Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Propiconazole

Product type: 8

ECHA/BPC/324/2022

Adopted

9 March 2022

Opinion of the Biocidal Products Committee

on the application for renewal of the approval of the active substance propiconazole for product type 8

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 renewal of the approval in product type 8 of the following active substance:

Common name:	**Propiconazole**
Chemical name:	**(2RS,4RS;2RS,4SR)-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**

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 27 September 2018. The ED Expert Group of ECHA was consulted in written procedure in October 2019 and the substance was subsequently discussed at the 16th ED EG meeting in December 2019. The evaluating Competent Authority (Finnish Safety and Chemicals Agency) submitted an assessment report and the conclusions of its evaluation to ECHA on 2 June 2021. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via, BPC (BPC-42) and its Working Groups (WG-IV-2021). 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/potential-candidates-for-substitution-previous-consultations on 8 July 2021, 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 6 September 2021.

Adoption of the BPC opinion

Rapporteur: Finland

The BPC opinion on the renewal of the approval of the active substance propiconazole in product type 8 was adopted on 9 March 2022.

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 simple majority of the members present having the right to vote.

The opinion and the minority position including their grounds are 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

Since propiconazole fulfils the criteria set in Article 5(1) of Regulation (EU) No 528/2012, the overall conclusion of the BPC is that the approval of propiconazole in product type 8 should normally not be renewed, unless one of the condition for derogation in Article 5(2) is met. The process related to the demonstration of whether the conditions for derogation set in Article 5(2) are met, is not in the remit of the BPC. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1.1. 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 8, approved as an existing active substance under the Biocidal Products Directive in 2008 via Directive 2008/78/EC. Following the application for renewal it was decided that according to Article 14(2) of the BPR a full evaluation was necessary. Due to this and some delays in the peer review process, the expiry date of the approval was postponed twice and is now 31 December 2022 as laid down in Implementing Decision (EU) 2021/354 of 25 February 2021.

The following information was generated since the initial approval and was submitted by the applicant:

i. A new representative product has been evaluated.
ii. Physical hazards have been evaluated according to the criteria of CLP and 4 new studies (explosives, self-reactive substances, oxidising liquids and corrosive to metals) have been provided.
iii. New analytical methods have been evaluated as follows: analysis of propiconazole and the impurities in technical propiconazole, monitoring methods for determination of propiconazole and its metabolites in soil, water and air as well as determination of propiconazole in body fluids and tissues.
iv. Repr. 1B; H360D classification was added to the active substance due to updated harmonized classification.
v. Dermal absorption values were re-calculated according to EFSA Guidance on Dermal Absorption (2017).
vi. AEL $_{\text{long term}}$ was added to the evaluation to complete the set of previously agreed toxicological reference values.
vii. Seven new studies altogether (acute oral, acute dermal, primary skin irritation, primary eye irritation and 3 *in vitro* genotoxicity) had been completed since the initial active substance approval, mostly to support regulatory requirements in other regions.
viii. New statistical analyses for sub-chronic oral toxicity and carcinogenicity had been completed.
ix. One new *in vivo* genotoxicity study was conducted and reported in the published literature and in addition one subsequent analysis and two evaluations of this study had been completed.
x. All the above-mentioned new toxicity data support the existing conclusions. However, based on the new study on skin irritation and supported by old studies, propiconazole needs to be labelled with EUH066 — Repeated exposure may cause skin dryness or cracking.

xi. New laboratory studies on degradation in soil and freshwater were conducted. In the soil studies three new major metabolites were identified.
xii. Data on soil adsorption/desorption, degradation and ecotoxicity of the new soil metabolites were provided.
xiii. ED assessment of propiconazole for both human health and the environment (non-target organisms) has been included. There were relevant data from the literature and/or regulatory studies available.
xiv. The applicant has carried out a survey on the technical feasibility of the alternatives among the manufacturers of wood preservative products and downstream users. The results from this survey was used in an assessment of possible non-renewal which was submitted for the renewal application. The eCA prepared an analysis of potential alternatives based on the authorised wood preservative products in the EU as disseminated on the ECHA website. The applicant has submitted two documents on potential measures to minimise human exposure to propiconazole in wood preservatives and environmental exposure via leaching of propiconazole.

The active substance consists of four isomers which all have biocidal activity. Specification for the reference source was not established in the first approval and therefore following the Renewal guidance the reference specification of propiconazole was established for the renewal of its approval. The reference specification now includes two sources previously assessed as technically equivalent.

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 significant impurities. Validated analytical methods are available for the relevant matrices water, soil, air and animal and human body fluids and tissues. Analytical methods for residues in food and feedstuffs are not required based on the classification of the active substance and authorised uses of the biocidal products.

The approval of the active substance propiconazole under Plant Protection Products Regulation, EC No 1107/2009, was not renewed[1] based on its classification as Repr. 1B according to Regulation (EC) No 1272/2008 (CLP Regulation). EFSA peer review (EFSA Conclusion) on propiconazole from year 2017 is available at https://www.efsa.europa.eu/en/efsajournal/pub/4887.

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

Current classification according to the CLP Regulation	
Hazard Class and Category Codes	Repr. 1B Acute Tox. 4 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS08 GHS07 GHS09

[1] COMMISSION IMPLEMENTING REGULATION (EU) 2018/1865 of 28 November 2018 concerning the non-renewal of approval of the active substance propiconazole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011.

Signal Word	Danger
Hazard Statement Codes	H360D H302 H317 H410
Specific Concentration limits, M-Factors	M = 1 M = 1
Justification for the proposal	
-	

As mentioned above it is proposed that propiconazole needs to be labelled with EUH066 — Repeated exposure may cause skin dryness or cracking.

b) Intended use, target species and effectiveness

Propiconazole has been evaluated for its use as wood preservative (PT 8). It is intended to be used as fungicide against wood destroying and discolouring fungi. The submitted dossier for renewal supports the use of propiconazole as wood preservative for use class (UC) 2 and 3 of a solvent based formulation for industrial and professional users. The evaluated application methods cover brushing/rolling, automated spraying and fully automated dipping. It should be noted that there are also authorisations of propiconazole containing products for UC 3 and 4 wood vacuum-pressure impregnation in the EU. However, the representative product is not used in vacuum-pressure impregnation and this use was not evaluated.

Propiconazole is a triazole derivative and acts by inhibition of the C_{14} demethylation step in the ergosterol biosynthesis of fungi. The data on propiconazole and the representative biocidal product has demonstrated sufficient efficacy against the target species. In the dossier submitted for the renewal the efficacy against wood discolouring fungi in use class 3 was validated with the use of a top coat.

Resistance to fungicides is a normal phenomenon embodied in the natural process of the evolution of biological systems and all DMIs (demethylation inhibitors), including propiconazole, have a similar risk for resistance development, although resistance factors may differ. The risk of resistance development can be reduced by the combined use of active substances with different modes of action.

Products containing triazole derivatives are also used as a medicine and resistance of a human pathogen *Aspergillus fumigatus* to triazole derivatives used for medical purposes has been reported (e.g. casualties due to treatment failure reported in the Netherlands). There are indications that there may be multiple sources of resistance including agricultural use of (tri)azole derivatives. The concern has further strengthened by the results from a couple of recent studies about triazole-resistance selection of fungi (*A. fumigatus*) in the environment from the Netherlands. In these studies several hotspots of azole-resistant A. fumigatus were identified, including flower bulb waste, green waste, and wood chip waste. Genetic analysis showed that identical resistance mechanisms were found in azole resistant strains from these hotspots and in strains isolated from patients. In samples of wood waste of type B (painted, lacquered or glued) and C (treated with wood preservatives) containing propiconazole and tebuconazole high levels of resistance were found at biomass processing facilities. The texture of the material was found to be of importance; azole-resistant *A. fumigatus* was only found in fine to semi-coarse material. Furthermore, a study showing the presence of azole-resistant *Aspergillus fumigatus* in sawmills of Eastern France processing wood treated with propiconazole and tebuconazole has recently been published. The possible role of other sources of use of triazole derivatives such as in animal health or cosmetics is not yet clear.

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

Human health

Propiconazole is moderately toxic via oral administration, the liver being its target organ. In addition it is a moderate skin sensitiser and reproductive toxicant causing adverse effects on development. It is not genotoxic or carcinogenic. The available data on corrosion and irritation does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP). Due to dry and cracked surface of the skin observed after one exposure in a skin irritation study, EUH066 labelling is proposed.

Propiconazole has endocrine disrupting properties with respect to humans. It has adverse effects (increased anogenital distance and disturbed oestrus cyclicity) in the studies on rats from literature. Propiconazole has activity on steroidogenesis as it is an inhibitor of aromatase enzyme (CYP19). Aromatase converts testosterone to estradiol, and its inhibition leads to imbalance in circulating hormone levels. There is a plausible link between endocrine activity and adverse effects so propiconazole is considered to have endocrine disrupting properties according to Section A of Regulation (EU) 2017/2100.

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**
Automated spraying	Primary dermal and inhalation (only when spraying) exposure during connecting the transfer lines, spraying, handling of treated wood and maintenance work in industrial scale treatment unit.	Industrial user	No conclusion possible
Fully automated dipping	Primary dermal exposure during connecting the transfer lines, dipping process, handling of treated wood and maintenance work in the industrial scale treatment unit.	Industrial user	No conclusion possible
Professional brush/roller application	Primary dermal and inhalation exposure during brushing/rolling and cleaning the brush/roller.	Professional user	No conclusion possible
Professional sanding of treated wood	Secondary dermal and inhalation exposure when sanding of treated wood.	Professional user	No conclusion possible
Post-application	Secondary dermal and inhalation exposure when sanding of treated wood	General public (adult)	No conclusion possible
Post-application	Secondary dermal exposure when handling contaminated work clothes prior to putting to washing machine.	General public (adult)	No conclusion possible
Post-application	Secondary oral exposure when chewing wood off-cut.	General public (toddler)	No conclusion possible

Post-application	Secondary dermal and oral exposure when playing on weathered treated wood (playground) structure.	General public (toddler)	No conclusion possible
Post-application	Secondary inhalation exposure to volatilised residues from treated wood installed indoors.	General public (adult, toddler)	No conclusion possible

With regard to human health exposure, the risk related to primary exposure is considered acceptable with a conventional risk assessment (excluding ED properties) for industrial and professional users when appropriate personal protection equipment (PPE) are worn.

Concerning the secondary exposure, the risk is considered acceptable with a conventional risk assessment (excluding ED properties). Indirect exposure via food has not been assessed because no contact with food or feed is foreseen considering the intended uses.

With regard to endocrine disrupting properties, a risk assessment was presented for peer review, although no agreed methodology on how to assess such risks under the BPR is available. HH WG-IV 2021 (Working Group – Human Health) concluded that it was not possible to agree on the methodology to perform the risk assessment, on the point of departure and on the margin of exposure that would give confidence in a conclusion on safe use. Thus, it is not possible to conclude on the risk derived from the ED properties.

Regarding the acceptability of the risk, no conclusion is possible. It is concluded that given the uncertainties of the assessment and lack of methodology, it is currently not possible to determine whether the risk is acceptable or not for the industrial and professional user, or for the general public.

Exposure of industrial workers and professional to the propiconazole should be minimised as far as possible since it meets the exclusion criteria, and as no conclusion on risk derived from ED properties could be established. Secondary exposure of the general public must be minimized as fas as possible.

Environment

Propiconazole is hydrolytically and photolytically stable. Propiconazole is not readily biodegradable. Two water/sediment systems were investigated, with both systems having whole system DT50 values that exceed the criteria for both persistent (P) and very persistent (vP). In water/sediment systems, no major metabolite was formed.

For laboratory studies soil the DT50 exceeded the criteria for P/vP. Two of the four relevant soil metabolites of propiconazole (CGA91305 and 1,2,4-triazole) do not fulfil the P/vP criteria. NOA436613 and SYN547889 (isomers) fulfil the P-criterion, but not the vP-criterion.

Propiconazole adsorbs to soil and sediment and is therefore of limited mobility. All relevant soil metabolites are more mobile than propiconazole.

Propiconazole has a low bioaccumulation potential (not B or vB), but it fulfils the criteria for Toxic (T) due to its classification as Repr. 1B. It has adverse effects on fish reproduction (decrease in number of eggs). Propiconazole has an endocrine mode of action as it shows endocrine activity by interfering steroidogenesis. There is a biologically plausible link between the endocrine mode of action (activity on steroidogenesis by aromatase enzyme inhibition) and the adverse effects (reduced number of eggs). Thus, propiconazole is considered to have endocrine disrupting properties according to Section B of Regulation (EU) 2017/2100.

Propiconazole has a low vapour pressure, which, together with the intended use, suggests that emissions to air will be negligible.

The table below summarises the exposure scenarios assessed. The scenarios are UC 3 wood, no environment exposure is assumed from UC 2 wood. In the risk assessment for soil compartment a major metabolite 1,2,4-triazole is included. The other three major soil metabolites (NOA436613, SYN547889, and CGA91305) are not ecotoxicologically relevant and thus, no PECsoil (Predicted Environmental Concentration) is calculated.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Application		
Automated spraying and fully automated dipping methods for UC 3	Industrial, emission to surface water/sediment via STP and to soil via application of STP sludge	No conclusion possible. Timber treatment with propiconazole must be undertaken at industrial sites where application processes must be carried out within a contained area; situated on impermeable hard standing, with bunding to prevent run-off and a recovery system in place (e.g. sump).
Storage of freshly treated timber at application plant	Industrial, direct emission to soil and surface water/sediment	No conclusion possible. Freshly treated timber must be stored after treatment under shelter or on impermeable hardstanding, or both, to prevent direct losses to soil, sewer or water. Any losses of wood treatment solution shall be collected for reuse or disposal.
Application in situ + service life of treated wood		
Professional brush/roller application UC 3 House	Direct emission to soil	No conclusion possible. Ground must be covered during application of the products.
Professional brush/roller application UC 3 Bridge over pond	Direct emission to surface water/sediment	No conclusion possible.
Service life of treated wood		
Noise barrier, in service only UC 3	Leaching to STP (and secondary via STP to surface water/sediment and application of sludge to soil) and direct emission to soil	No conclusion possible.

Bridge over pond, in service only UC 3	Direct emission to surface water/sediment	No conclusion possible.
House, in service only UC 3	Direct emission to soil	No conclusion possible.
House, in service only UC 3	Emission to groundwater	Acceptable for propiconazole. Three major metabolites. NOA436613 exceed 0.1 µg/L for the Hamburg, Jokioinen and Okehampton scenarios.

In a conventional risk assessment (excluding ED properties), no unacceptable risks are calculated for the STP (Sewage Treatment Plant), surface water and sediment except for industrial spray application in large plants for surface water and sediment and industrial dipping for sediment. However, the ESD (Emission Scenario Document) for PT 8 (2013) confirms that the release of wood preservatives from treatment installations to the STP is not permitted in EU countries. Emissions to the sewer system from industrial sites should therefore not occur in practice and the theoretical risks can be considered acceptable.

In a conventional risk assessment (excluding ED properties), no unacceptable risks to soil are calculated for all scenarios except of the storage scenarios after 20 years and the in-situ house scenario after 30 days service-life (brushing). For the storage scenarios, the risks are acceptable, when the following RMM (Risk Mitigation Measure) is applied: freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of wood treatment solution shall be collected for reuse or disposal. For the in-situ scenario, the unacceptable risk is mainly due to losses during the application step. Therefore, as an RMM, the ground should be covered during application, which will minimize the risks for soil organisms during the application step. Scenarios for the service-life of treated wood show acceptable risk in the conventional risk assessment.

Modelled concentrations in groundwater were below 0.1 µg/L for propiconazole and its major soil metabolites except for NOA436613 in Hamburg, Jokioinen and Okehampton scenarios.

Currently no thresholds/safe concentration limits with regard to environmental non-target organisms can be derived for the endocrine disrupting properties of propiconazole due to a variety of uncertainties associated with such an approach. In practice, lack of threshold concentrations means that no PNECs (Predicted No Effect Concentration) can be derived, and therefore, a quantitative risk assessment with respect to ED properties cannot be conducted. In addition, a qualitative risk assessment is neither possible at this point of time as release cannot be excluded.

Negligible exposure cannot be assumed for wood preservatives of UC3 and UC4 due to lack of generally accepted RMMs for wood in service. Exposure to the environment shall be minimised as far as possible, since no conclusion on risk derived from ED properties could be established.

In the assessment it is assumed that a certain area of wood (1 m^2) treated via any superficial application method (brushing/rolling, dipping or spraying) releases a similar daily amount of active substance during the wood service-life outdoors (UC 3).

Overall conclusion

No unacceptable risks to human health and the environment are identified by the conventional risk assessment methods (excluding ED properties) of BPR guidance Vol. III and IV when risk mitigation methods are applied. However, no conclusion on the level of risks of using

propiconazole considering its endocrine disrupting properties can currently be drawn, as neither guidance nor a harmonised understanding on the principles of an ED risk assessment is available.

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	Propiconazole fulfils criterion (c) of Article 5(1)
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	Cat 1B	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	P and vP	Propiconazole does not fulfil criterion (e) of Article 5(1) but fulfils criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	Yes	Propiconazole fulfils criterion (d) of Article 5(1) and criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	Yes	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification is required for respiratory sensitisation. Propiconazole does not fulfil criterion (b) of Article 10(1).		

Property		Conclusions
Concerns linked to critical effects other than those related to endocrine disrupting properties	Propiconazole is considered to have concerns linked to critical effects and therefore it fulfils the criterion (e) of Article 10 (1).	
Proportion of non-active isomers or impurities	Propiconazole does not contain a significant proportion of non-active isomers or impurities and hence does not fulfil the criterion (f) of Article 10(1).	

Consequently, the following is concluded:

Propiconazole meets the exclusion criteria laid down in Article 5(1)(c) and (d) of Regulation (EU) No 528/2012.

Propiconazole meets the conditions laid down in Article 10(1)(a), (d) and (e) 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"[2], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment[4]" agreed at the 54th, 58th and 77th 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 and T, but not considered to be 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. Thus, propiconazole does not meet POP criteria.

2.2.3. Identification of potential alternatives substances or technologies, including the results of the public consultation for potential candidates for substitution

As propiconazole is considered a potential candidate for substitution ECHA launched the public consultation in accordance with Article 10(3) of Regulation (EU) 528/2012, which took place from July 2021 to September 2021. During the consultation 78 contributions were received.

According to the submitted statements lack of sufficient amount of alternatives is obvious. Wood preservative active substances, propiconazole among others, are typically used in combination in biocidal products. According to the search made using the ECHA website in August 2020, around 60% of total authorisations in PT 8 contain propiconazole. Therefore, it

[2] 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)

[3] 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)

[4] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

can be assumed that exclusion of propiconazole will have a major impact on the market of wood preservatives and the availability of wood preservatives to the users.

There are currently 12 fungicides for PT 8 that do not fulfil the exclusion criteria or are not candidates for substitution. In addition, there are alternatives either meeting the exclusion or substitution criteria or having not been commercialised in wood preservative products so far (no existing product authorisations).

The table summarises the analysis of the alternatives:

	Temporary treatment against wood discolouring fungi (anti-sapstain uses)	**Use classes 3 in prolonged wetting conditions and 4 (industrial treatment of structural wood)**	**Use classes 2 and 3 in limited wetting conditions (professional treatment of joinery)**	**Brush or spraying applications by professional users**
IPBC	Products with IPBC alone authorised against wood discolouring fungi	-	Products with IPBC alone authorised against wood discolouring fungi	Does not cover the full spectrum of basidiomycetes but in combination with penflufen potential alternative
Copper compounds: • Basic Copper carbonate • Copper (II) oxide • Copper hydroxide • Cu-HDO • Granulated copper	-	Need a co-biocide of sufficient spectrum of efficacy	-	-
Quaternary ammonium compounds: • ADBAC/BKC (C12-16) • ATMAC/TMAC • DDACarbonate • DDAC • Bardap 26	Target species included in the a.s. approvals, one TMAC/ disodium tetraborate pentahydrate product in the market (transitional period)	Need a co-biocide of sufficient spectrum of efficacy	-	-
Penflufen	-	Potential alternative at least in oil-based products	Potential alternative	In combination with IPBC potential alternative
Tebuconazole	Fulfils substitution criterion in Article 10(1)(d)			
Boron compounds: • Boric acid • Disodium tetraborate	Fulfil exclusion criterion in Article 5(1)(c)			

	Temporary treatment against wood discolouring fungi (anti-sapstain uses)	**Use classes 3 in prolonged wetting conditions and 4 (industrial treatment of structural wood)**	**Use classes 2 and 3 in limited wetting conditions (professional treatment of joinery)**	**Brush or spraying applications by professional users**
pentahydrate				
Isothiazolinones: • DCOIT • OIT	No products for PT8 in the market although active substances approved under BPR			

It has to be highlighted that for none of the other active substances for PT8, the endocrine disrupting properties have been evaluated according to the scientific criteria specified in Regulation (EU) 2017/2100.

Kiln drying (i.e. drying the timber in an oven) alone does not offer long-term protection for freshly sawn timber against wood discolouring fungi (sapstain), since upon exposure to moisture, the wood may become susceptible to fungal attack again. Heat treatment of wood and to a less extent chemical modification such as acetylation and furfurylation are used to produce wood for UC 2 and UC 3. Due to the technical characteristics of these kinds of wood they are not suitable for all of the forms of timber construction materials that propiconazole is currently used to treat.

There are alternative materials for use in outdoor construction (i.e. part of UC 3 and UC 4). These, however, may not always be technically or economically feasible and may raise their own sustainability issues. With respect to other materials than wood such as steel, concrete, plastic and composite one should bear in mind that wood is an abundant and sustainable construction material which also provides a store for biogenic carbon. No new information about the availability of alternative technologies was provided in the public consultation.

To conclude, alternative active substances are available for at least some uses but their technical feasibility and the availability of products in different Member States have not been analysed in detail. As propiconazole is a broad-spectrum fungicide its substitution may require more than one active substance. Non-chemical alternatives are also available for some uses but cannot substitute all uses of wood treated with propiconazole.

2.3. BPC opinion on the application for approval of the active substance propiconazole in product type 8

As the exclusion criteria are met, propiconazole should normally not be approved unless one of the condition for derogation set in Article 5(2) of BPR is met.

The BPC is of the opinion that specific provisions for treated articles containing propiconazole are needed as propiconazole meets the exclusion criteria laid down in Article 5(1)(c) and (d) of Regulation (EU) No 528/2012. However, considering that propiconazole should normally not be approved unless one of the condition for derogation set in Article 5(2) of BPR is met, the BPC considered it premature to include such specific provisions.

If propiconazole is renewed, the renewal shall be subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 950 g/kg. The cis/trans isomeric ratio is 1.25-1.60.

2. Propiconazole is considered a candidate for substitution in accordance with Article 10(1)(a), (d) and (e).

3. 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. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.

    b. Products shall only be authorised for use in Member States where at least one of the condition set in Article 5(2) of Regulation (EU) No 528/2012 is met.

    c. According to point (d) of Article 19(4) of Regulation (EU) No 528/2012, products shall not be authorised for making available on the market for use by the general public.

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

        i. industrial users;

        ii. the soil compartment;

        iii. groundwater.

    e. Labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses from the application of the product shall be collected for reuse or disposal.

    f. Labels and, where provided, safety data sheets of products authorised shall indicate that for in-situ treatment at a site outdoors the soil shall be protected with a plastic foil or tray and any losses from the application of product shall be collected and disposed by safe means.

    g. For products containing propiconazole that may lead to residues in food or feed, Member States shall verify the need to set new or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

4. 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 propiconazole 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 it is reproduction toxic category 1B, skin sensitising category 1 and toxic to aquatic life of acute category 1. Furthermore, the active substance is considered to have endocrine disrupting properties according to Section A and B of Regulation (EU) 2017/2100.

2.4. Elements to be taken into account when authorising products

1. The active substance propiconazole 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 national authorisation.

2. The potential involvement of propiconazole with resistance of a human pathogen *Aspergillus fumigatus* to triazole derivatives used for medical purposes is 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.

3. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products or renewing product authorisations, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

    a. In line with Article 5(2) of Regulation (EU) No 528/2012, the use of a biocidal product containing propiconazole shall be subject to appropriate measures to ensure that exposure of humans, animals and the environment is minimised as far as possible taking into account that it is considered to have endocrine disrupting properties.

    b. To minimise the exposure for industrial and/or 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 by other means taking into account the properties of propiconazole.

    c. For products that may lead to residues in food or feed a dietary risk assessment has to be performed at product authorisation level.

    d. Losses during industrial treatment must be contained and recycled or collected and treated as waste in accordance with the national regulations of the Member State authorising propiconazole products.

    e. Unacceptable risk is identified for soil following in-situ treatment at a site outdoors. 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.

    f. For wood in service groundwater concentration > 0.1 µg/L is identified for one of the major soil metabolites of propiconazole (NOA436613) in Hamburg, Jokioinen and Okehampton scenarios. If these scenarios are considered relevant for national product authorisation in the respective Member State and the concentrations cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance propiconazole.

Applicants should provide within the application for the next renewal all new data available to them on resistance of Aspergillus fumigatus to the active substance in the EU, including resistance to triazole derivatives used for medical purposes.

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