Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Imiprothrin

Product type: 18

ECHA/BPC/155/2017

Adopted

27 June 2017

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Opinion of the Biocidal Products Committee

on the application for approval of the active substance imiprothrin 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 approval in product type 18 of the following active substance:

Common name:	**Imiprothrin**
Chemical name:	**Reaction mass of: 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1*R*)-*cis*-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate; 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1*R*)-*trans*-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate**
EC No.:	**428-790-6**
CAS No.:	**72963-72-5**
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) PLC on 30 April 2006, the evaluating Competent Authority UK submitted an assessment report and the conclusions of its evaluation to ECHA on 20 July 2016. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-21) and its Working Groups (WG I 2017). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: United Kingdom

The BPC opinion on the approval of the active substance imiprothrin in product type 18 was adopted on 27 June 2017.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including their grounds are published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that imiprothrin in product type 18 may 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 imiprothrin in product type 18. Imiprothrin is a synthetic pyrethroid insecticide.

Imiprothrin is a reaction mass of; 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1*R*)-*cis*-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate; 2,5-dioxo-3-prop-2-ynylimidazolidin-1-ylmethyl (1*R*)-*trans*-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (ca 20:80). 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 active substance as manufactured and for the relevant and significant impurities. Monitoring methods for soil, body fluids and tissues and food and feed are not required. The validation data provided for the monitoring of residues in air, surface and drinking water are not complete and will be required before the date of approval of the active substance as detailed in Section 2.5.

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

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox 4, H302 Aquatic acute 1, H400 Aquatic chronic 1, H410
Labelling	
Pictogram codes	GHS07 GHS09
Signal Word	WARNING
Hazard Statement Codes	H302: Harmful if swallowed H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects

The proposed classification and labelling for imiprothrin 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, H332 Acute Tox 4, H302 Repro Tox 2, H361d Aquatic acute 1, H400 Aquatic chronic 1, H410
Labelling	

Pictogram codes	GHS07 GHS09
Signal Word	WARNING
Hazard Statement Codes	H332: Harmful if inhaled. H302: Harmful if swallowed H361d: Suspected of damaging the unborn child H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 10 (acute and chronic)

A CLH dossier has been submitted to ECHA and a RAC opinion is expected to be adopted in 2017.

b) Intended use, target species and effectiveness

Insecticidal products containing imiprothrin are ready to use aerosols designed to be used by non-professionals (indoors) as surface sprays for spot, crack and crevice treatments in domestic or restaurant kitchens and other areas in buildings where small infestations and harbourages of crawling insects may occur.

Imiprothrin is a synthetic pyrethroid insecticide. Pyrethroid insecticides act on the sodium channel in the nerve membranes of the invertebrate nervous system and are termed sodium channel modulators. They cause pronounced repetitive activity and a prolongation of the transient increase in sodium permeability of the nerve membranes. This results in continual nerve impulse transmission leading to tremors and death. This action is demonstrated by the rapid knockdown action caused by pyrethroid compounds, such as imiprothrin, against target insects.

The data on imiprothrin and the representative biocidal product have demonstrated a sufficient level of innate efficacy against the target species.

Resistance to pyrethroids has been reported. Therefore, the issue of resistance needs to be addressed at product authorisation stage for all imiprothrin-containing products.

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

Human health

Imiprothrin is classified as harmful by the inhalation and oral routes but does not meet the criteria for classification for skin, eye or respiratory tract irritation or skin sensitisation. Therefore no local effects assessment was necessary. The liver, salivary gland and red blood cells were identified as the target organs for toxicity in the repeated dose studies. Imiprothrin does not meet the criteria for classification as a mutagen or carcinogen, however a category 2 classification for reproductive toxicity is considered to be appropriate.

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**
Surface spray application indoors: crack & crevice/spot application	**Primary exposure** during application and for a short duration afterwards Use of whole can	Non professional	Acceptable without PPE
Surface spray application indoors: crack & crevice/spot application	**Secondary exposure** of adult, child or infant touching treated area and inhaling imiprothrin in atmosphere	Adult, child or infant	Acceptable
Surface spray application indoors: crack & crevice/spot application	**Secondary exposure** of toddler crawling over treated area	Toddler	Acceptable
Surface spray application indoors: crack & crevice/spot application	**Combined exposure –** user of spray is also a resident	Non-professional adult	Acceptable

No unacceptable risks are identified for primary, secondary or combined exposure scenarios. A dietary risk assessment was not undertaken as exposure to food from the use pattern is not expected.

Environment

It is considered that hydrolysis will not be a significant degradation route for imiprothrin under normal environmental conditions. Taking into account the low vapour pressure of imiprothrin and considering the limited indoor use pattern, exposure via air is unlikely. Imiprothrin does not readily biodegrade. Based upon the study results, it is evident that emissions of imiprothrin reaching surface waters will first dissipate from the water phase to the sediment phase and then undergo rapid degradation in water/ sediment systems. Both imiprothrin *cis* and *trans* isomers were shown to rapidly degrade in water/ sediment systems with whole system half-lives of < 5.40 days (at 20 ºC).

Imiprothrin has been shown to degrade in soil and accumulation to soils is therefore unlikely. In addition the compound is moderately mobile in soil. Due to the low toxicity, low potential for bioaccumulation in terrestrial organisms, and minimal exposure, it is considered that there is negligible risk of bioaccumulation in the terrestrial environment.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Surface spray application indoors: crack & crevice/spot application - Tier 1 (10% cleaning efficiency[1])	Exposure to terrestrial and aquatic compartments.	Acceptable risk to STP. Unacceptable risk to surface water, sediment and soil.
Surface spray application indoors: crack & crevice/spot application - Tier 2 (3% cleaning efficiency)	Exposure to terrestrial and aquatic compartments.	Acceptable risk.
Surface spray indoors: surface treatment[2] (to treat bed bugs or cat fleas) – 20% cleaning efficiency	Exposure to terrestrial and aquatic compartments.	Acceptable risk to STP. Unacceptable risk to surface water, sediment and soil.
Combined scenarios (crack & crevice in domestic & large buildings)	Exposure to terrestrial and aquatic compartments.	Acceptable risk to STP (Tier 1&2) and surface water, sediment and soil at Tier 2.

Acceptable risks are identified for all environmental compartments following use of products containing imiprothrin indoors for crack and crevice treatment when a refined assessment (Tier 2), using the ESD agreed cleaning efficiency of 3 %, is applied.

Unacceptable risks to surface water, sediment and soil are identified following use of products containing imiprothrin for indoor surface treatment (to treat bed bugs or cat fleas).

Overall conclusion

Overall, a safe use has been identified for both human health and the environment when a product containing imiprothrin is used to treat areas indoors as a crack and crevice / targeted spot application.

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:

[1] Cleaning efficiency: removal - expressed as a fraction of the applied dose - by wet cleaning a treated area.
[2] The environmental risk assessment has considered surface treatment to take into account treatment for cat fleas and bed bugs.

Property		Conclusions	
CMR properties	Carcinogenicity (C)	No classification required	Imiprothrin does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	Cat 2	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Parent not P or vP (but one of the major metabolites fulfils P and another fulfils vP)	Imiprothrin 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)	Not B or vB: parent and metabolites	
	Toxic (T)	Parent T (Imiprothrin *cis* and *trans* isomers); metabolites: not T	
Endocrine disrupting properties	Imiprothrin is not considered to have endocrine disrupting properties. Imiprothrin does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. Imiprothrin does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	Imiprothrin does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Imiprothrin does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

Imiprothrin 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"[3] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[4] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

[3] 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)

[4] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

2.2.2. POP criteria

Imiprothrin does not meet the criteria for being a persistent organic pollutant.

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

In view of the conclusions of the evaluation, it is proposed that imiprothrin 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: 870 g/kg w/w

2. The authorisations of biocidal products are subject to the following condition(s):

    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

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

        i. Surface water, sediment and soil for products used indoors as a spray for surface treatment.

3. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/20092[5] or Regulation (EC) No 396/20053[6] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

The active substance does not fulfil the criteria according to Article 28(2)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012 as it is Acute Tox 4 (H302) and Aquatic Chronic 1 (H410).

2.4. Elements to be taken into account when authorising products

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

    a. An unacceptable risk is identified for surface water, sediment and soil for products used indoors as a spray for surface treatment. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

2. The potential resistance of target insects to imiprothrin could be of concern and, as such, resistance management measures should be included in the authorisation of products. For professional users these could include (but should not be restricted to) the following factors:

    a. Good sanitation procedures and all other measures that prevent infestations from developing (i.e. non-chemical measures) have to be established.

[5] Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11.
[6] Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1.

b. Products should always be used in accordance with label recommendations, in terms of dose to be applied and treatment intervals. The effective dose must be applied and no higher or lower doses.

c. Where an extended period of control is required, treatments should be alternated with products with different modes of action.

d. Levels of effectiveness should be monitored (periodic checks), and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.

e. In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing the same class of chemistry should cease.

f. If signs of resistance begin to appear (as indicated either by control failures or through the test procedure) then every effort should be made to eradicate the population. The measures necessary for eradication will vary in different situations; they may involve a number of procedures using both chemical and non-chemical means.

For household products applied by non-professionals the following resistance management measure is proposed:

g. In the case of reduced efficacy or suspected development of resistance, the use of the product has to be discontinued. The user is advised to contact a professional pest control operator.

3. 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.

4. An assessment of the risk to companion animals may be required at product authorisation where use of the product may lead to exposure of companion animals.

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 imiprothrin.

However, further data on the active substance are required and must be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (UK):

- A new 5 batch analysis study conducted in accordance with GLP using batches representative of current production will be required to support the technical specification and using material manufactured within the last 5 years. In addition, further information needs to be provided for several impurities;
- An analytical method for the determination of imiprothrin in drinking water;
- Further data to support the proposed method of analysis for determination of imiprothrin in air and surface water for monitoring purposes:
    - Data to address the air temperature and relative humidity used to validate the GC-FID method;
    - Validate a LOQ in accordance with the proposed PNEC of 0.038 µg/L.