Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Biphenyl-2-ol

Product-type: PT 6

ECHA/BPC/057/2015

Adopted

15 June 2015

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Opinion of the Biocidal Products Committee

on the approval of the active substance Biphenyl-2-ol 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:	**Biphenyl-2-ol**
Chemical name(s):	***ortho-Phenylphenol (OPP) and 2-Phneylphenol***
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 the Commission 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 6 was adopted on 15th June 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 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 biphenyl-2-ol in Product-type 6, but it does not cover sodium 2-biphenylate and potassium 2-biphenylate. The most important mechanism is the interaction with biomembranes. 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 the active substance as manufactured and for the analysis of impurities. Validated analytical methods are available for the technical active substance and 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	H319
	Skin Irrit. 2	H315
	STOT SE 3	H335
	Aquatic Acute 1	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	H351*
	Eye Irrit. 2	H319
	Skin Irrit. 2	H315
	STOT SE 3	H335
	Aquatic Acute 1	H400
	Aquatic Chronic 1	H410*
Labelling		
Pictograms	GHS07 GHS09	
Signal Word	Warning	
Hazard Statement Codes	H351: Suspected of causing cancer 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	
Specific Concentration limits, M-Factors	M = 1 for Aquatic Acute 1* M = 1 for Aquatic Chronic 1*	
Justification for the proposal		
* 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 bacteria, e.g. *Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Pseudomonas fluorescens, Pseudomonas oleovorans, Pseudomonas rubescens, Pseudomonas stutzeri, Alcaligenes faecalis, Citrobacter freundii* and *Corynebacterium sp*.

The biocidal products evaluated correspond to

- PT 6.01: In can preservative for detergents and household cleaning products:

  Biphenyl-2-ol is an antimicrobial preservative for aqueous products. The aim of the application of in-can preservatives is the preservation of manufactured products in cans, tanks or other closed containers. Thus, bio-spoilage during the shelf life of the product is avoided. Concentration in preserved products is 0.1% to 0.5% w/w biphenyl-2-ol.

- PT 6.02: Preservation of paper additives:

  Aqueous suspensions of inorganic minerals are known to provide a suitable environment for the growth of micro-organisms. Aerobic organisms are supported by oxygen that is introduced through mixing or pumping. Addition of chemicals which are required for processing can serve as nutrients and as source for microbiological contamination. Areas that are not circulated tend to become anaerobic, supporting the growth of anaerobic micro-organisms. The product is added to the suspension/solution at a final concentration of 225 ppm biphenyl-2-ol.

The efficacy tests available demonstrate the efficacy of the product against bacteria. Efficacy against fungi and yeasts should be demonstrated at product authorisation stage.

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 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 b.p. into preserved products	**Primary exposure:** mixing/loading the biocidal product (weight/dump solid) to prepare the premixed concentrate, 10 minutes, daily; pumping of b.p. concentrate (mixing and loading) 10 minutes, daily RMM: safe operational procedures, appropriate organisational and technical risk mitigation measures must be implemented to reduce Biphenyl-2-ol levels in air, including the appropriate PPE (gloves, coverall).	Industrial users
Use of preserved liquid cleaners and cleaning agents	**Primary exposure to the preserved product:** use of glass cleaners; application by spraying (hand held trigger spray, 50 minutes) and wiping (220 minutes), PPE (cotton coverall, gloves) is required if the concentration in the final-end use preserved cleaner is higher than or equal to 0.25% w/w biphenyl-2-ol.	Professional users
Use of preserved mineral slurries in paper manufacture	**Primary exposure to the preserved product:** automated pumping of preserved mineral slurry (mixing and loading), 10 minutes	Professional users
Use of preserved liquid detergents in hand laundry	**Primary exposure to the preserved detergents and cleaning agents:** Loading and application by hand wash, daily	Non-professional users
Use of preserved liquid detergents in hand dishwashing	**Primary exposure to the preserved detergents and cleaning agents:** Loading and application by hand dishwash, daily	Non-professional users
Use of preserved liquid cleaners in surface cleaning	**Primary exposure to the preserved detergents and cleaning agents:** Application by spraying and cleaning, daily	Non-professional users
Preserved liquid detergents used in hand laundry	**Secondary exposure to the preserved detergents and cleaning agents**: dermal exposure to textiles washed with detergents, daily.	General public
Preserved liquid detergents used in hand dishwashing	**Secondary exposure to the preserved detergents and cleaning agents**: oral ingestion of dried residues of cleaning agents in dishes, daily.	General public

Preserved liquid liquid cleaners used in surface cleaning	**Secondary exposure to the preserved detergents and cleaning agents**: dermal contact of children when crawling on wet surfaces, occasional.	General public

Primary and secondary exposure of professionals is considered acceptable (for both local and systemic effects). The use of adequate PPE (coverall and gloves) is required during formulation and during cleaning of surfaces by spraying and wiping when the concentration in the final-end use preserved cleaner is higher than or equal to 0.25% w/w biphenyl-2-ol. Acceptable risks were identified for non-professionals and the general public in the scenarios assessed without the need to require risk mitigation measures.

Based on assessment of the scenarios listed above, it is concluded that exposure levels of professionals, non-professionals and consumers are acceptable.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Washing and cleaning fluids (general) and other detergents (dishwashing liquids) (professional use)	Waste water emission to the sewage tretatment plant (STP). Emissions to surface water, soil and groundwater via STP.
Washing and cleaning fluids (general) and other detergents (dishwashing liquids) (non professional use)	Waste water emission to STP. Emissions to surface water, soil and groundwater via STP.
Preserved paper additives used in paper production	Newsprint: waste water emission to STP. Emissions to surface water, soil and groundwater via STP. Tissue: waste water emission to STP. Emissions to surface water, soil and groundwater via STP. Printing and writing paper: waste water emission to STP. Emissions to surface water, soil and groundwater via STP.

When Biphenyl-2-ol is **used in diswashing liquids,** the estimated PEC/PNEC values for the STP show a safe use for all the scenarios (professional and non-professional uses). There is an acceptable risk for the surface water and sediment compartments for the total of the domestic uses with a 1% of the influent residues being present in the STP effluent water

phase (Tier2). However, an unacceptbale risk has been identified for the total of the professional uses. For the soil compartment, an acceptable risk has been identified for the for all scenarios and for both grassland and arable land situations when a refined DT_{50} of 15.08 days and a 1% of the STP influent residues being present in STP sludge were considered. When FOCUS groundwater scenarios were applied, no unacceptable risk has been identified.

When Biphenyl-2-ol is **used in preserved paper additives** (in a formulation containing 17.7% of active substance in alkaline solution) an acceptable risk has been identified for the STP, surface water, sediment and soil compartments. Moreover, when FOCUS groundwater scenarios were applied, no unacceptable risk has been identified. However, the risks for water, sediment and soil are unacceptable when using a formulation containing ≥99.5% of active substance.

Therefore, safe uses are identified for Biphenyl-2-ol when used in dishwashing liquids by non-professional users and when it is used as in-can preservative for paper additives.

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 is 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	Active substance is not considered to have endocrine disrupting properties.	

Concerns linked to critical effects	Biphenyl-2-ol does not meet this criterion.
Proportion of non-active isomers or impurities	Biphenyl-2-ol is put on the market as an active substance with purity above 99.5%; therefore, Biphenyl-2-ol does not contain a significant proportion of non-active isomers or relevant impurities. Given this, Biphenyl-2-ol does not fulfil this criterion.

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 of 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 6

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:

i. 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)

ii. 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.

iii. For industrial and professional 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.

iv. In view of the risks identified for environment,biocidal products shall not be authorised for the preservation of washing and cleaning fluids and other detergents for professional use, unless it can be demonstrated that risks can be reduced to an acceptable level.

2.4. Elements to be taken into account when authorising products

1. An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs. Attention shall be paid to the formation of by-products.

2. Appropriate personal protective equipment might be required at product authorisation when the concentration of biphenyl-2-ol in the final end-use preserved cleaner is higher than or equal to 0.25% w/w.

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 months before the date of approval of the active substance.

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