



2023/2596

22.11.2023

**COMMISSION IMPLEMENTING REGULATION (EU) 2023/2596**

**of 21 November 2023**

**renewing the approval of propiconazole as an active substance for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products <sup>(1)</sup>, and in particular Article 14(4), point (a), thereof,

Whereas:

- (1) The active substance propiconazole was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council <sup>(2)</sup> as an active substance for use in biocidal products of product-type 8. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved under that Regulation subject to the requirements set out in Annex I to Directive 98/8/EC.
- (2) On 1 October 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of propiconazole for use in biocidal products of product-type 8 (‘the application’). The application was evaluated by the competent authority of Finland (‘the evaluating competent authority’).
- (3) On 2 June 2021, the evaluating competent authority submitted a recommendation on the renewal of the approval of propiconazole to the European Chemicals Agency (‘the Agency’).
- (4) In accordance with Article 14(3) of Regulation (EU) No 528/2012, on 9 March 2022 the Agency adopted an opinion <sup>(3)</sup> formulated by its Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) Propiconazole is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(4)</sup>, and therefore meets the exclusion criterion set out in Article 5(1), point (c), of Regulation (EU) No 528/2012. Furthermore, according to the opinion of the Agency, propiconazole is considered as having endocrine-disrupting properties that may cause adverse effects in humans, and therefore meets the exclusion criterion set out in of Article 5(1), point (d), of Regulation (EU) No 528/2012.
- (6) Pursuant to Article 12(1) of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed if the active substance still meets the conditions laid down in Article 4(1) and at least one of the conditions set out in Article 5(2) of that Regulation.
- (7) The Commission, with the support of the Agency, carried out a public consultation in order to gather information as to whether the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

<sup>(3)</sup> Biocidal Products Committee (BPC) opinion on the application for approval of the active substance: propiconazole, Product type: 8, ECHA/BPC/324/2022, adopted on 9 March 2022.

<sup>(4)</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

- (8) The opinion of the Agency and the contributions to the public consultation were discussed with Member States representatives in the Standing Committee on Biocidal Products. Member States were also requested to indicate whether they consider that at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 would be met in their respective territory, and to provide justifications.
- (9) From the information collected and the views expressed by Member States, it appears that propiconazole is still needed in Member States for certain uses.
- (10) Propiconazole is still needed for temporary treatment against wood-discolouring fungi (anti-sapstain use through industrial treatment). Tebuconazole could be a possible alternative of propiconazole, commonly used together with propiconazole in biocidal products for such use. However, tebuconazole has a lower efficacy against discolouring fungi compared to propiconazole. Tebuconazole also meets the criterion in Article 10(1), point (d), of Regulation (EU) No 528/2012, being very persistent (vP) and toxic (T) in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council <sup>(5)</sup>. Boron compounds (boric acid, disodium tetraborate pentahydrate) could act as possible alternatives to propiconazole for such use due to their anti-sapstain use. They meet the criterion in Article 5(1), point (c), of Regulation (EU) No 528/2012, as being classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008. The opinion of the Agency on the application of propiconazole and the opinion <sup>(6)</sup> of the Agency on the evaluation of the availability and suitability of alternatives to boron compounds do not allow to assess whether boron compounds would be more appropriate for this use compared to propiconazole. Other alternative biocidal products for this use include products containing the active substance IPBC, alone or in combination with propiconazole. However, IPBC might not be effective against all occurring discolouring fungi.
- (11) Propiconazole is still needed for industrial and professional treatment of structural wood (wood used in a loadbearing capacity in buildings and structures where the strength of the timber is the primary consideration, such as sheds, joists, bridges, jetties, poles, decking, fence poles, etc.) in certain use classes <sup>(7)</sup> as described in the European standard EN 335:2013 and defined in terms of service conditions, with reference to the generalised moisture content and the prevailing biological agents of deterioration, and in particular for use class 3 (situation in which the wood or wood-based product is above ground and exposed to the weather, particularly rain) and use class 4 (situation in which the wood or wood-based product is in direct contact with ground or fresh water) against discolouring and wood-rotting fungi. Several alternative biocidal products for such uses contain copper compounds, which need to be used in combination with another wood preservative active substance to formulate a water-based biocidal product of sufficient efficacy. Propiconazole and/or tebuconazole are commonly used in combination with copper compounds for such uses. Tebuconazole cannot replace propiconazole due to the same reasons as explained in recital 10. Moreover, tebuconazole has a complementary efficacy to propiconazole against wood-rotting fungi, having a different spectrum of rotting fungicidal activity in wood. Other alternative water-based biocidal products contain quaternary ammonium salts ('quats'), which on their own do not have sufficient efficacy against discolouring and wood-rotting fungi. There are biocidal products containing mixtures of copper/quats formulations, but they present technical limitations (e.g. lower long-term efficacy, may give rise to the corrosion of metal joints which are in contact with the treated wood). Boron compounds are usually not technically suitable for such use, since they are highly water soluble, making them prone to leaching. Finally, alternative oil-based biocidal products based on penflufen as an active substance have been recently developed, but more time is needed to test and have a sufficient return on experience of these biocidal products.
- (12) Propiconazole is still needed for industrial and professional treatment of joinery (wood products coming from the practice of physically joining pieces of wood together, such as windows, doors, rooflights, cladding, lining boards, cover floors, fence rails, etc.) in use class 2 (situation in which the wood or wood-based product is under cover and not exposed to the weather, particularly rain and driven rain, but where occasional, but not persistent, wetting can

<sup>(5)</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

<sup>(6)</sup> Biocidal Products Committee (BPC) opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on the evaluation of the availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate, ECHA/BPC/271/2020, adopted on 2 December 2020.

<sup>(7)</sup> ECHA Guidance on the Biocidal Products Regulation, Volume II: Efficacy, Parts B+C: Assessment and Evaluation, Version 5.0, November 2022.

occur) and use class 3 against discolouring and wood-rotting fungi. Biocidal products for such uses usually contain IPBC, propiconazole and/or tebuconazole. Tebuconazole cannot replace propiconazole for the same reasons as explained in recital 11. Biocidal products containing only IPBC for such uses exist but are not always suitable due to their insufficient efficacy against wood-rotting fungi. Higher concentrations of IPBC could increase its efficacy but may give rise to yellowing of the treated wood. The isothiazolinones 2-octyl-2H-isothiazol-3-one ('OIT') and 4,5-Dichloro-2-octyl-2H-isothiazol-3-one ('DCOIT') bear technical limitations compared to propiconazole for wood preservation (OIT is known to exhibit a high leaching from treated wood; DCOIT is highly corrosive and exhibits a low stability in many wood preservative formulation types). There are currently no authorised biocidal products for wood preservation on the market containing OIT or DCOIT. As a result, biocidal products containing OIT or DCOIT cannot act as alternatives to propiconazole in the short term. Alternative biocidal products based on penflufen as an active substance have been recently developed, but more time is needed to test and have a sufficient return on experience of them.

- (13) Propiconazole is still needed for *in situ* brush, spraying or injection applications by professional users for use classes 2 and 3. Biocidal products for such uses usually contain IPBC, propiconazole and/or tebuconazole. Tebuconazole cannot replace propiconazole for the same reasons as explained in recitals 10 and 11. Biocidal products containing only IPBC for such uses are not suitable because IPBC does not have sufficient efficacy against wood-rotting fungi. Biocidal products with higher concentration of IPBC could provoke skin sensitising issues and yellowing of the treated wood. Alternative biocidal products based on penflufen and IPBC as active substances have been recently developed, but more time is needed to test and have a sufficient return on experience of them.
- (14) Alternative methods to the use of biocidal products to extend the durability of wood against fungi exist. Heat treatment of wood and to a lesser extent chemical modification, such as acetylation and furfurylation, are used to produce wood products for use classes 2 and 3. Due to the technical characteristics of these types of wood, they are not suitable for all the forms of timber construction materials that propiconazole is currently used to treat. Another alternative is the use of durable tropical hardwood, but it is less available, results in higher costs and negative impacts on sustainability.
- (15) Alternative materials to wood for the required use applications exist, such as steel, plastic, aluminum, and concrete, but those materials may not always be technically or economically feasible and may raise their own sustainability issues.
- (16) On the basis of the information collected, it is concluded that the non-renewal of the approval of propiconazole as an active substance for use in biocidal products of product-type 8 would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance for temporary treatment against wood-discolouring fungi (anti-sapstain use through industrial treatment), for industrial and professional treatment of structural wood in use classes 3 and 4, for industrial and professional treatment of joinery in use classes 2 and 3, and for *in situ* brush, spraying or injection applications by professional users in use classes 2 and 3. The condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is thus satisfied for those uses.
- (17) The Agency concluded that there are no unacceptable risks to human health and the environment from the use of biocidal products containing propiconazole, when leaving aside the endocrine disrupting properties of propiconazole, and when risk mitigation measures are applied to limit the exposure of humans, animals and the environment to propiconazole as far as possible, for example through the wearing of personal protective equipment by workers; by requiring that industrial application is to be conducted within a contained area, situated on impermeable hard standing, with bunding to prevent run-off and a recovery system in place (e.g. sump); that freshly treated timber is to 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 are collected for reuse or disposal; and providing that the ground is covered with a plastic foil or tray during outdoor professional brushing/rolling applications, and any losses from the applications of products should be collected and disposed by safe means. However, no conclusion on the level of risks of using propiconazole to human health and the environment considering its endocrine disrupting properties was drawn by the Agency.

- (18) Therefore, it has ultimately not been demonstrated based on the data available in the application that the representative biocidal product containing propiconazole for product-type 8 may be expected not to have unacceptable effects itself, or as a result of its residues, on human health and on the environment, and that it may be expected to satisfy the criteria set out in Article 19(1), point (b)(iii) and (iv), of Regulation (EU) No 528/2012.
- (19) However, the factor set out in Article 19(5) of Regulation (EU) No 528/2012 should be taken into account when considering the conditions for approval set out in Article 4(1) of that Regulation. In accordance with Article 19(5) of that Regulation, and notwithstanding paragraphs 1 and 4 of that Article, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) of that Article are not fully met where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation, which is similar to the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012. Since the condition set out in Article 5(2), point (c), of that Regulation is met for certain uses of propiconazole, the condition set out in Article 19(5) of that Regulation is also considered satisfied for the same uses. Therefore, the conditions set out in Article 4(1) of Regulation (EU) No 528/2012 in conjunction with the conditions set out in Article 5(2), point (c), of that Regulation are considered satisfied.
- (20) It is therefore appropriate to renew the approval of propiconazole for use in biocidal products of product-type 8, subject to compliance with certain conditions.
- (21) In particular, propiconazole is a candidate for substitution in accordance with Article 10(1), points (a), (d) and (e), of Regulation (EU) No 528/2012 and therefore the period of renewal should not exceed 7 years, pursuant to Article 10(4) of that Regulation.
- (22) Pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment should include an evaluation as to whether the conditions of Article 5(2) of that Regulation are satisfied. It should be provided that products may only be authorised for use in Member States where the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied.
- (23) Exposure of the environment to propiconazole should be minimised as far as possible since no conclusion on the risk derived from the endocrine disrupting properties of propiconazole could be established. Based on the views expressed by Member States, spray-drift by manual spraying is impossible to be mitigated at a site outdoors. Therefore, to guarantee the protection for the environment, *in situ* spraying applications of products by professional users should only be authorised for indoor use.
- (24) Furthermore, to ensure a high level of safety for human health, animal health and the environment and to ensure equal treatment between EU-manufactured and imported treated articles, the placing on the market of wood treated with propiconazole should be subject to conditions. In particular, in line with the conditions set out in the renewal of approval for the authorisation of biocidal products of product-type 8 containing propiconazole, treated articles treated with or incorporating propiconazole may be placed on the market only for use as wood treated for protection against wood-discolouring fungi (anti-sapstain industrial treatment), as structural wood for use class 3 (situation in which the wood or wood-based product is above ground and exposed to the weather, particularly rain) and use class 4 (situation in which the wood or wood-based product is in direct contact with ground or fresh water), and as joinery for use class 2 (situation in which the wood or wood-based product is under cover and not exposed to the weather, particularly rain and driven rain, but where occasional, but not persistent, wetting can occur) and use class 3.
- (25) In order to guarantee a safe use of treated articles treated with or incorporating biocidal products containing propiconazole and to enable users of treated articles to make informed choices, the person responsible for the placing on the market of a treated article treated with or incorporating propiconazole should ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012. Furthermore, Member States competent authorities should specify in the summary of the biocidal product characteristics of a biocidal product containing propiconazole the relevant instructions for use and precautions to be included on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012. Precautions should also include appropriate measures to reduce leaching and minimise exposure of humans, animals and the environment to propiconazole as far as possible.

- (26) Furthermore, to ensure a high level of safety for human health and taking into account that no conclusion on the risk derived from endocrine disrupting properties could be established, wood treated with propiconazole should not be placed on the market to produce furniture and play structures.
- (27) In order to allow sufficient time for economic operators to adapt to the requirements set down in this Regulation, a period of transition should be set to ensure that after such period, wood treated with biocidal products containing propiconazole is no longer placed on the market other than as wood treated for protection against wood-discolouring fungi (anti-sapstain industrial treatment), as structural wood for use classes 3 and 4, and as joinery for use classes 2 and 3 (excluding furniture and play structures).
- (28) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

*Article 1*

The approval of propiconazole as an active substance for use in biocidal products of product-type 8 is renewed, subject to the conditions set out in the Annex.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 21 November 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance <sup>(1)</sup>	Expiry date of approval	Product type	Specific conditions
Propiconazole	IUPAC 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	Minimum purity of the active substance evaluated: 950 g/kg.	30 November 2030	8	Propiconazole is a candidate for substitution in accordance with Article 10(1), points (a), (d) and (e), of Regulation (EU) No 528/2012. The authorisation of biocidal products using propiconazole as an active substance is subject to the following conditions: (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) pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied; (c) products may only be authorised for use in Member States where the condition set out in Article 5(2), point (c), of Regulation (EU) No 528/2012 is satisfied; (d) the use of biocidal products containing propiconazole shall be subject to appropriate measures to ensure that exposure of humans, animals and the environment to propiconazole is minimised as far as possible; (e) products may only be authorised for: (i) temporary treatment against wood-discolouring fungi (anti-sapstain use through industrial treatment); (ii) industrial and professional treatment of structural wood (wood used in a loadbearing capacity in buildings and structures where the strength of the timber is the primary consideration, such as sheds, joists, bridges, jetties, poles, decking, fence poles, etc.) in use class <sup>(2)</sup> 3 (situation in which the wood or wood-based product is above ground and exposed to the weather, particularly rain) and use class 4 (situation in which the wood or wood-based product is in direct contact with ground or fresh water);

				<ul style="list-style-type: none"> <li>(iii) industrial and professional treatment of joinery (wood products coming from the practice of physically joining pieces of wood together, such as windows, doors, rooflights, cladding, lining boards, cover floors, fence rails, etc.) in use class 2 (situation in which the wood or wood-based product is under cover and not exposed to the weather, particularly rain and driven rain, but where occasional, but not persistent, wetting can occur) and use class 3;</li> <li>(iv) <i>in situ</i> brush, spraying or injection applications by professional users of wood in use classes 2 and 3; <i>in situ</i> spraying applications are authorised for indoor use only;</li> <li>(f) in view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:             <ul style="list-style-type: none"> <li>(i) industrial and professional users;</li> <li>(ii) the soil compartment;</li> <li>(iii) groundwater;</li> </ul> </li> <li>(g) 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;</li> <li>(h) labels and, where provided, safety data sheets of products authorised shall indicate that for <i>in situ</i> treatment at a site outdoors, the soil shall be protected with a plastic foil or tray, and that any losses from the application of product shall be collected and disposed by safe means;</li> </ul>
--	--	--	--	--

			<p>(i) Member States competent authorities shall specify in the summary of the biocidal product characteristics of a biocidal product containing propiconazole the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), point (e), of Regulation (EU) No 528/2012, including a statement that wood treated with propiconazole shall not be used to produce furniture and play structures; precautions shall also include appropriate measures to be taken to reduce leaching and minimise exposure of humans, animals and the environment to propiconazole as far as possible.</p> <p>The placing on the market of treated articles treated with or incorporating propiconazole is subject to the following conditions:</p> <p>(a) as from 1 July 2024, treated articles treated with or incorporating propiconazole may be placed on the market only for use as:</p> <ul style="list-style-type: none"> <li>(i) wood treated for protection against wood-discolouring fungi (anti-sapstain industrial treatment);</li> <li>(ii) structural wood for use class 3 (situation in which the wood or wood-based product is above ground and exposed to the weather, particularly rain) and use class 4 (situation in which the wood or wood-based product is in direct contact with ground or fresh water);</li> <li>(iii) joinery for use class 2 (situation in which the wood or wood-based product is under cover and not exposed to the weather, particularly rain and driven rain, but where occasional, but not persistent, wetting can occur) and use class 3;</li> </ul> <p>(b) as from 1 July 2024, treated articles treated with or incorporating propiconazole shall not be placed on the market for the production of furniture and play structures;</p>
--	--	--	---



				<p>(c) 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 Article 58(3), second subparagraph, of Regulation (EU) No 528/2012, including a statement as from 1 July 2024 that wood treated with propiconazole shall not be used to produce furniture and play structures.</p>
<p>(<sup>1</sup>) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product made available on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.</p> <p>(<sup>2</sup>) The use classes described in EN 335:2013 are defined in terms of service conditions, with reference to the generalised moisture content and the prevailing biological agents of deterioration (ECHA Guidance on the Biocidal Products Regulation, Volume II: Efficacy, Parts B+C: Assessment and Evaluation, Version 5.0, November 2022).</p>				