

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product:

Aero-Sense Aircraft Insecticide ASD

ECHA/BPC/262/2020

Adopted

17 June 2020

Opinion of the Biocidal Products Committee

on the Union authorisation of biocidal product

Aero-Sense Aircraft Insecticide ASD

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 application for authorisation of:

Name of the biocidal product: Aero-Sense Aircraft Insecticide ASD

Authorisation holder: Aero-Sense NV

Active substance common name: 1R-trans phenothrin

Product type: 18

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

Process for the adoption of opinions

Following the submission of an application on 02 February 2018, recorded in R4BP3 under case number BC-DX037393-17, 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 07 May 2020. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-35) and its Working Groups (WG I 2020). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Belgium

The BPC opinion on the Union authorisation of the biocidal product Aero-Sense Aircraft Insecticide ASD was reached on 17 June 2020.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA website.

Detailed opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the biocidal product is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012.

The biocidal product Aero-Sense Aircraft Insecticide ASD meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of Aero-Sense Aircraft Insecticide ASD 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.

General

The biocidal product Aero-Sense Aircraft Insecticide ASD is ready-to-use aerosolized formulation authorised for general aircraft disinsection. The product is authorised only for professional use by the cabin crew of an aircraft according to the aircraft disinsection protocols recommended by the World Health Organisation (WHO).

Aero-Sense Aircraft Insecticide contains 2% w/w of 1R-trans phenothrin (technical concentration) as active substance and no substance of concern has been identified in the biocidal product.

Physico-chemical properties

The product is an aerosol spray with 2% w/w 1R-trans phenothrin. Upon spraying, any propellants will evaporate immediately, rendering most parameters not relevant for the mixture itself. Nonetheless reference is made to the Competent Authority Report (CAR) of the active substance for appearance, relative density, surface tension and viscosity.

Accelerated storage stability testing at 40°C for 8 weeks showed no significant changes to the packaging nor active substance content. A long term stability test was performed and deemed acceptable to support a 2 year shelf-life. Storage at low temperature did not significantly affect the product.

The aerosol has a spray diameter of 4 cm. As the spray pattern at 30 cm distance did not yield interpretable results, this was measured at 10 cm distance. The discharge rate was 1.16 g/s and a bimodal particle size distribution was observed with 98 % of the particles < 50 µm. Storage does not significantly affect these parameters.

With regard to physical and chemical hazards, the product is classified as a non-flammable aerosol category 3 (as it contains ≤ 1% flammable components), and the chemical heat of combustion is < 20 kJ/g.

Efficacy

The results of the efficacy tests submitted show rapid knock down of *Aedes*, *Culex* and *Anopheles* mosquitoes within 30 minutes after product application, where *Culex* mosquitoes are the least sensitive. Knock Down of 80% was achieved within 30 min for *C. quiquefasciatus*, 15 min for *An. Stephensi* and 20 min for *Ae. aegypti* and *Ae. albopictus*.

The results of the simulated-use and field test show that 24 h after product application >97% of the mosquitoes are immobilized and unable to spread. Mortality after 24 h ranges from 65.8% (*Culex* spp.) to 80.4% (*Anopheles* spp.), which is below the requirement of the Guidance on the BPR: Volume II Efficacy, Assessment and Evaluation (Parts B and C). However, given the intended use of the product, the submitted test shows good efficacy to prevent the spread of mosquitoes by air traffic. The knocked down mosquitoes are dying and are not expected to recover from the treatment.

For the intended use, WHO Aircraft Insecticide test protocols are required. These standards allow to validate test results with negative control mortality up to 20%. The tests performed with propellant 2 (product for which authorisation is sought) are therefore considered to be validated.

Tests performed on product with propellant 1 are considered as supportive information.

It was noted that temperatures during testing were low. The applicant provides the following justification:

"The test chamber was heated by use of 4 x 2Kw fan heaters positioned throughout the chamber. The intention was for tests to be carried out at a higher temperature more akin to room (cabin) temperatures, however, due to the time of the year the tests were conducted, and due to the fact that no central heating system was in place, the temperature range was lower."

The applicant performed tests during winter, when airplane availability was not an issue, but also to ensure that if mosquitoes escaped, they would not be able to survive or establish an invasive population due to cold weather conditions. This justification was accepted since negative control results are still within the limits of the WHO test standards.

Human health

Assessment of effects on Human Health:

- No toxicological tests were performed on Aero-Sense Aircraft Insecticide ASD product.
- With regard to human health hazards, no classification is required for this biocidal product.

Human exposure:

- For primary exposure, only professional cabin crew personnel is expected to use the product Aero-Sense Aircraft Insecticide ASD. As it is delivered as a ready-to-use spray, exposure during mixing/loading is not relevant. During the application phase (spraying with aerosol cans), inhalation and dermal exposure is possible as well as an oral uptake of the non-respirable fraction.

The Secondary exposure of bystanders and general public exposed to the product will mainly occurs from inhalation of spray during application. They will also be exposed through contact with the deposited residues. Specifically for toddler passengers also hand-to mouth oral exposure is considered. Toddlers are deemed the most vulnerable given their relatively low body weight and their extensive hand-mouth contact whilst crawling/playing on the floor. For infants, only inhalation exposure is considered to be relevant because infants will

be held or transported in their own carriers and will have very limited opportunity for contact with aircraft surfaces.

Risk characterisation for human health:

- Conclusion for professional user:

When the product Aero-Sense Aircraft Insecticide ASD is used as proposed by professionals (airplane cabin crew), it has a sufficiently large safety margin for the scenario 1 (one application of the product by a cabin crew member per day) without use of PPE. In addition, the following risk mitigation measures are proposed:

- o The product should be applied only once per flight;
- o If more than one application per day is required, each application must be applied by a different member of the aircrew.

- Conclusion for general public:

- o When the product Aero-Sense Aircraft Insecticide ASD is used as proposed, no unacceptable risks are expected for adults, children and infants exposed secondary to the use of the product. However, a risk is identified for toddlers.
- o Performing a refinement on the inhalation rate (considering the more adequate inhalation rate considering light intensity activities), the risk is shown to be acceptable.
- o The risk via residues in food is considered negligible. However, a worst case exposure via residues in food have been estimated. It indicates very low exposure and supports negligible exposure. However, in order to avoid any misuse of the product, the following risk mitigation measure are mandatory on the label: "Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, drinks".
- o It is concluded that Aero-Sense Aircraft Insecticide ASD does not pose unacceptable risks for the general public.

Animal Health

Some aircrafts may transport small animals in cabins. However, due to the lack of appropriate guidance, exposure is assumed to be similar to toddlers and children and no specific measure is needed (except for cats).

Cats are known to be more sensible to pyrethroids than others animals due to a slower metabolism of these substances. Intoxication are very common and may be dangerous.

In order to protect cats, the following Risk Mitigation Measure must be added on the label:

"Contain 1R-trans phenothrin (pyrethroids), may be dangerous to cats. Care must be taken when the product is used in the presence of cats. Cats must be kept away during treatment".

Environment

Risks posed by cleaning events undertaken by passengers (bathing and laundering of contaminated clothing once they return home) are all shown to be acceptable.

If it is assumed that significant discharges to local STP can occur during routine wet cleaning of aircraft (daily after each flight plus at routine maintenance), then unacceptable risks are demonstrated to the aquatic compartment, sediment compartment, soil compartment and to non-target predatory biota.

However, a reasoned argument has been submitted to demonstrate that cleaning procedures adopted within the aviation industry would prevent losses to local STP as wet cleaning of surfaces is not routinely undertaken so liquid waste is not discharged to drains. It is further argued that airlines and airports utilise specialist products and disposable equipment (such as brushes and cloths), undertake vacuuming on carpeted areas and replace stained upholstery, which is then sent for specialist dry cleaning with a chlorinated solvent.

These procedures are undertaken to comply with other waste management legislation and WHO recommendations and, whilst the evidence is based upon working practises within one major airline in one EU MS, the same measures can be expected to be adopted across the industry. This position is accepted as a mitigating factor.

As the product will be applied by cabin crew, then additional labelling requirements for the product would have no impact on processes used for cleaning the aircraft between flights and at routine maintenance. Therefore, the applicant must ensure that all relevant parties (airlines, third party cleaning/maintenance companies etc) receive appropriate information to control and prevent emissions to environmental compartments as part of stewardship of their disinsection product.

This could be achieved by provision of additional guidance on technical data sheets / MSDS or on leaflets distributed with each batch of product sold to airlines or sent direct to interested parties, with the instruction that following application of the disinsection product:

- Cleaning of treated aircraft must only be undertaken with specialised products that do not require discharge of liquid waste to drains and local STP;
- When cleaning equipment (brushes, cloths etc) have been used, they must be disposed of as solid waste and must not be rinsed out for re-use.

Any such cleaning measures have no bearing on predicted emissions resulting from SCENARIO 3 (washing passenger clothes back home) as they arise from actual contamination of passengers, resulting from deposition of product and this cannot be avoided when product is applied. However, all risks have been shown to be acceptable.

Overall conclusion

The BPC considers that using the product according to the conditions as stated in the SPC, the product will be efficacious and will not present an unacceptable risk to human and animal health nor the environment.

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

The description of the biocidal product is available in the SPC.

The hazard and precautionary statements of the biocidal product 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 substance 1R-trans phenothrin contained in the biocidal product Aero-Sense Aircraft Insecticide ASD does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product 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 have been evaluated.

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

The physico-chemical properties of the biocidal product 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 is sufficiently effective;
2. the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance;
3. the biocidal product 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 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 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 on non-target organisms,
 - the impact of the biocidal product 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

As the conditions of Article 19(1) are met it is proposed that the biocidal product Aero-Sense Aircraft Insecticide ASD shall be authorised for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.