Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Biphenyl-2-ol

Product-type: PT 13

ECHA/BPC/50/2015

Adopted

5 February 2015

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance Biphenyl-2-ol for Product-type 13

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 13 of the following active substance:

Common name:	**Biphenyl-2-ol**
Chemical name(s):	**ortho Phenylphenol (OPP) and 2-Phenylphenol**
EC No.:	**201-993-5**
CAS No.:	**90-43-7**

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 and DOW Benelux B. V on 12 July 2007, the evaluating Competent Authority Biphenyl-2-ol submitted an assessment report and the conclusions of its evaluation to ECHA on 2 June 2014. 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. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC member for Spain

The BPC opinion on the approval of the active substance Biphenyl-2-ol in Product-type PT 13 was adopted on 5 February 2015.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the Biphenyl-2-ol in Product-type 13 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 Biphenyl-2-ol in Product-type 13, but it does not cover sodium 2-biphenylate and potassium 2-biphenylate. The most important mechanism is the interaction with bio-membranes. In the first step an adsorption of Biphenyl-2-ol to the cell membrane takes place. The greater the proportion of undissociated molecules of the biocide in the surrounding medium the stronger will be the adsorption. In further steps the function of membrane proteins is disturbed, substrate transport and ATP synthesis are inhibited. The cell membrane looses its semi-permeability and ions and organic molecules escape.

Specifications for the reference source are established.

The physico-chemical properties of the active substance and of 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 Biphenyl-2-ol as manufactured and for the analysis of impurities. Validated analytical methods are also available for the determination of Biphenyl-2-ol in soil, water, air and food/feeding stuffs matrices. Other analytical methods are not required because Biphenyl-2-ol is not classified as toxic or highly toxic.

A harmonised classification according to Regulation (EC) No 1272/2008 (CLP Regulation) is available for biphenyl-2-ol.

Classification according to the CLP Regulation		
Hazard Class and Category Codes	Eye Irrit. 2 Skin Irrit. 2 STOT SE 3 Aquatic Acute 1	H319 H315 H335 H400
Labelling		
Pictograms	GHS07 GHS09	
Signal Word	Warning	

Hazard Statement Codes	H319: Causes serious eye irritation H315: Causes skin irritation H335: May cause respiratory irritation H400: Very toxic to aquatic life
Specific Concentration limits, M-Factors	

A new proposal to amend the harmonised classification according to Regulation (EC) No 1272/2008 was submitted to ECHA by the MSCA Spain in October 2014. The proposed classification and labelling for Biphenyl-2-ol is:

Proposed classification according to the CLP Regulation		
Hazard Class and Category Codes	Carc 2 Eye Irrit. 2 Skin Irrit. 2 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H351[a] H319 H315 H335 H400 H410[a]
Labelling		
Pictograms	GHS07 GHS09	
Signal Word	Warning	
Hazard Statement Codes	H351: Suspected of causing cancer[a] H319: Causes serious eye irritation H315: Causes skin irritation H335: May cause respiratory irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects[a]	
Specific Concentration limits, M-Factors	M = 1 for Aquatic Acute 1[a] M = 1 for Aquatic Chronic 1[a]	
Justification for the proposal		
[a] proposal submitted to ECHA		

b) Intended use, target species and effectiveness

Biphenyl-2-ol and Biphenyl-2-ol Solution (active substance Biphenyl-2-ol in alkaline solution) are a multi-site bactericides and fungicides with basic activity at the cell wall, disruption of membrane potentials and general membrane permeability of cytoplasmic membranes.

Biphenyl-2-ol and Biphenyl-2-ol in alkaline solution have a broad efficacy against potentially harmful germs as fungi and yeasts, e.g. *Acremonium strictum, Fusarium solani, Geotrichium candidum* and *Rhodotorula rubra.*

The specific use being supported is the addition of biocidal product to act as a preservative of metal working fluids (MWF).

Biphenyl-2-ol and Biphenyl-2-ol in alkaline solution are antimicrobial preservatives for aqueous products. Metal working fluids are usually emulsified or dissolved with water prior to being used).

Efficacy against fungi and yeasts has been proven to protect cooling lubricants against microbial spoilage. The results show that the efficacy concentration of Biphenyl-2-ol is ≥ 0.15% w/w.

The tests were considered relevant to the evaluation for PT 13. Efficacy against bacteria was not demonstrated and it should be shown at product authorisation stage.

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

Human health

Biphenyl-2-ol is irritant to the skin and may causes serious irritation to the eye. Data from studies in humans and animals show that Biphenyl-2-ol is not a skin sensitiser. After repeated exposure in male rats urinary bladder tumours were observed. Biphenyl-2-ol is not genotoxic, mutagenic, reproductive or developmental toxicant. The tumours found in mice are not predictive of carcinogenicity for humans, however the relevance of urinary bladder tumours in male rats cannot be completely excluded.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**
Formulation of preserved MWF concentrate	**Primary exposure:** mixing/loading the biocidal product (weight/dump solid) to prepare the MWF concentrate (max. 6% Biphenyl-2-ol), daily 10 minutes. RMM: safe operational procedures, appropriate organisational and technical risk mitigation measures must be implemented to reduce Biphenyl-2-ollevels in air, including the appropriate PPE (gloves, coverall).	Industrial users
Tank side addition of preserved MWF concentrate or biocidal product concentrate	**Primary exposure:** mixing/loading (either biocidal product concentrate or preserved MWF concentrate, containing max. 6% Biphenyl-2-ol) into the system by pouring or fully automatically; once per week, 10 minutes (max. 3000 ppm Biphenyl-2-ol). Preparation of biocidal product concentrate (weight/dump solid, weekly, 10 minutes) is also considered. RMM: safe operational procedures, appropriate organisational and technical risk mitigation measures must be implemented, including the appropriate PPE (gloves, coverall)	Professional users
Application of preserved MWF	**Primary exposure to Biphenyl-2-ol through use of the preserved MWF:** Operators working in metalworking premises machine working, 1 h/daily, max 3000 ppm Biphenyl-2-ol PPE: impermeable coverall, no gloves* other tasks than machine working (includes maintenance, monitoring, cleaning, disposal and transfer); 7 hrs/daily, max 3000 ppm Biphenyl-2-ol PPE: impermeable coverall and gloves RMM: safe operational procedures, appropriate organisational and technical risk mitigation measures must be implemented to reduce dermal load.	Professional users
Post application activities	**Secondary exposure**: Dermal exposure to contaminated coveralls at home laundering	

*The use of protective gloves during machine work can represent a health risk (HEEG opinion on Human exposure assessment to biocidal products used in metalworking fluids (PT13))

Primary exposure of industrial users is considered acceptable. Risk mitigation measures are required to reduce exposure via the inhalation route (LEV or RPE if dust or aerosols are formed) and the dermal route (gloves, coverall).

Primary and secondary exposure of professionals is considered acceptable. Risk mitigation measures are required to reduce exposure via the dermal route: reducing contact with contaminated surfaces/rags, rinsing of drilled/cut work pieces after metal working processes prior to manual handling, washing hands regularly.

General public is not exposed to metalworking preserved fluids containing Biphenyl-2-ol.

Based on assessment of the scenario listed above, it is concluded that exposure levels of professionals are acceptable. Furthermore, residues in food or feed are not expected.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Preservatives for both emulsifiable and water soluble metal working fluids	Emission to wastewater for a waste treatment facility receiving spent metal-working fluids and subsequent release to a sewage treatment plant (STP), surface water, sediment, soil and groundwater.

For the environmental risk assessment, two different emission rates (0.30% = 3000 mg/kg Biphenyl-2-ol and 0.15% = 1500 mg/kg Biphenyl-2-ol) resulting from the exchange of the functional fluid have been assessed.

All evaluated scenarios are identified as safe uses for all the environmental compartments with a emission rate of 0.15%.

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)	Cat 2
	Mutagenicity (M)	No classification is required
	Toxic for reproduction (R)	No classification is required
Respiratory sensitisation properties	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Biphenyl-2-ol is not considered to fulfil the P or vP criteria.
	Bioaccumulative (B) or very Bioaccumulative (vB)	Biphenyl-2-ol is not B or vB
	Toxic (T)	Biphenyl-2-ol meets the Toxic criterion.
Endocrine disrupting properties	Biphenyl-2-ol is not considered to have endocrine disrupting properties	

Consequently, the following is concluded:

Biphenyl-2-ol does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Biphenyl-2-ol does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not 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"[1] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[2] 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 vapour pressure of Biphenyl-2-ol is 0.906 Pa at 25°C, the half-life in air is 0.587 days, indicating that the criteria for long-range transport potential (vapour pressure < 1000 Pa and half-life in air > 2 days) is not fulfilled. Biphenyl-2-ol does not fulfil the P/vP and B/vB criteria.In conclusion, considering the above rationale, it can be concluded that Biphenyl-2-ol does not fulfil the POPs criteria.

2.3. BPC opinion on the application for approval of the active substance Biphenyl-2-ol in Product-type 13

In view of the conclusions of the evaluation, it is proposed that Biphenyl-2-ol shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: The active substance Biphenyl-2-ol, as manufactured, shall have a minimum purity of 995 g/kg.

2. 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.

3. For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

The active substance does not fulfill the criteria according to Article 28(2)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012.

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[1] 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)

[2] 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)

2.4. Elements to be taken into account when authorising products

1. The environmental exposure assessment for PT 13 as described in the Emission Scenario Document (ESD) is being revised currently. The exposure for Biphenyl-2-ol was estimated based on an intermediate revision of the ESD agreed at the Environment Working Group, which is described in the assessment report. At product authorisation, if available, the revised ESD has to be considered. The revised ESD will also contain on-site treatment of waste which was not considered in the current evaluation.

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 Biphenyl-2-ol. However, a sewage treatment plant simulation test shall be provided to the evaluating Competent Authority (Spain) as soon as possible but no later than 6 month before the date of approval of the active substance.

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