

Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Permethrin

Product type: 8

ECHA/BPC/003/2014

Adopted

8 April 2014

Opinion of the Biocidal Products Committee

on the application for approval of the active substance permethrin for product type 8

In accordance with Article 89(1) of Regulation (EU) No 528/2012 (BPR) of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 8 of the following active substance:

Common name:	permethrin
Chemical name(s):	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC No.:	258-067-9
CAS No.:	52645-53-1
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority and Technical Meeting. The assessment report (AR) and conclusions, as a supporting document to the opinion, contain the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of applications by Bayer Environmental Science/Sumitomo Chemicals (UK) Plc. and Tagros Chemicals India Ltd on 24 March 2004, the evaluating Competent Authority Ireland submitted an assessment report and the conclusions of its evaluation to the Commission on 21 June 2010. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and the Commission via the Biocides Technical Meetings. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC member for Ireland

The BPC opinion on the approval of the active substance permethrin in product type 8 was adopted on 8 April 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 permethrin in product type 8 may be approved. The assessment report contains the detailed grounds for the overall conclusion.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance and representative biocidal product including classification of the active substance

This evaluation covers the use of permethrin in product type 8. Permethrin belongs to a class of pesticides known as synthetic pyrethroids. Permethrin is a reaction mass of four stereo-isomers: 1Rcis (5-10% w/w), 1Scis (15.0 – 20.0% w/w), 1Rtrans (45.0-55.0% w/w) and 1Strans (17.0-27.0% w/w). 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 analysis of permethrin as manufactured and for the determination of impurities. However, a validated chiral method for analysis of the four stereo-isomers in the biocidal product was not available. Validated analytical methods are available for water, soil and air. Other analytical methods are not required for the intended use.

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

Current classification according to CLP Regulation		
Hazard Class and Category Codes	Acute Tox. 4	H302
Hazard Statement Code(s)	Acute Tox. 4	H332
	Skin Sens. 1	H317
	Aquatic Acute 1	H400
Labelling		
Pictograms	GHS07 GHS09	
Signal Word	Warning	
Hazard Statement Codes	H302+H332: Harmful if swallowed or if inhaled H317: May cause an allergic skin reaction H410: Very toxic to aquatic life with long lasting effects	
Specific Concentration limits, M-Factors		
	M-Factor: 1000	

A change is incurred according to the Regulation (EU) 286/2011 amending the CLP Regulation: H400 (Acute Cat 1) will be changed to H410 (Acute Cat 1; Chronic Cat 1): very toxic to aquatic life with long lasting effects, in accordance with the principles of precedence for hazard statements outlined in Article 27 of the CLP Regulation.

Additionally, under the CLP Regulation the classification of permethrin as a skin sensitizer may be distinguished between category 1A and 1B. This was not possible under the previous dangerous substances legislation. The data evaluated comprise five studies three from the biocide process and two from the pesticide process. As the substance is currently classified sensitizer R43 and the two positive studies from the pesticide process the evaluating Competent Authority proposed retaining the classification as sensitizer according to the CLP Regulation and propose the classification of permethrin as a skin sensitizer category 1B. The proposed classification and labelling by the evaluating Competent Authority is shown below.

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4 H302 Acute Tox. 4 H332
Hazard Statement Code(s)	Skin Sens. 1 B H317 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
Labelling	
Pictograms	GHS07 GHS09
Signal Word	Warning
Hazard Statement Codes	H302+H332: Harmful if swallowed or if inhaled H317: May cause an allergic skin reaction H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	
	M-Factor: 100 (acute) and 10000 (chronic)

This active substance is included in the rapporteurs' member state harmonised classification work programme and a proposal to amend the current classification will be progressed as soon as is possible.

b) Intended use, target species and effectiveness

Permethrin is used in industrial preventive wood preservation applied in automated spraying, vacuum pressure, double vacuum pressure, flow coating or dipping treatment plants. Timber treated with permethrin may be placed in use classes 1, 2, 3 and 4a. Permethrin containing products in professional and non-professional use may be applied by brushing and spraying and in professional use by remedial brushing and spraying and remedial injection.

The function of permethrin is insecticidal to control wood-destroying insects, such as *Hylotrupes bajulus* (old-house borer), *Reticulitermes santonensis* (European subterranean termite), *Anobium punctatum* (furniture beetle) *Lyctus brunneus* (powderpost beetle), *Xestobium rufovillosum* (deathwatch beetle), *Reticulitermes speriaus* (Japanese termite); *Coptotermes formosanus* (Formosan subterranean termite) during both larval and adult life-cycle stages.

The data on permethrin and the representative biocidal product have demonstrated sufficient efficacy against the target species. No information was provided or available on the efficacy of the different permethrin stereo-isomers. No resistance has been reported for the use of permethrin as a wood preservative. However, cases of resistance have been documented in a wide variety of insects when permethrin has been used as a

general insecticide as documented for use of permethrin as an insecticide in product type 18.

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

Human health

The table below summarises the exposure scenarios assessed.

Summary table: scenarios –exposure		
Scenario	Primary or secondary exposure Description of scenario	Exposed group
Mixing / loading	Professional workers will wear coveralls and gloves; these are included in Tier 1 assessments. Non-professionals will only use ready to use (RTU) products.	Professionals
Application	Product application stage covers: 1) industrial preventive wood preservation treatments and 2) preventive or curative treatments performed <i>in-situ</i> by professionals and non-professionals including do-it-yourself individuals. Preventive: <ul style="list-style-type: none"> ▪ Spray application (automated spraying) ▪ Dipping/immersion application ▪ Vacuum pressure application ▪ Double Vacuum Low Pressure application ▪ Flow coating (dipping is considered to represent a worst case and therefore this scenario was not assessed separately) Curative: <ul style="list-style-type: none"> ▪ Remedial spray treatment (Professionals) ▪ Brushing (professionals, indoor/outdoor) ▪ Brushing (amateurs, indoor/outdoor) ▪ Spray treatment (amateurs) Professional workers will wear coveralls and gloves, these are included in Tier 1 assessments.	Professionals and non-professionals and bystanders (infant, child and adult)
Post application or in-service life	Adults – handling treated timber, handling work wear, machining/sanding treated timber. Child – playing on preserved timber playground equipment Infant – chewing preserved wood, playing and mouthing with treated timber. All ages – inhalation of volatile residues from treated timber	Adults, infants and children

For primary exposure to professionals, workers wearing coveralls and gloves was assumed, except for the cleaning of brushes by professionals. Safe uses have been

found for all use scenarios. Nonetheless, personal protective equipment (PPE) should be considered for products containing permethrin because the active substance is currently classified as a potential sensitiser.

Combined exposure to permethrin through mixing and loading, application and system maintenance steps were calculated. No unacceptable risks from the use of permethrin during professional timber treatment processes was found. Nonetheless PPE should be considered at product authorisation because permethrin is currently classified as a potential skin sensitiser.

For non-professionals, primary exposure to the use of ready to use products was evaluated. With regards to systemic exposures, in all cases safe use was found. A qualitative risk characterisation for local effects is needed at product authorisation because permethrin is currently classified as a potential sensitiser.

Indirect exposure through handling timber when wearing protective gloves and *via* cutting/sanding treated timber does not present a concern. It is considered likely that the adult handling treated timber would wear gloves, as much to protect their hands against splinters as for any potential exposure to permethrin. Indirect exposure of an infant /child from volatilised residues of permethrin indoors or from playing on a play ground structure treated with permethrin does not present a concern. The potential for skin sensitisation from indirect exposure to permethrin treated wood should be considered at product authorisation because it is currently classified as a potential skin sensitiser.

Environment

The table below summarises the exposure scenarios assessed.

Summary table scenarios	
Scenario	Description of scenario including environmental Scenario compartments assessed
Industrial and preventive uses: process and storage	
Automated spraying (high and low volume)	Application (sewage treatment plant (STP), surface water, sediment, soil, groundwater and secondary poisoning for the aquatic and terrestrial compartment) and storage (surface water, sediment, soil and groundwater)
Dipping / immersion	
Vacuum pressure and double vacuum low pressure penetration	
Treated wood in service: use class 3	
Dip / spray treatment	Fence (soil and groundwater), house (soil and groundwater) and noise barrier (sewage treatment plant, surface water, sediment, soil and groundwater)
Penetration treatment	
Curative applications	
Professional and non-professional	Transmission pole and fence post (soil and groundwater) (injection scenario)
In-service	
Treated wood in service: use class 4a	
Application and in-service	Transmission pole and fence post (soil and groundwater) (injection scenario)

For industrial and preventive uses unacceptable risks were identified for multiple environmental compartments across all the scenarios assessed at both the application

and storage stages. As these scenarios take place in industrial facilities an appropriate risk mitigation measure, specifically, the containment of the emission to the facility drain and subsequent storage under cover on an impermeable surface would reduce the risk to acceptable levels.

For treated wood in service use class 3 unacceptable risks were identified for the noise barrier scenario for surface water and sediment following leaching of the active substance to a drain followed by passage through an STP.

For curative treatment an unacceptable risk was identified for soil during application in both the fence and house scenarios. However this risk can possibly be eliminated by covering the soil during the application stage. During the service life there is a risk to soil for the fence and house scenario even when degradation of the active substance is taken into account. For the bridge over pond scenario an unacceptable risk was identified for surface water during both the application and service life stages.

For treated wood in service under use class 4a for the injection scenario of transmission poles no risk was identified and the use can be considered as safe. It should be noted that for use class 4a only the niche scenario "Injection Treatment – Transmission Pole" was assessed; the conclusions of this evaluation do not concern the other uses in use class 4a.

Environmentally safe uses could also be expected for products for use on wood that will not be exposed to weathering, i.e. use classes 1 and 2 (situations in which wood is under cover and fully protected from the weather, e.g. framing, roof timbers etc.), since in these cases the potential emissions from treated wood to the environment are considered negligible.

In addition to permethrin two relevant metabolites were assessed: 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA). For the metabolites DCVA and PBA for several scenarios and use classes evaluated unacceptable risks were identified. However, it is noted that (a) metabolite risk ratios are significantly lower than those of the parent compound permethrin due to the lower toxicity for aquatic organisms of both metabolites and (b) there are far fewer metabolite failures than there are for the parent compound permethrin. In addition given the highly conservative nature of the exposure assessment carried out for the metabolites any risk identified is significantly lower than that due to permethrin itself.

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)	potential P

	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB
	Toxic (T)	T
Endocrine disrupting properties	permethrin is not considered not have endocrine disrupting properties	

Consequently, the following is concluded:

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

Permethrin 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" agreed at the 55th meeting 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 ([CA-March14-Doc.4.1 - Final - Principles for the approval of AS.doc](#)). This implies that the assessment of the exclusion criteria is based on Article 5(1) using the temporary criteria for the determination of endocrine-disrupting properties in Article 5(3) and the assessment of substitution criteria is based on Article 10(1)(a, b and d).

Guidance on PBT assessment (ECHA Guidance: Chapter R.11: PBT Assessment, v.1.1, November 2012) indicates that since the *cis* isomer constituent is present within permethrin at amounts ≥ 0.1 % w/w then the multi-constituent substance, permethrin, should also be treated as potentially persistent. In this situation permethrin may potentially fulfill the persistency criteria and, hence, fulfill two out of the three PBT criteria. Due to this borderline status and to the difficulties pertaining to the determination of the P classification, it is the agreed opinion of the Committee that permethrin should be further assessed by the ECHA PBT Expert Group. Depending on the outcome of the ECHA PBT Expert Group there may be a requirement for the substance to be considered as a candidate for substitution as identified in the provisions of Article 10(1) of Regulation (EU) No 528/2012.

2.2.2. POP criteria

As permethrin is not B or vB and only potentially P, it does not meet the criteria for being a persistent organic pollutant.

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

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

1. Specification: minimum purity of the active substance evaluated: $\geq 93.0\%$ w/w with a *cis* : *trans* ratio of 25 : 75.

2. Specific conditions:

- a. The Union level risk assessment did not address all potential uses and exposure scenarios; When assessing the application for authorisation of a product in accordance with Article 19 and Annex VI of the Biocidal Products Regulation, Member States shall assess exposure to populations and environmental compartments and uses or exposure scenarios that have not been representatively addressed in the risk assessments presented in the CAR.
- b. For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
- c. Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular: 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 hardstanding, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
- d. Products shall not be authorised for wood that will be exposed to frequent weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 19 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
- e. Products shall not be authorized for treatment of outdoor constructions near or above water or for the treatment of wood that will be used for outdoor constructions near or above water, unless data are submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures.
- f. Where a treated article has been treated with or intentionally incorporates permethrin, and where necessary due to the possibility of skin contact as well as the release of permethrin under normal conditions of use, the person responsible for placing the 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 active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012.

2.4. Elements to be taken into account when authorising products

1. The possibility of skin sensitisation to non-professionals from products containing permethrin should be addressed by a risk assessment at product authorisation since the active substance is classified as a potential sensitiser.
2. Whilst the efficacy data provided is sufficient to recommend approval, 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.

3. Curative spray applications outdoors to wood may present a risk to bees. This possible risk has to be addressed at product authorisation.
4. The dossier submitted for the review program of permethrin as a wood preservative in wood for Use Class 3 has demonstrated potential risks to the environment, whereas for Use Class 4a the evaluation was limited to only the injection scenario. At product authorisation it is required that a suitable leaching study from treated wood and appropriate risk mitigation measures is considered.
5. Whilst no incidence of resistance has been reported involving the use of permethrin in preventative wood preservation, the authorisation holder and professional end-users shall for remedial curative applications monitor for observed resistance incidents and report these 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 permethrin. However, further data shall be required as detailed below:

2.5.1. Methods of analysis

It should be noted that the applicant needs to provide a validated chiral method of analysis for the permethrin enantiomers in the representative product formulation. The validated chiral method of analysis should be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (Ireland).

2.5.2. Environment

A soil dwelling arthropod study for permethrin should be considered necessary as confirmatory data and should be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (Ireland).

The applicants need to provide a confirmatory water/sediment degradation study for the permethrin metabolite – DCVA. The study should be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (Ireland).

2.5.3. Biocidal product

The applicants used “dummy” products as part of their submission. Further data may be required, in particular regarding the physical and chemical properties, efficacy and dermal absorption of the products and should be provided by applicants at the product authorization stage. In addition, a leaching test for each general application method (penetration and superficial) by which the wood preservative is to be applied. A leaching test will be required for each formulation type (water and solvent based) of the wood preservative.