Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Fludioxonil

Product type: 7

ECHA/BPC/142/2017

Adopted

2 March 2017

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance fludioxonil for product type 7

In accordance with Article 8(4) 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 7 of the following active substance:

Common name:	**Fludioxonil**
Chemical name:	**4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile**
EC No.:	**-**
CAS No.:	**131341-86-1**
New 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 on 8 October 2014, the evaluating Competent Authority Denmark submitted an assessment report and the conclusions of its evaluation to ECHA on 5 April 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-19) and its Working Groups (WG IV 2016). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Denmark

The BPC opinion on the approval of the active substance fludioxonil in product type 7 was adopted on 2 March 2017.

The BPC opinion was adopted by consensus.The opinion is published on the ECHA webpage at:

http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the fludioxonil in product type 7 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 fludioxonil in product type 7. Fludioxonil is a fungicide that works by inhibiting the osmotic signal pathway which results in the inhibition of spore germination and prevention of mycelia growth. Specifications for the reference source are established.

The physico-chemical properties of the active substance and 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 active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are required and available for the relevant matrices soil, air and water.

Fludioxonil is approved in EU as an active substance for a plant protection product under Regulation (EU) No 540/2011. An application for renewal of the approval is currently under evaluation.

There is no current classification according to Regulation (EC) No 1272/2008 for fludioxonil. However, a classification proposal was submitted to ECHA in 2015. The public consultation phase has taken place and discussions in the Risk Assessment Committee (RAC) are planned for the second half of 2017.

The proposed classification and labelling for fludioxonil according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Labelling	
Pictogram codes	GHS09
Signal Word	Warning
Hazard Statement Codes	H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 1 (acute and chronic)

b) Intended use, target species and effectiveness

Fludioxonil is used in biocidal preservative products which are applied to, or incorporated into various end-applications covering protection of paints, silicon coatings, mineral and silicon sealants and grout products. Fludioxonil provides specific activities against *Alternaria alternata*, *Aspergillus versicolor*, *Stachybotrys chartarum*, *Scopulariopsis brevicaulis,* some *Penicillium* spp., *Alternaria* spp. and some wood decaying fungi, such as *Conophora puteana*, *Gloeophyllum trabeum* and *Sydowia pythiophila*.

The end-use treated items may be used indoor by professional workers and by the general public (non-professional), depending on the individual item. Concentrations of fludioxonil in end-use materials are between 0.003 and 0.032% in paints and silicon coatings and between 0.002 and 0.032% in mineral and silicon sealants and grouts, respectively.

Fludioxonil is a fungicide not intended to be used as a stand-alone substance, it is intended to be used in combination with other fungicides for indoor material preservation in PT 7. Biocidal products containing *inter alia* the active substance fludioxonil are intended to inhibit the growth of fungi associated with odours, staining and, in general, bio-deterioration. Target fungi includes in example *Alternaria alternata* and *Stachybotrys chartarum*.

The representative biocidal product contains the fungicide active substances fludioxonil, azoxystrobin and thiabendazole. The use of three active substances ensures that the product maintains its efficacy by presenting multiple mechanisms of fungicidal activity, thereby minimising the possibility of resistance development.

The product has broad spectrum efficacy, but the principal target organisms are fungi of the Ascomycota division which can cause staining, odour and deterioration of materials. Tests conducted to ASTM and EN standard test methods have confirmed the efficacy of the representative product in styrene and vinyl acrylic paint at the intended use concentrations of 0.15 to 1.6% w/w and a mineral sealant/groutpowder product at the intended use concentrations of 0.08 to 1.6% w/w. The available test results are considered acceptable to allow approval of fludioxonil as a fungicidal active substance for use in material preservation in PT 7.

Fludioxonil has a single site mode of action and is therefore more prone to the development of resistance, because any change(s) that might occur in the fungus to alter that single site could render the fungus resistant to the fungicide. The potential for resistance development therefore exists, but is restricted, because fludioxonil will be used in combination with other fungicides, that present different modes of action and thereby ensuring that resistance potential is limited.

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

Human health

Fludioxonil is of low acute toxicity by the oral, dermal and inhalation routes. Fludioxonil is not classified as a skin or eye irritant or a skin sensitiser.

Following repeated oral administration of fludioxonil in the various animal species tested, the target organs identified were the liver in rats, mice and dogs and the kidneys in rats and mice.
Fludioxonil does not meet the criteria for classification as a mutagen, carcinogen or reproductive toxicant.

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**
Industrial manufacture and formulation of paints	Primary exposure to the biocidal product**:** • Mixing and loading, i.e., connecting or disconnecting pipes or hoses using automated or semi-automated processes for the blending of the biocidal product (b.p.) into the paint. • Maintenance of the different parts of production machines used in paint manufacture and formulation. Dermal contact to a thin film of the biocidal product was considered. (PPE: gloves) • Combined exposure (PPE: gloves)	Industrial users	Acceptable with PPE
Spraying application	Primary exposure to preserved paints: Applying preserved water-based paints by spraying (PPE: gloves) Cleaning of spray equipment after application	Professionals	Acceptable with PPE
Spraying application	Primary exposure to preserved paints: Applying preserved water-based paints by spraying Cleaning of spray equipment after application	Non-professionals	Acceptable
Brush and roller application and post-application	Primary exposure to preserved paints: Applying preserved water-based paints using a brush or roller and washing out paint brushes after application.	Professionals; non-professionals	Acceptable
Application of mineral sealants and grout	Primary exposure to preserved mineral sealant or grout: Applying preserved mineral sealant or grout	Professionals; non-professionals	Acceptable
Toddler	Secondary (indirect) exposure to preserved paint: Toddler – touching wet or dried painted surface and mouthing	General public	Acceptable
Adult	Secondary (indirect) exposure to preserved paint: Adult – laundry of contaminated coveralls after paint spraying activities	General public	Acceptable
Toddler	Secondary (indirect) exposure exposure to preserved material: Toddler – dermal contact with wet preserved materials (e.g. mineral sealants and grouts) and mouthing	General public	Acceptable
Toddler	Secondary (indirect) exposure to volatilized residues: Toddler – inhalation exposure to volatilized residues	General public	Acceptable

Sanding preserved paint or sealant	Secondary (indirect) exposure to preserved paint or sealant: Adult (professional worker or non-professional) – removing dried preserved paint and sealant by sanding	Non-professionalProfessionals, non-professionals	Acceptable

Industrial, professional and non-professional systemic exposures were evaluated for the scenarios summarized in the table above.

Acceptable risks were identified for industrial workers in contact with the biocidal product conducting maintenance work done for the different parts of the production machines (used in paint manufacture and formulation) when wearing appropriate personal protective equipment PPE (gloves). Acceptable risk was also found for professionals applying preserved water-based paints by spraying when wearing appropriate personal protective equipment PPE (gloves).
All other scenarios for industrial, professionals, non-professional users or the general public resulted in acceptable risks without the use of PPE.

An acceptable risk from combined exposure to fludioxonil in the representative product is identified for industrial workers mixing and loading/blending formulated product into the paint and performing maintenance activities on the same day provided gloves are worn.

All other combined exposures to fludioxonil in the representative product for professionals and non-professionals resulted in acceptable risks without wearing appropriate personal protective equipment PPE.

Due to no classification for local effects of either the active substance or the product, based on specific product studies, there is no need to consider local effects separately.

Environment

Fludioxonil is hydrolytically stable and is not readily biodegradable. Slow degradation is found in soil and water/sediment degradation studies. However significant degradation is found in soil and water photolysis studies forming five relevant photo-degradation products. Fludioxonil fulfils the criteria for being very persistent. The photo-degradation products are also found to be very persistent based on QSARs. Volatilisation from soil or water is not expected to be a significant entry route into air.

Fludioxonil is classified as very toxic to the aquatic life with long lasting effects.Based on QSAR estimates it could be concluded that the photo-degradation products are less toxic than fludioxonil and are therefore covered by the effect assessment of fludioxonil. Fludioxonil is very unlikely to reach the groundwater compartment. However the photo-degradation products CGA339833, CGA 192155 and CGA 265378 have low sorption values and are therefore more prone to reach the groundwater.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Release estimation from industrial use of biocidal product in preparation of paint, coatings, mineral sealants and fillers	Exposure via sewage treatment plant to terrestrial and aquatic compartments	Acceptable risk to all environmental compartments for fludioxonil and photo-degradation products
Release estimation from application and service life from decorative paint (indoor use)	Exposure via sewage treatment plant to terrestrial and aquatic compartments	Acceptable risk to all environmental compartments for fludioxonil and photo-degradation products
Release estimation from application and service life from sealants (indoor use)	Exposure via sewage treatment plant to terrestrial and aquatic compartments	Acceptable risk to all environmental compartments for fludioxonil and photo-degradation products

No unacceptable risk is identied for any environmental compartment following use of fludioxonil in the biocidal product for preparation, application and use of paint, coatings, mineral sealants and fillers. Only indoor use of end-products treated with fludioxonil is specified and therefore only indoor use has been assessed. However outdoor use might be relevant for treated articles. Special attention should therefore be paid to outdoor use of treated articles containing fludioxonil.

Overall conclusion

Acceptable risks have been identified for both human health and the environment when fludioxonil is used in biocidal products for the preparation and indoor use of paints, coatings, mineral sealants and fillers.

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)	No classification required	Fludioxonil does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	vP	Fludioxonil does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB	

	Toxic (T)	Not T	10(1)
Endocrine disrupting properties	Fludioxonil is not considered to have endocrine disrupting properties. Fludioxonil does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. Fludioxonil does not fulfil criterion (b) of Article 10 (1).		
Concerns linked to critical effects	Fludioxonil is not considered to have any concerns linked to critical effects and therefore it does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Fludioxonil does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Fludioxonil does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Fludioxonil 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 criteria for a substance being a persistent organic pollutant (POP) are not met. Fludioxonil fulfils the criteria for being vP. However fludioxonil does not demonstrate the potential for long range transport.

2.3. BPC opinion on the application for approval of the active substance fludioxonil in product type 7

In view of the conclusions of the evaluation, it is proposed that fludioxonil 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: 950 g/kg.

   Relevant impurites: sodium 4-toluene sulphonate (SYN549410): maximum 5 g/kg and 1-[2-cyano-1-(2,2-difluoro-1,3-benzodioxol-4-yl)ethyl]-4-(2,2-difluoro-1,3-benzodioxol-4-yl)pyrrole-3-carbonitrile (SYN549129): maximum 1 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 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. Industrial and professional users.

3. The placing on the market of treated articles is subject to the following condition(s):
    a. The person responsible for the placing on the market of a treated article treated with or incorporating the active substance fludioxonil shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 as fludioxonil is toxic to aquatic life of acute category 1 (Aquatic Acute 1).

2.4. Elements to be taken into account when authorising products

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 is identified for industrial 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.

b. Altough fludioxonil has shown innate efficacy, it is not intended to be used as a stand-alone substance; it is intended to be used in combination with other fungicides to prevent the development of resistance.

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 fludioxonil.

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