Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Empenthrin

Product type: 18

ECHA/BPC/182/2017

Adopted

13 December 2017

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance empenthrin 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 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the application for approval in product type 18 of the following active substance:

Common name:	**Empenthrin**
Chemical name:	1-ethynyl-2-methylpent-2-enyl 2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropanecarboxylate
EC No.:	N/A
CAS No.:	54406-48-3
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Sumitomo Chemical (UK) on 26 April 2006, the evaluating Competent Authority Belgium submitted an assessment report and the conclusions of its evaluation to ECHA on 24 June 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-23) and its Working Groups (WG IV 2017). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Belgium

The BPC opinion on the non-approval of the active substance empenthrin in product type 18 was adopted on 13 December 2017.

The BPC opinion was adopted by consensus. The opinion is published on ECHA webpage:

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

The overall conclusion of the BPC is that empenthrin in product type 18 may not be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of empenthrin in product type 18.

Empenthrin is a pyrethroid insecticide.

The identity of the active substance could not be proven due to the lack of a validated analytical method.

The currently provided analytical methods for monitoring in soil, air and water as well as for substance identification are not validated and therefore not acceptable. At the current state, the applicant claims that no additional information is available, which could be used for the identification of the active substance.

A harmonised classification is not available.

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

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox 4 STOT (SE) 2 Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictogram codes	GHS07 GHS08 GHS09
Signal Word	Warning
Hazard Statement Codes	H302: Harmful if swallowed H371: May cause damage to organs (nervous system) H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	Acute 1: M = 100, based on 96h EC50 of 0.0017 mg/L for *Oncorhynchus mykiss* Chronic 1: M = 100, based on M-factor for aquatic acute 1
Justification for the proposal	

b) Intended use, target species and effectiveness

Empenthrin is used in mothproofing strips made of empenthrin-impregnated filter paper framed with plastic holder intended for indoor use only by the non-professional (general public). It is intended to protect stored clothing and other textiles in domestic premises in wardrobes and drawers against textile-attacking insects, i.e. clothes/fur moth (*Tinea pellionella*) and webbing clothes moth (*Tineola bisselliella*) at all the development stages of

the insects.

Sufficient effectiveness against eggs and mid-instar larvae of *Tineola bisselliella* could be demonstrated at an application rate of 1.38 g a.i./m^3 (designed as mothproofing strips made of empenthrin-impregnated filter paper strips).

Empenthrin is a pyrethroid insecticide. Once taken up by contact or vapour exposure it exerts strong neurotoxic action. In principle, empenthrin prevents the transmission of nervous impulses along nerve fibres by preventing sodium channel function. This disruption of the nervous system results in the death of the insects.

No resistance cases for empenthrin have been reported.

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

Human health

There is no evidence of genotoxic, embryotoxic or teratogenic potential of empenthrin. Based on neurotoxicity symptoms (tremor and muscular fibrillation) in the acute oral and inhalation toxicity studies, classification for STOT SE is proposed for empenthrin. Empenthrin is neither a skin nor an eye irritant. Empenthrin did not show indications of being a skin sensitser. Since no carcinogenicity data are available for empenthrin, the carcinogenic potential of active substance could not be determined.

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**
Mixing and loading (adults)	Primary exposure to biocidal product when opening the units (includes cutting and distributing the cassette among the clothes – with 10 min exposure); twice a year	Non-professional	**Acceptable**
Application (adults, children and toddlers)	Primary exposure to biocidal product when opening the wardrobes or drawers where the biocidal product is used.	Non-professional	**Not acceptable**
Post-application (adults, children and toddlers)	Secondary exposure post-application to biocidal product via contact with clothes or bed linen. Dermal uptake for adults, children and toddlers and oral uptake for toddlers (hand-to-mouth) only.	Non-professional	**Not acceptable**
Combined exposure	Exposure via inhalation and via contact with textiles (clothes or bed linen) which can occur simultaneously.	Non-professional	**Not acceptable**

Five units containing the biocidal product are used per closet to be in accordance with the closet volume of 1.5 m^3 and with the efficacious dose of 1.38 g a.s./m^3.
For mixing and loading the risk is acceptable for adults. The primary exposure via inhalation to the biocidal product is considered relevant for adults, children and toddlers. This exposure will pose a chronic risk to adults, children and toddlers.

Since the active substance may adhere to all materials in the wardrobe, such as clothes or bed linen, a secondary dermal exposure after application to the biocidal product is considered for adults, children and toddlers.

For toddlers, additionally secondary oral exposure is considered relevant. The hand-to-mouth exposure scenario is assumed to cover the non-expected cloth-to-mouth exposure.
The risk assessment for secondary dermal and oral exposure results in an unacceptable risk to adults, children and toddlers.

Combined exposure via inhalation and via dermal contact to textiles is considered and the assessment results also in an unacceptable risk.

A dietary risk assessment was not undertaken as exposure to food from the use pattern is not expected.

In summary, unacceptable risks are identified for primary exposure (via inhalation) to the biocidal product for adults, children and toddlers. Additionally, for secondary exposure scenarios (via dermal and oral route), the exposure to empenthrin is unacceptable for adults, children and toddlers.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Indoor application via passive diffuser used in wardrobes by general public (OECD ESD No 18) - Tier 1 considering 2.5 wardrobes per household will be equipped with the efficacious amount of empenthrin containing Mothproofer units (i.e. 4.15 units for a standard wardrobe of 1.5 m^3) Only emission during application and cleaning events will be considered, more particularly efficacious application of diffusers in standard wardrobes throughout the house, resulting in emission to floor which is transferred to wastewater via wet room cleaning	Exposure to aquatic compartments	**Unacceptable risk to surface water** Acceptable risk to sediment and STP
	Exposure to terrestrial compartments	**Unacceptable risk to soil** Acceptable risk to groundwater
	Secondary poisoning	Unacceptable => Acceptable risk to fish-eating mammals when considering other calculated BCF-values for empenthrin Acceptable risk to worm-eating mammals Risk to fish-eating & to worm-eating birds : No conclusions due to lacking data on toxicity of empenthrin to birds
Indoor application via passive diffuser used in wardrobes by general public (OECD ESD No 18) - Tier 2 considering a single wardrobe being equipped with the efficacious amount of units (assessment following more the traditional ESD assumption). Only emission during application and cleaning events will be considered, more particularly efficacious application of diffusers in standard wardrobes throughout the house, resulting in emission to floor which is transferred to wastewater via wet room cleaning	Exposure to aquatic compartments	**Uncceptable risk to surface water** Acceptable risk to sediment and STP
	Exposure to terrestrial compartments	**Uncceptable risk to soil** Acceptable risk to groundwater
	Secondary poisoning	Acceptable risk to fish-eating & worm-eating mammals Risk to fish-eating & to worm-eating birds : No conclusions due to lacking data on toxicity of empenthrin to birds

The possible emission routes of the product are emission to outdoor air through the ventilation of the house, to wastewater through the cleaning of surfaces and possible exposure to soil either through deposition of empenthrin from the atmosphere and/or through STP sludge application.

The predicted environmental concentrations in the different environmental compartments (aquatic and terrestrial) were calculated using the OECD Emission Scenario Document No.18 (ESD, July 2008) and the Guidance on Biocidal Product Regulation under the assumption that one to 2.5 wardrobes per household will be equipped with the efficacious amount of the active substance.

Based on the available data and the proposed use pattern of empenthrin in the representative product, there are unacceptable risks in surface water and soil, and more particularly for soil organisms, identified, but no risks are expected for the Sewage Treatment Plant or for sediment dwellers.

Concerning secondary poisoning, for the aquatic food chain, no risks are found for fish-eating mammals and for the terrestrial food chain, no risks are expected for worm-eating mammals. Overall, no conclusions for fish-eating or worm-eating birds could be made, due to lacking toxicity data of empenthrin to birds.

Overall conclusion

The applicant did not provide a clear substance identification which is required within the active substance approval process. In the human health risk assessment the relevant exposure scenarios have been assessed and have been considered as unacceptable for the intended uses.

It was agreed at the BPC-WG IV (Sept. 2017), that the lack of carcinogenicity data, which the applicant failed to provide, although requested by the eCA results in an unacceptable data gap.

Due to this the eCA could consequently not conclude on the assessment of the exclusion criterion for empenthrin, which also results in a non-approval of the active substance empenthrin in product type 18.

Regarding environmental risk assessment unacceptable risk to the aquatic environment, and more particularly for the surface water is identified for the proposed use pattern of empenthrin in the representative product. No unacceptable risks are identified for the Sewage Treatment Plant or for sediment dwellers. Risks are also calculated for the terrestrial environment, for soil organisms.

Overall, it can be concluded that no safe use is demonstrated for empenthrin and that the data provided by the applicant neither allows clear substance identification nor the assessment of the carcinogenic potential of empenthrin.

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 conclusion possible	No conclusion possible for criterion (a) of Article 5(1) due to lack of data relevant for carcinogenicity assessment. Empenthrin does not fulfil criterion (b) and (c) of Article 5(1).
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	According to the P screening criteria, empenthrin should be considered potentially P or vP	Empenthrin does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Empenthrin is not considered B or vB	
	Toxic (T)	Empenthrin should be classified as toxic (T)	
Endocrine disrupting properties	Empenthrin is not identified as having endocrine disrupting properties according to Article 5(3). Empenthrin does not fulfil criterion (d) of Article 5(1)		
Respiratory sensitisation properties	No classification required. Empenthrin does not fulfil criterion (b) of Article 10(1)		
Concerns linked to critical effects	Empenthrin does not fulfil criterion (e) of Article 10(1)		
Proportion of non-active isomers or impurities	No clear substance identification possible		

Consequently, the following is concluded:

Empenthrin does not meet the exclusion criteria laid down in Article 5(1)(b and c) of Regulation (EU) No 528/2012. No conclusion is possible for criterion (a) of Article 5(1) due to lack of data relevant for carcinogenicity assessment. Empenthrin is not a candidate for substitution according to the Article 10(1)(d) of the BPR. However, it was agreed that according to the P screening criteria, empenthrin should be considered potentially P or vP in the aquatic environment.

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 54th and 58th 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[1]. 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

Since empenthrin has a vapour pressure and a half-life in air well below the criterion, empenthrin has no potential for long range transport. Since empenthrin is not considered B or vB, empenthrin is not considered meeting the POP criteria.

2.3. BPC opinion on the application for approval of the active substance empenthrin in product type 18

In view of the conclusions of the evaluation, it is concluded that biocidal products containing empenthrin as an active substance for the use as insecticide may not be expected to meet the criteria laid down in point (b)(iii), (b)(iv) and (c) of Article 19(1). Consequently, it is proposed that empenthrin shall not be approved and included in the Union list of approved active substances in product type 18.

It was not possible to assess the exclusion criteria:

Empenthrin does not meet the exclusion criteria laid down in Article 5(1)(b and c) of Regulation (EU) No 528/2012. No conclusion is possible for criterion (a) of Article 5(1) due to lack of data relevant for carcinogenicity assessment.

Empenthrin does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 as empenthrin gives rise to the following concerns:
it is proposed for classification as specific target organ toxicant by single exposure (STOT SE 2) and as toxic to aquatic life of acute category 1 (Aquatic Acute 1).

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[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)