Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Biphenyl-2-ol

Product type: 3

ECHA/BPC/078/2015

Adopted

8 December 2015

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Opinion of the Biocidal Products Committee

on the application for approval of the active substance Biphenyl-2-ol for product type 3

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 3 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 3 was adopted on 8 December 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 3 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 3, 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 loses 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 potentially harmful germs (bacteria, fungi and yeasts), e.g., *Proteo vulgaris, Pseudomonas aeruginosa, Enterococcus hirae, Staphylococcus aureus, Aspergillus niger* and *Candida albicans*, according to EN1656 and EN1657 protocols.

The biocidal product is used to control pathogenic micro-organisms in industrial poultry barn, other intensive livestock farming installations and similar facilities. It is intended for disinfection of surfaces in pig and poultry units by professional users. It is applied to surfaces using a rod and nozzle that sprays an even layer across the surface to be disinfected. A solution containing 5,000 ppm (0.5%) Biphenyl-2-ol is recommended for the application.

Disinfection of livestock husbandries is performed when no animals are present and the bedding has been removed and discarded. The treatment solution is left to dry on the treated walls and floors. Re-entry is then allowed after a specific period of time when most of the residues have been removed through ventilation.

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**	**Conclusion**
Disinfection in intensive livestock farming installations	**Primary exposure:** Application by medium pressure spraying; 126 minutes daily, 5000 ppm Biphenyl-2-ol. Includes mixing/loading. PPE: coverall, gloves, waterproof boots, face shield, RPE. Cleaning of spray equipment, daily. Repair of spray equipment, once a year.	Professionals	Acceptable with PPE Acceptable without PPE Acceptable without PPE
Re-entry following disinfection	**Indirect exposure:** Inhalation exposure during 2 hours at 0.00207 mg Biphenyl-2-ol/m^3 (estimated amount in air 8 hours after treatment). Dermal contact with treated surfaces; area exposed is 420 cm^2 (palms of hands) at 0.075 mg Biphenyl-2-ol /cm^2 (application rate of Biphenyl-2-ol in treated surfaces).	Professionals	Acceptable without PPE

Primary exposure of professionals is considered acceptable provided that adequate PPE (coverall, gloves and RPE) is used.

Indirect exposure of professionals is considered acceptable assuming re-entry eight hours after treatment. Specific safety 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 for professionals is acceptable.

Exposure of consumers to Biphenyl-2-ol residues via meat or edible offal from mammals (ruminants and pigs) can be excluded. However, no conclusion can be drawn regarding birds (chicken, turkey).

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Sows in individual pens	Emissions from foam or low or medium pressure spraying application to the manure. The manure will be spread on grassland or arable land and may lead to exposure of surface water, sediment, soil and groundwater.	Unacceptable risks identified for surface water, sediment and soil.
Sows in groups	Emissions from foam or low or medium pressure spraying application to the manure. The manure will be spread on grassland or arable land and may lead to exposure of surface water, sediment, soil and groundwater.	Unacceptable risks identified for surface water, sediment and soil.
Fattening pigs	Emissions from foam or low or medium pressure spraying application to the manure. The manure will be spread on grassland or arable land and may lead to exposure of surface water, sediment. soil and groundwater.	Unacceptable risks identified for surface water, sediment and soil.
Broilers free range with litter floor	Emissions from foam or low or medium pressure spraying application to the manure. The manure will be spread on grassland or arable land and may lead to exposure of soil and groundwater. Emissions from the manure to the STP.	Acceptable
Turkeys free range with litter floor	Emissions from foam or low or medium pressure spraying application to the manure. The manure will be spread on grassland or arable land and may lead to exposure of soil and groundwater. Emissions from the manure to the STP.	Unacceptable risks identified for surface water, sediment and soil.

Unacceptable risks were identified for the animal categories sows (in individual pens as well as in groups), fattening pigs and turkeys in free range with litter floor. Acceptable risk were identified for the STP, soil, surface water and sediment compartments for the broilers free range with litter floor scenario, for both grassland and arable land situations.

When FOCUS groundwater scenarios were applied, no unacceptable risks have been identified for all scenarios and for both grassland and arable land situations.

Therefore, no unacceptable risks to soil, groundwater, the STP, surface water and sediment after application of a biocidal product containing Biphenyl-2-ol is indicated for the broilers free range with litter floor scenario.

General conclusion

Acceptable risks are identified for the use of Biphenyl-2-ol for the disinfection of livestock husbandries by professionals provided adequate PPE is used during application. For the environment unacceptable risks are identified for surface water, sediment and soil for all animal categories except broilers in free range with litter floor.

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	Biphenyl-2-ol is not considered to have endocrine disrupting properties.	
Concerns linked to critical effects	Biphenyl-2-ol does not fulfil criterion (e) of Article 10(1).	
Proportion of non-active isomers or impurities	Biphenyl-2-ol is placed on the market as a active substance with a 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 POP criteria.

2.3. BPC opinion on the application for approval of the active substance Biphenyl-2-ol in product type 3

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 authorisations of biocidal products are subject to the following condition(s):

    a. 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.

    b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

        i. Professional users;

        ii. Surface water, sediment and soil compartment.

    c. 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.

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

---

[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 following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:
    a. If an unacceptable risk for industrial and professional users is identified for the product, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products should be used with appropriate personal protective equipment.
    b. An unacceptable risk for the surface water, sediment and soil is identified for uses in animal housings other than broilers in free range with litter floor. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

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.

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.

o0o