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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;

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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
						(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.

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