

COMMISSION IMPLEMENTING REGULATION (EU) 2021/368**of 1 March 2021****granting a Union authorisation for the single biocidal product 'Aero-Sense Aircraft Insecticide ASD'****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 2 February 2018, Aero-Sense NV submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a single biocidal product named 'Aero-Sense Aircraft Insecticide ASD' of product-type 18, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Belgium had agreed to evaluate the application. The application was recorded under case number BC-DX037393-17 in the Register for Biocidal Products.
- (2) 'Aero-Sense Aircraft Insecticide ASD' contains 1R-trans phenothrin, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.
- (3) On 7 May 2020, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').
- (4) On 2 July 2020, the Agency submitted to the Commission an opinion ⁽²⁾, the draft summary of the biocidal product characteristics ('SPC') of 'Aero-Sense Aircraft Insecticide ASD' and the final assessment report on the single biocidal product in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'Aero-Sense Aircraft Insecticide ASD' is a biocidal product, that it is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.
- (6) On 4 August 2020, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'Aero-Sense Aircraft Insecticide ASD'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0024297-0000 is granted to Aero-Sense NV for the making available on the market and use of the single biocidal product 'Aero-Sense Aircraft Insecticide ASD' in accordance with the summary of the biocidal product characteristics set out in the Annex.

⁽¹⁾ OJL 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 17 June 2020 on the Union authorisation of the biocidal product 'Aero-Sense Aircraft Insecticide ASD' (ECHA/BPC/262/2020), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>

The Union authorisation is valid from 22 March 2021 until 28 February 2031.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 1 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

Aero-Sense Aircraft Insecticide ASD

Product type 18 – Insecticides, acaricides and products to control other arthropods (Pest control)

Authorisation number: EU-0024297-0000

R4BP asset number: EU-0024297-0000

1. ADMINISTRATIVE INFORMATION**1.1. Trade name(s) of the product**

Trade name(s)	Aero-Sense Aircraft Insecticide ASD
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Aero-Sense NV
	Address	Schaapbruggestraat 50, 8800 Roeselare, Belgium
Authorisation number	EU-0024297-0000	
R4BP asset number	EU-0024297-0000	
Date of the authorisation	22 March 2021	
Expiry date of the authorisation	28 February 2031	

1.3. Manufacturer(s) of the product

Name of manufacturer	Volcke Aerosol Connection
Address of manufacturer	Industrielaan 15, 8520 Kuurne Belgium
Location of manufacturing sites	Industrielaan 15, 8520 Kuurne Belgium

Name of manufacturer	Envasado Xiomara, S.L.
Address of manufacturer	Polígono Industrial La Torrecilla Chica, 6, 45220 Yeles – Toledo Spain
Location of manufacturing sites	Polígono Industrial La Torrecilla Chica, 6, 45220 Yeles – Toledo Spain

Name of manufacturer	Aero-Sense NV
Address of manufacturer	Kachtemsestraat 289, 8800 Roeselare Belgium
Location of manufacturing sites	Kachtemsestraat 289, 8800 Roeselare Belgium

1.4. Manufacturer(s) of the active substance(s)

Active substance	1R-trans phenothrin
Name of manufacturer	Endura S.p.A
Address of manufacturer	Viale Pietro Pietramellara 5, 40121 Bologna Italy
Location of manufacturing sites	39 Wenfeng Road, 225009 Yangzhou, Jiangsu China

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
1R-trans phenothrin	3-phenoxybenzyl (1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate	Active Substance	26046-85-5	247-431-2	2,0

2.2. Type of formulation

AE – Aerosol dispenser

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Pressurised container: May burst if heated Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use. Avoid release to the environment. Collect spillage. Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F. Dispose of contents/container to hazardous or special waste collection point.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 1 – Mosquitoes – Aircraft treatment – Professionals

Product type	PT18 – Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide

Target organism(s) (including development stage)	Scientific name: Culex spp. Common name: Culex mosquitoes Development stage: Adults Scientific name: Aedes spp. Common name: Aedes mosquitoes Development stage: Adults Scientific name: Anopheles spp. Common name: Anopheles mosquitoes Development stage: Adults
Field(s) of use	Indoor Application in cockpit and cabin for aircraft disinsection.
Application method(s)	Aerosol spray Spraying
Application rate(s) and frequency	Recommended application rate: 35 g/100 m ³ (i.e. 0,7 g a.i./100 m ³). Ready-to-use product. Treatment should be repeated on each flight for which a disinsection treatment is required. One application per flight only.
Category(ies) of users	Professional
Pack sizes and packaging material	Aluminium (ALU) printed can 18 bar – Full colour printed White cap (One Shot actuator) or Blue cap (Multi Shot actuator) Packed in cardboard packaging per 24 pieces Available in different can sizes: <ul style="list-style-type: none"> • 40 g (34 mL) • 60 g (52 mL) • 100 g (86 mL)

4.1.1. Use-specific instructions for use

- Please refer to the onboard manual for the number of cans required for a disinsection treatment for each specific aircraft type.
- The disinsection procedure should be announced to passengers prior to the application of the product in the aircraft. Passengers should be advised to close their eyes and cover their faces whilst the procedure is carried out.
- Do not spray directly on skin or in eyes.
- Do not spray on or near food, food preparation areas or food utensils.
- Wash hands after handling.
- Prevent use by unauthorised personnel.
- Remove the cap.
- Hold can(s) vertically at arm's length.
- 'One shot' white cap: depress tab on spray nozzle until it locks down. The aerosol product is released in one continuous spray.
- 'Multi shot' blue cap: depress tab on spray nozzle until sufficient quantity is released or until product is completely discharged.
- The insecticide aerosol should be sprayed by directing the nozzle of the aerosol dispenser at an angle of approximately 45° towards the ceiling throughout the aircraft.
- The spray should be directed slightly behind the user.
- Spray evenly throughout the whole area.

40 g (34 mL) – One can effectively treats 114 m³ of air volume;

60 g (52 mL) – One can effectively treats 171 m³ of air volume;

100 g (86 mL) – One can effectively treats 285 m³ of air volume.

‘Blocks away’ disinsection

This procedure takes place prior to take off, after passengers have boarded and the doors have been closed.

The flight deck is sprayed prior to boarding by the cabin crew.

For disinsection to be effective, the aircraft air conditioning system must be switched off whilst spraying. The cabin crew must treat all possible insect harbourages including toilets, galleys and wardrobes, unless these areas have been sprayed together with the flight-deck prior to boarding.

‘Top-of-descent’ (in-flight spraying)

According to WHO guidance: pre-flight and top-of-descent spraying is a two-part disinsection method. ‘Top-of-descent’ (in-flight spraying) is the second technique of this method and is carried out at ‘top-of-descent’, as the aircraft starts its descent to the destination airport. Air re-circulation shall be set at normal flow.

No residual efficacy has been demonstrated.

Products containing 1R-trans phenothrin should not be used for both pre-flight and in-flight treatment in the same aircraft.

4.1.2. Use-specific risk mitigation measures

- The product should be applied only once per flight.
- A member of the cabin crew shall perform no more than one application per day.
- Do not use/apply the product directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food and drinks.
- Contains 1R-trans phenothrin (pyrethroids), may be dangerous to cats. Care must be taken in using the product when cats are present in the aircraft. Cats must be kept away during treatment.
- Cleaning of treated aircraft must only be undertaken using specialised products that do not require discharge of liquid waste to drains and local sewage treatment plants.
- Cleaning equipment (brushes, cloths, etc.) used on an aircraft after application of the product must be disposed of as solid waste and must not be re-used.

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First Aid instructions:

General

- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash with soap and water. If symptoms occur call a POISON CENTRE or a doctor.
- IF IN EYES: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If symptoms occur call a POISON CENTRE or a doctor.
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: seek medical advice.

Emergency measures to protect the environment in case of accident

- Contain and control any leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, or diatomaceous earth in drums for waste disposal.

- Prevent any material from entering drains or waterways.
- Do not direct water spray at the point of leakage or of spillage.
- Allow any product remaining as a result of the leak or spill to evaporate.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

- An appropriate entry should be made in the Aircraft General Declaration, giving details of the disinsection procedure together with the serial numbers of the spray cans used.
- The empty spray cans are to be retained for inspection by the Port Health Authority.
- Do not pour the product into drains or waterways.
- Ensure that waste management is carried out without endangering human health, without harming the environment and, in particular, without risk to water, air, soil, plants or animals.
- Recycle or dispose of waste product in compliance with applicable legislation, preferably via a certified collector or company.
- Do not contaminate the ground or water with waste product.
- Do not dispose of waste product into the environment.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See directions for use

5. **GENERAL DIRECTIONS FOR USE** ⁽¹⁾

5.1. **Instructions for use**

See section 4.1.1

5.2. **Risk mitigation measures**

See section 4.1.2

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

See section 4.1.3

5.4. **Instructions for safe disposal of the product and its packaging**

See section 4.1.4

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

- Store in original packaging in a cool (below 40 °C), dry and well-ventilated place. Protect from frost.
- Store out of direct sunlight, even when empty.

Shelf life: 2 years

6. **OTHER INFORMATION**

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for all authorised uses.