Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

2,2-Dibromo-2-cyanoacetamide (DBNPA)

Product type: 6

ECHA/BPC/388/2023

Adopted

12 September 2023

Opinion of the Biocidal Products Committee

on the application for approval of the active substance 2,2-Dibromo-2-cyanoacetamide (DBNPA) for product type 6

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 6 of the following active substance:

Common name:	**DBNPA**
Chemical name:	**2,2-Dibromo-2-cyanoacetamide**
EC No.:	**233-539-7**
CAS No.:	**10222-01-2**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of the BPC opinion

Following the submission of an application by Microbial Control (Switzerland) GmbH and ICL Europe on 29 July 2007, the evaluating Competent Authority Denmark submitted an assessment report and the conclusions of its evaluation to ECHA on 16 December 2022. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-48) and its Working Groups (WG-II-2023). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at *https://echa.europa.eu/da/potential-candidates-for-substitution-previous-consultations* on 31 January 2023 in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 25 March 2023.

Adoption of the BPC opinion

Rapporteur: Denmark

The BPC opinion on the application for approval of the active substance DBNPA in product type 6 was adopted on 12 September 2023.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR. 32 comments were received from interested third parties during the public consultation in accordance with Article 10(3) of BPR.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority positions including their grounds are published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

DBNPA fulfils the exclusion criteria set in Article 5(1)(d) of Regulation (EU) No 528/2012 on the basis of the criteria defined in Regulation (EU) No 2017/2100. The overall conclusion of the BPC is that DBNPA should normally not be approved unless one of the conditions for derogation set in Article 5(2) of Regulation (EU) No 528/2012 is applicable. The process related to the demonstration of whether the conditions for derogation set in Article 5(2) are met, is not in the remit of the BPC[1].

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of DBNPA in product type 6. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are required and available for the relevant matrices soil, air, water, blood and tissue, milk and beef.

A harmonised classification according to Regulation (EC) No 1272/2008 is available for DBNPA (ATP17). A CLH dossier was submitted in 2018 and was evaluated by the Risk Assessment Committee at RAC-49. The classification and labelling for DBNPA according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 3 Acute Tox. 2 Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS05, GHS06, GHS08, GHS09
Signal Word	Danger
Hazard Statement Codes	H301, H330, H315, H318, H317, H372 (respiratory tract) (inhalation), H410

[1] See document: Further guidance on the procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2) (CA-Nov14-Doc.4.5-Final).

Specific Concentration limits, M-Factors	Oral ATE = 118 mg/kg bw Inhalation ATE = 0.24 mg/L (dust/mist) M = 1 (acute and chronic)

b) Intended use, target species and effectiveness

DBNPA inactivates enzymes by converting functional –SH groups to the oxidised S-S form. This reaction irreversibly disrupts the function of cell-surface components, interrupting transport across cell membranes, and inhibiting key biological functions. It is a fast-acting biocide and exerts its biocidal action directly after its application via bromine. DBNPA in PT6 is intended for use as short-term preservation of mineral slurries for use in paper production. Based on the submitted efficacy studies, DBNPA is sufficiently effective for short-term preservation of mineral slurry for up to 7 days at a concentration of 50 ppm. According to TAB (Technical Agreements for Biocides (TAB), Efficacy (EFF), November 2022) entry 17, tier 2 testing can be omitted if ageing is demonstrated not relevant for the specific use, e.g. a PT 6 product would not require tier 2 tests with an aged matrix if the matrix is only preserved for periods that are covered by the biological testing (typically preservation for 1-6 weeks). In this case, preservation of the treated matrix is only claimed for up to 7 days and consequently Tier 2 testing (ageing studies) are not relevant for the representative use as submitted Tier 1 testing covers the short-term preservation. The preservation of and use of the mineral slurry takes place in an industrial setting and only industrial workers may come into contact with DBNPA.

DBNPA is a fast-acting biocide and is exerting its biocidal action directly after its application via bromine, which inactivates enzymes by converting functional –SH groups to the oxidised S-S form. This reaction irreversibly disrupts the function of cell-surface components, interrupting transport across cell membranes, and inhibiting key biological functions.

The data on DBNPA and the representative biocidal product have demonstrated sufficient efficacy against the target species bacteria. The risk of the development of resistance to the active substance is considered to be low due to the mode of action for the active substance which affects multiple cellular targets.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

DBNPA is well-absorbed by oral administration, extensively metabolised, and rapidly excreted. It is harmful by the oral and inhalation route following acute exposure but is of low toxicity by the acute dermal route. It is both a skin irritant, skin sensitizer and causes eye damage.

In short term studies hemorrhage in the lumen of the colon was identified as the most critical effect. Dyspnoea[2] and subsequent death was observed in gavages studies due to a bolus effect of the test material.

DBNPA is not a mutagenic, carcinogenic or reproductive toxicant. There is no evidence that it is neurotoxic or immunotoxic.

DBNPA is considered to have endocrine-disrupting properties with respect to humans as it meets the criteria set out in section A of Regulation (EU) No 2017/2100. The conclusion is based on the observed adverse effects in the thyroid gland in studies on rats and dogs

[2] Difficult or labored breathing; shortness of breath.

combined with data obtained from a literature search conducted on the metabolite/degradation product bromide. Studies performed with bromide show clear evidence of its thyroid-disturbing effects. Bromide may substitute iodide in the sodium/iodide symporter of the thyroid, thus creating a relative iodide insufficiency for further synthesis of thyroid hormones. This link between the observed adverse effects in the thyroid and endocrine activity is relevant for humans and non-target animals.

Evaluation of risk for human health from the endocrine disruptive properties of DBNPA

On 8 July 2020 the European Commission submitted to the ECHA a mandate according to article 75(1)g of the Biocidal Products Regulation (EU) 528/2012 (BPR).

The mandate[3] requested the opinion of ECHA on the risks associated with the endocrine disrupting properties of DBNPA from the use in PT4. Specific for human health, the mandate requested to clarify the level of risks for humans by considering the acceptable daily intake for bromide already derived by WHO and EMA for bromide salts, taking into account the levels of bromide considered essential for human life, assessing the contribution of bromide from use of DBNPA in PT4 to the average daily exposure from other sources and finally provide an opinion on the risk from use of DBNPA in PT4 including these considerations.

The BPC Opinion[4] was adopted on 30 November 2021.

From the information obtained and evaluated for this mandate, it was concluded[5], that bromide is natural occurring and essential for human life. Therefore, a threshold of adversity must exist for the thyroid-disturbing effects of bromide. Below this threshold of toxicity the biological response in the human body will be beneficial (or adaptive). However, a quantifiable threshold level cannot be set due to multiple uncertainties, cf. the BPC Opinion. In addition, it was concluded the already established acceptable daily intake reference values derived by WHO and EMA cannot be used as safe reference values against the thyroid-disturbing effects. In search of data on relevant bromide exposure, European Union reports on pesticide residues were consulted. Within these, EFSA evaluates the chronic exposure to bromide from used consumed by the European population.

The exposure to DBNPA-derived bromide from use in PT6 has been evaluated against the reference values from the 2019 European Union report on pesticide residues[6]. Based on this assessment, no endocrine disruptive effects in humans are expected from exposure to bromide from the use in PT6, as this contribution of bromide is within the natural range of what the European population is already exposed to through the diet. Therefore, no unacceptable risks of endocrine disrupting effects are associated with exposure to DBNPA-derived bromide from use in PT 6.

The table below summarises the exposure scenarios assessed.

[3] Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR "Evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product type 4"
[4] ECHA/BPC/300/2021
[5] https://echa.europa.eu/documents/10162/c984aeda-ac67-8be2-57f3-43c797cf293d
[6] 2019 EU report on pesticide residues in food, EFSA Journal 2021;19(4):6491

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure[7] and description of scenario**	**Exposed group**	**Conclusion**
Formulation of representative product DBNPA and bromide	Primary exposure by dermal and inhalation route PPE: Chemically resistant gloves, coveralls and RPE	Industrial user	Acceptable with PPE/RPE
Short-term preservation of mineral slurry - Connecting/ disconnecting IBC to dosing system DBNPA and bromide	Primary exposure by dermal and inhalation route Connecting/disconnecting IBC (Intermediate Bulk Container) to automatic dosing system PPE: Chemically resistant gloves, coveralls	Industrial user	Acceptable with PPE
Short-term preservation of mineral slurry - Exposure to treated paper Bromide	Secondary exposure to metabolite (bromide) by oral route Dietary exposure via treated paper used for food packaging	General public	Acceptable

For industrial users, exposure from formulation of the 20% dilution is acceptable with PPE/RPE. The potential local effects of DBNPA and the potential endocrine disrupting effects of the metabolite bromide require the use of PPE/RPE, i.e. chemically resistant gloves, coated coverall, and face screen/goggles and self-breathing respiratory apparatus when formulating the 20% dilution in order to provide sufficient protection.

For industrial users handling the 20% dilution, exposure is acceptable with PPE. The potential local effects of DBNPA and the potential endocrine disrupting effects of the metabolite bromide require the use of PPE, i.e. chemically resistant gloves, coated coverall, and face screen/goggles when connecting the IBC to the automated system in order to provide sufficient protection.

For the general public no unacceptable risk was identified when exposed to the metabolite/degradation product bromide via paper used for food packaging, as this exposure is within the natural range of dietary intake of bromide, and therefore the exposure to DBNPA-derived bromide from PT6 would have no significant impact on the overall exposure.

Environment

According to its chemical properties, DBNPA can be degraded via two pathways; hydrolysis and nucleophilic reaction. For PT 6 nucleophilic reaction is the relevant pathway after DBNPA

[7] See document: Terminology primary and secondary exposure (available from https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/80f71044-fce2-43b3-a73c-e156effc9fcb/Terminology%20primary%20and%20secondary%20exposure.pdf)

comes into contact with sulphur containing reducing species ("nucleophiles"), light or organic material (e.g., proteins, bacteria, humus/fulvic acids, etc.). DBNPA will quickly be degraded to cyanoacetamide (CAM).

DBNPA is not readily biodegradable, but inherently biodegradable. A soil transformation study was provided, which determined the DT_{50} in soil to be 1.2 days (28.84 hours) at 12°C.

Exposure of the atmospheric compartment to DBNPA is considered not to raise a concern, as DBNPA has a very low vapour pressure, a low Henry's law constant and is additionally not used in a manner, which leads to direct release to the atmosphere.

There is no risk of bioaccumulation of DBNPA in aquatic organisms as indicated by the log POW and supported by the results of the bioconcentration study in fish.

The toxicity of DBNPA to aquatic organisms is well documented by acute and long-term studies.

The mixing and loading process takes place in completely closed systems. Thus, the environmental exposure during mixing and loading is considered to be negligible compared to the actual application of DBNPA. The representative product is to be used for short-term preservation of mineral slurries for use in paper production.

Acute aquatic toxicity studies/QSAR estimations clearly shows that CAM has a significantly lower toxicity to aquatic organisms, compared to DBNPA. CAM is shown to be readily biodegradable. Exposure of DBNPA-derived bromide has also been assessed.

Evaluation of risk for the environment from the endocrine disruptive properties of DBNPA

DBNPA has endocrine disrupting properties with respect to non-target organisms as it meets the criteria set out in section B of Regulation (EU) No 2017/2100. This conclusion is based on evidence from studies conducted on DBNPA in rats and studies conducted on bromide in rat, guppy and medaka in combination with additional information showing that the postulated Mode of Action affects amphibian metamorphosis, which is considered relevant at population level.

In relation to the mandate under PT4 mentioned in the human health section above, an assessment was made of the risk to the environment associated with the ED properties of DBNPA-derived bromide[8].

From the information obtained and evaluated for this mandate, it was concluded[9] that bromide is a naturally occurring substance in the environment, and therefore a threshold for the endocrine disrupting effects must be assumed. However, there is currently no scientific consensus how such a threshold might be established and there are several uncertainties to consider and therefore, it is not possible to quantify such a threshold at the moment.

The background concentrations of bromide in the aquatic environment shows a large variety and is influenced by natural factors (distance to the sea, geology, seasonal fluctuations) and anthropogenic sources (chemical industry, pharmaceutical industry, mining, waste incineration). From an available study, it was estimated that 2 % of the bromide load to a Swiss water body in 2016 could be attributed to a general biocides use (i.e. not DBNPA-specific). Although data is very limited, it is clear that concentrations of bromide are higher

[8] https://echa.europa.eu/documents/10162/c984aeda-ac67-8be2-57f3-43c797cf293d ECHA
[9] BPC/300/2021

in areas of industrial activity. Due to the many factors influencing the background concentration of bromide in the environment, a fixed value could not be established.

The exposure concentration of bromide to the aquatic environment following the PT6 use is 0.00588 mg/L and therefore considered within the range of natural background concentration, and the contribution of DBNPA-derived bromide from PT6 use would have no significant input on the exposure.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Use of mineral slurry treated with DBNPA. Release to waste water from "broke". DBNPA.	Direct exposure to STP via drains. Indirect exposure to surface water (including sediment) via STP effluent; to soil (including groundwater) via STP sludge application to land; and biota via surface water and soil. Assessed with and without degradation of DBNPA in the sewer system.	Acceptable
Use of mineral slurry treated with DBNPA. Release to waste water from "broke". CAM.	Based on 100% transformation of DBNPA to CAM in the influent of the STP. Direct exposure to STP via drains. Indirect exposure to surface water (including sediment) via STP effluent; to soil (including groundwater) via STP sludge application to land; and biota via surface water and soil. Assessed with and without degradation of CAM in the sewer system.	Acceptable
Use of mineral slurry treated with DBNPA. Release to waste water from "broke". Bromide.	Based on 100% transformation of DBNPA to bromide in the influent of the STP. Direct exposure to STP via drains. Indirect exposure to surface water via STP effluent.	Acceptable

The above results show that an acceptable risk was demonstrated for the assessment of the entire plant for all scenarios for DBNPA with respect to non-target organisms.

Overall conclusion

Without considering that DBPNA has endocrine-disrupting properties, the risk assessment performed using the usual methodology showed no unacceptable risks for DBNPA for humans and for the environment including the environmental relevant metabolite CAM.

DBNPA is however considered to have endocrine disrupting properties relevant for both humans and non-target organisms in the environment. There is currently no agreed guidance document available on how to perform a risk assessment of substances with endocrine disrupting properties. The risk assessment performed for DBNPA in PT6 is therefore based on the methodology proposed for evaluating the risks of the endocrine disrupting properties of DBNPA in PT4[10]. This methodology was agreed by the BPC at BPC-41 and is specific to DBNPA.

[10] https://echa.europa.eu/documents/10162/c984aeda-ac67-8be2-57f3-43c797cf293d

Although a threshold must exist for the ED effects of bromide for human health and the environment, it was not possible to quantify such a threshold.

Based on this assessment, no endocrine disruptive effects in humans are expected from exposure to bromide from the use in PT6, as this contribution of bromide is within the natural range of what the European population is already exposed to through the diet. Therefore, no unacceptable risks of endocrine disrupting effects are associated with exposure to DBNPA-derived bromide from use in PT 6.

The risk associated with the ED effects of bromide are considered to be acceptable for the non-target organisms in the environment, due to the natural variation of bromide, and anthropogenic sources of bromide from many other uses. The exposure from DBNPA derived bromide is within the range of these values. The data available is scarce but is considered adequate to reach this conclusion.

By-products may be formed as a consequence of specific uses of DBNPA. An assessment of the formation or risks of by-products was not performed at active substance approval level. Provided that guidance is available, at product authorisation stage, an assessment of the risks of by-products will have to be performed.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		**Conclusions**	
CMR properties	Carcinogenicity (C)	No classification required	DBNPA does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P or vP (DBNPA) Not P or vP (CAM)	DBNPA and CAM do not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB (DBNPA) Not B or vB (CAM)	
	Toxic (T)	T (DBNPA) Not T (CAM)	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	Yes	DBNPA fulfills Article 5(1)(d) and Article 10(1)(e)

Property		Conclusions	
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	Yes	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s)	No	
Respiratory sensitisation properties	DBNPA does not fulfil criterion (b) of Article 10(1). No classification required.		
Concerns linked to critical effects other than those related to endocrine disrupting properties	DBNPA does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	DBNPA does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

DBNPA meets the exclusion criteria laid down in Article 5(1)(d) of Regulation (EU) No 528/2012 due to its endocrine disrupting properties related to humans.

DBNPA meets the conditions laid down in Article 10(1)(a) of Regulation (EU) No 528/2012 due to its endocrine disrupting properties, which are relevant for non-target organisms and humans, and is therefore also considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[11], "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[12] and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment"[13] agreed at the 54th, 58th and 77th meeting, respectively of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion

[11] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc).
[12] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc).
[13] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

DBNPA does not fulfil the criteria for being a persistent organic pollutant (POP).

2.2.3. Identification of potential alternatives substances or technologies, including the results of the public consultation for potential candidates for substitution

As the condition of art. 5(1)(d) is met for DBNPA in PT 6, it also meets the condition of art. 10(1)(a). A public consultation on potential candidates for substitution was therefore launched between 31 January 2023 and 25 March 2023. 32 comments were received.

The inputs received compared DBNPA in PT6 to already approved substances and active substances still under review. Furthermore, inputs concerned both the use of DBNPA in PT6 as a preservative of mineral slurries, but also two additional uses (preservation of paints and coatings and preservation of polymer dispersions), which has not been evaluated by the eCA in the active substance approval assessment. In addition, efficacy has only been claimed and demonstrated for bacteria in mineral slurries, but several comments received in the consultation claimed that DBNPA has a broader spectrum of biocidal activity than other potential candidates for substitution. Considering that only bacteria has been claimed and only preservation of mineral slurries has been evaluated by the eCA, the identification of potential alternatives has to be based primarily on this use.

According to the submitted comments, there is no suitable alternative for DBNPA in PT6 for preservation of mineral slurries, paints and coatings and in polymer dispersions. A comprehensive comparision of the approved active substances to DBNPA can be found in table 2.4.2 in Annex I to the CAR, while a brief explanation is below.

11 active substances are approved for use in PT6. All 11 approved active substances have a longer contact time. Of these, two are only fungicidal (IPBC, Folpet). Two are not effective at the typical pH of mineral slurries (Folpet, L-(+)-lactic acid) and several have a high cost-to-treat at the effective application rate compared to DBNPA (DBDCB, Chlorocresol, MBIT, CMIT:MIT). One active substance has the same Mode of Action (DBDCB; activation of bromide) with similar systemic effects due to the bromide ion, although it has not been evaluated for its ED properties. One is already a candidate for substitution (Glutaral).

There are 25 other active substances still under review in PT6: (benzyloxy)methanol, (ethylenedioxy)dimethanol (Reaction products of ethylene glycol with paraformaldehyde (EGForm)), 1,3-bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione (DMDMH), 2,2′,2′′-(hexahydro-1,3,5-triazine-1,3,5- triyl)triethanol (HHT), 2,2′-dithiobis[N-methylbenzamide] (DTBMA), 2-butyl-benzo[d]isothiazol-3-one (BBIT), 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride, 2-methyl-2H-isothiazol-3-one (MIT), 2-octyl-2H-isothiazol-3-one (OIT), 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT), Benzyl Alcohol, Bronopol, Didecyldimethylammonium chloride (DDAC (C8-10)), Didecyldimethylammonium chloride(DDAC), Dodecylguanidine monohydrochloride, Ethanol, Hexa-2,4-dienoic acid (Sorbic acid), Monochloramine generated from ammonium carbamate and a chlorine source, N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine), 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), and Tetrakis(hydroxymethyl)phosphonium sulphate (2:1) (THPS). A comparison of these substances against DBNPA for the intended use(s) is available in annex I to the CAR (table

2.4.3) and is based on inputs from the public consultation on potential candidates for substitution and the applicant's input. As these substances are still under assessment under the BPR, it is not possible to determine whether they can be suitable alternatives for DBNPA in PT6. Four substances have been assessed but are awaiting the Commission Decision: 1,2-benzisothiazol-3(2H)-one (BIT), Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1), Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) and formic acid. BIT has a slow mode of action, high cost-to-treat and is ineffective against the typical contaminants in the mineral slurry. The formaldehyde-releaser active substances meet the exclusion criteria as they are classified as Carc 1B. Lastly, formic acid has limited performance at the pH of mineral slurry, high cost-to-treat and can influence the pH of the mineral slurry. Thus, none of these four active substances are suitable alternatives.

Also, other issues not related to the biocidal activity were raised e.g. discolouration of the preserved products (DBDCB, IPBC), low solubility in aqueous solutions leading to dispersion issues(IPBC, biphenyl-2-ol), odour issues (glutaral, chlorocresol, peracetic acid, oxidation of products (peroxides; H2O2, peracetic acid), issues with freezing (Glutaral, CMIT:MIT), storage safety concern due to explosion hazard (H2O2, peracetic acid), issues with foaming (H2O2), changing of properties by altering the pH value of the matrix (L-(+)-lactic acid), hydrolysis at the typical pH range (Folpet), highly sensitizing properties (isothiazolinones; CMIT:MIT, MBIT), slower degradation (CMIT:MIT, MBIT).

Several comments referred to the combined use of DBNPA with slower-acting active substances for long-term preservation, in which the use of the fast-acting DBNPA would lower the overall use of the other active substances, as the microbial load is thus considerably smaller. By not having DBNPA available, a much higher volume of other active substances would be needed.

Several non-chemical alternatives, like thermal or irradiation techniques, are under research, but have not yet reached a sufficient technology readiness level and are therefore not considered as suitable alternatives.

In conclusion, alternative active substances are available, but they cannot substitute DBNPA without decreasing performance severely. There is no other active substance available offering similarly short contact time at such low concentrations without affecting the preserved product. Short term preservation is critical in the performance of the overall preservation, as the use of short-term preservatives such as DBNPA lowers the overall load of long-term preservatives necessary to ensure sufficient preservation of the mineral slurry.

2.3. BPC opinion on the application for approval of the active substance DBNPA in product type 6

As the exclusion criteria are met, DBNPA should normally not be approved unless one of the conditions for derogation set in Article 5(2) of BPR is met.

DBNPA fulfils the criteria for having endocrine disrupting properties laid down in Article 5(1)(d) of Regulation (EU) No 528/2012 as defined in Regulation (EU) No 2017/2100. This implies that biocidal products containing DBNPA should not be used for the general public according to Article 19(4)(d) of Regulation (EU) No 528/2012 (see note "The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation" (CA-March18-Doc.7.3.b-final)).

If DBNPA is approved, the approval shall be subject to the following conditions:

1. Specification: minimum purity of the active substance evaluated: 98.0 %
2. Relevant impurities: dibromoacetonitrile (DBAN) 0.14 % w/w.
3. DBNPA is considered a candidate for substitution in accordance with Article 10(1)(a) and (e) of Regulation (EU) No 528/2012.
4. The authorisations of biocidal products are subject to the following condition(s):
    a. The product assessment shall pay 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 risk assessment of the active substance.
    b. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.
    c. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
        i. industrial users
    d. For products containing DBNPA that may lead to residues in food or feed, Member States shall verify the need to set new or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.
5. The placing on the market of treated articles is subject to the following condition(s):
    a. The person responsible for the placing on the market of a treated article treated with or incorporating DBNPA shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012. DBNPA gives rise to concern for human health and the environment, i.e. it is classified as Acute Tox 2, Skin Sens 1, STOT RE 1 and Aquatic Acute 1. DBNPA furthermore meets the exclusion criteria in Article 5(1) and substitution criteria in Article 10(1) in Regulation (EU) 528/2012.

2.4. Elements to be taken into account when authorising products

1. The active substance DBNPA is considered a candidate for substitution in accordance with Article 10(1)(a) and (e) of Regulation (EU) No 528/2012, and consequently a comparative assessment shall be carried out as part of the evaluation of an application for national authorisation.
2. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

a. If an unacceptable risk is identified for industrial users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

b. In line with Article 5(2) of Regulation (EU) No 528/2012, the use of a biocidal product containing DBNPA shall be subject to appropriate measures to ensure that exposure of humans, animals and the environment is minimised as far as possible taking into account that it is considered to have endocrine disrupting properties.

c. Where relevant, a dietary risk assessment will need to be performed at product authorisation.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance DBNPA.

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