# Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

***epsilon*-Momfluorothrin**

**Product type: 18**

ECHA/BPC/119/2016

Adopted

16 June 2016

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# Opinion of the Biocidal Products Committee

**on the application for approval of the active substance *epsilon*-Momfluorothrin for product type 18**

In accordance with Article 90(2) 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:** | ***epsilon*-Momfluorothrin**[1] |
| **Chemical name**[2]**:** | **All isomers**: 2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (EZ)-(1RS,3RS;1SR,3SR)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate<br>**RTZ isomer**: 2,3,5,6-Tetrafluoro-4-(methoxymethyl)benzyl *(Z)-(1*R*,3*R)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate |
| **EC No.:** | **None** |
| **CAS No.**: | **All isomers: 609346-29-4**<br>**RTZ isomer: 1065124-65-3** |
| **New 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 29 May 2013, the evaluating Competent Authority UK submitted an assessment report and the conclusions of its evaluation to ECHA on 6 October 2015. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-16) and its Working Groups (WG II 2016). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

[1] Also known by the manufacturer's code: S-1563.
[2] Two names are included; both are IUPAC names but *epsilon*-Momfluorothrin refers to the RTZ-isomer.

## Adoption of the BPC opinion

**Rapporteur: United Kingdom**

The BPC opinion on the approval of the active substance *epsilon*-Momfluorothrin in product type 18 was adopted on 16 June 2016.

The BPC opinion was adopted by consensus.

# Detailed BPC opinion and background

## 1. Overall conclusion

The overall conclusion of the BPC is that *episilon*-Momfluorothrin 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 *epsilon*-momfluorothrin in product type 18. *epsilon*-Momfluorothrin is a synthetic pyrethroid which acts by interfering with nerve function of insects. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal products have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal products.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. The validation data provided for the monitoring of the parent in air is fully validated. Monitoring methods for body fluids and tissues and food and feed are not required. The validation data provided for the monitoring of residues in soil and water are not complete and will be required before the date of approval of the active substance as detailed in section 2.5.

The harmonised classification and labelling for *epsilon*-Momfluorothrin according to Regulation (EC) No 1272/2008 (CLP Regulation) is (agreed by RAC on 15 September 2015):

| **Classification according to the CLP Regulation** | |
|---|---|
| Hazard Class and Category Codes | Acute Tox. 4, H302<br>STOT-SE 2, H371<br>Aquatic Acute 1, H400<br>Aquatic Chronic 1, H410 |
| **Labelling** | |
| Pictogram codes | GHS07<br>GHS08<br>GHS09 |
| Signal Word | Danger |
| Hazard Statement Codes | H302: Harmful if swallowed<br>H371: May cause damage to the organs (Central Nervous System)<br>H400:Very toxic to aquatic life<br>H410: Very toxic to aquatic life with long lasting effects |
| | |
| **Specific Concentration limits, M-Factors** | M = 100 (acute)<br>M = 100 (chronic) |

**b) Intended use, target species and effectiveness**

Insecticidal products containing *epsilon*-momfluorothrin are ready to use, household aerosols that are designed to be used by non-professionals (indoors and outdoors) to control crawling and flying insects, as a directed spray and as a crack and crevice treatment (indoors and outdoors).

*epsilon*-Momfluorothrin is a synthetic pyrethroid which exerts its biocidal effect by interfering with nerve function of insects.

The assessment of the biocidal activity of *epsilon*-Momfluorothrin demonstrates that it has a sufficient level of efficacy against the target organisms and the evaluation of the summary data provided in support of the efficacy of the accompanying products, establishes that the products may be expected to be efficacious. However, *epsilon*-Momfluorothrin acts primarily as a knock-down agent and so will always be used in combination with another pyrethroid active substance to provide the 'kill' effect.

The resistance of the target organisms to *epsilon*-Momfluorothrin is not currently an issue. However, it is anticipated that there will be the potential to develop resistance to *epsilon*-momfluorothrin and so a resistance management strategy will need to be considered at the product authorisation stage.

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

### Human health

*epsilon*-Momfluorothrin is classified as harmful by the oral route following a single exposure but does not require classification for acute toxicity following inhalation and dermal exposure. Neurotoxic effects are observed following single oral and inhalation exposure, meeting the criteria for classification. *epsilon*-Momfluorothrin is not an irritant or sensitiser.

Following repeated exposure, liver toxicity is the lead health effect.

*epsilon*-Momfluorothrin does not meet the criteria for classification as a mutagen, carcinogen or reproductive toxicant.

*epsilon*-Momfluorothrin is most potent by the inhalation route and so, route-specific systemic Acceptable Exposure Level (AEL) values were established for use in the human health risk characterisation.

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** |
| Air space spray application indoors | **Primary exposure** during application and for a short duration afterwards. | Non-professional | Acceptable |
| Air space spray application indoors | **Primary exposure** during application and via inhalation to the droplets in the air dispersing 4 hours after application. | Non-professional | Acceptable* |
| Surface spray application indoors: crack and crevice /targeted spot application | **Primary exposure** during application and for a short duration afterwards. | Non-professional | Acceptable* |

| | | | |
|---|---|---|---|
| Surface spray application indoors: crack and crevice /targeted spot application | **Primary exposure** during application and via inhalation to the droplets in the air dispersing 4 hours after application. | Non-professional | Acceptable* |
| Air space spray application indoors | **Secondary exposure** of adult, toddler or infant during application or entering the room post application and via inhalation to droplets in the air dispersing 4 hours after application | Adult, toddler, infant | Acceptable† |
| Surface spray application indoors: crack and crevice /targeted spot application | **Secondary exposure** of adult, toddler or infants during application or entering the room post application and via inhalation to droplets in the air dispersing 4 hours after application. | Adult, toddler, infant | Acceptable† |
| Air space spray application indoors | **Secondary exposure** of toddler or infant crawling across treated floor. | Toddler, infant | Acceptable§ |
| Surface spray application indoors: crack and crevice /targeted spot application | **Secondary exposure** of toddler or infant crawling across treated floor. | Toddler, infant | Acceptable§ |
| Air space spray application indoors | **Combined exposure** – Adult, toddler, infant | Adult, toddler, infant | Acceptable† |

* *Based on exposure values for adult (tier 1) as the most conservative approach*
† *Based on exposure values for toddlers (tier 1) as the most conservative approach*
§ *Based on exposure values for infants as the most conservative approach*

No unacceptable risks are identified for primary, secondary or combined exposure scenarios.

**Environment**

*epsilon*-Momfluorothrin is hydrolytically stable and is not classified as "readily biodegradable". However significant degradation was shown in a water/ sediment degradation study and rapid degradation of *epsilon*-Momfluorothrin in soil was also observed. It was concluded that *epsilon*-Momfluorothrin will be subject to significant levels of degradation in both the aquatic and terrestrial environments.

As the active substance is not considered to be volatile, the air compartment is not considered in the exposure assessment.

Accumulation of *epsilon*-Momfluorothrin in soil is extremely unlikely to occur.

epsilon-Momfluorothrin is very toxic to fish and freshwater aquatic invertebrates, moderately toxic to aquatic algae and aquatic plants and is of low toxicity to aquatic microbial activity.

The table below summarises the exposure scenarios assessed.

| Summary table: environment scenarios | | |
|---|---|---|
| **Scenario** | **Description of scenario including environmental compartments** | **Conclusion** |
| Air space spray application indoors | Exposure to terrestrial and aquatic compartments. | Acceptable risk to STP. Unacceptable risk to surface water, sediment and soil. |
| Surface spray application indoors: crack and crevice /targeted spot application | Exposure to terrestrial and aquatic compartments. | Acceptable risk. |
| Surface spray application outdoors: crack and crevice /targeted spot application | Exposure to terrestrial and aquatic compartments. | Acceptable risk to STP. Unacceptable risk to surface water, sediment and soil. |
| Combined scenarios | Exposure to terrestrial and aquatic compartments. | Acceptable risk to STP. Unacceptable risk to surface water, sediment and soil. |

Acceptable risks are identified for all environmental compartments following use of products containing *epsilon*-Momfluorothrin indoors for crack and crevice treatment.

Unacceptable risks to surface water, sediment and soil are identified following use of products containing *epsilon*-Momfluorothrin indoors as an air space spray and as an outdoor surface spray.

**Overall conclusion**

Overall, a safe use has been identified for both human health and the environment when a product containing *epsilon*-Momfluorothrin is used indoors 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:

| **Property** | | **Conclusions** | |
|---|---|---|---|
| CMR properties | Carcinogenicity (C) | No classification required | *epsilon*-Momfluorothrin 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) | Not P or vP (the major metabolites fulfil the P, and potentially vP, | *epsilon*-Momfluorothrin does not fulfil |

| | | | |
|---|---|---|---|
| | | criteria) | 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 | |
| | Toxic (T) | T | |
| Endocrine disrupting properties | *epsilon*-Momfluorothrin is not considered to have endocrine disrupting properties. | | |
| Respiratory sensitisation properties | No classification required. *epsilon*-Momfluorothrin does not fulfil criterion (b) of Article 10(1). | | |
| Concerns linked to critical effects | *epsilon*-Momfluorothrin does not fulfil criterion (e) of Article 10(1). | | |
| Proportion of non-active isomers or impurities | *epsilon*-Momfluorothrin does not fulfil criterion (f) of Article 10(1). | | |

Consequently, the following is concluded:

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

*epsilon*-Momfluorothrin 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).

### 2.2.2. POP criteria

*epsilon*-Momfluorothrin does not meet the criteria for being a persistent organic pollutant.

## 2.3. BPC opinion on the application for approval of the active substance *epsilon*-momfluorothrin in product type 18

In view of the conclusions of the evaluation, it is proposed that *epsilon*-Momfluorothrin 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:

   All isomers: 93.0 % w/w

[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)

RTZ isomer: 82.5 % 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 risks identified for the uses assessed, the product assessment shall pay particular attention to:

        i. Surface water, sediment and soil for products used (i) indoors as a space spray; and (ii) outdoors as a surface spray.

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 or Regulation (EC) No 396/20053 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 fulfill the criteria according to Article 28 (1) to enable inclusion in Annex I of Regulation (EU) No 528/2012 as it is currently classified as STOT-SE 2 (H371) and Aquatic Acute 1 (H400).

## 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 space spray. 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.

    b. An unacceptable risk is identified for surface water, sediment and soil for products used outdoors as a surface spray. 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 *epsilon*-Momfluorothrin 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.

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 *epsilon*-Momfluorothrin.

The data gaps identified with the identity and batch analysis data must be addressed. The current information is sufficient for the approval. However, the data gaps identified shall be addressed via an application for technical equivalence according to Article 54 of Regulation (EU) No 528/2012.

However, the following data must be provided before the date of approval to the eCA (UK):

- The temperature dependence on the solubility in water and organic solvents should be addressed. The data should be generated in accordance with the Guidance on regulation (EC) 528/2012 concerning the making available on the market and use of biocidal product, version 1.0, ECHA July 2013.
- An appropriate residue definition for monitoring soil must be proposed and fully justified. Fully validated methods of analysis must be provided for each analyte in the residue definition. The validation data must be generated in accordance with Guidance on regulation (EC) 528/2012 concerning the making available on the market and use of biocidal products, version 1.0, ECHA July 2013.

  If the parent is included as part of the residue definition for soil then further validation data to support a lower LOQ or a justification as to why it is not technically feasible to support a lower LOQ may also be required.
- An appropriate residue definition for monitoring water must be proposed and fully justified. Fully validated methods of analysis must be provided for each analyte in the residue definition. The validation data must be generated in accordance with Guidance on regulation (EC) 528/2012 concerning the making available on the market and use of biocidal products, version 1.0, ECHA July 2013.