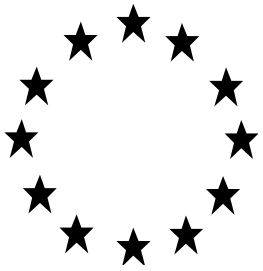
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Aero-Sense Aircraft Insecticide ASD

Product type 18

1R-trans phenothrin

Case Number in R4BP: BC-DX037393-17

Evaluating Competent Authority: Belgium

Date: June 2020

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1 CONCLUSION

The outcome of the assessment for the biocidal product 'Aero-Sense Aircraft Insecticide ASD' is specified in the BPC opinion following discussions at the BPC-35 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
Aero-Sense Aircraft Insecticide ASD	European Union

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Aero-Sense NV
	Address	Schaapbruggestraat 50, BE-8800 Roeselare
Pre-submission phase started on	12 May 2017	
Pre-submission phase concluded on	22 June 2017	
Authorisation number	To be determined	
Date of the authorisation	To be determined	
Expiry date of the authorisation	To be determined	

2.1.1.3 Manufacturer(s) of the products of the family

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

[1] Please fill in here the identifying product name from R4BP 3.

	8800 Roeselare Belgium
Location of manufacturing sites	Kachtemsestraat 289 8800 Roeselare Belgium

2.1.1.4 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	Jiangsu Yangnon Chemical Co. Ltd. 39 Wenfeng Road Yangzhou, Jiangsu 225009, P.R. China

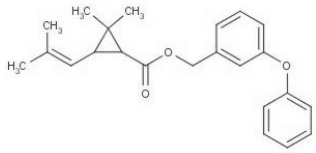
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	1R-trans phenothrin
IUPAC or EC name	3-Phenoxy-benzyl(1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate
EC number	247-431-2
CAS number	26046-85-5
Index number in Annex VI of CLP	/
Minimum purity / content	≥89% (≥95.5% sum of all isomers)
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance is not a candidate for substitution.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

The product contains 2% w/w (technical), corresponding to min. 1.78% w/w (pure) 1R-trans phenothrin [redacted] as active substance.

[redacted]

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

Reference is made to the confidential annex (section 3.5) for the full composition of the biocidal product.

2.1.2.4 Information on technical equivalence

A Tier II assessment was requested covering the assessment of the toxicological and/or ecotoxicological relevance of the presence of new impurities and/or an increase in the concentration of the impurities present in the alternative source as compared to the reference source.
The outcome is that the alternative source of 1R-trans phenothrin is considered technically equivalent compared to the reference source in respect of which the initial risk assessment was carried out. For more information, please refer to :

Decision number : TAP-D-1179353-16-00/F
Asset number : EU-0012144-0000

2.1.2.5 Information on the substance(s) of concern

The product Aero-Sense Aircraft Insecticide ASD does not contain substance of concern. Please see the confidential annex for further details.

2.1.2.6 Type of formulation

AE – Aerosol dispenser

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

[2] Phenothrin is the ISO common name for the racemic mixture of 4 stereoisomers. The active substance originally identified and notified under the biocides review programme for active substances during 2002 was "d-Phenothrin" (CAS 188023-86-1). d-phenothrin is the 4:1 mixture of the [1R,trans] and [1R,cis] isomers. However, during the evaluation of the active substance and Technical Meeting peer review procedure it was identified that the data submitted in relation to the identity and physical-chemical characteristics of the substance allowed conclusions to be drawn on only a certain form of d-phenothrin. The form of d-phenothrin concluded during the review process indicated a substance containing at least 89% w/w of the 1R-trans isomer. Therefore, the evaluation of the a.s during the review process refers to the active substance of the form 1R-trans phenothrin (min. 89% w/w of the 1R- trans isomer and min. 95.5% sum of all isomers) and only 1R-trans phenothrin was included in Annex I to Directive 98/8/EC. The active substance was included on Annex I of the BPD with inclusion date 1st September 2015 for use as a product-type 18 (PT 18) biocidal product (Directive 2013/41/EU). The BPD has since been replaced by the BPR and the Annex I list by a Union list of approved active substances.

Classification is based on the composition of the mixture. An aerosol is classified as 'non-flammable (cat. 3)' if it contains 1 % or less flammable components and the chemical heat of combustion is less than 20 kJ/g:

- None of the ingredients is classified as flammable.
- Heat of combustion of the product is <20kJ/g (cf. section 2.2.3).

Classification	
Hazard category	Aerosol (cat. 3) Aquatic acute 1 Aquatic chronic 1
Hazard statement	H229 – Pressurised container: May burst if heated H400 – Very toxic to aquatic life H410 – Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning
Hazard statements	H229 – Pressurised container: May burst if heated H410 – Very toxic to aquatic life with long lasting effects
Precautionary statements	P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P251 - Do not pierce or burn, even after use. P273 – Avoid release to the environment. P391 – Collect spillage. P410 + P412 - Protect from sunlight. Do not expose to temperatures exceeding 50 °C. P501 - Dispose of container to hazardous or special waste collection point.
Note	**-**

2.1.4 Authorised use(s)

2.1.4.1 Use description

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

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Mosquitoes – *Culex spp.* ; *Aedes spp.* and *Anopheles spp.*
Field of use	Indoor Application in cockpit and cabin for general aircraft disinsection.

Application method(s)	Spraying**.**
Application rate(s) and frequency	Recommended application rate: 35g/100m³ (i.e. 0,7g a.i./100m³). Treatment should be repeated on each flight for which a disinsection treatment is required. One application/flight only
Category(ies) of users	Professional
Pack sizes and packaging material	ALU printed can 18 bar - Full color printed White cap (One Shot actuator) or Blue cap (Multi Shot actuator) Packed in cardboard outer packaging per 24 pieces Available in different can sizes: • 40g (34ml) • 60g (52ml) • 100g (86ml)

2.1.4.2 Use-specific instructions for use

Please refer to your onboard manual for the number of cans required for a disinsection treatment for each specific aircraft type.

• Prior to disinsection, the procedure should be announced and the passengers should be advised to close their eyes and/or cover their faces for a few seconds whilst the procedure is carried out if they feel that it may cause them inconvenience.
• Do not spray directly on skin or in eyes.
• Do not spray on exposed food, food preparation areas or food utensils.
• Always wash hands after handling.
• Prevent access by unauthorised personnel.

• Remove the cap.
• '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 complete discharge or until right quantity is released.

• Hold can(s) vertically at arm's length.
• The insecticide aerosol shall be sprayed in the aircraft directing the nozzle of the aerosol dispenser at an angle of approximate 45° towards the ceiling throughout.
• Spray uniformly through whole area.
• The spray should be directed slightly behind the user.

• 40g (34ml) - One can will effectively treat 114 m³ of air volume;
60g (52ml) - One can will effectively treat 171 m³ of air volume;
100g (86ml) - One can will effectively treat 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.

• For disinsection to be effective, the aircraft air conditioning system must be switched off whilst spraying is carried out, and the 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 the boarding.
• The flight deck is sprayed prior to boarding by the crew.

"Top-of-descent" (in-flight spraying)
• According WHO guidance, this disinsection treatment is the second step in a two-part disinsection process: preflight and top-of-descent spraying.
• This disinsection method is carried out at "top-of-descent" as the aircraft starts its descent to the airport of arrival. Air re-circulation is set at normal flow.

No residual efficacy has been demonstrated.

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

2.1.4.3 Use-specific risk mitigation measures

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

2.1.4.4 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 symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Emergency measures to protect the environment in case of accident
• Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, 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. • Allow to evaporate

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

• An appropriate entry on the Aircraft General Declaration should be made giving details of the disinsection procedure together with the serial numbers of the used spray cans. • The empty spray cans are to be retained for inspection by the Port Health Authority. • Do not pour into drains or waterways. • 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 in compliance with current legislation, preferably via a certified collector or company. • Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

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

See section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

See section 2.1.4.2

2.1.5.2 Risk mitigation measures

See section 2.1.4.3

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

See section 2.1.4.4

2.1.5.4 Instructions for safe disposal of the product and its packaging

See section 2.1.4.5

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

• Store in original packaging and in a dry, frost-free and well ventilated place. Should not be stored above 40°C. • Even when empty, store in a cool place out of the sun. Shelf life : 2 years.

2.1.6 Other information

/

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Aerosol can 18 bar	Available in different can sizes: • 40g (34ml) • 60g (52ml) • 100g (86ml)	Aluminium	White (one-shot actuator) or blue (multi-shot actuator) polypropylene cap (pictures below for illustration)	Professional	Yes, based on the available storage stability data.

The Multi-Shot Volcano actuators has only one difference compared to the One-Shot Volcano actuator. A One-Shot actuator has a small extra part that locks down when depressing the tab on spray nozzle completely down. As such, the can will continue spraying until it is exhausted without the need to continuously press the nozzle (see pictures above). The choice depends on the preference of the customer.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Physical, chemical and technical properties of the product and efficacy tests have been determined. Long term stability tests are still ongoing. For an overview of the available tests, and the tests that are still ongoing, reference is made to Annex 3.1.

[redacted]

2.1.8.2 Access to documentation

The applicant is owner of the tests performed on the biocidal product.
A letter of access is available to the original dossier of the active substance 1R-trans phenothrin (CAS No. 26046-85-5) from Endura S.p.A, which is an approved supplier for PT18 according to Article 95(1) of Regulation (EU) No 528/2012.

2.1.8.3 Similar conditions of use

The biocidal product "Aero-Sense Aircraft Insecticide ASD" is deemed to be eligible for Union authorisation. Based on the information provided by the applicant, it appears that the application could meet the basic requirements of Article 42(1) of the Biocidal Products Regulation.
No objections were raised from either the Commission or the Member States Competent Authorities (MSCAs) as regards the eligibility of the prospective application for Union authorisation on the grounds that the biocidal product "Aero-Sense Aircraft Insecticide ASD" falls outside of the scope of the BPR, or had been attributed the wrong product type, or that it would have non-similar conditions of use across the Union.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – name of the use[3]

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Aero-Sense Aircraft Insecticide ASD is a ready-to-use aerosolized formulation intended for general aircraft disinsection. Only for professional use according the aircraft disinsection protocols recommended by the World Health Organisation (WHO).
Target organism (including development stage)	Mosquitoes
Field of use	Indoor Application in cockpit and cabin for general aircraft disinsection.
Application method(s)	**"Blocks away" Disinsection** • This procedure takes place prior to take off after passengers have boarded and the doors have been closed. • An announcement must be made by the crew to inform passengers of the upcoming disinsection. • An aircraft is treated by crew members walking through the cabins and discharging aerosols containing 2% m/m 1R-trans phenothrin. • The disinsection treatment requires a standard application rate of 35g of formulation per 100m³ (i.e. 0.7 g a.i./100 m³). • Spraying is carried out at an average spray rate of 1 g per second which generally equates to one step or one row per second. • For disinsection to be effective, the aircraft air conditioning system must be turned off whilst spraying is carried out, and the 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 the boarding. • Foodstuffs and galley utensils should be protected from contamination. • The flight deck is sprayed prior to boarding by the crew. **"Top-of-descent" (in-flight spraying)**

3 Copy this section as many times as necessary (one table per use).

	This disinsection treatment is the second step in a two-part disinsection process: preflight and top-of-descent spraying. Pre-flight disinsection is performed with an aerosolized product based on the active substance permethrin which has a residual effect. • This disinsection method is carried out at "top-of-descent" as the aircraft starts its descent to the airport of arrival • An in-flight announcement must be made by the crew to inform passengers of the upcoming disinsection. • An aircraft is treated by crew members walking through the cabins and discharging aerosols containing 2% m/m 1R-trans phenothrin. • The disinsection treatment requires a standard application rate of 35g of formulation per 100m³ (i.e. 0.7 g a.i./100 m³). • Spraying is carried out at an average spray rate of 1 g per second which generally equates to one step or one row per second.
Application rate(s) and frequency	Recommended application rate: 35g/100m³ (i.e. 0,7g a.i./100m³). Treatment should be repeated on each flight for which a disinsection treatment is required.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	ALU printed can 18 bar - Full color printed White cap (One Shot actuator) or Blue cap (Multi Shot actuator) Packed in cardboard outer packaging per 24 pieces Available in different can sizes: • 40g (34ml) • 60g (52ml) • 100g (86ml)

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Organoleptic	min. 89% w/w 1R-trans phenothrin	[redacted]	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			[redacted] Oily liquid	[redacted]
Colour at 20 °C and 101.3 kPa	Organoleptic	min. 89% w/w 1R-trans phenothrin	[redacted] Pale yellow	[redacted]
Odour at 20 °C and 101.3 kPa	Organoleptic	min. 89% w/w 1R-trans phenothrin	[redacted] Slight petrol odour [redacted] neutral odour.	[redacted]
Acidity / alkalinity	Not relevant since the product is not to be applied as aqueous dilutions or dispersion.			[redacted]
Relative density / bulk density	CIPAC MT 3.2	96.75% w/w 1R-trans isomer & 99.4% w/w sum of isomers	[redacted] 1.06 at 20°C	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (40±2°C for 8 weeks, original packaging) [using HPLC-UV and GC-FID respectively, as validated in section 2.2.5] FEA 644 (spray pattern) Laser diffraction Malvem (particle size distribution)	2% 1R-trans phenothrin (sum of isomers)	<u>AS content (sum of isomers)</u> **Start**: 2.075% (w/w) **8 weeks**: 2.023% (w/w) <u>AS content (single isomer)</u> **Start**: 2.039% (w/w) **8 weeks**: 1.991% (w/w) <u>Weight loss</u> **Start**: 39.41g **8 weeks**: 39.15g No change in aspect of the test item or significant loss of weight. <u>Nozzles and actuator buttons</u> **Start**: Satisfactory operation, discharge rate of 1.16g/s **8 weeks**: Satisfactory operation, discharge rate of 1.19 g/s <u>Spray pattern</u> Note: the recommended distance of 30 cm did not yield interpretable results, as such a distance of 10cm was chosen.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Start: Circular concentric circles with 10 mm foam spot at centre. Spray diameter of 4 cm at 10 cm distance. **8 weeks**: Circular, concentric circles with 13 mm foam spot at centre. Spray diameter of 4 cm at 10 cm distance <u>Particle (droplet) size distribution (aerosol)</u> **Start** (n=2): Bimodal appearance [redacted] Particles <50 µm = 98.2% [redacted] **8 weeks** (n=1): [redacted] Particles <50 µm = 98.4% [redacted]	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**	CropLife International monograph N°17 (a.s. content, spray pattern, compatibility with packaging) [using HPLC-UV and GC-FID respectively, as validated in section 2.2.5]	2% 1R-trans phenothrin (sum of isomers)	<u>AS content (sum of isomers)</u> **Start**: 2.075% (w/w) **6M** : 2.093% (w/w) (+0.9%) **12M** : 2.081% (w/w) (+0.3%) **18M** : 2.038% w/w (-1.8%) **24M** : 2.138% w/w (+3.0%) <u>AS content (stereo-isomer ratio)</u> **Start**: 1R-trans-phenothrin : 98.30% (w/w) **6M** : 1R-trans phenothrin : 98.31% (w/w) **12M** : 1R-trans phenothrin : 98.40% (w/w) **18M** : 1R-trans phenothrin : 98.45% (w/w) **24M** : 1R-trans phenothrin : 98.40% (w/w) <u>Spray pattern</u> Note: the recommended distance of 30 cm did not yield interpretable results, as such a distance of 10 cm was chosen. **Start**: Circular concentric circles with 10 mm foam spot at centre.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Spray diameter of 4 cm at 10 cm distance. **24M** : Circular concentric circles with 21 mm foam spot at centre. Spray diameter of 4 cm at 10 cm distance. <u>Nozzles and actuator buttons</u> **Start**: Satisfactory operation, discharge rate of 1.16g/s **24M**: Satisfactory operation, discharge rate of 1.19 g/s <u>Particle (droplet) size distribution (aerosol)</u> **Start** (n=2): Bimodal appearance [redacted] Particles <50 µm = 98.2% [redacted] **24M** : Bimodal appearance [redacted]	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Particles <50 µm = 98.0% [redacted] <u>Weight loss</u> **6 M:** -0.03% **12M:** -0.3% **18M:** -0.5% **24M:** -0.7% No change in appearance of the test item or significant loss of weight after 6M, 12M, 18M or 24M of storage [redacted] <u>Internal pressure (bar) (n=3) at 20°C</u> **Start:** 40g packaging: 4.84 60g packaging: 5.41 100g packaging: 4.94 [redacted]	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 (0±2°C for 7 days; in 100 ml glass, cone tube)	2% 1R-trans phenothrin (sum of isomers)	No alteration of container. No change in appearance of the test item or layer separation (homogenous pale yellow liquid). No significant weight loss.	[redacted]
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Waived	-	The product is intended to be placed on the market in a lightproof packaging, so that the effect of light can be excluded.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waived	-	- Any influence by humidity would have shown in the storage stability tests (see above), which is not the case. [redacted]	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			[redacted] - Effects of temperature have been studied during the storage stability tests (see above).	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT 46.3 / CIPAC MT 39.3 / Crop Life International monograph N° 17	2% 1R-trans phenothrin (sum of isomers)	No significant changes in the aspect and weight after 8 weeks at 40°C or 7 days at 0°C (see above results storage stability tests). No significant weight changes after 6M, 12M, 18M or 24M of storage at ambient temperature. The aforementioned test results support the use of both actuators and the different pack sizes (section cf. 2.1.7).	[redacted]
Wettability	Waived	-	Not applicable, product is not a solid.	-
Suspensibility, spontaneity and dispersion stability	Waived	-	Not applicable, product is ready for use and not	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			intended to be diluted.	
Wet sieve analysis and dry sieve test	Waived	-	Not applicable, product is ready for use and not intended to be diluted.	-
Emulsifiability, re-emulsifiability and emulsion stability	Waived	-	Not applicable, product not an emulsion.	-
Disintegration time	Waived	-	Not applicable, product not a tablet.	-
Particle size distribution, content of dust/fines, attrition, friability	See stability studies above. Partially waived	-	Particle size: has been studied during the storage stability tests (see above). For others : Not applicable, product is not a powder/granule.	-
Persistent foaming	Waived	-	Not applicable, product is ready for use and not intended to be diluted.	-
Flowability/Pourability/Dustability	Waived	-	Not applicable since biocidal product is not granular/a suspension.	-
Burning rate — smoke generators	Waived	-	Not applicable, product is not a smoke generator.	-
Burning completeness — smoke generators	Waived	-	Not applicable, product is not a smoke generator.	-
Composition of smoke — smoke generators	Waived	-	Not applicable, product is not a smoke generator.	-
Spraying pattern — aerosols	See stability studies above.	-	This item has been studied during the	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			storage stability tests (see above).	
Physical compatibility	Waived	-	Product is not intended for use together with other products.	-
Chemical compatibility	Waived	-	Product is not intended for use together with other products.	-
Degree of dissolution and dilution stability	Waived	-	Not applicable, product is ready for use and not intended to be diluted, and is not a tablet.	-
Surface tension	Reference is made to the CAR of the active substance. For the active substance, determination of surface tension is technically not feasible (water solubility of the test substance < 1 mg/L).			[redacted]
Viscosity	OECD Guideline 114	min. 89% w/w 1R-trans phenothrin	[redacted] 75 mPa.s at 25°C 23.1 mPa.s at 45°C	[redacted]

Conclusion on the physical, chemical and technical properties of the product
The product is an aerosol spray with 2% w/w 1R-trans phenothrin (as an active substance). [redacted]

[redacted]

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 could not be analysed, this result 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.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	No chemical groups associated with explosive properties: • Active substance: No explosive properties based on the structure of the compound and the percentage oxygen balance. • Propellant: Does not possess explosive properties.			[redacted]
Flammable gases	Not relevant, not a gas. In addition, aerosols do not fall under the hazard class of flammable gases (Annex I, 2.3.2.1 CLP Regulation)			-
Flammable aerosols	<u>Heat of combustion</u>: ASTM D 240-17 <u>Ignition distance</u>: point 3.1 of the Annex F of BOE 230/2009 <u>Enclosed space ignition</u>: point 3.1 of the Annex F of BOE 230/2009	min. 89% w/w 1R-trans phenothrin	<u>Heat of combustion</u>: < 20 kJ/g (100g; 60g; 40g) <u>Ignition distance:</u> No ignition at 15-90 cm (100g; 60g; 40g) <u>Enclosed space ignition:</u> - 100g: equivalent time: 395 s/m3	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			deflagration density: 364 g/m3 - 60 & 40 g: no deflagration	
Oxidising gases	No chemical groups associated with oxidizing properties (A substance is not considered to have oxidising properties if it does not contain any oxygen, chlorine or fluorine atoms, or if the molecule contains these atoms but bound to carbon and/or hydrogen atoms only.)			-
Gases under pressure	Aerosols do not fall additionally within the scope of sections 'flammable gases", "gases under pressure", "flammable liquids" and "flammable solids."			[redacted]
Flammable liquids	Aerosols do not fall additionally within the scope of sections "flammable gases", "gases under pressure", "flammable liquids" and "flammable solids."			[redacted]
Flammable solids	Not relevant, not a solid			
Self-reactive substances and mixtures	No chemical groups associated with self-reactive properties			
Pyrophoric liquids	Not relevant. The classification procedure for pyrophoric liquids need not be applied when experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquid is known to be stable at room temperature for prolonged periods of time (days)).			[redacted]
Pyrophoric solids	Not relevant, not a solid			
Self-heating substances and mixtures	Not relevant, not a solid			
Substances and mixtures which in contact with water emit flammable gases	Test not required; the chemical structure of the ingredients does not contain metals or metalloids.			[redacted]
Oxidising liquids	No chemical groups associated with oxidizing properties			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	(A substance is not considered to have oxidising properties if it does not contain any oxygen, chlorine or fluorine atoms, or if the molecule contains these atoms but bound to carbon and/or hydrogen atoms only.)			
Oxidising solids	Not relevant, not a solid			
Organic peroxides	Not relevant, not a peroxide			
Corrosive to metals	According to the ECHA Guidance on application of CLP criteria (2015), following substances and mixtures should be considered for classification in this class: - subst. and mixtures having acidic or basic functional groups - substances or mixtures containing halogen - subst. able to form complexes with metals and mixtures containing such substances.	-	[redacted] Considering that the test for corrosive to metals is not designed for gases, it cannot be performed on the complete BP. Therefore, a test need not to be provided.	-
Auto-ignition temperatures of products (liquids and gases)	The auto-ignition temperatures of the active substance and the propellant are >300°C			[redacted]
Relative self-ignition temperature for solids	Not relevant, not a solid			
Dust explosion hazard	Not relevant, not a solid			

Conclusion on the physical hazards and respective characteristics of the product
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.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD (repeatability)		
Active substance (sum of all isomers)	GC-FID based on CIPAC 356/AE/(M)/3 Principle: Sample is dissolved in acetone. The A.S. is then determined via GC-FID and m-terphenyl as internal standard. [using HP model 7890A,	n=10 (Repeatability) n=4 (Accuracy) – duplicate injection Spiked sample: 20 g/kg, equivalent to 0.04 % in total container. n=7 (Linearity) – duplicate injection	y=1.5414E-02x-0.14 r=0.99708 between 204-306 µg/ml (corresponding to 816-1124 g/kg in liquid phase, and 1.75-2.63% in total container)	No interference substances observed.	98.8-98.9[4] 97.9-98.3[5]	98.9 98.1	0.49 (< 1.35, according to modified Horwitz equation, thus good consistency)	/	[redacted]

[4] The determination of two test item preparations spiked with a certified reference item.
[5] The determination of another reference item than the reference item used for the preparation of the calibration solution.

	column: DB-5MS, 30m, internal diameter: 250µm, film thickness: 0.25µm)								
Active substance (stereoisomers ratio)	HPLC-UV based on CIPAC 356/AE/(M)/2.2 Principle: Sample is dissolved in n-hexane. The A.S. is then determined via HPLC-UV with a specific chiral column. [using Alliance 2695, column: Chiralpak AD-	5 (Repeatability)	/	Retention time match	/	/	3.96 (1R-cis) 7.45 (1S-cis) 0.05 (1R-trans) 7.53 (1S-trans)	/	[redacted]

	3, 4.6x250mm, 3 µm particle size, detection at 230nm)								

Analytical methods for monitoring
For the analysis of the active substance in the product, the method referenced above [redacted] is applicable as a monitoring method as well. For the other matrices, please see below (Reference is made to the active substance dossier of 1R-trans phenothrin.)

Analytical methods for soil
The following methods are available: GC-MS and GC-MS/MS. The methods determine geometric isomers and the "sum of all isomers". Reference is made to the active substance dossier of 1R-trans phenothrin.

Analytical methods for air
The following method is available: GC-MS. The method determines the "sum of all isomers". Reference is made to the active substance dossier of 1R-trans phenothrin.

Analytical methods for water
The following methods are available: GC-MS (drinking water) and GC-MS/MS (surface water). The methods determine geometric isomers and the "sum of all isomers". Reference is made to the active substance dossier of 1R-trans phenothrin.

Analytical methods for animal and human body fluids and tissues
Not applicable. Reference is made to the active substance dossier of 1R-trans phenothrin.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
Reference is made to the active substance dossier of 1R-trans phenothrin. It is considered that methods for residues of 1R-trans phenothrin in food of plant and animal origin are not applicable since: • In case the product is applied according to the protocol "Blocks away", the application occurs before take-off. It is not expected that aerosol particles will still be in the air once the airplane is at full height/speed, when food and drinks are being served. In addition, the instructions for use mention that foodstuffs and galley utensils should be protected from contamination. • In case the product is applied according to the protocol "Top-of-descent", application occurs after the last food/drinks service, just before landing is started. Therefore, it is not expected that aerosol particles are (still) in the air at the moment food or drinks are being served.

Conclusion on the methods for detection and identification of the product
The CIPAC method 356, which is equal to CIPAC 777, can be used for the analysis of the active substance in the biocidal product. This method consists of two individual methods. The first method is capable of determining the "sum of all isomers" (GC-FID), the second method is capable of determining the optical isomers (HPLC-UV). For a detection method in air, soil and water, reference is made to the active substance dossier of 1R-trans phenothrin. The product is applied in a closed, indoor environment, and no food is served at the moment of product application or foodstuffs and galley utensils should be protected from contamination (in accordance with the instructions for use).

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Aero-Sense Aircraft Insecticide ASD is used for the disinsection of aircrafts interior, according to WHO guidelines[6]. The product is either applied according to the 'Blocks-away' or the 'Top-of-descent' protocol. In the 'Top-of-descent' protocol, disinsection with Aero-Sense Aircraft Insecticide ASD is carried out at "top-of-descent" as the aircraft starts its descent to the airport of arrival. The pre-flight disinsection is performed by using another aerosolized product containing an active substance which has a residual effect (generally with permethrin).

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Aero-Sense Aircraft Insecticide ASD is aimed to be used against mosquitoes. A 2% 1R-trans phenothrin formulation at a rate of 35g/100m^3 is the WHO recommended formulation for aircraft disinsection. Mosquitoes can act as vectors of pathogens and parasites. Aircraft disinsection is performed to avoid the spread of mosquitoes by airplane.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The intended effect is a rapid "knockdown" with eventually a killing activity, at the recommended rate of 35 g/100m^3.

2.2.5.4 Mode of action, including time delay

1R-trans phenothrin acts by being absorbed by invertebrate neuronal membranes and binding to the sodium channels. The prolonged opening of sodium channels produces a protracted sodium influx which leads to repetitive firing of sensory nerve endings which may progress to hyper-excitation of the entire nervous system. At high pyrethroid concentrations conduction block can occur and the insects will die (CAR 1R-trans phenothrin, 2003). There is no time delay; the product has a rapid knockdown effect.

[6] Environmental Health Criteria 243: Aircraft disinsection insecticides (http://www.capsca.org/Documentation/Zika/WHO-IPCSehc243.pdf).

2.2.5.5 Efficacy data

Laboratory tests and simulated use trials have been performed on both the current product [redacted] and a previous version of the product [redacted] containing a different type of propellant gas (referred to in this report as propellant 1). Due to a changed EU aerosol legislation, the carrier gas of the product for which authorisation is requested, is replaced by a different gas, further referred to as propellant 2. For more information on the types of propellant gas used, reference is made to the confidential annex. Data obtained with product containing propellant 1 are included in the data table as supportive information, as the change of propellant is not expected to have an impact on the efficacy of the product.

Efficacy tests with the product containing propellant 2 are performed according to the Guidance on the Biocidal Products Regulation (Vol. II, A & B) and the WHO guidelines for testing the efficacy of insecticide products used in aircrafts. A lab test, simulated use test and semi-field trial are performed to support the label claim.

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>PT 18
Insecticide</td>
<td>Lab test
[redacted]</td>
<td><u>Product tested:</u>

Aero-Sense Aircraft Insecticide ASD (Batch 070717) with 2% w/w 1R-trans phenothrin

propellant 2

aerosol</td>
<td>Mosquitoes:

Aedes aegypti
50 ♀ 2-5 days

Aedes albopictus
50 ♀ 2-5 days

Culex quinquefasciatus
50 ♀ 2-5 days

Anopheles gambiae
50 ♀ 2-5 days

[redacted]</td>
<td>WHO: Guidelines for testing the efficacy of insecticide products used in aircraft: section 2.4.1: Aerosol for rapid action.
[redacted]</td>
<td><u>Application rate :</u>
0.65 g product / 5.8 m³ (by spraying) = 0.11g / m³
Claimed application rate = 35 g / 100m³ (= 0.35g / m³)

[redacted]

[redacted]

<u>Time of exposure :</u>
1 h
After 1 h exposure, mosquitoes were monitored for mortality for 24 h

[redacted]

[redacted]</td>
<td>
<table>
<tr><th></th><th>KD_{80%}</th><th>KDT₁₀₀</th><th>Mortality after 24h</th></tr>
<tr><td>Aedes aegypti</td><td>10 min</td><td>15 min</td><td>100%</td></tr>
<tr><td>Aedes albopictus</td><td>20 min</td><td>30 min</td><td>100%</td></tr>
<tr><td>Culex quinquefasciatus</td><td>20 min</td><td>25 min</td><td>100%</td></tr>
<tr><td>Anopheles gambiae</td><td>20 min</td><td>25 min</td><td>100%</td></tr>
</table>
[redacted]

The results fulfill requirement of TNsG PT 18 (2016).

[redacted]
</td>
<td>[redacted]</td>
</tr>
</table>

PT 18 Insecticide

Simulated use test

[redacted]

Product tested:

Aero-Sense Aircraft Insecticide ASD (Batch 070717) with 2% w/w 1R-trans phenothrin

propellant 2

aerosol

Mosquitoes

Culex quinquefasciatus
80-100 ♀ 2-5 days

Anopheles stephensi
100 ♀ 2-5 days

Aedes aegypti
100 ♀ 2-5 days

Aedes albopictus
70-100 ♀ 2-5 days

Lab strains

WHO: Guidelines for testing the efficacy of insecticide products used in aircraft

[redacted]

Application rate :
35 g product/100 m³

[redacted]

Time of exposure :
60 minutes

[redacted]

Culex quinquefasciatus

	Mortality 24h	KD + mortality 24h	Mortality 48h
treatment	82.5 %	92 %	87.9 %
Negative control	6.1 %	6.1 %	8.2 %

Anopheles stephensi

	Mortality 24h	KD + mortality 24h	Mortality 48h
treatment	99 %	100 %	100 %
Negative control	7.3 %	14 %	15.7 %

Aedes aegypti

	Mortality 24h	KD + mortality 24h	Mortality 48h
treatment	72 %	100 %	99,7 %
Negative control	9 %	18.3 %	18.6 %

Aedes albopictus

	Mortality 24h	KD + mortality 24h	Mortality 48h
treatment	93 %	100 %	99,6 %
Negative control	4.4 %	10.7 %	9.3 %

$KD_{80\%}$ was achieved within:
- 30 min for *C. quiquefasciatus*
- 15 min for *An. stephensi*
- 20 min for *Ae. aegypti* and *Ae. albopictus.*

For the target organisms tested, $KD_{80\%}$ is achieved within 30 minutes & mortality >90% after 24h is achieved, except for *Culex quinquefasciatus* and *Aedes aegypti*.

[redacted]

<table>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>However, after 24h, all Aedes aegypti mosquitoes are knocked down and do not recover, as shown by the mortality results after 48h.

For Culex quinquefasciatus, the eCA considers the results are acceptable, given that >90% of the mosquitoes are immobilised at 24h, and are considered as moribund.

Therefore, the Aero-Sense (containing 2% 1R-trans phenothrin) sprayed in cabin at 35 g product/100 m³ shows rapid knock down and sufficient mortality against Culex, Anopheles & Aedes mosquitoes.</td>
<td></td>
</tr>
<tr>
<td>PT 18
Insecticide</td>
<td>Field test</td>
<td><u>Product tested:</u>

Aero-Sense Aircraft Insecticide ASD
with 2% w/w 1R-trans phenothrin

propellant 2</td>
<td>Mosquitoes
Culex quinquefasciatus
500 ♀ 2-5 days

Anopheles stephensi
500 ♀ 2-5 days

Aedes aegypti
500 ♀ 2-5 days</td>
<td>WHO: Guidelines for testing the efficacy of insecticide products used in aircraft: section 3.1.1: Study design for passenger cabins and 3.1.3 Cage bioassay method</td>
<td><u>Application rate :</u>
=35 g /100 m³

<u>Time of exposure :</u></td>
<td>
<table>
<tr><th colspan="4">Culex quinquefasciatus</th></tr>
<tr><th></th><th>Mortality 24h</th><th>KD + Mortality 24h</th><th>Mortality 48h</th></tr>
<tr><td>treatment</td><td>65.8 %</td><td>97.5 %</td><td>85.5 %</td></tr>
<tr><td>Negative control</td><td>2.9 %</td><td>4.9 %</td><td>7 %</td></tr>
</table>
<table>
<tr><th colspan="4">Anopheles stephensi</th></tr>
<tr><th></th><th>Mortality 24h</th><th>KD + Mortality 24h</th><th>Mortality 48h</th></tr>
<tr><td>treatment</td><td>80.4 %</td><td>100 %</td><td>93.1 %</td></tr>
<tr><td>Negative control</td><td>12.2 %</td><td>17.1 %</td><td>18.8 %</td></tr>
</table>
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</table>

		aerosol	*Aedes albopictus* 500 ♀ 2-5 days Lab strains		60 minutes	**Aedes aegypti** **Mortality 24h**: ***treatment*** 80.2 %; ***Negative control*** 12.3 % **KD + Mortality 24h**: ***treatment*** 99.8 %; ***Negative control*** 17.4 % **Mortality 48h**: ***treatment*** 91.1 %; ***Negative control*** 16.7 % **Aedes albopictus** **Mortality 24h**: ***treatment*** 71.2 %; ***Negative control*** 5.5 % **KD + Mortality 24h**: ***treatment*** 100 %; ***Negative control*** 3.2 % **Mortality 48h**: ***treatment*** 88.4 %; ***Negative control*** 6.5 % KD80% was achieved within: - 20 min for *C. quiquefasciatus, An. stephensi and Ae. albopictus.* - 15 min for *Ae. aegypti* Rapid knock down is achieved for all species tested. Mortality + knock down after 24h show >97.5 % of the mosquitoes are immobilized and dying, and will not be able to spread. Given the intended use of the product, these results confirm the efficacy of the product, when applied according to the intended use.	

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr>
<td>PT 18
Insecticide</td>
<td>Lab test</td>
<td><u>Product tested:</u>

Aero-Sense Aircraft Insecticide ASD

with 2% w/w 1R-trans phenothrin

propellant 1

aerosol</td>
<td>Mosquitoes
Culex pipiens
100 ♀ 2-5 days

Aedes albopictus
100 ♀ 2-5 days

Negative control group: 25

Lab strains</td>
<td>WHO, 2012: Guidelines for testing the efficacy of insecticide products used in aircraft: section 2.4.1</td>
<td><u>Application rate :</u>
40 g product was used in 115m³
=35 g /100 m³

<u>Time of exposure :</u>
4 hours</td>
<td>
<table>
<tr><th colspan="3">Aedes albopictus</th></tr>
<tr><th></th><th>KD 1h</th><th>Mortality 24h</th></tr>
<tr><td>treatment</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Negative control</td><td>0 %</td><td>0 %</td></tr>
</table>
<table>
<tr><th colspan="3">Culex pipiens</th></tr>
<tr><th></th><th>KD 1h</th><th>Mortality 24h</th></tr>
<tr><td>treatment</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Negative control</td><td>0 %</td><td>0 %</td></tr>
</table>
For all the target organisms tested, KD_{100} & 100% mortality after 24h is achieved.
The results fulfill requirement of TNsG PT 18 (2016).

Therefore, the product Aero-Sense (containing 2% 1R-trans phenothrin) sprayed at 35 g product / 100 m³ shows complete mortality against Aedes and Culex mosquitoes.
</td>
<td></td>
</tr>
<tr>
<td>PT 18
Insecticide</td>
<td>Simulated use test</td>
<td><u>Product tested:</u>

Aero-Sense Aircraft</td>
<td>Mosquitoes
Culex pipiens
100 ♀ 2-5 days</td>
<td>WHO, 2012: Guidelines for testing the efficacy of insecticide products used</td>
<td><u>Application rate :</u>
40 g product was used in 115m³
=35 g /100 m³</td>
<td>
<table>
<tr><th></th><th>KD 4h</th><th>Mortality 24h</th></tr>
<tr><td>Culex pipiens</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Anopheles gambiae</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Aedes aegypti</td><td>100 %</td><td>100 %</td></tr>
<tr><td>Aedes albopictus</td><td>100 %</td><td>100 %</td></tr>
</table>
</td>
<td></td>
</tr>
</table>

		Insecticide ASD with 2% w/w 1R-trans phenothrin **propellant 1** *aerosol*	*Anopheles gambiae* 100 ♀ 2-5 days *Aedes aegypti* 100 ♀ 2-5 days *Aedes albopictus* 100 ♀ 2-5 days Lab strains	in aircraft: section 2.4.1	<u>Time of exposure :</u> 4 hours	The test is not considered valid, as no negative control results are provided. The test results are mentioned to act as an indicator for the efficacy, provided for information only.	

Conclusion on the efficacy of the product
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. KD80% 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 show 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 eCA therefore considers the tests performed with propellent 2 (product for which authorisation is sought) to be validated. Tests performed on product with propellent 1 are considered as supportive information. The eCA noted that temperatures during testing were low. [redacted] 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. The eCA accepts this justification, since negative control results are still within the limits of the WHO test standards.

2.2.5.6 Occurrence of resistance and resistance management

There are reports of development of resistance against pyrethroids in mosquitoes. Also the CAR of 1R-trans phenothrin mentions resistance development to pyrethroid insecticides in general and 1R-trans phenothrin. Both active substances which are approved for use in aircraft disinsection according to WHO are pyrethroids.
1,R-trans phenothrin is a class 1 pyrethroid (1,R-trans phenothrin PT18 AR, 2013/03). It is classified by IRAC in mode of action group 3A insecticide (sodium channel modulators, pyrethroids and pyrethrins). Any insect or mite population may contain individuals naturally resistant to 1,R-trans phenothrin and other group 3A insecticides. If these insecticides are used repeatedly, the resistant individuals may eventually dominate the pest insect or mite population. These resistant insects and mites may not be controlled by 1,R-trans phenothrin or by other group 3A insecticides.
Pyrethroid resistance is known to occur and measures, such as those detailed below, are known to be effective in reducing the occurrence of resistance. The principle strategies for managing the development of resistance are as follows: Establish a baseline and monitor levels of effectiveness on populations in key areas in order to detect any significant

changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.

However, because of its specific use, Aero-Sense Aircraft Insecticide ASD is unlikely to contribute to resistance of mosquitoes to pyrethroids. The product is applied in a closed environment, and performed by professionals. Therefore, there is no risk that a same population of mosquitoes is exposed to the product multiple times. The efficacy of the product is based on rapid effect, and not on residual effect from the insecticide.

2.2.5.7 Known limitations

During application (spraying) of the product the ventilation must be switched off. After application, ventilation can be switched on again.

2.2.5.8 Evaluation of the label claims

[redacted]

In conclusion, the requirement for rapid knock down as described in the TNsG PT18 (2012) is considered as supported by the efficacy data provided. The requirement of >90% mortality after 24h is not demonstrated by the tests provided, however, the guidance also indicates 'Deviations from these norms is possible but should be justified in the application.' Given the intended use of the product to prevent the spread of mosquitoes,

the eCA considers that the level of knock down + mortality that is reached in all tests prove the efficacy of the product when used according to the instructions for use.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Please note that the 'Top-of-Descent' protocol is a two-step disinsection, that is performed as described in Annex I of the guidelines for testing the efficacy of insecticide products used in aircraft published by the WHO (2012).

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No toxicological tests were performed on Aero-Sense Aircraft Insecticide ASD product.

Skin corrosion and irritation

Data waiving	
Information requirement	Study scientifically unjustified. None of ingredient of the product Aero-Sense Aircraft Insecticide ASD is classified for skin corrosion/irritation. Please refer to the confidential annex for information on the substances and their concentration.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The product is not classified for skin corrosion or irritation.
Justification for the value/conclusion	According to the information from ECHA's C&L Inventory, the Active Substance Assessment Report and MSDS submitted, none of the ingredients are classified for skin corrosion/irritation. Therefore no classification is required.
Classification of the product according to CLP and DSD	No classification.

Eye irritation

Data waiving	
Information requirement	Study scientifically unjustified. None of ingredient of the product Aero-Sense Aircraft Insecticide ASD is classified for eye irritation. Please refer to the confidential annex for information on the substances and their concentration.

Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The product is not classified for eye irritation.
Justification for the value/conclusion	According to the information from ECHA's C&L Inventory, the Active Substance Assessment Report and MSDS submitted, none of the ingredients are classified for eye irritation. Therefore no classification is required.
Classification of the product according to CLP and DSD	No classification.

Respiratory tract irritation

Data waiving	
Information requirement	Study scientifically unjustified. None of ingredient of the product Aero-Sense Aircraft Insecticide ASD is classified for respiratory tract irritation. Please refer to the confidential annex for information on the substances and their concentration.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	The product is not classified for respiratory tract irritation.
Justification for the conclusion	According to the information from ECHA's C&L Inventory, the Active Substance Assessment Report and MSDS submitted, none of the ingredients are classified for respiratory tract irritation. Therefore no classification is required.
Classification of the product according to CLP and DSD	No classification.

Skin sensitization

Data waiving	
Information requirement	Study scientifically unjustified. None of ingredient of the product Aero-Sense Aircraft Insecticide ASD is classified for skin sensitization. Please refer to the confidential annex for information on the substances and their concentration.

Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The product is not classified for skin sensitization
Justification for the value/conclusion	According to the information from ECHA's C&L Inventory, the Active Substance Assessment Report and MSDS submitted, none of the ingredients are classified for skin sensitisation. Therefore no classification is required.
Classification of the product according to CLP and DSD	No classification.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Study scientifically unjustified. None of ingredient of the product Aero-Sense Aircraft Insecticide ASD is classified for respiratory sensitization. Please refer to the confidential annex for information on the substances and their concentration.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The product is not classified for respiratory sensitization (ADS)
Justification for the value/conclusion	According to the information from ECHA's C&L Inventory, the Active Substance Assessment Report and MSDS submitted, none of the ingredients are classified for respiratory sensitisation. Therefore no classification is required.
Classification of the product according to CLP and DSD	No classification.

Acute toxicity

Acute toxicity by oral/inhalation/dermal route

Data waiving	
Information requirement	Study scientifically unjustified. None of ingredient of the product Aero-Sense Aircraft Insecticide ASD is classified for acute toxicity. Please refer to the confidential annex for information on the substances and their concentration.

Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Value used in the Risk Assessment – Acute toxicity	
Value	The product is not classified for acute toxicity.
Justification for the selected value	According to the information from ECHA's C&L Inventory, the Active Substance Assessment Report and MSDS submitted, none of the ingredients are classified for acute toxicity. Therefore no classification is required.
Classification of the product according to CLP and DSD	No classification.

Information on dermal absorption

No dermal absorption study was performed for the product Aero-Sense Aircraft Insecticide ASD. The applicant has proposed to use the value of 4.5% derived from the assessment report of the active substance and literature data. Please find applicant justification in the confidential annex.
According EFSA guidance on dermal absorption (2017), default values could be used in first intention. If exposure assessments are below the AOEL, then no further data generation or evaluation are required (flow chart 1b - Procedures to follow when there are no dermal absorption data on the actual formulation under evaluation). Therefore, in first intention, BE proposes to use the default of 70% for dermal absorption based on flow chart 1a (Procedure to select default absorption values). If necessary, BE will consider the value proposed by the applicant based on the justification provided in second intention (for refinement). Please note that no refinement was performed as the dermal exposure values was below the AOEL.

Value used in the Risk Assessment – Dermal absorption	
Substance	1R-trans phenothrin
Value(s)	70 %
Justification for the selected value(s)	default value

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

The product does not contain substance of concern for human health.

Available toxicological data relating to a mixture

Not applicable.

2.2.6.2 Exposure assessment

Aero-Sense Aircraft Insecticide ASD is ready-to-use aerosolized formulation intended for general aircraft disinsection. It will be used only by professional user according the aircraft disinsection protocols recommended by the World Health Organisation (WHO).

Apart from the active substance, 1R-trans phenothrin, the product Aero-Sense Aircraft Insecticide ASD does not contain any other relevant substance for toxicological concern.

The PAR section "2.2.1 Intended use(s) as applied for by the applicant" describes the routine aircraft disinsection procedure with treatment timings at 'blocks away' and 'top-of-descent' stages.

The product is intended to be supplied as either a 'one–shot' container or a 'multi-shot' container. It is supposed that the same exposure assessment applies to both container types.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	**yes**	n.a.	n.a.	n.a.	**yes**	n.a.
Dermal	n.a.	**yes**	n.a.	n.a.	n.a.	**yes**	n.a.
Oral	n.a.	No	n.a.	n.a.	n.a.	**yes**	n.a.

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 are 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.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Application	Primary exposure : dermal and inhalation exposure for users (cabin crew)	Professionals
2.	Application and post-application phase	Secondary exposure: dermal, inhalation and oral exposure for aircraft passengers	General public

Industrial exposure

Not relevant since the product Aero-Sense Aircraft Insecticide ASD is not intended to be used by industrial user.

Professional exposure

Scenario 1: Primary exposure : dermal and inhalation exposure for users (cabin crew)

Description of Scenario 1

This scenario is based on the guidance in World Health Organisation for aircraft disinsection Insectides (International Programme on Chemical Safety, Environmental Health Criteria 243). Some default values, as body weight, are updated according the most recent European guidance's (Biocide Human Health Exposure Methodology - Oct 2015 or Recommendation of the BPC Ad hoc Working Group on Human Exposure).

In addition, the Coordination Group has recently discussed the scenario proposed in the WHO 243 for a similar product and the conclusion of this referral was taken into account (Coordination Group public documents (CIRCABC) – library – Record of agreements – Non Flammable aircraft insecticide phen_disar to CG formal_public.pdf).

Inhalation exposure was calculated considering ConsExpo Web version 1.0.6 : Inhalation Exposure › Model : Exposure to spray › Mode of release : Spraying and corresponding parameters.

Remark : Due to an update of ConsExpo, it is required that the maximum diameter of aerosol distribution should be superior than inhalation cut-off value. Previously, ConsExpo 4.1 did not require to introduce a maximal diameter value and therefore, this parameter was not clearly precise in WHO 243 guidance (and this parameter also deviate from the assessment of the similar product).

Dermal exposure :
Two scenarios are considered for dermal exposure in the WHO guidance. The guideline scenarios represent a situation where label instructions are being followed and assume that the products used are in good working order. Touching surfaces is the only source of dermal exposure in the guideline scenario. In the lax standard scenario the spray nozzle may leak leading to fingers becoming contaminated.

- Guideline scenario which calculated the dermal exposure due to contact with the surfaces only
  Systemic exposure (dermal route) / day = (Conc x P x ESA x AbsD) ÷ (BW)
  Systemic exposure (dermal route) / year = (Conc x P x ESA x AbsD x EF) ÷ (BW x AT)
  Where :
  Conc = concentration of a.s. on the surface (mg/m^2)
  P = proportion translodged onto skin
  ESA = exposed skin area
  AbsD = dermal absorption of the a.s.
  EF = exposure frequency
  BW = body weight
  AT = averaging time

- And the LAX Standard scenario which calculated the dermal exposure due to contact with the surfaces **and** due to the contamination of the fingers with spray liquid from the aerosol nozzle.
  Exposure from contamination/day = (VS_{dermal} x CS x AbsD) ÷ (BW)
  Exposure from contamination/year = (VS_{dermal} x CS x EF x AbsD) ÷ (BW x AT)
  Where :
  VS_{dermal} = volume of spray on fingers
  CS = concentration of the a.s. in the spray (mg/ml)
  AbsD = dermal absorption of the a.s.
  EF = exposure frequency
  BW = body weight
  AT = averaging time

  Systemic exposure (dermal route) / day = Systemic exposure from dermal route (according guideline scenario per day) + Exposure from contamination (per day)
  Systemic exposure (dermal route) / year = Systemic exposure from dermal route (according guideline scenario per year) + Exposure from contamination (per year)

Total exposure :
Is the addition of the inhalation, dermal and when relevant oral exposure.

	Parameters	Value	Source
	Application rate	35g b.p./ 100 m^3	Product specific

	Weight fraction a.s. in product	2%	Product specific
	Molecular weight of a.s.	350.46 g/mol	AR on 1R-trans phenothrin (rMS: IE / March 2013)
	Log Kow of a.s. (at 20°C)	6.8	AR on 1R-trans phenothrin (rMS: IE / March 2013)
	Vapour pressure a.s. (Pa, at 20°C)	2.37 x 10^{-5}	AR on 1R-trans phenothrin (rMS: IE / March 2013)
	Body weight (adult)	60 kg	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Respiration rate (adult)	1.25 m^3/h	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Dermal absorption	70%	Default value
	Inhalation absorption	100%	Default value
	Oral absorption	100%	Default value
Inhalation exposure			
TIER 1	Exposure frequency	240/year	EHC 243 (WHO, 2013)
	Spray duration	200 s	EHC 243 (WHO, 2013)
	Exposure duration	30 min	EHC 243 (WHO, 2013)
	Room volume	1000 m^3	EHC 243 (WHO, 2013) (large aircraft)
	Room height	2 m	EHC 243 (WHO, 2013)
	Ventilation rate	0/h	EHC 243 (WHO, 2013) (as a worst case it is assumed that there is no effect due to ventilation)
	Mass generation rate	2.2 g/s	ConsExpo and EHC 243 (WHO, 2013): 2 x 1.1 g/s (default of ConsExpo) reflecting the possibility that 2 cans are discharged simultaneously.
	Airborne non-volatile fraction (worst case)	100%	EHC 243 (WHO, 2013)
	Density non-volatile	1.8 g/cm^3	EHC 243 (WHO, 2013)
	Initial particle distribution	Median: 8 µm cv : 0.45	EHC 243 (WHO, 2013)
		Maximum diameter: 50 µm	Particle size distribution study (Section 2.2.2)
	Inhalation cut-off diameter	15 µm	EHC 243 (WHO, 2013)
Dermal exposure			

"Guideline scenario"	Conc	0.032 mg/m^2	Based on EHC 243 (WHO, 2013), the following assumptions are made : - Large aircraft cabin surface area : 2500 m^2 - Large aircraft cabin volume :1000 m^3 - Amount of sprayed material deposited on surfaces : 1% - The application rate of this product is 35g/100 m^3. Therefore, for a large aircraft, it is assumed that four cans of 100g would be discharged. This would result on a concentration of biocidal product onto the surface of : 400 g x 1% / 2500 m^2 = 1.6 mg/m^2 As the concentration of active substance is 2% in the b.p. : 1.6 mg/m^2 x 2% = 0.032 mg/m^2
	P	11%	EHC 243 (WHO, 2013) : proportion translodged onto skin = 11% of the amount present on the surfaces (USEPA, 2009)
	ESA	0.097 m^2	EHC 243 (WHO, 2013) : Exposed skin area for cabin crew is considered to be 50% of hands and forearms. This has been recalculated considering Recommendation 14 of the BPC Ad hoc Working Group on Human Exposure ((0.082+0.11288)*0.5 = 0.097m^2)
	EF	240 d/y	EHC 243 (WHO, 2013) : exposure frequency = default, 240 days/year
	AT	365 d/y	EHC 243 (WHO, 2013) : averaging time = default, 1 year, 365 days
"Lax scenario" TIER 1	VS_{dermal}	0.82 mL	Based on EHC 243 (WHO, 2013), the following assumptions are made : - The film thickness of a non-viscous liquid likely to be in contact with unprotected, immersed skin is assumed to be 0.01 cm after runoff. - For use of an aerosol spray it is estimated that the area of fingers exposed will be one-tenth of the surface area of the hands (total surface area of hands according Recommendation 14 : 820 cm^2, therefore, 1/10 of 820 = 82 cm^2). - The maximum amount of liquid on exposed fingers will be 0.82 ml (0.01x82= 0.82 cm^3 if we considered a density of 1 = 0.82mL).
	CS	20 mg/mL	Product specific (2% of a.s. in the product and density of 1)
"Lax scenario" **TIER 2**	VS_{dermal}	0.04 mL	It is more realistic to assume that contamination would be confined to 4 finger tips: 2 finger tips on each hand (2 cm2 per hand) as it was discussed in the Coordination Group. Therefore, it can be calculated that the volume of spray on fingers would be : 4 cm^2 x 0.01 = 0.04 cm^3 if density = 1, 0.04mL.

Calculations for scenario 1 - primary exposure for users (cabin crew)

Please for details calculations refer to annex 3.2.1

Estimated exposure from primary exposure for users (cabin crew)						
Exposure scenario	**Tier/PPE**	**Daily exposure or average yearly exposure**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1: primary exposure for users (cabin crew)	'Guideline scenario' 1 /No PPE	Daily exposure	0.03	0.000004	-	0.03
		yearly exposure	0.02	0.0000026	-	0.02
	'LAX standard scenario' 1 /No PPE	Daily exposure	0.03	0.19	-	0.22
		yearly exposure	0.02	0.13	-	0.15
	'LAX standard scenario' 2 /No PPE	Daily exposure	0.03	0.009	-	0.04
		yearly exposure	0.02	0.006	-	0.03

Non-professional exposure

Not applicable. The product is for professional use only.

Exposure of the general public

Scenario 2 : Secondary exposure for aircraft passengers

Description of Scenario 2

This scenario is based on the guidance in World Health Organisation for aircraft disinsection Insectides (International Programme on Chemical Safety, Environmental Health Criteria 243). Some default values, as body weight, are updated according the most recent European guidance's (Biocide Human Health Exposure Methodology - Oct 2015 or Recommendation of the BPC Ad hoc Working Group on Human Exposure).

In addition, the Coordination Group has recently discussed the scenario proposed in the WHO 243 for a similar product and the conclusion of this referral was taken into account (Coordination Group public documents (CIRCABC) – library – Record of agreements – Non Flammable aircraft insecticide phen_disar to CG formal_public.pdf).

Inhalation exposure was calculated considering ConsExpo Web program : Inhalation Exposure › Model : Exposure to spray › Mode of release : Spraying and corresponding parameters.

Remark : Due to an update of ConsExpo, it is required that the maximum diameter of aerosol distribution should be superior than inhalation cut-off value. Previously, ConsExpo 4.1 did not require to introduce a maximal diameter value and therefore, this parameter was not clearly precise in WHO 243 guidance (and this parameter also deviate from the assessment of the similar product).

TIER 2 for inhalation exposure: Inhalation rates originated from the Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure are based on US EPA Exposure Factors Handbook, during moderate intensity of activity. Moderate intensity activity is defined as fast walking (3.3 to 4 miles per hour) and slow running (3.5 to 4 miles per hour). According Recommendation no. 14: "*There may be situations where one or more of these default values* (inhalation route) *do not make sense. In such cases, deviations from the agreed values may be used, but such deviations will need to be thoroughly justified in the assessment."* This activity pattern does not correspond to the situation modelled in this application : passengers present during and shortly after spraying are expected to be in their seats and therefore a refinement based on a more adequate inhalation rate is proposed for toddler, value derived from Table 6-2 from the EPA Exposure Factors Handbook (2011; Chapter 6—Inhalation Rates), considering light intensity activity level (1.5< METS ≤3.0 – e.g. Travel to/from work / Participate in hobbies / Visit museums / Shower, bathe, pers. Hygiene/…):

- 95th percentile value : 1.6E-02 m^3/minute = 0.96 m^3/h

Dermal exposure :

Dermal exposure via indirect contact (contact with the material deposited on surface) and direct contact (when the product is sprayed) is considered for passenger in the WHO guidance.

- Indirect contact due to contact with the surfaces

  Systemic exposure (dermal route) / day = (Conc x P x ESA x AbsD) ÷ (BW)

  Systemic exposure (dermal route) / year = (Conc x P x ESA x AbsD x EF) ÷ (BW x AT)

  Where :

  Conc = concentration of a.s. on the surface (mg/m^2)

  P = proportion translodged onto skin

  ESA = exposed skin area

  AbsD = dermal absorption of the a.s.

  EF = exposure frequency

  BW = body weight

  AT = averaging time

- Direct contact due to the spraying

  Systemic exposure (dermal route) / day = (Conc x ESA x AbsD) ÷ (BW)

  Systemic exposure (dermal route) / year = (Conc x ESA x AbsD x EF) ÷ (BW x AT)

  Where :

  Conc = concentration of a.s. on the surface (mg/m2)

  ESA = exposed skin area

  AbsD = dermal absorption of the a.s.

  EF = exposure frequency

  BW = body weight

  AT = averaging time

Oral exposure :

Oral exposure due to hand-to-mouth activity is considered for toddler in the WHO guidance.

Systemic exposure (oral route) / day = (Conc x P x ESA x THM x AbsO) ÷ (BW)

Systemic exposure (oral route) / year = (Conc x P x ESA x THM x AbsO x EF) ÷ (BW x AT)

Where :

Conc = concentration of a.s. on the surface (mg/m^2)

P = proportion translodged onto skin

ESA = exposed skin area

THM = extent of transfer from hands to mouth

AbsO = oral absorption of the a.s.

EF = exposure frequency

BW = body weight

AT = averaging time

Total exposure :

Is the addition of the inhalation, dermal and when relevant oral exposure.

	Parameters	Value	Source
	Application rate	35g b.p./ 100 m^3	Product specific
	Weight fraction a.s. in product	2%	Product specific
	Molecular weight of a.s.	350.46 g/mol	AR on 1R-trans phenothrin (rMS: IE / March 2013)
	Log Kow of a.s. (at 20°C)	6.8	AR on 1R-trans phenothrin (rMS: IE / March 2013)
	Vapour pressure a.s. (Pa, at 20°C)	2.37×10^{-5}	AR on 1R-trans phenothrin (rMS: IE / March 2013)
	Body weight (adult)	60 kg	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Body weight (child 6-12 years)	23.9 kg	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Body weight (child 2-6 years)	15.6 kg	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Body weight (toddler)	10 kg	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Body weight (infant)	8 kg	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Dermal absorption	70%	Default value
	Inhalation absorption	100%	Default value
	Oral absorption	100%	Default value
Inhalation exposure			
TIER 1	Respiration rate (adult)	1.25 m^3/h	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Respiration rate (child 6-12 years)	1.32 m^3/h	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Respiration rate (child 2-6 years)	1.26 m^3/h	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Respiration rate (toddler)	1.26 m^3/h	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure

	Respiration rate (infant)	0.84 m^3/h	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure
	Exposure frequency (adult)	40/year	EHC 243 (WHO, 2013) – business travel
	Exposure frequency (child, toddler and infant)	5/year	EHC 243 (WHO, 2013) – holiday travel
	Spray duration	200 s	EHC 243 (WHO, 2013)
	Exposure duration	30 min	EHC 243 (WHO, 2013)
	Room volume	1000 m^3	EHC 243 (WHO, 2013) (large aircraft)
	Room height	2 m	EHC 243 (WHO, 2013)
	Ventilation rate	0/h	EHC 243 (WHO, 2013) (as a worst case it is assumed that there is no effect due to ventilation)
	Mass generation rate	2.2 g/s	ConsExpo and EHC 243 (WHO, 2013): 2 x 1.1 g/s (default of ConsExpo) reflecting the possibility that 2 cans are discharged simultaneously.
	Airborne non-volatile fraction (worst case)	100%	EHC 243 (WHO, 2013)
	Density non-volatile	1.8 g/cm^3	EHC 243 (WHO, 2013)
	Initial particle distribution	Median: 8 µm cv : 0.45	EHC 243 (WHO, 2013)
		Maximum diameter: 50 µm	Particle size distribution study (Section 2.2.2)
	Inhalation cut-off diameter	15 µm	EHC 243 (WHO, 2013)
TIER 2	Respiration rate (toddler)	0.96 m^3/h	Inhalation rates toddlers values derived from Table 6-2 from the EPA Exposure Factors Handbook, considering **Light Intensity** activity level. (95th percentile value : 1.6E-02 m^3/minute = 0.96 m^3/h)
Dermal exposure			
"Indirect exposure"	Conc	0.032 mg/m^2	Based on EHC 243 (WHO, 2013), the following assumptions are made : - Large aircraft cabin surface area : 2500 m^2 - Large aircraft cabin volume :1000 m^3 - Amount of sprayed material deposited on surfaces : 1% - The application rate of this product is 35g/100 m^3. Therefore, for a large aircraft, it is assumed that four cans of 100g would be discharged. This would result on a concentration of biocidal product onto the surface of : 400 g x 1% / 2500 m^2 = 1.6 mg/m^2 As the concentration of active substance is 2% in the b.p. : 1.6 mg/m^2 x 2% = 0.032 mg/m^2
	P	11%	EHC 243 (WHO, 2013) : proportion translodged onto skin = 11% of the amount present on the surfaces (USEPA, 2009)

	ESA	Adult : 0.25 m^2 Child : 0.16 m^2 Toddler : 0.2 m^2 Infant : not exposed	EHC 243 (WHO, 2013) : exposed skin area (0.25 m^2 for adults, 0.16 m^2 for older children, 0.2 m2 for toddlers); for toddlers, additionally, some of the insecticide on the hands is transported to the mouth by hand-to-mouth activity, leading to ingestion exposure. **For new born 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.
	EF : Exposure frequency (adult)	40/year	EHC 243 (WHO, 2013) – business travel
	EF : Exposure frequency (child, toddler and infant)	5/year	EHC 243 (WHO, 2013) – holiday travel
	AT	365 d/y	EHC 243 (WHO, 2013) : averaging time = default, 1 year, 365 days
"direct exposure"	C	0.032 mg/m^2	EHC 243 (WHO, 2013), C = concentration settling on surfaces, including exposed skin (calculated as 1% of the amount of a.i. sprayed divided by the aircraft internal surface area). See above Conc.
	ESA	Adult : 0.33 m^2 Child : 0.26 m^2 Toddler : 0.15 m^2 Infant : not exposed	EHC 243 (WHO, 2013) : exposed skin area ((0.33 m2 for adults, 0.26 m2 for older children, 0.15 m2 for toddlers) For newborn 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.
	EF : Exposure frequency (adult)	40/year	EHC 243 (WHO, 2013) – business travel
	EF : Exposure frequency (child, toddler and infant)	5/year	EHC 243 (WHO, 2013) – holiday travel
	AT	365 d/y	EHC 243 (WHO, 2013) : averaging time = default, 1 year, 365 days
Oral exposure			
TIER 1	Conc	0.032 mg/m^2	Based on EHC 243 (WHO, 2013) as above.
	P	11%	EHC 243 (WHO, 2013) : proportion translodged onto skin = 11% of the amount present on the surfaces (USEPA, 2009)
	ESA	Toddler : 0.032 m^2	EHC 243 (WHO, 2013) : relevant hand area for toddlers is 0.032 m2.
	THM	10%	EHC 243 (WHO, 2013) : THM = extent of transfer from hands to mouth (10%)
	EF : Exposure frequency (toddler)	5/year	EHC 243 (WHO, 2013) – holiday travel
	AT	365 d/y	EHC 243 (WHO, 2013) : averaging time = default, 1 year, 365 days

Calculations for scenario 2 - dermal, inhalation and oral exposure for aircraft passengers

Please for details calculations refer to annex 3.2.1

Estimated exposure from secondary exposure for aircraft passengers						
Exposure scenario	**Tier/PPE**	**Acute or Chronic exposure**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 2: secondary exposure for aircraft passengers	Adult TIER 1 /No PPE	Acute exposure	0.0319	0.00013347	-	0.03203347
		Chronic exposure	0.00349	1.4626E-05	-	0.00350463
	Child (6-12) TIER 1 /No PPE	Acute exposure	0.0844	0.00026018	-	0.08466018
		Chronic exposure	0.00116	3.5641E-06	-	0.00116356
	Child (2-6) TIER 1 /No PPE	Acute exposure	0.123	0.00024697	-	0.12324697
		Chronic exposure	0.00169	3.3832E-06	-	0.00169338
	Toddler TIER 1 /No PPE	Acute exposure	0.193	0.00038528	1.126E-06	0.19338641
		Chronic exposure	0.00264	5.2778E-06	1.543E-08	0.00264529
	Infant TIER 1 /No PPE	Acute exposure	0.161	0	-	0.161
		Chronic exposure	0.0022	0	-	0.0022
	Toddler TIER 2 /No PPE	Acute exposure	0.147	0.00038528	1.126E-06	0.147386406
		Chronic exposure	0.00201	5.2778E-06	1.543E-08	0.002015293

Monitoring data

Not applicable

Dietary exposure

No exposure is foreseen as regards to the intended use of the product. According the instruction of use, it is expected that the product would not be used while food is being served or is being eaten. See also Risk for consumers via residues in food.

Exposure associated with production, formulation and disposal of the biocidal product

Occupational exposure during production and formulation of biocidal product is not covered by the BPR. It is expected that production and formulation are performed in conformity with European and national worker protection legislation.

2.2.6.3 Risk characterisation for human health

The following AEL values were derived during assessment of the active substance for the purpose of inclusion into Annex I of 98/8/EC for as insecticides, acaricides and or as a products to control other arthropods. Please refer to the Assessment Report of **1R-trans phenothrin** (RMS IE, March 2013) for more information.

Reference values to be used in Risk Characterisation for 1R-trans phenothrin

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short\text{-}term}$	Rabbit oral development toxicity study	30 mg/kg bw/d	100 (inter-& intra-specific differences)	Yes (60%)	0.18 mg/kg bw/d
$AEL_{medium\text{-}term}$	1-year, oral, dog	8.2 mg/kg bw/day	100 (inter-& intra-specific differences)	Yes (60%)	0.05 mg/kg bw/d
$AEL_{long\text{-}term}$	1-year, oral, dog	8.2 mg/kg bw/day	100 (inter-& intra-specific differences)	Yes (60%)	0.05 mg/kg bw/d
ADI	1-year, oral, dog	8.2 mg/kg bw/day	100 (inter-& intra-specific differences)	None	0.08 mg/kg bw/d
ARfD	Rabbit oral development toxicity study	30 mg/kg bw/day	100 (inter-& intra-specific differences)	None	0.3 mg/kg bw/d

Risk for industrial users

Not relevant. The product is not intended for industrial use.

Risk for professional users

Systemic effects

Scenario	Exposure / TIER	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [1]	"Guideline scenario" TIER 1	0.05	0.03	63.81	Yes
	"Lax Standard scenario" TIER 1	0.05	0.22	446.47	No
	"Lax Standard scenario" **TIER 2**	0.05	0.04	82.47	Yes

** For professional, daily exposure are compared with long term AEL, as this type of exposure could approximate by a continuous exposure and not by spontaneous events.*

Combined scenarios

Not required. Aircraft disinsection treatments are conducted according the WHO guidelines/recommendations on aircraft Disinsection. Only one application per flight is required with an 1R-trans phenothrin aerosolized product. For flights in EU and for flights leaving Europe, aircraft disinsection treatments are generally not required.
Currently there is not a 'WHO List of countries requiring aircraft Disinsection'. Each country is responsible and can state (and adapt on regulatory basis) the requirements regarding aircraft disinsection for its territory.
Generally, aircraft disinsection is required for a flight coming from high risk zones where vector borne diseases are an imminent threat and so can be spread via mosquitoes entering aircraft. If there is an outbreak (f.e. 2016 – ZIKA), a lot of countries adapt their policy regarding aircraft disinsection.
Please note that the following RMM was added due to the discussion by the Coordination Group for a similar product (Coordination Group public documents (CIRCABC) – library – Record of agreements – Non Flammable aircraft insecticide phen_disar to CG formal_public.pdf): "If more than one application per day is required, each application must be applied by a different member of the aircrew". This RMM refers to the very exceptional situation: if the same plane + staff performs more than 1 flight a day AND the consecutive flights require both an aircraft disinsection treatment.
However, on the EU territory, this exceptional case - the same staff will have two consecutive flights requiring aircraft disinsection in the same aircraft - is not likely and so a combined scenario is not required.

Local effects

Not required.

Conclusion

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 without use of PPE.

The following instructions of use were added:

- Hold can(s) vertically at arm's length.
- The insecticide aerosol shall be sprayed in the aircraft directing the nozzle of the aerosol dispenser at an angle of approximate 45° towards the ceiling throughout.
- Spray uniformly through whole area.
- The spray should be directed slightly behind the user

In addition, the following Risk Mitigation Measures are proposed to exclude several exposures per day of the cabin crew:

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

Risk for non-professional users

Not relevant. The product is not intended to be used by non-professional users.

Risk for the general public

Systemic effects

Scenario	Exposure / TIER	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Acute exposure					
Scenario [2]	Adult TIER 1 /No PPE	0.18	0.032	17.80	Yes
	Child (6-12) TIER 1 /No PPE	0.18	0.085	47.03	Yes
	Child (2-6) TIER 1 /No PPE	0.18	0.123	68.47	Yes
	Toddler TIER 1 /No PPE	0.18	0.193	107.44	No
	Infant TIER 1 /No PPE	0.18	0.161	89.44	Yes
	Toddler TIER 2 /No PPE	0.18	0.147	81.88	Yes
Chronic exposure					
Scenario [2]	Adult TIER 1 /No PPE	0.05	0.0035	7.01	Yes
	Child (6-12) TIER 1 /No PPE	0.05	0.0012	2.33	Yes
	Child (2-6) TIER 1 /No PPE	0.05	0.0017	3.39	Yes
	Toddler TIER 1 /No PPE	0.05	0.0026	5.29	Yes
	Infant TIER 1 /No PPE	0.05	0.0022	4.4	Yes

Combined scenarios
Not required.

Local effects
Not required.

Conclusion
When the product Aero-Sense Aircraft Insecticide ASD is used as proposed, no unacceptable risks are expected for adult, children and infants exposed secondary to the use of the product. However, a risk is identified for toddlers.
Performing a refinement on the inhalation rate (considering the more adequate inhalation rate considering the intensity of the activity), the risk is shown acceptable.
It is concluded that Aero-Sense Aircraft Insecticide ASD does not pose unacceptable risk for public.

Risk for consumers via residues in food

Negligible.

According the instruction of use, it is expected that the product would not be used while food is being served or is being eaten.

However, a worst case exposure via residues in food could be estimated using the Guidance on the Biocidal Products Regulation, Volume III Human Health, Assessment & Evaluation (Parts B+C) / (version 4.0 - Dec 2017) and likewise the similar product discussed recently in coordination group.

Airspace treatment:

- Calculation of biocide residues deposited from air to surfaces ($R_{surface}$) :
  Based on the information provided previously,

Based on EHC 243 (WHO, 2013), the following assumptions are made : - Large aircraft cabin surface area : 2500 m^2 - Large aircraft cabin volume :1000 m^3 - Amount of sprayed material deposited on surfaces : 1% - The application rate of this product is 35g/100 m^3. Therefore, for a large aircraft, it is assumed that four cans of 100g would be discharged. This would result on a concentration of biocidal product onto the surface of : 400 g x 1% / 2500 m^2 = 1.6 mg/m^2 As the concentration of **active substance** is 2% in the b.p. : 1.6 mg/m^2 x 2% = **0.032 mg/m^2**

- Therefore, the exposure could be calculated as:

$$Exp_{cons} = R_{surface} \times A_{food\ contact} / bw$$

$$\text{Toddler } Exp_{cons} = 0.032\ mg/m^2 \times 0.2\ m^2 / 10\ kg$$

$$= 6.4 \times 10^{-4}\ mg\ a.s./kg\ bw/d$$

This 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"

Remark : the applicant proposed at first the following RMM "Do not spray on exposed food, food preparation areas or food utensils". However, BE would advise the above RMM for harmonization.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

No assessment required as the product contains one active substance and no identified toxicological substance of concern.

2.2.7 Risk assessment for 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 these of 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 metabolisation 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".

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The product contains only one active substance and no substances of concern. Therefore all toxicity data can be obtained from the CAR on 1R-trans phenothrin (March 2013).
PNEC values are summarized in the table below.

Compartment	**PNEC**
STP	10 mg/L
Fresh water	4.7x 10^{-5} mg/L
Fresh water sediment*	0.0129 mg/kgwwt
Soil	0.0104 mg/kgwwt
Log Pow	6.8

* As 1R-trans phenothrin is likely to deposit on/adsorb to sediment (K_{oc} = 125 892.5 L/kg and log K_{ow} >5), sediment dwelling organisms might take up 1R-trans phenothrin via sediment ingestion. Hence, an additional factor of 10 is taken into account when assessing the risk to sediment dwellers based on the aquatic risk assessment. This value differs from PNECsed available in the CAR where the ksusp-water was not properly used.

In this PAR, the PNECsed takes into account the ksusp-water = 3150.9 resulting in a PNECsed= 0.0129mg/kgwwt.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

No information is available on the ecotoxicity of the biocidal products. As regards the classification of the products in this BPF, CLP mixture rules are applied[7]. Only the active substance 1R-trans phenothrin is classified for the environment:
Aquatic acute 1 (H400) M-factor = 100
Aquatic chronic 1 (H410) M-factor = 100
Considering a final concentration of 2% in the formulation, the product is classified as:
Aquatic acute 1 (H400)
Aquatic chronic 1 (H410)

Further Ecotoxicological studies

No new data available.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No new data available.

Supervised trials to assess risks to non-target organisms under field conditions

No new data available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Not relevant.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Aero-Sense Aircraft Insecticide ASD is applied in aircrafts when doors are closed. Hence, direct emissions to the environment are unlikely. Nevertheless, an amount of 1R-trans

[7] Guidance on the application of the CLP criteria. Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures (July 2017).

phenothrin will be in the gaseous phase when the doors of the aircraft are opened and will be released into the outdoor air. However, 1R-trans phenothrin has a short half-life in air (DT_{50} of 3.63 hours for photo-oxidative degradation; RMS Ireland, 2013). Given the high dilution of the aircraft air in the outdoor air and the rapid degradation of the active substance, this route of emission will not be considered further.

Indirect emissions to the environment are more likely and may result from exposure to the product during application, which may result in emissions to the environment in subsequent cleaning steps, with releases to either dry waste or wastewater. Since the product is sold 'ready to use', risk of exposure during mixing and loading is not considered.

Overall, the 'main receiving compartment' following application of Aero-Sense Aircraft Insecticide ASD is the STP. Via the STP, indirect emissions of insecticide to surface water and sediment are possible. Although sludge application on soil is not common practice in most European countries, emissions to soil from sludge application is also considered, as Union authorisation in requested. Consequently, also groundwater contamination will be calculated.

Further studies on fate and behaviour in the environment (ADS)

No new data available.

Leaching behaviour (ADS)

Not relevant.

Testing for distribution and dissipation in soil (ADS)

No new data available.

Testing for distribution and dissipation in water and sediment (ADS)

No new data available.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant. Product is not intended for outdoor use : it will be sprayed on board aircraft for disinsection prior to departure and during return flight to EU airport.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Disinsection treatment of aircraft on return flight to EU, with emissions resulting from daily (wet) cleaning at EU arrival airport ; Scenario 2: Disinsection treatment of aircraft on return flight to EU, with emissions resulting from "deep" (wet) cleaning at EU hangar during routine maintenance ; Scenario 3: Disinsection treatment of aircraft on return flight to EU, with emissions resulting from passengers washing themselves and laundering clothes on their return home.
ESD(s) used	Basic principles set out in Emission Scenario Document for Product Type 18: insecticides, acaricides and products to control other arthropods for household and professional uses (July 2008). Tier 1 scenarios developed by UK CA (eCA) as emissions models not available in existing ESD (following e:consultation with other MSand decision of the BPC WG IV 09/2019). IPCS Environmental health criteria 243: Aircraft disinsection insecticides (WHO, 2013)
Approach*	Scenario 1: Average consumption based upon mean size (600m³) of aircraft used for long haul flights and appropriate quantity of product needed for that volume / area ; Scenario 2: Average consumption based upon mean size (600m³) of aircraft used for long haul flights, appropriate quantity of product needed for that volume / area and number of aircraft undergoing deep cleaning at same time ; Scenario 3: Average consumption based upon mean size (600m³) of aircraft used for long haul flights, appropriate quantity of product needed for that volume / area and mean number of passengers per flight.
Distribution in the environment	Calculations based on ECHA Guidance on Environmental Risk Assessment (ERA), Volume IV Environment- Part B Risk Assessment (version 1, 2015).
Groundwater simulation	FOCUS PEARL 4.4.4 modelling not performed for any scenario – as losses to soil are indirect (following discharges via drains to local STP), a Tier 1 porewater calculation has been undertaken as screening tool for the active and the three main metabolites.
Confidential Annexes	None for Env.
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No

Remarks	* The application rates used in ENV and HH risk assessment are the same (e.g. 35 g/100 m3). However, the default volume of the aircraft are considered different (1000m³ for HH and 600m³ for ENV). It should be noted that for HH risk assessment the relevant parameters are concentration in the air and residual concentration on the floor which are determined by the application rate. While for HH assessment using a different aircraft volume would not change the conclusion, for the ENV assessment the aircraft volume is determinant for the emission estimation. Therefore was considered more accurate to base the default value on statistical data (DGAC – BULLETIN STATISTIQUE - TRAFIC AERIEN COMMERCIAL 2015 stat.sdeep.dta@aviation-civile.gouv.fr) and on the scenario used for another similar product

Emission estimation

The application of insecticide indoor (onboard aircraft) is not covered by the PT18 insecticide ESD. For a similar use, did the UK eCA developed an Emission Scenario in collaboration with other MS through a e-consultation which was finally agreed at BPC level in 2016. During the same period, the applicant for Aero-Sense Aircraft Insecticide ASD developed his own scenario. It was agreed during BPC-WG IV 2019 (25-27/09/2019) that the UK approach would be followed for this product as TIER I evaluation. The assumption made by the applicant in the environmental evaluation as originally provided may be used if necessary to refine the environmental assessment (TIERII). Since the UK approach has to be followed for harmonisation reasons, most of the following text has been taken over from the evaluation made by UK for the concurrent product. For the sake of transparency, this text is provided in *"italic"* in the following paragraphs.

Indoor insecticide use (on board aircraft before and/or during return flight from "at risk" overseas airport to EU destination), with application of product by cabin crew (professional users) made specifically at potentially 3 different time points :

- *"Pre-flight" or "Pre-arrival" boarding : product is applied when the aircraft is on the ground and remains empty (at least 20 – 40 min before passengers are allowed to board the aircraft at the overseas airport) ;*
- *"Blocks away" : application takes place when passengers have boarded and when doors are closed but before take-off ;*
- *"Top of descent" : at the point when the aircraft begins descent to land at the EU (return) airport.*

According to the applicant for Aero-Sense Aircraft Insecticide ASD the preflight or pre-arrival application of the product is not performed with this product but with another one formulated with a different active substance. For the sake of comparison, this application has been left in the scenario but it should be considered in this case that resulting emissions will be overestimated.

The application is undertaken by cabin crew, who typically walk through the aircraft cabin discharging aerosols at the prescribed dosage. All possible harbourages must be treated,

including toilets, galleys, wardrobes and lockers. Holds and the flight deck are sprayed before departure – the flight deck before boarding by the flight crew.

Therefore, on the basis that rapid (and complete) removal of 1R-trans-phenothrin from cabin air to cabin surfaces can be expected during the return flight to an EU airport, it is assumed that choice of application method ("Pre-flight", "Blocks away" or "Top of descent") for the disinsection product will have no impact on the behaviour of the a.s., as the return flight would offer sufficient time for product to always deposit to surfaces. As such, only one emissions assessment need be used to determine risks posed to EU environment following various disinsection regimes and subsequent discharges from aircraft and passengers due to cleaning events.

The applicant has indicated that the product may be applied as a single treatment at the "Blocks away" stage and this is denoted in assessment as SCENARIO (n)A. However, treatment may be undertaken twice at both the "Pre-flight" + "Top of descent" stages so this is identified as SCENARIO (n)B in emissions modelling. As a result, there will be risk assessment undertaken for scenarios 1A, 1B, 2A, 2B, 3A and 3B.
Full details of defaults and calculations undertaken to predict quantity of a.s. applied within the aircraft are provided in Annex 3 to this PAR.

In the case of the Aero-Sense product, pre-flight application is not performed with this product. As a consequence, only the result of SCENARIO (n) A are relevant in this case. For comparison and completeness, both scenarios have been run in this PAR.

Scenario [1] Routine cleaning of aircraft after each flight:

Routine cleaning of aircraft after each flight : key areas of aircraft such as galley, toilets etc, are quickly cleaned and wiped by contracted cleaning staff at airport. Due to rapid turnaround of the plane, cleaning is limited to those areas that directly affect passenger wellbeing and health. It is stated by applicants that many areas are not wet cleaned routinely.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *Cleaning of limited areas within the aircraft (galley areas, toilets etc) after every flight by routine cleaning staff*			
Quantity of biocidal product applied in average long haul aircraft	210* 420	g	Scenario 1A Scenario 1B
Concentration of active substance in the product	2	%	Technical a.s.
Fraction of a.s. deposited to surfaces	1	/	
Fraction of aircraft surfaces available for wet cleaning (worst case)	0.1	/	
Cleaning efficiency from surfaces	0.5	/	ESD F_{CE} value
Average daily number of long haul aircraft arriving at EU "hub" airport	100	/	

* Applic rate = 35g/100m³ and mean aircraft vol = 600m³

Calculations for Scenario [1] TIER I

Resulting local emission to relevant environmental compartments		
	Scenario 1A	**Scenario 1B***
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Local emission ($Elocal_{compartment}$) [kg/d]**
Water	2.1E-2	4.2E-2

*not relevant for this product

Scenario [2] Aircraft subjected to planned maintenance

All aircraft are subject to planned maintenance after a fixed number of "air hours" when all systems and major parts are inspected whilst the aircraft is out of service. It is understood that this also allows the aircraft to be subject to prolonged cleaning and this would reach locations in the cabin etc that are hardly touched by daily cleaning procedures. In many cases, residues built up from multiple treatments would be cleaned for the first time.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *Deep cleaning of internal surfaces every 2 months when aircraft is taken out of service for routine maintenance*			
Quantity of biocidal product applied in average long haul aircraft	210* 420	g	Scenario 2A Scenario 2B
Concentration of active substance in the product	2	%	Technical a.s.
Fraction of a.s. deposited to surfaces	1	/	
Fraction of aircraft surfaces available for wet cleaning (worst case)	0.7	/	
Cleaning efficiency from surfaces	0.5	/	ESD F_{CE} value
Number of repeat treatments applied to aircraft between maintenance events	30	/	30 treatments in 2 months service
Average daily number of long haul aircraft arriving at routine maintenance	5	/	

* Applic rate = 35g/100m³ and mean aircraft vol = 600m³

Calculations for Scenario [*2*]

The emissions during the application and cleaning phase were calculated by means of EUSES.

Resulting local emission to relevant environmental compartments		
	Scenario 2A	**Scenario 2B***
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Local emission ($Elocal_{compartment}$) [kg/d]**
Water	2.21E-1	4.41E-1

*not relevant for this product

Scenario [3] Washing of passenger's clothings

Passengers who may have been sprayed with insecticide or picked up a.s. from treated surfaces then remove these residues by personal washing and laundering of contaminated clothes

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: *Passengers who may have been sprayed with insecticide then remove these residues by personal washing and laundering of contaminated clothes*			
Quantity of biocidal product applied in average long haul aircraft	210* 420	g	Scenario 3A Scenario 3B
Concentration of active substance in the product	2	%	Technical a.s.
Fraction of a.s. deposited to surfaces	1	/	
Fraction of total applied a.s. likely to fall on areas occupied by passengers (worst case)	0.3	/	
Cleaning efficiency from skin/ laundry	1	/	ESD F_{CE} value
Average number of passengers on long haul aircraft	300	/	30 treatments in 2 months service
Average number of passengers discharging a.s to local STP on same day	30	/	

* Applic rate = 35g/100m³ and mean aircraft vol = 600m³

Calculations for Scenario [3]

Resulting local emission to relevant environmental compartments		
	Scenario 3A	**Scenario3B***
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Local emission ($Elocal_{compartment}$) [kg/d]**
Water	1.26E-4	2.52E-4

*not relevant for this product

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other (Biota)
Scenario 1	yes	yes	no	no	yes	no	yes	yes	Yes
Scenario 2	yes	yes	no	no	yes	no	yes	yes	Yes
Scenario 3	yes	yes	no	no	yes	no	yes	yes	Yes

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	350.46	g/mol	
Melting point	-41.4	°C	
Boiling point	>301	°C	
Vapour pressure (at 20°C)	2.37 x 10^{-5}	Pa	
Water solubility (at 21°C)	0.002	mg/l	
Log Octanol/water partition coefficient	6.8	Log 10	
Organic carbon/water partition coefficient (Koc)	125 892.5	l/kg	
Henry's Law Constant (at 20°C)	4.2	Pa/m^3/mol	
Biodegradability	Not readily biodegradable		
Rate constant for STP *Fstp_air* *Fstp_water* *Fstp_sludge*	0 2.71E-3 1.29E-1 8.68E-1	h^{-1}	Default 0.271% 12.9% 86.8%
DT_{50} for hydrolysis in surface water	578	d (at 12ºC /pH 7)	
DT_{50} for photolysis in surface water	13.9	hr	
DT_{50} for degradation in soil	27.2	d (at 12ºC)	
DT_{50} for degradation in air	3.63	hr	24 hr day, 5E+5 OH radicals
$K_{soil-water}$	3776.98	m^3/m^3	
Ksusp-water	3150.9	m^3/m^3	

Metabolites (HO-PHN, PBalc and PBacid)
In the CAR for 1R-trans-phenothrin, PEC values for each metabolite were estimated directly from the PEC values for the parent a.s., taking into account the molecular weight difference between parent and metabolites along with the maximum observed levels of

the metabolites. In addition, it was stated that HO-PHN, PBalc and PBacid, are considered to be much less toxic than the parent material, on the basis of a QSAR assessment conducted with the ECOSAR model. Therefore the toxic data for the active substance was applied in the risk assessment for the metabolites as a worst case approach.
Therefore, as the metabolites all rely upon the endpoints of the parent a.s. but are formed at much lower concentrations and have lower MW values, then no further consideration need be undertaken. If acceptable risks of parent can be shown in relevant environmental compartments, then risks posed by metabolites must also be acceptable. If acceptable risks of parent can be shown in relevant environmental compartments, then risks posed by metabolites must also be acceptable and therefore no pearl calculcation is required.

Calculated fate and distribution in the STP *[if STP is a relevant compartment]*		
Compartment	Percentage [%]	Remarks
	Scenario 1-3	
Air	0.27	/
Water	12.9	
Sludge	86.8	
Degraded in STP	0	

Calculated PEC values

Tier I

	Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{soil\ (1)}$**	**$PEC_{soil\ (10)}$**	**PEC_{GW}**
	[mg/m^3]	[mg/l]	[mg/kg_{dwt}]	[mg/kgwwt]	[mg/kgwwt]	[µg/l]
Scenario 1A	1,35E-03	1,14E-04	0.312	2.64E-02	3.78E-02	3,66E-06
Scenario 1B*	2.71E-03	2,28E-04	0.624	5.27E-02	7.55E-02	7,31E-06
Scenario 2A	1,35E-02	1.20E-03	3.28	2.78E-01	3.97E-01	3.85E-05
Scenario 2B*	2,84E-02	2,39E-03	6,55	5.54E-01	7.93E-01	7,64E-05
Scenario 3A	8,13E-06	6,84E-07	1,87E-01	1.58E-04	2.27E-04	2,20E-08
Scenario 3B*	1,45E-05	1,22E-06	3,34E-01	3.16E-04	4.53E-04	4,E-08

*not relevant for this product

Primary and secondary poisoning

Primary poisoning

As the direct consumption of insecticide by birds or mammals is thought to mainly occur when insecticides are applied with a food attractant or as a granular formulation then, in line with Chapter 5 of the PT 18 ESD, spray application on board aircraft for mosquito and fly control does not need to be considered for primary poisoning.

Secondary poisoning

a) Via the consumption of worms from contaminated soil

The exposure of soil to 1R-trans phenothrin could result from the indirect application of sewage sludge to agricultural land.

Resulting local emission to relevant worm eating predator	
Scenario	**PEC_{biota} (mg/kg.food)**
Scenario 1A Scenario 1B*	0.25 0.505
Scenario 2A Scenario 2B*	2.66 5.30
Scenario 3A Scenario 3B*	1.52E-3 3.03E-3

*not relevant for this product

b) Via the aquatic food chain

The exposure of water to 1R-trans phenothrin could result from the indirect discharge of product to drains and release of treated effluent into surface waters.

Resulting local emission to relevant fish eating predator	
Scenario	**PEC_{biota} (mg/kg.food)**
Scenario 1A Scenario 1B*	0.56 1.13
Scenario 2A Scenario 2B*	5.97 11.9
Scenario 3A Scenario 3B*	3.4E-3 6.08E-3

*not relevant for this product

2.2.8.3 Risk characterisation

Atmosphere

Conclusion:

Based upon published literature, all a.s. applied on board the aircraft is assumed to deposit onto passengers and internal surfaces quickly after product has been applied. Therefore, direct releases to air compartment from Scenarios 1, 2 and 3 are considered negligible and the risks are zero.

A small fraction of a.s. reaching local STP in each scenario can reach the air compartment but calculated values at 100 meters from the filter beds are all negligible.

Moreover, as any a.s. reaching the atmosphere is expected to be decomposed with a half-life of 4 h, it can be expected that the level of risk to air posed by this product will be acceptable.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
Scenario	**PEC/PNEC$_{STP}$**
Scenario 1A Scenario 1B*	1.35E-4 2.71E-4
Scenario 2A Scenario 2B*	1.43E-3 2.84E-3
Scenario 3A Scenario 3B*	8.13E-7 1.45E-6

*not relevant for this product

Conclusion:

As the PEC/PNEC ratio is below 1 for all scenarios considered, the use of the product does not pose any risk to the micro-organisms in the STP.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
Scenario	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$****
Scenario 1A Scenario 1B*	**2.42** **4.85**	**24.2** **48.5**
Scenario 2A Scenario 2B*	**25.45** **50.9**	**254.5** **509**
Scenario 3A Scenario 3B*	1.45E-2 2.6E-2	0.145 0.26

*not relevant for this product

** Due to PNECsed being derived by EPM and the a.s. having a log Kow >5 (actual value reported as log 6.8), then an additional safety factor of 10 has been applied to sediment risk : values are now 10 times higher than aquatic risk

Conclusion:

Risks posed by 1R-trans phenothrin to aquatic organisms and sediment dwelling organisms are unacceptable in SCENARIOS 1 & 2 as a result of potential cleaning events on board aircraft after they have landed at EU airports. However, risks posed by passengers contaminated with a.s. are considered acceptable.
[It is noted that the risks posed to aquatic organisms and sediment dwelling organisms are identical and therefore indicates that both PNECsed and PECsed must have been predicted via EPM].

As unacceptable risks have been identified in 2 out of 3 scenarios and this would prevent authorisation of the product, the Applicant for the product assed by UK authorities has

submitted a detailed appraisal of cleaning processes undertaken on board aircraft within the EU to demonstrate that the assessment provided in this PAR represents an extreme worst case (Tier 1) approach. This cleaning process is independent of the insecticide biocidal product used onboard. Therefore, for the sake of harmonization, it is considered that the same argumentation should be considered and agreed for the Aero-Sense Aircraft Insecticide ASD product. The full document as presented is the previous dossier can be found in Annex 3 of the PAR and key arguments will be discussed after the summary table of PEC/PNEC results.

Terrestrial compartment

Calculated PEC/PNEC values		
Scenario	**PEC/PNEC$_{soil\ (1)}$**	**PEC/PNEC$_{soil(10)}$**
Scenario 1A Scenario 1B*	**2.54** **5.07**	**3.63** **7.26**
Scenario 2A Scenario 2B*	**26.1** **53.2**	**38.2** **76.2**
Scenario 3A Scenario 3B*	1.52E-2 3.04E-2	2.18E-2 4.36E-2

*not relevant for this product

Risks posed by 1R-trans phenothrin to soil organisms are unacceptable in SCENARIOS 1 & 2 as a result of potential cleaning events on board aircraft after they have landed at EU airports. However, risks posed by passengers contaminated with a.s. are considered acceptable. This is true following single application of sludge to soil (realistic worst case) as initially evaluated or after ten years application (as according to vol IV part B).

As unacceptable risks have been identified in 2 out of 3 scenarios and this would prevent authorisation of the product, the Applicant of the product assed by UK authorities has submitted a detailed appraisal of cleaning processes undertaken on board aircraft within the EU to demonstrate that the assessment provided in this PAR represents an extreme worst case (Tier 1) approach. This cleaning process is independent of the insecticide biocidal product used onboard. Therefore, for the sake of harmonization, it is considered that the same argumentation should be considered and agreed for the Aero-Sense Aircraft Insecticide ASD product. The full document as presented is the previous dossier can be found in Annex 3 of the PAR and key arguments will be discussed after the summary table of PEC/PNEC results.

Groundwater

The calculated PEC$_{GW}$ values in all scenarios for 1R-trans phenothrin, based on a simplistic Tier 1 porewater calculation after single application of sludge on soil, are all under the regulatory threshold of 0.1µg/L and therefore risks are acceptable using this screening approach. Higher tier FOCUS PEARL 4.4.4 modelling is not necessary

Calculated PEC/PNEC values

Scenario	PEC/PNEC$_{Gw}$
Scenario 1A	3.66E-2
Scenario 1B*	7.31E-2
Scenario 2A	3.85E-1
Scenario 2B*	7.67E-1
Scenario 3A	2.20E-4
Scenario 3B*	4.39E-4

*not relevant for this product

For the three main metabolite, considering 10 year application of sludge on soil, 100% transformation of the active into each metabolite (where the current are below 12.9% in reality) give the following results:

Calculated PEC/PCEc value for the metabolites							
Scenario	Metabolite	Mw metabolite	Mw parent	PECgw parent (µg/l)	F compartment	PECgw metabolite (µg/l)	PEC/PNEC
	HO-PHN	367,4	350,4	3,66E-06	1	3,84E-06	3,84E-05
	Pbalc	200,23	350,4	3,66E-06	1	2,20E-05	2,20E-04
1A	Pbacid	214,22	350,4	3,66E-06	1	2,24E-06	2,24E-05
	HO-PHN	367,4	350,4	3,85E-05	1	4,04E-05	4,04E-04
	Pbalc	200,23	350,4	3,85E-05	1	2,20E-05	2,20E-04
2A	Pbacid	214,22	350,4	3,85E-05	1	2,35E-05	2,35E-04
	HO-PHN	367,4	350,4	2,20E-08	1	2,31E-08	2,31E-07
	Pbalc	200,23	350,4	2,20E-08	1	1,26E-08	1,26E-07
3A	Pbacid	214,22	350,4	2,20E-08	1	1,34E-08	1,34E-07

Primary and secondary poisoning

Primary poisoning

As the direct consumption of insecticide by birds or mammals is thought to mainly occur when insecticides are applied with a food attractant or as a granular formulation then, in line with Chapter 5 of the PT 18 ESD, spray application on board aircraft for mosquito and fly control does not need to be considered for primary poisoning.

Secondary poisoning

Summary table on secondary poisoning of worm-eating predators		
Scenario	**PEC/PNEC$_{worms}$**	**PEC/PNEC $_{fish}$**
Scenario 1A	1.35E-1	3.03E-1
Scenario 1B*	2.7E-1	6.07E-1
Scenario 2A	**1.42**	**3.19**
Scenario 2B*	**2.83**	**6.37**

Scenario 3A	8.11E-4	1.82E-3
Scenario 3B*	1.62E-3	3.25E-3

*not relevant for this product

Conclusion:

Risks to fish-eating and worm-eating mammals and birds are acceptable in only 2 out of 3 scenarios when compared against a $PNEC_{biota}$ of 1.87 mg/kg food derived from avian data.
As unacceptable risks have been identified in 2 out of 3 scenarios and this would prevent authorisation of the product, the Applicantof the product assed by UK authorities has submitted a detailed appraisal of cleaning processes undertaken on board aircraft within the EU to demonstrate that the assessment provided in this PAR represents an extreme worst case (Tier 1) approach. This cleaning process is independent of the insecticide biocidal product used onboard. Therefore, for the sake of harmonization, it is considered that the same argumentation should be considered and agreed for the Aero-Sense Aircraft Insecticide ASD product. The full document as presented is the previous dossier can be found in Annex 3 of the PAR and key arguments will be discussed after the summary table of PEC/PNEC results.

Mixture toxicity

Screening step

Not required because the product contains only one active substance and no other substances of concern.

Conclusion:

No further consideration of non-active components needs to be undertaken in the ERA, as any risks posed by the product to environmental compartments will be driven by the presence of 1R-trans phenothrin (a.s.).

Aggregated exposure (combined for relevant emmission sources)

1R-trans phenothrin (and the related pyrethroid, d-phenothrin) have limited uses apart from their use in biocidal products to control insects and arthropods (PT 18). It has been noted that the compound has previously been used as treatment for headlice on humans (medicine) or ectoparasites on animals (veterinary medicine).

At present, this product represents the first authorisation granted for 1-R-trans phenothrin in the UK so it is extremely difficult to consider implications under Parts 1, 2 or 3 of the aggregated emissions process with regard to uses within 1 or more PTs. However, the ERA has concluded that, whilst significant emissions to ENV compartments could be possible from use of this product for disinsection of aircraft, cleaning processes operated within the EU aviation industry will actively prevent most losses.

Aggregated toxicity for the product and its a.s. has not been fully considered as the concept has not been agreed as a part of a harmonised approach to product assessment and no appropriate guidance is currently available.

Overall results of ENV risk assessment and possible mitigation factors

Summary table of PEC/PNEC results : part I				
	PEC/PNEC$_{STP}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{soil}$**
Scenario 1A	1.35E-3	**2.42**	**24.2**	**2.54**
Scenario 1B*	2.71E-3	**4.85**	**48.5**	**5.07**
Scenario 2A	1.43E-3	**25.45**	**254.5**	**26.1**
Scenario 2B*	2.84E-3	**50.9**	**509**	**53.2**
Scenario 3A	8.13E-7	1.45E-2	1.45E-1	1.52E-2
Scenario 3B*	1.45E-6	2.6E-2	2.6E-1	3.04E-2

*not relevant for this product

Summary table of PEC/PNEC results : part II			
	PEC/PNEC$_{GW}$	**PEC/PNEC$_{Predator_worms}$**	**PEC/PNEC$_{Predator_Fish}$**
Scenario 1A	3.66E-2	1.35E-1	3.03E-1
Scenario 1B*	7.31E-2	2.7E-1	6.07E-1
Scenario 2A	3.85E-1	**1.42**	**3.19**
Scenario 2B*	7.67E-1	**2.83**	**6.37**
Scenario 3A	2.20E-4	8.11E-4	1.82E-3
Scenario 3B*	4.39E-4	1.62E-3	3.25E-3

*not relevant for this product

Summary table of PEC/PNEC results : part III		
PEC/PNEC GW metabolite		
Scenario	Metabolite	PEC/PNEC
1A	HO-PHN	3,84E-04
	Pbalc	2,20E-03
	Pbacid	2,24E-04
2A	HO-PHN	4,04E-03
	Pbalc	2,20E-03
	Pbacid	2,35E-03
3A	HO-PHN	2,31E-06
	Pbalc	1,26E-06
	Pbacid	1,34E-06

The assessment of the emission to the environment of the Aero-Sense Aircraft Insecticide ASD product has been performed in the exact same way as the evaluation performed by UK CA for a similar product. Both product being very similar in composition and with identical use, the result are therefore closely related. In the current case, the concentration

of active in the product being inferior, the result of the emission and consequently the concentration in the respective environmentally relevant compartment are also slightly lower. Nevertheless, the same risk appears for the same compartment in the same order of magnitude. It is therefore logical that the same conclusion and argumentation should be made for the product Aero-Sense Aircraft Insecticide ASD.

BE eCA acknowledge that the majority the following argumentation and Proposal for RMM was originally provided by another applicant. Nevertheless, the applicant for Aero-Sense Aircraft Insecticide ASD did provided in his own evaluation, documentation, publication papers and justification which are fully in line with the argumentation provided to UK CA for the concurrent product. Therefore, BE eCA consider that the following conclusion, justification and proposal for RMM are also fully applicable to this product and support the position that authorisation of the Aero-Sense product, "Aero-Sense Aircraft Insecticide ASD", can be recommended.

Unacceptable risks to most environmental compartments have been identified in relation to SCENARIO 1 (aircraft are wet cleaned daily after flights return to EU airports) and SCENARIO 2 (deep cleaning of aircraft at routine maintenance) that would result in non-authorisation of this product. However, acceptable risks are always noted for losses discharged to STP following washing events by passengers (SCENARIO 3) from bathing and laundering of their contaminated clothing.
Therefore, careful consideration must be made on the potential for losses to be discharged at EU airports and whether the assumptions made in the emissions models for SCENARIO 1 & 2 are actually realistic to working practises in the aviation industry. It has been assumed as a simple "worst case" that cleaning events in both SCENARIOs (cleaning of aircraft after every flight plus deep cleaning at maintenance) would be undertaken using wet cleaning processes (i.e. re-usable cloths, mops and soapy water) so that all pick-up from all available surfaces will be discharged to drains as waste water.
This simplistic worst case approach has been undertaken for the purposes of a Tier 1 assessment, in an attempt to quantify potential risks to the environment in a situation where there are either no controls on emissions to the environment or where there is a failure to comply with the control measures. The UK CA (as eCA) accepts that given the highly specialised nature of the aviation industry, this is likely to represent an unrealistic worst case.
To support this assessment, the applicant, has submitted a supplementary document looking at aircraft cleaning measures within the aviation industry and whilst it focusses on operations at FR airports (ROISSY CDG and ORLY) plus cleaning procedures undertaken by a major FR airline, it is argued that these are applied throughout this industry sector in order to comply with waste management regulations and hygiene / sanitation recommendations for aviation (WHO). The Applicant has further stated that each airline must draw up their own programme for maintenance / cleaning based on existing regulations and recommendations but these are likely to be consistent as they will be operated by third parties (airports, cleaning companies, maintenance companies) so processes and conclusions from this supporting document can therefore be applied across the EU aviation industry.

Whilst the simplistic Tier 1 emissions models built and used by the eCA indicate significant risks to organisms in the aquatic, sediment and terrestrial compartments can be demonstrated if internal surfaces of the aircraft are wet cleaned and wastewater is discharged to drains, the Applicant considers that procedures operated by airlines and EU

airports actively prevents routine wet cleaning (either on a daily basis or when deep cleaning occurs during routine maintenance).
As supporting evidence to these conclusions, the applicant has indicated that in relation to cleaning of aircraft between flights :
The in-depth nature of the cleaning depends on the stopover time and the possible presence of passengers remaining on board for their onward journey. The aircraft is therefore on the tarmac waiting for its next flight: 30 minutes to 1 hour for short or medium haul, 2 to 8 hours for long haul. The parking stand may be in France, Europe or elsewhere in the world.
As a routine it involves vacuuming the carpet and cleaning some surfaces with a dry cloth. If soiling is notified by the crew, single use wipes impregnated with detergent or disinfectant, are used on the dirty surfaces. Used vacuum cleaner bags, cloths and wipes are added to the circuit of solid waste removed from the aircraft to be incinerated in most cases (this is the case for ROISSY CDG and ORLY). Cloths are not washed for re-use, unlike those used to clean the outside of the aircraft.
There is no routine cleaning of holds after flights, but only on request if there is proven pollution (e.g. leak from a barrel).
In relation to cleaning processes used at routine maintenance, the following measures are taken :

During aircraft servicing in the hangar (Check A, B or C), i.e. about every two to three months, in-depth cleaning lasting about 8 hours is scheduled. Then all surfaces are concerned. The resources used are vacuum cleaners, brushes and cloths. The products are detergents approved by the aircraft manufacturers so as not to damage the materials of the structure (also their fire-resistance properties), screens, etc. In APPENDIX 2 for example you will find the cleaning procedures (used by a major FR airline) *for a Boeing 777 cabin.*
If a textile seat cover appears dirty, it is taken off and sent to be dry-cleaned (perchlorethylene). Leather seats are treated with a sponge impregnated with a specific nourishing cleanser.
More and more these maintenance operations requiring many labour hours are performed abroad: China and South Africa for long haul, Morocco or Tunisia for short and medium haul (for European airlines of course).
In no circumstances is traditional washing "with plenty of water" authorised for safety reasons: corrosion, electrical short circuits, or proliferation of germs.
As indicated, a check list used by a major FR airline has also been provided, to outline cleaning procedures followed on their fleet of aircraft. It is clear that carpets will be vacuumed and all hard surfaces will be cleaned using specialised cleaning products applied by brush or cloth. Stained upholstery and curtains will be noted on the check list so that they can be replaced. Finally, whilst it is noted that for reasons of cost, increasing numbers of aircraft may be deep cleaned outside of EU, this cannot be used as a mitigating argument (but more an indication that proposed Tier 1 models may be over-estimating numbers being cleaned during routine maintenance).
When considering the cleaning procedures specified by a major airline and how these processes should also be adopted by other airlines, it is acceptable to assume that they represent working practises within the aviation industry.
On that basis, it is clear that wet cleaning of aircraft after each flight and at routine maintenance represent "extreme worst case" SCENARIOs and do not accurately reflect procedures taking place at EU airports. Therefore, it is acknowledged that emissions to

drains (and local STP) in SCENARIOs 1 & 2 will most likely be negligible and therefore risks to surface water (and other receiving compartments can be considered as zero.
However, this is ultimately dependant on the airline and contracted companies to continue using cleaning equipment and specialised detergents/solvents that do not require wet cleaning plus disposal of all waste material (such as surplus product, waste liquid, cleaning equipment) safely, presumably as solid waste to landfill site. 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 sets / MSDS or on leaflets distributed with each batch of product sold to airlines or sent direct to interested parties, with instruction that following application of 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."

Such information will be included in the PAR and also in the SPC under "Other information" (in Section 6).
Any such cleaning measures have no bearing on predicted emissions resulting from SCENARIO 3 as they arise from actual contamination of passengers, resulting from deposition of product and this cannot be avoided when product is applied , especially at "Blocks away" and "Top of descent".
Conclusion:
Worst case (Tier 1) assessment of emissions following daily and 2-monthly cleaning events on board aircraft generally give rise to unacceptable risks in many environmental compartments. However, the Applicant has adequately demonstrated that these represent an "extreme" worst case approach and do not take account of cleaning processes undertaken within the (EU) aviation industry. As a consequence, realistic emissions for aircraft (covered in both SCENARIOS 1 & 2) can be considered as negligible and ultimately their risks will be zero. However, cleaning processes within the aviation industry have no bearing on emissions in SCENARIO 3 but all risks have been shown to be acceptable.

Overall conclusion on the risk assessment for the environment of the product

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.
Risks posed by cleaning events undertaken by passengers (bathing and laundering of contaminated clothing once they return home) are all shown to be acceptable.
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 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 sets / MSDS or on leaflets distributed with each batch of product sold to airlines or sent direct to interested parties, with instruction that following application of 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."*

Such information will be included in the PAR and also in the SPC under "Risk mitigation measures" (in Section 4.1.2).

Any such cleaning measures have no bearing on predicted emissions resulting from SCENARIO 3 as they arise from actual contamination of passengers, resulting from deposition of product and this cannot be avoided when product is applied , especially at "Blocks away" and "Top of descent". However, all risks have been shown to be acceptable.

On that basis, authorisation of the Aero-Sense product, "Aero-Sense Aircraft Insecticide ASD", can be recommended.

2.2.9 Assessment of ED properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Aero-Sense Aircraft Insecticide ASD:

2.2.9.1 Assessment of the ED properties of the active substances in Aero-Sense Aircraft Insecticide ASD:

- According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As 1R-trans phenothrin is not part of the list of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.

- Therefore, BE eCA considers that there are no concerns regarding ED properties of 1R-trans phenothrin.

2.2.9.2 Assessment of the ED properties of non-active substances (co-formulants) in Aero-Sense Aircraft Insecticide ASD:

- After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants has been identified as having ED properties or are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

2.2.9.3 Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the data provided by the applicant, there is no indication of concern regarding the ED properties of the substances used in the biocidal product Aero-Sense Aircraft Insecticide ASD. This conclusion is valid for adverse effects on the endocrine system of humans and non-target organisms.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

2.2.10 Measures to protect man, animals and the environment

Please see section 2.1.4.3.

For more details, please see relevant sections of the risk assessment.

In addition, pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation) in susceptible persons. This local effect is normally not severe and disappears when direct exposure is terminated. However, an advice in the "First Aid instructions" section of the SPC is proposed:

- "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice."

2.2.11 Assessment of a combination of biocidal products

The product is not intended to be used in combination with other biocidal products.

2.2.12 Comparative assessment

Not relevant. 1R-trans phenothrin is not a candidate for substitution.

3 Annexes

3.1 List of studies for the biocidal product

Author	Year	Title	Testing laboratory	Report no.	Report date
[redacted]	2013	Laboratory assessment of an insecticide speciality intended to control insects as a space treatment in aircrafts	[redacted]	[redacted]	[redacted]
[redacted]	2013	Laboratory assessment of an insecticide speciality intended to control insects as a space treatment in aircrafts Complementary trial – “simulated-use trial with choice”	[redacted]	[redacted]	[redacted]
[redacted]	2018	Method validation for the determination of 1R-trans phenothrin (single isomer) content in one batch of 1R-trans phenothrin (sum of isomers) AE formulation.	[redacted]	[redacted]	[redacted]
[redacted]	2018	Physical and chemical properties of one batch of 1R-trans phenothrin AE formulation	[redacted]	[redacted]	[redacted]
[redacted]	2018	Physical and chemical properties of one batch of 1R-trans phenothrin AE formulation	[redacted]	[redacted]	[redacted]
[redacted]	2018	Physical and chemical properties of one batch of 1R-trans phenothrin AE formulation – 6 months of storage	[redacted]	[redacted]	[redacted]
[redacted]	2019	Physical and chemical properties of one batch of 1R-trans phenothrin AE formulation – 12 months of storage	[redacted]	[redacted]	[redacted]

Author	Year	Title	Testing laboratory	Report no.	Report date
[redacted]	2019	Physical and chemical properties of one batch of 1R-trans phenothrin AE formulation	[redacted]	[redacted]	[redacted]
[redacted]	2019	Physical and chemical properties of one batch of 1R-trans phenothrin AE formulation – 18 months of storage	[redacted]	[redacted]	[redacted]
[redacted]	2020	Physical and chemical properties of one batch of 1R-trans phenothrin AE formulation – 24 months of storage	[redacted]	[redacted]	[redacted]
[redacted]	2017	Laboratory bioassay to determine the efficacy of an insecticidal aerosol designed for use in aircraft	[redacted]	[redacted]	[redacted]
[redacted]	2017	FIELD TRIAL TO DETERMINE THE EFFICACY OF AN INSECTICIDAL AEROSOL DESIGNED FOR USE IN AIRCRAFT	[redacted]	[redacted]	[redacted]
[redacted]	2017	SIMULATED-USE STUDY TO DETERMINE THE EFFICACY OF AN INSECTICIDAL AEROSOL DESIGNED FOR USE IN AIRCRAFT	[redacted]	[redacted]	[redacted]
[redacted]	2018	Internal assessment report : Odour ASD	[redacted]	[redacted]	[redacted]
[redacted]	2019	Flammability classification of spray aerosols products (36ml)	[redacted]	[redacted]	[redacted]

Author	Year	Title	Testing laboratory	Report no.	Report date
[redacted]	2019	Flammability classification of spray aerosols products (89ml)	[redacted]	[redacted]	[redacted]
[redacted]	2019	Flammability classification of spray aerosols products (53ml)	[redacted]	[redacted]	[redacted]
[redacted]	2020	ANALYSE PAR DIFFRACTION DE LA LUMIERE DE LA GRANULOMETRIE DE SPRAYS AEROSOL ONE SHOT PHENOTHRIN	[redacted]	[redacted]	[redacted]
[redacted]	2020	Letter of Access to Data for Aero-Sense Aircraft Insecticide ASD dossier (Case number UA-APP: BC-DX037393-17) under the EU BPR	[redacted]	[redacted]	[redacted]

3.2 Output tables from exposure assessment tools

3.2.1 Human health risk assessment

[redacted]

3.2.2 Environmental risk assessment

Emissions to the environment

This section is completely taken out from the first product assessed by the UK authorities. It is provided here in order to allow CMS to have a better view on how the product was assessed. Since an agreement was already made on this scenario and on the rmm, this is not subjected to be commented again.

Indoor insecticide use (on board aircraft before and/or during return flight from "at risk" overseas airport to EU destination), with application of product by cabin crew (professional users) made specifically at potentially 3 different time points :

- "Pre-flight" or "Pre-arrival" boarding : product is applied when the aircraft is on the ground and remains empty (at least 20 – 40 min before passengers are allowed to board the aircraft at the overseas airport) ;
- "Blocks away" : application takes place when passengers have boarded and when doors are closed but before take-off ;
- "Top of descent" : at the point when the aircraft begins descent to land at the EU (return) airport.

Looking at all treatments made at the departure airport and return flight, then this non-volatile a.s. is likely to completely deposit onto available surfaces before / during the return flight as demonstrated within work conducted by the Fraunhofer Institute, German Federal Environmental Agency and German Federal Institute for Risk Assessment (in the published paper *"Aircraft disinsection : Exposure assessment and evaluation of a new pre-embarkation method*"; Berger-Preiß *et al*, 2005).
This paper investigated a new ''pre-embarkation'' method for aircraft disinsection using two different 2% d-phenothrin containing aerosols. Experiments were undertaken in Airbus 310 and Boeing 747–400 aircraft in the absence of passengers and crew. Concentrations of d-phenothrin were determined at different time periods after application of the aerosol spray. In the Boeing 747–400 (with the air conditioning system operating), concentrations of 800 – 1800 mg/m^3 were noted during spraying and up to 5 minutes after spraying had started. Within 5 – 20 min of completing the treatment, airborne levels had fallen by 90% (35 – 200 mg/m^3) at the same sampling points and after 20 – 40 min, only 1 mg/m^3 of d-phenothrin/m^3 was detectable. On cabin interior surfaces, the median values (for mainly horizontal areas) ranged from 100 - 1160 ng/cm^2 of d-phenothrin, supporting deposition as the reason for complete removal from air rather than filtration by the air conditioning system.
The application is undertaken by cabin crew, who typically walk through the aircraft cabin discharging aerosols at the prescribed dosage. All possible harbourages must be treated, including toilets, galleys, wardrobes and lockers. Holds and the flight deck are sprayed before departure – the flight deck before boarding by the flight crew.
Therefore, on the basis that rapid (and complete) removal of 1R-trans phenothrin from cabin air to cabin surfaces can be expected during the return flight to an EU airport, it isassumed that choice of application method ("Pre-flight", "Blocks away" or "Top of descent") for the disinsection product will have no impact on the behaviour of the a.s., as the return flight would offer sufficient time for product to always deposit to surfaces.
As such, only one emissions assessment need be used to determine risks posed to EU environment following various disinsection regimes and subsequent discharges from aircraft and passengers due to cleaning events.

Points to note in the ERA :
a) The applicant, for the 1R-trans phenothrin product evaluated by UK indicates that the "Pre-flight" and "Top-of-descent" spraying is considered to be a 2-part process. The "pre-flight" spray is carried out before the passengers board and is usually performed in conjunction with a pre-flight disinsection of the hold. The timing of this spray allows lockers to be open and causes minimum inconvenience to passengers. A subsequent in-flight spraying is required to be carried out at "top-of-descent", i.e. as the aircraft starts its descent to the destination.
On that basis, two different treatment programs on board aircraft are possible, namely :
- 1 application of product made at the "Blocks away" stage ;
- 2 applications of product consisting of 1 application made at "Pre-flight" stage plus 1 application made at "Top of descent" stage.
b) Furthermore, the applicant has based its product assessment on a 2.0% m/m concentration of 1R-trans phenothrin within the formulation but this relates to a content based on pure a.s. However, as the effects data provided in the CAR appear to be based upon technical grade material, it is more appropriate to compare PECs and PNECs

derived for technical material. As a consequence, the ERA will be revised to assess an actual product concentration of 2.25 % a.s. (technical).

However The Aero-Sense Product was evaluated based on a 2.0% concentration based on the information provided in the confidential annex and for the efficacy of the product. In addition, The applicant for the Aero-Sense product have informed Be eCA that the pre-flight application is not performed with the product containing 1R-trans phenothrin but with a product with a different formulation. Therefore the SCENARIO'S (n) B are not relevant for this Aero-Sense product.

c) In terms of likely size of long haul aircraft, the applicant has provided comprehensive information on typical passenger numbers and amount of the product evaluated by UK" required to treat each model of (European) Airbus aircraft operated by Air France. It is assumed that these are comparable to Boeing aircraft that may have been purchased by other airlines.

It is noted that evidence from the applicant indicates that typical long haul aircraft (>150 passengers) may require significantly different quantities of product, with an approximate range from 130 – 400 g of product per treatment. In order to determine losses from daily cleaning at a single airport, it is extremely difficult to determine an average value as that must take account of frequency of each type of aircraft arriving at the airport and not simply be based upon multiple arrivals of the largest A380-800 aircraft. There are only limited numbers in service and each airport requires special two-level air bridges to unload/load passengers. CDG Paris is reported to receive only 3 such aircraft per day at present.
Based upon an argument submitted by the applicant, then an **average quantity of product per aircraft would be 210 g per treatment** (as the majority of long haul flights are carried out using aircraft of the size of the Airbus A330-300 which has a mean volume of 600m³ and using the 35g/100m³ appli rate). Smaller aircraft can be used on such flights and these would balance out the potential impact on emissions driven by larger A380-800 aircraft. This justification appears sound and will be used in emissions assessment.

In terms of environmental emissions within the EU Member State where the aircraft has landed, there are 3 potential cleaning events that can occur following disinsection treatment of aircraft :

• **Scenario 1** : cleaning of limited areas within the aircraft (galley areas, toilets etc) after every flight by routine cleaning staff ;

• **Scenario 2** : deep cleaning of internal surfaces every 2 months when aircraft is taken out of service for routine maintenance ;
• **Scenario 3** : passengers who may have been sprayed with insecticide or picked up a.s. from treated surfaces then remove these residues by personal washing and laundering of contaminated clothes.

However, each scenario can result in the same emissions pathway :

Emissions from treated both hard surfaces (in galley areas and toilets) plus fabrics / soft furnishings as a result of wet cleaning, resulting in:

- Direct exposure to the sewage treatment plant (STP) compartment via drains with,
  i. indirect exposure to surface waters (including sediment) via STP effluent,

ii. indirect exposure to soil compartment (including groundwater) via 10 year of STP sludge application to land and

iii. indirect exposure to biota via surface waters (bioconcentration in fish leading to secondary poisoning of fish-eating birds).

Arguments have been provided in an additional supporting document by PSA to demonstrate how current working practises in the aviation industry will minimise predicted losses through extensive use of disposable cloths : these are removed as solid waste to landfill site or even controlled disposal of waste material (such as contaminated wastewater) to specialist contractor for hazardous waste disposal. However, the worst case (Tier 1) approach must still assume losses to STP in the first instance and then mitigating arguments will be applied.

This simplistic worst case approach has been undertaken for the purposes of a Tier 1 assessment, in an attempt to quantify potential risks to the environment in a situation where there are either no controls on emissions to the environment or where there is a failure to comply with the control measures. The UK CA (as eCA) accepts that given the highly specialised nature of the aviation industry, this is likely to represent an unrealistic worst case.

Summary of relevant physicochemical properties of 1R-trans phenothrin

Property	**Value**
MW	350.46 (g mol-1)
Solubility in water	2.0E-3 mg l-1 (21 ºC)
Partition co-efficient (log Kow)	6.8 (20 ºC)
Vapour pressure	2.37E-5 Pa (at 20 ºC)
Henry's law constant	4.2 Pa m3 mol-1
Koc (l kg-1)	125,892.5
Readily biodegradable	No

Metabolites (HO-PHN, PBalc and PBacid)

In the CAR for 1R-trans phenothrin, PEC values for each metabolite were estimated directly from the PEC values for the parent a.s., taking into account the molecular weight difference between parent and metabolites along with the maximum observed levels of the metabolites. In addition, it was stated that HO-PHN, PBalc and PBacid, are considered to be much less toxic than the parent material, on the basis of a QSAR assessment conducted with the ECOSAR model. Therefore the toxic data for the active substance was applied in the risk assessment for the metabolites as a worst case approach.

Degradation rates of metabolites in soil were not explicitly assessed, since they generally formed at low levels and only one transient detection of an individual metabolite in excess of 10% of AR was detected. Under aerobic conditions, 3-phenoxybenzyl alcohol (PBalc) was detected at a maximum level of 12.9% of AR and showed a decrease from this level of greater than 95% within 11 days, while 3-phenoxybenzoic acid (PBacid) was detected at a maximum level of 8.1% of AR and showed a decrease from this level of greater than 50% within 2 days.

Aquatic biodegradation of parent a.s. was investigated in a water-sediment system and all 3 main metabolites were detected, with 3-phenoxybenzoic acid (PBacid) exceeding 10% to reach a maximum level in the total system of 18.6% of AR. The other identified metabolites were PBalc and HO-PHN, which reached maximum respective whole-system levels of 9.7% and 7.9% of AR.

Therefore, as the metabolites all rely upon the endpoints of the parent a.s. but are formed at much lower concentrations and have lower MW values, then no further consideration need be undertaken. If acceptable risks of parent can be shown in relevant environmental compartments, then risks posed by metabolites must also be acceptable.

3.2.2.2 PEC calculations and RISK ASSESSMENT

EMISSIONS To waste water (Elocalwater) following disinsection treatment on board aircraft

An emissions assessment has been carried out on 1R-trans phenothrin using all available relevant information such as that found within the latest ECHA Guidance on BPR, Volume IV, Part B, the OECD ESD for insecticides, acaricides and products to control other arthropods for household and professional uses (PT 18, 5th draft, 2008) plus any relevant refinements accepted at Technical Meetings or Working Groups (including the Technical Agreements for Biocides (TAB)). In addition, information provided during an MS e:consultation on aircraft disinsection (Jan 2017) and by the applicant (based upon activities at CDG Paris airport and Air France) has also been included in order to model potential cleaning processes of aircraft and determine likely simultaneity for emissions from exposed passengers.
As a realistic worst case assumption (as outlined in published literature by Berger-Preiß et al, 2005), then 100% of applied a.s. could be expected to land onto surfaces or deposit onto surfaces including passengers. This expectation would indicate that emissions modelling based on all applied product remaining airborne and dispersing rapidly into the air compartment once aircraft doors are opened is not appropriate or sufficiently protective for ENV compartments.
THREE POSSIBLE SCENARIOS have been identified by the UK CA (and supported by other MS), where it could be envisaged that a.s. may be discharged / released into environmental compartments at local level :

1. Routine cleaning of aircraft after each flight : key areas of aircraft such as galley, toilets etc are quickly cleaned and wiped by contracted cleaning staff at airport.

Due to rapid turnaround of the plane, cleaning is limited to those areas that directly affect passenger wellbeing and health. It is stated by applicants that many areas are not wet cleaned routinely and may only be subject to brief dry cleaning methods (litter removal, hoovering) that could still remove significant quantity of a.s. as dry waste to landfill site.
In the absence of EU agreed guidance or emissions models, the UK CA has considered potential losses and how discharges for limited cleaning can be quantified. At a major airport, there will be multiple flights from "at risk" countries where disinsection will be required during flight. If cleaning cloths, equipment etc are routinely washed out by cleaning staff for re-use, then significant discharges each day are likely to reach local STP (and subsequently enter surface waters plus agricultural soil in sewage sludge).
To proceed to quantitative ERA, then some quantification of wet cleaned area per aircraft must be made : due to operational time constraints, then only 5 – 10% of total area where a.s. could deposit can be assumed to be subject to wet cleaning. With a cleaning efficiency of 50% for surfaces, then 5% of total applied a.s. could be discharged to drains. Based upon evidence supplied by the applicant regarding activities at CDG Paris, the eCA has accepted that a typical long haul flight may use A330-300 aircraft, giving rise to application of 210 g of product per treatment and a large number could be subject to limited wet cleaning each day at hub airports following flights from "at risk" overseas destinations.

Defaults for modelling :

Maximum fraction of surface area available for wet cleaning – 10%
Cleaning efficiency in line with ESD – 50% from surfaces (FCE of 0.5)
Concentration of a.s. in product – 2.25 % of technical grade a.s. (In UK product)

-> Concentration of a.s. in Aero-Sense product : 2.0%

Maximum product application per long haul aircraft - average of 210 g per treatment

Total a.s. applied per aircraft is 210 (g) x 0.0200 x 1.0E-3 = 4.2E-3 kg

However, it must be noted that this represents only one treatment on board aircraft (ie. "Blocks away") yet the applicant for the product evaluated by UK has indicated that treatment at "Pre-flight" + "Top of descent" can be routinely undertaken. This is not the case for the Aero-Sense product Therefore :

One treatment delivers 4.2E-3 kg of a.s. per aircraft ;
Two treatments deliver 8.2E-3 kg of a.s. per aircraft.*

*not relevant for this product

With 10% of surfaces available for cleaning and an FCE of 0.5, total amount that could be discharged to drains from wet cleaning would be :

One treatment: 4.725E-3 x 0.5 x 0.1 = 2.1E-4 kg of a.s. ;
Two treatments: 9.450E-3 x 0.5 x 0.1 = 4.2E-4 kg of a.s*.

*not relevant for this product

Although difficult to quantify, the UK CA has assumed that up to 100 flights may arrive each day at hub airports from such "at risk" overseas destinations based upon publicly available data. Based upon information available on "busiest airports by aircraft movements" in 2015, it is noted that CDG Paris, London Heathrow, Frankfurt and Schiphol Amsterdam are reported to have between 465 – 475k movements per year. All other international hubs in EU Member States have movements of <380,000 per year. The vast majority of these movements will presumably be internal flights or international flights from countries where aircraft disinsection is not required so it was considered that 365 x 100 = 36,500 annual movements per airport might reflect the proportion of at risk flights (between 5 – 10% of total) across each MS as a worst case.
A reasoned argument by the applicant concludes that a similar number of treated aircraft could arrive at CDG Paris on a daily basis. **Elocalwater values discharged to local STP** via drains could reach Although difficult to quantify, the UK CA has assumed that up to 100 flights may arrive each day at hub airports from such "at risk" overseas destinations based upon publicly available data. Based upon information available on "busiest airports by aircraft movements" in 2015, it is noted that CDG Paris, London Heathrow, Frankfurt and Schiphol Amsterdam are reported to have between 465 – 475k movements per year. All other international hubs in EU Member States have movements of <380,000 per year. The vast majority of these movements will presumably be internal flights or international flights from countries where aircraft disinsection is not required so it was considered that 365 x 100 = 36,500 annual movements per airport might reflect the proportion of at risk flights (between 5 – 10% of total) across each MS as a worst case.
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drains could reach Although difficult to quantify, the UK CA has assumed that up to 100 flights may arrive each day at hub airports from such "at risk" overseas destinations based upon publicly available data. Based upon information available on "busiest airports by aircraft movements" in 2015, it is noted that CDG Paris, London Heathrow, Frankfurt and Schiphol Amsterdam are reported to have between 465 – 475k movements per year. All other international hubs in EU Member States have movements of <380,000 per year. The vast majority of these movements will presumably be internal flights or international flights from countries where aircraft disinsection is not required so it was considered that 365 x 100 = 36,500 annual movements per airport might reflect the proportion of at risk flights (between 5 – 10% of total) across each MS as a worst case.
A reasoned argument by the applicant concludes that a similar number of treated aircraft could arrive at CDG Paris on a daily basis. **$Elocal_{water}$ values discharged to local STP** via drains could reach

One treatment: 2.363E-4 x 100 = 2.1E-2 kg/d of a.s. ;
Two treatments: 4.725E-4 x 100 = 4.2E-2 kg/d of a.s*.

*not relevant for this product

2. Deep cleaning of aircraft interior during engineering maintenance of aircraft (typically once every 2 months whilst aircraft is taken out of service).

All aircraft are subject to planned maintenance after a fixed number of "air hours" when all systems and major parts are inspected whilst the aircraft is out of service. It is understood that this also allows the aircraft to be subject to prolonged cleaning and this would reach locations in the cabin etc that are hardly touched by daily cleaning procedures. In many cases, residues built up from multiple treatments would be cleaned for the first time. It is stated by applicants that many areas would still not be wet cleaned routinely as they contain sensitive avionics so water as cleaning solvent would not be permitted. Furthermore, dry cleaning methods (litter removal, hoovering) could still remove significant quantity of a.s. as dry waste to landfill site.
Whilst some MS concluded (Jan 2017) that there may be "delicate" areas around avionics, wiring etc, these areas only make up a small part of the internal area of an aircraft that would require deep cleaning. Most surfaces such as seating, floor, overhead lockers etc could be cleaned more quickly and cost effectively by use of typical wet cleaning methods (cloth rinsed out in cleaning solution and disposal to drain). This approach will be used as a Tier 1 assessment.

To proceed to quantitative ERA, then some quantification of wet cleaned area per aircraft during deep clean processes must be made. Although it is possible that up to 10% of applied dose has been removed from basic cleaning after each flight (Scenario1), it is difficult to rely upon this as a reduction to overall contamination if aircraft require a fast turnaround so the fraction available for cleaning should remain as 100% (worst case). However, MS accept that a significant proportion of airborne a.s. could deposit onto passengers in the cabin and this could make up approximately 30% of the area available for a.s. to land on. This is discussed in SCENARIO 3 but assumes that there are 300 passengers on board, which fits with the evidence supplied by the applicant that a typical (average) long haul aircraft would be the Airbus A330-300 : the second number denotes maximum seating.
Defaults for modelling :
Maximum surface area available for wet cleaning – (100 – 30) = 70%
Cleaning efficiency in line with ESD – 50% from surfaces (FCE of 0.5)

Concentration of a.s. in product – 2.25% technical a.s. (In UK product)
Maximum product application per long haul aircraft - 210 g (average)

-> Concentration of a.s. in Aero-Sense product 2.0%

Disinsection treatments between deep clean events - 30 "at risk" flights (based upon the potential of routine maintenance every 60 d (applicant information) and 30 return journeys but treatment only on return journey

Total a.s. applied per aircraft is :

One treatment delivers 4.2E-3 kg of a.s. per aircraft ;
Two treatments deliver 8.4E-3 kg of a.s. per aircraft*.

*not relevant for this product

With 30 repeated treatments, 70% of surfaces available for deep cleaning and an FCE of 0.5, total amount of a.s. that could be discharged to drains from wet cleaning at the routine service event of one aircraft would be :

One treatment : 4.2E-3 x 0.7 x 0.5 x 30 = 4.41E-2 kg of a.s. ;
Two treatments :8.4E-3 x 0.7 x 0.5 x 30 = 8.82E-2 kg of a.s*.

*not relevant for this product

Please note that this conservatively assumes no other loss mechanisms occur over this 60-d period on board aircraft.
Maintenance hangars would typically deal with several aircraft at the same time so there is potential for discharges to STP on the same day from more than one aircraft so the UK CA has assumed a default of 5. Although some EU airports may maintain more than 5 aircraft at the same time, there is no guarantee that every one of these aircraft will have been treated repeatedly (or even once) with insecticide – this site is used for routine maintenance and cleaning of all aircraft in service. If it is accepted that no more than 10% of aircraft movements relate to flights from "at risk" countries, then the default value of 5 will represent a worst case value and need not be revised further.

Elocal$_{water}$ discharged to local STP via drains could reach :

One treatment: 4.41E-2 x 5 = 0.21 kg/d of a.s. ;
Two treatments: 8.82E-2 x 5 = 0.42 kg/d of a.s*.

*not relevant for this product

3. Potential contamination of passengers and their clothing as a result of aerosol landing onto them as product deposits from air.

Although arguments for non-wet cleaning of aircraft might result in negligible emissions to local STP, they cannot be guaranteed in a Tier 1 approach (see SCENARIOS 1 and 2) and certainly do not apply to likely contamination of passengers or their clothing. Product may deposit on seats before passengers embark or may deposit onto passenger skin / clothing if treatment occurs when the aircraft is occupied. Any residue carried home by passengers can then be expected to be washed off during bathing activities or laundering of dirty clothing (in line with current guidance).

Again, applying some consideration of the number of contaminated passengers arriving at a hub airport per day from overseas, there could be 100 flights per airport x 300 travellers per long haul flight, representing 30,000 passengers contaminated with product. However, such an airport may have a large passenger catchment as it may act as hub airport for many regions within the country – with a population of 60 million people, the UK probably has no more than 5 or 6 airports that accommodate flights from "at risk" countries (so an "average" catchment of 10 million people per hub airport). Assuming 10,000 people per STP, this might represent approximately 1000 STP per hub airport, where passenger wastewater could be discharged. The average number of "contaminated" passengers per STP could be 30000 / 1000 = 30 and 100% of a.s. landing on / transferring to skin and clothing could be discharged to local STP on any single day.

Other MS have considered an alternative approach based upon likely area occupied by passengers and agree that 30 passengers discharging a.s. per day to local STP appears appropriate.

However, it is difficult to determine is the amount of product landing on each passenger or their clothing so a simplistic approach would be required. When considering the spaces in the cabin where the product could reach, the space occupied by passengers may make up only 30% of total area where product could deposit as a reasonable worst case estimate.

Defaults for modelling :
Concentration of a.s. in product – 2.25% technical a.s.(In K product)
Maximum product application per long haul aircraft - 210 g (average)

-> Concentration in Aero-Sense product – 2.0%

Total a.s. applied per aircraft is :
One treatment delivers 4.2E-3 kg of a.s. per aircraft ;
Two treatments deliver 8.4E-3 kg of a.s. per aircraft*.

*not relevant for this product

Fraction of a.s. falling onto area occupied by passengers - 0.3 (i.e. 30 % applied)
Number of passengers per aircraft - 300
Amount deposited onto or transferred to each passenger (skin and clothing) could therefore be :

One treatment: 4.2E-3 x 0.3 x 1 / 300 = 4.2E-6 kg of a.s. ;
Two treatments: 8.4E-3 x 0.3 x 1 / 300 = 8.4E-6 kg of a.s*.

*not relevant for this product

Once the passengers have returned home, it is assumed that the individuals are shower/bathe and launder dirty clothing on the same day, with waste water discharged to local STP (as a "realistic" worst case approach).
Number of passengers washing / laundering at same STP on same day – 30

Elocal$_{water}$ discharged to local STP via drains could reach :

One treatment: 4.2E-6 x 30 = 1.26E-4 kg/d of a.s. ;
Two treatments: 8.4E-6 x 30 = 2.52E-4 kg/d of a.s*.

*not relevant for this product

PEC in aquatic compartment (STP, surface water, sediment)

PECSTP

The PECSTP presented below represents the dissolved portion of 1-R-trans phenothrin after removal to sludge at STP. Using the values derived earlier for Elocalwater in each of the 3 relevant SCENARIOS plus accompanying assumptions, the calculations are shown below;

Calculation of Clocalinf

Value	
Daily cleaning of aircraft, giving rise to an $Elocal_{water}$ (kg/d) of SCENARIO 1A : one treatment during return flight SCENARIO 1B : two treatments during return flight	 2.1E-2 4.2E-2
Regular deep cleaning of aircraft, giving an $Elocal_{water}$ (kg/d) of SCENARIO 2A : one treatment during return flight SCENARIO 2B : two treatments during return flight	 0.221 0.442
Laundering / washing by passengers, giving an $Elocal_{water}$ (kg/d) of SCENARIO 3A : one treatment during return flight SCENARIO 3B : two treatments during return flight	 1.26E-4 2.52E-4
Effluent discharge rate of local STP	2.0E+6
Scenario 1A : Clocal inf (= $E_{local\ water}$ x 10_6) / EFFLUENT stp) in mg/l Scenario 1B : Clocal inf (= $E_{local\ water}$ x 10_6) / EFFLUENT stp) in mg/l	1.05E-2 2.1E-2
Scenario 2A : Clocal inf (= $E_{local\ water}$ x 10_6) / EFFLUENT stp) in mg/l Scenario 2B : Clocal inf (= $E_{local\ water}$ x 10_6) / EFFLUENT stp) in mg/l	0.11 0.21
Scenario 3A : Clocal inf (= $E_{local\ water}$ x 10_6) / EFFLUENT stp) in mg/l Scenario 3B : Clocal inf (= $E_{local\ water}$ x 10_6) / EFFLUENT stp) in mg/l	6.30E-5 1.13E-4

When added to water at normal environmental conditions (12 °C), based upon results from laboratory studies, 1R-trans phenothrin is not expected to hydrolyse and will reach the local STP unchanged. As outlined in the CAR, this a.s. is not classified as being readily biodegradable. Computer modelling using SimpleTreat v3.1 indicates STP behaviour as :

Fraction of emissions in STP according to SimpleTreat v3.1, assuming zero degradation from OECD 301 results

Distribution in STP	**Unit**	**Value**
Fraction of emission directed to air by STP	[%]	0.271
Fraction of emission directed to water by STP $Fstp_{water}$	[%]	12.9
Fraction of emission directed to sludge by STP	[%]	86.8
Fraction of emission degraded	[%]	0

SCENARIO (n) B not relevant for this product

Typically, the PEC_{STP} can be considered as being either the $Clocal_{inf}$ or $Clocal_{eff}$ value, representing either the concentration of compound in untreated wastewater or the concentration of compound in STP effluent. In situations where release of a chemical into drains is intermittent, the use of $Clocal_{in}f$ is more appropriate for PEC_{STP} but the alternative is true in the case of daily release ($Clocal_{eff}$ should be used to represent

PEC_{STP}). However, releases are likely to be continuous if discharges to drains can occur from cleaning events so the PEC should be based upon the value for $Clocal_{eff}$.

$Clocal_{eff} = Clocal_{inf} * Fstp_{water}$

Where $Fstp_{water}$ = fraction emission directed to water by STP (0.129 according to SimpleTreat v3.1)

Emission Scenario	**$Clocal_{inf}$ (mg/l)**	**$Clocal_{eff}$ / PEC_{stp} (mg/l)**
SCENARIO 1A	1.05E-2	**1.35E-3**
SCENARIO 1B	2.1E-2	**2.71E-3**
SCENARIO 2A	0.11	**1.43E-2**
SCENARIO 2B	0.21	**2.84E-2**
SCENARIO 3A	6.30E-5	**8.13E-6**
SCENARIO 3B	1.13E-4	**1.45E-5**

SCENARIO (n) B not relevant for this product

A PNECstp has been set in the CAR for 1R-trans phenothrin at 10.0 mg/l. However, when other a.s. have been shown to be poorly or sparingly soluble in water (such as in the case of another pyrethroid, permethrin), then the PNEC for this compartment has been set as thelimit of solubility (2.0E-3 mg/l in the case of 1R-trans phenothrin).

Emission Scenario	**PEC_{stp} (mg/l)**	**$PNEC_{stp}$ (mg/l)**	**PEC / PNEC**
SCENARIO 1A	1.35E-3	10.0	1.35E-4
SCENARIO 1B	2.71E-3		2.71E-4
SCENARIO 2A	1.43E-2	10.0	1.43E-3
SCENARIO 2B	2.84E-2		2.84E-3
SCENARIO 3A	8.13E-6	10.0	8.13E-7
SCENARIO 3B	1.45E-5		1.45E-6

SCENARIO (n) B not relevant for this product

Risks posed by 1R-trans phenothrin to STP micro-organisms are acceptable in all scenarios when compared against a PNECstp of 10 mg/l.

$PEC_{surface\ waters}$

The proposed use pattern for disinsection products on board aircraft does not allow for direct exposure to surface waters, only the potential for indirect exposure via discharges to the local STP (following cleaning operations). The local concentration arising from the indirect emission to a watercourse via the STP during the proposed use of this product was calculated to take into account dilution and removal to suspended sediments (ECHA guidance on ERA, equation 45) as follows:

$$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} * SUSP_{water} * 10^{-6}) * DILUTION}$$

Where:

$Clocal_{water}$ = concentration in surface water during episode (mg/l) so = $PEC_{surface\ water}$
$Clocal_{eff}$ = concentration in the STP effluent (and equates to PEC_{STP} value)
Kp_{susp} = solids-water partitioning coefficient of suspended matter (12589.25 L/kg; based upon FOC_{sus} x K_{oc} = 0.1 x 125,892.5 L/kg for 1R-trans phenothrin)
$SUSP_{water}$ = concentration of suspended matter in the river (default: 15 mg/l)
DILUTION = dilution factor (default: 10)

Emission Scenario	**$Clocal_{eff}$ (mg/l)**	**$Clocal_{water}$ / PEC_{water} (mg/l)**
SCENARIO 1A	1.35E-3	**1.14E-4**
SCENARIO 1B	2.71E-3	**2.28E-4**
SCENARIO 2A	1.43E-2	**1.20E-3**
SCENARIO 2B	2.84E-2	**2.39E-3**
SCENARIO 3A	8.13E-6	**6.84E-7**
SCENARIO 3B	1.45E-5	**1.22E-6**

Emission Scenario	**PEC_{water} (mg/l)**	**$PNEC_{water}$ (mg/l)**	**PEC / PNEC**
SCENARIO 1A	1.14E-4	4.70E-5	**2.42**
SCENARIO 1B	2.28E-4		**4.84**
SCENARIO 2A	1.20E-3	4.70E-5	**25.5**
SCENARIO 2B	2.39E-3		**50.9**
SCENARIO 3A	6.84E-7	4.70E-5	0.014
SCENARIO 3B	1.22E-6		0.025

SCENARIO (n) B not relevant for this product

Risks posed by 1R-trans phenothrin to aquatic organisms are unacceptable in SCENARIOS 1 & 2 as a result of potential cleaning events on board aircraft after they have landed at EU airports when compared against a PNECwater of 4.7E-5 mg/l. However, risks posed by passengers contaminated with a.s. are considered acceptable.

<u>$PEC_{sediment}$</u>

A mean K_{OC} value of 125,892.5 L/kg would suggest a high degree of affinity for sediment. As 1R-trans phenothrin has not been shown to be readily biodegradable, it is expected to pass through the STP and reach surface waters. The concentration of a.s. in bulk sediment (represented in wet weight) can be derived from the corresponding water body concentration, assuming thermodynamic partitioning equilibrium as outlined in the (ECHA guidance on ERA, Vol IV, Part B, equation 50);

$$PEClocal_{ed} = \frac{Ksusp-water}{RHOsusp} * \mathrm{PEClocal}_{water} * 1000$$

Where:
RHO_{susp} = bulk density of wet suspended matter (1150 kg m-3 as default value)
$PEClocal_{water}$ = local concentration in surface water (taken as Clocalwater or PECsurface water)
$K_{susp\text{-}water}$ = 3148.21 $m^3\ m^{-3}$ (calculated from ECHA guidance on ERA, equation 24)

Scenario	PEC_{water} (mg/l)	$PEClocal_{sed}$ (mg/kg wwt)
SCENARIO 1A	1.14E-4	**0.312**
SCENARIO 1B	2.28E-4	**0.624**
SCENARIO 2A	1.20E-3	**3.28**
SCENARIO 2B	2.39E-3	**6.55**
SCENARIO 3A	6.84E-7	**1.87E-3**
SCENARIO 3B	1.22E-6	**3.34E-3**

Scenario	PECsed (mg/kg wwt)	PNECsed (mg/kg wwt)	PEC/PNEC
SCENARIO 1A	0,312	0,0129	2,41
SCENARIO 1B	0,324	0,0129	4,83
SCENARIO 2A	3,28	0,0129	25,44
SCENARIO 2B	6,55	0,0129	50,77
SCENARIO 3A	1,87E-03	0,0129	0,014
SCENARIO 3B	3,34E-03	0,0129	0,025

SCENARIO (n) B not relevant for this product

* As a result of PNECsed being derived by EPM and a.s. having a log Kow >5 (reported to be log 6.8), then an additional safety factor of 10 must be applied to overall risk, in line with ERA Guidance outlined in Vol IV, Part B (at time of evaluation) and Vol IV, Parts B+C (Oct 2017).

Risks posed by 1R-trans phenothrin to sediment dwelling organisms are unacceptable in SCENARIOS 1 & 2 as a result of potential cleaning events on board aircraft after they have landed at EU airports when compared against a PNECsediment of 0.0129 mg/kg wwt. However, risks posed by passengers contaminated with a.s. are considered acceptable. [This is identical to the risks posed to aquatic organisms and therefore indicates that both PNECsed and PECsed must have been predicted via EPM].

<u>PEC in air</u>

Losses from on board treatment are expected to be minimal as the product is applied when cabin doors are closed, so product remains within the aircraft. A published report (Berger-Preiß et al, 2005) on aircraft disinsection indicated that 1R-trans phenothrin can be expected to deposit rapidly to surfaces (or potentially even deposit onto passengers if present during the treatment). Within 20 – 40 min, airborne levels of a.s. from commercially available products were shown to be negligible, thus indicating complete deposition. As such, losses to the air compartment following application can be considered negligible and further assessment would not be required.
Negligible losses to air are expected during daily and deep cleaning of aircraft, so the only potential route to air would be potential discharges from local STP. Due to the low vapour pressure of the compound (2.37E-5 Pa at 20 ºC), SimpleTreat v3.1 modelling of the behaviour of 1R-trans phenothrin at the local STP predicts that the fraction directed to air (Fstpair) would represent 0.271 % of the quantity of compound arriving at the treatment plant in wastewater.
Estimated values for Estpair would likely be very low such that further quantitative assessment of compartmental risk would not be required (in line with conclusions reached in the CAR). By way of confirmation, modelling within ECHA guidance on ERA (Vol IV, Part B) allows the indirect emission from the STP to air to be quantified using the equation as follows :

$Estp_{air}$ = $Fstp_{air}$ x $Elocal_{water}$

Where:
$Estp_{air}$ = local emission to air from STP during emission episode (in kg/d)
$Elocal_{water}$ = local emission to wastewater during episode (in kg/d)
$Fstp_{air}$ = fraction emission directed to air by STP (2.71E-3 according to SimpleTreat v3.1)

Emission Scenario	**$Elocal_{water}$ (kg/d)**	**$Estp_{air}$ (kg/d)**
SCENARIO 1A	2.1E-2	5.69E-5
SCENARIO 1B	4.2E-2	1.14E-4
SCENARIO 2A	0.211	5.99E-4
SCENARIO 2B	0.422	1.20E-3
SCENARIO 3A	1.26E-4	2.783E-7
SCENARIO 3B	2.25E-4	6.10E-7

SCENARIO (n) B not relevant for this product

The concentration in air (PEClocalair) is then calculated as an average concentration at a distance of 100 metres for a point source – this distance is chosen to represent the typical distance between the emission source (local STP in this case) and the border of that "industrial site". With no other losses to air predicted from application of the disinsection product, then equations within current ERA guidance predict that :-
$Clocal_{air}$ = $Estp_{air}$ x $Cstd_{air}$

Where:
$Estp_{air}$ = local indirect emission to air from STP during episode (in kg/d)
$Clocal_{air}$ = local concentration in air during emission episode (in mg/m3)
$Cstd_{air}$ = concentration in air at source strength of 1 kg d-1 (default of 2.78E-4 mg/m3)

Emission Scenario	**$Estp_{air}$ (kg/d)**	**$Clocal_{air}$ (mg/m3)**
SCENARIO 1A	5.69E-5	1.58E-8
SCENARIO 1B	1.14E-4	3.16E-8
SCENARIO 2A	5.99E-4	1.66E-7
SCENARIO 2B	1.20E-3	3.32E-7
SCENARIO 3A	2.78E-7	9.49E-11
SCENARIO 3B	6.10E-7	1.70E-10

SCENARIO (n) B not relevant for this product

As the predicted values for local concentration in air from losses at STP are so low (and probably undetectable), then no further consideration would be necessary. Furthermore, it should be noted that if 1R-trans phenothrin were to reach the air compartment, it would be expected to degrade quickly as the calculated half-life based upon photo-transformation is predicted to be < 4 hours. The risk of long range transport is therefore negligible.

<u>PEC in soil (including groundwater)</u>

PEC_{soil}

Direct exposure of the soil compartment as a result of the proposed usage pattern, namely indoor application on board aircraft returning to EU airports from "at risk" countries would not be expected. The only exposure routes to soil would be indirect via wet cleaning of

aircraft surfaces (limited daily cleaning of galley areas and toilets or 2-monthly "deep clean"
events) plus washing of passengers and laundering of their clothing, with all subsequent emissions discharged to the local STP. Soil would then only become exposed to 1R-trans phenothrin
if contaminated sludge from the STP is then applied to fields as agricultural fertiliser.
A mean degradation DT50 at 12 °C was determined in the CAR as being 27.2 d.
The concentration of active substance in dry sewage sludge can be calculated using equations (36 and 37) taken from the ECHA guidance on ERA plus default parameters presented in the same guidance document;

$$C_{sludge} = \frac{Fstp_{sludge} \times Elocal_{water} \times 10^6}{SLUDGERATE}$$

where:
SLUDGERATE = 0.66 x SUSPCONCinf x EFFLUENTstp + SURPLUSsludge x CAPACITYstp
and: EFFLUENTstp = CAPACITYstp x WASTEWinhab

Application of sewage sludge parameters for a.s. reaching STP

Parameter	**Value**	
SUSPCONCinf	concentration of suspended matter (kg/m3) in STP influent	0.45
EFFLUENTstp	effluent discharge rate of STP (m3/d)	2000
$SURPLUS_{sludge}$	surplus sludge per inhabitant equivalent (kg/d eq-1)	0.011
CAPACITYstp	capacity of STP (eq)	1E+4
$WASTEW_{inhab}$	Sewage flow per inhabitant (l/d eq-1)	200
SLUDGERATE	rate of sewage sludge production (kg/d)	710*
$Elocal_{water}$	local emission rate to water during treatment episode (kg/d)	
$Fstp_{sludge}$	Fraction of emission directed to sludge by STP (SimpleTreat)	0.868
Csludge	concentration in dry sewage sludge (mg/kg dwt)	

*For consistency, a value of 710 kg/d (according to Simple treat v3.1) has been used but modelling with SimpleTreat v4 will introduce a value of 790 kg/d so emissions in sludge expressed in mg/kg would decrease by about 10%. This approach is not in agreement with the TAB ENV 9, but represent a worst case, has no impact on the outcome and on the conclusion and /or on risk mitigation measure is therefore made on purpose to allow direct comparison with the UK product.

Emission Scenario	**$Elocal_{water}$ (kg/d)**	**C_{sludge} (mg/kg dwt)**
SCENARIO 1A	2.1E-2	25.67
SCENARIO 1B	4.25E-2	51.35
SCENARIO 2A	0.211	270.2
SCENARIO 2B	0.422	539.1
SCENARIO 3A	1.26E-4	0.154
SCENARIO 3B	2.52E-4	0.308

SCENARIO (n) B not relevant for this product

Therefore, small releases of active substance to agricultural land can be predicted following the discharge of wastewater via drains to a local STP after domestic and commercial wet

cleaning. Where sewage sludge is applied to agricultural soil, an application rate of 5000 kg.ha-1 per year has been assumed (based on typical application rates across the EU) whilst the rate for grassland is considered lower at 1000 kg.ha-1.yr-1 - these applications are considered to occur once per year. If removal via volatilisation and leaching from topsoil are ignored as being very minor processes (based upon low water solubility and vapour pressure of the a.s.), then losses would solely be as a result of soil degradation, then the pseudo-first order rate constant k (represented by Kbiosoil) can be derived from the following equation:

$$Kbio_{soil} = \frac{\ln 2}{DT_{50}bio_{soil}}$$

Where DT50biosoil is the half-life for (bio) degradation in aerobic soil (corrected to 12 °C) Using a mean degradation DT50 value of 27.2 days (presented in the CAR for 12 °C) the equivalent rate constant k would be 2.548E-2 d-1: this would crudely represent the removal
rate of 1R-trans phenothrin from top soil. At the end of each year, a fraction of the initial concentration (Facc) may potentially remain in the top soil layer and this can be determined
by use of the equation stating:

$$Facc = e^{-365k}$$

Where Facc = fraction accumulation in 1 year
k = first order rate constant for removal from top soil via degradation (2.548E-2 d-1)
The fraction of initial concentration (Facc) remaining in the top soil layer after one year has
therefore been determined as 9.13E-5 (<0.01 % remaining). In line with guidance presented
in the ECHA guidance on ERA (equation 60), the concentration of 1R-trans phenothrin in soil (represented as Csludge soil 1 (0)) after the first year of manure application can be given
as;

$$Csludge_{soil\,1}\,(0) = \frac{C_{sludge} \cdot APPL_{sludge}}{DEPTH_{soil} \cdot RHO_{soil}}$$

Where:
C_{sludge} is the concentration in sludge (in mg kg-1 dwt)
$APPL_{sludge}$ is the sludge application rate (0.1 kg m2 yr-1 for grass for cattle or 0.5 kg m2 yr-1
for terrestrial ecosystems and crops for human consumption (arable))
$DEPTH_{soil}$ is the mixing depth of soil (0.1 for grass for cattle or 0.2 m for terrestrial ecosystems and crops for human consumption (arable))
RHO_{soil} is the bulk density (wet) of soil (1700 kg m-3; default)
Csludge $_{soil\ 1}$ (0) is the concentration in soil due to sludge application in first year at t = 0
The PEC for local soil (referred to as Clocalsoil) has been calculated using the following equation taken from the ECHA guidance on ERA (equation 55);

$$Clocal_{soil} = \frac{D_{air}}{k} + \frac{1}{k\,T}\left[\, C_{soil}(0) - \frac{D_{air}}{k} \,\right] \cdot \left[1 - e^{-kT}\right]$$

Where
D_{air} is the aerial deposition flux per kg of soil (taken to be zero mg.kg-1.d-1 as deposition from transport of 1R-trans phenothrin is air is extremely unlikely)
T is the averaging time (180 d for arable land and grassland as a representative growing period for crops and 30 days for terrestrial ecosystems)
k is the first order rate constant for removal from top soil (calculated for aerobic degradation as 2.548E-2 d-1)
C_{soil} (0) is the initial concentration in soil after sludge application (calculated in mg.kg-1)
$Clocal_{soil}$ is the average concentration in soil over T days

Scenario	**PEClocal$_{soil}$ (mg/kg wwt)**	**PEC$_{arable}$** (mg/kg wwt)	**PEC$_{grass}$** (mg/kg wwt)
SCENARIO 1A	**2.64E-2**	8.13E-3	3.52E-3
SCENARIO 1B	**5.27E-2**	1.62E-2	6.50E-3
SCENARIO 2A	**0.278**	8.56E-2	3.42E-2
SCENARIO 2B	**0.554**	1.71E-1	6.82E-2
SCENARIO 3A	**1.58E-4**	4.48E-5	1.95E-5
SCENARIO 3B	**3.16E-4**	9.74E-5	3.90E-5

Scenario	**PEC$_{soil}$ (mg/kg wwt)**	**PNEC$_{soil}$ (mg/kg wwt)**	**PEC / PNEC**
SCENARIO 1A	2.64E-2	1.04E-2	**2.54**
SCENARIO 1B	5.27E-2		**5.07**
SCENARIO 2A	0.278	1.04E-2	**26.7**
SCENARIO 2B	0.554		**53.2**
SCENARIO 3A	1.58E-4	1.04E-2	0.0152
SCENARIO 3B	3.16E-4		0.0304

SCENARIO (n) B not relevant for this product

Risks posed by 1R-trans phenothrin to soil dwelling organisms are unacceptable in SCENARIOS 1 & 2 as a result of cleaning events on board aircraft after they have landed at EU airports when compared against a PNECsoil of 1.04E-2 mg/kg wwt. However, risks posed by passengers contaminated with a.s. are considered acceptable.

PEC$_{groundwater}$

If unacceptable risks have already been identified and prevent authorisation of the product, then risks to groundwater need not be investigated.
The KOC value of 125,892.5 L.kg-1 (log Koc of 5.1) demonstrates that 1R-trans phenothrin will not likely be mobile in soil and so therefore indirect exposure of groundwater (and even surface waters via run-off from fields) is unlikely. However, it is noted that 86.8 % of emissions from STP are directed to agricultural land via sewage sludge.

Predicted concentrations of 1R-trans phenothrin in local agricultural soil (arable values are taken as representing highest risk) can be used to crudely indicate groundwater levels in

line with the following equation presented in the ECHA guidance on ERA (equation 67) but the approach is very simplistic and takes no account of soil characterisation (neglecting consideration of transformation plus dilution in deeper soil layers);

$$PEClocal_{soil,\ porewater} = \frac{PEClocal_{soil} \times RHO_{soil}}{K_{soil\text{-}water} \times 1000}$$

$PEClocal_{soil}$, porewater is the predicted concentration in porewater (calculated in mg/l)
$PEClocal_{soil}$ is the predicted environmental concentration in arable soil
RHO_{soil} is the bulk density of wet soil (default of 1700 kg m-3)
$K_{soil\text{-}water}$ is the soil-water partitioning co-efficient (calculated as 3776.98 m3 m-3)

Scenario	**PEC_{GW} (mg/l)**	**PNECGW (mg/l)**	**PEC / PNEC**
SCENARIO 1A SCENARIO 1B	3.66E-6 7.31E-6	1.0E-4	3.66E-2 7.31E-2
SCENARIO 2A SCENARIO 2B	3.85E-5 7.67E-5	1.0E-4	0.385 0.86
SCENARIO 3A SCENARIO 3B	2.2E-8 4.385E-8	1.0E-4	2.2E-4 4.38E-4

SCENARIO (n) B not relevant for this product

With a drinking water standard of 0.1 µg/l (1.0E-4 mg/l) set for "pesticide actives", then this can act as a notional $PNEC_{porewater}$. As failures are not noted in the screening calculations, then further modelling with FOCUS PEARL 4.4.4 is not required : risks to groundwater are considered acceptable.

PEC in biota

Primary Poisoning
As the direct consumption of insecticide by birds or mammals is thought to mainly occur when insecticides are applied with a food attractant or as a granular formulation then, in line with Chapter 5 of the ESD, spray application on board aircraft for mosquito and fly control does not need to be considered for primary poisoning.

Secondary poisoning

Secondary poisoning concerns toxic effects in organisms at high trophic levels based on ingestion of organisms from lower trophic levels. Measured or predicted concentrations of residues in top predators are compared to no effect concentrations for the predators. The key components of the assessment of secondary poisoning are the assessment of potential bioaccumulation and potential toxicity of the substance following exposure to residues of the active substance.

A) Via the consumption of worms from contaminated soil

As described earlier, the exposure of soil to 1R-trans phenothrin could result from the indirect application of sewage sludge to agricultural land. The PECsoil value is taken for the arable ecosystem, and using the equations previously described, a corresponding porewater concentration can be calculated;

$$PEClocal_{soil,\ porewater} = \frac{PEClocal_{soil} \times RHO_{soil}}{K_{soil\text{-}water} \times 1000}$$

PEClocalsoil, porewater is the predicted concentration in porewater (calculated in mg/l)
PECsoil is the predicted concentration in arable soil (presented as mg kgwwt-1)
RHOsoil is the bulk density of wet soil (default of 1700 kg m-3)
Ksoil-water is the soil-water partitioning co-efficient (calculated as 3776.98 m3 m-3)

Scenario	**PEC_{arable_soil} (mg/kg wwt)**	**$PEC_{porewater}$ (mg/l)**
SCENARIO 1A	8.17E-3	3.61E-6
SCENARIO 1B	1.63E-2	7.31E-6
SCENARIO 2A	9.56E-2	3.85E-5
SCENARIO 2B	1.71E-1	7.67E-5
SCENARIO 3A	4.88E-5	2.2E-8
SCENARIO 3B	1.10E-4	4.95E-8

SCENARIO (n) B not relevant for this product

According to the ECHA guidance on ERA, when birds and mammals consume worms, this includes the gut of the earthworms (which may contain substantial amounts of soil). The exposure of these predators (birds and small mammals) may be affected by the amount of active substance in the consumed soil.

The PECoral predator is calculated as PECoral predator = Cearthworm, where Cearthworm is the total concentration of the active substance in the worm as a result of bioaccumulation in worm tissues and the adsorption of the active substance to the soil present in the earthworm's gut. The total concentration in an entire worm can be calculated as the weighted average of the worm's tissues (through BCF and porewater) and contents of the gut (through soil concentration) using the following equation (82c);

$$C_{earthworm} = \frac{[(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})]}{[1+(F_{gut} \times CONV_{soil})]}$$

Where C_{soil} = $PEClocal_{soil}$ (Ecosystem)
Cporewater = $PEClocal_{soil}$, porewater
F_{gut} = 0.1 (ECHA guidance default)
$CONV_{soil}$ = RHO_{soil} / (F_{solid} x RHO_{solid}) = 1700 / (0.6 x 2500) = 1.13
$BCF_{earthworm}$ = 75,716 (calculated value taken from Doc II-A of the a.s. CAR)

$$BCF_{earthworm} = (0.84 + 0.012K_{ow}) / RHO_{earthworm}$$

And $RHO_{earthworm}$ is taken to be 1 kg_{wwt}. L^{-1}

Scenario	**$PEC_{predator\_worm}$ (mg/kg.food)**	**PNECbiota (mg/kg.food)**	**PEC / PNEC**
SCENARIO 1A	0.252	1.87	0.13
SCENARIO 1B	0.504		0.27
SCENARIO 2A	2.66	1.87	1.42
SCENARIO 2B	5.30		2.83
SCENARIO 3A	1.52E-3	1.87	8.11E-4
SCENARIO 3B	3.03E-3		1.62E-3

SCENARIO (n) B not relevant for this product

Risks to earthworm-eating mammals and birds are acceptable in only 2 out of 3 scenarios when compared against a $PNEC_{biota}$ of 1.87 mg/kg food derived from avian data. Although

a higher value of 10 mg/kg food can be derived for predatory mammals, the lower value must be used in risk assessment as being protective for birds.

B) Via the aquatic food chain
According to ECHA guidance on ERA, the simplest way to estimate the potential of a substance to bioaccumulate in aquatic species is by the experimental measure of the Bioconcentration Factor (BCF).

The concentration in fish is given by;

$$PEC_{oral,predator} = PEC_{water} \times BCF_{fish} \times BMF$$

Where:
$PEC_{oral,predator}$ is the Predicted Environmental Concentration in food (in mg kgwet fish -1)
PEC_{water} is the Predicted Environmental Concentration in surface water (in mg/l)
BCF_{fish} is reported as a mean value of 2849 L/Kg for trans-isomers based upon study values presented in the a.s. CAR

As a first tier approach, the worst case PECs for local surface water (assuming no degradation at STP) can be used in the assessment, in combination with a BCF of 2849 and BMF of 2 (relating to the measured data). However this may lead to an overestimation of the risk as fish eating birds and mammals may also forage on fish from sites other than the site of discharge.

Scenario	**PEC_{water} (mg/l)**	**PEC_{biota} (mg/kg wet fish)**
SCENARIO 1A	1.14E-4	**0.567**
SCENARIO 1B	2.28E-4	**1.13**
SCENARIO 2A	1.20E-3	**5.97**
SCENARIO 2B	2.39E-3	**11.9**
SCENARIO 3A	6.84E-7	**3.40E-3**
SCENARIO 3B	1.22E-6	**6.08E-3**

Scenario	**$PEC_{predator\_fish}$ (mg/kg.food)**	**PNECbiota (mg/kg.food)**	**PEC / PNEC**
SCENARIO 1A	0.567	1.87	0.303
SCENARIO 1B	1.13		0.607
SCENARIO 2A	5.97	1.87	**3.19**
SCENARIO 2B	11.9		**6.37**
SCENARIO 3A	3.40E-3	1.87	1.82E-3
SCENARIO 3B	6.08E-3		3.25E-3

SCENARIO (n) B not relevant for this product

Risks to earthworm-eating mammals and birds are acceptable in only 2 out of 3 scenarios when compared against a $PNEC_{biota}$ of 1.87 mg/kg food derived from avian data. Although a higher value of 10 mg/kg food can be derived for predatory mammals, the lower value must be used in risk assessment as being protective for birds.

3.2.3 ACCEPTABILITY OF RISKS POSED BY PRODUCT when used to disinsect aircraft AND USE OF MITIGATION MEASURES

Risks posed to local stp

SCENARIO	RISK : PASS / FAIL?
Scenario 1 : Losses to local STP following daily cleaning of aircraft on return to EU	
1A : One treatment during return flight	**PASS**
1B : two treatments during return flight	**PASS**
Scenario 2 : Losses to local STP following deep clean of aircraft (every 2 months)	
2A : One treatment during return flight	**PASS**
2B : two treatments during return flight	**PASS**
Scenario 3 : Losses to local STP following washing events by passengers on return home	
3A : One treatment during return flight	**PASS**
3B : two treatments during return flight	**PASS**

All risks to STP micro-organisms are considered to be acceptable and therefore no further mitigation measures are required.

Risks posed to surface waters via local stp

SCENARIO	RISK : PASS / FAIL?
Scenario 1 : Losses to local STP following daily cleaning of aircraft on return to EU	
1A : One treatment during return flight	**FAIL**
1B : two treatments during return flight	**FAIL**
Scenario 2 : Losses to local STP following deep clean of aircraft (every 2 months)	
2A : One treatment during return flight	**FAIL**
2B : two treatments during return flight	**FAIL**
Scenario 3 : Losses to local STP following washing events by passengers on return home	
3A : One treatment during return flight	**PASS**
3B : two treatments during return flight	**PASS**

SCENARIO (n) B not relevant for this product

Risks to aquatic organisms have been shown to be unacceptable following potential discharge of waste water if aircraft are wet cleaned daily (SCENARIO 1 : after flights return to EU airports) or deep cleaning occurs at routine maintenance (SCENARIO 2). However, acceptable risks are noted for losses discharged to STP following washing events by passengers (SCENARIO 3) from bathing and laundering of clothing. Therefore, careful consideration must be made on the potential for losses to be discharged at EU airports and whether the assumptions made in the emissions models for SCENARIO 1 & 2 are actually realistic to working practises in the aviation industry. It has been assumed as a simple "worst case" that cleaning events in both SCENARIOs (cleaning of aircraft after every flight plus deep cleaning at maintenance) would be undertaken using wet cleaning processes (i.e. re-usable cloths, mops and soapy water) so that all pick-up from all available surfaces will be discharged to drains as waste water. This simplistic worst case approach has been undertaken for the purposes of a Tier 1 assessment, in an attempt to quantify potential risks to the environment in a situation where there are either no controls on emissions to the environment or where there is a failure to comply with the control measures. The UK CA (as eCA) accepts that given the

highly specialised nature of the aviation industry, this is likely to represent an unrealistic worst case.

[redacted]

[redacted]

When considering the cleaning procedures specified by a major airline and how these processes must also be adopted by other airlines, it is acceptable to assume that they represent working practises within the aviation industry.
On that basis, it is clear that wet cleaning of aircraft after each flight and at routine maintenance represent "extreme worst case" SCENARIOs and do not accurately reflect procedures taking place at EU airports. Therefore, it is acknowledged that emissions to drains (and local STP) in SCENARIOs 1 & 2 will most likely be negligible and therefore risks to surface water (and other receiving compartments can be considered as zero. However, this is ultimately dependant on the airline and contracted companies to continue using cleaning equipment and specialised detergents/solvents that do not require wet cleaning plus disposal of all waste material (such as surplus product, waste liquid, cleaning equipment) safely, presumably as solid waste to landfill site. 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. stewardship leaflets to distribute with the product or direct to other relevant parties
This could be achieved by provision of additional guidance on technical data sets / MSDS or on leaflets distributed with each batch of product sold to airlines or sent direct to interested parties, with instruction that following application of 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."
Such information will be included in the PAR and SPC under "Other information" in Section 6.
Any such cleaning measures have no bearing on predicted emissions resulting from SCENARIO 3 as they arise from actual contamination of passengers, resulting from deposition of product and this cannot be avoided when product is applied , especially at "Blocks away" and "Top of descent".

<u>risks posed to sediment compartment via local stp</u>

SCENARIO	RISK : PASS / FAIL?
Scenario 1 : Losses to local STP following daily cleaning of aircraft on return to EU	
1A : One treatment during return flight	**FAIL**
1B : two treatments during return flight	**FAIL**
Scenario 2 : Losses to local STP following deep clean of aircraft (every 2 months)	
2A : One treatment during return flight	**FAIL**
2B : two treatments during return flight	**FAIL**
Scenario 3 : Losses to local STP following washing events by passengers on return home	
3A : One treatment during return flight	**PASS**
3B : two treatments during return flight	**PASS**

SCENARIO (n) B not relevant for this product

Risks to sediment dwelling organisms have been shown to be unacceptable following potential discharge of waste water if aircraft are wet cleaned daily (SCENARIO 1 : after flights return to EU airports) or deep cleaning occurs at routine maintenance (SCENARIO 2). However, acceptable risks are noted for losses discharged to STP following washing events by passengers (SCENARIO 3) from bathing and laundering of clothing.
As unacceptable risks only arise from potential losses of a.s. in wastewater as a result of routine wet cleaning of internal surfaces in aircraft, the applicant submitted a supplementary document on cleaning processes within the aviation industry, particularly in the EU. This has been considered in detail within the previous "aquatic risk" section and it has been accepted that losses to drains can now be considered as negligible if additional information are made available to interested/relevant parties (airlines, third party cleaning/maintenance companies etc).

<u>risk to air compartment</u>
No further consideration is required as only negligible emissions are predicted from the aircraft themselves when doors are opened at airports, due to rapid and complete removal from the air during the return flight. Furthermore, negligible losses are expected at local STP following discharge of waste water in all 3 SCENARIOs (daily cleaning of aircraft, deep cleaning during routine maintenance of aircraft and washing of passenger / laundering of contaminated clothing).

<u>risks posed to soil compartment via local stp</u>

SCENARIO	RISK : PASS / FAIL?
Scenario 1 : Losses to local STP following daily cleaning of aircraft on return to EU	
1A : One treatment during return flight	**FAIL**
1B : two treatments during return flight	**FAIL**
Scenario 2 : Losses to local STP following deep clean of aircraft (every 2 months)	
2A : One treatment during return flight	**FAIL**
2B : two treatments during return flight	**FAIL**
Scenario 3 : Losses to local STP following washing events by passengers on return home	
3A : One treatment during return flight	**PASS**
3B : two treatments during return flight	**PASS**

SCENARIO (n) B not relevant for this product

Risks to soil dwelling organisms dwelling organisms have been shown to be unacceptable following potential discharge of waste water if aircraft are wet cleaned daily (SCENARIO 1 : after flights return to EU airports) or deep cleaning occurs at routine maintenance (SCENARIO 2). However, acceptable risks are noted for losses discharged to STP following washing events by passengers (SCENARIO 3) from bathing and laundering of clothing.

As unacceptable risks only arise from potential losses of a.s. in wastewater as a result of routine wet cleaning of internal surfaces in aircraft, the applicant submitted a supplementary document on cleaning processes within the aviation industry, particularly in the EU. This has been considered in detail within the previous "aquatic risk" section and it has been accepted that losses to drains can now be considered as negligible if additional information are made available to interested/relevant parties (airlines, third party cleaning/maintenance companies etc).

risks posed to groundwater via local stp

SCENARIO	**RISK : PASS / FAIL?**
Scenario 1 : Losses to local STP following daily cleaning of aircraft on return to EU	
1A : One treatment during return flight	**PASS**
1B : two treatments during return flight	**PASS**
Scenario 2 : Losses to local STP following deep clean of aircraft (every 2 months)	
2A : One treatment during return flight	**PASS**
2B : two treatments during return flight	**PASS**
Scenario 3 : Losses to local STP following washing events by passengers on return home	
3A : One treatment during return flight	**PASS**
3B : two treatments during return flight	**PASS**

SCENARIO (n) B not relevant for this product

All risks to groundwater are considered to be acceptable and therefore no further mitigation measures are required.

risks posed to biota via local stp

SCENARIO	**RISK : PASS / FAIL?**
Scenario 1 : Losses to local STP following daily cleaning of aircraft on return to EU	
1A : One treatment during return flight	**PASS**
1B : two treatments during return flight	**PASS**
Scenario 2 : Losses to local STP following deep clean of aircraft (every 2 months)	
2A : One treatment during return flight	**FAIL**
2B : two treatments during return flight	**FAIL**
Scenario 3 : Losses to local STP following washing events by passengers on return home	
3A : One treatment during return flight	**PASS**
3B : two treatments during return flight	**PASS**

SCENARIO (n) B not relevant for this product

Risks to biota (fish-eating and worm-eating predators) have been shown to be unacceptable following potential discharge of waste water if aircraft are wet cleaned during deep cleaning occurs at routine maintenance (SCENARIO 2). However, acceptable risks are noted for losses discharged to STP following daily cleaning of aircraft (after each flight – SCENARIO 1) plus washing events undertaken by passengers from bathing and laundering of clothing (SCENARIO 3).
As unacceptable risks only arise from potential losses of a.s. in wastewater as a result of wet cleaning of internal surfaces in aircraft , the applicant submitted a supplementary document on cleaning processes within the aviation industry, particularly in the EU. This has been considered in detail within the previous "aquatic risk" section and it has been accepted that losses to drains can now be considered as negligible if additional

information are made available to interested/relevant parties (airlines, third party cleaning/maintenance companies etc).

3.2.4 OVERALL CONCLUSIONS

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.
Risks posed by cleaning events undertaken by passengers (bathing and laundering of contaminated clothing once they return home) are all shown to be acceptable.
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 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. The UK CA (as eCA) accepts this position.
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 sets / MSDS or on leaflets distributed with each batch of product sold to airlines or sent direct to interested parties, with instruction that following application of 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."
Such information will be included in the PAR and SPC under "Other information" in Section 6.

During the EU mutual recognition process in 2018 of the product evaluated by UK, concerns were raised by several Member States (MS) over procedures needed at airports to ensure that any wastewater that could potentially be generated from aircraft cleaning (emissions scenarios 1 and 2) is not discharged to drains. Reassurances were sought that such emissions would be negligible so that risks subsequently posed to STP, aquatic compartment and terrestrial compartment were effectively zero.
The applicant of that product submitted a revised "control measure" document (supplied in full as Annex 3.9 of the PAR with UK CA comments) and this provides detailed explanation of measures that will be taken and other applicable EU legislation that impacts on discharge of waste at airports.

These measures are considered by BE CA independent of the product and by means also applicable for the Aero-Sense product

It was concluded for the product evaluated by UK that:

• EC Regulation 1069/2009 (concerning safe use and disposal of animal by-products) sets up stringent disposal measures to remove liquid and solid waste on site ;
• The EU aviation industry follows WHO Recommendations from the "Guide to Hygiene and Sanitation in Aviation" (2009), whereby it can be assumed that whilst aircraft surfaces could be wet cleaned, they are required to be wiped dry. Disposable (paper) towels are used to avoid cross-contamination, and these are then disposed of as waste. Waste is always disposed of as hazardous waste as it might contain catering waste (for which special "disposal" guidelines exist).
Therefore, safe use of the Aero-Sense AIRCRAFT INSECTICIDE ASD product does not solely rely upon communication of suitable RMMs via leaflets, MSDS and TDS (as proposed by the applicant) but is also guaranteed under existing legislation.
Both mitigation measures must continue to appear on product labels and in associated literature/safety sheets but existing legislation/guidance ensures control of waste from treated aircraft.

Any such cleaning measures have no bearing on predicted emissions resulting from SCENARIO 3 as they arise from actual contamination of passengers, resulting from deposition of product and this cannot be avoided when product is applied , especially at "Blocks away" and "Top of descent".

On that basis, authorisation of the product, "Aero-Sense AIRCRAFT INSECTICIDE ASD", can be recommended.

3.3 New information on the active substance

Not applicable

3.4 Residue behaviour

Not applicable

3.4. Summaries of the efficacy studies (B.5.10.1-xx)

Reference is made to the IUCLID file.

3.5. Confidential annex

The confidential annex is included in the dossier as a separate file.