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of 17 March 2026

approving 2,2-Dibromo-2-cyanoacetamide (DBNPA) as an existing active substance for use in biocidal products of product-type 11 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 2,2-Dibromo-2-cyanoacetamide ('DBNPA') (EC No: 233-539-7, CAS No: 10222-01-2) for product-type 11.

(2) DBNPA has been evaluated for use in biocidal products of product-type 11 (preservatives for liquid-cooling and processing systems), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which corresponds to product-type 11 (preservatives for liquid-cooling and processing systems), as described in Annex V to Regulation (EU) No 528/2012.

(3) Denmark 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 8 March 2024.

(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 opinion of the Agency on 26 November 2024 ([4]), having regard to the conclusions of the evaluating competent authority.

(5) According to the opinion of the Agency, DBNPA is considered as having endocrine-disrupting properties that may cause adverse effects in humans, and therefore meets the exclusion criterion set out in Article 5(1), point (d), of Regulation (EU) No 528/2012, and thus it is also a candidate for substitution in accordance with Article 10(1), point (a), of that Regulation. Moreover, DBNPA is considered as having endocrine-disrupting properties that may cause adverse effects in non-target organisms, and therefore it is also a candidate for substitution in accordance with Article 10(1), point (e), of that Regulation.

([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 2,2-Dibromo-2-cyanoacetamide (DBNPA); Product-type: 11; ECHA/BPC/448/2024, adopted on 26 November 2024.

(6) 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.

(7) From 27 June 2024 to 26 August 2024, the Agency carried out a third parties consultation concerning information on potential available substitutes in accordance with Article 10(3) of Regulation (EU) No 528/2012, and in order to gather information as to whether the conditions set out in Article 5(2), first subparagraph, of that Regulation were satisfied.

(8) In its opinion, the Agency concluded that biocidal products of product-type 11 containing DBNPA may be expected to satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that certain conditions concerning their use are complied with. In addition, the Agency concluded that at least one of the conditions set out in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is met for specific uses.

(9) The opinion of the Agency and the contributions to the third parties consultation have been discussed with Member State representatives in the Standing Committee on Biocidal Products. Member State 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.

(10) The analysis of all data collected from the application, the public consultation, the opinion of the Agency and the views expressed by Member States indicates that DBNPA is currently needed in all Member States for certain uses due to the absence of sufficient and suitable alternatives.

(11) DBNPA is currently needed for short-term preservation (preservation up to 14 days) of liquids used in closed recirculating cooling water systems by industrial or professional users. 96 active substances were examined as potential alternatives to DBNPA for that use. Among them, oxidizers are not technically compatible with such use due to their extensive corrosivity and non-compatibility with water treatment additives. Non-oxidizers active substances are either too slow-acting or incompatible with water treatment additives or they cannot provide sufficient curative action as that of DBNPA. Therefore, no suitable chemical alternatives could be identified to the use of DBNPA for short-term preservation of liquids used in closed recirculating cooling water systems.

(12) DBNPA is currently needed for short-term preservation of liquids used in open cooling water systems by industrial or professional users. The treatment of open cooling water systems is of special concern due to the risk of proliferation of the bacteria *Legionella* spp. 96 active substances were examined as potential alternatives to DBNPA for that use. Among them, oxidizers exhibit a greater risk of corrosivity and they are non-compatible with water treatment additives. Non-oxidizers active substances fail to decrease the level of bacteria rapidly enough, in particular to avoid *Legionella* proliferation. Therefore, no suitable chemical alternatives could be identified to the use of DBNPA for short-term preservation of liquids used in open cooling water systems.

(13) Non-chemical alternative methods (ultra violet radiation, electrolytic treatment, pulsed power, various types of membrane filtration, media filtration, active carbon filtration, thermal treatment, cavitation, gamma irradiation) for the short-term preservation of liquids used in closed recirculating cooling water systems and of liquids used in open cooling water systems can be applied as spot treatments. However, non-chemical alternative methods cannot reach the fast-acting properties of DBNPA. The Agency concluded that non-chemical alternative methods for the examined uses should be recognized as a supplement but not as a total replacement for DBNPA. Member State representatives in the Standing Committee on Biocidal Products agreed with this conclusion.

(14) The analysis of the information collected shows that a non-approval of DBNPA as an active substance for use in biocidal products of product-type 11 for short-term preservation of liquids used in open cooling water systems would result in an increased number of Legionellosis cases and potential fatalities in the absence of suitable alternatives to DBNPA. Since Legionnaire's Disease is considered as a serious danger to human health, the condition set out in Article 5(2), first subparagraph, point (b), of Regulation (EU) No 528/2012 is thus satisfied for this use of DBNPA.

(15) In addition, a non-approval of DBNPA as an active substance for use in biocidal products of product-type 11 for short-term preservation of liquids used in closed recirculating cooling water systems and of liquids used in open cooling water systems would result in equipment damage, increased waste and enhanced need for cleaning and repairs. In the absence of suitable alternatives to DBNPA for those uses and considering that no unacceptable risks have been identified to human health, animal health or the environment from the use assessed, a non-approval of DBNPA as an active substance for use in biocidal products of product-type 11 would have a disproportionate negative impact on society in comparison to the risks to human health, animal health or the environment arising from the use of the substance for short-term preservation of liquids used in closed recirculating cooling water systems, and for short-term preservation of liquids used in open cooling water systems. The condition set out in Article 5(2), first subparagraph, point (c), of Regulation (EU) No 528/2012 is thus satisfied for those uses.

(16) 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 (b), of that Regulation for the use of DBNPA for short-term preservation of liquids used in open cooling water systems, and in Article 5(2), first subparagraph, point (c), of that Regulation for the use of DBNPA for short-term preservation of liquids used in closed recirculating cooling water systems and of liquids used in open cooling water systems, are considered to be satisfied.

(17) It is therefore appropriate to approve DBNPA for use in biocidal products of product-type 11, subject to compliance with certain conditions.

(18) As DBNPA meets the exclusion criterion laid down in Article 5(1), point (d), 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.

(19) 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 conditions of Article 5(2), first subparagraph, points (b) or (c), of that Regulation are satisfied in the respective Member State territory. It should be provided that biocidal products of product-type 11 containing DBNPA may only be authorised for use in Member States where the conditions set out in Article 5(2), first subparagraph, points (b) or (c), of Regulation (EU) No 528/2012 are satisfied.

(20) Since biocidal products of product-type 11 containing DBNPA may only be authorised for short-term preservation of liquids used in closed recirculating cooling water systems and of liquids used in open cooling water systems, it is not expected that there can be treated articles treated with or incorporating DBNPA placed on the EU market which can be associated with these particular uses. Therefore, the placing on the market of treated articles treated with or incorporating DBNPA for product-type 11 should not be allowed.

(21) 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.

(22) 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

2,2-Dibromo-2-cyanoacetamide (DBNPA) is approved as an active substance for use in biocidal products of product-type 11, 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, 17 March 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
DBNPA	IUPAC name: 2,2-Dibromo-2-cyanoacetamide EC No: 233-539-7 CAS No: 10222-01-2	Minimum purity of the active substance evaluated: 98,0 %	1 July 2027	30 June 2032	11	2,2-Dibromo-2-cyanoacetamide ('DBNPA') is a candidate for substitution in accordance with Article 10(1), points (a) and (e), of Regulation (EU) No 528/2012. The authorisation of biocidal products using DBNPA 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 conditions set out in Article 5(2), first subparagraph, points (b) or (c), of Regulation (EU) No 528/2012 are satisfied; (c) products may only be authorised for use in Member States where the conditions set out in Article 5(2), first subparagraph, points (b) or (c), of Regulation (EU) No 528/2012 are satisfied; (d) products may only be authorised for the short-term preservation (preservation up to 14 days) by industrial or professional users of: (i) liquids used in closed recirculating cooling water systems; (ii) liquids used in open cooling water systems; (e) the product assessment pays particular attention to industrial or professional users. Treated articles treated with or incorporating DBNPA are not allowed to be placed on the market.

[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.