Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Biphenyl-2-ol

Product-type: PT 2

ECHA/BPC/49/2015

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 2

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 2 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 Spain 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 2 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 2 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 2, but it does not cover sodium 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 is a multi-site bactericide and fungicide with basic activity at the cell wall, disruption of membrane potentials and general membrane permeability of cytoplasmic membrane.

Biphenyl-2-ol has a broad efficacy against potentially harmful germs (bacteria, fungi and yeasts), e.g. *Escherichia coli, Pseudomonas aeruginosa, Enterococcus hirae, Staphylococcus aureus, Aspergillus niger* and *Candida albicans.*

Biphenyl-2-ol is an antimicrobial used in liquid disinfectants to be applied to surfaces (floor, tabletops, etc.) as biocidal Product-type 2 for surface disinfection in health care settings. Users comprise both professionals (cleaners in hospitals and health care personnel in hospitals) and non-professionals (residential area). Likely in-use concentration is 0.15% w/v Biphenyl-2-ol.

Due to the unspecific mode of action (multi-site activity) a development of resistance against biocidal use of Biphenyl-2-ol is not expected.

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

Human health

Biphenyl-2-ol is irritant to the skin and may cause 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**
Surface disinfection in public areas	**Primary exposure:** Professional cleaners and health care personnel in hospitals; application by mopping and wiping, (includes diluting and mixing), 330 minutes daily*. Liquid disinfectant containing 0.25% Biphenyl-2-ol max. PPE: standard coverall, gloves.	Professional users
Surface disinfection in private areas	**Primary exposure:** Non-professionals in private homes. Use of all purpose cleaners /liquid cleaners. Includes mixing and loading and application. 20 minutes daily. Liquid disinfectant containing 0.25% Biphenyl-2-ol max	Non-professionals users
Re-entry after treatment, exposure via inhalation	**Secondary exposure:** Inhalation of volatilised residues during 8 hours after application.	General public
Re-entry after treatment, dermal exposure	**Secondary exposure:** Infant crawling on wet surface; 1,170 cm^2 skin are exposed, 100% transference.	Infants
Re-entry after treatment ,dermal exposure	**Secondary exposure:** Hand contact with wet surface. 20% of the surface area of hands are exposed, 100% transference.	Adults, children
Re-entry after treatment, oral exposure	**Secondary exposure:** Oral uptake from hand-to-mouth contact after dermal exposure to wet surface; 50% of hand's area is licked, 100% bioavailability.	Infants

* BPC Ad hoc Working Group on Human Exposure Recommendation No.2 "Professional mopping and wiping time used for cleaning hard surfaces (PT2)

The evaluation is based on both a concentrated and diluted product. The exposure during application by mopping and wipping at the specified concentration of the active substance includes exposure associated to diluting and mixing a concentrate. Primary exposure of professionals is considered acceptable provided that adequate PPE (standards gloves and coverall) is used.

Primary exposure of non-professionals is considered acceptable. The exposure scenario includes the dilution of a concentrate containing 10% Biphenyl-2-ol and the application at the specified concentration of the active substance. Specific safety measures for non-professionals are not required.

Secondary exposure of the general public is considered acceptable.

Based on assessment of the scenarios listed above, it is concluded that primary and secondary exposure are acceptable.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Sanitary purposes in hospitals (consumption)	Waste water emission to STP (sewage treatment plant). Emissions to surface water, soil and groundwater via STP.
Sanitary purposes in hospitals (tonnage)	Waste water emission to STP. Emissions to surface water, soil and groundwater via STP.

All evaluated scenarios are identified as safe uses.

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	Biphenyl-2-ol is not considered to fulfil the P or

	Persistent (vP)	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 2

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.

[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. 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 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.

2.4. Elements to be taken into account when authorising products

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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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