# Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

**Permethrin**

Product type: 18

ECHA/BPC/004/2014

**Adopted**

**8 April 2014**

# Opinion of the Biocidal Products Committee

**on the application for approval of the active substance permethrin for product type 18**

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, the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 18 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 Tagros Chemicals India Ltd on 28 April 2006 and and TANATEX B.V. (with a letter of access to data held by Bayer Environmental Science) on 27 January 2009, 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.

It should be noted that the application in support of permethrin by TANATEX was originally submitted under product-type 9 (fibre, leather, rubber and polymerised materials preservatives). However, following discussions at the 41$^{th}$ meeting of the representatives of Member States Competent Authorities for the implementation the BPR it was concluded:

*"The meeting took note of the document submitted by Tanatex on the subject of the change of PT (from PT 9 to 18) for the dossier submitted for permethrin under the review programme. The meeting however concluded that the protection of wool carpets against larvae of moths and carpets beetles should fall under PT 18, as PT 9 cover substances intended to protect textiles from micro-organisms only. However, it was noted that the ESD for PT9 could be utilised for this assessment."*

## Adoption of the BPC opinion

**Rapporteur: BPC member for Ireland**

The BPC opinion on the approval of the active substance permethrin in product-type 18 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 18 may be approved. The detailed grounds for this conclusion are described in the assessment report.

## 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 18. 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 Regulation (EC) No 1272/2008 (CLP Regulation) is:

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

A change is incurred according to Regulation (EU) 286/2011 amending Regulation (EC) 1272/2008: 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 evaluatedcomprise five studies three from the biocide process and two from the pesticide process. As the substance is currently classified sensitizer R43 and there are 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 (skin sensitiser Cat. 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<br>Hazard Statement Code(s) | Acute Tox. 4<br>Acute Tox. 4<br>Skin Sens. 1<br>Aquatic Acute 1<br>Aquatic Chronic 1 | H302<br>H332<br>H317<br>H400<br>H410 |
| **Labelling** | | |
| Pictograms | GHS07<br>GHS09 | |
| Signal Word | Warning | |
| Hazard Statement Codes | H302+H332: Harmful if swallowed or if inhaled<br>H317: May cause an allergic skin reaction<br>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 as an insecticide in product type 18 is used for spot treatment (crack and crevice application and targeted spot application) and for treatment of textile fibres. For spot treatment the function of permethrin is to control a wide range of flying and crawling insects and is intended for indoor use only by professionals and non-professionals. The species targeted by permethrin include flying insects (e.g. flies and mosquitoes) and crawling insects (e.g. cockroaches, mites, fleas and ticks). For treatment of textile fibres the function of permethrin is to control keratin feeding textile pests, such as *Tineola* (moths), *Arthrenus* (carpet beetle), *Attagenus* (fur beetle) and *Hofmannophilia Ps* (false cloth moth), specifically in fibres used in the manufacture of carpets, by professionals only in an industrial application situation. The following use was investigated: treatment of wool textile fibres with permethrin and use of these fibres in the manufacture of carpets or rugs.

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. Resistance has been reported for the use of permethrin as a general insecticide in a wide variety of insects. The level of resistance is less than tenfold in some of the species but high levels of resistance have been observed for example in cockroaches.

**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** | | |
|---|---|---|
| **Spot treatments** | | |
| **Scenario** | **Primary or secondary exposure<br>Description of scenario** | **Exposed group** |
| Mixing/ loading | Primary exposure: handling containers of 5% w/w Permethrin for professional use requiring dilution to a 0.24% in-use solution.<br>Tier 1: With PPE (gloves)<br>Tier 2: With PPE (gloves and coated coverall)<br><br>Non-professionals will only use RTU products. | Professionals |
| Application (Spraying) | Primary exposure:<br>Professionals (knapsack sprayer)<br>Non-professionals (RTU product) | Professionals, non-professionals |
| Post-application | Secondary exposures:<br>Acute phase post-application | Bystanders (Child) |
| **Fibre treatments** | | |
| **Scenario** | **Primary or secondary exposure<br>Description of scenario** | **Exposed group** |
| Mixing/ loading | Primary exposure, handling containers of EULAN SPA 01 (pumped transfer):<br>Connection of container to mixing vessel. Removing the cap, inserting the pump lines into the container and then recapping the old container and disposing it as hazardous waste.<br><br>Tier 1: No PPE (gloves)<br>Tier 2: With PPE (gloves) | Professionals |
| Rinsing/cleaning (also applicable for repair work) | Primary exposure:<br>Foulard chassis and pipelines which contained the working solution of EULAN SPA 01 are rinsed/cleaned with water and water from this process is discarded for waste treatment.<br>It is assumed that workers are exposed to the working solution (0.25 g EULAN SPA 01/L) which was present in the Foulard Chassis and pipelines.<br><br>Tier 1: No PPE (gloves)<br>Tier 2: With PPE (gloves) | Professionals |
| In-service life | Secondary exposures:<br>Child crawling on treated carpet with mouthing<br>Inhalation exposure to carpet fitters | Bystanders (child, adult) |

Safe use was demonstrated for spot treatment by professional users wearing appropriate personal protective equipment (PPE) including gloves and coated coverall. PPE should

also be considered for products containing permethrin because the active substance is currently classified as a potential sensitiser.

Safe use was demonstrated for non-professional users when applying permethrin as a ready-to-use trigger spray. Although exposure is considered to be negligible compared to the acceptable exposure levels a qualitative local risk assessment should be performed prior to authorisation because the active substance is currently classified as a potential sensitiser.

Secondary exposure of infants who would be in contact or ingest residues following exposure due to the use of relevant permethrin containing products does not present a concern. Secondary exposure of children crawling on treated surface is also acceptable.

For textile treatment by industrial users safe use was demonstrated without wearing PPE. Nonetheless, PPE should be considered for products containing permethrin because the active substance is currently classified as a potential sensitiser.

For textile preservation, combined exposure has been considered for a worker who may perform both mixing/loading and rinsing/cleaning/repair tasks in the same working day. It was shown that combined exposure will not add a significant additional exposure to the professional exposure encountered.

Secondary exposure of carpet fitters and child crawling on treated carpet to permethrin does not present a concern.

**Environment**

The table below summarises the exposure scenarios assessed.

| **Summary table scenarios** | |
|---|---|
| **Scenario** | **Description of scenario** |
| Spot treatment | |
| Use by professional and non-professional by spraying indoor (houses and large buildings) | Emission to wastewater via washing of applicator cloths and wet cleaning of treated surfaces (air, sewage treatment plant (STP), surface water, sediment, soil, groundwater and secondary poisoning) |
| Treatment of textile fibres applied to wool fibres used in carpets and rugs | |
| Application: treating textile fibres | Emission to wastewater (air, sewage treatment plant (STP), surface water, sediment, soil, groundwater and secondary poisoning) |
| Service life | Emission to wastewater via cleaning of treated carpets and rugs (air, sewage treatment plant (STP), surface water, sediment, soil, groundwater and secondary poisoning) |

For spot treatment unacceptable risks were identified for surface water and sediment for use by professional and non-professionals. If the product is either restricted to use in dry cleaned areas or, following treatment in areas subject to wet cleaning, excess product is removed by dry or damp cloths that are disposed of as waste, emissions to waste water from wet cleaning of treated surfaces would be eliminated. Consequently, the risk for surface water and sediment would be reduced, as it would now solely depend on the emissions from the washing of applicators clothes. This results in acceptable risks for both use by professionals and non-professionals. It shall be noted that if there was no

release of wastewater (i.e. 100 % of the applicators coveralls are disposable and 100% of surfaces are cleaned by vacuum/broom or cloths disposed as waste) there would only be emissions to municipal wastes and none to the environment via wastewater following application in houses or large buildings.

For treatment of textile fibres unacceptable risks were identified in the application scenario for surface water. This risk can be mitigated against by containment of the emissions to the facility drains. For the service life scenario no unacceptable risks were identified except for sediment where a slight risk was identified. It may not be possible to mitigate against the risk for the release during service life. However, in this instance given the conservative nature of the calculation carried out during the exposure assessment (assuming 100% loss of permethrin during service life and no provision made for degradation of permethrin during the various stages of the lifetime of the carpet) the risk is not considered significant.

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 some scenarios 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 of the metabolites for aquatic organisms 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 to 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 18

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: ≥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. Labels and, where provided, safety data sheets of products authorised shall indicate such measures required. In particular: products authorised

for the application to textile fibres or other materials to control insect damage shall indicate that freshly treated fibres and other appropriate materials shall be stored 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. 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 substances is classified as a potential sensitiser.

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

3. The use of insecticides containing permethrin must take into specific account the aquatic compartment of the environment. The potential risk of direct emissions, via drains, to water bodies should be considered for each Member State's product authorisation. In particular, wastewater from the industrial application stage of the process (to textile fibres or other materials) must not be released directly to surface water or indirectly via a sewage treatment plant. Application solutions shall be collected and reused or disposed as hazardous waste. Member States shall ensure that these risk mitigation measures are practical. If the risk cannot be reduced to an acceptable level by the application of these risk mitigation measures, or by other means, products should not be authorised for industrial treatment of textile fibres.

4. Spray applications outdoor may present a risk to bees. This possible risk has to be addressed at product authorisation.

5. An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs.

6. The potential resistance of target insects to permethrin could be of concern and, as such, resistance management measures should be included in the authorisation of products. These could include (but should not be restricted to) the following factors:

    a. The population size of the target insect should be evaluated before a control campaign. The dose and frequency of applications and the timing of the control campaign should be in proportion to the size of the infestation.
    b. A complete elimination of insects in the infested area should be achieved.

c. The use instruction of products should contain guidance on resistance management for insecticides.
d. Resistant management strategies should be developed, and permethrin should not be used in an area where resistance to this substance is suspected.
e. The authorisation holder and professional end-users shall report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management.

7. Appropriate risk mitigation measures must be taken to minimise the potential exposure of humans, of non-target species and of the aquatic environment. In particular, Member States should consider that labels and/or safety-data sheets of products authorised clearly indicate that:

   a. Products shall not be placed in areas accessible to infants, children and companion animals.
   b. In particular, permethrin toxicity to felines should be taken into consideration, especially where there is insecticide application in domestic dwellings with cats.

## 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 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).

### 2.5.2 Efficacy

Permethrin is a reaction mass of four stereoisomers. No information was available to evaluate the efficacy of the different isomers and, therefore, it is not known whether it fulfils the Art 10(1) (f)) substitution criteria, namely 'contains a significant proportion of non-active isomers'. However, there are currently no clear rules, methodology or guidance for the assessment of this criterion and this issue cannot be considered further at this time. However, the efficacy of the permethrin isomers will have to be considered when such guidance does become available.

### 2.5.3 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).

### 2.5.4 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 wash-off test may be required for each general application method (surface and space applications) by which the insecticide is to be applied. In addition, a wash-off test may also be required for each formulation type (such as for water/solvent based or gel products) of the insecticide.

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