Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Azoxystrobin

Product type: 9

ECHA/BPC/168/2017

Adopted 3 October 2017

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 azoxystrobin for product type 9

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 9 of the following active substance:

Common name:	**Azoxystrobin**
Chemical name:	Methyl(E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
EC No.:	-
CAS No.:	131860-33-8
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 Deutschland GmbH on 13 April 2014, the evaluating Competent Authority United Kingdom submitted an assessment report and the conclusions of its evaluation to the ECHA on 1 December 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via BPC (BPC-22) and it's Working Groups (WG III2017). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at https://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations on 10 February 2017, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 11 April 2017.

Adoption of the BPC opinion

Rapporteur: United Kingdom

The BPC opinion on the approval of the active substance azoxystrobin in product type [PT] was adopted on 3 October 2017.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

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 azoxystrobin in product type 9 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 azoxystrobin in product type 9. Azoxystrobin belongs to the strobilurin class of fungicides and acts by inhibition of mitochondrial respiration. 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 formulated product) and for the relevant and significant impurities. However, a validated method for the determination of the z-isomer in the product is required.

Validated analytical methods are available for the relevant matrices Water, Soil, Air and Blood. However a validated method is required for Tissues.

A harmonised classification according to Regulation (EC) No 1272/2008 is available. However, a classification proposal was submitted to ECHA by the UK in March 2017 to amend the existing harmonised classification by removing "*" and adding M-factors. The dossier has undergone an accordance check and was made available for public consultation in July 2017.

The classification and labelling for azoxystrobin according to (CLP Regulation) is:

(Current) Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Toxicity category 3* Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS06 GHS09
Signal Word	Danger
Hazard Statement Codes	H331 H400 H410
Specific Concentration limits, M-Factors	
Justification for the proposal	

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

(Proposed) Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Toxicity category 3 Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS06 GHS09
Signal Word	Danger
Hazard Statement Codes	H331 H400 H410
Specific Concentration limits, M-Factors	M = 10 (acute) and 10 (chronic)
Justification for the proposal	
Azoxystrobin has a harmonised classification of Acute Tox. 3 H331 Toxic if inhaled. The data provided (Parr-Dobrzanski (1992)) supports this classification. Acute category 1 consideration: Aquatic a.s endpoints are <1 mg a.s/L (fish LC_{50} 0.47 mg/l, crustacean EC_{50} 0.055mg/l, algae E_rC_{50} 0.146 mg/l) and therefore acute category 1 is required. M factor of 10 (>0.01 to ≤ 0.1). Chronic category 1 consideration: Fish NOEC 0.147 mg a.s/L, crustacean NOEC 0.00954 mg a.s/L, algae NOEC 0.02 mg a.s/l. Active classified as chronic category 1 based on these species and assumption of 'not' readily biodegradable. M factor of 10 (>0.001 to ≤ 0.01).	

b) Intended use, target species and effectiveness

Azoxystrobin is used in biocidal preservative products which are applied to or incorporated into various end applications covering protection of paper that is used for the production of wall linings. Biocidal products containing azoxystrobin will be used by industrial users while the end-use treated items will be used by professionals and non-professionals indoors.

Azoxystrobin acts through the inhibition of mitochondrial respiration (inhibition of Complex III: cytochrome bc1 (ubiquinol oxidase) at the Qo site (cyt b gene)). The data on azoxystrobin and the representative biocidal product have demonstrated sufficient efficacy against the target species.

Azoxystrobin has a single site mode of action and therefore there is the potential for resistance development. However, as it is intended that azoxystrobin will normally be used in conjunction with other fungicides, this restricts the potential for resistance to develop.

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

Human health

Azoxystrobin is classified as Toxic by inhalation following acute exposure, but is of low oral and dermal toxicity. Azoxystrobin does not meet the classification criteria for skin, eye and respiratory tract irritation or skin sensitisation. In repeated dose studies, the liver was identified as the target organ for toxicity. Azoxystrobin 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 production of preserved paper	Primary exposure to biocidal product – industrial worker mixing/loading the representative biocidal product into automated machinery and associated handling of equipment in the production of preserved paper	Industrial worker	Acceptable without PPE.
Industrial production of preserved paper	Primary exposure to biocidal product – industrial worker cleaning and maintenance of machinery and vessels after use	Industrial worker	Acceptable without PPE.
Cutting, sawing or drilling gypsum board (drywall)	Primary exposure to preserved material – adult cutting, sawing or drilling plasterboard	Professional	Acceptable without PPE.
Cutting, sawing or drilling gypsum board (drywall)	Secondary exposure to preserved material – adult cutting, sawing or drilling plasterboard	Non-professional	Acceptable.
Chewing gypsum board (drywall) off-cut	Secondary exposure to preserved material – a young child (toddler) oral exposure to plasterboard off-cut	General public	Acceptable.

In the production of gypsum boards (drywall), preserved paper is used and falls therefore under PT 9.

Primary exposure of industrial workers to the representative biocidal product during mixing and loading and cleaning and maintenance operations showed acceptable risks without use of PPE.

Primary exposure of professional and non-professional users to the preserved material following cutting, sawing or drilling showed acceptable risk without use of PPE.

Secondary exposure of the general public to preserved materials showed no unacceptable risks.

A dietary risk assessment was not undertaken as exposure to food from the use pattern is not expected.

Environment

Azoxystrobin is stable to hydrolysis under environmental conditions. The whole system $DegT_{50}$'s for both water sediment systems exceed the criteria for both persistent (P) and very persistent (vP). In soil laboratory and field studies (in the dark) the criteria for P and/ vP was triggered for several soils. Azoxystrobin has a medium to low potential for mobility in soil. There is no indication of bioaccumulation potential for azoxystrobin. Azoxystrobin is toxic to aquatic organisms (in particular to aquatic invertebrates). As a result, toxic (T) criteria is triggered.

Azoxystrobin can degrade via hydrolysis to form R401553 and R402173, or via microbial degradation to form R234886. R401553 and R402173 were not observed in sediment in freshwater sediment systems. R401553 has a high to low potential mobility in soil, whilst R402173 is classified as having a medium to very high mobility. R402173 exhibits pH dependent adsorption with maximum adsorption occurring under acidic conditions. R401553

and R402173 are considered potentially P or vP. R234886 is hydrolytically stable. Degradation and adsorption in soil was found to be pH dependent with degradation rates and the potential for leaching greater at higher pH values. R234886 fulfils the criteria for P properties and is potentially vP. R234886, R402173 and R401553 are unlikely to bioaccumulate and are not considered to be toxic to aquatic organisms.

Azoxystrobin has a low vapour pressure which together with the intended use suggests that emissions to air will be negligible. Vapour pressure was not determined for the metabolites.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Treatment, use and recycling of drywall paper.	Environmental compartments: STP, aquatic (freshwater), terrestrial, groundwater, atmospheric.	Atmospheric: acceptable STP: acceptable Aquatic: acceptable providing <40 % treated paper is recycled. Terrestrial: acceptable Groundwater: acceptable

Acceptable risks are identified for the atmospheric, STP and terrestrial compartments.

A potential risk to the aquatic compartment is identified for the recycling of treated paper formed as a waste at the industrial site, if > 40 % of treated paper is recycled. However, given the described use in drywall manufacture, it is considered unlikely that large quantities of waste treated paper will be produced and sent for recycling. Thus, the risk to the aquatic compartment is considered to be acceptable.

For groundwater all PECgw values were < 0.1 µg/L and therefore the trigger value for groundwater in all scenarios is not exceeded noting that for PT 9 a refined application rate was used in the modelling.

Overall conclusion

Acceptable risks have been identified for both human health and the environment when azoxystrobin is used in biocidal products for the preparation, application and use of paper on drywall/gypsum wall boards.

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:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>no classification required</td><td rowspan="3">Azoxystrobin does not fulfil criterion (a), (b) and (c) of Article 5(1).</td></tr>
<tr><td>Mutagenicity (M)</td><td>no classification required</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>no classification required</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>vP

R401553: potential P or vP
R402173: potential P or vP
R234886: potential P or vP</td><td>Azoxystrobin does not fulfil criterion (e) of Article 5(1).</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>Not B or vB

R401553, R402173 and R234886: not B or vB</td><td rowspan="2">Azoxystrobin does fulfil criterion (d) of Article 10(1).</td></tr>
<tr><td>Toxic (T)</td><td>T

R401553, R402173 and R234886: not T</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">Azoxystrobin is not considered to have endocrine disrupting properties. Azoxystrobin does not fulfil criterion (d) of Article 5(1).</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="3">No classification required. Azoxystrobin does not fulfil criterion (b) of Article 10(1).</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="3">Azoxystrobin is not considered to have any concerns linked to critical effects and therefore it does not fulfil criterion (e) of Article 10(1)</td></tr>
<tr><td>Proportion of non-active isomers or impurities</td><td colspan="3">Azoxystrobin does not fulfil criterion (f) of Article 10(1).</td></tr>
</table>

Consequently, the following is concluded:

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

Azoxystrobin does meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore 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

Azoxystrobin fulfils the criteria for classification as vP and T, but not vB. Azoxystrobin does not have the potential for long range transport. Therefore, azoxystrobin does not fulfil the criteria for classification as a POP.

2.2.3. Public consultation for potential candidates for substitution

A public consultation regarding azoxystrobin PTs 7, 9 and 10 took place from 10 February 2017 to 10 April 2017. At the end of this period, 2 submissions were received (including one from the Applicant supporting azoxystrobin) arguing against the proposal for classification as Toxic for the environment. No information on alternatives was received.

The following active substances are approved for PT 9 and are not candidates for substitution: chlorocresol (CMK), fludioxonil and folpet.

2.3. BPC opinion on the application for approval of the active substance azoxystrobin in product type 9

In view of the conclusions of the evaluation, it is proposed that azoxystrobin 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: 965 g/kg**.**

   There are 4 relevant impurities:

   Z-isomer – maximum content 7 g/kg
   Toluene - maximum content 2 g/kg
   Methanol - maximum content 5 g/kg
   Dimethylformamide - maximum content 0.1 g/kg

2. Azoxystrobin is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 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)

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

   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.

4. The placing on the market of treated articles is subject to the following condition(s):

   The person responsible for the placing on the market of a treated article treated with or incorporating the active substance azoxystrobin 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)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012 as it is Acute Tox 3 (H331), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), and is very persistent (vP) and Toxic (T) in the environment).

2.4. Elements to be taken into account when authorising products

1. The active substance, azoxystrobin, is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for either national or Union authorisation.

2. Although azoxystrobin 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 azoxystrobin.

However, further data on the active substance are required and should be provided to the evaluating Competent Authority (UK) as soon as possible but no later than the date of approval of the active substance:

- Determination of the relevant impurity z-isomer of azoxystrobin;
- Validated method of analysis for the determination of azoxystrobin in tissues, with an appropriate LOQ;
- Ames test on a representative batch of azoxystrobin.

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