Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Biphenyl-2-ol

Product-type: PT 4

ECHA/BPC/056/2015

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 4

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 4 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 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 4 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 4 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 4, 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 deemed 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 has a broad efficacy against potentially harmful germs (bacteria, fungi and yeasts), e.g. *Escherichia coli, Staphylococcus aureus, Listeria monocytogenes, Enterococcus hirae, Pseudomonas aeruginosa, Salmonella enterica subsp. enterica, Penicillium chrysogenum, Penicillium candidum, Penicillium cyclopium, Geotrichum candidum, Monascus rubber, Aspergillus fumigatus, Candida pelliculosa* and *Candida albicans*.

The biocidal product is a smoke generator preparation used for the disinfection of surfaces, by air route, in closed premises free from presence of humans, animals, plants or non-packed food. The following locations are intended to be treated with Fumispore Biphenyl-2-ol (Smoke Generator):

- Storage silos in the factory;
- Factories: transformation rooms, maturation and conditioning/packaging rooms; corridors and goods lifts; packaging storages; ventilation shafts; technical premises; waste zones;
- Food stuffs storage;
- Food trucks.

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 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**
disinfection of food/ feed areas	**Primary exposure:** Disinfection by smoke generation includes ignition of smoke generator units and collecting the used smoke tins after the recommended contact time and ventilation of premises. Maximum application 160 mg Biphenyl-2-ol/m ^{3} air Doses estimated using field studies. PPE: gloves at collecting used units	Professionals
re-entry after treatment	**Indirect exposure:** inhalatory exposure at re-entering after treatment and ventilation of premises. Doses estimated using field studies.	Professionals

Primary exposure of professionals is considered acceptable (both local and systemic effects) provided that adequate PPE (gloves) is used as risk mitigation measures for professionals with respect to human health exposure assessment.

Secondary (indirect) exposure of professionals is considered acceptable. Risk mitigation measures for professionals with respect to human health exposure assessment and risk characterisation are not required.

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

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Slaughterhouses	Waste water emission to a sewage treatment plant (STP). Emission to surface water, soil and groundwater via the STP.
Large scale catering kitchens	Waste water emission to STP. Emission to surface water, soil and groundwater via the STP.

The disinfection in slaughterhouses and butcheries takes into account an area of 10,000 m^2 and a height of 5 m, and the disinfection in large scale catering kitchens and canteens takes into account an area of 2,000 m^2 and a height of 3 m. Therefore, two scenarios (50,000 m^3 and 6,000 m^3) have been considered.

When considering the scenario of **disinfection in slaughterhouses**, there is an acceptable risk for microorganisms in a STP caused by Biphenyl-2-ol in the smoke generator formulation. However, there is an unacceptable risk for the surface water, sediment and soil compartments. Simulations with FOCUS PEARL for groundwater prove that there is an acceptable risk for groundwater in all scenarios.

When the scenario of **disinfection in large kitchens** is taken into account, an acceptable risk has been identified for the STP, surface water, sediment and soil compartments. Simulations with FOCUS PEARL for groundwater prove that there is an acceptable risk for groundwater in all scenarios.

The risks identified for the environment were related to the scale of the area used in the models. Therefore, though large kitchen disinfection is acceptable, large scale disinfection (e.g. assessed for slaughter houses) was not acceptable.

It is therefore concluded that the use of Biphenyl-2-ol as disinfectant in large kitchens does not represent an unacceptable risk to the environment compartments.

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 4

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

[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)

substance Biphenyl-2-ol, as manufactured, shall have a minimum purity of 995 g/kg.

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. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

v. Products containing Biphenyl-2-ol shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of Biphenyl-2-ol into food or it has been established pursuant to that Regulation that such limits are not necessary.

vi. In view of the risks identified for environment, biocidal products shall not be authorised for large scale disinfection, 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. Conditions for the application of products and post application measures must be clearly specified by the Applicant and included in label instructions for use.

2. 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.

3. Potential outdoor exposure of environment during and after ventilation should be assessed for product authorisation supported by further data on the released fraction.

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.