Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Propiconazole

Product type: 7

ECHA/BPC/33/2014

Adopted

4 December 2014

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Opinion of the Biocidal Products Committee

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

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 7 of the following active substance:

Common name:	**Propiconazole**
Chemical name(s):	**[1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole]**
EC No.:	**262-104-4**
CAS No.:	**60207-90-1**
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 Syngenta European Center on 30 October 2008 and the replacement of the applicant by LANXESS Deutschland GmbH on 6 April 2011, the evaluating Competent Authority Finnish Safety and Chemicals Agency submitted an assessment report and the conclusions of its evaluation to the Commission on 6 November 2013. 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 Finland.

The BPC opinion on the approval of the active substance propiconazole in product type 7 was adopted on 4 December 2014.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the propiconazole 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 propiconazole in product type 7. Propiconazole is a triazole substance and acts by inhibition of the C_{14} demethylation step in the ergosterolbiosynthesis of fungi. The active substance consists of four isomers which all have biocidal activity. 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 which are present at quantities > 0.1 g/kg. Validated analytical methods are required and available for the relevant matrices soil, surface water, sediment, drinking water and air, and shown to be sufficiently sensitive with respect to the levels of concern.

The harmonised classification and labelling for propiconazole according to the Regulation (EC) No 1272/2008 (CLP Regulation) is presented below. The re-evaluation of the active substance under the PPP process is currently ongoing. If new data submitted under the PPP process leads to the conclusions that an update of the classification is required, a CLH dossier will be prepared by the Finnish CA for the CLP Regulation, and will be submitted to ECHA by June 2015 in alignment with the PPP process.

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4, H302 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Labelling	
Pictograms	GHS07 GHS09
Signal Word	Warning
Hazard Statement Codes	H302 Harmful if swallowed H317 May cause allergic skin reaction H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	**-**

b) Intended use, target species and effectiveness

Propiconazole has been applied and evaluated for its use as a film preservative (PT7) to be used in paints and adhesives. Propiconazole protects the paint or adhesive film against fungal infestation. Application of paints containing the biocidal product is performed by brushing, rolling or spraying. As an adhesive, propiconazole is used in tile glues. These products are water-based ready-to-use glues. The likely concentration of propiconazole in the paint coatings and tile glues is 0.3 % (w/w).

In the microtiter test propiconazole showed innate efficacy for fungal species (*Penicillium citrinum, Chaetomium globosum, Cladosporium cladosporioides, Alternaria tenuissima, Aspergillus niger and Aureobasidium pullulans*) with the concentration of 0.3 %. MIC tests alone are not sufficient for an approval of the active ingredient as a product type 7 preservative. However, in the specific efficacy tests with paint coatings the concentration of 0.3 % was supported at least against one test species (*Aureobasidium pullulans*). Efficacy in tile glues was not demonstratated in the dossier.

Propiconazole is a triazole substance and triazoles are also used as medicines. Resistance of a human pathogen *Aspergillus fumigatus* to medically used triazoles has been found (e.g. casualties due to treatment failure reported in the Netherlands) and a concern about the use of triazoles in biocides and other chemicals has been raised. However, the source of the resistance is not yet clear and may also lie in agricultural or animal health use of triazoles and, therefore, no specific precautionary measurements with respect to biocide use are taken at this moment.

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

Human health

The evaluation of active substance did indicate that propiconazole is moderately toxic *via* oral administration, the liver being its target organ, and that it is a moderate skin sensitiser. It is free of mutagenic and carcinogenic effects as well as adverse effects on reproduction and development. Propiconazole interfers the steroid hormone synthesis but there is not enough data to conclude whether it has endocrine disrupting properties or not. The potential for endocrine disruption should be re-assessed once EU harmonised guidelines will be available.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Acceptable / Unacceptable**
Connecting/ Disconnecting transfer lines	Primary exposure - industrial use	Professionals	Acceptable with gloves
Maintenance of production machines	Primary exposure - industrial use	Professionals	Acceptable (gloves needed due to sensitizing property of a.s.)
Brush/roller painting including cleaning of brush, indoors	Primary exposure	Professionals	Acceptable with gloves and coated coveralls
		Non-professionals	Acceptable
Brush/roller painting including cleaning of brush, outdoors	Primary exposure	Non-professionals	Acceptable
Spraying including cleaning of equipment	Primary exposure	Professionals	Acceptable with gloves, double coveralls and RPE
		Non-professionals	Acceptable
Applying ready-to-use tile glue	Primary exposure	Professionals	Acceptable with gloves
		Non-professionals	Acceptable
Removal coating by sanding	Secondary exposure	Professionals	Acceptable
		Non-professionals	Acceptable
Ingestion of paint chips containing biocide residue	Secondary exposure	Infant	Acceptable
Dermal contact with wet paint	Secondary exposure	Toddler	Acceptable
Dermal contact with wet paint and mouthing	Secondary exposure	Infant	Acceptable
Cleaning work clothes at home	Secondary exposure	Professionals	Acceptable
Playing on weathered (playground) structure	Secondary exposure - dermal contact and mouthing	Infant	Acceptable

Chronic inhalation exposure to evaporated residues	Secondary exposure	Child	Acceptable

Professional and non-professional systemic exposures were evaluated for the scenarios summarized in the table above. Safe uses were identified for professionals when wearing appropriate personal protective equipment. The use of gloves is obligatory in all primary scenarios, in addition to coveralls during brushing and spraying and RPE during spraying. All primary non-professional scenarios are safe uses. The secondary exposure to propiconazole in coatings does not pose a risk to non-professionals or professionals.

Propiconazole is classified as Skin sens. 1 according to the Regulation (EC) No 1272/2008 (CLP Regulation). Due to skin sensitizing property PPE (gloves, coveralls) is required in the industrial use of the biocidal product. Non-professionals and professionals will be exposed during painting and applying ready-to-use tile glue for propiconazole concentration below the threshold for classification of the product as sensitizing according to the CLP Regulation. Secondary exposure may occur also to the propiconazole concentration below the threshold for classification of the product as sensitizing.

Environment

The table below summarises the exposure scenarios assessed for paint coatings. Most of them are related to wooden surfaces. Within PT7, propiconazole is also used to preserve adhesives as tile glues for indoor-use. Tile glues have a higher viscosity than coatings and therefore no splashing or dripping takes place during application. Since the active substance incorporated in the solidified tile glue will be located in a sealed compartment between wall (or floor) and tile after application, no potential for environmental release is given. Thus no environmental risk assessment is required for the use of propiconazole in adhesives as tile glues.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Dipping	Industrial, emission to surface water/sediment via STP and to soil via application of STP sludge
Dipping, storage	Industrial, direct emission to soil and surface water/sediment
Automated spraying, small plant and big plant	Industrial, emission to surface water/sediment via STP and to soil via application of STP sludge
Automated spraying, storage	Industrial, direct emission to soil and surface water/sediment
Noise barrier, in-service, wood treated in dipping or automated spraying application	Leaching to surface water/sediment via STP and directly to soil and via application of STP sludge to soil
City scenario, in-service, mineral surfaces	Application *in situ* Leaching from several houses to surface water/sediment via STP and to soil via application of STP sludge
Bridge over pond, in-service	Application *in situ* by brush, application *in situ* by brush + leaching in service, leaching in service after brushing, leaching in service after dipping or spraying Direct emission to surface water due to leaching Application *in situ* both by amateurs and professionals
House, in-service	Application *in situ* by brush, application *in situ* by brush + leaching in service, leaching in service after brushing, leaching in service after dipping or spraying Direct emission to soil due to leaching Application *in situ* both by amateurs and professionals
Fence, in-service	Application *in situ* by brush, application *in situ* by brush + leaching in service, leaching in service after brushing, leaching in service after dipping or spraying Direct emission to soil due to leaching Application *in situ* both by amateurs and professionals

With regard to surface water no unacceptable risk (PEC/PNEC < 1) was calculated for industrial use (application and storage) of propiconazole containing paint except for automated spraying plant of large size using the coating with 0.3% propiconazole. For sediment compartment unacceptable risk (PEC/PNEC > 1) was calculated for automated spraying plant of large size using the coating with 0.1% or 0.3% propiconazole. The conclusion remains the same if the PECs from the application and storage scenarios are summed up assuming that the releases from application via STP and from storage enter the same small creek at the same time which is, however, rather unusual. With regard to the industrial application scenarios it should be considered that emissions to sewage water and further to surface water during the applications process are not likely to occur, because it is common practice that in industrial big plants residues and waste solvent will be treated as hazardous waste and not allowed to enter the STP.

Unacceptable risk (PEC/PNEC > 1) to soil was calculated for *in situ* treatment in amateur use up to 30 days from the treatment. Both the parent compound and the main metabolite contribute to the identified risk. However, to prevent unacceptable risk to soil organisms risk mitigation is possible during *in situ* treatment by covering the soil with

protective sheeting.

The calculation example for 5 years' service-life of paints for mineral surfaces with the city scenario using 100 % leaching shows unacceptable risk (PEC/PNEC > 1) to sediment. For surface water the risk ratio is very close to 1 while risk ratios for STP and soil (via STP sludge application) are well below 1 indicating no unacceptable risk. Emission to STP from the application phase of the paint was calculated to correspond to approximately the same amount per day as daily leaching during 5 years of service-life so the risk ratios would also be corresponding. Leaching during the first 30 days of service-life according to the assumptions of the city scenario would mean much higher risk ratios. These conclusions substantiate the need for leaching tests on mineral surfaces with the relevant products for the product authorisation stage and the guidance to protect the surroundings of the façade to be treated for the time of application with temporary sheeting.

With regard to air, groundwater and the aquatic and terrestrial biota no concern was identified. Groundwater modelling was carried out with FOCUS PEARL according to the guidance in the revised OECD ESD for wood preservatives (2013).

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
	Mutagenicity (M)	No classification required
	Toxic for reproduction (R)	No classification required
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	vP
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B and not vB
	Toxic (T)	not T
Endocrine disrupting properties	Active substance is not considered to have endocrine disrupting properties; however, it has shown to have endocrine mechanism of action.	

Consequently, the following is concluded:

Propiconazole does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012. These conclusions have to be reviewed during the product authorisation stage if new evidence of endocrine disrupting properties is published.

Propiconazole 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

Propiconazole has been identified as vP, but not considered to be T or B.

Propiconazole is not expected to have long-range transport potential because the estimated half-life in air is between 10.2 and 42 hours, i.e. below the criterion of 2 days given for persistent organic pollutants (POP) as defined in the Annex D of the Stockholm Convention 2001.

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

In view of the conclusions of the evaluation, it is proposed that propiconazole shall be approved and be included in the Union list of approved active substances, subject to following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 960 g/kg

2. 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.

3. For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Only where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

4. Labels and, where provided, safety data sheets of biocidal products authorised for the preservation of films for outdoor use shall indicate that measures shall be taken to protect the soil during the application of the film to prevent losses and minimise emissions to the environment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means.

5. Biocidal products shall not be authorised for the preservation of paints used for outdoor application of mineral surfaces, unless it can be demonstrated in the application for product authorisation that risks for the aquatic compartment can be reduced to an acceptable level.

6. Where treated articles as paints and adhesives have been treated with or

[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)

intentionally incorporates propiconazole, and where necessary due to the possibility of skin contact as well as the release of propiconazole under normal conditions of use, the person responsible for placing the treated article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

The following options were proposed for an additional provision by the BPC to be considered in the decision making process in Article 9(1) of the BPR:

1. Due to the risks identified for the soil compartment the label and where provided the safety data sheets of paints for outdoor use preserved with propiconazole shall indicate that measures shall be taken to protect the soil when they are applied, unless it can be demonstrated that risks can be mitigated by other means.

2. Due to the risks identified for the soil compartment the label and where provided the safety data sheets of paints for outdoor use preserved with propiconazole shall indicate that measures shall be taken to protect the soil when they are applied.

3. Treated articles with propiconazole shall not be imported without a label stating that brushing outdoors without protection of the soil may pose risks; unless the use corresponding to the treatment has been authorised without labelling provisions at least in one Member State.

4. No further provision required.

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 it is skin sensitising category 1 and toxic to aquatic life of acute category 1.

2.4. Elements to be taken into account when authorising products

1. Whilst the efficacy data provided is sufficient to recommend approval of the substance, data demonstrating the efficacy of the product at the minimum application rate against the range of proposed target organisms using the recommended application equipment must be provided at the product authorisation stage.

2. The environmental risk assessment of *in situ* application only covered brushing (rolling) but not spraying. If the *in situ* spraying application method is relevant for coatings where the preservative product is to be included, the environmental risk assessment of the spraying method has to be carried out at the product authorisation stage.

3. Based on suspected properties of the azole group and insufficient data propiconazole is listed in the Annexes of the EU Commission document on implementation of the Community Strategy for Endocrine Disruptors as a substance which may have the potential to cause endocrine disruption in both humans and animals. With this in mind, the recent literature on endocrine disrupting effects of propiconazole has to be assessed and compared with its endocrine disrupting mechanism of action (MoA) described in section 2.2 when authorising products. The conclusion of this assessment might lead to review of the active substance approval.

4. The potential involvement of propiconazole with resistance of a human pathogen *Aspergillus fumigatus* to triazoles used for medical purposes could be of concern; the current status of reported cases of triazole resistance in human clinical settings should be taken into account. In addition, the substance supplier shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

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 propiconazole. However, further data shall be required as detailed below:

An aerobic water-sediment simulation test with 14C-phenyl labelled propiconazole is required. The study should be provided as soon as possible and at the latest 6 months before the date of approval to the evaluating Competent Authority (Finland).

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