Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

DBDCB

Product type: 6

ECHA/BPC/075/2015

Adopted

8 December 2015

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance DBDCB 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:	**DBDCB**
Chemical name(s):	**2-bromo-2-(bromomethyl)pentanedinitrile**
EC No.:	**252-681-0**
CAS No.:	**35691-65-7**
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 BPC opinions

Following the submission of an application by Lanxess Deutschland GmbH on 31st July 2007 the evaluating Competent Authority the Czech Republic submitted an assessment report and the conclusions of its evaluation to the Commission on 21st January 2009. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups and the Commission via the Biocides Technical Meetings (TM IV 2010 and ENV-WG III 2015). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Czech Republic

The BPC opinion on the approval of the active substance DBDCB in product type 6 was adopted on 8 December 2015.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that DBDCB in product type 6 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

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 DBDCB (1,2-Dibromo-2,4-dicyanobutane) in product type 6. DBDCB contains several highly electrophilic centres making the compound strongly reactive with nucleophilic groups in the microbial cell. The consequence is a broad activity spectrum covering bacteria, yeasts, fungi and algae. No time delay is expected.

The physico-chemical properties of the active substance and the representative 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 determination of the active substance as manufactured and for the analysis of impurities. Validated analytical methods are available for the technical active substance and the active substance in aqeuous solutions.

No harmonised classification for DBDCB is available according to regulation (EC) No 1272/2008. A CLH dossier will be submitted by the evaluating CA within one month after the BPC meeting.

The proposed classification and labelling for DBDCB according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4, H302 Acute Tox. 2, H330 Skin Sens. 1, H317 Eye Dam. 1, H318 Aquatic Chronic 2, H411
Labelling	
Pictograms	GHS05, GHS06, GHS09
Signal Word	Danger
Hazard Statement Codes	H 302: Harmful if swallowed H 330: Fatal if inhaled H 317: May cause allergic skin reaction H 318: Causes serious eye damage H 411 Toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	-

The representative biocidal product is identical to the active substance.

b) Intended use, target species and effectiveness

DBDCB is used as an antimicrobial preservative in product type 6 for water based decorative paints applied by brush or roller indoors. The substance is incorporated into the product to be preserved homogeneously either directly or pre-dispersed in water or pre-dissolved in organic solvent. Paints containing DBDCB may be used by professionals and non-professionals. Typical application is manual by brush or roller, the maximum end use concentration in the treated paint is 1 g a.s./kg.

DBDCB takes effect via reacting with nucleophilic groups in the microbial cell. Development of resistance is neither expected nor has it been observed.

The data on the active substance and the representative product have demonstrated sufficient efficacy against the target organisms for approval to be recommended.

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

Human health

The only systemic effect was enlargement of thyroid gland observed in dogs. This effect is ascribed to release of bromide from the DBDCB molecule. The other systemic effects were either secondary to the damage of thyroid gland or local effects such as gastro-intestinal tract irritation.

The substance is not corrosive, nor is it irritating to the skin on single exposure. However, skin irritation was observed on repeated exposure. Other local effects are skin sensitization, irritation of the respiratory tract (observed in animal studies) and eye irritation.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Mixing and loading	Primary exposure through use of the biocidal product: adding the biocidal product to a pre-mix tank containing the paint	Industrial users	Acceptable with PPE (gloves, goggles and long sleeved coveralls)
Brush and roller application	Primary exposure through use of preserved paint: indoor	Professionals	Acceptable with PPE (gloves and long sleeved coveralls)
Brush and roller application	Primary exposure through use of preserved paint: indoor	Non-professional users	Acceptable without PPE
Oral ingestion	Secondary exposure through use of preserved paint: oral ingestion of freshly applied treated paint by child	General public (child)	Acceptable
Oral ingestion	Secondary exposure through use of preserved paint: oral ingestion of dry treated paint by child	General public (child)	Acceptable
Inhalation exposure	Secondary exposure through use of preserved paint: inhalation exposure by child	General public (child)	Acceptable

Systemic effects:
The evaluated uses of DBDCB are given in the above table**.** The handling of undiluted active substance takes place in industrial settings. Appropriate RMM must be used in the industrial settings during handling of the active substance to minimize exposure.

The use of DBDCB-containing paint by amateurs is intermittent with an estimated duration of one event of less than 3 hours: predicted systemic doses cover less than 20% of the Acceptable Exposure Level (AEL) for acute exposure. For professionals without PPE, the daily dose represents 11% of AEL for long term exposure. Nonetheless, the use of PPE is recommended for professionals repeatedly exposed to DBDCB treated paint due to local effects.

The ingestion of paint chips by children is likely to be a rare and intermittent event which can be assessed using the short-term or intermediate AEL. Domestic inhalation exposure of adult residents living in the treated rooms is supposed to be limited to 3 months after painting and intermediate AEL is the relevant reference value for this endpoint. Predicted daily doses are lower than 2% of the relevant AELs for all cases of secondary exposure to the preserved paint.

Local Effects:
The handling of undiluted active substance takes place in industrial settings. Appropriate RMM must be used in the industrial settings during handling of the active substance to minimize the exposure to acceptable levels.

The level of DBDCB in the preserved paint (end-use product/treated material) in the risk assessment did not trigger classification as a skin sensitizer according to the proposed classification, therefore a local risk assessment was not triggered for this effect. Repeated

dermal exposure of skin to mixtures containing low levels of DBDCB cause local effects. For this reason professional users repeatedly exposed to products containing DBDCB are advised to use appropriate PPE including gloves and long sleeved coveralls. Regarding short term exposure, risks of local effects due to exposure to the treated paint are considered to be acceptable for professionals and non-professionals without the use of PPE.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Formulation phase of the preserved paint	Both consumer and tonnage approaches were used. STP (sewage treatment plant) was the primary compartment. Both risks to the aquatic (surface water and sediment) and to the terrestrial (soil and groundwater) compartments resulting from emissions to the STP have been assessed.	Acceptable for all compartments.
Use phase of the preserved paint	Tonnage approach was used for indoor painting, the primary compartment was STP. Both risks to the aquatic (surface water and sediment) and to the terrestrial (soil and groundwater) compartments resulting from emissions to the STP have been assessed.	Acceptable for all compartments.

DBDCB is to be used to treat paints for indoor decorative painting. It will enter the aquatic compartment only via the STP. The emissions to other compartments due to this use are considered as negligible. The risk due to the proposed use was found to be acceptable. Also the risks for the formulation phase of the preserved paint were found to be acceptable.

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	DBDCB 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[1]	Persistent (P) or very Persistent (vP)	Potentially P	DBDCB does 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 and not vB	
	Toxic (T)	Not T	
Endocrine disrupting properties	Not considered to have endocrine disrupting properties. DBDCB does not fulfil criterion (d) of Article 5(1)		
Respiratory sensitisation properties	No classification required. DBDCB does not fulfil criterion (b) of Article 10(1)		
Concerns linked to critical effects	DBDCB does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	As the proportion of impurities is below 20% DBDCB does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

DBDCB does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012. DBDCB does not meet the conditions laid down in Article 10(1)(d) of Regulation (EU) No 528/2012.

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"[2] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[3] agreed at the 54th and 58th 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 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

The substance does not fulfil the POP criterion for bioaccumulation. The potential for persistence and long-range environmental transport (water) could not be excluded as the data available on biodegradation of DBDCB in surface water are not sufficiently reliable. As the bioaccumulation criterion is not fulfilled the substance cannot be considered a persistent organic pollutant (POP).

2.3. BPC opinion on the application for approval of the active substance DBDCB

In view of the conclusions of the evaluation, it is proposed that DBDCB shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

[1] For the metabolite 2-MGN it was concluded that it is: not P and not vP; not B and not vB and not T.
[2] 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).
3 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).

1. Specification: minimum purity of the active substance evaluated: 980 g/kg.
2. The authorisations of biocidal products are subject to the following condition(s):
    a. The product assessment shall pay particular attention to the exposure, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed at the Union level risk assessment of the active substance.
    b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
        i. industrial and professional users.
3. 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 the active substance DBDCB 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.

DBDCB cannot be included in Annex I of Regulation (EU) No 528/2012 because it meets the following criteria of Article 28(2): classified as skin sensitiser category 1 and acute toxicity category 2 (inhalation).

2.4. Elements to be taken into account when authorising products

1. 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 for industrial and professional users is identified for the concerned product, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products should be used with appropriate personal protective equipment.
2. For product authorization, information on dermal absorption has to be re-evaluated according to Scientific Opinion, Guidance on Dermal Absorption, EFSA Panel on Plant Protection Products and their Residues (PPR) (EFSA Journal 2012; 10(4): 2665). Particularly, transferability and applicability for end-use products have to be considered.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of DBDCB. However, further data shall be required to clarify the status of the P-criterion: additional data on sediment and soil degradation should be provided to the evaluating Competent Authority (CZ) as soon as possible but no later than 6 months before the date of approval of the active substance.

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