Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Biphenyl-2-ol

Product-type: PT 1

ECHA/BPC/48/2015

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 1

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 1 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 1 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 1 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 1 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.

Laboratory tests under a variety of use conditions have been submitted against potentially harmful germs as bacteria, fungi and yeasts, e.g. *Escherichia coli* and *Candida albicans*. Innate efficacy of biphenyl-2-ol has been demonstrated. In addition, efficacy against bacteria has been demontrated for the product.

The biocidal product is a ready-to-use formulation for hygienic hand disinfection and hand decontamination in hospitals and medical practice by professional users. Likely in-use concentration is 2.0% w/v Biphenyl-2-ol. With the representative biocidal product formulation hand washing and hand disinfection are achieved in one step.

Due to the unspecific mode of action (multi-site activity) 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 causes serious irritation to the eye. Data from studies in humans and animals show that Biphenyl-2-ol is not a skin sensitizatiser. 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**
Hand disinfection	**Primary exposure**: Application: hand wash using liquid soap containing 2% Biphenyl-2-ol in hospitals and medical practice; 10 events daily, 30 seconds per event, followed by rinse with water.	Professional users

Primary exposure of professionals is considered acceptable assuming a frequency of use of 10 events per day and 30 seconds contact time per each application maximum. The representative biocidal product (Biphenyl-2-ol hand soap) is classified as irritant to skin. This is the current precautionary evaluation by the RMS due to the absence of an acceptable test with the product, which may be overruled by submission of e.g. experimental data on product authorization level.

Risk mitigation measures for professionals with respect to human health exposure assessment and risk characterisation are not required.

Non-professional use is not foreseen.

Based on assessment of the scenario listed above, it is concluded that primary exposure of professionals is 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**
Antimicrobial active ingredient in soaps for use by professional health care only	According to the Emission Scenario Document (ESD) for PT1 the model hospital has 400 beds, 75% of them are occupied. It is assumed that one nurse is responsible for one bed with 10 applications per day and nurse with an application rate of 3 g of soap per application. Antimicrobial soaps are used as rinse-off products, which are left on skin for a short time and then rinsed off with water. The sewage treatment plant (STP) is the only directly receiving compartment. Indirectly receiving comparments are surface water, sediment, soil and groundwater.

Biphenyl-2-ol in PT1 poses no unacceptable risks neither for microorganisms in STP, aquatic organisms in surface water and sediment, soil organisms nor for groundwater. Therefore, no unacceptable risks for any environmental compartment and in the food chains (secondary poisoning) are expected.

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 1

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.

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

1. A local risk assessment will be necessary if the biocidal product is classified for local effects.

[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)

2.5. 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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