa.eu/eli/reg_impl/2015/405/oj).

(7) After the postponement of the expiry date of the approval, alpha-cypermethrin remains approved for use in biocidal products of product-type 18 subject to the conditions set out in the Annex to Implementing Regulation (EU) 2015/405,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of alpha-cypermethrin for use in biocidal products of product-type 18 set out in the Annex to Implementing Regulation (EU) 2015/405 is postponed to 31 December 2028.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 13 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

Official Journal
of the European Union

EN
L series

2026/373

23.2.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/373

of 20 February 2026

approving formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) as an existing active substance for use in biocidal products of product-types 2, 11 and 13 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 89(1), third subparagraph, thereof,

Whereas:

(1) Annex II to 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 reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) ('HPT') for product-types 2, 11 and 13.

(2) HPT has been evaluated for use in biocidal products of product-type 2 (private area and public health area disinfectants and other biocidal products), 11 (preservatives for liquid-cooling and processing systems) and 13 (metalworking-fluid preservatives) as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond to product-type 2 (disinfectants and algaecides not intended for direct application to humans or animals), 11 (preservatives for liquid-cooling and processing systems) and 13 (working or cutting fluid preservatives) as described in Annex V to Regulation (EU) No 528/2012.

(3) Austria was designated as the rapporteur Member State, and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 29 September 2016. After the submission of the assessment report, discussions took place in technical meetings organised by the Agency.

(4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinions of the Agency on 29 June 2017 for each product-type assessed ('the opinions of 29 June 2017' ([4]) ([5]) ([6])), having regard to the conclusions of the evaluating competent authority.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([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, ELI: http://data.europa.eu/eli/reg_del/2014/1062/oj).

([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, ELI: http://data.europa.eu/eli/dir/1998/8/oj).

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product-type: 2; ECHA/BPC/161/2017, adopted on 29 June 2017.

([5]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product-type: 11; ECHA/BPC/163/2017, adopted on 29 June 2017.

([6]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product-type: 13; ECHA/BPC/164/2017, adopted on 29 June 2017.

(5) According to the opinions of 29 June 2017, HPT is classified as carcinogenic category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([7]), and therefore meets the exclusion criterion set out in Article 5(1), point (a), of Regulation (EU) No 528/2012.

(6) According to the opinions of 29 June 2017, HPT did not meet the criteria to be classified as toxic for reproduction category 2 in accordance with Regulation (EC) No 1272/2008, and therefore it was not considered as having endocrine-disrupting properties in accordance with Article 5(3) of Regulation (EU) No 528/2012, pending the adoption of delegated acts specifying the scientific criteria for the determination of endocrine-disrupting properties.

(7) Commission Delegated Regulation (EU) 2017/2100 ([8]) setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 entered into force on 7 December 2017 and applies as of 7 June 2018.

(8) In anticipation of the application of the new scientific criteria set out in Delegated Regulation (EU) 2017/2100, and to provide clarity as regards the hazard properties and the risks resulting from the use of HPT, on 26 April 2018, pursuant to Article 75(1), second subparagraph, point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([9]) to revise its opinions of 29 June 2017 and to clarify whether HPT has also endocrine-disrupting properties on the basis of the scientific criteria laid down in that Delegated Regulation.

(9) The Agency adopted its revised opinions on 8 June 2022 ('the opinions of 8 June 2022') ([10]) ([11]) ([12]). According to the opinions of 8 June 2022, no conclusion could be drawn based on the available data whether HPT has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms) on the basis of the criteria laid down in Delegated Regulation (EU) 2017/2100. However, considering the known severe hazard properties of this substance, meeting already the exclusion criterion set out in Article 5(1), point (a), of Regulation (EU) No 528/2012, and based on scientific reasons, further data were not requested by the Agency.

(10) On 18 July 2023, pursuant to Article 75(1), second subparagraph, point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([13]) to revise its opinion concerning product-type 13 as the efficacy of the representative biocidal product had not been appropriately assessed according to the applicable guidance document on efficacy ([14]), and this had not been adequately identified by the evaluating competent authority during the evaluation nor during the peer review by the Agency. Tier 2 data representing real-life conditions should have been requested and assessed. The Biocidal Products Committee adopted the revised opinion of the Agency for product-type 13 on 29 May 2024 ([15]).

([7]) 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

([8]) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1, ELI: http://data.europa.eu/eli/reg_del/2017/2100/oj).

([9]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Evaluation of the Endocrine disrupting properties of certain biocidal actives substances according to the new scientific criteria'.

([10]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product-type: 2; ECHA/BPC/330/2022, adopted on 8 June 2022.

([11]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product-type: 11; ECHA/BPC/332/2022, adopted on 8 June 2022.

([12]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product-type: 13; ECHA/BPC/333/2022, adopted on 8 June 2022.

([13]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Examination of efficacy tier 2 data on specific active substances acting as preservatives (product-types 6-13)'.

([14]) Technical notes for guidance in support of Annex VI of Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market; Common principles and practical procedures for the authorisation and registration of products; short title: TNsG on Product Evaluation; February 2008.

([15]) Biocidal Products Committee Opinion on the application for approval of the active substance: Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1); Product type: 13; ECHA/BPC/427/2024, adopted on 29 May 2024.

(11) Pursuant to Regulation (EU) No 528/2012, active substances meeting an exclusion criterion may only be approved if they meet the conditions laid down in Article 4(1), and at least one of the conditions set out in Article 5(2), first subparagraph, of that Regulation.

(12) Between 5 September and 4 November 2017, the Commission, with the support of the Agency, carried out a public consultation in order to contribute to gathering information as to whether the conditions set out in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 were satisfied.

(13) On 17 February 2023, pursuant to Article 75(1), second subparagraph, point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([16]) to provide an opinion on the evaluation of the availability and suitability of alternatives to HPT for the associated product-types. The Biocidal Products Committee adopted the related opinion of the Agency on 23 November 2023 ('the opinion of 23 November 2023') ([17]). In that opinion, HPT was renamed by the Agency to formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) ('RP 1:1').

(14) The opinion of 23 November 2023 and the contributions to the public consultation have been discussed with Member States representatives in the Standing Committee on Biocidal Products. Member States' representatives have also been requested to indicate whether their Member States considered that at least one of the conditions set out in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 would be met, and to provide justifications for that position.

(15) The analysis of all data collected from the application dossiers, the public consultation and the views expressed by Member States indicates that RP 1:1 is currently needed in all Member States for certain uses.

(16) RP 1:1 was assessed for the use in biocidal products of product-type 2 for industrial and professional use as system cleaner formulation for metal working systems. Several active substances were investigated as potential alternatives to RP 1:1 for such use: active chlorine generated from sodium chloride by electrolysis, active chlorine released from calcium hypochlorite, active chlorine released from chlorine, active chlorine released from hypochlorous acid, active chlorine released from sodium hypochlorite, amines N-C10-16-alkyltrimethylenedi- reaction products with chloroacetic acid ('Ampholyt'), biphenyl-2-ol, calcium dihydroxide/calcium hydroxide/caustic lime/hydratedlime/slaked lime, calcium magnesium oxide/dolomitic lime, calcium magnesium tetrahydroxide/calcium magnesium hydroxide/hydrated dolomitic lime, calcium oxide/lime/burnt lime/quicklime, chlorocresol, citric acid, copper sulphate pentahydrate, didecyldimethylammonium chloride ('DDAC'), formaldehyde, glutaraldehyde, hydrochloric acid, hydrogen peroxide, L-(+)-lactic acid, mixture of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one ('mixture of CMIT/MIT'), nonanoic acid, ozone generated from oxygen, peracetic acid, peracetic acid generated from tetra-acetylethylenediamine and sodium percarbonate, propan-1-ol, propan-2-ol, reaction mass of peracetic acid and peroxyoctanoic acid, vinegar, 5-chloro-2-(4-chlorphenoxy)phenol ('DCPP'), formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) ('RP 3:2'). However, according to the analysis of the information collected none of those active substances could be a suitable alternative for RP 1:1 for the examined use due to lack of efficacy or technical compatibility issues or hazard issues. No non-chemical alternatives were identified for the examined use of RP 1:1 in biocidal products of product-type 2. Disinfection of metal working systems is needed for the correct operation of these systems due to the possible spoilage of equipment (vessels, tubes, filters) and subsequent contamination of metal working fluids. There is also a greater risk to metalworkers due to the possibility of pathogens contaminating end-use fluids and equipment.

([16]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)'.

([17]) Biocidal Products Committee Opinion on a request according to Article 75(1)(g) on the evaluation of the availability and suitability of alternatives to Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) and (ratio 3:2), short: RP 1:1 and RP 3:2 for PT 2, 6, 11, 12 (only RP 3:2) and 13; ECHA/BPC/405/2023, adopted on 23 November 2023.

(17) RP 1:1 was assessed for the use in biocidal products of product-type 11 for the preservation of liquid cooling and processing systems, only in closed systems and handled by industrial or professional users. Several active substances were investigated as potential alternatives to RP 1:1 for such use: 2-methyl-2H-isothiazol-3-one ('MIT'), 1,2-benzisothiazolin-3-one ('BIT'), 2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol ('HHT'), 2,2-dibromo-2-cyanoacetamide ('DBNPA'), glutaraldehyde, mixture of CMIT/MIT, peracetic acid, polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1 600 and a mean polydispersity (PDI) of 1,8 ('PHMB'), ozone generated from oxygen, tetrakis(hydroxymethyl)phosphonium sulphate (2:1) ('THPS'), tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione ('TMAD'), and RP 3:2. However, according to the analysis of the information collected none of the above active substances could be a suitable alternative for RP 1:1 for the examined use due to technical compatibility issues or hazard issues. No non-chemical alternatives were identified for the examined use of RP 1:1 in biocidal products of product-type 11. Due to possible corrosion and biofouling, preservation of liquid cooling and processing systems in closed systems is needed for their correct operations and to avoid environmental pollution, for example, due to break of pipelines due to corrosion.

(18) RP 1:1 was assessed for the use in biocidal products of product-type 13 for the preservation of metal working or cutting fluids, handled by industrial or professional users. Several active substances were investigated as potential alternatives to RP 1:1 for such use: 3-iodo-2-propynylbutylcarbamate ('IPBC'), BIT, biphenyl-2-ol, chlorocresol, DBNPA, diamine, HHT, MBIT, MIT, mixture of CMIT/MIT, phenoxyethanol, TMAD and RP 3:2. However, according to the analysis of the information collected none of the above active substances could be a suitable alternative for RP 1:1 for the examined use due to lack of efficacy or technical compatibility issues or hazard issues. No non-chemical alternatives were identified for the examined use of RP 1:1 in biocidal products of product-type 13. Due to possible spoilage, preservation of metal working or cutting fluids is needed for the correct operation of those systems and availability of products to downstream users. Without proper preservation, there is also a greater risk to metalworkers due to the possibility of pathogens contaminating end-use fluids.

(19) Therefore, the analysis of the information collected shows that the non-approval of RP 1:1 as an active substance for use in biocidal products of product-types 2, 11 and 13 would have a disproportionate negative impact on society in comparison to the risk to human health, animal health or the environment arising from the use of the substance as system cleaner formulation for metal working systems (biocidal products of product-type 2), for the preservation of liquid cooling and processing systems, only in closed systems (biocidal products of product-type 11) and for the preservation of metal working or cutting fluids (biocidal products of product-type 13). The condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is thus satisfied for those uses.

(20) The Agency concluded that there are no unacceptable risks to human health and the environment from the use of biocidal products containing RP 1:1 for product-types 2, 11 and 13, when leaving aside the absence of conclusion on whether RP 1:1 has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms) on the basis of the criteria laid down in Delegated Regulation (EU) 2017/2100, and when risk mitigation measures are applied to limit the exposure of humans, animals and the environment to RP 1:1 as far as possible. However, no conclusion on the level of risks of using RP 1:1 to human health and the environment considering its endocrine-disrupting properties was drawn by the Agency due to the missing information.

(21) Therefore, it has ultimately not been demonstrated based on the data available in the applications that the representative biocidal products containing RP 1:1 for product-types 2, 11 and 13 may be expected not to have unacceptable effects themselves, or as a result of their residues, on human health and on the environment, and that they may be expected to satisfy the criteria set out in Article 19(1), point (b)(iii) and (iv), of Regulation (EU) No 528/2012.

(22) However, the factor set out in Article 19(5) of Regulation (EU) No 528/2012 should be taken into account when considering the conditions for approval set out in Article 4(1) of that Regulation. In accordance with Article 19(5) of that Regulation, and notwithstanding paragraphs 1 and 4 of that Article, a biocidal product may be authorised when the conditions laid down in paragraph 1, point (b)(iii) and (iv), of that Article are not fully met where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation, which is similar to the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012. Since the condition set out in Article 5(2), first subparagraph, point (c), of that Regulation is met for certain uses of RP 1:1 for each assessed product-type, the condition set out in Article 19(5) of that Regulation is also considered satisfied for the same uses. Therefore, the conditions set out in Article 4(1) of Regulation (EU) No 528/2012 in conjunction with the conditions set out in Article 5(2), first subparagraph, point (c), of that Regulation are considered satisfied.

(23) It is therefore appropriate to approve RP 1:1 for use in biocidal products of product-types 2, 11 and 13, subject to compliance with certain conditions.

(24) As RP 1:1 meets the exclusion criterion laid down in Article 5(1), point (a), of Regulation (EU) No 528/2012, the approval should be for a period not exceeding five years as set out in the second sentence of Article 4(1) of that Regulation.

(25) Pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the biocidal product assessment should include an evaluation as to whether the condition of Article 5(2), first subparagraph, point (c), of that Regulation is satisfied in the respective Member State territory. It should be provided that biocidal products of product-types 2, 11 and 13 containing RP 1:1 may only be authorised for use in Member States where the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied.

(26) Furthermore, pursuant to Article 4(3), points (d) and (g), and Article 58(2), of Regulation (EU) No 528/2012, to ensure a high level of safety for human health, animal health and the environment and to ensure equal treatment between treated articles manufactured in the Union and imported treated articles, the placing on the market of treated articles treated with or intentionally incorporating RP 1:1 should be subject to restrictions and conditions. In particular, in line with the conditions set out in the approval for the authorisation of biocidal products of product-types 2, 11 and 13 containing RP 1:1, the only treated articles treated with or incorporating RP 1:1 that should be allowed to be placed on the market are those where RP 1:1 has been used as system cleaner formulation for metal working systems, those where RP 1:1 has been used for the preservation of liquid cooling and processing systems - only in closed systems, and metal working or cutting fluids.

(27) 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.

(28) 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 released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) is approved as an active substance for use in biocidal products of product-types 2, 11 and 13, subject to the 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, 20 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

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 released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) ('RP 1:1')	IUPAC name: Reaction products of paraformaldehyde and2-hydroxypropylamine (ratio 1:1) EC No: not applicable CAS No: not applicable	The active substance has to be considered as substance of Unknown or Variable composition or Complex reaction products or Biological materials (UVCB). Therefore the minimum purity is 1 000 g/kg (100 % by weight).	1 June 2027	31 May 2032	2	RP 1:1 is a candidate for substitution in accordance with Article 10(1), point (a), of Regulation (EU) No 528/2012. The authorisation of biocidal products using RP 1:1 as an active substance is subject to the following conditions: (a) the product assessment pays 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 assessment of the active substance; (b) pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment includes an evaluation as to whether the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (c) products may only be authorised for use in Member States where the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (d) the use of biocidal products containing RP 1:1 is subject to appropriate measures to ensure that exposure of humans, animals and the environment to RP 1:1 is minimised as far as possible; (e) products may only be authorised for industrial or professional use as system cleaner formulations for metal working systems; (f) the product assessment pays particular attention to: (i) professionals and industrial workers; (ii) sewage treatment plant, surface water and the terrestrial compartment; (g) Member States competent authorities shall specify in the summary of the biocidal product characteristics of a biocidal product containing RP 1:1 the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012.

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
						The placing on the market of treated articles treated with or incorporating RP 1:1 is subject to the following conditions: (a) only treated articles treated with or incorporating RP 1:1 may be placed on the market, where RP 1:1 has been used as system cleaner formulation for metal working systems; (b) the person responsible for the placing on the market of a treated article treated with or incorporating RP 1:1 shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.
					11	RP 1:1 is a candidate for substitution in accordance with Article 10(1), point (a), of Regulation (EU) No 528/2012. The authorisation of biocidal products using RP 1:1 as an active substance is subject to the following conditions: (a) the product assessment pays 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 assessment of the active substance; (b) pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment includes an evaluation as to whether the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (c) products may only be authorised for use in Member States where the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (d) the use of biocidal products containing RP 1:1 is subject to appropriate measures to ensure that exposure of humans, animals and the environment to RP 1:1 is minimised as far as possible; (e) products may only be authorised for the preservation of liquid cooling and processing systems, only in closed systems, handled by industrial or professional users;

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
						(f) the product assessment pays particular attention to: (i) professionals and industrial workers; (ii) sewage treatment plant, surface water and the terrestrial compartment; (g) Member States competent authorities shall specify in the summary of the biocidal product characteristics of a biocidal product containing RP 1:1 the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012. The placing on the market of treated articles treated with or incorporating RP 1:1 is subject to the following conditions: (a) only treated articles treated with or incorporating RP 1:1 may be placed on the market, where RP 1:1 has been used for the preservation of liquid cooling and processing systems, only in closed systems; (b) the person responsible for the placing on the market of a treated article treated with or incorporating RP 1:1 shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.
					13	RP 1:1 is a candidate for substitution in accordance with Article 10(1), point (a), of Regulation (EU) No 528/2012. The authorisation of biocidal products using RP 1:1 as an active substance is subject to the following conditions: (a) the product assessment pays 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 assessment of the active substance; (b) pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment includes an evaluation as to whether the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied;

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
						(c) products may only be authorised for use in Member States where the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (d) the use of biocidal products containing RP 1:1 is subject to appropriate measures to ensure that exposure of humans, animals and the environment to RP 1:1 is minimised as far as possible; (e) products may only be authorised for the preservation of metal working or cutting fluids, handled by industrial or professional users; (f) the product assessment pays particular attention to: (i) professionals and industrial workers; (ii) sewage treatment plant, surface water and the terrestrial compartment; (g) Member States competent authorities specify in the summary of the biocidal product characteristics of a biocidal product containing RP 1:1 the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), second subparagraph, point (e), of Regulation (EU) No 528/2012. The placing on the market of treated articles treated with or incorporating RP 1:1 is subject to the following conditions: (a) only metal working or cutting fluids treated with or incorporating RP 1:1 may be placed on the market; (b) the person responsible for the placing on the market of a treated article treated with or incorporating RP 1:1 ensures that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product made available on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

ELI: http://data.europa.eu/eli/reg_impl/2026/373/oj

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postponing the expiry date of the approval of *Bacillus sphaericus* 2362 serotype H5a5b, strain ABTS1743 for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) *Bacillus sphaericus* 2362 serotype H5a5b, strain ABTS1743 was approved as an active substance for use in biocidal products of product-type 18 by Commission Implementing Regulation (EU) 2015/417 ([2]) subject to the conditions set out in the Annex to that Regulation.

(2) The approval of *Bacillus sphaericus* 2362 serotype H5a5b, strain ABTS1743 for use in biocidal products of product-type 18 ('the approval') is to expire on 30 June 2026. On 20 December 2024, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of *Bacillus sphaericus* 2362 serotype H5a5b, strain ABTS1743 for use in biocidal products of product-type 18 ('the application').

(3) On 27 August 2025, the evaluating competent authority of Italy informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(6) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the Agency of its opinion and the time needed for the Commission to decide whether to renew the approval of *Bacillus sphaericus* 2362 serotype H5a5b, strain ABTS1743 for use in biocidal products of product-type 18, the expiry date should be postponed to 31 December 2028.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([2]) Commission Implementing Regulation (EU) 2015/417 of 12 March 2015 approving *Bacillus sphaericus* 2362 serotype H5a5b, strain ABTS1743 as an active substance for use in biocidal products for product-type 18 (OJ L 68, 13.3.2015, p. 33, ELI: http://data.europa.eu/eli/reg_impl/2015/417/oj).

(7) After the postponement of the expiry date of the approval, *Bacillus sphaericus* 2362 serotype H5a5b, strain ABTS1743 remains approved for use in biocidal products of product-type 18 subject to the conditions set out in the Annex to Implementing Regulation (EU) 2015/417,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of *Bacillus sphaericus* 2362 serotype H5a5b, strain ABTS1743 for use in biocidal products of product-type 18 set out in the Annex to Implementing Regulation (EU) 2015/417, is postponed to 31 December 2028.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 20 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

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of 20 February 2026

not renewing the approval of etofenprox for use in biocidal products of product-types 8 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 14(4), first subparagraph, point (b), thereof,

Whereas:

(1) Etofenprox was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) as an active substance for use in biocidal products of product-type 8 (wood preservatives). Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved under that Regulation subject to the requirements set out in Annex I to Directive 98/8/EC.

(2) The approval of etofenprox for use in biocidal products of product-type 8 was to expire on 31 January 2020. On 27 July 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of that approval.

(3) Commission Implementing Decision (EU) 2019/994 ([3]) postponed the expiry date of the approval of etofenprox for use in biocidal products of product-type 8 to 31 October 2022, to allow sufficient time for the examination of the application for the renewal of that approval. Commission Implementing Decision (EU) 2022/1487 ([4]) postponed further the expiry date of the approval of etofenprox for use in biocidal products of product-type 8, to 31 October 2026, due to delays linked with the delivery of additional studies needed to assess the criteria for the determination of endocrine-disrupting properties of etofenprox.

(4) Etofenprox was also approved as an active substance for use in biocidal products of product-type 18 by Commission Implementing Regulation (EU) No 1036/2013 ([5]) subject to the conditions set out in the Annex to that Regulation.

(5) The approval of etofenprox for use in biocidal products of product-type 18 was to expire on 30 June 2025. On 25 October 2023, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of that approval.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) 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, ELI: http://data.europa.eu/eli/dir/1998/8/oj).
([3]) Commission Implementing Decision (EU) 2019/994 of 17 June 2019 postponing the expiry date of approval of etofenprox for use in biocidal products of product-type 8 (OJ L 160, 18.6.2019, p. 26, ELI: http://data.europa.eu/eli/dec_impl/2019/994/oj).
([4]) Commission Implementing Decision (EU) 2022/1487 of 7 September 2022 postponing the expiry date of the approval of etofenprox for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 233, 8.9.2022, p. 85, ELI: http://data.europa.eu/eli/dec_impl/2022/1487/oj).
([5]) Commission Implementing Regulation (EU) No 1036/2013 of 24 October 2013 approving etofenprox as an existing active substance for use in biocidal products for product-type 18 (OJ L 283, 25.10.2013, p. 35, ELI: http://data.europa.eu/eli/reg_impl/2013/1036/oj).

(6) Commission Implementing Decision (EU) 2025/434 ([6]) postponed the expiry date of the approval of etofenprox for use in biocidal products of product-type 18 to 31 December 2027, to allow sufficient time for the examination of the application for the renewal.

(7) However, on 12 June 2025, the applicant who submitted the applications for the renewal of the approval of etofenprox for use in biocidal products for both product-types 8 and 18 informed the Commission that it withdrew its applications for the renewal of the approval.

(8) Consequently, as it has not been established that etofenprox still meets the conditions laid down in Article 4(1) of Regulation (EU) No 528/2012, it is appropriate to not renew the approval.

(9) In order to allow sufficient time for economic operators to adapt, treated articles treated with or incorporating etofenprox for use in biocidal products of product-types 8 and 18 may be placed on the market for a period of 180 days after the entry into force of this Decision.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The approval of etofenprox as an active substance for use in biocidal products of product-types 8 and 18 is not renewed.

Article 2

Treated articles treated with or intentionally incorporating etofenprox for use in biocidal products of product-types 8 and 18 shall no longer be placed on the market as from 11 September 2026.

Article 3

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 20 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

([6]) Commission Implementing Decision (EU) 2025/434 of 5 March 2025 postponing the expiry date of the approval of etofenprox for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2025/434, 6.3.2025, ELI: http://data.europa.eu/eli/dec_impl/2025/434/oj).

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repealing Implementing Decisions (EU) 2022/1487 and (EU) 2025/434 postponing the expiry dates of the approval of etofenprox for use in biocidal products of product-types 8 and 18, respectively, in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Etofenprox was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) as an active substance for use in biocidal products of product-type 8. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved under that Regulation subject to the requirements set out in Annex I to Directive 98/8/EC.

(2) The approval of etofenprox for use in biocidal products of product-type 8 was to expire on 31 January 2020. On 27 July 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of that approval.

(3) By Commission Implementing Decision (EU) 2019/994 ([3]), the Commission postponed the expiry date of the approval of etofenprox for use in biocidal products of product-type 8 to 31 October 2022, in order to allow sufficient time for the examination of the application for the renewal of that approval. By Commission Implementing Decision (EU) 2022/1487 ([4]), the Commission further postponed the expiry date of that approval to 31 October 2026, due to delays linked with studies needed to assess the criteria for the determination of endocrine-disrupting properties of etofenprox.

(4) Etofenprox was also approved as an active substance for use in biocidal products of product-type 18 by Commission Implementing Regulation (EU) No 1036/2013 ([5]), subject to the specifications and conditions set out in the Annex to that Implementing Regulation.

(5) The approval of etofenprox for use in biocidal products of product-type 18 was to expire on 30 June 2025. On 25 October 2023, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of that approval.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) 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, ELI: http://data.europa.eu/eli/dir/1998/8/oj).
([3]) Commission Implementing Decision (EU) 2019/994 of 17 June 2019 postponing the expiry date of approval of etofenprox for use in biocidal products of product-type 8 (OJ L 160, 18.6.2019, p. 26, ELI: http://data.europa.eu/eli/dec_impl/2019/994/oj).
([4]) Commission Implementing Decision (EU) 2022/1487 of 7 September 2022 postponing the expiry date of the approval of etofenprox for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 233, 8.9.2022, p. 85, ELI: http://data.europa.eu/eli/dec_impl/2022/1487/oj).
([5]) Commission Implementing Regulation (EU) No 1036/2013 of 24 October 2013 approving etofenprox as an existing active substance for use in biocidal products for product-type 18 (OJ L 283, 25.10.2013, p. 35, ELI: http://data.europa.eu/eli/reg_impl/2013/1036/oj).

(6) By Commission Implementing Decision (EU) 2025/434 ([6]), the Commission postponed the expiry date of the approval of etofenprox for use in biocidal products of product-type 18 to 31 December 2027, to allow sufficient time for the examination of the application for the renewal of the approval of etofenprox for use in biocidal products of product-type 18.

(7) However, on 12 June 2025, the applicant who submitted the applications for the renewal of the approval of etofenprox for use in biocidal products of product-types 8 and 18 informed the Commission that it had withdrawn both applications.

(8) Consequently, as it has not been established that etofenprox still meets the conditions laid down in Article 4(1) of Regulation (EU) No 528/2012, pursuant to Commission Implementing Decision (EU) 2026/378 ([7]) the approval of etofenprox for use in biocidal products of product-types 8 and 18 was not renewed. Therefore, it is appropriate to repeal Implementing Decisions (EU) 2022/1487 and (EU) 2025/434 postponing the expiry dates of the approval of etofenprox for use in biocidal products of product-types 8 and 18, respectively,

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decisions (EU) 2022/1487 and (EU) 2025/434 are repealed.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 20 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

([6]) Commission Implementing Decision (EU) 2025/434 of 5 March 2025 postponing the expiry date of the approval of etofenprox for use in biocidal products of product-type 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2025/434, 6.3.2025, ELI: http://data.europa.eu/eli/dec_impl/2025/434/oj).

([7]) Commission Implementing Decision (EU) 2026/378 of 20 February 2026 not renewing the approval of etofenprox for use in biocidal products of product-types 8 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2026/378, 23.2.2026, ELI: http://data.europa.eu/eli/dec_impl/2026/378/oj).

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postponing the expiry date of the approval of propan-2-ol for use in biocidal products of product-types 1, 2 and 4 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Propan-2-ol was approved as an active substance for use in biocidal products of product-types 1, 2 and 4 by Commission Implementing Regulation (EU) 2015/407 ([2]) subject to the conditions set out in the Annex to that Regulation.

(2) The approval of propan-2-ol for use in biocidal products of product-types 1, 2 and 4 ('the approval') is to expire on 30 June 2026. On 19 December 2024, applications were submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of propan-2-ol for use in biocidal products of product-types 1, 2 and 4 ('the applications').

(3) On 11 February 2025, the evaluating competent authority of Germany informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the applications was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(6) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the applications. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the Agency of its opinions and the time needed for the Commission to decide whether to renew the approval of propan-2-ol for use in biocidal products of product-types 1, 2 and 4, the expiry date should be postponed to 31 December 2028.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) 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 (OJ L 67, 12.3.2015, p. 15, ELI: http://data.europa.eu/eli/reg_impl/2015/407/oj).

(7) After the postponement of the expiry date of the approval, propan-2-ol remains approved for use in biocidal products of product-types 1, 2 and 4 subject to the conditions set out in the Annex to Implementing Regulation (EU) 2015/407,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of propan-2-ol for use in biocidal products of product-types 1, 2 and 4 set out in the Annex to Implementing Regulation (EU) 2015/407, is postponed to 31 December 2028.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 20 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

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23.2.2026

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postponing the expiry date of the approval of tebuconazole for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Tebuconazole was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) as an active substance for use in biocidal products of product-type 8. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved until 31 March 2020 under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.

(2) On 27 September 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of tebuconazole for use in biocidal products of product-type 8 ('the application').

(3) On 6 February 2019, the evaluating competent authority of Denmark informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(6) Commission Implementing Decision (EU) 2019/1951 ([3]) postponed the expiry date of the approval of tebuconazole for use in biocidal products of product-type 8 to 30 September 2022, in order to allow sufficient time for the examination of the application.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) 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, ELI: http://data.europa.eu/eli/dir/1998/8/oj).
([3]) Commission Implementing Decision (EU) 2019/1951 of 25 November 2019 postponing the expiry date of approval of tebuconazole for use in biocidal products of product-type 8 (OJ L 304, 26.11.2019, p. 21, ELI: http://data.europa.eu/eli/dec_impl/2019/1951/oj).

(7) Commission Implementing Decision (EU) 2022/1496 ([4]) postponed again the expiry date of the approval to 30 June 2026 due to delays in the evaluation of the application.

(8) On 29 September 2025, the evaluating competent authority informed the Commission that the evaluation is delayed due to additional time needed by the authority to assess the endocrine-disrupting properties of the substance.

(9) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to further postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the Agency of its opinion and the time needed for the Commission to decide whether to renew the approval of tebuconazole for use in biocidal products of product-type 8, the expiry date should be postponed to 30 June 2027.

(10) After the further postponement of the expiry date of the approval, tebuconazole remains approved for use in biocidal products of product-type 8 subject to the conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of tebuconazole for use in biocidal products of product-type 8 set out in Annex I to Directive 98/8/EC is postponed to 30 June 2027.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 20 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

([4]) Commission Implementing Decision (EU) 2022/1496 of 8 September 2022 postponing the expiry date of the approval of tebuconazole for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 234, 9.9.2022, p. 28, ELI: http://data.europa.eu/eli/dec_impl/2022/1496/oj).

Official Journal
of the European Union

EN
L series

2026/385

23.2.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/385

of 20 February 2026

approving formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) as an existing active substance for use in biocidal products of product-types 2, 6, 11, 12 and 13 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 89(1), third subparagraph, thereof,

Whereas:

(1) Annex II to 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 reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) ('MBO') for product-types 2, 6, 11, 12 and 13.

(2) MBO has been evaluated for use in biocidal products of product-type 2 (private area and public health area disinfectants and other biocidal products), 6 (in-can preservatives), 11 (preservatives for liquid-cooling and processing systems), 12 (slimicides) and 13 (metalworking-fluid preservatives) as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond to product-type 2 (disinfectants and algaecides not intended for direct application to humans or animals), 6 (preservatives for products during storage), 11 (preservatives for liquid-cooling and processing systems), 12 (slimicides) and 13 (working or cutting fluid preservatives) as described in Annex V to Regulation (EU) No 528/2012.

(3) Austria was designated as the rapporteur Member State, and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 29 September 2016. After the submission of the assessment report, discussions took place in technical meetings organised by the Agency.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([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, ELI: http://data.europa.eu/eli/reg_del/2014/1062/oj).

([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, ELI: http://data.europa.eu/eli/dir/1998/8/oj).

(4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinions of the Agency on 29 June 2017 for each product-type assessed ('the opinions of 29 June 2017' ([4]) ([5]) ([6]) ([7]) ([8])), having regard to the conclusions of the evaluating competent authority.

(5) According to the opinions of 29 June 2017, MBO is classified as carcinogenic category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([9]), and therefore meets the exclusion criterion set out in Article 5(1), point (a), of Regulation (EU) No 528/2012.

(6) According to the opinions of 29 June 2017, MBO did not meet the criteria to be classified as toxic for reproduction category 2 in accordance with Regulation (EC) No 1272/2008, and therefore it was not considered as having endocrine-disrupting properties in accordance with Article 5(3) of Regulation (EU) No 528/2012, pending the adoption of delegated acts specifying the scientific criteria for the determination of endocrine-disrupting properties.

(7) Commission Delegated Regulation (EU) 2017/2100 ([10]) setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 entered into force on 7 December 2017 and applies as of 7 June 2018.

(8) In anticipation of the application of the new scientific criteria set out in Delegated Regulation (EU) 2017/2100, and to provide clarity as regards the hazard properties and the risks resulting from the use of MBO, on 26 April 2018, pursuant to Article 75(1), second subparagraph, point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([11]) to revise its opinions of 29 June 2017 and to clarify whether MBO has also endocrine-disrupting properties on the basis of the scientific criteria laid down in that Delegated Regulation.

(9) The Agency adopted its revised opinions on 8 June 2022 ('the opinions of 8 June 2022') ([12]) ([13]) ([14]) ([15]) ([16]). According to the opinions of 8 June 2022, no conclusion could be drawn based on the available data whether MBO has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms) on the basis of the criteria laid down in Delegated Regulation (EU) 2017/2100. However, considering the known severe hazard properties of this substance, meeting already the exclusion criterion set out in Article 5(1), point (a), of Regulation (EU) No 528/2012, and based on scientific reasons, further data were not requested by the Agency.

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-type: 2; ECHA/BPC/156/2017, adopted on 29 June 2017.
([5]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-type: 6; ECHA/BPC/157/2017, adopted on 29 June 2017.
([6]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-type: 11; ECHA/BPC/158/2017, adopted on 29 June 2017.
([7]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-type: 12; ECHA/BPC/159/2017, adopted on 29 June 2017.
([8]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-type: 13; ECHA/BPC/160/2017, adopted on 29 June 2017.
([9]) 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).
([10]) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1, ELI: http://data.europa.eu/eli/reg_del/2017/2100/oj).
([11]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Evaluation of the Endocrine disrupting properties of certain biocidal actives substances according to the new scientific criteria'.
([12]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-type: 2; ECHA/BPC/334/2022, adopted on 8 June 2022.
([13]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-type: 6; ECHA/BPC/335/2022, adopted on 8 June 2022.
([14]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-type: 11; ECHA/BPC/336/2022, adopted on 8 June 2022.
([15]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-type: 12; ECHA/BPC/337/2022, adopted on 8 June 2022.
([16]) Biocidal Products Committee Opinion on the application for approval of the active substance Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product-type: 13; ECHA/BPC/338/2022, adopted on 8 June 2022.

(10) On 18 July 2023, pursuant to Article 75(1), second subparagraph, point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([17]) to revise its opinions concerning product-types 6 and 13 as the efficacy of the representative biocidal products had not been appropriately assessed according to the applicable guidance document on efficacy ([18]), and this had not been adequately identified by the evaluating competent authority during the evaluation nor during the peer review by the Agency. Tier 2 data representing real-life conditions should have been requested and assessed. The Biocidal Products Committee adopted the revised opinions of the Agency for product-types 6 and 13 on 29 May 2024 ([19]) ([20]).

(11) Pursuant to Regulation (EU) No 528/2012, active substances meeting an exclusion criterion may only be approved if they meet the conditions laid down in Article 4(1), and at least one of the conditions set out in Article 5(2), first subparagraph, of that Regulation.

(12) Between 5 September and 4 November 2017, the Commission, with the support of the Agency, carried out a public consultation in order to contribute to gathering information as to whether the conditions set out in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 were satisfied.

(13) On 17 February 2023, pursuant to Article 75(1), second subparagraph, point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([21]) to provide an opinion on the evaluation of the availability and suitability of alternatives to MBO for the associated product-types. The Biocidal Products Committee adopted the related opinion of the Agency on 23 November 2023 ('the opinion of 23 November 2023') ([22]). In that opinion, MBO was renamed by the Agency to formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) ('RP 3:2').

(14) The opinion of 23 November 2023 and the contributions to the public consultation have been discussed with Member States representatives in the Standing Committee on Biocidal Products. Member States' representatives have also been requested to indicate whether their Member States considered that at least one of the conditions set out in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 would be met, and to provide justifications for that position.

(15) The analysis of all data collected from the application dossiers, the public consultation and the views expressed by Member States indicates that RP 3:2 is currently needed in all Member States for certain uses.

(16) RP 3:2 was assessed for the use in biocidal products of product-type 2 for industrial and professional use as system cleaner formulation for metal working systems. Several active substances were investigated as potential alternatives to RP 3:2 for such use: active chlorine generated from sodium chloride by electrolysis, active chlorine released from calcium hypochlorite, active chlorine released from chlorine, active chlorine released from hypochlorous acid, active chlorine released from sodium hypochlorite, amines N-C10-16-alkyltrimethylenedi- reaction products with chloroacetic acid ('Ampholyt'), biphenyl-2-ol, calcium dihydroxide/calcium hydroxide/caustic lime/hydratedlime/slaked lime, calcium magnesium oxide/dolomitic lime, calcium magnesium tetrahydroxide/calcium magnesium hydroxide/hydrated dolomitic lime, calcium oxide/lime/burnt lime/quicklime, chlorocresol, citric acid, copper sulphate pentahydrate, didecyldimethylammonium chloride ('DDAC'), formaldehyde, glutaraldehyde, hydrochloric acid, hydrogen peroxide, L-(+)-lactic acid, mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one ('mixture of CMIT/MIT'), nonanoic acid, ozone generated from oxygen, peracetic acid, peracetic acid

([17]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Examination of efficacy tier 2 data on specific active substances acting as preservatives (product-types 6-13)'.

([18]) Technical notes for guidance in support of Annex VI of Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market; Common principles and practical procedures for the authorisation and registration of products; short title: TNsG on Product Evaluation; February 2008.

([19]) Biocidal Products Committee Opinion on the application for approval of the active substance: Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product type: 6; ECHA/BPC/428/2024, adopted on 29 May 2024.

([20]) Biocidal Products Committee Opinion on the application for approval of the active substance: Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2); Product type: 13; ECHA/BPC/429/2024, adopted on 29 May 2024.

([21]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Evaluation of the availability and suitability of alternatives to RP 1:1 (PT 2, 6, 11, 13) and RP 3:2 (PT 2, 6, 11, 12, 13)'.

([22]) Biocidal Products Committee Opinion on a request according to Article 75(1)(g) on the evaluation of the availability and suitability of alternatives to Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) and (ratio 3:2), short: RP 1:1 and RP 3:2 for PT 2, 6, 11, 12 (only RP 3:2) and 13; ECHA/BPC/405/2023, adopted on 23 November 2023.

generated from tetra-acetylethylenediamine and sodium percarbonate, propan-1-ol, propan-2-ol, reaction mass of peracetic acid and peroxyoctanoic acid, vinegar, 5-chloro-2-(4-chlorphenoxy)phenol ('DCPP'), and formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) ('RP 1:1'). However, according to the analysis of the information collected, none of those active substances could be a suitable alternative for RP 3:2 for the examined use due to lack of efficacy or technical compatibility issues or hazard issues. No non-chemical alternatives were identified for the examined use of RP 3:2 in biocidal products of product-type 2. Disinfection of metal working systems is needed for the correct operation of these systems due to the possible spoilage of equipment (vessels, tubes, filters) and subsequent contamination of metal working fluids. There is also a greater risk to metalworkers due to the possibility of pathogens contaminating end-use fluids and equipment.

(17) RP 3:2 was assessed for the use in biocidal products of product-type 6 for the preservation of fuels, handled by industrial or professional users. Several active substances were investigated as potential alternatives to RP 3:2 for such use: 1,2-benzisothiazolin-3-one ('BIT'), 2-bromo-2-(bromomethyl)pentanedinitrile ('DBDCB'), 2,2-dibromo-2-cyanoacetamide ('DBNPA'), 2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol ('HHT'), 3-iodo-2-propynylbutylcarbamate ('IPBC'), 5-Chloro-2-methyl-2H-isothiazol-3-one ('CIT'), biphenyl-2-ol, chlorocresol, glutaraldehyde, hydrogen peroxide, L-(+)-lactic acid, MBIT, mixture of CMIT/MIT, N-(trichloromethylthio)phthalimide ('Folpet'), peracetic acid, sodium benzoate, tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione ('TMAD'), and RP 1:1. However, according to the analysis of the information collected none of the above active substances could be a suitable alternative for RP 3:2 for the examined use due to lack of efficacy or technical compatibility issues or hazard issues. No non-chemical alternatives were identified for the examined use of RP 3:2 in biocidal products of product-type 6. Compared to RP 1:1, RP 3:2 is considered a more suitable active substance for that particular use since fuel is preserved with as less as possible water content; thus, the use of RP 1:1 for fuel preservation would be counter-productive. Preservation of fuels is needed for the correct operation of engines, for example, in trains, truck and bus fleets, shipping and security of installations, for example in power generators at critical utilities such as hospitals and nuclear plants.

(18) RP 3:2 was assessed for the use in biocidal products of product-type 11 for the preservation of liquid cooling and processing systems, only in closed systems and handled by industrial or professional users. Several active substances were investigated as potential alternatives to RP 3:2 for such use: 2-methyl-2H-isothiazol-3-one ('MIT'), BIT, DBNPA, glutaraldehyde, HHT, mixture of CMIT/MIT, peracetic acid, polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1600 and a mean polydispersity (PDI) of 1.8 ('PHMB'), ozone generated from oxygen, tetrakis(hydroxymethyl)phosphonium sulphate (2:1) ('THPS'), TMAD, and RP 1:1. However, according to the analysis of the information collected none of the above active substances could be a suitable alternative for RP 3:2 for the examined use due to technical compatibility issues or hazard issues. No non-chemical alternatives were identified for the examined use of RP 3:2 in biocidal products of product-type 11. Due to possible corrosion and biofouling, preservation of liquid cooling and processing systems in closed systems is needed for their correct operations and to avoid environmental pollution, for example due to break of pipelines due to corrosion.

(19) RP 3:2 was assessed for the use in biocidal products of product-type 12 for the prevention or control of slime growth on materials, equipment and structures in offshore oil industry installations in contact with drilling muds, handled by industrial and professional users. Several active substances were investigated as potential alternatives to RP 3:2 for such use: acrolein, DBNPA, glutaraldehyde, HHT, MIT, mixture of CMIT/MIT, peracetic acid, THPS, and TMAD. However, according to the analysis of the information collected none of the above active substances could be a suitable alternative for RP 3:2 for the examined use due to technical compatibility issues or hazard issues. No non-chemical alternatives were identified for the examined use of RP 3:2 in biocidal products of product-type 12. Due to possible spoilage, prevention or control of slime growth on materials, equipment and structures in offshore oil industry installations in contact with drilling muds is needed for the correct operation of those systems, and consequently, for the security of the workers in those installations.

(20) RP 3:2 was assessed for the use in biocidal products of product-type 13 for the preservation of metal working or cutting fluids, handled by industrial or professional users. Several active substances were investigated as potential alternatives to RP 3:2 for such use: BIT, biphenyl-2-ol, chlorocresol, DBNPA, diamine, HHT, MBIT, MIT, IPBC, mixture of CMIT/MIT, phenoxyethanol, TMAD, and RP 1:1. However, according to the analysis of the information collected none of the above active substances could be a suitable alternative for RP 3:2 for the examined use due to lack of efficacy or technical compatibility issues or hazard issues. No non-chemical alternatives were identified for the examined use of RP 3:2 in biocidal products of product-type 13. Due to possible spoilage, preservation of metal working or cutting fluids is needed for the correct operation of those systems and availability of products to downstream users. Without proper preservation, there is also a greater risk to metalworkers due to the possibility of pathogens contaminating end-use fluids.

(21) Therefore, the analysis of the information collected shows that the non-approval of RP 3:2 as an active substance for use in biocidal products of product-types 2, 6, 11, 12 and 13 would have a disproportionate negative impact on society in comparison to the risk to human health, animal health or the environment arising from the use of the substance as system cleaner formulation for metal working systems (biocidal products of product-type 2), for the preservation of fuels (biocidal products of product-type 6), for the preservation of liquid cooling and processing systems, only in closed systems (biocidal products of product-type 11), for the prevention or control of slime growth on materials, equipment and structures in offshore oil industry installations in contact with drilling muds (biocidal products of product-type 12), and for the preservation of metal working or cutting fluids (biocidal products of product-type 13). The condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is thus satisfied for those uses.

(22) The Agency concluded that there are no unacceptable risks to human health and the environment from the use of biocidal products containing RP 3:2 for product-types 2, 6, 11, 12 and 13, when leaving aside the absence of conclusion on whether RP 3:2 has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms) on the basis of the criteria laid down in Delegated Regulation (EU) 2017/2100, and when risk mitigation measures are applied to limit the exposure of humans, animals and the environment to RP 3:2 as far as possible. However, since the Agency did not conclude whether RP 3:2 has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms), it was not possible to conclude on the acceptability of the risks concerning human health and the environment related to the use of the representative biocidal products containing RP 3:2.

(23) Therefore, it has ultimately not been demonstrated based on the data available in the applications that the representative biocidal products containing RP 3:2 for product-types 2, 6, 11, 12 and 13 may be expected not to have unacceptable effects themselves, or as a result of their residues, on human health and on the environment, and that they may be expected to satisfy the criteria set out in Article 19(1), point (b)(iii) and (iv), of Regulation (EU) No 528/2012.

(24) However, the factor set out in Article 19(5) of Regulation (EU) No 528/2012 should be taken into account when considering the conditions for approval set out in Article 4(1) of that Regulation. In accordance with Article 19(5) of that Regulation, and notwithstanding paragraphs 1 and 4 of that Article, a biocidal product may be authorised when the conditions laid down in paragraph 1, point (b)(iii) and (iv), of that Article are not fully met where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation, which is similar to the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012. Since the condition set out in Article 5(2), first subparagraph, point (c), of that Regulation is met for certain uses of RP 3:2 for each assessed product-type, the condition set out in Article 19(5) of that Regulation is also considered satisfied for the same uses. Therefore, the conditions set out in Article 4(1) of Regulation (EU) No 528/2012 in conjunction with the conditions set out in Article 5(2), first subparagraph, point (c), of that Regulation are considered satisfied.

(25) It is therefore appropriate to approve RP 3:2 for use in biocidal products of product-types 2, 6, 11, 12 and 13, subject to compliance with certain conditions.

(26) As RP 3:2 meets the exclusion criterion laid down in Article 5(1), point (a), of Regulation (EU) No 528/2012, the approval should be for a period not exceeding five years as set out in the second sentence of Article 4(1) of that Regulation.

(27) Pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the biocidal product assessment should include an evaluation as to whether the condition of Article 5(2), first subparagraph, point (c), of that Regulation is satisfied in the respective Member State territory. It should be provided that biocidal products of product-types 2, 6, 11, 12 and 13 containing RP 3:2 may only be authorised for use in Member States where the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied.

(28) Furthermore, pursuant to Article 4(3), points (d) and (g), and Article 58(2), of Regulation (EU) No 528/2012, to ensure a high level of safety for human health, animal health and the environment and to ensure equal treatment between treated articles manufactured in the Union and imported treated articles, the placing on the market of treated articles treated with or intentionally incorporating RP 3:2 should be subject to restrictions and conditions. In particular, in line with the conditions set out in the approval for the authorisation of biocidal products of product-types 2, 6, 11, 12 and 13 containing RP 3:2, the only treated articles treated with or incorporating RP 3:2 that should be allowed to be placed on the market are those where RP 3:2 has been used as system cleaner formulation for metal working systems, fuels, those where RP 3:2 has been used for the preservation of liquid cooling and processing systems - only in closed systems, those where RP 3:2 has been used for the prevention or control of slime growth on materials, equipment and structures in offshore oil industry installations in contact with drilling muds, and metal working or cutting fluids.

(29) 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.

(30) 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 released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) is approved as an active substance for use in biocidal products of product-types 2, 6, 11, 12 and 13, subject to the 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, 20 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

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 released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) ('RP 3:2')	IUPAC name: Reaction products of paraformaldehyde and2-hydroxypropylamine (ratio 3:2) EC No: not applicable CAS No: not applicable	The active substance has to be considered as substance of Unknown or Variable composition or Complex reaction products or Biological materials (UVCB). Therefore the minimum purity is 1 000 g/kg (100% by weight).	1 June 2027	31 May 2032	2	RP 3:2 is a candidate for substitution in accordance with Article 10(1), point (a), of Regulation (EU) No 528/2012. The authorisation of biocidal products using RP 3:2 as an active substance is subject to the following conditions: (a) the product assessment pays 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 assessment of the active substance; (b) pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment includes an evaluation as to whether the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (c) products may only be authorised for use in Member States where the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (d) the use of biocidal products containing RP 3:2 is subject to appropriate measures to ensure that exposure of humans, animals and the environment to RP 3:2 is minimised as far as possible; (e) products may only be authorised for industrial or professional use as system cleaner formulations for metal working systems; (f) the product assessment pays particular attention to: (i) professionals and industrial workers; (ii) sewage treatment plant, surface water and the terrestrial compartment; (g) Member States competent authorities shall specify in the summary of the biocidal product characteristics of a biocidal product containing RP 3:2 the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012.

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
						The placing on the market of treated articles treated with or incorporating RP 3:2 is subject to the following conditions: (a) only treated articles treated with or incorporating RP 3:2 may be placed on the market, where RP 3:2 has been used as system cleaner formulation for metal working systems; (b) the person responsible for the placing on the market of a treated article treated with or incorporating RP 3:2 shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.
					6	RP 3:2 is a candidate for substitution in accordance with Article 10(1), point (a), of Regulation (EU) No 528/2012. The authorisation of biocidal products using RP 3:2 as an active substance is subject to the following conditions: (a) the product assessment pays 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 assessment of the active substance; (b) pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment includes an evaluation as to whether the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (c) products may only be authorised for use in Member States where the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (d) the use of biocidal products containing RP 3:2 is subject to appropriate measures to ensure that exposure of humans, animals and the environment to RP 3:2 is minimised as far as possible; (e) products may only be authorised for the preservation of fuels, handled by industrial or professional users;

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						(f) the product assessment pays particular attention to: (i) professionals and industrial workers; (ii) sewage treatment plant, surface water and the terrestrial compartment; (g) Member States competent authorities specify in the summary of the biocidal product characteristics of a biocidal product containing RP 3:2 the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), second subparagraph, point (e), of Regulation (EU) No 528/2012. The placing on the market of treated articles treated with or incorporating RP 3:2 is subject to the following conditions: (a) only fuel treated with or incorporating RP 3:2 may be placed on the market, where RP 3:2 has been used as preservative of fuel; (b) the person responsible for the placing on the market of fuel treated with or incorporating RP 3:2 ensures that the label of that fuel provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.
					11	RP 3:2 is a candidate for substitution in accordance with Article 10(1), point (a), of Regulation (EU) No 528/2012. The authorisation of biocidal products using RP 3:2 as an active substance is subject to the following conditions: (a) the product assessment pays 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 assessment of the active substance; (b) pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment includes an evaluation as to whether the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied;

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
						(c) products may only be authorised for use in Member States where the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (d) the use of biocidal products containing RP 3:2 is subject to appropriate measures to ensure that exposure of humans, animals and the environment to RP 3:2 is minimised as far as possible; (e) products may only be authorised for the preservation of liquid cooling and processing systems, only in closed systems, handled by industrial or professional users; (f) the product assessment pays particular attention to: (i) professionals and industrial workers; (ii) sewage treatment plant, surface water and the terrestrial compartment; (g) Member States competent authorities shall specify in the summary of the biocidal product characteristics of a biocidal product containing RP 3:2 the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012. The placing on the market of treated articles treated with or incorporating RP 3:2 is subject to the following conditions: (a) only treated articles treated with or incorporating RP 3:2 may be placed on the market, where RP 3:2 has been used for the preservation of liquid cooling and processing systems, only in closed systems; (b) the person responsible for the placing on the market of a treated article treated with or incorporating RP 3:2 shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.
					12	RP 3:2 is a candidate for substitution in accordance with Article 10(1), point (a), of Regulation (EU) No 528/2012. The authorisation of biocidal products using RP 3:2 as an active substance is subject to the following conditions: (a) the product assessment pays 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 assessment of the active substance;

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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
						(b) pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment includes an evaluation as to whether the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (c) products may only be authorised for use in Member States where the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (d) the use of biocidal products containing RP 3:2 is subject to appropriate measures to ensure that exposure of humans, animals and the environment to RP 3:2 is minimised as far as possible; (e) products may only be authorised for the prevention or control of slime growth on materials, equipment and structures in offshore oil industry installations in contact with drilling muds, handled by industrial or professional users; (f) the product assessment pays particular attention to: (i) professionals and industrial workers; (ii) sea water; (g) Member States competent authorities shall specify in the summary of the biocidal product characteristics of a biocidal product containing RP 3:2 the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012. The placing on the market of treated articles treated with or incorporating RP 3:2 is subject to the following conditions: (a) only treated articles treated with or incorporating RP 3:2 may be placed on the market, where RP 3:2 has been used for the prevention or control of slime growth on materials, equipment and structures in offshore oil industry installations in contact with drilling muds;

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
						(b) the person responsible for the placing on the market of a treated article treated with or incorporating RP 3:2 shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.
					13	RP 3:2 is a candidate for substitution in accordance with Article 10(1), point (a), of Regulation (EU) No 528/2012. The authorisation of biocidal products using RP 3:2 as an active substance is subject to the following conditions: (a) the product assessment pays 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 assessment of the active substance; (b) pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment includes an evaluation as to whether the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (c) products may only be authorised for use in Member States where the condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is satisfied; (d) the use of biocidal products containing RP 3:2 is subject to appropriate measures to ensure that exposure of humans, animals and the environment to RP 3:2 is minimised as far as possible; (e) products may only be authorised for the preservation of metal working or cutting fluids, handled by industrial or professional users; (f) the product assessment pays particular attention to: (i) professionals and industrial workers; (ii) sewage treatment plant, surface water and the terrestrial compartment;

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
						(g) Member States competent authorities specify in the summary of the biocidal product characteristics of a biocidal product containing RP 3:2 the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), second subparagraph, point (e), of Regulation (EU) No 528/2012. The placing on the market of treated articles treated with or incorporating RP 3:2 is subject to the following conditions: (a) only metal working or cutting fluids treated with or incorporating RP 3:2 may be placed on the market; (b) the person responsible for the placing on the market of a treated article treated with or incorporating RP 3:2 ensures that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product made available on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.