

EUROPEAN COMMISSION

> Brussels, XXX PLAN/2103/2024 ANNEX (POOL/E4/2024/2103/2103-EN ANNEX.docx) [...](2024) XXX draft

ANNEX

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

approving 2,2-Dibromo-2-cyanoacetamide (DBNPA) as an 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

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	NumbersIUPAC name:2,2-Dibromo-2- cyanoacetamideEC No: 233-539-7CAS No: 10222-01-2	of the active substance ¹ Minimum purity of the active substance evaluated: 98.0 %	1 August 2026	approval 31 July 2031	6 6	 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 condition set out in Article 5(2), 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), point (c), of Regulation (EU) No 528/2012 is satisfied; (d) products may only be authorised for the short-term preservation (preservation only during the
						 manufacturing process) by industrial users of: i) mineral slurries and of other raw material (e.g., starch, fillers, binders, defoamers and pigments) used in paper production; ii) paints and coatings (including pigments,

ANNEX

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.

			varnishes and inks);
			 iii) polymer dispersions (e.g., adhesives, non-woven fabrics, carpet making compounds, premix plasters, wall fillers);
		((The j	 (e) the product assessment pays particular attention to industrial users; (f) for products that may lead to residues in food or feed, Member States' competent authorities assess whether new maximum residue levels or maximum residue limits need to be set or the existing maximum residue levels or maximum residue limits need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council² or Regulation (EC) No 396/2005 of the European Parliament and of the Council³, and any appropriate risk mitigation measures are taken to ensure that such maximum residue levels or maximum residue limits are not exceeded; (g) Member States' competent authorities specify in the summary of the biocidal product characteristics of a biocidal product containing DBNPA 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. (a) treated articles treated with or intentionally
			incorporating DBNPA may be placed on the market

² Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11, ELI: http://data.europa.eu/eli/reg/2009/470/oj).

2

³ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: <u>http://data.europa.eu/eli/reg/2005/396/oj</u>).

		only for use as: i) mineral slurries and other raw material (e.g., starch, fillers, binders, defoamers and pigments) used in paper production;
		ii) paints and coatings (including pigments, varnishes and inks);
		iii) polymer dispersions (e.g., adhesives, non-woven fabrics, carpet making compounds, premix plasters, wall fillers);
		(b) DBNPA has been used in the treated articles referred in point (a) only to ensure a short-term preservation;
		 (c) the person responsible for the placing on the market of a treated article treated with or incorporating DBNPA ensures that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012.