Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Alpha-cypermethrin

Product type: 18

ECHA/BPC/009/2014

Adopted

17 June 2014

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 alpha-cypermethrin 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: **alpha-cypermethrin**

Chemical name:

Reaction mass of
(S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2 dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
and
(R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (1:1)

EC No.: **not available**

CAS No.: **67375-30-8**

Existing active substance

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

Process for the adoption of opinions

Following the submission of an application by BASF AG on 28th April 2006, the evaluating Competent Authority Belgium submitted a Competent Authority Report (CAR) to the Commission on 17th November 2011. In order to review the assessment report and the conclusions of the evaluating Competent Authority the Agency organised consultations and the Commission via the biocides Technical Meetings (TM-I-2013). Alpha-cypermethrin was also discussed at the BPC Environment Working Group during WG-I-2014. Revisions agreed upon were presented and the CAR was amended accordingly.

Adoption of the opinion

Rapporteur: BPC member for Belgium

The BPC opinion on the approval of the active substance alpha-cypermethrin in product-type 18 was adopted on 17 June 2014.

The BPC opinion was adopted by consensus.

Detailed opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the alpha-cypermethrin in product type 18 may be approved. The assessment report contains the detailed grounds for the overall conclusion.

2. Opinion

2.1. 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 alpha-cypermethrin in product type 18. Alpha-cypermethin acts by preventing transmission of impulses along nerves on adult insects by blocking the passage of positive sodium ions through sodium channels in nerve membranes, thus preventing action potentials passing down axons. Typically, the intoxication results in a rapid "knockdown" and mortality. Alpha-cypermethrin is a synthetic pyrethroid and as such does not depend on conversion or degradation to an active form in order to exert its insecticidal activity.

Alpha-cypermethrin is a reaction mass of (S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (1:1). Specifications for the reference source are established.

The physico-chemical properties of alpha-cypermethrin are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

The methods of analysis of active substance as manufactured (technical grade active ingredient) and for determination of identified impurities present in pure active ingredient at quantities ≥ 0.05 % w/w have been validated and shown to be sufficiently specific, linear, accurate and precise. The methods of analysis of alpha-cypermethrin in environmental matrices, as appropriate, have been validated and shown to be sufficiently sensitive with respect to the levels of concern. However, the validation of the confirmatory method for residues in water is still required.

Alpha-cypermethrin is listed in Annex VI table 3.1 and 3.2 of Regulation (EC) No 1272/2008 (CLP Regulation). The evaluating Competent Authority (eCA) is proposing to add the classification as Acute tox. 4 -H332 (harmful if inhaled) based on the result of recent inhalation toxicity studies.

No CLH dossier has been submitted yet for this active substance to ECHA.

The proposed classification and labelling by the evaluating Competent Authority of the active substance alpha-cypermethrin based on the CLP Regulation is shown below.

Classification according to the CLP Regulation		
Hazard Class and Category Codes Hazard Statement Code(s)	Acute Tox. 3; Acute Tox. 4; STOT SE 3; STOT RE 2; Aquatic Acute 1; Aquatic Chronic 1;	H301 H332 H335 H373 H400 H410
Labelling		
Pictograms	GHS06 GHS08 GHS09	
Signal Word	Danger	
Hazard Statement Codes	H301: Toxic if swallowed H332: Harmful if inhaled H373: May cause damage to the Central Nervous System (CNS) through prolonged or repeated exposure H335: May cause respiratory irritation H410: Very toxic to aquatic life with long lasting effects	
Specific Concentration limits, M-Factors	M = 1000 for both Aquatic Acute 1 (based on 48h EC_{50} of 0.0003 mg/L for *Daphnia magna*) and Aquatic Chronic 1 (based on a long term NOEC of 0.00003 mg/L for both fish and crustaceans and on the fact that alpha-cypermethrin is not ready degradable)	

b) Intended use, target species and effectiveness

Alpha-cypermethrin is an insecticide intended to be used indoor by professionals for hard surfaces, crack and crevice treatments and areas behind furnishings applied by low-pressure spraying. Alpha-cypermethin is intended to control a broad range of insects. Use in industrial processes and by the general public is not envisaged.

Efficacy tests have demonstrated the effectiveness of alpha-cypermethrin at application rates of 7.5 and 15 mg a.i./m^2 against German cockroaches *(Blattella germanica)*, cat fleas (*Ctenocephalides felis*) and bed bugs (*Cimex lectularius*) on porous (carpet) and non-porous (glazed tiles) surfaces. These application rates are equivalent to those of alpha-cypermethrin in the representative biocidal product which also contains an additional active substance. In conclusion, sufficient efficacy has been demonstrated against the claimed target organisms.

There is no information available on the efficacy of the different alpha-cypermethrin isomers/enantiomers.

c) Overall conclusion on the risks for human health and environment including the need for risk management measures

Human health

For acute and subchronic repeated dose studies the adverse effect seen at the lowest dose levels for alpha-cypermethrin was neurotoxicity. Alpha-cypermethrin is not genotoxic, mutagenic, reproductive or developmental toxiciticant. According to the CLP regulation labelling for irritation is not necessary. There was no evidence of sensitisation.

The table below summarises the exposure scenarios assessed.

Summary table: scenarios		
Scenario (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
Application	Primary exposure Low-pressure spraying (<2bar) (including mixing and loading) Application duration: 120 min Frequency: Daily Tier 1: no PPE Tier 2a: PPE, no RPE Tier 2b: PPE, including RPE	Professional pest control operators
Post-application	Indirect exposure through inhalation, dermal contact and oral route	bystanders (adult, child, infant)

Unacceptable risks were identified for professional users exposed to alpha-cypermethrin when no personel protective equipment (PPE) was used. No unacceptable risks were identified however for professional users wearing protective clothing (at least a coverall and protective gloves). It is noted that when low-pressure insecticide sprayers are applied professional operators by default wear protective clothing including gloves and RPE (Respiratory Protective Equipment).

Secondary exposure to residues of alpha-cypermethrin on treated surfaces and residues in air does not pose a significant risk to consumers even under worst case assumptions for infants playing on treated carpet and mouthing hands.

Since releases to the environment including crop-growing areas are very limited, any quantitatively relevant exposure of humans via the food chain can therefore be safely excluded. Thus, aggregated exposure is considered to be of limited relevance. Therefore, aggregated exposure of children is considered to be fully covered by the secondary exposure scenarios and subsequent risk characterisations presented above. Furthermore, it seems highly unlikely that an adult individual working as a pest control operator is also exposed in his or her residential area to the same active substance that he or she applies during the workweek. Thus, aggregated exposure from biocidal use going beyond those sources already covered is not considered to be relevant.

Environment

Summary table scenarios	
Scenario	**Description of scenario**
Total surface application	
Use by professionals by spraying indoor (houses and large buildings)	Preparation and application result to emission to wastewater via washing of applicator clothes and wet room cleaning (subsequent release to sewage treatment plant (STP), surface water, sediment, soil, groundwater and secondary poisoning)
Barrier treatment	
Use by professionals by spraying indoor (houses and large buildings)	Preparation and application result to emission to wastewater via washing of applicator clothes and wet room cleaning (subsequent release to sewage treatment plant (STP), surface water, sediment, soil, groundwater and secondary poisoning)
Cracks and crevices treatment	
Use by professionals by spraying indoor (houses and large buildings)	Preparation and application result to emission to wastewater via washing of applicator clothes and wet room cleaning (subsequent release to sewage treatment plant (STP), surface water, sediment, soil, groundwater and secondary poisoning)

The main emission route of alpha-cypermethrin through its use in the representative biocidal product is via wastewater to sewage water treatment plants (STP) and subsequent release via effluents to surface water and sediment after the cleaning of the treated areas or the spraying materials or washing of applicator cloths. There are no direct emissions to surface water or sediment, and aquatic or sediment organisms are not directly exposed to the active substance. Direct exposures of the environment via the pathways air, soil or groundwater are considered to be negligible. However, STP sludge might be applied to soil and contaminate soil. Therefore, the risk was calculated also for soil and groundwater. In addition secondary poisoning was assessed.

Three treatment or application scenarios were considered: surface application, barrier treatment and crack and crevice treatment.

Total surface application: when evaluating the total surface application, only the rooms subject to wet cleaning are taken into account to estimate emissions to waste water after treatment. Unacceptable risks to the aquatic compartment (including sediment) at all envisaged uses are identified, even when restricting use to 1 to 2 applications per year. In one instance a concentration exceeding the EU threshold acceptable limit for drinking water was calculated. Based on these results, the use of alpha-cypermethrin is not deemed safe to use as a total surface application.

Barrier treatment: when evaluating the limited surface application or barrier treatment, only the areas subjected to wet cleaning are taken into account to estimate emissions to waste water after treatment. Unacceptable risks to the aquatic compartment (including sediment) at all envisaged uses are identified, even when restricting use to 1 to 2 applications per year. Based on these results, the use of alpha-cypermethrin is not deemed safe to use as a barrier application.

Crack and crevice treatment: Unacceptable risks to the aquatic compartment (including sediment) are identified at both use-concentrations (15 mg a.s./m² and 7.5 mg a.s./m²) for which efficacy data are available, when no restrictions are in place. When taking into account a label restriction of 1 to 2 applications per year, no unacceptable risks for the environment are calculated. Based on these results, the use of alpha-cypermethrin as formulated in the representative biocidal product can be considered acceptable for crack and crevices treatments, providing that a restriction to 1 to 2 applications per year is included on the label.

2.2. Exclusion, substitution criteria 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		Conclusion
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)	Not P
	Bioaccumualtive (B) or very Bioaccumulative (vB)	Not B
	Toxic (T)	T
Endocrine disrupting properties	Alpha-cypermethrin is not classified as Carc. 2 or Repr. 2 and has not been identified as having endocrine disrupting properties.	

Consequently, the following is concluded:

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

Alpha-cypermethrin 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).

No information is available on the persistency, bioaccumulation or toxicity of the individual alpha-cypermethrin enantiomers. However, guidance on PBT assessment (ECHA Guidance: Chapter R.11: PBT Assessment, v.1.1, November 2012) indicates that isomer constituents present at amounts ≥0.1 % w/w for multi-constituent substances should also be treated as potentially persistent, bioaccumulative or toxic. In this case alpha-cypermethrin would need to have its individual isomers further investigated to determine the PBT nature of the constituent components of this isomeric substance.

2.2.2. POP criteria

The criteria for a substance being a persistent organic pollutant (POP) are 'P', 'B' and having the potential for long range transport. In addition, high toxicity can breach the 'B' criterion, in which case a substance will be a persistent organic pollutant if it is 'P', demonstrates the potential for long range transport, and is either 'B' or 'T'. Alpha-cypermethrin has been identified as T, but is not considered to be P nor B. This active substance shows a half-life of 3.47 hours in air and a vapour pressure of 5.6×10^{-7} Pa, well below the cut-off value of 1000 Pa. Thus alpha-cypermethrin does not show a potential for long-range transport. Given the above, alpha-cypermethrin does not meet the criteria for being a persistent organic pollutant (POP).

2.2.3. Water Framework Directive (WFD)

Cypermethrin is introduced as a priority substance in Directive 2013/39/EU, which amends Directive 2000/60/EC and Directive 2008/105/EC as regards priority substances in the field of water policy. Cypermethrin is listed as a priority substance, where no distinction is made between cypermethrin and its individual isomers including alpha-cypermethrin. This means that alpha-cypermethrin is covered and listed as a priority substance in Annex II of Directive 2013/39/EU. Consequently, it has to be investigated if the approval of alpha-cypermethrin will undermine the achievement of compliance with the standard laid down in the WFD.

Under this Directive, two types of quality standards are established to ensure good water quality: AA-EQS (annual average environmental quality standard) and MAC-EQS (maximum allowable concentration environmental quality standard).

In the case of cypermethrin the AA-EQS is 8×10^{-8} mg/L (inland surface waters, total concentration of all isomers). According to the WFD the arithmetic mean of all measured concentrations over a twelve month monitoring period within a body of water should not exceed this value.

This AA-EQS is 60 times lower than the aquatic Predicted No-Effect Concentration (PNEC) established for alpha-cypermethrin (4.8×10^{-6} mg/L). The reason for this difference is not so much based on a difference in the endpoints forming the basis of the AA-EQS and PNECaquatic, but has more to do with the choice of assessment factor. While for the derivation of the PNECaquatic an assessment factor of 5 was used, the AA-EQS was derived with an assessment factor of 50. The choice of this higher factor is explained by the availability of many low endpoints (EC50s or NOECs) for species from sensitive taxa, which were derived from studies of unassignable reliability or where the exposure concentrations were likely not maintained during the course of the experiments. Additionally, for the derivation of PNECs for biocide active substances, mesocosm studies can be accepted to lower the assessment factor, while for the derivation of AA-EQS the mesocosm studies are merely used as a confirmation of toxicity. It is recommended to further investigate the differences in both values.

In addition to an AA-EQS, also a MAC-EQS was established for cypermethrin. The MAC-EQS (6×10^{-7} mg/L for cypermethrin) may not be exceeded by any measured concentration at any point of the water body or at any point in time.

Again, this standard is lower than the established aquatic PNEC, this time by a factor of 8. Also here this is a result of the choice of assessment factor, which is more conservative for the EQS-derivation.

Before comparing the calculated aquatic Predicted Environmental Concentrations (PECs) from this evaluation with any quality standard, one should first consider what this PEC represents and if it can be compared with the established standards. In the case of alpha-cypermethrin, the aquatic PECs are derived from a daily, local emission and represent a concentration in surface water during an emission period: the emission pattern can be considered as intermittent. Therefore, the comparison between the AA-EQS (annual average environmental quality standard) and the MAC-EQS (maximum allowable concentration environmental quality standard) and the PEC may not be appropriate.

Considering the above and when comparing the lowest calculated PEC ($2.76x10^{-7}$ mg/L) with the AA-EQS, it can be concluded that (because the PEC exceeds the AA-EQS over 3 times) a single source of alpha-cypermethrin already exceeds the established standard, allowing no more room for other sources of the substance (e.g. plant protection). However, as indicated, the PEC calculated here is the concentration resulting from an emission episode, while the AA-EQS is an annual average. Comparing the two and drawing conclusions merely on these numbers does not seem correct.

Comparing the PECs to MAC-EQS seems more relevant, as this EQS represents a single concentration that may not be exceeded. For alpha-cypermethrin, neither of the PECs calculated in the identified safe use scenario for crack and crevice treatement (5.52×10^{-7} and 2.76×10^{-7} mg/L) exceed this standard.

In conclusion, and based on the fact that at the time of adoption of this opinion no monitoring data for this substance are available, the comparison of the PECs with the EQS values listed for alpha-cypermethrin as a priority substance under the WFD alone is not reason enough to prevent the approval of alpha-cypermethrin because approval would undermine the achievement of compliance with the standards laid won in the WFD. However, when monitoring data for this substance become available under the WFD, these should be taken into account at product authorisation level. Where relevant, MSCAs have to inform the Commission as a review of the approval in line with Article 15 of the BPR may be initiated.

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

In view of the conclusions of the evaluation, it is proposed that alpha-cypermethrin 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: ≥ 930 g/kg (93.0 % w/w) (sum of the isomers in a 1:1 ratio);

2. 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.

3. For 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.

4. To prevent risks for the aquatic environment products shall not be used for the treatment of surfaces that are prone to frequent wet cleaning, other than crack and crevice treatment, unless data are submitted demonstrating that the product will meet the requirements of Article 19 and Annex VI of Regulation (EU) No 528/2012, if necessary by the application of appropriate risk mitigation measures.

Alpha cypermethrin cannot be included in Annex I of Regulation (EU) No 528/2012 because it meets the following criteria of Article 28(2): i) acutely toxic of category 3 (H301); ii) specific target organ toxicant by single (STOT SE 3) and repeated exposure (STOT RE 2); and iii) toxic to aquatic life of acute category 1.

2.4. Elements to be taken into account when authorising products

1. The representative product contains alpha-cypermethrin and flufenoxuron. However the risk assessment was performed on alpha-cypermethrin only and not on the second active substance.

2. For products containing alpha-cypermethrin the following statement should be added to the label: "The product contains: Alpha-cypermethrin. May cause paraesthesia."

3. Use of biocidal products containing alpha-cypermethrin and used in a sensitive area (hospital, kitchens, restaurants, food-processing and storage areas) may lead to residues in foods. Therefore a label restriction for such products used in sensitive areas is required (e.g. "Do not contaminate foodstuffs, eating utensils or food contact surfaces"; "Keep away from food, drink and animal feeding stuffs"). Additionally for such products, a dietary risk assessment (DRA) will be required at product authorisation stage.

4. 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.

5. Alpha-cypermethrin is a 1:1 mixture (racemate) of the pair of enantiomers. There is no information available on the efficacy of the different enantiomers and therefore it is not known whether it fulfils the Article 10(1)(f) on the 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 alpha-cypermethrin isomers will have to be considered when such guidance does become available.

6. For the purpose of the evaluation of alpha-cypermethrin the $PNEC_{sediment}$ was converted from dry weight to wet weight taking into account the default conversion factor of 4.6 instead of a measured factor. However, at the Environment Working Group (WG) of January 2014 it was agreed that the conditions of the use of a measured conversion factors instead of a default conversion factor would be further discussed. Therefore, at product authorisation stage this conversion factor should be revised based on the outcome of these discussions.

7. When authorising products containing alpha-cypermethrin it must be shown that the concentration of the active substance in the product, the application rate, the

frequency of use and its amount allow a safe use regarding the aquatic compartment (including sediment).

8. Alpha-cypermethrin, as a constituent of the isomeric mixture cypermethrin, is listed as a priority substance under Directive 2013/39/EU. When monitoring data become available for cypermethrin, these should be considered during product authorisation stage.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the approval of alpha-cypermethrin. However, further data shall be required as detailed below.

Analytical methods:

Validation of the confirmatory method for residues in water is still required. This information has to be provided as soon as possible but at the latest 6 months before the date of approval to the evaluating Competent Authority (Belgium).

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