Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Cyfluthrin

Product type: 18

ECHA/BPC/090/2016

Adopted

16 February 2016

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 cyfluthrin 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:	**Cyfluthrin**
Chemical name(s):	**(RS)-α-Cyano-4-fluoro-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate**
EC No.:	**269-855-7**
CAS No.:	**68359-37-5**
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 Bayer SAS, Bayer CropScience, Environmental Science Division, France on 06 April 2006, the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to the Commission on 23 December 2010. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Commission and the Agency organised consultations via the Technical Meeting (TM III 2011) as well as the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at *http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/biocidal-products-regulation/public-consultation-on-potential-candidates-for-substitution* on 10 February 2014, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 11 April 2014.

Adoption of the BPC opinion

Rapporteur: BPC member of Germany

The BPC opinion on the approval of the active substance cyfluthrin in product type 18 was adopted on 16 February 2016.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR. One confidential comment was received from interested third parties during the public consultation in accordance with Article 10(3) of BPR. Due to this information, cyfluthrin is no longer considered as a candidate for substitution.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the cyfluthrin 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 cyfluthrin in product type 18. Cyfluthrin is a non-systemic type II pyrethroid insecticide with neurotoxic effects. After uptake, cyfluthrin modifies, as do other pyrethroids, the gating features of the pre-synaptic voltage-sensitive sodium channels to delay their closure. If long and/or large enough, the protracted sodium influx then lowers the action potential threshold, causing repetitive firing. The physiological manifestations include sensory hyper excitation leading successively to a loss in coordination, ataxia, prostration, and convulsions. Ultimately, the increase in frequency of the postsynaptic potentials can result in death of the insects.

Cyfluthrin consists of roughly equal amounts of four diastereomers (I, II, III, IV). Each diastereomer is a diastereoisomeric pair of enantiomers with an enantiomeric ratio of 1:1 No information was available on the efficacy of the individual diastereomers. The minimum purity of the active substance is 95.5 % w/w. None of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern. 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. Residue analytical methods are available for the active substance in soil, drinking and surface water, air and body tissues. However, the method for surface water is not sufficiently sensitive. A validated residue analytical method for the quantification of cyfluthrin in surface water with an LOQ of 0.01 µg/L is required. Confirmatory methods are available only for soil and air. For the metabolites DCVA[1] and FPB-acid[2], an analytical method in urine is available.

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

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 2*, H300 Acute Tox. 3*, H331 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Labelling	
Pictograms	GHS06 GHS09
Signal Word	Danger
Hazard Statement Codes	H300: Fatal if swallowed H331: Toxic if inhaled H410: Very toxic to aquatic life with long lasting effects

[1] cis- and trans-methyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate (permethric acid)
[2] methyl 4-fluoro-3-phenoxybenzoate

Specific Concentration limits, M-Factors	M=1000 (acute and chronic)

The evaluating CA proposes the following amendment of the existing harmonised classification:

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 2, H300 Acute Tox. 2, H330 STOT-SE3, H335 Lact., H362 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Labelling	
Pictograms	GHS06 GHS09
Signal Word	Danger
Hazard Statement Codes	H300: Fatal if swallowed H330: Fatal if inhaled H335: May cause respiratory irritation H362: May cause harm to breast-fed children H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 1 000 000 (acute) M = 100 000 (chronic)

A CLH dossier will be submitted to ECHA by the evaluating CA in the first half of 2016.

b) Intended use, target species and effectiveness

The intended uses of cyfluthrin based products are to control flying and crawling insects, such as house flies, litter beetles as well as fleas and red mites in animal housings (spray application for use by professionals) as well as cockroaches (adults, nymphs), ants and termites indoors (ready to use spray foam for use by non-professionals in households). The spray application is done by spraying a strip on window frames and to ceilings using a low pressure Knapsack (backpack) sprayer, while the foam product is applied to crack and crevices around skirting and door frames, supplied with a directional tube applicator.

The efficacy of cyfluthrin is well established and acceptable studies indicating sufficient efficacy of the active substance have been provided. Evaluation of the data submitted in support of the efficacy of the accompanying products establishes that the products are expected to be efficacious.

Resistance against pyrethroids can occur in relevant susceptible pests. In Europe, the main problems have occurred in some areas with pests of agricultural significance among some species of flies and cockroach populations. Cross-resistance of pest species to the group of synthetic pyrethroids is to be anticipated due to a common mode of action and instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported. Therefore precautions have to be taken to reduce the possibility of insects developing resistance to synthetic pyrethroids.

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

Human health

Cyfluthrin is acutely very toxic after oral exposure and toxic when inhaled. Cyfluthrin can lead to sensory irritation and is acutely neurotoxic. Cyfluthrin might cause harm to breast-fed babies but was found to be neither genotoxic, teratogenic nor carcinogenic.

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**
Spray application in animal housing	Primary dermal exposure during manual dilution of the biocidal product (b.p.) and loading of diluted b.p. in spray equipment and during cleaning of spray equipment. Primary dermal and inhalation (aerosol) exposure during spraying (spray pressure 2-3 bar).	Professional user	Concern identified for sensory irritation which can be mitigated by requiring gloves, coverall and RPE
Working in animal housing	Secondary dermal exposure during working in the stable	Professional user	Acceptable
Crack and crevice treatment (ready-to-use spray foam)	Primary exposure during application	Non-professionals	Acceptable
Crack and crevice treatment	Secondary exposure of infant crawling on treated floor	Infants	Acceptable
Re-entry of animal housing	Secondary exposure upon re-entry of treated animal housing	Adults, children	Acceptable
Residues from crack and crevice treatment and treatment of animal housing	Secondary exposure via residues in food	General public	Not assessed

<u>Professional user:</u>

Systemic effects:

For both professional uses (spray application in animal housing and secondary exposure during professional work in animal housing) no unacceptable risk is identifiedregarding systemic effects of cyfluthrin.

Local effects (sensory irritation)

Inhalation:

Sensory irritation in the upper respiratory tract occurs at lower air-borne concentrations of cyfluthrin than systemic effects.

In a first tier assessment a concern to upper respiratory tract sensory irritation is identified for professional spray application in animal housing. The assumption of wearing adequate respiratory protection equipment (RPE) during spray application yields a reduced exposure mitigating the concern for sensory irritation.

Secondary exposure by inhalation is considered negligible, so therefore it is concluded that there is no concern for local effects by inhalation for the bystander.

Dermal:

For cutaneous paraesthesia, health risks due to dermal contact will essentially depend on the concentration of cyfluthrin in the biocidal product and on the emulsifier/vehicle used for formulation of the active substance. A qualitative local risk assessment for cutaneous paraesthesia was not performed, but with wearing of a spray-tight protective coverall and protective gloves no risk is expected for the professional user.

Non-professional user:

A safe use has been identified for non-professional users during application of the crack and crevice treatment. Treatment of animal housing is only performed by professional users and therefore not a relevant primary non-professional scenario. Secondary exposure of bystanders (adults, infants and children) is also considered acceptable for both intended uses. Measurable residues in food are not expected from either one of the intended uses. However, a detailed dietary risk assessment was not performed due to missing guidance. Regarding local effects, there is no concern regarding upper respiratory tract sensory irritation for the non-professional user and the general public. Further information or a quantitative assessment of the dermal sensory irritation potential is not considered necessary, because the nature of the effect is not severe and does not lead to classification.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Spray application in animal housings (professional use)	Emission to • soil due to manure applications carried out according to maximum nitrogen immission limits (Europe), afterwards to groundwater and aquatic compartment (surface water and sediment)	Acceptable for 2 specific animal (sub)categories: beef cattle and laying hens in battery cages without treatment. Unacceptable for all other animal (sub)categories (unacceptable risks in aquatic compartment for surface water and sediment).
	• waste water from poultry housings, which is either directly released to surface water or treated in a sewage treatment plant (STP), leading to releases to the aquatic compartment (surface water, sediment) and via sludge deposition to the terrestrial compartment (soil and groundwater).	Unacceptable for STP as well as for aquatic and sediment-dwelling organisms.
Ready-to-use spray foam for use in crack and crevices inside domestic premises (non-professional use)	Releases to STP after wet cleaning, in consequence emission to the aquatic compartment (surface water, sediment) and to the terrestrial compartment (soil and groundwater) due to sludge deposition on soil.	Unacceptable for aquatic and sediment-dwelling organisms.

Unacceptable risks were identified for the STP as well as for aquatic and sediment-dwelling organisms following indoor application by professionals in poultry housings, where discharges to sewer or direct releases to surface water cannot be excluded.

An acceptable risk for the environment could be demonstrated for indoor application by professionals in animal housings and subsequent manure/slurry application on agricultural soil in two specific animal housings, i.e. beef cattle and laying hens in battery cages (no treatment).

For the domestic use as foam (non-professional use) unacceptable risks were identified for aquatic and sediment-dwelling organisms.

Overall conclusion

A safe use for both human health and environment has been identified for the spray application in animal housings (professional use) limited to two specific animal housings (beef cattle and laying hens in battery cages (no treatment)) and provided that discharges to sewer or direct releases to surface water are excluded.

No safe use could be identified for the domestic use as foam (non-professional use) due to unacceptable risks for the environment.

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	Cyfluthrin does not fulfil criterion (a), (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)	Cyfluthrin is not P and vP	Cyfluthrin does not fulfil criterion (e) of Article 5(1) and criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Cyfluthrin is not B and vB	
	Toxic (T)	Cyfluthrin is T	
Endocrine disrupting properties	Cyfluthrin does not fulfil criterion (d) of Article 5(1)		
Respiratory sensitisation properties	No classification required. Cyfluthrin does not fulfil criterion (b) of Article 10(1)		
Proportion of non-active isomers or impurities	Based on the availalble information cyfluthrin does not fulfil criterion (f) of Article 10(1)		
Concerns linked to critical effects	Cyfluthrin does not fulfil criterion (e) of Article 10(1)		

Based on the data available in 2014, a public consultation took place as the evaluation of the eCA demonstrated that cyfluthrin met the substitution criteria according to 10(1)(d), being P and T. In course of the public consultation a new biodegradation study in soil was submitted by the applicant. Taking the results of this study into account, cyfluthrin no longer meets the P criterion.

Consequently, the following is concluded:

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

Cyfluthrin 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 metabolites FPB-acid[2] and FPB-ald[3] are not P and vP. The metabolite permethric acid (DCVA[1]) is vP. Based on screening criteria the metabolites FPB-acid, FPB-ald and permethric acid (DCVA) are not B or vB. The metabolites FPB-acid, FPB-ald and permethric acid (DCVA) are not T.

The exclusion and substitution criteria were assessed in line with the "Note on the principles

[3] 4-fluoro-3-phenoxy-benzaldehyde

for taking decisions on the approval of active substances under the BPR"[4] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] 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).

2.2.2. POP criteria

Cyfluthrin does not fulfil the criteria for being a persistent, organic pollutant.

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

In view of the conclusions of the evaluation, it is proposed that cyfluthrin 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: 955 g/kg (95.5 % 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 unacceptable risks identified for the uses assessed, the product assessment shall pay particular attention to:

        i. surface water and sediment for products used in domestic premises and animal housing with release to a STP;

        ii. surface water and sediment for products used in animal housing with direct release to surface water;

        iii. surface water and sediment after manure application on agricultural soil for products used in animal housings.

    c. 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 470/2009[4] or Regulation (EC) No 396/2005[5] 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) to enable inclusion in Annex I of Regulation (EU) 528/2012 as it is currently classified as Acute Tox. 2*, Acute Tox. 3* and Aquatic Acute 1 (H400). Furthermore, the eCA proposes classification as STOT SE 3 and Lact.

---

[4] 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)

[3] 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)

[4] Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11)

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

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. If an unacceptable risk for professional users is identified for the product, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products should be used with appropriate personal protective equipment.

    b. An unacceptable risk for surface water and sediment is identified for uses in domestic premises as well as animal housings where releases to a STP or direct emission to surface water cannot be excluded. 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.

    c. An unacceptable risk for the surface water and sediment is identified for uses in animal housings other than beef cattle and laying hens in battery cages (no treatment[6]) following manure application on agricultural soil. 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 cyfluthrin 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. Good sanitation procedures and all other measures that prevent infestations from developing (i.e. non-chemical measures) have to be established.

    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.

[6] "no treatment" refers to the removement of manure/slurry via belts without drying the manure/slurry by aeration before it is collected in a pit

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.

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 cyfluthrin. However the following further data must be submitted to the evaluating Competent Authority (Germany) as soon as possible but no later than 6 months before the date of approval of the active substance:

1. A validated residue analytical method for the quantification of cyfluthrin in surface water with an LOQ of 0.01 µg/L.

2. Confirmatory methods for drinking water and for body tissues.

In addition, further information will need to be provided at renewal of the active substance approval:

3. The effect assessment for aquatic invertebrates is only based on data from crustacea (*D. magna, P. clarkii, H. azteca, A. bahia*), whereas no further data for other arthropoda subphyla have been submitted. However, results from two additional microcosm studies showed that aquatic insects are significantly more sensitive to cyfluthrin, especially Chaoboridae, but also Ephemeroptera (*Cloen* spec.) and c.f. Bryophaenocladius spec. Therefore, it was decided at BPC WG ENV that further data on aquatic insects have to be provided to the eCA at renewal stage, preferably for chaoboridae.

4. Additional data on the efficacy of the individual isomers will be required to clarify the proportion of non-active isomers.

o0o