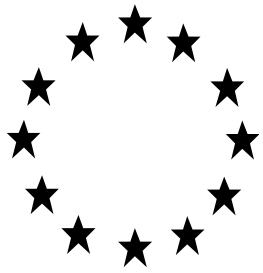
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



[ACARDUST]

Product type(s) [18]

[1,R trans phenothrin as included in the Union list of approved active substances]

Case Number in R4BP: [BC-DT019657-17]

Evaluating Competent Authority: [FR]

Date: [25/12/2017]

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1 CONCLUSION

Conclusion on physico-chemical properties

The formulation ARCADUST is an Aerosol (AE) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.
The appearance of the product is a homogeneous limpid liquid colourless with a characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in aluminium can packaging material (commercial packaging material). The long term storage stability study (36 months) is on-going. Available intermediate results should be provided.
After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.

Its technical characteristics are acceptable for an AE formulation. Quality control data have been provided for net content of formulation, internal pressure and discharge rate only for the product ARCADUST 400. Mean net content is 353.06g, mean internal pressure is 5.09 bars at 20°C and 9.57 bars at 50°C and the mean discharge rate is 1.56 g/s. No data have been provided for the product ARCADUST 200.

The liquid formulation is classified H304. As the product is a sealed aerosol, the liquid formulation is not intended to be available to be swallowed. Therefore the product ACARDUST should not be classified H304.
The product should be stored at maximum 40°C.
The product is not explosive and has no oxidizing properties. The product is classified as flammable aerosol 2, H223 and H229.

Analytical methods have been provided for the determination of the active substance in the product: one for the sum of the phenothrin isomers and one for the 1R-trans isomer.
Analytical methods were provided at EU level for the determination of the sum of isomers residue in soil, water and air with respectively LOQ = 0.01mg/kg, 0.001 mg/m^3 and 0.1µg/L.
1R-trans phenothrin is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.

The product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of 1R-trans phenothrin residue in food/feed of plant and animal origin is not required.

Conclusion on efficacy

French competent authorities (FR CA) consider that efficacy of the product ACARDUST against House dust mites (*Dermatophagoïdes pteronyssinus*) has been demonstrated when the product is applied directly on target organisms.

Conclusion on human health

The risk for non-professional users during application is acceptable with the following risk mitigation measures:

- Leave the room for at least one hour after surface application AND
- Leave the room for 3 hours after automatic diffusion
- Do not combining direct spraying and automatic spraying the same day.

There is acceptable risk for adults, children and toddler who inhale residues volatile.

There is acceptable risk for person (adults, children and toddlers,) who sleeps in a dried treated bed, with the following risk mitigation measures:

- Do not treat bed linen, duvets and pillows.
- Do not use treated bedding until a full drying.

However, in case of combining direct spraying and automatic indirect surface spraying in the same day, a mitigation measure is needed:

- Do not apply in toddler rooms (children less than two years old).
- Do not touch treated surface when it is wet.

There is acceptable risk for adult who touches treated surface.

There is unacceptable risk for children who crawl on treated surface such as impervious surface (plastic, tile...). There is acceptable risk for children who crawl on treated surface such as carpets. In this context, a mitigation measure is needed:

- Do not apply on impervious surfaces.

Conclusion on indirect exposure via residues in food

For indoor spraying surface and space uses by non-professional in households and private area (mainly in bedrooms), no specific residue data were submitted in the context of this dossier.
No direct or indirect contamination of food is expected. Nevertheless, to avoid any contamination, the following precautionary statements are proposed:
"Do no use in rooms containing food, feed or drink, and in rooms containing surfaces and facilities likely to be in contact with food, feed or drinks."

Conclusion on ecotoxicology and environment

For indoor direct treatment of surfaces by spray, risks are unacceptable for the sediment compartment. For this use, risk mitigation measures are proposed to limit the risks for the non-target sediment organisms (*i.e. do not apply to washable surfaces or textiles and protect the adjacent surface during application with a non-washable plastic film*).
For indoor indirect surface spraying with a one-shot aerosol, risks are unacceptable for the aquatic compartment (including sediment) and the terrestrial compartment. No risk mitigation can be proposed.

Conclusion:

Considering unacceptable risk for the aquatic (including sediment) and terrestrial compartment identified for application with a one-shot aerosol, conditions of article 19 of Regulation 528/2012 are met only for uses of ACARDUST as direct spray application on restricted surfaces. The following risk mitigations measures are deemed necessary to prevent unacceptable risk for human health and the environment:

- Do not treat bed linen, duvets and pillows.
- Do not touch treated surface when it is wet.
- Do not apply to washable surfaces or textiles and protect the adjacent surface during application with a non-washable plastic film.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
ACARDUST ACARDUST 200 ACARDUST 400	France

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Laboratoires Oméga Pharma France
	Address	20 rue André Gide - BP80 92321 Chatillon cedex France
Authorisation number	FR-2017-0080	
Date of the authorisation	20/09/2017	
Expiry date of the authorisation	20/09/2027	

2.1.1.3 Manufacturers of the products

Name of manufacturer	AEROFARM
Address of manufacturer	Faréva, Division Pharma 13322 Marseille cedex 16 France
Location of manufacturing sites	468 chemin du littoral 13322 Marseille cedex 16 France

Name of manufacturer	F.C.A. (Fabrication Chimique Ardéchoise)
Address of manufacturer	Ile Feray 07300 Tournon-sur-Rhône France
Location of manufacturing sites	Ile Feray 07300 Tournon-sur-Rhône France

2.1.1.4 Manufacturer of the active substance

Active substance	1,R-Trans phenothrin
Name of manufacturer	Sumitomo Chemical (UK) Plc
Address of manufacturer	Hyte house 200 Shepherds Bush Road Hammersmith W 7NL London United Kingdom
Location of manufacturing sites	Aza-sabishirotai Oaza-misawa Aomori 033-0022 Japan

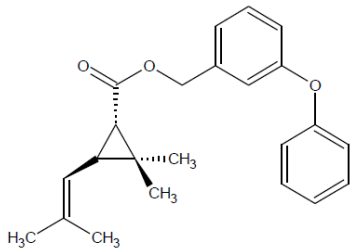
2.1.2 Product composition and formulation

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(s) 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-phenoxybenzyl (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	Min. 89% w/w 1Rtrans isomer Min. 95.5% w/w "sum of all isomers"
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance contained in the biocidal product is not candidate for substitution in accordance with Article 10 of BPR.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
1R-trans Phenothrin	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether	Active substance	26046-85-5	247-431-2	0.37 % (pure)
Isododecane	isododecane	Substance of concern	93685-81-5	297-629-8	59.58 %

Please see the confidential annex for further details.

2.1.2.4 Information on the substance(s) of concern

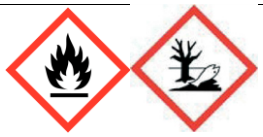
Please see the confidential annex for further details.

2.1.2.5 Type of formulation

Aerosol formulation (AE)

2.1.3 Hazard and precautionary statements[1]

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

Classification	
Hazard category	Flammable aerosol cat. 2 Aquatic acute tox cat .1 Aquatic chronic tox cat .1
Hazard statement	H223 – Flammable aerosol 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	H223: Flammable aerosol H229: Pressurised container: May burst if heated H410: Very toxic to aquatic life with long lasting effects
Precautionary statements	P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking. P211: Do not spray on an open flame or other ignition source. P251: Pressurized container: Do not pierce or burn, even after use. P410+P412: Protect from sunlight. Do no expose to temperatures exceeding 50 oC/122oF. P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P331: Do NOT induce vomiting. P273: Avoid release to the environment P391:Collect spillage P501: Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified).
Note	EUH066 – Repeated exposure may cause skin dryness or cracking.

1 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Direct spraying

Product Type	18
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	House dust mites (*Dermatophagoides pteronyssinus*) Adults, nymphs and larvae
Field of use	Indoor Porous surfaces (wood, fabric (up to 225 g/m²) and non porous surfaces.
Application method(s)	Direct spraying on mites.
Application rate(s) and frequency	12.5 g/m² The biocidal effect appears a few hours after application >90% mortality can be obtained after 24 - 48 h depending on the type of treated surface.
Category(ies) of users	Non-professional
Pack sizes and packaging material	Aluminium aerosol can with an epoxy varnish inside of 270 and 520 mL (with 200 or 400 mL of aerosol).

2.1.4.2 Use-specific instructions for use

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2.1.4.3 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.5 General directions for use

2.1.5.1 Instructions for use

- Always read the label or package leaflet before use and follow all instructions.
- Respect the doses of use of the product.
- Treat only the infested surfaces (curative treatment).
- Allow 24 to 48 hours depending on the type of surface to be treated.
- The product has no residual effect and therefore no preventive action.
- The effectiveness of the product can also be optimized by maintaining the areas to be treated in good hygienic conditions and, if possible, when used in combination with ovicidal treatment.
- Inform the authorization holder in case of the product is ineffective.

2.1.5.2 Risk mitigation measures

- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
- Keep out of the children.
- Leave the room for at least one hour after surface application
- Do not treat bed linen, duvets and pillows.
- Do not use treated bedding until full drying.
- The product has to be applied in zone unattainable to children.
- Do not apply to washable surfaces or textiles.
- Do not apply on impervious surfaces.
- Avoid any direct or indirect contact with food and feed.
- Do not apply to washable surfaces or textiles and protect the adjacent surface during application with a non-washable plastic film.
- Maximum 4 applications per year.

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

- Impaired consciousness: do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately.
- Keep the container or label available.
- Inhalation: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- Mouth contact/Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or in case of mouth contact with large quantities.
- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with warm water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Dispose of unused product, its packaging and all other waste (as plastic film) in

accordance with local regulations. - Do not discharge the product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.

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

- Shelf-life: 2 years. - Do not store at a temperature above 40° C.

2.1.6 Other information

- The final results of the long term stability study at 2 years should be provided in post-authorisation within 1 year.

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)**
Can	270 mL and 520 mL	Aluminium with an epoxy varnish	No data	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Identity, physico-chemical and analytical method data

Physico-chemical properties studies and analytical methods on the biocidal product ACARDUST were provided by Laboratoire Omega Pharma France.

Efficacy data

Following laboratory studies have been taken into account for the assessment of the efficacy of the product ACARDUST:

- Efficacy of the product "ACARDUST 200" against *Dermatophagoïdes pteronyssinus*;
- Efficacy of the product "ACARDUST 400" against *Dermatophagoïdes pteronyssinus*.

Toxicology data

No toxicology study was submitted in the context of this dossier.

Residues data

No specific residue data was submitted in the context of this dossier.

Ecotoxicology data
No specific data was submitted in the context of this dossier.

2.1.8.2 Access to documentation

Laboratoire Omega Pharma France has access to data on the active substance 1R-trans phenothrin with a Letter of Access of Sumitomo, one applicant of the active substance 1R-trans phenothrin.

2.2 Assessment of the biocidal product

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

Table 1. Intended use # 1 – Spraying indoor by non-professional

Product Type(s)	18
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Pyroglyphidae: House dust mites (*Dermatophagoides pteronyssinus*) Adults, hyphae and eggs
Field of use	Indoor
Application method(s)	Ready-for-use product, applied by two methods : - Direct spraying on surfaces (ACARDUST 200 and ACARDUST 400) - Indirect spraying on surfaces by automatic diffusion on space (ACARDUST 400) Direct application can be done up to 4 times per year, every 3 months. Spatial application can be done up to twice a year, every 6 months.
Application rate(s) and frequency	12.5 g/m²
Category(ies) of user(s)	General public (non-professional)
Pack sizes and packaging material	Aerosol can (metal: aluminium ; 270 and 520 mL)

2.2.2 Physical, chemical and technical properties

The biocidal product is not the same as the one assessed for the inclusion of the active substance in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 0.42 % of technical active substance and 0.37 % of pure 1R-trans phenothrin.

The product does not contain PT6 preservative and is not diluted for use.

Formulation type: Aerosol (AE)

Hydrocarbon and H304 co-formulant content: 59.58%
The product ACARDUST 200 (multi-shot aerosol) is packaged in aerosol in aluminium can of 270 mL (with 200 mL of aerosol) and ACARDUST 400 (one-shot aerosol) is packed in aerosol in aluminium can of 520 mL (with 400 mL of aerosol).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR Evaluation	Reference
Physical state at 20 °C and 101.3 kPa	Visual method	ACARDUST Batch H775 and K072	Homogeneous limpid liquid Same observation after accelerated storage stability study	Acceptable	Demangel B. 2015 Study report No 15-912035-003
Colour at 20 °C and 101.3 kPa	Visual method	ACARDUST Batch H775 and K072	Colourless Same observation after accelerated storage stability study	Acceptable	Demangel B. 2015 Study report No 15-912035-003
Odour at 20 °C and 101.3 kPa	Visual method	ACARDUST Batch H775 and K072	Characteristic odour Same observation after accelerated storage stability study	Acceptable	Demangel B. 2015 Study report No 15-912035-003
Acidity / alkalinity	Statement	ACARDUST	The measurement of pH value is not required as Acardust is a non-aqueous ready-to-use product.	Acceptable	IUCLID
Relative density / bulk density	Method EC.A3 Pycnometer method	Liquid formulation of ACARDUST without the propellant gas 0.67% all isomers Batch H775	D_4^{20} = 0.750 at 19.9°C	Acceptable The propellant gas is mixed with the other co-formulants in the product but after pulverisation the propellant gas is gone. This explained the content of active substance which is higher than the content in the product with the propellant gas.	Demangel B. 2015 Study report No 15-912035-001

<table>
<tr>
<td>Storage stability test – accelerated storage</td>
<td>CIPAC MT 46.3
8 weeks at 40°C in aluminium aerosol can

Analytical method GC-FID (15-912035-005)

Internal method

Internal method</td>
<td>Liquid formulation of ACARDUST without the propellant gas

ACARDUST (200mL and 400mL)
Batch H775 and K072</td>
<td>- Active substance content:
<table>
<tr><td>T0</td><td>T8w</td></tr>
<tr><td>0.668%</td><td>0.672%</td></tr>
</table>
- Satisfactory operation of the aerosol and spray volume:

One-shot aerosol:
Weight of full aerosol, weight of empty aerosol and calculation of the volume with the density has been made.

Multi-shot aerosol:
Weight of full aerosol, weight aerosol after 5s spray and calculation of the volume with the density has been made.
<table>
<tr><td>mL</td><td>T0</td><td>T8w</td></tr>
<tr><td>One</td><td>463.5</td><td>464.0</td></tr>
<tr><td>multi</td><td>12.1</td><td>11.5</td></tr>
</table>
Nozzles of the aerosol were checked and no blocking were observed

- Spray diameter:

One-shot aerosol:
Diameter when spraying at 30 cm (one shot) has been measured.

Multi-shot aerosol:
Diameter when spraying at 30 cm during 5s has been measured.</td>
<td>Acceptable

The analytical method allows the determination of the sum of the phenothrin isomers and not only the 1R-trans isomer. Content of the 1R-trans isomer has been obtained with calculation based on the purity declared in the certificate of analysis and the assumption that the different isomers remain unchanged when formulated in the product and over storage (no conversion of one isomer to another) which is not acceptable without a full justification or 1R-trans phenothrin content should be determined with a specific analytical method.

Based on the interim data (at 12 months) provided in the long term storage stability study no conversion of one isomer to another has been demonstrated. Moreover a method to determine only 1R-trans phenothrin has been provided.

The propellant gas is mixed with the other co-formulants in the bottle. After</td>
<td>Demangel B. 2015 Study report No 15-912035-003</td>
</tr>
</table>

			<table><tr><td>cm</td><td>T0</td><td>T8w</td></tr><tr><td>One</td><td>13</td><td>15</td></tr><tr><td>multi</td><td>21</td><td>28</td></tr></table> The shape was circular in each case	pulverisation of the product, the propellant gas is gone. This explained the measured content of active substance which is higher than the content in the product with the propellant gas. Remark: difference is observed in the spray diameter between the two types of aerosol (multi-shot and one shot).	

<table>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>36months at 20°C in aluminium aerosol can

Technical monograph no.17

Analytical method GC-FID (15-912035-005 and 16-912035-001)

Internal method

Internal method</td>
<td>Liquid formulation of ACARDUST without the propellant gas and ACARDUST (200mL and 400mL)
Batch H775 and K072</td>
<td>The study is on-going.
Beginning: May 2015
End: June 2018

Active substance content, Satisfactory operation of the aerosol and spray volume and spray diameter will be determined after 6, 12, 24 and 36 months.

Intermediate results after 6 months and 12 months have been provided:

Content of all isomers and of 1R-trans phenothrin have been measured (multi-shot aerosol).
<table>
<tr><td>% (w/w)</td><td>T0</td><td>T6m</td><td>T12m</td></tr>
<tr><td>All</td><td>0.668</td><td>0.670</td><td>0.654</td></tr>
<tr><td>1R-Trans</td><td>0.620</td><td>0.658</td><td>0.648</td></tr>
<tr><td>Ratio 1R-trans</td><td>93.8</td><td></td><td>93.9</td></tr>
</table>
Variation < 10% after 6 months and 12 months for the active substance content.

Appearance of the packaging and weight variation is the same after 6 and 12 months for the two products (one shot and multi-shot aerosol)

Spray volume and spray diameter for the two products:</td>
<td>Acceptable

Intermediate results after 6 months and 12 months have been provided.

The propellant gas is mixed with the other co-formulants in the bottle. After pulverisation of the product, the propellant gas is gone. This explained the measured content of active substance which is higher than the content in the product with the propellant gas.</td>
<td>Demangel B. 2015 and 2016
Study report No 15-912035-004</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>Spray volume:
<table><tr><td>mL</td><td>T0</td><td>T6m</td><td>T12m</td></tr><tr><td>One</td><td>461.95</td><td>460.78</td><td>461.31</td></tr><tr><td>multi</td><td>11.936</td><td>12.636</td><td>11.899</td></tr></table>
Spray diameter
<table><tr><td>cm</td><td>T0</td><td>T6m</td><td>T12m</td></tr><tr><td>One</td><td>12</td><td>12</td><td>12</td></tr><tr><td>multi</td><td>14</td><td>15</td><td>20</td></tr></table>
The shape was circular in each case

The nozzles were checked and no blocking was observed in each case</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage stability test – low temperature stability test for liquids</td>
<td>CIPAC MT 39.3
7 days at 0°C in aluminium aerosol can

Internal method

Internal method</td>
<td>Liquid formulation of ACARDUST without the propellant gas and ACARDUST (200mL and 400mL)
Batch H775 and K072</td>
<td>- Stability:
<table><tr><td>T0</td><td>T7d</td></tr><tr><td colspan="2">Homogeneous colourless limpid liquid</td></tr><tr><td colspan="2">No sign of corrosion or degradation in the aluminium aerosol can</td></tr></table>
- Satisfactory operation of the aerosol and spray volume:

One-shot aerosol:
Weight of full aerosol, weight of empty aerosol and calculation of the volume with the density has been made.

Multi-shot aerosol:</td>
<td>Acceptable

Remark: difference is observed in the spray diameter between the two types of aerosol (multi-shot and one shot).</td>
<td>Demangel B. 2015
Study report No 15-912035-003</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>Weight of full aerosol, weight aerosol after 5s spray and calculation of the volume with the density has been made.

<table><tr><td>mL</td><td>T0</td><td>T7d</td></tr><tr><td>One</td><td>463.5</td><td>461.5</td></tr><tr><td>multi</td><td>12.1</td><td>11.7</td></tr></table>
Nozzles of the aerosol were checked and no blocking were observed

- Spray diameter:

One-shot aerosol:
Diameter when spraying at 30 cm (one shot) has been measured.

Multi-shot aerosol:
Diameter when spraying at 30 cm during 5s has been measured.

<table><tr><td>cm</td><td>T0</td><td>T7d</td></tr><tr><td>One</td><td>13</td><td>11</td></tr><tr><td>multi</td><td>21</td><td>16</td></tr></table>
The shape was circular in each case</td><td></td><td></td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product - light</td><td>Statement</td><td>ACRADUST</td><td>Not required as the commercial packagings of the product Acardust are opaque (white aluminium one-shot and multi-shot aerosols)</td><td>Acceptable</td><td>IUCLID</td></tr>
<tr><td>Effects on content of the</td><td>Statement</td><td>ACRADUST</td><td>The test item Acardust was considered to be stable after 8 weeks</td><td>Data on temperature have been provided in the</td><td>IUCLID</td></tr>
</table>

active substance and technical characteristics of the biocidal product – **temperature and humidity**			at 40 ± 2°C (please refer to section 3.4.1.1) and after 7 days at 0 ± 2°C (please refer to section 3.4.1.3). The individual commercial packaging (aerosol) is sealed. With this closure system, the packaging is leak-tight (see section 12.3).	accelerated storage stability study and in the low temperature stability study.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT 46.3 8 weeks at 40°C in aluminium aerosol can, two sizes of packaging	ACARDUST (200mL and 400mL) Batch K072	No sign of corrosion and degradation after accelerated storage stability study Weight difference: g / T0 / T8w Multi / 247.6 / 247.4 One / 461.7 / 461.3 -0.1% of difference in each case	Acceptable	Demangel B. 2015 Study report No 15-912035-003
Wettability			No data provided.	Not relevant for an AE	
Suspensibility, spontaneity and dispersion stability			No data provided.	Not relevant for an AE	
Wet sieve analysis and dry sieve test			No data provided.	Not relevant for an AE	
Emulsifiability, re-emulsifiability and emulsion stability			No data provided.	Not relevant for an AE	
Disintegration time			No data provided.	Not relevant for an AE	

Particle size distribution, content of dust/fines, attrition, friability			No data provided.	Not relevant for an AE	
Persistent foaming			No data provided.	Not relevant for an AE	
Flowability/Pourability/Dustability			No data provided.	Not relevant for an AE	
Burning rate — smoke generators			No data provided.	Not relevant for an AE	
Burning completeness — smoke generators			No data provided.	Not relevant for an AE	
Composition of smoke — smoke generators			No data provided.	Not relevant for an AE	
Spraying pattern — aerosols	Internal method	ACARDUST (200mL and 400mL) Batch H775 and K072	Spray diameter: One-shot aerosol: Diameter when spraying at 30 cm (one shot) has been measured. Multi-shot aerosol: Diameter when spraying at 30 cm during 5s has been measured. cm / T0 / T8w One / 13 / 15 multi / 21 / 28	Acceptable Remark: difference is observed in the spray diameter between the two types of aerosol (multi-shot and one shot).	Demangel B. 2015 Study report No 15-912035-003

			The shape was circular in each case		
Physical compatibility	Statement	ACARDUST	Not applicable. The product is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of Acardust with other biocidal products, chemicals or active substances is required.	Acceptable	IUCLID
Chemical compatibility	Statement	ACARDUST	Not applicable. The product is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of Acardust with other biocidal products, chemicals or active substances is required.	Acceptable	IUCLID
Degree of dissolution and dilution stability			No data provided.	Not relevant for an AE	
Surface tension	Method EC.A5 Ring method	Liquid formulation of ACARDUST without the propellant gas 0.67% all isomers Batch H775	21.6 mN/m at 20.1°C The liquid formulation is surface active.	Acceptable The liquid formulation is surface active. The propellant gas is mixed with the other co-formulants in the product but after pulverisation the propellant gas is gone. This explained that the content of active substance which is higher than the content in the product with the propellant	Demangel B. 2015 Study report No 15-912035-001

				gas.	
Viscosity	Method OECD 114 Viscometer with rotational spindles	Liquid formulation of ACARDUST without the propellant gas 0.67% all isomers Batch H775	Dynamic viscosity: 1.43 mPa.s at 20°C 1.10 mPa.s at 40°C	Acceptable Newtonian liquid Cinematic viscosity at 40°C should be provided to conclude on the classification H304 of the liquid formulation. Estimation by calculation with the density (but no value at 40°C): Cinematic viscosity at 40°C has been provided by calculation= 1.1/0.750= 1.47mm^2/s Classification H304 of the liquid formulation As the product is a sealed aerosol, the liquid formulation is not intended to be available to be swallowed. Therefore the product ACARDUST should not be classified H304. The propellant gas is mixed with the other co-formulants in the product but after pulverisation the propellant gas is gone. This explained that the content of active substance which is higher	Demangel B. 2015 Study report No 15-912035-001

<table>
<tr><td></td><td></td><td></td><td></td><td>than the content in the product with the propellant gas.</td><td></td></tr>
<tr><td>Internal pressure</td><td>Quality control data: Internal pressures at 20°C and 50°C, measured with specific manometer</td><td>ACARDUST 400</td><td>
<table>
<tr><td>bars</td><td>20°C</td><td>50°C</td></tr>
<tr><td>14/06/16 – 16h38</td><td>5.00</td><td>9.40</td></tr>
<tr><td>14/06/16 – 18h06</td><td>5.40</td><td>9.60</td></tr>
<tr><td>14/06/16 – 18h54</td><td>5.20</td><td>9.60</td></tr>
<tr><td>14/06/16 – 19h54</td><td>5.00</td><td>9.60</td></tr>
<tr><td>15/06/16 – 5h44</td><td>5.00</td><td>9.60</td></tr>
<tr><td>15/06/16 – 6h46</td><td>5.00</td><td>9.60</td></tr>
<tr><td>15/06/16 – 8h37</td><td>5.00</td><td>9.60</td></tr>
</table>
Mean: 5.09 bars at 20°C
9.57 bars at 50°C

The acceptable quality control ranges are:
4.00-5.5 at 20°C
8.00-10.00 at 50°C</td><td>Acceptable range have been provided, with QC data (7 measures) and mean of the 7 measures

Acceptable

Only data have been provided for the product Arcadust 400.

No data has been provided for the product Arcadust 200.</td><td>AEROFARM, 2016 Study report Edition du 09/06/2016 – Lot H782

AEROFARM, 2013 Report QLT814/13</td></tr>
<tr><td>Net content of formulation</td><td>Quality control data: Net content of product</td><td>ACARDUST 400</td><td>
<table>
<tr><td>Weight (g)</td><td>liquid</td><td>propellant</td><td>Total</td></tr>
<tr><td>14/06/16 – 16h38</td><td>210. 97</td><td>140.00</td><td>350.97</td></tr>
<tr><td>14/06/16 – 18h06</td><td>211.39</td><td>141.4</td><td>352.79</td></tr>
<tr><td>14/06/16 – 18h54</td><td>211.43</td><td>140.59</td><td>352.02</td></tr>
</table></td><td>Acceptable range have been provided, with QC data (7 measures) and mean of the 7 measures
Acceptable

Only data have been provided for the product</td><td>AEROFARM, 2016 Study report Edition du 09/06/2016 – Lot H782

AEROFARM,</td></tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>
<table>
<tr><td>14/06/16 – 19h54</td><td>211.37</td><td>140.09</td><td>351.46</td></tr>
<tr><td>15/06/16 – 5h44</td><td>214.61</td><td>142.79</td><td>357.40</td></tr>
<tr><td>15/06/16 – 6h46</td><td>210.36</td><td>142.00</td><td>352.36</td></tr>
<tr><td>15/06/16 – 8h37</td><td>212.18</td><td>142.25</td><td>354.43</td></tr>
</table>
Mean total: 353.06g

The acceptable quality control range is: 339.52-360.48g
</td>
<td>Arcadust 400.

No data has been provided for the product Arcadust 200.</td>
<td>2013
Report
QLT814/13</td>
</tr>
<tr>
<td>Discharge rate</td>
<td>Quality control data measured on the aerosol can equipped with the valve and actuator at 20°C: The can containing the product is weighed (P1 in grams), then emptied by continuous spraying. The spraying time (t in seconds) is determined and the can is weighed again (P2 in grams). The discharge rate (d in grams/second) is calculated with the following equation: d = (P1 – P2) / t</td>
<td>ACARDUST 400</td>
<td>
<table>
<tr><td></td><td>Net weight (g)</td><td>Emptying time (s)</td><td>Discharge rate (g/s)</td></tr>
<tr><td>14/06/16 – 16h45</td><td>346.69</td><td>203</td><td>1.71</td></tr>
<tr><td>14/06/16 – 17h45</td><td>347.17</td><td>206</td><td>1.69</td></tr>
<tr><td>14/06/16 – 18h50</td><td>347.82</td><td>222</td><td>1.57</td></tr>
<tr><td>14/06/16 – 19h50</td><td>346.26</td><td>268</td><td>1.29</td></tr>
<tr><td>15/06/16 – 6h00</td><td>350.41</td><td>217</td><td>1.61</td></tr>
<tr><td>15/06/16 – 7h00</td><td>350.39</td><td>228</td><td>1.53</td></tr>
<tr><td>15/06/16 – 8h50</td><td>350.69</td><td>226</td><td>1.55</td></tr>
</table>
Mean: 1.56g/s
</td>
<td>QC data (7 measures) and mean of the 7 measures have been provided

Acceptable
However acceptable quality control range values should be provided for the discharge rate.

Only data have been provided for the product Arcadust 400.

Data from the accelerated storage stability have been used for the product Acardust 200 to calculate its discharge rate: results were provided for the spray volume during 5s, therefore a discharge rate has been calculated at 1.81g/s.</td>
<td>AEROFARM, 2016
Study report
Edition du 09/06/2016 – Lot H782

AEROFARM, 2013
Report
QLT814/13</td>
</tr>
<tr>
<td>Clogging of aerosol</td>
<td>Quality control data</td>
<td>ACARDUST 400</td>
<td>Satisfactory operation of the valve) is determined during the quality control</td>
<td>Acceptable</td>
<td>AEROFARM, 2016</td>
</tr>
</table>

dispenser valves			of the aerosol packaging containing Acardust	Only data have been provided for the product Arcadust 400. No data has been provided for the product Arcadust 200.	Study report Edition du 09/06/2016 – Lot H782 AEROFARM, 2013 Report QLT814/13

Conclusion on the physical, chemical and technical properties of the product
The formulation ARCADUST is an Aerosol (AE) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is an homogeneous limpid liquid colourless with a characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in aluminium can packaging material (commercial packaging material). The long term storage stability study is on-going. 2 year final results should be provided. After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C. Its technical characteristics are acceptable for an AE formulation. Quality control data have been provided for net content of formulation, internal pressure and discharge rate only for the product ARCADUST 400. Mean net content is 353.06g, mean internal pressure is 5.09 bars at 20°C and 9.57 bars at 50°C and the mean discharge rate is 1.56g/s. No data has been provided for the product ARCADUST 200. The liquid formulation is classified H304. As the product is a sealed aerosol, the liquid formulation is not intended to be available to be swallowed. Therefore the product ACARDUST should not be classified H304. The product should be stored at maximum 40°C.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR evaluation	Reference
Explosives	Statement	ACARDUST	The product is formulated as an aerosol. Thus, no explosive properties' test is required.	The justification is not acceptable. Further justification has been provided which is acceptable: active substance, co-formulants and propellant gas are not explosive therefore the product is not considered as explosive.	IUCLID
Flammable gases			No data provided.	Not relevant for an AE	
Flammable aerosols	Inflammation test according to Directive 2008/47	ACARDUST 200 Batch K053	Distance of inflammation higher than 15 cm. The product is flammable and is classified Flam. Aerosol 2, H223 according to Regulation (EC) No. 1272/2008.	Acceptable The product is classified Flam. Aerosol 2, H223	Walbrou C., Narcy B., 2010
Oxidising gases			No data provided.	Not relevant for an AE	
Gases under pressure			No data provided.	The product is classified H229	
Flammable liquids			No data provided.	Not relevant for an AE	
Flammable solids			No data provided.	Not relevant for an AE	
Self-reactive substances and mixtures			No data provided.		

Pyrophoric liquids	Statement	ACARDUST	Not required as experience in manufacture and handling shows that the product Acardust does not ignite spontaneously on coming into contact with air at normal temperature.		IUCLID
Pyrophoric solids			No data provided.	Not relevant for an AE	
Self-heating substances and mixtures			No data provided.		
Substances and mixtures which in contact with water emit flammable gases	Statement	ACARDUST	Not required as the product Acardust contains no ingredient classified as Water-react. 1 or Water-react. 2 according to Regulation (EC) No. 1272/2008 and as the chemical structures of the ingredients do not contain metals or metalloids.		IUCLID
Oxidising liquids	Statement	ACARDUST	Based on literature data and structure the active substance and the co-formulants are not expected to have oxidising properties	Acceptable	Detrimont H., Abrosi D., 2015
Oxidising solids			No data provided.	Not relevant for an AE	
Organic peroxides			No data provided.		
Corrosive to metals	Statement	ACARDUST	Not required as experience shows that the product Acardust is not corrosive to metals		
Auto-ignition temperatures of products (liquids and gases)	Statement	ACARDUST	Not required as the product Acardust is already classified as a flammable aerosol and no ingredient is considered to be auto-flammable based on available data found in literature.	Acceptable	IUCLID
Relative self-ignition temperature for solids			No data provided.	Not relevant for an AE	

Dust explosion hazard			No data provided.	Not relevant for an AE	

Conclusion on the physical hazards and respective characteristics of the product
The product is not explosive and has no oxidizing properties. The product is classified as flammable aerosol 2, H223 and H229.

2.2.4 Methods for detection and identification

Report: Ricau H. 2015 Validation of the analytical method for the determination of sumithrin (sum of isomers) in the liquid formulation of ACARDUST without the propellant gas
Report no 15-912035-005
Test facilities: DEFITRACES Z.A. des Andrés 150, rue Pré-Magne 69126 BRINDAS, France

Principle of the method:
The liquid formulation is dissolved in acetone and the sum of isomers is analysed by GC-FID by external standard calibration.
The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

<table>
<tr><td>Specificity</td><td colspan="2">To demonstrate the specificity of the method, several solution are analyzed:
- Solvent blank (acetone)
- Formulation blank
- Reference item of all isomers
- Test item of the product
No interference was found: no peak appears in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item.

The method is not stereoselective, the different isomers are not differentiated.</td></tr>
<tr><td rowspan="3">Linearity</td><td colspan="2">Linearity was studied by carrying out five concentrations between 50% and 150% of the reference item.
Calibration curve has been provided with a R^2 higher than 0.99.</td></tr>
<tr><td>Compound</td><td>Linearity %</td></tr>
<tr><td>all isomers</td><td>50% to 100%
$Y = 1.89.10^4 X - 1.8510^5$
$R^2 = 0.9964$
n=5</td></tr>
<tr><td rowspan="3">Precision</td><td colspan="2">Repeatability was evaluated by analyzing twice five test item solutions.</td></tr>
<tr><td>Compound</td><td>Repeatability (RSD)</td></tr>
<tr><td>all isomers</td><td>RSD = 0.84% < 2.85% (RSD calculated with modified equation of Horwitz)</td></tr>
<tr><td rowspan="3">Accuracy</td><td colspan="2">Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.</td></tr>
<tr><td>Compound</td><td>Accuracy (recovery)</td></tr>
<tr><td>all isomers</td><td>101.5%</td></tr>
</table>

The active substance is only the 1R-trans phenothrin. The analytical method allows the determination of the sum of the phenothrin isomers and not only the 1R-trans isomer.

A specific analytical method to determine the 1R-trans phenothrin content has been provided.

Report: Ricau H. 2016 Validation of the analytical method for the determination of 1R-trans phenothrin in the liquid formulation of ACARDUST without the propellant gas in compliance with SANCO/3030/99 rev.4 from 11/07/00
Report no 16-912035-001
Test facilities: DEFITRACES Z.A. des Andrés 150, rue Pré-Magne 69126 BRINDAS, France

Principle of the method:
A CIPAC method (356/TC/(M)/2 is available for the analysis of 1R-trans phenothrin in technical material:
The liquid formulation is dissolved in hexane and 1R-trans phenothrin is analysed by liquid chromatography with UV detector (HPLC-UV) with external standard calibration.

As it is a CIPAC method, partial validation data have been provided: specificity, accuracy and precision.
The reduced validation data of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

<table>
<tr><td>Specificity</td><td>To demonstrate the specificity of the method, several solution are analyzed:
- Solvent blank (hexane)
- Formulation blank
- Reference item
- Test item of the product
No interference was found: no peak appears in the solvent blank and in the formulation blank. 4 peaks are observed in the reference item and only 3 peaks are observed in test item:

<table><tr><td></td><td>Reference item</td><td>Test item</td></tr><tr><td>1R-cis phenothrin</td><td>29.259min</td><td>30.601min</td></tr><tr><td>1S-cis phenothrin</td><td>31.472min</td><td></td></tr><tr><td>1R-trans phenothrin</td><td>34.544min</td><td>36.261min</td></tr><tr><td>1S-trans phenothrin</td><td>36.509min</td><td>38.398min</td></tr></table>
No additional peak in the reference and test item.</td></tr>
<tr><td rowspan="3">Accuracy</td><td>Accuracy was determined by analysis of 2 reconstituted samples in comparison with reference item. The accuracy results are expressed as the recovery rate.</td></tr>
<tr><td><table><tr><td>Compound</td><td>Accuracy (recovery)</td></tr><tr><td>1R-trans phenothrin</td><td>99.2%</td></tr></table></td></tr>
<tr><td></td></tr>
<tr><td rowspan="3">Precision</td><td>Repeatability was evaluated by analyzing twice five test item solutions.</td></tr>
<tr><td><table><tr><td>Compound</td><td>Repeatability (RSD)</td></tr></table></td></tr>
<tr><td></td></tr>
</table>

	1R-trans phenothrin	RSD = 0.29% < 2.86% (RSD calculated with modified equation of Horwitz)

Analytical methods for 1R-trans phenothrin residues in soil, air, water (drinking water) and sediment are available in Assessment Report 1R-trans phenothrin Product-type 18 (insecticides), (Mars 2013) and additional document (May 2016). The applicant Laboratoires Omega Pharma France have a Letter of Access from Sumitomo for these data.

As the active substance 1R-trans phenothrin is not classified Toxic or Very Toxic, an analytical method for the determination of 1R-trans phenothrin residue in human body fluids and tissues is unnecessary.

As the product ACARDUST is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of 1R-trans phenothrin residue in food/feed of plant and animal origin is unnecessary.

Conclusion on the methods for detection and identification of the product
Analytical methods have been provided for the determination of the active substance in the product: one for the sum of the phenothrin isomers and one for the 1R-trans isomer. Analytical methods were provided at EU level for the determination of the sum of isomers residue in soil, water and air with respectively LOQ = 0.01mg/kg, 0.001 mg/m^3 and 0.1µg/L. 1R-trans phenothrin is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required. The product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of 1R-trans phenothrin residue in food/feed of plant and animal origin is not required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main Group 03: Pest Control
Product Type 18: Insecticides, acaricides and products to control other arthropods.

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

The product ACARDUST (0.37 % w/w 1R-trans phenothrin) is a ready-for-use acaricide product for direct and indirect surface treatment against house dust mites (*Dermatophagoïdes pteronyssinus*). According to the applicant, the product is an aerosol applied at a rate of 12.5 g aerosol / m^2 corresponding to 7 seconds of spraying per m^2. It is intended to be used by non-professionals, indoors, mainly in bedrooms. The product ACARDUST is intended to be used for the curative treatment of bedrooms (mattress, bed base, armchairs, carpets...) against all developmental stages (eggs, larvae, adults) of

house dust mites. No residual efficacy is claimed and vacuum cleaning is recommended a few hours after application, to remove dead mites and residual product.

ACARDUST is packaged either as ACARDUST 200, which is used to treat surfaces directly, or as ACARDUST 400, which is used to treat surfaces directly or indirectly by space spraying.

The product is used for the purpose of the protection of human health.

2.2.5.3 Effects on target organisms, including unacceptable suffering

As described in the Assessment Report, 1R-trans phenothrin acts on harmful organisms by contact and ingestion. Target insects are knocked down and killed upon contact with the active ingredient.

2.2.5.4 Mode of action, including time delay

The active substance 1,R-trans phenothrin is a pyrethroid insecticide and acaricide. It 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 and mites will die (1R-trans phenothrin PT18 Assessment Report, March 2013).
In the IRAC (Insecticide Resistance Action Committee[3]) mode of action, 1,R-trans phenothrin belongs to Group 3 (sodium channel modulators), sub-group 3A (pyrethroids and pyrethrins).

The submitted laboratory studies only permits to conclude that mortality occurs within 24 hours.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT 18	Acaricide Direct surface spraying Indoor application	ACARDUST 200 1,R-trans phenothrin 0.37% w/w	*Dermatophagoides pteronyssinus* (house dust mites) Approx. 50 mites per replicate, 10 adults of mixed sex, various nymphal stages (30) and 10 eggs.	Laboratory test The mites were laid on the surfaces 1 hour pre-treatment. Application: direct spraying on the surfaces. After spraying treatment, the mites were kept on the surfaces for 14 days. Mortality of the mites was evaluated after 1, 2, 3, 5, 7 and 14 days of exposure. For each surface and each treatment (test product / untreated control), 5 replicates.	Temperature: 24-25°C Relative humidity: 65-66% Light cycles during test: darkness Nutrient supply: yes, dry fish food Application rate: 12.5 g aerosol/m2 (average 0.31 g aerosol / surface). Surfaces: 225 cm² (15*15 cm), of glazed tile (non-porous), mattress fabric and plywood (porous).	On all the treated surfaces, the mites were killed after 1 day exposure, with no recuperation within the 14 days test period. On the untreated control surfaces, no mortality was observed. The laboratory confirmed that this test doesn't permit to conclude on an ovocidal activity. It has to be noted that no raw data have been submitted.	Radecki C., 2015 RI=2
PT 18	Acaricide Space spraying (indirect surface spraying) Indoor application	ACARDUST 400 1,R-trans phenothrin 0.37% w/w	*Dermatophagoides pteronyssinus* (house dust mites) Approx. 50 mites per replicate, 10 adults of mixed sex, 30 various nymphal stages and 10 eggs.	Laboratory test The mites were laid on the surfaces 1 hour pre-treatment. Application: space spraying from the bottom to the top of a 20 m^3 test chamber with the surfaces laid on the floor. After spraying treatment, 3 hours incubation in the test chamber. Then the mites were kept on the surfaces for 14 days. Mortality of the mites was evaluated after 1, 2, 3, 5, 7 and 14 days of	Temperature: 25-26°C Relative humidity: 64-66% Light cycles during test: darkness Nutrient supply: yes, dry fish food. Application rate: 12.5 g aerosol/m2 of floor (93.8 g aerosol / 20 m^3 test chamber with a 7.5 m² floor). Surfaces: 225 cm² (15*15 cm), of glazed tile (non-porous), mattress fabric and plywood (porous).	On all the treated surfaces, the mites were killed after 1 day exposure, with no recuperation within the 14 days test period. On the untreated control surfaces, no mortality was observed. The laboratory confirmed that this test doesn't permit to conclude on an ovocidal activity. It has to be noted that no raw data have been	Radecki C., 2015 RI=2

				exposure. For each surface and each treatment (test product/untreated control), 5 replicates.		submitted.	
PT 18	Acaricide Direct surface spraying Indoor application	ACARDUST 200 1,R-trans phenothrin 0.37% w/w	*Dermatophagoides pteronyssinus* (house dust mites) Approx. 50 mites per replicate, mixed population of age and sex.	Laboratory test The mites were laid on the surfaces 1 hour pre-treatment. Application: direct spraying on the surfaces. After spraying treatment, the mites were kept on the surfaces for 7 days. Mortality of the mites was evaluated after 1, 3, 5, 7 hours and daily 1 up to 7 days after exposure. For each surface and each treatment (test product / untreated control), 5 replicates.	Temperature: 25°C Relative humidity: 61-64% Light cycles during test: darkness Nutrient supply: yes, dry fish food Application rate: 12.5 g aerosol/m2 (average 0.28 g aerosol / surface). Surfaces: 225 cm² (15*15 cm), of fabric (100% new wool, hidden black herring bone, approx. 255 g/ running metre) and plywood (porous). The tiles were covered with an aluminium foil with a centre part (Ø 6 cm) uncovered. The mites were exposed on the uncovered centre part of the surfaces 1 hour before treatment. Directly after treatment the aluminium foil was removed and a glass ring (Ø 9.5 cm) prepared with talcum placed around the centre part to prevent mites from escaping. Mites had the possibility to enter an untreated area in a width of 1.75 cm.	Percentage of mortality: Plywood: 1h => 51% 3h => 61% 5h => 79% 7h => 84% 1 to 7 days => 100% Fabric: 1h => 35% 3h => 49% 5h => 66% 7h => 71% 1 day => 98% 2 to 7 days => 100% No mortality has been recorded in the controls.	Werner L., 2017 RI=2

PT 18	Acaricide Space spraying (indirect surface spraying) Indoor application	ACARDUST 400 1,R-trans phenothrin 0.37% w/w	*Dermatophagoides pteronyssinus* (house dust mites) Approx. 50 mites per replicate, mixed population of age and sex.	Laboratory test The mites were laid on the surfaces 1 hour pre-treatment. Application: indirect spraying on the surfaces. The treatment was conducted in a 20 m^3 chamber with a floor area of 7.5 m², where the surfaces to be treated have been positioned on the bottom, horizontally and semi-vertically (at 45°) in 1 metre and 2 metres height. The spray can was positioned in the centre of the room on the bottom. Incubation time: 3 hours After spraying treatment, the mites were kept on the surfaces for 7 days. Mortality of the mites was evaluated after 3, 5, 7 hours and daily 1 up to 7 days after exposure. For each surface and each treatment (test product / untreated control), 5 replicates.	Temperature: 24-27°C Relative humidity: 47-52% Light cycles during test: darkness with a little day light. Nutrient supply: yes, dry fish food Application rate: 93.8 g i.e. 4.69 g / m^3 and 12.5 g/m². Surfaces: 225 cm² (15*15 cm), of fabric (100% new wool, hidden black herring bone, approx. 255 g/ running metre) and plywood (porous). The tiles were covered with an aluminium foil with a centre part (Ø 6 cm) uncovered. The mites were exposed on the uncovered centre part of the surfaces 1 hour before treatment. 3 hours after treatment the aluminium foil was removed and a glass ring (Ø 9.5 cm) prepared with talcum placed around the centre part to prevent mites from escaping. Mites had the possibility to enter an untreated area in a width of 1.75 cm.	Percentage of mortality: **Plywood:** *Bottom* 3h => 52% 5h => 84% 7h => 84% 1 day => 98% 2 to 7 days => 100% *1 metre height* 3h => 74% 5h => 88% 7h => 88% 1 to 7 days => 100% *2 metres height* 3h => 72% 5h => 92% 7h => 92% 1 to 7 days => 100% **Fabric:** *Bottom* 3h => 38% 5h => 56% 7h => 60% 1 day => 91% 2 days => 98% 3 to 7 days => 100% *1 metre height* 3h => 72% 5h => 74% 7h => 76% 1 day => 97% 2 to 7 days => 100% *2 metres height*	Werner L., 2017 RI=2

						3h => 70% 5h => 70% 7h => 70% 1 day => 93% 2 days => 94% 3 days => 94% 4 to 7 days => 100% No mortality has been recorded in the controls.	

Submitted efficacy data are not compliant with the requirements of the TNsG PT18/19 (2012). Indeed, part 8.2.3 of the TNsG on PT18 and PT19 products efficacy[2], mentions "When specific mite species are mentioned in the claim (e.g. dust mite, red mite) both laboratory and simulated-use tests are required with target species".
The submitted studies cannot be considered as simulated-use tests but only as laboratory tests. Indeed, when products for general surface treatment are tested, mites must have a choice to be in contact with the biocide or not. This is not the case in these studies; mites were forced to be contact with the product. Furthermore, instructions of use have not been reproduced in these tests and contact time is not consistent with the claim (mortality is not systematically complete 24H after application).
Concerning space treatment, no data has been provided on product dispersion. Since the product is intended to treat a whole room it should be demonstrated that the claimed application rate of 12.5 g/m² is really spread on the entire treated surface (horizontal, vertical) and the provided test doesn't permit to conclude on this. Furthermore, it is questionable if the type of fabric used in these tests is sufficiently representative (100% new wool, hidden black herring bone, approx. 255 g/ running metre).

Two new simulated-use tests have been provided by the applicant (Werner L, 2017a, Werner L. 2017b). Methodological biases have been noted in these tests. In particular, it seems that the product is applied directly on the mites. Even if after the treatment the mites have access to an untreated part of the surface, they are already recovered with the product. Considering the provided data set, a direct spraying of the product ACARDUST leads to 100% mortality within maximum 4 days with a restriction on the developmental stage (only adults and nymphs of *D. pteronyssinus*). According to the TNsG (Appendix 1), contact (direct) spray treatments are normally only possible when the target organisms are visible and available to be sprayed, which is not the case of house dust mites.

Conclusion on the efficacy of the product
In conclusion, in accordance with the requirements of the TNsG on PT18/19, French competent authorities (FR CA) consider that the elements presented in the dossier allow to demonstrate the efficacy of the product ARCADUST against House dust mites (*Dermatophagoïdes pteronyssinus*) when applied directly on the target organisms.

2.2.5.6 Occurrence of resistance and resistance management

1,R-trans phenothrin 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.
No specific references concerning resistance of house dust mites to 1,R-trans phenothrin have been found in the literature.
To delay the development of resistance:
- Integrate other control measures such as frequent aeration of the bedrooms, avoidance of fabric furnishings and fitted carpet.
- Avoid exclusive repeated use of insecticides from the same chemical subgroup (IRAC subgroup 3A, pyrethrins and pyrethroids for 1,R-trans phenothrin).
- Alternate with products from other IRAC mode of action groups.

[2] PT18 and PT 19, Draft guidance to replace part of appendices to chapter 7 (page 187 to 200) from TNsG on Product Evaluation

2.2.5.7 Known limitations

None

2.2.5.8 Evaluation of the label claims

French competent authorities (FR CA) consider that the elements presented in the dossier are not sufficient to demonstrate the efficacy of the product ARCADUST against House dust mites (*Dermatophagoïdes pteronyssinus*).

French competent authorities (FR CA) consider that efficacy of the product ACARDUST against House dust mites (*Dermatophagoïdes pteronyssinus*), adults, nymphs and larvae, has been demonstrated when the product is applied directly on target organisms. Application rate is 12.5 g/m². The delay of action is 24 to 48 hrs depending on the type of treated surface.

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

According to the applicant, the product ACARDUST can be used on surfaces already treated against house dust mites (e.g. mattresses) by other products or methods, but no robust data have been submitted to justify the compatibility of treatments between them.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

In order to avoid unnecessary testing, especially on vertebrates, justification on non-submission of data is provided for skin and eye irritation, skin sensitisation acute oral, dermal and inhalation toxicity.
According to the detailed composition and the MSDS of each component, the product ACARDUST is not classified for acute toxicological properties (see Section 12 and Section 13 of the IUCLID file).

Skin corrosion and irritation
No skin irritation/corrosion study was conducted. Classification is based on the available data on each component (see Section 12 of the IUCLID file).

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	According to the composition, none of the component is toxicologically relevant for skin irritation or corrosion.
Classification of the product according to CLP	Not classified

Eye irritation
No eye irritation/corrosion study was conducted. Classification is based on the available data on each component (see Section 12 of the IUCLID file).

Conclusion used in Risk Assessment – Eye irritation

Value/conclusion	According to the composition, none of the component is toxicologically relevant for eye irritation or corrosion.
Classification of the product according to CLP	Not classified

Respiratory tract irritation
No study of respiratory tract irritation is available. Classification is based on the available data on each component Classification is based on the available data on each component Classification is based on the available data on each component Classification is estimated based on the available data on the components Classification is based on the available data on each component.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Classification of the product according to CLP	Not classified

Skin sensitization
Skin sensitization study was not conducted. Classification is based on the available data on each component (see Section 12 of the IUCLID file).

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	According to the composition, none of the component is toxicologically relevant for skin sensitisation.
Classification of the product according to CLP	Not classified

Respiratory sensitization (ADS)
No study of respiratory tract sensitisation is available (see Section 12 of the IUCLID file). Classification is based on the available data on each component.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	According to the composition, none of the component is toxicologically relevant for respiratory sensitisation.
Classification of the product according to CLP	Not classified

Acute toxicity
No acute toxicity studies were conducted. Classification is based on the available data on each component (oral, inhalation and dermal route) (see Section 12 of the IUCLID file).

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	According to the composition, none of the component is

	toxicologically relevant for acute oral toxicity.
Classification of the product according to CLP	Not classified

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	According to the composition, none of the component is toxicologically relevant for acute toxicity by inhalation.
Classification of the product according to CLP	Not classified

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	According to the composition, none of the component is toxicologically relevant for acute dermal toxicity.
Classification of the product according to CLP	Not classified

Based on the available data, the product ACARDUST is classified according to CLP Regulation:

- Asp. Tox. 1 H304: May be fatal if swallowed and enters airways.
- EUH 066: Repeated exposure may cause skin dryness or cracking.

Information on dermal absorption

As defined in the EFSA guidance on dermal absorption (2012), if a product or in use dilutions contains ≤ 5 % of active substance, a default dermal absorption value of 75 % should be used. Also, if oral absorption is < 75 %, this can be used as a surrogate dermal absorption value.
According to the Assessment Report of 1R-trans phenothrin (March 2013), the oral absorption is 60%. Therefore, 60 % can be used as the default dermal absorption value for 1R-trans phenothrin.

Moreover, according to the 1R-trans phenothrin Assessment Report (March 2013), a dermal absorption value of 4.5 % is defined for a nominal 1 % w/v formulation in ethanol with an in vitro study, through human epidermis. It is mentioned that this value deems appropriate for higher concentration (5.25 %) products and lower concentration products (0.04 %).

As the product ACARDUST contains 1R-trans phenothrin with similar solvent (isododecane, a non-aqueous based solvent,) the read across with the 1% formulation in ethanol is acceptable. Therefore, a dermal absorption of 4.5 % for the active substance will be used for human risk assessment of ACARDUST.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	1R-trans phenothrin
Value(s)	4.5 %
Justification for the	After evaporation of propellant, ACARDUST is composed

selected value(s)	essentially of 1R-trans phenothrin and solvent. Therefore, a read across for dermal absorption with a formulation of 1R-trans phenothrin in ethanol is acceptable. As it is mentioned in the CAR that the dermal absorption value is appropriate for lower concentration products (0.04 %), the value of 4.5 % proposed in the CAR is used without correction.

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

ACARDUST contains isododecane which classifies the product Aspiration hazard cat. 1
H304 May be fatal if swallowed and enters airways and EUH 066 Repeated exposure may cause skin dryness or cracking.

2.2.6.2 Exposure assessment

ACARDUST is a ready-for-use used by non-professionals indoor, mainly in bedrooms, as an acaricide product for direct and indirect surface treatment. The product is applied by spray application at the dose of 12.5 g aerosol/m². Direct application can be done up to 4 times per year and spatial application can be done up to twice a year. It is intended to be used for the curative treatment of bedrooms (mattress, bed base, armchairs, carpets...) against house dust mites.
It is presented as aerosol cans and the intended uses are surface and air space spraying. As exposure is intended to be higher for air space application than for surface application (according to the orientation of the can), air space application is considered as the worst-case scenario. Also, it is assumed as a worst case that the applicator stays in the room during the application and that all the product deposits on the entire surface of the room.
Human exposure of indoor non-professional use is assessed using the consumer exposure model ConsExpo 5.0.

Inhalation and dermal exposure:
These routes are the main route of exposure for primary exposure, as the uses of ACARDUST are surface and air space spraying.
For secondary exposure, these routes of exposure are also considered.

Oral exposure:
Oral exposure to ACARDUST can be expected for secondary exposure.

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Air space and surface application	**Primary exposure, inhalation and dermal** Human exposure of indoor amateur use is assessed using the consumer exposure model ConsExpo 5.0 Air space application considered as the worst-case scenario and covers the surface application. As a worst case it is considered that the person stays in the room during spraying.	Non-professional
2.	Exposure to volatile residue	**Secondary exposure, inhalation** In the post-application phase, inhalation exposure of volatile residues is assessed for adults, children and toddlers.	Non-professional (Adults and children)
3.	Exposure of children who crawl on treated surface with a hand to mouth transfer	**Secondary exposure, dermal and oral** In the post-application phase, children can be exposed, due to their specific time-activity pattern: crawling on treated surface and hand to mouth contact.	Non-professional (Children)
4.	Exposure of adults touching a treated surface	**Secondary exposure, dermal** In the post-application phase, the treated surfaces can be accidentally touched by an adult with its hands.	Non-professional (Adults)
5.	Exposure of adults, children and toddlers who sleep in a treated bed	**Secondary exposure, dermal** In the post-application phase, adults, children and toddlers could be exposed during sleeping in a treated bed.	Non-professional (Adults and children)

Industrial exposure

No industrial exposure is foreseen. ACARDUST is an acaricide product for direct and indirect surface treatment. It is used by non-professionals indoors, mainly in bedrooms. Therefore the assessment of industrial exposure is not relevant.

Professional exposure

No professional exposure is foreseen. ACARDUST is an acaricide product for direct and indirect surface treatment. It is used by non-professionals indoors, mainly in bedrooms. Therefore the assessment of professional exposure is not relevant.

Non-professional exposure

Scenario [1] Air space application: Inhalation and dermal models

Description of Scenario [1]			
Exposure of air space application is considered as the worst-case scenario and covers surface applications. Exposure is calculated using ConsExpo 5.0 model, with the pest control products/sprays/air space/application scenario. This scenario is based on a private user who sprays with an aerosol can in the living room to control flies or mosquitoes. Default values are proposed by ConsExpo.			
	Parameters	Value	Reference
Inhalation model: Exposure to spray : spraying			
Tier 1	Weight fraction compound (%)	0.4	Applicant data
	Exposure duration (minutes)	240	It is assumed that the user stays in the treated room for 4 hours after the application
	Room volume (m^3)	58	Default value proposed by ConsExpo for a living room
	Room height (m)	2.5	It corresponds also to the values of room surface and volume from the General Product fact sheet (2014)
	Ventilation rate (1/hour)	0.5	Default value proposed for a middle ventilation rate (General Product fact sheet (2014), page 31/102)
	Mass generation rate (g product/sec)	1.56	Mean value for Acardust 400 (no data for Acardust 200)
	Spray duration (seconds)	186	Considering as a default the entire surface of the room is treated (23.2 m^2), and with an application rate of 12.5 g product/m^2 with 1.56 g of product released in 1 second, the spray duration is 186 seconds (23.2 m^2 * 12.5 g/m^2 / 1.56 g/s)
	Airborne fraction	30%	Default value for the spray model ("air space, spray can" value), RIVM, March 2010.
	Weight fraction non-volatile (%)	60%	The aerosol can contains 60% of liquid and 40% of propellant (volatile)
	Density non-volatile (g/cm^3)	0.75	Density of the active substance (after evaporation)
	Inhalation cut-off diameter (µm)	15	Default value proposed by ConsExpo

	Non-respirable uptake fraction (oral uptake fraction) (%)	60%	CAR 1R-trans phenothrin (AR, 2013)
	Uptake fraction	100%	Default value
	Inhalation rate (m^3/hour)	1.25	HEEG opinion No. 17, 2013
Dermal model: Direct dermal contact with product: constant rate			
Tier 1	Weight fraction compound	0.4%	Applicant data
	Contact rate (mg/minutes)	270	Default value proposed by ConsExpo
	Release duration (seconds)	186	Equal to spray duration
	Dermal absorption (DA) (%)	4.5%	CAR 1R-trans phenothrin (AR, 2013)

Calculations for Scenario [1]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake (*via* inhalation exposure)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1] Air space	1	$5.3*10^{-3}$	$1.9*10^{-3}$	$3.4*10^{-3}$	$1.1*10^{-2}$

Further information and considerations on scenario [1]
None.

Exposure of the general public

Scenario [2] Exposure to volatile residue

Description of Scenario [2]			
The assessment was realised according to the HEEG opinion 13 "Assessment of inhalation exposure of volatilised biocides active substance".			
	Parameters	**Value**	**Reference**
Tier 1	Vapour pressure (Pa)	$2.4*10^{-5}$	CAR 1R-trans phenothrin (AR, 2013)
	Molecular weight (g/mol)	350	CAR 1R-trans phenothrin (AR, 2013)
	Inhalation rate (m^3/24h)	16 (adults) 12 (children) 5.4 (toddler)	HEEG opinion No. 17, 2013
	Saturated vapour concentration (SVC) (mg/m^3)	$3.45*10^{-3}$	HEEG opinion 13, 2011

	Body weight (kg)	60 (adults) 23.9 (children) 10 (toddler)	HEEG opinion No. 17, 2013

Calculations for Scenario [2]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2] **Adults**	1	$9.2*10^{-4}$	n.a.	n.a.	$9.2*10^{-4}$
Scenario [2] **Children**	1	$1.7*10^{-3}$	n.a.	n.a.	$1.7*10^{-3}$
Scenario [2] **Toddler**	1	$1.9*10^{-3}$	n.a.	n.a.	$1.9*10^{-3}$

Further information and considerations on scenario [2]
None.

Scenario [3] Exposure of toddler who crawls on treated surface with a hand to mouth transfer

Description of Scenario [3]
In the post-application phase, toddlers can be exposed, due to their specific time-activity pattern (crawling on treated surface, hand to mouth contact and relatively low body weight). This exposure was estimated based on the approach proposed in ConsExpo fact sheet "Cleaning products". ConsExpo software was not used for the calculation. Dermal exposure of toddlers can take place on any uncovered skin, that is: the head, the arms and hands, and on the legs and feet. According to ConsExpo and the Ad hoc Recommendation 12, the transfer coefficient of 0.21 m^2/h will be used. From this surface a fraction of active substance is dislodgeable: - For dried surface, the value of 30 % proposed in TNsG and ConsExpo will be used (Tier 1). - For carpets, the value of 9% proposed in TNsG will be used (Tier 2). If dermal exposure of children occurs, they can also be exposed orally via hand–mouth contact. The hands form about 20 % of the total uncovered skin. It is assumed that 50 % of the product that ends up on the hands is taken in orally (ConsExpo: Pest control Fact Sheet). This means that via hand-mouth contact 10 % of the calculated external dermal exposure is ingested and that the internal dermal exposure is 90 % of the calculated external dermal exposure.

	Parameters	**Value**	**Reference**
Tier	Application rate (g product/m²)	12.5	Applicant data

1 and 21	Concentration of active substance (% w/w)	0.7%	Concentration of active substance after spraying and evaporation of propellant
	Dislodgeable fraction from floor to skin (dried impervious surface) (Tier 1)	30%	TNsG
	Dislodgeable fraction from floor to skin (carpet) (Tier 2)	9%	TNsG
	Transfer coefficient (m²/hr)	0.21	2,100 cm²/hr for children from 1 to 2 years old (75th percentile) Ad hoc Working group on Human Exposure Recommendation 12
	Duration of crawling (hr)	1	Default value proposed by ConsExpo
	Hand to mouth transfer	10%	Default value proposed by ConsExpo
	Amount on skin	90%	Default value proposed by ConsExpo
	Dermal absorption (%)	4.5%	CAR 1R-trans phenothrin (AR, 2013)
	Oral absorption (%)	60%	CAR 1R-trans phenothrin (AR, 2013)
	Body weight (kg)	10 (toddler)	HEEG opinion No. 17, 2013

Calculations for Scenario [3]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3] **toddler Dried impervious surface**	1	n.a.	$2.2*10^{-2}$	$3.3*10^{-2}$	$5.5*10^{-2}$
Scenario [3] **toddler Carpet**	2	n.a.	$6.7*10^{-2}$	$9.9*10^{-2}$	$1.7*10^{-2}$

Further information and considerations on scenario [3]
None.

Scenario [4] Exposure of adults touching a treated surface

Description of Scenario [4]			
In the post-application phase, an adult can be exposed if he touches a treated surface (wet or dried) with its hands (palms of both hands). From this surface a fraction of active substance is dislodgeable: - For wet surface, the value of 100 % (default value) will be used (Tier 1). - For dried surface, the value of 30 % proposed in TNsG will be used (Tier 2).			
	Parameters	**Value**	**Reference**
Tier 1 and 2	Application rate (g product/m²)	12.5	Applicant data
	Surface in contact with treated surface (palm of two hands) (cm²)	410	HEEG opinion No. 17, 2013
	Dislodgeable fraction from floor to skin (wet) (Tier 1)	100%	Default value
	Dislodgeable fraction from floor to skin (dried) (Tier 2)	30%	TNsG
	Dermal absorption (%)	4.5%	CAR 1R-trans phenothrin (AR, 2013)
	Body weight (kg)	60 (adults)	HEEG opinion No. 17, 2013

Calculations for Scenario [4]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4] **Adults Wet**	1	n.a.	$2.7*10^{-3}$	n.a.	$2.7*10^{-3}$
Scenario [4] **Adults Dried**	2	n.a.	$8.1*10^{-4}$	n.a.	$8.1*10^{-4}$

Further information and considerations on scenario [4]
None.

Scenario [5] Exposure of adults, children and toddlers who sleep in a treated bed

Description of Scenario [5]

Adults, children and toddlers could be exposed during sleeping in a treated bed. In order to determine the exposure, as a worst case it is considered that they sleep naked and all the surface body can be exposed. The surface body used were determined according to the HEEG opinion 17. The body will not be in direct contact with bed, as there are sheets. In this context, a protection factor of 50 % is considered (Ad hoc Working group on Human Exposure Recommendation 8). From this surface a fraction of active substance is dislodgeable: - For dried surface, the value of 30 % proposed in TNsG for dried surface will be used.			
	Parameters	**Value**	**Reference**
Tier 1	Application rate (g product/m²)	12.5	Applicant data
	Concentration of active substance (% w/w)	0.7%	Concentration of active substance after spraying and evaporation of propellant
	Body area in contact with bed (cm²)	16600 (adults) 9200 (children) 4800 (toddler)	HEEG opinion No. 17, 2013
	Protection factor (sheet)	50%	Ad hoc Working group on Human Exposure Recommendation 8
	Dislodgeable fraction from sheets to skin	30%	30% for dried surface (TNsG)
	Dermal absorption (%)	4.5%	CAR 1R-trans phenothrin (AR, 2013)
	Body weight (kg)	60 (adults) 23.9 (children) 10 (toddler)	HEEG opinion No. 17, 2013

Calculations for Scenario [5]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [5] **Adults**	1	n.a.	$1.6*10^{-2}$	n.a	$1.6*10^{-2}$
Scenario [5] **Children**	1	n.a.	$2.3*10^{-2}$	n.a.	$2.3*10^{-2}$
Scenario [5] **Toddler**	1	n.a.	$2.8*10^{-2}$	n.a.	$2.8*10^{-2}$

Further information and considerations on scenario [5]
None.

Monitoring data
None.

Dietary exposure

The product ACARDUST is intended for indoor spraying on surface or coupled to spraying on space use by non-professional in households and private areas (mainly bedrooms). No specific residue data were submitted in the context of this dossier.
As regards the intended use of the product ACARDUST mainly in bedrooms, no direct or indirect contamination of food is expected.
No specific residue data were submitted in the context of this dossier. Nevertheless to avoid any contamination, the following precautionary statement should be indicated on the labels:
"Avoid any direct or indirect contact with food and feed."
List of scenarios

Not relevant.

Information of non-biocidal use of the active substance

Not relevant.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not relevant.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	Developmental study in rabbit	30 mg/kg bw/day	100	60%	0.18 mg/kg bw
AELmedium-term and long-term	52 week study in dog	8.2 mg/kg bw/day	100	60%	0.05 mg/kg bw
ARfD	Developmental study in rabbit	30 mg/kg bw/day	100	-	0.3 mg/kg bw/d
ADI	52 week study in dog	8.2 mg/kg bw/day	100	-	0.08 mg/kg bw/d

[1] 10 x 10 for intra and inter species.

Maximum residue limits or equivalent
Not relevant.

Risk for industrial users
No exposure is foreseen.

Risk for professional users
No exposure is foreseen.

Risk for non-professional users
Considering that application can be done up to 4 times per year, every 3 months (direct application) added to 2 times per year, every 6 months (spatial application), exposure is compared to AEL medium / long term.

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [1] Primary non-professional exposure Air space and surface application	1	8.2	0.05	$1.1*10^{-2}$	22%	Yes

Risk is assessed considering that the person stays in the room during application and after application. However, the applicant recommends:

- To leave the room for at least one hour after surface application AND
- To leave the room for 3 hours after automatic diffusion

Applicant recommends also not combining direct spraying and automatic spraying in the same day.

Combined scenarios
No combined exposure is foreseen.

Local effects
No need to consider local effects separately.

Conclusion
There is acceptable risk for non-professional users when applying the product ACARDUST.

Risk for the general public

Systemic effects: 1 application

Task/ Scenario		Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
Scenario [2] exposure to volatile residues	**Adults**	1	8.2	0.05	$9.2*10^{-4}$	1.8 %	Yes
	Children	1	8.2	0.05	$1.7*10^{-3}$	3.5 %	Yes
	Toddler	1	8.2	0.05	$1.9*10^{-3}$	3.7 %	Yes
Scenario [3] child crawling on treated surface	**Toddler**	1	8.2	0.05	$5.5*10^{-2}$	**111 %**	**No**
	Toddler	2	8.2	0.05	$1.66*10^{-2}$	33 %	Yes
Scenario [4] adult touching treated surface	**Adults**	1	8.2	0.05	$2.7*10^{-3}$	5.4 %	Yes
	Adults	2	8.2	0.05	$8.1*10^{-4}$	1.6 %	Yes
Scenario [5] person sleeping in treated bed	**Adults**	1	8.2	0.05	$1.6*10^{-2}$	33 %	Yes
	Children	1	8.2	0.05	$2.3*10^{-2}$	45 %	Yes
	Toddler	1	8.2	0.05	$2.8*10^{-2}$	57 %	Yes

Considering one application, the risk linked to secondary exposure is acceptable except for toddler who crawls on impervious treated surface. Therefore a mitigation measure is needed:

- Do not apply on impervious surfaces.

Combined scenarios
Combined scenarii are considered for treatment done by an adult who can also be exposed to volatile residues, by touching treated surface and by sleeping in treated bed.

Considering that a bottle of ACARDUST 400 can be used for spraying on air space and spraying on surfaces, the risk linked to two applications for secondary exposure is estimated for contact with treated surfaces and bed. Combined scenarii are also considered for children and toddlers.

Combined exposures are summarised in the following tables for adults, children and toddlers:

Adults (after 2 applications):

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
Scenario [1] Primary non-professional exposure Air space and surface application*	1	8.2	0.05	$1.1*10^{-2}$	22%	Yes
Scenario [2] exposure to volatile residues	1	8.2	0.05	9.2*10-^{4}	1.8 %	Yes
Scenario [4] adult touching treated surface (wet)	1	8.2	0.05	5.4*10-^{3}	10.8 %	Yes
Scenario [4] adult touching treated surface (dry)	2	8.2	0.05	1.6*10-^{3}	3.2 %	Yes
Scenario [5] person sleeping in treated bed	1	8.2	0.05	3.3*10-^{2}	65.4 %	Yes
Total (Scenario 4 Tier 1)	1	8.2	0.05	5.*10-^{2}	**100 %**	**No**
Total (Scenario 4 Tier 2)	2	8.2	0.05	4.7*10-^{2}	92.4 %	Yes

*As the applicant recommends to not combining direct spraying and automatic spraying in the same day, no combined exposure for application is estimated**.**

The risk for scenario 4 tier 1 is unacceptable. The risk for scenario 4 tier 2 is acceptable. Therefore, a mitigation measure to not touch wet treated surface is needed:

- Do not touch treated surface when it is wet.

Children (after 2 applications):

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
Scenario [2] exposure to volatile residues	1	8.2	0.05	1.7*10-^{3}	3.5 %	Yes
Scenario [5] child sleeping in treated bed	1	8.2	0.05	4.6*10-^{2}	91 %	Yes

Total	1	8.2	0.05	$4.7*10^{-2}$	94 %	Yes

The combined risk assessment is acceptable.

Toddler (after 2 applications):

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
Scenario [2] exposure to volatile residues	1	8.2	0.05	$1.9*10^{-3}$	3.7 %	Yes
Scenario [3] toddler crawling on treated surface (carpet)	2	8.2	0.05	$3.3*10^{-2}$	66.5 %	Yes
Scenario [5] toddler sleeping in treated bed	1	8.2	0.05	$5.7*10^{-2}$	**113 %**	**No**
Total		8.2	0.05	$9.18*10^{-2}$	**184 %**	**No**

The risk for toddler who sleeps in a bed which has been treated by air space spraying and surface spraying is unacceptable. Therefore, a mitigation measure is needed to exclude the combined application in a toddler room:

- Do not apply combined treatment (air space spraying **and** surface spraying) in toddler rooms (children less than two years old).

Toddler (after 1 application):

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
Scenario [2] exposure to volatile residues	1	8.2	0.05	$1.9*10^{-3}$	3.7 %	Yes
Scenario [3] toddler crawling on treated surface (carpet)	2	8.2	0.05	$1.66*10^{-2}$	33 %	Yes
Scenario [5] toddler sleeping in treated bed	1	8.2	0.05	$2.8*10^{-2}$	57 %	Yes
Total	1	8.2	0.05	$4.65*10^{-2}$	93%	Yes

The risk linked to combined exposure after one application is acceptable for toddler.

Local effects
No need to consider local effects separately.

Conclusion

The risk for primary exposure is acceptable.

There is acceptable risk for adults, children and toddlers who inhale residues volatile.
There is acceptable risk for adult who touches treated surface.
There is acceptable risk for person (adults, children and toddlers,) who sleeps in a dried treated bed, considering the following mitigation measures, proposed by the applicant:

- Do not treat bed linen.
- Do not use treated bedding until full drying.

There is unacceptable risk for children who crawl on treated surface such as impervious surface (plastic, tile…). There is acceptable risk for children who crawl on treated surface such as carpets. In this context, a mitigation measure is needed:

- Do not apply on impervious surfaces.

Moreover, in case of combining surface spraying and air space spraying in the same areas, mitigation measures are needed:

- Do not apply combined treatment (air space spraying **and** surface spraying) in toddler rooms (children less than two years old).
- Do not touch treated surface when it is wet.

Risk for consumers via residues in food

Based on the intended uses and the proposed risk mitigation measure, the acute and chronic exposure to residues resulting from the intended uses are unlikely to cause a dietary risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

Conclusion

The intended use descriptions of the 1R-trans-phenothrin-containing biocidal products for which authorisation are sought indicate that these uses are not relevant in terms of residues in food and feed. It does not come in direct contact with food and feedstuffs. Nevertheless to avoid any contamination, the following precautionary statement should be indicated on the labels:
"Avoid any direct or indirect contact with food and feed".
No further data are required concerning the residue behaviour. The intended uses are not relevant in terms of consumer health protection.

2.2.7 Risk assessment for the environment

The risk assessment of the product ACARDUST is based on the information provided in the Assessment Report 1,R-trans phenothrin PT18 (March 2013).

2.2.7.1 Effects assessment on the environment

PNEC derivation – Active substance

PNEC values were proposed in the Assessment Report 1,R-trans phenothrin PT18.

Summary table on PNEC for 1R-trans phenothrin	
Environmental compartment	**PNEC value**

PNEC STP	10 $mg.L^{-1}$
Surface water	4.7E-05 $mg.L^{-1}$
Freshwater sediment	0.129 $mg.kg_{wwt}^{-1}$
Soil	0.0104 $mg.kg_{wwt}^{-1}$
Predator organisms (small	10 $mg.kg_{food}^{-1}$
Predator organisms (birds)	1.87 $mg.kg_{food}^{-1}$

Three major metabolites of 1-R trans-phenothrin are considered as major and relevant for risk assessment:

- The metabolite PBacid was identified in the water/sediment study of 1-R trans-phenothrin at a maximum level of 18.6% at 30 days. A DT50 of 143.6 days for whole system can be derived;
- The metabolite PBalc was identified and quantified in the soil degradation study and in the photolysis study of 1-R trans-phenothrin at a level of 12.9% and 20% respectively.
- The metabolite HO-PHN was identified and quantified in the photolysis study of 1-R trans-phenothrin at a level of 21.1%.

Regarding these metabolites, PBalc, PBacid and HO-PHN, from the results obtained with the Q(S)AR model, ECOSAR contained within the US-EPA EPISuite program - version 4.10, it has been shown that the PBalc and PBacid metabolites are significantly (> 100 x) less toxic than the parent compound and the HO-PHN metabolite is also less toxic than the parent compound. Therefore it is considered that the PNECaquatic value derived for 1R-trans phenothrin (4.7*10-5 mg/L) will provide a sufficient level of protection.

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

Classification of the Active Substance	
Value/conclusion	Very toxic to aquatic life Very toxic to aquatic life with long-lasting effects
Justification for the value/conclusion	Very acutely toxic to fish, Daphnia and algae, with LC_{50}/EC_{50}`s ≤ 1 mg/L in all cases. The lowest chronic ecotoxicity endpoint: invertebrates 72h NOEC 0.47 $\mu g.L^{-1}$.
Classification of the product according to CLP and DSD	The following classification in accordance with the criteria in Regulation (EC) No 1272/2008 is proposed in the AR: ▪ Aquatic Acute 1; H400; M = 100 ▪ Aquatic Chronic 1, H410, M = 10

Classification of the Product Acardust	
Value/conclusion	Aquatic Acute 1 Aquatic Chronic 1

Further Ecotoxicological studies

No data is available.

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

No data is available.

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

No data is available.

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

No data is available.

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

No data is available.

Foreseeable routes of entry into the environment on the basis of the use envisaged
Please refer to section Fate and distribution in exposed environmental compartments.

Further studies on fate and behaviour in the environment (ADS)
No data is available.

Leaching behaviour (ADS)
No data is available.

Testing for distribution and dissipation in soil (ADS)
No data is available.

Testing for distribution and dissipation in water and sediment (ADS)
No data is available.

Testing for distribution and dissipation in air (ADS)
No data is 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)
No data is available.

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.

2.2.7.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: ACARDUST - ready-for-use acaricide used by non-professionals for the curative treatment of bedrooms (mattress, bed frame, bed base, armchairs, carpets, pillows, blankets, duvets...) against house dust mites – **Direct treatment of surfaces by spray** Scenario 2: ACARDUST - ready-for-use acaricide used by non-professionals for the curative treatment of bedrooms (mattress, bed frame, bed base, armchairs, carpets...) against house dust mites – **Indirect treatment of surfaces by spatial application with a one-shot aerosol**
ESD(s) used	Emission scenario document for insecticides, acaricides and products to control arthropods for household and professional use (ESD for PT18, OECD, 17/07/2008)
Approach	Scenario 1: Average consumption Scenario 2: Average consumption
Distribution in the environment	Calculated based on ECHA Guidance on the BPR Vol IV Part B ; April 2015
Groundwater simulation	A higher tier model (FOCUS model) wasn't performed
Confidential Annexes	No
Life cycle steps assessed	**Scenario 1** ✓ *Application step* During the indoor application on surfaces, the product ACARDUST can reach directly the targeted surfaces (mattress, bed frame, bed base, armchairs, carpets...) and also the adjacent floor, the applicator clothes and the indoor air. ✓ *Cleaning step* Cleaning events result only in emission to wastewater in considering that the adjacent floor and clothes of the applicator are washable. As proposed by the applicant, treated surfaces as duvets and pillows are also washed. On the other hand, mattress, bed frame, bed base, armchairs, carpets are considered as not regularly wet cleaned.
	Scenario 2 ✓ *Application step* After application in the air of the bedroom, the product ACARDUST will fall onto the furniture of the room and onto the floor. The product will not reach the environmental compartments during the indoor application. ✓ *Cleaning step* It has been considered, according to the ESD PT18 for RTU

	aerosol application by space diffuser, that 100% of emission after application is wet cleaned. The applicant proposed that cleaning events result only in emission to wastewater considering that the floor and clothes of the applicator are washable. It has to be noted that it is considered that the furniture are not intended to be cleaned by wet methods. It is recommended to empty the room before the treatment, materials such as duvets or pillows are not intended to be contaminated.
Remarks	

The STP is considered as the main receiving compartment following wet cleaning events. Surface water bodies (including sediment) as well as the soil compartment (including groundwater) are secondary exposed compartments for residues via sewage treatment plant effluents and sewage sludge applications, respectively.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway						
	Freshwater	Sediment	STP	Air	Soil	Groundwater
Scenario 1	yes	yes		no	yes	yes
Scenario 2	yes	yes		no	yes	yes

Active substance: 1,R-trans phenothrin

Input parameters used in the environmental exposure assessments according to the CAR (December, 2013)		
Input	Value	Unit
CAS number	26002-80-2 /26046-85-5	-
Molecular weight	350.46	$g.mol^{-1}$
Vapour pressure (at 20°C)	2.37E-05	Pa
Water solubility (at 21°C)	2.00E-03	$mg.L^{-1}$
Partition coefficient (log P_{OW}) (pH 7)	6.8	Log 10
Degradation in water/sediment (DT_{50}) (at 12°C)	19.15 (1,R-trans phenothrin) 143.6 (PBacid – major metabolite for water/sediment compartment)	days
Degradation in soil (DT_{50}) (at 12°C)	27.2	days
Adsorption / desorption Koc	125 892.5	$l.kg^{-1}$
Henry's Law Constant (at 20°C)	4.2	$Pa.m^{-3}.mol^{-1}$
Photo-oxidative degradation in air (DT_{50})	3.6	h
Biodegradability	Not Ready biodegradable	
BCF fish	1 878	$l.kg^{-1}$
BCF earthworms	75 716	$l.kg^{-1}$

Calculated fate and distribution in the STP (EUSES model 2.1)		
Compartment	Percentage [%]	
	Scenario 1	Scenario 2
Air	0.271	

Water	12.9
Sludge	86.8
Degraded in STP	0

Emission estimation

Scenario [1]

No scenario is available to cover the use of product on soft furnishings as mattress, bed frame, bed base, armchairs, carpets... to treat dust house mite. Consequently two complementary approaches are considered:

- ✓ Scenario 1.1 (wet cleaning of duvets and pillows): the applicant proposed that only duvets and pillows are washed. Other treated surfaces like mattresses, armchairs, carpets are not considered to be cleaned with wet methods. Nevertheless, the release to wastewater from this scenario alone is underestimated considering only a treatment area reduced to duvets and pillows. Therefore, the scenario 1.2 has been added.

- ✓ Scenario 1.2 (wet cleaning of adjacent soil contaminated during application): to cover releases to soil during application, the UK approach proposed and adopted in WG-I-2017 for a substance with similar intended uses was followed. Treatment is intended to take place on soft furnishings and carpeted areas (general surface area of 22 m^2 - ESD). However both of these would not be expected to be subject to regular wet cleaning. So an area of 5.9 m^2 to reflect the area wet cleaned in a domestic home (barrier) and use the default cleaning efficiency of 20 % for a surface application (taken from the ESD) have been adopted.

Scenario 1.1

Input parameters for calculating the local emission				
Parameter	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario [1.1]: ready-for-use acaricide used by non-professionals for the curative treatment of bedrooms (mattress, bed base, armchairs, carpets...) against house dust mites – **Direct treatment of surfaces by spray (wet cleaning of duvets and pillows)**				
INPUTS				
Fraction of active substance in the product	F_{AI}	0.42	[% $_{w/w}$]	d-Phenothrin (sum of all isomers)
Surface or air space treatment	Surface treatment (area)			-
Application scope	Targeted spot application			-
Quantity of product applied	Q_{prod}	12.5	[$g.m^{-2}$]	-
Area treated per house (duvet and pillows)	$AREA_{treated}$	4	[m^2]	The product is intended to be applied on bedding (duvets, pillows, mattress, bed frame) armchairs or carpets. It is considered that the area of 4 m^2, corresponding to a bed of 200 cm * 200 cm. The

				applicant considered an area of 3.2 (160 cm * 160 cm).
Number of applications per day per house	N_{appl}	1	[d^{-1}]	Intended to be used once every three months.
Fraction emitted to air during application step	F_{air}	0.02	[-]	Default value - ESDP PT18
Fraction emitted to applicator during application step	$F_{applicator}$	0.004	[-]	Table 3.3-1 - ESDP PT18 (self-pressurised aerosol dispenser for surface treatment)
Fraction emitted to floor during application step	F_{floor}	0.126	[-]	Table 3.3-3 - ESDP PT18 (self-pressurised aerosol dispenser for surface treatment)
Fraction emitted to treated area during application step	$F_{treated}$	0.85	[-]	(1 – (0.02 + 0.004 + 0.126))
Fraction emitted to wastewater during cleaning	F_{ww}	1	[-]	-
Cleaning efficiency of the floor	F_{CE}	1	[-]	Worst case as no value is proposed in the ESD for the cleaning of textile. Here the treated area is also the cleaned area.
Number of private houses connected to a STP	N_{HOUSE}	4 000	[-]	Default value – Technical Agreements for Biocides (2016)
Simultaneity factor	$F_{simultaneity}$	0.815	[%]	ACARDUST 200 & 400 may be applied by spraying on surfaces up to 4 times per year
OUTPUTS				
Emission during the application				
Emission to the applicator	$E_{applicator}$	8.40E-07	[$kg.d^{-1}$]	O
$E\,applicator = N\,appl \times F\,applicator \times Q\,prod \times FAI \times AREA\,treated$				
Emission to duvet and pillows	$E_{floor + treated}$	2.05E-04	[$kg.d^{-1}$]	O
$E\,floor = N\,appl \times (F\,floor + F\,treated) \times Q\,prod \times FAI \times AREA\ treated$				
Emission during the cleaning step for one house				
Emission from duvet and pillows to wastewater for one house	$E_{treated/floor,\,ww}$	2.05E-04	[$kg.d^{-1}$]	O
$E\,treated/floor, ww = (E\,floor + E\,treated) \times F\,ww \times F\,CE$				
Emission from applicator to wastewater for one house	$E_{applicator,\,ww}$	8.40E-07	[$kg.d^{-1}$]	O
$E\,applicator, ww = E\,applicator \times F\,ww$				

Total emission to the wastewater	$E_{total,ww}$	2.06E-04	[kg.d^{-1}]	O
$E_{total,ww} = E_{treated/floor,ww} + E_{applicator,ww}$				
Total Emission to the wastewater for one STP				
Total emission to the STP	$E_{local\ water}$	6.68E-03	[kg.d^{-1}]	O
$E_{local\ water} = E_{total,ww} \times N_{HOUSE} \times F_{simultaneity}$				

Scenario 1.2

Input parameters for calculating the local emission				
Parameter	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario [1.2]: ready-for-use acaricide used by non-professionals for the curative treatment of bedrooms (mattress, bed base, armchairs, carpets...) against house dust mites – **Direct treatment of surfaces by spray (wet cleaning of adjacent soil contaminated during application)**				
INPUTS				
Fraction of active substance in the product	F_{AI}	0.42	[% $_{w/w}$]	d-Phenothrin (sum of all isomers)
Surface or air space treatment	Surface treatment (area)			-
Application scope	Barrier treatment covering the application on non-wet cleaned soft furnishings			-
Quantity of product applied	Q_{prod}	12.5	[g.m^{-2}]	-
Area treated per house	$AREA_{treated}$	20	[m^2]	Default value for barrier treatment – Technical Agreements for Biocides (2016)
Area wet cleaned per house	$AREA_{wet\ cleaned}$	5.9	[m^2]	WG I 2017, reflect the area wet cleaned in a domestic home (barrier)
Number of applications per day per house	N_{appl}	1	[d^{-1}]	Intended to be used once every three months.
Fraction emitted to air during application step	F_{air}	0.02	[-]	Default value - ESDP PT18
Fraction emitted to applicator during application step	$F_{applicator}$	0.004	[-]	Table 3.3-1 - ESDP PT18 (self-pressurised aerosol dispenser for surface treatment)
Fraction emitted to floor during application step	F_{floor}	0.126	[-]	Table 3.3-3 - ESDP PT18 (self-pressurised aerosol dispenser for surface treatment)
Fraction emitted to treated area during application step	$F_{treated}$	0.85	[-]	(1 – (0.02 + 0.004 + 0.126))
Fraction emitted to wastewater during cleaning	F_{ww}	1	[-]	-

Cleaning efficiency of the floor	F_{CE}	0.2	[-]	Table 3.3-8 - ESDP PT18 (RTU Aerosols – surface)
Number of private houses connected to a STP	N_{HOUSE}	4 000	[-]	Default value – Technical Agreements for Biocides (2016)
Simultaneity factor	$F_{simultaneity}$	0.815	[%]	ACARDUST 200 & 400 may be applied by spraying on surfaces up to 4 times per year
OUTPUTS				
Emission during the application				
Emission to the applicator	$E_{applicator}$	4.20E-06	[kg.d^{-1}]	O
$E\ applicator = N\ appl \times F\ applicator \times Q\ prod \times FAI \times AREA\ treated$				
Emission to the floor	E_{floor}	3.90E-05	[kg.d^{-1}]	O
$E\ floor = N\ appl \times F\ floor \times Q\ prod \times FAI \times AREA\ wet\ cleaned$				
Emission to treated surface	$E_{treated}$	2.63E-04	[kg.d^{-1}]	O
$E\ treated = N\ appl \times F\ treated \times Q\ prod \times FAI \times AREA\ wet\ cleaned$				
Emission during the cleaning step for one house				
Emission from treated area/floor to wastewater for one house	$E_{treated/floor,\ ww}$	6.05E-05	[kg.d^{-1}]	O
$E\ treated/floor, ww = (E\ floor + E\ treated) \times F\ ww \times F\ CE$				
Emission from applicator to wastewater for one house	$E_{applicator,\ ww}$	4.20E-06	[kg.d^{-1}]	O
$E\ applicator, ww = E\ applicator \times F\ ww$				
Total emission to the wastewater	$E_{total,ww}$	6.47E-05	[kg.d^{-1}]	O
$E\ total, ww = E\ treated/floor, ww + E\ applicator, ww$				
Total Emission to the wastewater for one STP				
Total emission to the STP	$E_{local\ water}$	2.11E-03	[kg.d^{-1}]	O
$E\ local\ water = E\ total, ww \times N\ HOUSE \times F\ simultaneity$				

Scenario [2]

Input parameters for calculating the local emission				
Parameter	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario [2]: ready-for-use acaricide used by non-professionals for the curative treatment of bedrooms (mattress, bed base, armchairs, carpets...) against house dust mites – **Indirect treatment of surfaces by spatial application with a one-shot aerosol**				
INPUTS				

Fraction of active substance in the product	F_{AI}	0.42	[% $_{w/w}$]	d-Phenothrin (sum of all isomers)
Surface or air space treatment	Surface treatment (area)			Even if the product is sprayed in the air of the room, the aim of the application is to treat the floor.
Application scope	General surface application			-
Quantity of product applied	Q_{prod}	12.5	[$g.m^{-2}$]	-
Area treated with the product by non-professionals in private houses	$AREA_{treated}$	22	[m^2]	Default value - ESDP PT18 (General surface area)
Number of applications per day per house	N_{appl}	1	[d^{-1}]	Intended to be used once or twice a year
Fraction emitted to air during application	F_{air}	0.02	[-]	Default value
Fraction emitted to the applicator during application	$F_{applicator}$	0	[-]	Negligible because the applicator leave the room at the start of the diffusion
Fraction emitted to floor during application	F_{floor}	0.968	[-]	Table 3.3-2 - ESDP PT18 (self-pressurised aerosol dispenser for surface treatment)
Fraction emitted to waste water from applicator clothes and washable treated surfaces (duvets, pillows)	F_{ww}	1	[-]	-
Cleaning efficiency of the floor	F_{CE}	1	[-]	Table 3.3-8 - ESDP PT18 (RTU Aerosols – Space spray/diffuser)
Number of private houses connected to a STP	N_{HOUSE}	4 000	[-]	Default value – Technical Agreements for Biocides (2016)
Simultaneity factor	$F_{simultaneity}$	0.204	[%]	Value for one to two times per year ESD for PT18
OUTPUTS				
Emission during the application				
Emission to the floor	E_{floor}	1.16E-03	[$kg.d^{-1}$]	O
$E\,floor = N\,appl \times (F\,floor + F\,air) \times Q\,prod \times FAI \times AREA\,treated$ Even if the product is sprayed in the air of the room, the aim of the application is to treat the floor				
Emission during the cleaning step				
Emission from floor to wastewater for one house	$E_{floor,\,ww}$	1.16E-03	[$kg.d^{-1}$]	O
$E\,floor,ww = E\,floor \times F\,ww \times F\,CE$				
Total Emission to the wastewater for one STP				

Total emission to the STP	$E_{local\ water}$	9.42E-03	[kg.d^{-1}]	O
$E\ local\ water = E\ floor, ww \times N\ HOUSE \times F\ simultaneity$				

Calculated PEC values

The PECs via the emission to the STP are calculated in EUSES v2.1.2, using as input data the local emissions into the STP calculated in the section above. The results are summarised in the following table.

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}[1]**
	[mg.L^{-1}l]	[mg.L^{-1}]	[mg.kg$_{wwt}^{-1}$]	[mg.kg$_{wwt}^{-1}$]	[µg.L^{-1}]
Scenario 1.1	4.31E-04	3.63E-05	9.86E-02	7.53E-03	1.05E-03
Scenario 1.2	1.36E-04	1.14E-05	3.13E-02	2.38E-03	3.30E-04
Scenario 2	6.08E-04	5.11E-05	1.40E-01	1.06E-02	1.48E-03

Primary and secondary poisoning

Primary poisoning

Primary poisoning, i.e. the direct consumption of the product by birds or mammals is not considered as relevant for the product ACARDUST. Indeed, primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation, which is not the case of the product ACARDUST.

Secondary poisoning

As the active substance d-Phenothrin (sum of all isomers) has a log Kow > 3 (log Kow = 6.8) and a BCF > 100 (mean BCF in fish = 1 878 l.kg^{-1} and BCF in earthworm = 75 716 L.kg^{-1}), secondary poisoning may occur via the aquatic food chain and via the terrestrial food chain. The concentration of d-Phenothrin in food (i.e. in fish and in earthworm) of fish-eating and worm-eating predators (birds or mammals) has been calculated. The results are summarised in the following table.

Summary table on estimated theoretical exposition (ETE)		
	PEC	**PEC**
	[mg.kg $_{wet\ fish}^{-1}$]	[mg.kg $_{wet\ earthworm}^{-1}$]
Scenario 1.1 *Treatment of surfaces directly*	3.41E-01	3.58E-02
Scenario 1.2 *Treatment of surfaces directly*	1.07E-01	1.13E-02

Scenario 2 *Treatment of surfaces indirectly by space spraying/diffuser*	4.80E-01	5.05E-02

2.2.7.3 Risk characterisation

Atmosphere

Conclusion: A calculated DT_{50} value for air was determined at 3.63 hours (24 hour day, $5*10^5$ OH radicals cm^{-3}), using the US EPA AOPWIN model. Whilst d-Phenothrin is likely to partition to some degree to air based on its method of application (i.e. spraying), its indoor use will limit atmospheric exposure and when in the atmosphere it is expected to rapidly degrade. The vapour pressure of $2.37*10^{-5}$ Pa (at 20°C, for 1R-trans phenothrin) indicates further that d-Phenothrin will not readily volatilise into the atmosphere at ambient temperature and pressure. It is not expected that the substance will fulfil the screening criteria for the potential for long-range environmental transport. Furthermore, there is no monitoring data available or other evidence indicating potential for long-range environmental transport.
Therefore, emissions and PECs in air are considered as negligible. It can be concluded that the use of the product ACARDUST will not induce a significant risk to the atmospheric compartment.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values		**Conclusion**
	$PEC/PNEC_{STP}$	
Scenario 1.1 *Treatment of surfaces directly*	4.31E-05	Acceptable
Scenario 1.2 *Treatment of surfaces directly*	1.36E-05	Acceptable
Scenario 2 *Treatment of surfaces indirectly by space spraying/diffuser*	6.08E-05	Acceptable

Conclusion: The risk characterisation ratios are below 1 for the application by spraying on surfaces and for the application by space spraying/diffuser. Therefore, the risk for the STP is acceptable when using the product ACARDUST.

Aquatic compartment

Summary table on calculated PEC/PNEC values			**Conclusion**
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	
Scenario 1.1 *Treatment of surfaces directly*	7.72E-01	**7.65E+00**	**Unacceptable**

Scenario 1.2 *Treatment of surfaces directly*	2.43E-01	**2.43E+00**	**Unacceptable**
Scenario 2 *Treatment of surfaces indirectly by space spraying/diffuser*	**1.09E+00**	**1.09E+01**	**Unacceptable**

Aquatic compartment: Risk assessment for the major metabolites

According to the Assessment Report 1,R-trans phenothrin PT18 (March 2013), three metabolites were identified as major environmental metabolites, PBalc and PBacid and HO-*trans*-PHN. In using the same approach that developed in the AR (PEC values for metabolites are estimated from PEC values for d-phenothrin taking into account the molecular weight and the maximum observed levels of the metabolites), PEC/PNEC values for the sum of PBalc and PBacid and HO-*trans*-PHN are calculated and shown below.

Summary table on calculated PEC/PNEC values for Total metabolites			**Conclusion**
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	
Scenario 1.1 *Treatment of surfaces directly*	3.47E-01	3.43	**Unacceptable**
Scenario 1.2 *Treatment of surfaces directly*	1.09E-01	1.09E+00	**Unacceptable**
Scenario 2 *Treatment of surfaces indirectly by space spraying/diffuser*	4.88E-01	4.88E+00	**Unacceptable**

Conclusion: The risk characterisation ratios are above 1 for the surface water and/or the sediment compartment whatever the application mode. Therefore, the risk for the aquatic compartment is unacceptable when using the product ACARDUST.

The applicant underlines that several parameters utilised in the model used for the risk assessment are clearly overestimated (see below). Nevertheless, this argument has not been taken into account to refine the risk conclusions for the aquatic compartment as scenarios harmonized at EU level have been considered. Moreover, the use of a tonnage approach to refine the risk assessment for PT18 has been discussed several times amongst MSs and clearly refused for these types of applications.

- **the fraction of active substance emitted in the STP during the cleaning step**: the contamination of the environment occurs via wet cleaning events only. The fraction of active substance considered to be emitted during the cleaning step is therefore a key parameter.

  In the scenario for the direct application on surfaces, the majority of the emissions occurs during the washing of duvets and pillows. It is considered that 100% of the active substance applied on textiles is emitted in the STP during the first washing. It is clearly a worst case assumption. Moreover, it is highlighted that generally, duvets and pillows are cleaned with dry methods, because they are too voluminous to enter into a washing machine.

  In the scenario for application by space spraying, it is considered that the majority of the emissions occur during the wet cleaning of the floor. However, the product ACARDUST 400 is used in curative treatment against house dust mites who live on surfaces like bedding, carpet, armchair etc... When a room is contaminated and needs to be treated by space spraying, it is therefore normally a room with carpet and is therefore normally cleaned with dry methods (vacuum).

- **the simultaneity factor**: in both scenarios, it is necessary to determine how many houses connected to the STP are treated simultaneously because, as mentioned in the ESD p.38, tonnage values are not always available. Therefore this scenario doesn't take into account the real tonnage of the product but is based on default assumptions on the number of houses treated.
  By default, it is considered that 4000 individual houses are connected to a STP which has a 10 000 equivalent habitant capacity.
  In the exposure assessment of the product ACARDUST, a refined simultaneity factor of 0.815% is used for the direct application on surfaces and a refined simultaneity factor of 0.204% is used for the application by space spraying.

  It is therefore considered in the scenario for the direct application on surfaces that 32.6 individual houses (4000*0.815%) connected to the same STP are treated simultaneously. Considering the cleaned surfaces of 3.2 m^2 and the application rate of the product of 12.5 g/m2, the quantities of product ACARDUST 200 or ACARDUST 400 considered by the scenario to be applied in one day are calculated as follow:

  Qproduct = (32.6 houses * 3.2 m^2 * 12.5 $g.m^{-2}$) = 1 304 g

  The scenario considers that 1.304 kg of product ACARDUST 200 or 400 is applied the same day for an equivalent of 10 000 habitants. This corresponds to the daily use of 8.69 T of product ACARDUST in France, considering the French population of 66 630 000 of habitants in 2016 (source Insee).
  This value is totally overestimated in comparison with the real data of sales for the product ACARDUST. Indeed, the applicant provided the following data on total sales for the product ACARDUST (both ACARDUST 200 and ACARDUST 400 packaging) for the years 2016, 2017 and 2018:

  - ✓ 2016: 16.8 T
  - ✓ 2017: 17.3 T
  - ✓ 2018: 17.5 T

  The model estimates that the quantity of product ACARDUST used in one day is equal to almost 50% of the real sale forecast for one year. This is clearly overestimated.

- Regarding the **application by space spraying** (relevant only for the product ACARDUST 400) the model considers that 8.16 individual houses (4000*0.204%) connected to the same STP are treated simultaneously. Considering the cleaned

surfaces of 22 m^2 and the application rate of the product of 12.5 g/m^2, the quantity of product ACARDUST 400 considered by the scenario to be applied the same day is calculated as follow:

$$Qproduct = (8.16 \text{ houses} * 22 \text{ m}^2 * 12.5 \text{ g.m}^{-2}) = 2\,244 \text{ g}$$

The scenario considers that 2.244 kg of product ACARDUST 400 is applied the same day for an equivalent of 10 000 habitants only. This corresponds to the daily use of 14.9 T of product ACARDUST 400 in France, considering the French population of 66 630 000 of habitants in 2016.
This value is totally overestimated in comparison with the real data of sales for the product ACARDUST 400. Indeed, the applicant provided the following data on total sales for the years 2016, 2017 and 2018:

- ✓ 2016: 10.15 T
- ✓ 2017: 10.5 T
- ✓ 2018: 10.5 T

Therefore it can be considered that the environmental model used in the risk assessment clearly overestimates the quantity of product ACARDUST 400 used in one day compared to the real sale forecast for one year.

In conclusion, considering that the washing of treated object is very limited and that the model clearly overestimates the exposure level of the environment, and as the RCR are just a little above 1 (4.88 for the application directly on surfaces and 1.97 for the application by space spraying), it is considered that the risk for the sediment is acceptable when using the products ACARDUST 200 and ACARDUST 400 according to the label recommendations.

Terrestrial compartment

Summary table on calculated PEC/PNEC values		**Conclusion**
	$PEC/PNEC_{Soil}$	
Scenario 1.1 *Treatment of surfaces directly*	7.26E-01	Acceptable
Scenario 1.2 *Treatment of surfaces directly*	2.29E-01	Acceptable
Scenario 2 *Treatment of surfaces indirectly by space spraying/diffuser*	1.02E+00	**Unacceptable**

Terrestrial compartment: Risk assessment for the major metabolites

According to the information available in the Assessment Report 1,R-trans phenothrin PT18 (March 2013), PBalc and PBacid and HO-*trans*-PHN can be considered as the major metabolites in soil. It is considered that the $PNEC_{soil}$ value derived for d-trans-Phenothrin provides a sufficient level of protection. In using the same approach that developed in the AR (PEC values for metabolite are estimated from PEC values for d-phenothrin taking into account the molecular weight and the maximum observed levels of the metabolite),

PEC/PNEC values for the sum of PBalc and PBacid and HO-*trans*-PHN are calculated and shown below.

Summary table on calculated PEC/PNEC values for sum of PBalc and PBacid and HO-*trans*-PHN		**Conclusion**
	$PEC/PNEC_{Soil}$	
Scenario 1.1 *Treatment of surfaces directly*	3.26E-01	Acceptable
Scenario 1.2 *Treatment of surfaces directly*	1.03E-01	Acceptable
Scenario 2 *Treatment of surfaces indirectly by space spraying/diffuser*	4.59E-01	Acceptable

Conclusion: The risk characterisation ratios are below 1 for the application by spraying on surfaces. The risk characterisation ratios are above 1 for the application by space spraying/diffuser for the active substance. Therefore, the risk for the soil is acceptable when using the product ACARDUST for a direct treatment of surfaces only if duvets and pillows are not wet cleaned.

Groundwater

Summary table on calculated $PEC_{groundwater}$ (µg/L) Comparison with the limit value of 0.1 µg/L[1].		
		Conclusion
Scenario 1.1 *Treatment of surfaces directly*	1.05E-03 (<0.1)	Acceptable
Scenario 1.2 *Treatment of surfaces directly*	3.30E-04 (<0.1)	Acceptable
Scenario 2 *Treatment of surfaces indirectly by space spraying/diffuser*	1.48E-03 (<0.1)	Acceptable

Groundwater: Risk assessment for the major metabolites

According to the information available in the Assessment Report 1,R-trans phenothrin PT18 (March 2013), PBalc and PBacid and HO-*trans*-PHN can be considered as the major metabolites in groundwater. In using the same approach that developed in the AR (PEC values for metabolite are estimated from PEC values for d-phenothrin taking into account the molecular weight and the maximum observed levels of the metabolite), PEC values for the sum of PBalc and PBacid and HO-*trans*-PHN are calculated and shown below.

Summary table on calculated $PEC_{groundwater}$ (µg/L) sum of PBalc and PBacid and HO-*trans*-PHN - Comparison with the limit value of 0.1 µg/L[1].

		Conclusion
Scenario 1.1 *Treatment of surfaces directly*	4.74E-04 (<0.1)	Acceptable
Scenario 1.2 *Treatment of surfaces directly*	1.49E-04 (<0.1)	Acceptable
Scenario 2 *Treatment of surfaces indirectly by space spraying/diffuser*	6.69E-04 (<0.1)	Acceptable

Conclusion: PEC values in groundwater are below 0.1 µg/L for the application by spraying on surfaces and for the application by space diffuser for d-phenothrin and their major metabolites. Therefore, the risk for the groundwater is acceptable when using the product ACARDUST according to the label recommendations.

Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

Summary table on secondary poisoning			
Scenario	**$PEC_{oral\ predator}$**	**$PEC/PNEC_{birds}$**	**$PEC/PNEC_{mammals}$**
Scenario 1.1 *Direct treatment of surfaces*	3.41E-01 $mg.kg^{-1}$ wet fish	1.82E-01	3.41E-02
	3.58E-02 $mg.kg^{-1}$ wet earthworm	1.45E-02	3.58E-03
Scenario 1.2 *Direct treatment of surfaces*	1.07E-01 $mg.kg^{-1}$ wet fish	5.74E-02	1.07E-02
	1.13E-02 $mg.kg^{-1}$ wet earthworm	6.04E-03	1.13E-03
Scenario 2 *Indirect treatment of surfaces by space spraying/diffuser*	4.80E-01 $mg.kg^{-1}$ wet fish	2.57E-01	4.80E-02
	5.05E-02 $mg.kg^{-1}$ wet earthworm	2.70E-02	5.05E-03

Conclusion: The risk characterisation ratios are below 1 for the birds and for mammals in the aquatic and the terrestrial food chains. Therefore, the risk of secondary poisoning is acceptable when using the product ACARDUST according to the label recommendations.

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

According to the intended uses of the product ACARDUST, a contamination of the environment is likely to occur. Sewage treatment plants following wet cleaning are the primary receiving compartments. Indirect releases into freshwater bodies (including sediment) and onto the soil (including groundwater) are also possible via sewage treatment plant effluents and sewage sludge applications, respectively.

Screening Step 2: Identification of relevant substances

According to the detailed composition of the product given in Section 2 and in the confidential annex Section 13 of the IUCLID file, the product ACARDUST do not contain any substance of concern nor substance approved as active substance in other Products Types (PTs).

Screening Step 3: Screen on synergistic interactions

There are no indications for synergistic effects for the products or its constituents in the literature.

Conclusion

Screening step		
	Significant exposure of environmental compartments? (Y/N)	Yes
	Number of relevant substances >1? (Y/N)	No
	Indication for synergistic effects for the product or its constituents in the literature? (Y/N)	No

The environmental risk assessment of the product ACARDUST is based on the active substance only and no mixture assessment is deemed necessary.

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

Scenario 1	**ACARDUST 200 & ACARDUST 400** **Scenario [1]: ready-for-use acaricide used by non-professionals for the curative treatment of bedrooms (mattress, bed base, armchairs, carpets…) against house dust mites – Direct treatment of surfaces by spray**	**Conclusion**
STP	Acceptable	**Unacceptable**[1]
Surface water	Acceptable*	
Sediment	**Unacceptable**	

Soil	Acceptable	
Groundwater	< 0.1 µg.L^{-1}	
Secondary poisoning	Acceptable	
Scenario 2	**ACARDUST 400** **Scenario [2]: ready-for-use acaricide used by non-professionals for the curative treatment of bedrooms (mattress, bed base, armchairs, carpets…) against house dust mites – Indirect treatment of surfaces by spatial application with a one-shot aerosol**	**Conclusion**
STP	Acceptable	**Unacceptable**
Surface water	**Unacceptable**	
Sediment	**Unacceptable**	
Soil	**Unacceptable**	
Groundwater	< 0.1 µg.L^{-1}	
Secondary poisoning	Acceptable	

* Only if scenarios 1.1 and 1.2 are considered separately

[1] risk mitigation measure is proposed to limit the risks for the non-target sediment organisms (*i.e. do not apply to washable surfaces or textiles and protect the adjacent surface during application with a non-washable plastic film).*

2.2.8 Measures to protect man, animals and the environment

Please see SPC.

2.2.9 Assessment of a combination of biocidal products

Not relevant.

2.2.10 Comparative assessment

Not relevant.

3 ANNEXES[3]

3.1 List of studies for the biocidal product

Author	Year	Title	Owner
Demangel B.	2015	Physico-chemical tests and chemical analyses before and after an accelerated storage procedure for 8 weeks at 40 ± 2°C on the aerosol ACARDUST. In compliance with CIPAC Handbook J - MT 46.3 method (2000) Report 15-912035-003	LOP
Demangel B.	2015	Physico-chemical tests on liquid formulation of ACARDUST without the propellant gas Report 15-912035-001	LOP
Demangel B.	2015	Physico-chemical tests and chemical analyses during and after a storage procedure for 36 months at 20 ± 2°C on the aerosol ACARDUST. In compliance with Technical Monograph No.17, 2nd edition CropLife International interim results after 6 and 12 months Report 15-912035-004	LOP
Demangel B.	2015	Physico-chemical tests after a storage stability at 0 ± 2°C for 7 days on the aerosol ACARDUST. Report 15-912035-002	LOP
Walbrou C. Narcy B.	2010	Procès-verbal d'essai N°2-153/10 – Essai d'inflammabilité de générateurs d'aérosols dont le contenu sort sous la forme d'un spray ou d'un jet. Annexes No1 et 2, procès-verbal d'essai N°2-153/10 – Essai d'inflammabilité de générateurs d'aérosols dont le contenu sort sous la forme d'un spray ou d'un jet. Report 2-153/10	AEROFARM
Detrimont H., Ambrosi D.	2015	Literature review on oxidising properties of the ingredients of the product ACARDUST Report no.15/48	LOP
AEROFARM	2016	Dossier de lot de repartition/conditionnement – atelier aerosols 1 – Nom de produit : ACARDUST 400 / Paradust 400 Report : Edition du 09/06/2016 – Lot H782	AEROFARM
AEROFARM	2013	Procedure Contrôle Qualité – Contrôles de fabrication et de conditionnement des aérosols	AEROFARM

3 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

		Report QLT814/13	
Ricau H.	2015	Validation of the analytical method for the determination of sumithrin (sum of isomers) in the liquid formulation of ACARDUST without the propellant gas Report no 15-912035-005	LOP
Ricau H.	2016	Validation of the analytical method for the determination of 1R-trans phenothrin in the liquid formulation of ACARDUST without the propellant gas in compliance with SANCO/3030/99 rev.4 from 11/07/00 Report 16-912035-001	LOP
Radecki C.	2015	Acaricidal efficacy of aerosol ACARDUST 200 against House dust mites, *Dermatophagoides pteronyssinus*. Biogenius, BIO125a-15	LOP
Radecki C.	2015	Acaricidal efficacy of aerosol Acardust 400 against House dust mites, *Dermatophagoides pteronyssinus*. Biogenius, BIO126a-15	LOP
Werner L.	2017	Acaricidal efficacy of aerosol ACARDUST 200 against House dust mites, *Dermatophagoides pteronyssinus*. Biogenius, BIO125a-15	LOP
Werner L.	2017	Acaricidal efficacy of aerosol Acardust 400 against House dust mites, *Dermatophagoides pteronyssinus*. Biogenius, BIO126a-15	LOP

3.2 Output tables from exposure assessment tools

ACARDUST_ConsExpo.pdf

3.3 Summaries of the efficacy studies (B.5.10.1-xx)[4]

All efficacy studies have been summarized in Section 6.7 of the IUCLID file.

4 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.