Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Cypermethrin

Product type: PT 18

ECHA/BPC/153/2017

Adopted

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

Common name:	**cypermethrin**
Chemical name:	**cypermethrin *cis:trans* 40:60; (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate**
EC No.:	**257-842-9**
CAS No.:	**52315-07-8**
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 Arista Life Science on 30 March 2006, the evaluating Competent Authority Belgium submitted an assessment report and the conclusions of its evaluation to ECHA on 15 April 2015. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-19) and its Working Groups (WG IV 2016). The opinion was adopted via a written procedure after BPC-19. 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 approval of the active substance cypermethrin in product type 18 was adopted on 5 May 2017.

The BPC opinion was adopted by consensus. The opinion is 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 cypermethrin 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 cypermethrin in product type 18. Cypermethrin is a synthetic pyrethroid. 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. Validated analytical methods are required and available for the relevant matrices air, water and soil.

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

Current classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4 STOT SE3 Aquatic acute 1 Aquatic chronic 1
Labelling	
Pictogram codes	GHS07, GHS09
Signal Word	Warning
Hazard Statement Codes	H332 Harmful if inhaled H302 harmful if swallowed H335 May cause respiratory irritation H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	-

A CLH proposal to revise the current classification was submitted to ECHA by the evaluating Competent Authority (eCA; Belgium) in 2015. A revision of the proposal is necessary according to the result of the accordance check received. The proposed classification and labelling for cypermethrin 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 RE2 STOT SE3 Aquatic acute 1 Aquatic chronic 1

Labelling	
Pictogram codes	GHS07, GHS09
Signal Word	Warning
Hazard Statement Codes	H332 Harmful if inhaled H302 harmful if swallowed H373 May cause damage to organs through prolonged or repeated exposure H335 May cause respiratory irritation H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	Acute M =100 Chronic M= 1000
Justification for the proposal	
The results from the 5-week and 90-day repeated dose toxicity studies in dogs justify classification of cypermethrin because the neurotoxicity effects observed at 37.5 mg/kg bw/day are between the classification cut off of 10<C ≤100 mg/kg bw/day for STOT RE2. In addition, literature results indicate hepatotoxicity at 300 mg/kg bw/d (i.p, 7 days) and at 31.5 mg/kg bw/d, oral). M factors are derived according to the CLH proposal, which contains additional studies not belonging to Arysta. The lowest LC_{50} (fish), are between > 0.001 < 0.01 mg/L, cypermethrin should be classified as Aquatic Acute Category 1 and an M factor of 100 is proposed. NOEC values for cypermethrin are available for all trophic levels. The lowest acceptable NOEC is 0.00004 mg/L (obtained for invertebrates). Cypermethrin fulfills criteria for classification as Aquatic Chronic Category 1. The lowest NOEC is between 0.00001 mg/l and 0.0001 mg/l and cypermethrin is considered not rapidly degradable, therefore an M factor of 1000 for chronic toxicity is proposed.	

b) Intended use, target species and effectiveness

According to applicant's original submission, cypermethrin (in spray formulations) is intended to be used in and around domestic and public buildings including farms, animal housing and food processing facilities by professionals as a broad spectrum insecticide against crawling and flying insects. Products containing cypermethrin are used as spray formulations, primarily as a crack and crevice application, in application rates between 25 and 50 mg/m^2.

Cypermethrin is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon. Typically, this intoxication results in a rapid "knockdown". The affected insect shows uncoordinated movements and finally dies.

Efficacy tests (for indoor use – on hard surfaces) against house flies, cockroaches, cat fleas and garden ants have been submitted. Based on these studies efficacy has been demonstrated against cat fleas and German cockroaches. The claim for an outdoor use is not supported by efficacy data.

Resistance to pyrethroid insecticides has been reported for a number of pests both in agriculture and public health. Strategies such as alteration of insecticides with different modes of action and avoidance of over frequent use are standard practises in agriculture and should be applied also to biocide uses of cypermethrin.

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

Human health

The active substance cypermethrin is moderately toxic if swallowed or inhaled, and is of low toxicity if applied to the skin. Cypermethrin meets the criteria for classification as respiratory irritant, but not for skin or eye irritation or skin sensitisation. Cypermethrin has a neurotoxic potential. It is not genotoxic, carcinogenic or reproductive or developmental toxiciticant.

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**
Spraying	Primary exposure: Spraying indoor domestic and public buildings, including mixing and loading steps by low pressure spray application (Spraying model 1). The indoor spraying covers outdoor spraying. PPE: gloves	Professional users	Acceptable with PPE
Post-spraying Crack and crevices	Secondary exposure through inhalation, dermal contact and oral route (not all route of exposure are relevant for each age category).	Infants, toddlers, children and adults	Acceptable
Post-spraying General surface	Secondary exposure through inhalation, dermal contact and oral route (relevant for each age category).	Infants, toddlers, children and adults	Unacceptable for toddlers and infants

There is no concern for the professional operators, using biocidal product containing cypermethrin during spraying indoor, provided appropriate PPE is worn (gloves). A qualitative local risk assessment was performed because the reperentative product is classified as skin sens 1 (based on an LLNA study). However this hazard is probably triggered by a co-formulant and there is no concern for professional workers wearing gloves.

For secondary exposure of the general public infants, toddlers, children and adults exposed to residues of cypermethrin following general surface spraying and spraying limited to crack and crevice treatment was assessed. Adults may be subject to inhalation exposure only, whereas children may be exposed by inhalation and dermal contact (playing on the floor). Crawling on a treated surface, oral (mouthing) and inhalation exposure is considered for toddlers and infants.

The risk following secondary exposure of the general public was acceptable for all age groups following crack and crevice application. An unacceptable risk was identified for infants and toddlers in the post-spraying for general surface application, but not for children or adults. This risk can be mitigated by restricting this application to surfaces not accessible for infants and toddlers.

For uses that can lead to indirect exposure via food, no exposure and risk assessment was performed.

Environment

Cypermethrin is toxic for the aquatic fauna but less toxic for aquatic plants and algeae. Cypermethrin adsorbs strongly to soil and sediment particles. Cypermethrin is biodegradable and in natural soil and sediment it is degraded to three major metabolites (3PBA, CDCVC, TDCVC). Further metabolism of cypermethrin and/or these metabolites results in bound residue and mineralisation to carbon dioxide.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Indoor use in domestic premises and commercial buildings	Surface application: surface water, sediment, Sewage Treatment Plant (STP), soil and ground water	Unacceptable risks for surface water, sediment, and soil.
	Chemical barrier andcrack and crevice treatment): surface water, sediment, STP, soil and ground water	Unacceptable risks for sediment. Acceptable when applied in dry-cleaned areas.
Outdoor use	Wall (flying insects) treatment in urban areas: surface water, sediment, STP, soil and ground water	Unacceptable risks for surface water, sediment and soil and ground water.
	Wall (flying insects) treatment in rural areas: soil and ground water	Unacceptable risks for soil.
	Perimeter (crawling insects) treatment in urban areas: surface water, sediment, STP, soil and ground water	Unacceptable risks for surface water, sediment and ground water.
	Perimeter (crawling insects) treatment in rural areas: soil and ground water	Unacceptable risks for soil.

The risk following the use of cypermethrin as a spray application has been assessed for indoor (covering domestic premises and commercial buildings) and outdoor uses.

With respect to the indoor use unacceptable risks were identified for surface water, soil and sediment for surface application. The use was acceptable for the STP and ground water. For the chemical barrier treatment and crack and crevice treatments, a risk for sediment was identified. This risk can be mitigated if the product is only applied in rooms where only dry-cleaning methods are used.

Unacceptable risks were identified for soil for outdoor use treatment of walls in urban and rural areas and for perimeter treatment for rural areas. Unacceptable risks were identified for surface water, ground water and sediment for treatment of walls and perimeter in urban.

No unacceptable risks were identified for secondary poisoning. A qualitative assessment of the risks for beneficial arthropods (bees) demonstrated that there is no unacceptable risk due to the small scale indoor use.

Overall conclusion

The use of cypermethrin has been evaluated as acceptable when applied indoor by small scale applications by spraying (chemical barrier or cracks and crevices) against flying and crawling insects by professionals in spaces which are only dry-cleaned. The risk to human health is acceptable for spray application, with the restriction that for general surface applications only surfaces not accessible for infants and toddlers can be sprayed.

Unacceptable risks were identified for environment for surface application via spraying indoors (except for the use described above) and for outdoor use for all applications.

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:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>no classification required</td><td rowspan="3">cypermethrin does not fulfil criterion (a), (b) and (c) of Article 5(1)</td></tr>
<tr><td>Mutagenicity (M)</td><td>no classification required</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>no classification required</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>not P or vP (cyp.)

P (CDCVC and TDCVC)</td><td rowspan="3">cypermethrin does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>not B or vB (cyp)

not B or vB (CDCVC and TDCVC)</td></tr>
<tr><td>Toxic (T)</td><td>T criteria fulfilled (cyp)

Not T (CDCVC and TDCVC)</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">Cypermethrin is not considered to have endocrine disrupting properties according to the interim criteria of Article 5(3). Cypermethrin does not fulfil criterion (d) of Article 5(1).</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="3">No classification required. Cypermethrin does not fulfil criterion (b) of Article 10(1).</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="3">Cypermethrin does not fulfil criterion (e) of Article 10(1).</td></tr>
<tr><td>Proportion of non-active isomers or impurities</td><td colspan="3">Cypermethrin is 92 % pure. It is composed of 8 main isomers which has their own activity whilst the level of activity of each single isomer differs depending on the configuration of the cyclopropane C-1 and the α-cyano group. A R</td></tr>
</table>

	configuration at the cyclopropane C-1 position is essential for neurotoxicity; the corresponding 1-S enantiomer is non-toxic. The configuration of the α-cyano group also influences toxicity: a S configuration of the α-cyano carbon is a potent mammalian toxicant, whereas the α-R enantiomers are essentially non-toxic. Thus, the more active components of cypermethrin are 1R cis α S and 1R trans α S, e.g. approximately 25% of the mixture. Less active isomers are 1R cis α R; 1S cis α S ; 1R trans α R and 1S trans α S e.g. approximately 50% of the mixture . Less active isomers are 1S cis α R and 1 S trans α R e.g. approximately 25% of the mixture. It is concluded that cypermethrin does not meet criterion (f) of Article 10(1).

Consequently, the following is concluded:

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

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"[1] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[2] 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

Cypermethrin does not meet the P/vP and B/vB criteria. It also does not meet the criteria for long-range transport in the environment. Consequently, it can be considered that cypermethrin does not meet the POP criteria.

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. Consequently, it has to be investigated if the approval of 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).

[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)

[2] 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)

In the case of cypermethrin the AA-EQS is 8 x 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 50 times lower than the aquatic Predicted No-Effect Concentration (PNEC) established for cypermethrin (4 x 10^{-6} mg/L). The reason for this difference is based on a difference in the endpoints forming the basis of the AA-EQS and PNECaquatic, and the choice of assessment factor. While for the derivation of the PNECaquatic an assessment factor of 10 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. Additionnally, most of the studies used in the WFD are not part of the biocide dossier.

In addition to an AA-EQS, also a MAC-EQS was established for cypermethrin. The MAC-EQS ($6x10^{-7}$ 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 6. Also here this is a result of the choice of the 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 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 (3.21 x 10^{-8} mg/L) with the AA-EQS, it can be concluded that adding an additional source of 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 to be correct.

Comparing the PECs to MAC-EQS seems more relevant, as this EQS represents a single concentration that may not be exceeded. For cypermethrin, neither of the PECs calculated in the identified safe use scenario (1.66 x 10^{-7} and $3.21x10^{-8}$ mg/L for chemical barrier, dry cleaning and crack and crevice, dry cleaning) 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 cypermethrin as a priority substance under the WFD alone is not reason enough to prevent the approval of 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 cypermethrin in product type 18

In view of the conclusions of the evaluation, it is proposed that 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: 92% w/w. Isomeric ratio: *cis:trans* 40:60.

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. Professional users;

        ii. Secondary exposure of infants and toddlers;

        iii. Surface water, sediment, soil for: 1) surface application indoors; and 2) outdoor wall and perimeter applications in urban areas;

        iv. Soil for: 1) surface application indoors; and 2) outdoor wall applications in urban areas;

        v. Sediment following chemical barrier application indoor;

        vi. Soil following outdoor wall and perimeter applications in rural areas;

        vii. Groundwater following outdoor wall and perimeter applications in urban areas.

    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 or Regulation (EC) No 396/2005 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 requirements of Article 28(2)(a), and therefore cypermethrin cannot be included in Annex I of Regulation (EU) 528/2012.

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 is identified for professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

    b. If an unacceptable risk is identified for infants and toddlers following secondary

exposure in areas following treatment, labels, and where provided, safety data sheets, should indicate that products used in these areas shall be restricted to areas not accessible to infants and toddlers.

c. 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.

d. A local risk assessment may be required if the product is classified for skin sensitisation.

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

f. Unacceptable risks are identified for surface water and sediment for indoor surface treatment. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, such uses should not be authorised.

g. Unacceptable risks are identified for the sediment for indoor chemical barrier application. Products shall only be authorised if the risk can be mitigated by measures that minimise exposure to sediment (via sewage), for example restricted application to areas that are not normally wet-cleaned or if the risk can be mitigated by other means.

h. Unacceptable risks are identified for soil following outdoor wall application in urban and rural areas and following perimeter application in rural areas. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, such uses should not be authorised.

i. Unacceptable risks are identified for surface water, ground water and sediment following outdoor wall and perimeter applications in urban areas. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, such uses should not be authorised.

j. Due to the increased sensitivity of cats against pyrethroids a specific assessment and specific risk mitigation measures for pets might be required for product authorisation.

2. Cypermethrin is listed as a priority substance under Directive 2013/39/EU. When monitoring data become available, 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 proposal for the approval of cypermethrin.

However, a further study is required on developmental neurotoxicity. This study must be provided as soon as possible but no later than 6 months before the date of approval to the eCA (Belgium).

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