

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

INSECTICIDES FOR HOME USE

ECHA/BPC/228/2019

Adopted

26 June 2019

Opinion of the Biocidal Products Committee

on the Union authorisation of biocidal product family

INSECTICIDES FOR HOME USE

In accordance with Article 44(3) 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 Union authorisation of:

Name of the biocidal product family: INSECTICIDES FOR HOME USE

Authorisation holder: Agrobiothers Laboratoire

Active substances common names: permethrin, S-methoprene

Product type: 18

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 6 October 2016, recorded in R4BP3 under case number BC-TW023858-93, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 10 December 2018. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-31) and its Working Groups (WG II 2019). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the Union authorisation of the biocidal product family was reached on 26 June 2019.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including its grounds are published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s).

The biocidal product family maybe expected to fulfil the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of INSECTICIDES FOR HOME USE referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

General:

INSECTICIDES FOR HOME USE is a PT18 biocidal product family (BPF) based on permethrin and S-methoprene. The family is composed of one meta-SPC containing an aerosol product. The product of meta-SPC1 (INSECTICIDE HOUSEHOLD SPRAY) is a spray for direct surface application intended to be used indoor by non-professional users against mosquitoes, fleas and ticks.

The following non-active substances are identified as a substance of concern: propan-2-ol as it is an approved active substance with a content above 0.1% in the biocidal product, mixture of propellant (n-butane, propane and isobutane) as it is classified as Flam. Gas 1; and nitromethane due to its classification as Carc. 2. In addition, a co-formulant was identified as potentially having endocrine disruptor properties. It was however not possible to conclude on whether this co-formulant meets the scientific criteria for the determination of endocrine-disrupting properties as laid down in Regulation (EU) 2017/2100 before the expiration of the legal dead-line set in the BPR to decide on the application for product authorisation. This process should therefore take place at the post-authorisation stage (see paragraph 34 of the note CA-March18-Doc.7.3.b-final on "The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation").

Intended claims for the INSECTICIDES FOR HOME USE biocidal product family:

User	Meta-SPC	Uses
Non Professionals	Meta SPC 1	<p>Insecticide household spray against fleas (e.g. <i>Ctenocephalides felis</i>), ticks (<i>Ixodes ricinus</i> and <i>Rhipicephalus sanguineus</i>) and mosquitoes (<i>Aedes aegypti</i> and <i>Culex pipiens</i>) for indoor treatment of surfaces.</p> <p>After vacuuming the surface to be treated, the product is sprayed at a distance of 30 cm.</p>

Conclusions of the assessments of each section are given here below:

Physico-chemical properties

Physico-chemical studies were provided for INSECTICIDE HOUSEHOLD SPRAY. The product is stable after an accelerated storage of 8 weeks at 40°C and after 24 months at 20°C in this commercial packaging.

However, significant variations of the cis/trans ratio of permethrin during the shelf life studies with glass bottle were noticed and no rational explanation was provided by the applicant. These variations would lead to a non conformity of the results since the ratio cis/trans after storage is outside the range set for the approval of the active substance permethrin (cis/trans: 22-28: 78-72). However as permethrin is not known to isomerise, this result is expected to be due to experimental deficiency in the study. A new self life study is therefore requested at post authorisation for confirmation. Furthermore, some data were missing in the shelf life studies with the commercial packaging (tinplate can): the content of active substance before storage, the mass median aerodynamic diameter (MMAD) and the discharge rate were not reported. Consequently, the new requested shelf life study should be completed with the commercial packaging of INSECTICIDE HOUSEHOLDS SPRAY (tinplate can) and include active substance contents, cis/trans ratio of permethrin and determination of technical properties (all relevant properties for aerosol, discharge rate and MMAD) before and after storage. This study is required at post authorisation.

Product of meta-SPC1 (spray household) is classified H304 Category 1 (May be fatal if swallowed and enters airways). However, since the product is an aerosol (container with sealed spray attachment), there is no need to label the product H304 as mentioned in CLP regulation. The product should be stored at ambient temperature (20°C), protected from frost and from direct sunlight due to their nature (aerosols containing flammable gases).

Physico chemical dangers were assessed. Meta-SPC1 (spray household) is classified by default as H222 (Extremely flammable aerosol) and H229 Category 1 (Pressurised container: May burst if heated). Meta-SPC1 (spay household) is not explosive, does not possess oxidizing properties and is not autoflammable in the conditions of uses.

Analytical methods for the determination of active substances in the biocidal product and for the determination of active substances residues are validated.

Efficacy:

The family INSECTICIDES FOR HOME USE has shown sufficient efficacy as follows:

The curative efficacy of the product INSECTICIDE HOUSEHOLD SPRAY when used by spraying on surfaces against mosquitoes (*Aedes spp.* and *Culex spp.*), fleas (e.g. *Ctenocephalides felis*) and ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) at the application rate of 2.1 g product/m².

The following instructions for use have to be applied to ensure the efficacy of the product:

- Residual efficacy up to 6 months that can be lowered in case of normal cleaning (e.g. vacuum on carpets) or extensive use of the surfaces (e.g., walking, friction).
- In case of continuous infestation, to avoid the occurrence of resistance, alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population).
- If the infestation persists despite following the instructions of the label/leaflet, contact a pest control professional.
- Inform the authorization holder if the treatment is ineffective.

Human health risk assessment:

A classification for Eye Irritation category 2 - H319: Causes serious eye irritation is needed for INSECTICIDE HOUSEHOLD SPRAY.

In consequence, the risk mitigation measure "Avoid contact to eyes" should be implemented.

The risk for human health during application of INSECTICIDES FOR HOME USE is acceptable for non professionals. Some scenarios for secondary exposure are unacceptable. Risk mitigation measures (RMMs) have to be implemented:

- Avoid contact to eyes;
- After spraying, leave the room and let act one hour before airing;
- Keep children away during treatment;
- Do not apply the product in a room ever treated by fogging.

Dietary risk assessment:

Considering the use of the product of the biocidal product family INSECTICIDES FOR HOME USE, food or feed contamination is not expected. As a consequence the exposure via food, via livestock exposure or via transfer of biocidal active substances is considered as negligible, and no dietary risk assessment was performed. The following RMMs must be implemented to ensure no food contamination

- Remove all food, feed and drinks prior treatment;
- Do no use on surfaces and facilities in vicinity or likely to be in contact with food, feed and drinks.

Animal health Risk assessment:

Considering the toxic property of the active substances and notably permethrin regarding cats, a risk for pets cannot be excluded. Therefore, the following RMM have to be implemented:

- Remove or cover terrariums, aquariums and animal cages before application;
- Turn off aquarium air-filter while spraying;
- Keep cats away from treated surfaces due to high sensitivity to permethrin toxicity;
- Keep pets away during treatment.

Environment:

For the use of INSECTICIDE HOUSEHOLD SPRAY (meta SPC 1) for large spray application:

- risks are acceptable for STP and soil;
- concentrations in groundwater related to these uses of the products are lower than the trigger value set by Directive 98/83/EC;
- risks are unacceptable for the aquatic compartment (surface water and sediment).

For meta SPC 1, product INSECTICIDE HOUSEHOLD SPRAY, considering a restriction of use to treatment of non-washable furniture and home textile as carpets, mats, arm chairs and considering a refinement of the exposure scenario where only houses where pets are present are taken on board, which only covers uses against pet pests (fleas and ticks and not mosquitoes), risks are acceptable for all the environmental compartments. Therefore INSECTICIDE HOUSEHOLD SPRAY can lead to acceptable risk for the environment with the following RMM :

- The product is to be used for targeted treatment of non-washable furniture and home textile as carpets, mats, arm chairs;
- Do not use on wet washable surfaces and textile;
- Do not wash up furniture's with wet wiping clothes and do not wet clean carpets or mats to avoid discharges into the sewer system.

Overall conclusion

For meta-SPC 1 INSECTICIDE HOUSEHOLD SPRAY efficacy is demonstrated, leading to acceptable risks for human health and environment for targeted spray application to treat non-wet washable furniture and home textile against pet fleas and ticks.

Hence meta-SPC 1 INSECTICIDE HOUSEHOLD SPRAY can be authorised:

User	Meta-SPC	Uses
Non Professionals	Meta SPC 1	Insecticide household spray against fleas (e.g. <i>Ctenocephalides felis</i>) and ticks (<i>Ixodes ricinus</i> and <i>Rhipicephalus sanguineus</i>) for indoor treatment : after vacuuming the surface to be treated, the product is sprayed at a distance of 30 cm.

with the following risk mitigation measures:

- Do not use on wet washable surfaces and textile;
- Do not wash up furniture's with wet wiping clothes and do not wet clean carpets or mats to avoid discharges into the sewer system;
- Remove all food, feed and drinks prior treatment;
- Do no use on surfaces and facilities in vicinity or likely to be in contact with food, feed and drinks;
- Avoid contact to eyes;
- After spraying, leave the room and let act one hour before airing;
- Remove or cover terrariums, aquariums and animal cages before application;
- Turn off aquarium air-filter while spraying;
- Keep cats away from treated surfaces due to high sensitivity to permethrin toxicity;
- Keep children and pets away during treatment.

with the following instructions for use:

- The product is to be used for targeted treatment of non-washable furniture and home textile as carpets, mats and arm chairs;
- Residual efficacy up to 6 months that can be lowered in case of normal cleaning (e.g. vacuum on carpets) or extensive use of the surfaces (e.g., walking, friction);
- In case of continuous infestation, to avoid the occurrence of resistance, alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population);
- If the infestation persists despite following the instructions of the label/leaflet, contact a pest control professional;
- Inform the authorization holder if the treatment is ineffective.

b) Presentation of the biocidal product family including classification and labelling

The description of the structure of the family is available in the PAR.

The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substances permethrin and s-methoprene contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered candidates for substitution. Therefore, a comparative assessment of the biocidal product family is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product family were evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substances in the biocidal product family are met.

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

For the proposed authorised uses, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product family in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product family on non-target organisms,
 - the impact of the biocidal product family on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

It is proposed that the biocidal product family shall be authorised, for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

For the co-formulant identified as potentially having ED properties, a process under REACH will be triggered in line with paragraph 31(b) of the note CA-March18-Doc.7.3.b-final.

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Description	Due date
Provide a new shelf life study with the commercial packagings of INSECTICIDE HOUSEHOLDS SPRAY, including determination of active substance contents, cis/trans ratio of permethrin and determination of technical properties (before and after storage).	Not later than 30 months after the authorisation date

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