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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving 2,2-Dibromo-2-cyanoacetamide (DBNPA) as an existing active substance for use in biocidal products of product-type 6 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

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(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 6.

(2) DBNPA has been evaluated for use in biocidal products of product-type 6 (in-can preservatives), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council[3], which corresponds to product-type 6 (preservatives for products during storage), 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 16 December 2022. 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

[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).

Committee adopted the opinion of the Agency on 12 September 2023[4], having regard to the conclusions of the evaluating competent authority.

(5) In that opinion, the Agency concluded that biocidal products of product-type 6 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.

(6) 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 it is considered as having endocrine-disrupting properties that may cause adverse effects in non-target organisms, and therefore it is a candidate for substitution in accordance with Article 10(1), point (e), of that Regulation.

(7) 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.

(8) From 3 November 2023 to 4 January 2024, 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.

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

(10) The analysis of all data collected from the application dossier, the public consultation and the views expressed by Member States indicates that DBNPA is currently needed in all Member States for certain uses.

(11) DBNPA is needed for short-term preservation (preservation only during the manufacturing process) of mineral slurries and other raw material (e.g., starch, fillers, binders, defoamers and pigments) for use in paper production by industrial users. Several active substances were investigated as potential alternatives to DBNPA for such use: 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride, 2-Phenoxyethanol, (benzyloxy)methanol, 2-butyl-benzo[d]isothiazol-3-one ('BBIT'), benzyl alcohol, biphenyl-2-ol, 1,2-benzisothiazol-3(2H)-one ('BIT'), bronopol, chlorocresol, 5-chloro-2-methyl-2H-isothiazol-3-one ('CIT'), mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) ('mixture of CMIT/MIT'), 2-bromo-2-(bromomethyl)pentanedinitrile ('DBDCB'), didecyldimethylammonium chloride ('DDAC (C8-10)'), didecyldimethylammonium chloride ('DDAC'), 1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione ('DMDMH'), dodecylguanidine monohydrochloride, 2,2′-dithiobis[N-methylbenzamide] ('DTBMA'), (ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde ('EGForm')), ethanol, formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine ('RP

[4] Biocidal Products Committee Opinion on the application for approval of the active substance 2,2-Dibromo-2-cyanoacetamide (DBNPA); Product-type: 6; ECHA/BPC/388/2023, adopted on 12 September 2023.

1:1'), formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine ('RP 3:2'), formic acid, glutaral ('glutaraldehyde'), hexa-2,4-dienoic acid ('sorbic acid'), 2,2′,2″-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol ('HHT'), hydrogen peroxide, 3-iodo-2-propynylbutylcarbamate ('IPBC'), L-(+)-lactic acid, MBIT, 2-methyl-2H-isothiazol-3-one ('MIT'), monochloramine generated from ammonium carbamate and a chlorine source, N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine ('diamine'), N-(trichloromethylthio)phthalimide ('Folpet'), 2-octyl-2H-isothiazol-3-one ('OIT'), p-[diiodomethyl]sulphonyl]toluene, peracetic acid, potassium sorbate, pyridine-2-thiol 1-oxide sodium salt ('sodium pyrithione'), pyrithione zinc ('zinc pyrithione'), silver chloride, sulfur dioxide released from sodium metabisulfite, tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5(1H,3H)-dione ('TMAD'), tetrakis(hydroxymethyl)phosphonium sulphate (2:1) ('THPS'). However, according to the analysis of the information collected, none of those active substances could be a suitable substitute of DBNPA for the examined use due to their use for long-term preservation, technical compatibility issues or hazard issues.

(12) DBNPA is needed for short-term preservation of paints and coatings (including pigments, varnishes and inks) by industrial users. The same active substances as those listed in recital 11 were investigated as potential alternatives to DBNPA for such use. However, according to the analysis of the information collected, none of those active substances could be a suitable substitute of DBNPA for such use due to their use for long-term preservation, technical compatibility issues or hazard issues.

(13) DBNPA is needed for short-term preservation of polymer dispersions (e.g., adhesives, non-woven fabrics, carpet-making compounds, premix plasters, wall fillers) by industrial users. The same active substances as those listed in recital 11 were investigated as potential alternatives to DBNPA for such use. However, according to the analysis of the information collected, none of those active substances could be a suitable substitute of DBNPA for such use due to their use for long-term preservation, technical compatibility issues or hazard issues.

(14) Alternative methods to the use of biocidal products for the short-term preservation of mineral slurries and other raw material for use in paper production are currently under research (thermal or irradiation techniques) but they have not yet reached a sufficient technology readiness level and can therefore not currently be considered as suitable alternatives to the use of DBNPA. Concerning the short-term preservation of paints and coatings and the short-term preservation of polymer dispersions, non-chemical alternative methods could present technical compatibility issues (e.g., corrosion, destabilization, limited efficacy), economical burdens (energy intense processes) and safety issues (e.g., risk of burning for the operators, gamma radiation).

(15) Therefore, the analysis of the information collected shows that the non-approval of DBNPA as an active substance for use in biocidal products of product-type 6 would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance for short-term preservation of mineral slurries and of other raw material for use in paper production, for short-term preservation of paints and coatings, and for short-term preservation of polymer dispersions. The condition set out in Article 5(2), 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), point (c), of that Regulation, are considered to be satisfied.

(17) It is therefore appropriate to approve DBNPA for use in biocidal products of product-type 6, 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 5 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 condition of Article 5(2), point (c), of that Regulation is satisfied in the respective Member State territory. It should be provided that biocidal products of product-type 6 containing DBNPA may only be authorised for use in Member States where the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied.

(20) 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 DBNPA 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-type 6 containing DBNPA, the only treated articles treated with or incorporating DBNPA that may be placed on the market are mineral slurries and other raw material used in paper production, paints and coatings and polymer dispersions, while the DBNPA has been used in those treated articles only to ensure their short-term preservation.

(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 6, 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,

For the Commission
The President
Ursula VON DER LEYEN