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)

SANYTOL ANTIÁCAROS

Product type18

1R-trans phenothrin as included in the Union list of approved active substances

Case Number in R4BP: BC-LG018651-48

Evaluating Competent Authority: Spain

September 2019

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1 CONCLUSION

The assessment presented in this report has shown that, SANYTOL ANTIÁCAROS, with the active substance 1R-trans phenothrin, at a level of 0.45% w/w, may be authorised for use as an insecticide (product-type 18) for the control against crawling insects (house dust mites and bed bugs) by general public (non-professional users). Please, note that this Assessment Report includes the uses requested by the applicant, as information for the concerned Member States.

SANYTOL ANTIÁCAROS is a ready to use homogenous liquid formulation (not a dispersion, suspension, powder or emulsion). The biocidal product formulation is a homogeneous clear and colorless liquid with a moderate perfumed odor. The mean pH-value and relative density were determined to 6.7 and 1.0068 g/cm^3 at start, respectively.

The long-term storage study indicates that the variation of the active ingredient content on SANYTOL ANTIÁCAROS product after 36 months in the oven was -4.02%. Moreover, the appearance, the packaging, the weight loss and the content of active substance the data indicates that the biocidal product is stable under the conditions of the storage stability tests (36 months at 20ºC).
No low temperature study submitted, so the phrase "Protect from frost" has to be included on the label.

All the substances of the mixture do not classify as Physical Hazard according to CLP Regulation, except from the Ethanol. The concentration of this substance is very low and it does not effect to the flammable classification of the mixture. Therefore, the biocidal product is not considered to be potentially explosive or contain an oxidising or reducing agent. Moreover, the preparation is not recommended for use with other products.

A validated analytical method has been submitted for determining the concentration of 1R-trans phenothrin in the biocidal product by the applicant. Validated analytical methods are also available for the determination of 1R-trans phenothrin in soil, water and air matrices. Other analytical methods are not required.
There are Substances of Concern in the biocidal product since these substances are classified as dangerous (Directive 67/548/EEC) or hazardous (Regulation No 1272/2008). However, the concentration of these substances in the preparation does not exceed the classification limits set in Regulation (EC) Nº 1272/2008 and the biocidal product is not classified with regard to the physico chemical properties.

The product demonstrated in dedicated studies to be efficacious against the intended target organisms (house dust mites and bed bugs) in the proposed area for use (textiles in households/private areas).

The product SANYTOL ANTIÁCAROS is marketed as ready-to-use water solutions in plastic trigger spray bottles. It is only for use in domestic small-scale. Therefore, exposures from professional operators have not been assessed.

Based on the risk assessment results, the use of Sanytol Antiácaros as an insecticide is considered safe for human health taking into account primary and secondary exposure to the biocidal product as a consequence of use.

Dietary exposure as result of use (i.e., food contamination and livestock exposure) can be excluded. Furthermore measurable residues in food or feed from the use of Sanytol Antiácaros are not expected and so it is the transference of biocide residues to food. In addition the label must include restrictions and instructions of use to avoid food contamination and exposure of animals (livestock and companion animals).

Synergistic effects between any of the components are not expected. In addition, the active substance is not classified for human health hazards. There are no substances of concern.

Environment

The use of SANYTOL ANTIACAROS was assessed in an indoor scenario assuming the application against housedust mites and bed bugs by hand-held spraying on household textiles not frequently washed. However this use posed unacceptable risks to the environment due to emissions to wastewaters.

Therefore the authorisation of SANYTOL ANTIACAROS is granted if the field of use is restricted to non-washable home textiles (such as mattresses, carpets, curtains, upholsteries, etc.) and the application is conducted with a non-washable plastic sheet to protect the adjacent surfaces.

This restrictions must be included on the SPC and product label such as the following RMM: "Do not apply to washable home textiles" and "During application, protect the adjacent surfaces with a non-washable plastic sheet".

The field of use must be changed to: Textiles in households which are not wet washed (indoors).

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
SANYTOL ANTIÁCAROS	**SPAIN**
SANYTOL ANTIACARIENS	France
SANYTOL PROTI ROZTOČŮM	Czech Republic
SANYTOL PROTI ROZTOČŮM	Slovakia
SANYTOL SPRAY DISTRUGE ACARIENII DIN PRAF	Romania
SANYTOL HÁZI PORATKA IRTÓ PERMET	Hungary
SANYTOL MILBENVERNICHTER / SANYTOL ANTIACARIENS	Switzerland
SANYTOL ANTIACARIENS	Belgium
SANYTOL ANTIACARIENS	Luxembourg

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	GRUPO AC MARCA S.L.
	Address	Avda. Carrilet, 293-297 08907 - L'Hospitalet de Llobregat Barcelona - Spain
Authorisation number	ES/APP(NA)-2019-18-006662	
Date of the authorisation	25/09/2019	
Expiry date of the authorisation	25/09/2029	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	GRUPO AC MARCA S.L.
Address of manufacturer	Avda. Carrilet, 293-2970 8907 - L'Hospitalet de Llobregat Spain
Location of manufacturing sites	See confidential annex

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	1R-trans phenothrin
Name of manufacturer	Sumitomo Chemical (UK) PLC
Address of manufacturer	1-98, 3-chome, Kasugade-naka

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

	Konohana-ku 554-8558 Osaka, Japon
Location of manufacturing sites	See confidential annex

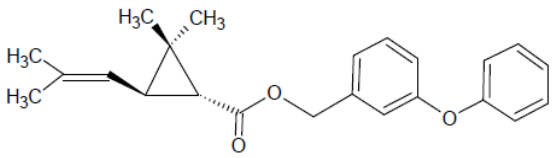
2.1.2 Product composition and formulation

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	1*R-trans* phenothrin	
IUPAC or EC name	3-phenoxybenzyl(1*R*,3*R*)-2,2-dimethyl- 3-(2-methylprop-1-enyl)cyclopropanecarboxylate	3-Phenoxyphenyl)methyl 2,2-dimethyl- 3-(2-methylprop-1-enyl)cyclopropane-1- carboxylate
EC number	247-431-2	247-404-5
CAS number	26046-85-5	26002-80-2
Index number in Annex VI of CLP	--	--
Minimum purity / content	min. 890 g/kg (≥89% w/w) - 1*R-trans* phenothrin	min. 950 g/kg (≥95% w/w) – sum of all isomers
Structural formula		

*__IMPORTANT NOTE ON THE ACTIVE SUBSTANCE__: The active substance originally identified and notified under the biocides review programme for active substances during 2002 was "d-Phenothrin" (CAS 188023-86-1). However, during the evaluation of the active substance and Technical Meeting peer review procedure it was identified that the data submitted in relation to the identity and physical-chemical characteristics of the substance allowed conclusions to be drawn on only a certain form of d-Phenothrin. The form of d-Phenothrin concluded during the review process indicated a substance containing at least 89% w/w of the 1R-trans isomer. Therefore, in accordance with the current ECHA guidance and practice for the identity and naming of substances it was determined that the active substance should be considered as a mono-constituent substance and named **1R-trans phenothrin (CAS 26046-85-5)**. The evaluation of data during the review process utilised data generated with both d-phenothrin (CAS 188023-86-1) and 1R-trans phenothrin (CAS 26046-85-5) and it was agreed in the Technical Meeting that extrapolation of data from d-Phenothrin to 1R-trans phenothrin was possible for assessment. However, whilst both forms of d-Phenothrin were utilised in the assessment, the conclusion on the identity did not allow conclusions to be drawn regarding any other substance complying with the definition of d-phenothrin in the list of active substances in Regulation (EC) No 1451/2007. Therefore, only 1R-trans phenothrin was included in Annex I to Directive 98/8/EC.

This evaluation refers to the active substance of the form 1R-trans phenothrin (min. 89% w/w of the 1R-trans isomer). However, data were assessed that utilised both mono- and multi-consitiuent forms of the active substance .

2.1.2.2 Candidate(s) for substitution

1*R-trans* phenothrin 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[2]

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
1R-trans phenothrin	3-phenoxybenzyl (1R,3R)-2,2-dimethyl- 3-(2-methylprop-1- enyl) cyclopropanecarboxylate	Active substance	26046-85-5	247-431-2	0.5 (TG) 0.45 (pure)
Co-formulants	See Confidential Annex				

2.1.2.4 Information on technical equivalence

The manufacturer of the active substance and the manufacturing site of the active substance used in the biocidal product are identical to the manufacturer of the active substance and the production site of the active substance included in Annex I of Directive 98/8/EC. Therefore no check for equivalence is necessary.

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

A.L.(Any other liquid)

2.1.3 Hazard and precautionary statements[3]

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

Classification	
Hazard category	Hazard to the aquatic environment – Aquatic Acute 1 Hazard to the aquatic environment –Aquatic Chronic 1
Hazard statement	H400: Very toxic to aquatic life. H410: Very Toxic to aquatic life, with long lasting effects.
Labelling	
Hazard pictogram	 GHS09

2 Please delete as appropriate.

3 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).

Signal words	Warning
Hazard statements	H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children P234: keep only in original container. P273 Avoid release to the environment. P501 (general public): Remove the content and / or its container as hazardous waste according to the regulations in force.
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Acaricide against house dust mites - General public - Indoor

Product Type	PT 18(Acaricide)
Where relevant, an exact description of the authorised use	Acaricide to control house dust mites.
Target organism (including development stage)	House dust mites (adults/nymphs) (*Dermatophagoides pteronyssinus; Dermatophagoides farinae*)
Field of use	Textiles in households which are not wet washed (indoors)
Application method(s)	Spray the ready-to-use product onto unwashable household textiles (hand-held sprayer)
Application rate(s) and frequency	Application rate: 10 mL/m^2 (Equivalent to 11 sprays for 1 m^2 of textile) Application frequency: Spray to non-washable textiles when elimination of house dust mites is needed. The product produces knockdown in several minutes and kill after 24 hours The product is efficacious up to 4 months after spray application. Maximum application frequency: 4 applications/year.
Category(ies) of users	General public (non-professional users)
Pack sizes and packaging material	Plastic (HDPE) trigger and bottle from 100up to 1800 mL *According to Spanish risk mitigation measures the maximum package for general public is 1000 mL.This limitation will be applied in our national authorisation.

2.1.4.2 Use-specific instructions for use

This is a ready-for-use product. No dilution is required.

SANYTOL ANTIÁCAROS should be used by spraying onto household textiles that are not wet washed (e.g. mattresses, carpets, curtains, upholsteries…) at a rate of 10 mL/m^2. Each spray delivers around 1 mL of product. On average, 11 sprays are needed to treat 1 m^2 of textile.

SANYTOL ANTIÁCAROS produces a knockdown effect on house dust mites in a few minutes. It kills 100% mites after 24 hours. The product is still effective against house dust mites up to 4 months after treatment of textiles. First, apply the product by hand spraying directly onto the textiles and allow them to dry for at least 8 hours. Then, hoover the surfaces to remove the dead mites. Finally, clean thoroughly the vacuum cleaner and discard the vacuum bag into a sealed plastic bag for disposal.

The untreated textiles that may be wet cleaned/washed should be washed at temperatures higher than 60ºC to kill the mites.

2.1.4.3 Use-specific risk mitigation measures

See section 2.1.5.2

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

Table 2. Use # 2 – Insecticide against bed bugs - General public - Indoor

Product Type	PT 18(Insecticide)
Where relevant, an exact description of the authorised use	Insecticide to control bed bugs.
Target organism (including development stage)	Bed bugs (adults) (*Cimex lectularius*)
Field of use	Textiles in households which are not wet washed (indoors)

Application method(s)	Spray the ready-to-use product onto unwashable household textiles (hand-held sprayer)
Application rate(s) and frequency	Application rate: 10 mL/m^2 On average 11 sprays for 1 m^2 of textile Application frequency: Spray to non-washable textiles in case of infestation. The product produces knockdown in several minutes and kill after 24 hours The product is efficacious up to 3 months after spray application. Maximum application frequency: 4 applications/year.
Category(ies) of users	General public (non-professional users)
Pack sizes and packaging material	Plastic (HDPE) trigger and bottle from 100up to 1800 mL. *According to Spanish risk mitigation measures the maximum package for general public is 1000 mL.This limitation will be applied in our national authorisation.

2.1.4.1 Use-specific instructions for use

This is a ready-for-use product. No dilution is required.

SANYTOL ANTIÁCAROS should be used by spraying onto household textiles that are not wet washed (e.g. mattresses, carpets, curtains, upholsteries…) at a rate of 10 mL/m^2. Each spray delivers around 1 mL of product. On average, 11 sprays are needed to treat 1 m^2 of textile.

For example:

- for a single bed mattress, apply 40 sprays

- for a double size mattress, apply 60 sprays

- a bottle containing 100 mL of the product will allow the treatment of a single bed and a double bed (10 m^2).

SANYTOL ANTIÁCAROS produces a knockdown effect on bed bugs in a few minutes. It kills 100% bed bugs after 24 hours. The product is still effective against bed bugs up to 3 months after the treatement of textiles. First, apply the product by hand spraying directly onto the textiles and allow them to dry for at least 8 hours. Then, hoover again the surfaces to remove the dead insects. Finally, clean thoroughly the vacuum cleaner and discard the vacuum bag into a sealed plastic bag for disposal.

Recommendations for the treatment against bed bugs:

Bed bugs hide also in crevices of walls, furniture, power cables strips, etc. To combat infestation in these areas, use other specific products

- Bed bugs may move to other rooms in the house and eventually to other adjacent houses. It is important to monitor the pest to make decisions on the adequate treatments.

- Even if this product is used to treat the mattresses, all the other areas around the beds should also be examined and treated with specific products in order to control bed

bugs pests. Please do not use this product on surfaces other than textiles not wet cleaned.

- The untreated textiles that may be wet cleaned should be washed at temperatures higher than 60ºC to kill adult and juvenile bed bugs.

- Tidiness and cleanliness are important to reduce places where bed bugs can hide - Treat the infested places until bed bugs are completely removed. If the treatment is not completely efficacious after several days, please contact with a trained professional.

- When this product is not used according to the label resistance of insects might occur. When infestation persists contact a professional.

2.1.4.2 Use-specific risk mitigation measures

See section 2.1.5.2

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

See sections 2.1.4.1
Always read the label or leaflet before use and follow all the instructions provided.
If the infestation persists contact a professional

2.1.5.2 Risk mitigation measures

Do not apply to wet washable textiles

During application, protect the adjacent surfaces with a non-washable plastic sheet

Do not smoke, eat or drink while you are using the product.

Avoid contact with eyes and skin.

Avoid contact of children with treated surfaces until the surfaces are dry.

After application allow drying for 8 hours and vacuum the applied surface.

Keep away and avoid any direct or indirect contact from food/feedingstuff, eating utensils or food/feed contact surfaces.Do not perform the operation in presence of people and/or pets.

Product must be securely applied in a way so as to minimize the risk of consumption by other animals or children.

The product contains a bitter substance that makes it repulsive to people or pets.

Contain a pyrethroid, may be lethal to cats. Cats must avoid contact with treated object/area.Do not apply on clothes or textiles intended to be used in direct contact with the skin

Spray the product preferably in the morning to allow drying the textiles for at least 8 hours

The mattresses must be enclosed in a protective cover before using them in order to avoid dermal contact with the product.

Spray to non-washable textiles in case of infestation.

This product should always be used in accordance with label recommendations in order to avoid possible resistance. If the treatment is not completely efficacious after several days, please contact with a trained professional.

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

Basic first aid procedures

- If contact in eyes, rinse with plenty of water for 15 minutes. Do NOT forget to remove the contact lenses.
- If contact on skin, wash with soap and plenty of water, without rubbing.
- If necessary take the person to a hospital and show the label or packaging whenever possible.

Medical advice for doctors and sanitary staff

- Symptomatic and supportive treatment.

IF MEDICAL ADVICE IS NEEDED, HAVE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER. ☎ [***INSERT LOCAL NUMBER HERE***]

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product and other waste generated during the treatment (non-washable plastic sheet) are considered hazardous waste. Dispose of in accordance with current regulations
Do not release to soil, ground, surface water or any kind of sewer

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

Shelf-life: 36 months.
Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

Protect from frost.

2.1.6 Other information

Definition: General public (non-professional user): Users who are not professionals and who apply the product in the context of their private life.

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)
Trigger Spray	100to 1800 mL *According to Spanish risk mitigation measures the maximum package for general public is 1000 mL.This limitation will be applied in our national authorisation.	HPDE	plastic	General public (Non-professional)	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

See the list of studies for the biocidal product in ANNEXES

2.1.8.2 Access to documentation

The applicant has submitted the following letters of access:
-a letter of access from Sumitomo (notifier and having on all the data included in the dossier for 1R trans phenothrin presented by Sumitomo) to all the documents about the active substance associated to the Annex I listing.
The applicant has provided the Physical, Chemical and Technical Properties of the biocidal product for supporting the Physical hazards and respective characteristics.
The applicant has provided the suitable analytical method for identifying the active substance in the biocidal product.
The applicant has not provided the rest of analytical methods. This information is not necessary because it is possible to use the Competent Authority Report on the active substance 1R-trans phenothrin supported by Sumitomo.
The applicant has not provided any toxicology studies to support the assessment of the effects in human health of the biocidal product.
The applicant has not provided any exposure study with the biocidal product.

2.2 Assessment of the biocidal product

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

Table 2. Intended use # 1 – Insecticide, acaricide. Non professional. Indoor

Product Type(s)	PT 18
Where relevant, an exact description of the authorised use	The biocidal product is intended for indoor use only by non-professional operators, to control house dust mites and bed bugs in textiles. Used for control of crawling insects: House dust mites and bed bugs.
Target organism (including development stage)	*Cimicidae*:-Adults-Bed bug *Pyroglyphidae*:-Adults-House dust mites *Pyroglyphidae*:-Nymphs-House dust mites
Field of use	Indoor
Application method(s)	Spraying
Application rate(s) and frequency	10 g/m^2 (33 strikes to treat a Queen Size mattress and 20 strikes to treat a single bed) - Application frequency: 1 time every 4 months, or 3 times per year (mattress).
Category(ies) of user(s)	General public (Non-professional)
Pack sizes and packaging material	Bottle - Plastic: HDPE from 100up to 1800 mL

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual determination	0.45% 1R-trans phenothrin Batch No: 20141105	Initially at 20ºC ± 2°C: **Homogeneous clear** After 8 weeks at 40°C ± 2°C: **Homogeneous clear**	
Colour at 20 °C and 101.3 kPa	Visual determination	0.45% 1R-trans phenothrin Batch No: 20141105	Initially at 20ºC ± 2°C: **Colourless liquid** After 8 weeks at 40°C ± 2°C: **Colourless liquid**	
Odour at 20 °C and 101.3 kPa	Comparison	0.45% 1R-trans phenothrin Batch No: 20141105	Initially at 20ºC ± 2°C: **Moderately perfumed** After 8 weeks at 40°C ± 2°C: **Moderately perfumed**	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Acidity / alkalinity	CIPAC MT75.3	0.45% 1R-trans phenothrin Batch No: 20141105	pH = 6.7 @ 21°C	
Relative density / bulk density	Regulation 440/2008 (EC) Annex A.3	0.45% 1R-trans phenothrin Batch No: 20141105	D_4^{20} = 1.0068	
Storage stability test – **accelerated storage**	CIPAC MT 46.3: accelerated storage procedure	0.45% 1R-trans phenothrin Batch No: 20141105	The results indicate that the active substance in the biocidal product is stable under the conditions of the storage stability test (8 weeks at 40ºC).	
1*R-trans* phenothrin content	Chiral HPLC-UV		Initially at 20ºC ± 2°C: **0.473% w/w** After 8 weeks at 40°C ± 2°C: **0.454% w/w** Diference: -4.02%	
Homogeneity of application			Not available	
Appearance and stability of the package			No appreciable change in the packaging of the test item with regards to the integrity, sealing, leakage and dimensional stability was observed after storage.	
Others: -weight loss			The weight loss was not more than 0.21%	
Storage stability test – **long term storage at ambient temperature**		0.45% 1R-trans phenothrin Batch No: 20141105	The results indicate that the active substance in the biocidal product is stable under the conditions of the storage stability test (36 months at 20ºC).	See confidential Annex [redacted]
1*R-trans* phenothrin content	Chiral HPLC-UV		Initially at 20ºC ± 2°C: **0.473% w/w**	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			After 12 months at 20°C ± 2°C: **0.457% w/w** Diference: -3.38% After 24 months at 20°C ± 2°C: **0.459% w/w** Diference: -2.96% After 36 months at 20°C ± 2°C: **0.454% w/w** Diference: -4.02%	
Homogeneity of application			Not available	
Appearance and stability of the package			No appreciable change in the packaging of the test item with regards to the integrity, sealing, leakage and dimensional stability was observed after storage.	
Others: -weight loss -particle size - Mean diameter - Discharge rate			The weight loss was not more than 1.11% No significant changes No significant changes No significant changes	
Storage stability test – **low temperature stability test for liquids**			Not applicable	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Not required	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		0.45% 1R-trans phenothrin Batch No: 20141105	No changes are observed	See confidential Annex [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		0.45% 1R-trans phenothrin Batch No: 20141105	No changes are observed	See confidential Annex [redacted]
Wettability	Only solid preparations		Not required	
Suspensibility, spontaneity and dispersion stability	Only solid preparations		Not required	
Wet sieve analysis and dry sieve test	for WPs, SCs, granules, tablets		Not required	
Emulsifiability, re-emulsifiability and emulsion stability	only for ECs and ready for use emulsions		Not required	
Disintegration time	only for tablets		Not required	
Particle size distribution, content of dust/fines, attrition, friability	Only for powders and granules	Batch No: 20170517	Dv (10%) = 47 µm. Dv (50%) = 100 µm. Dv (90%) = 227 µm.	See confidential Annex.
		0.45% 1R-trans phenothrin Batch No: 20170531	Dv (10%) = 51µm Dv (50%) = 126µm Dv (90%) = 200µm	See confidential Annex.
Persistent foaming			Not required	
Flowability/Pourability/Dustability	Flowability only for granular preparations, pourability only for suspensions, dustability only for dustable powders		Not required.	
Burning rate — smoke generators			Not applicable	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning completeness — smoke generators			Not applicable	
Composition of smoke — smoke generators			Not applicable	
Spraying pattern — aerosols	Methods of the European Aerosol Federation (FEA) 644 & 643	0.45% 1R-trans-phenothrin Batch: 20170531 0.45%	After 36 months at 20°C ± 2°C: Mean diameter = 26 cm Discharge rate = 0.98 g/hub	See confidential annex [redacted]
		1R-trans-phenothrin Batch: 20141105	After 27 months at 20°C ± 2°C: Mean diameter = 26 cm Discharge rate = 0.99 g/hub After 36 months at 20°C ± 2°C: Mean diameter = 23 cm Discharge rate = 0.97 g/hub	See confidential annex [redacted]
Physical compatibility			Not required	
Chemical compatibility			Not required	
Degree of dissolution and dilution stability			Not applicable	
Surface tension	Analogous to guideline 440/2008 (EC) consoliodated version, Annex A.5	0.45% 1R-trans phenothrin Batch No: 20170531	26.4 mN/m	See confidential annex [redacted]
Viscosity	CIPAC MT192	0.45% 1R-trans phenothrin Batch No: 20141105	**1.92 mPa s** at 20ºC ± 2°C **1.34 mPa s** at 40°C ± 2°C	

Conclusion on the physical, chemical and technical properties of the product
Note: the applicant has submitted the statement ensuring that all batches used in the dossier have the same compostion as the formulation to be marketed.

Appearance
The formulation of the test item was a homogeneous clear and colorless liquid with a moderate perfumed odor. No change in the appearance was observed after storage for 8 weeks at 40ºC and 36 months at 20ºC.

Acidity / alkalinity
The mean pH-value was determined to 6.7 at start.

Relative density / bulk density
The mean relative density was determined to 1.0068at start.

Storage stability – accelerate storage
The results indicate that the active substance in the test item is stable under the conditions of the storage stability tests.
No appreciable change in the packaging of the test item with regards to the integrity, sealing, leakage and dimensional stability was observed after storage for 8 weeks at 40ºC.
The weight loss was not more than 0.21% after storage for 8 weeks at 40ºC.
No significant changes in the active substance content of the test item were observed after storage for 8 weeks at 40ºC. The active substance content was within the FAO/WHO specification limits at all test times.
Under consideration of the appearance, the packaging, the weight loss and the content of active substance the data indicates that the test item is stable under the conditions of the storage stability tests.

Storage stability test – long term storage at ambient temperature
The results indicate that the active substance in the test item is stable under the conditions of the storage stability tests.
No appreciable change in the packaging of the test item with regards to the integrity, sealing, leakage and dimensional stability was observed after storage for 36 months at 20ºC.
The weight loss was not more than 1.11% after storage for 36 months at 20ºC.
No significant changes in the active substance content of the test item were observed after storage for 36 months at 20ºC. The active substance content was within the FAO/WHO specification limits at all test times.
Under consideration of the appearance, the packaging, the weight loss and the content of active substance the data indicates that the test item is stable under the conditions of the storage stability tests.

Storage stability test – low temperature stability test for liquids
The phrase "protect from frost" must be included in the biocidal product label.

Effects on content of the active substance and technical characteristics of the biocidal product - light
Although the semi product is sensitive to light, the packaging is appropriate to avoid the active ingredient degradation. The liquid formulation is in a closed plastic bottle which avoids the exposure to the light.
Effect of light exposure is therefore not required because our biocidal product is not sensitive to light.

Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity

The effects of Temperature and Humidity in the formulation stability and in the packaging integrity were conditions in which the physicochemical properties were conducted during the accelerated storage stability test and during the long storage stability test. At the present time, the results of the storage studies are satisfactory.

Effects on content of the active substance and technical characteristics of the biocidal product – reactivity towards container material

The reactivity towards the container material has already been evaluated in the stability studies. Both, the accelerated storage stability test and the long storage stability test included the evaluation of the integrity, sealing and leakage and the dimensional stability of the packaging. At the present time, the results of the storage studies are satisfactory and the test item was found in sound condition and without leakages at the end of the stability test.

Technical characteristics - Pourability:

The applicability of this property depends on the formulation type of the biocidal product. The study of the Pourability consists in the evaluation of the particles that rest in the packaging of the product after its use, with formulations that are suspensions, encapsulated suspensions or suspoemulsions. Since SANYTOL ANTIÁCAROS is a homogenous product, it will never leave any remaining particulate residues.

Technical characteristics - Spontaneity of dispersion:

The spontaneity of the dispersion is determined to show the behaviour of the product formulation when diluted in a fast dispersion with water. This property applies to solid products, non-water based products and products with one or more insoluble substances (suspension). Since SANYTOL ANTIÁCAROS is an homogenous liquid product, containing more than 91% of water and the coformulants are completely dissolved, the test does not apply.

Technical characteristics - Suspensibility of dispersion:

The Suspensibility is determined to demonstrate that enough active substance is suspended giving a homogeneous mixture during the application. Since SANYTOL ANTIÁCAROS is a homogenous liquid product, it is always applied as a homogenous solution, and the test does not apply.

Technical characteristics - Wet sieve test:

The Wet Sieve Test determines the possible particle residues that could cause blockages of nozzles or filters on the application equipment. The test is applicable on wettable powders, suspension, dispersible concentrates, suspoemulsions, water soluble granules and water-soluble powders. Since SANYTOL ANTIÁCAROS is an homogenous liquid, it is not necessary to perform this assay.

Technical characteristics - Persistent foaming:

This property applies to products that need to be diluted in water for its use. Since SANYTOL ANTIÁCAROS is a ready to use product, this assay does not apply.

Technical characteristics - Particle size distribution, spray pattern and amount of spray delivered:

This particle size test has been performed by the supplier of the spray trigger (WestRock) and it is also going to be performed by the external CRO GLP compliance (Biogenius).
This property will be evaluated only at the initial stability time point, as a parameter for

safety evaluation, but it will not be evaluated during the curse of the long-term stability study because particle size distribution depends on the mechanics of the trigger and on the composition of the sprayed liquid, and both characteristics are already independently evaluated during the stability assay.
Regarding the Spray pattern test, at test time 27 months among the two samples tested the spray diameter did not alter significantly although one shape was of no distinguished pattern in contrast to the other which was of round shape. A round shape pattern was also observed for both samples tested at 36 months. Their diameter differed though.
Concerning the amount of spray delivered, there was no significant change between the discharge rate at test time 27 months and 36 months for those samples which had been restored and used in a successive manner at the next of the study. No significant change in the discharge rate between those samples which had been in storage ever since until their discharge rate testing was observed.

Physical and chemical compatibility with other products
The physical and chemical compatibility with other products or active ingredients is not assessed because the application of the product does not require any mixture with any chemical compound.

Viscosity:
The viscosity has been determined at 20ºC and 40ºC at initial stability time point. The value of the viscosity measured at 20ºC is 2.72 mPa·s and at 40 ºC is less than 2 mPa·s. Then, the viscosity is not expected to change. The only possibility for a change like that could be the loss by evaporation of a considerable amount of water, and this fact could be also detected by the weigh change, which is carefully monitored through the study.

Surface tension:
The SANYTOL ANTIACAROS is an aqueous solution were surfactant is solubilized in the water, not an emulsion, so the concentration of surfactant is fixed and stable. Therefore, the surface tension is not expected to change during the aging of the product. . The surface tension is lower than 60 mN/m under the conditions of the plate method, therefore the biocidal product should be regarded as a surface-active material.

Conclusion:
SANYTOL ANTIÁCAROS is a ready to use homogenous liquid formulation (not a dispersion, suspension, powder or emulsion). The formulation of the test item is a homogeneous clear and colorless liquid with a moderate perfumed odor.
The mean pH-value and relative density were determined to 6.7 and 1.0068 at start, respectively.
One viscosity measurement at 20ºC determined the viscosity to a mean value of 2.72 mPa·s at test time start whereas all other measurements at 20ºC provided mean results < 2.0 mPa. The viscosity measured at 40ºC was < 2.0 mPa·s at test time start.
The accelerated storage study indicates that the variation of the active ingredient content on Sanytol Antiacaros product after 8 weeks at 40ºC and 36 weeks at 20ºC in the oven was -4.02%, respectively. The content did not suffer any modification in its appearance. Moreover, the appearance, the packaging, the weight loss and the content of active substance the data indicates that the test item is stable under the conditions of the storage stability tests.
No low temperature study submitted, therefore the phrase "Protect from frost" has to be included on the label.
No significant change in the discharge rate between those samples which had been in

storage ever since until their discharge rate testing was observed.
No significant changes in the active subsatance content of the test item were observed after storage for 8 weeks at 40ºC and after storage for up to 36 months at 20ºC.
The results indicate that the active substance in the test item is stable under the conditions of the storage stability test.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Theoretical assessment		The biocidal product is not explosive	
Flammable gases			Not applicable	
Flammable aerosols			Not applicable	
Oxidising gases				
Gases under pressure			Not applicable	
Flammable liquids	Theoretical assessment		The biocidal product is not flammable	
Flammable solids			Not applicable	
Self-reactive substances and mixtures			Not applicable	
Pyrophoric liquids			Not relevant	
Pyrophoric solids			Not applicable	
Self-heating substances and mixtures			Not applicable	
Substances and mixtures which in contact with water emit flammable gases	Theoretical assessment		The product is water based, therefore it is not expected that in contact with water, release flammable gas.	
Oxidising liquids	Theoretical assessment		The biocidal product has not oxidising properties	
Oxidising solids			Not applicable	
Organic peroxides			Not applicable	
Corrosive to metals			Not relevant	
Auto-ignition temperatures of products (liquids and gases)	Theoretical assessment		Auto-ignition is not foreseen	
Relative self-ignition temperature for solids			Not applicable	
Dust explosion hazard			Not applicable	

Conclusion on the physical hazards and respective characteristics of the product

Explosive properties
According to the classification of all the present ingredients in this biocidal product under Regulation 1272/2008, which do not classify as Explosives, it is not necessary to determine the explosive properties of this biocidal product.

Flammability
Only one of their components is flammable but the concentration is very low. Therefore flammability is not expected.
Substances and mixtures which in contact with water emit flammable gases
The product is an aqueous solution (>90 % w/w of water). Therefore, it is not necessary to determine flammable gases emission for this biocidal product.

Oxidizing properties
According to the classification of all the present ingredients in this biocidal product under Regulation 1272/2008, which do not classify as oxidising, it is not necessary to determine the oxidising properties of this biocidal product.

Auto-ignition temperatures of products (liquids and gases)
The product is an aqueous solution (>90 % w/w of water). Auto-ignition is not expected.

Conclusions
The product is a water-based liquid. The technical properties indicate that no particular problems are to be expected when it is handled, stored or applied as recommended.
This product does not classify as a consequence of its physico-chemical properties therefore there is no risk associated on it. The uses of this product do not consider its combination with any other product therefore cross reactivity is not expected.
The stability assays showed that the biocidal product is stable.
Hazards linked to explosive, oxidizing or flammable properties should not be considered because it does not contain ingredients with these properties..

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
1R-trans phenothrin	Chiral HPLC-UV	0.1765 – 0.3279 mg/mL / n = 3	0.1009 – 0.3531 mg/mL r = 0.999	Specific, no interference from other substances > 3% of total peak area	99.8 – 101.8	100.7	0.94	--	

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance, but not as 1R-trans Phenothrin. Similar to other residue	Achiral GC-MS (3 ions validated, 183, 123 and 184 m/z)	GC-MS and GC-MS/MS: 0.01 (n =5) and 0.1 mg/kg (n = 5) for all ions and ion	GC – MS and GC-MS/MS: $R^2 \geq 0.99$ for all ions and ion transitions when	No interference according to sample chromatograms. GC-MS and	79 % to 109 % for all ions and ion transitions for cis and trans	A mean of between 83 – 106% for all ions, ion	≤ 20% for all ions and ion transitions for cis and trans	0.01 mg/kg for GC-MS and GC-MS/MS	CAR (2016)

monitoring methods, the method determines individual cis and trans phenothrin, and the sum of cis and trans phenothrin	Achiral GC-MS/MS (3 ion transitions, 183-168 m/z 183-165 m/z 183-153 m/z	transitions for cis and trans.	monitoring for cis (7 point calibration over 4.0 – 1000 ng/mL), and trans (5 point calibrations, over 40 to 2500 ng/mL)	GC-MS/MS have a sufficient number of ions and ion transitions to be considered to be highly specific.	fortificatio n levels	transition s for cis and trans fortificati on levels.	fortificati on levels		

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
r-Phenothrin	GC-MS EI mode SIM (3 ions with m/z > 100 used for method validation)	0.0012 to 0.0120 mg/m^3 in duplicate	0.01 to 0.50 µg/mL; r^2 = 0.9933	No interferants	Ambient temp: 0.0012 mg/m^3: 91 – 108 0.0120 mg/m^3: 76 – 87. Elevated temp: 0.0012 mg/m^3:	Ambient temp: 0.0012 mg/m^3: 97%. 0.0120 mg/m^3: 84%. Overall mean = 91% Elevated temp: 0.0012 mg/m^3:	Ambient temp: 0.00120 mg/m^3: 6.8%. 0.0120 mg/m^3: 5.4%. Overall %RSD =10.0% Elevated temp: 0.00120 mg/m^3:	0.0012 mg/m^3	CAR (2011)

					73 - 95 0.0120 mg/m^3: 84 – 105.	87%. 0.0120 mg/m^3: 91%. Overall mean = 89%	10.3%. 0.0120 mg/m^3: 9.2%. Overall %RSD = 9.4%		
	Note that for the air study, ambient temperature was nominally 20°C and the elevated temperature and humidity was nominally 35°C with 80% humidity.								

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Drinking water / d-Phenothrin	GC-MS (3 ions with m/z > 100 used for method validation)	0.1 to 1.0 µg/L; 5 analysis at each concentration	0.02 to 2.0 µg/mL; r^2 = > 0.99	No interferants	87 to 99%	93%	< 15%	0.1 µg/L	CAR (2011)
Surface water / Active substance, but not as 1R-trans Phenothrin. Similar to	Achiral GC-MS/MS (3 ion transitions, 183-	0.10 µg/L (n = 5) and 1.0 µg/L (n = 5) for all ions for d-phenothrin	R2 ≥ 0.99 for all ions monitoring for cis (5 point calibration over 1.0 to	No interference according to sample chromatograms. GC-MS/MS	70 % to 110 % for all ions and ion transitions for d-phenothri	A mean of between 102 – 106% for all ions, ion transitions	≤20% for all ions and ion transitions for d-phenothrin	0.10 µg/L	CAR (2016)

other residue monitoring methods, the method determines individual cis and trans phenothrin, and d-phenothrin (the sum of cis and trans).	168 m/z 183-165 m/z 183-153 m/z		150 ng/mL), and trans (5 point calibrations, over 10 to 1000 ng/mL)	haS a sufficient number of ion transitions to be considered to be highly specific.	n fortification levels	for d-phenothrin fortification levels.	fortification levels		

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
1R-trans phenothrin	A method is not required for animal and human body fluids and tissues, as *d*-Phenothrin is not classified as toxic or highly toxic.								CAR (2011)

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
1R-trans phenothrin	A method is not required for food and feeding stuffs, as the active substance is not used on food of plant origin. The test substance is intended for indoor use only, in the control of household insect pests and it should not therefore come into contact with soil or plants in normal usage.								CAR (2011)

Conclusion on the methods for detection and identificationof the product
The analytical method "BioG AQ392: ACM: HPLC-Determination of 1R-trans phenothrin in SANYTOL ANTIÁCAROS" is found to be valid and has been used with success on the formulation "SANYTOL ANTIÁCAROS", which contains 0.45% of the active substance 1R-trans phenothrin. The validation parameters and acceptance criteria are in conformity with the requirements according to the European Commission Document SANCO/3030/99 rev.4 11/07/2000. The applicant has showed that they have access rights to the analytical methods studies contained in the CAR. The LoA has been submitted. Therefore, validated analytical methods are also available for the determination of 1R-trans phenothrin in soil, water, air, food and feeding stuffs matrices.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

SANYTOL ANTIÁCAROS is a ready-for-use liquid product presented in a plastic bottle with a hand-held spray nozzle. The formulation contains 0.45% of the active substance 1R-trans-phenothrin.

The product is to be used as an acaricide to control house dust mites and as an insecticide to control bed bugs by the general public (non-professional users) in order to protect human health. The product should be applied onto household textiles which are not wet cleaned or washed in order to control the target organisms.

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

SANYTOL ANTIÁCAROS is an acaricide to control house dust mites (*Dermatophagoides pteronyssinus; Dermatophagoides farinae*) and an insecticide to control bed bugs (*Cimex lectularius)* by the general public.

The product should be applied onto household textiles that are not wet cleaned or washed, where the target organisms live. Therefore SANYTOL ANTIÁCAROS protects human health by controlling house dust mites and bed bugs living in household textiles.

2.2.5.3 Effects on target organisms, including unacceptable suffering

SANYTOL ANTIÁCAROS produces the following effects on house dust mites and bed bugs:

- knockdown
- mortality

These effects were observed in the efficacy studies after direct spray onto the insects (direct efficacy) and after contact with treated textiles (residual efficacy) up to 3 months in bed bugs and up to 4 months in house dust mites.

2.2.5.4 Mode of action, including time delay

SANYTOL ANTIÁCAROS contains the active substance 1R-trans-phenothrin. The a.s. is pyrethroid substance.

1R-trans-phenothrin acts by being absorbed by invertebrate neuronal membranes, where it binds 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/arthropods will die.

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**
Acaricide / insecticide	Household textiles	Sanytol Antiácaros (1R-trans-phenothrin 0.45%)	*Dermatophagoides pteronyssinus* (mixed adults and nymphs; 300±30 mites/batch); *Cimex lectularius* (adults; 20 bed bugs/batch)	CEB No 135 (2007) Laboratory study Hand-hend spray to a 7-cm (38 cm^2) diameter parcel of textiles (wool, cotton, polyamide, polyester). Untreated controls included. 4 replicates/treatm. Observations: knockdown (from 1h after exposure up to several days until 100% achieved) and mortality after 24h.	Laboratory , direct efficacy. Dose: 3 mL(3 shots) /batch Exp.time: 4h	100% mortality after 24h dust mites: KT100 <5 min bed bugs: KT100 <10 min Controls: <10% mortality	IUCLID/Sec. 6.7/endpoint 001
					Laboratory , residual efficacy Dose: 10 mL/m^2 textile Residual activity assessed at day 0 (after drying) and after 1, 2, 3, 4, 5, 6 months. Exp.time: 4h	100% mortality after 24h KT100 <24h Mites: up to 4 months after application Bed bugs: up to 3 months after application Controls: <10% mortality	

Acaricide	Household textiles	Sanytol Antiácaros (1R-trans-phenothrin 0.45%)	*Dermatophagoides farinae* (mixed adults and nymphs; 300±30 mites/batch)	CEB Nº135 (2007) Laboratory study Hand-held spray to a 7-cm (38 cm^2) diameter parcel of textiles (wool, cotton, polyamide, polyester). Untreated controls included. Observations: knockdown (from 1h after exposure up to several days until 100% achieved) and mortality after 24h.	Laboratory , direct efficacy Dose: 3 mL(3 shots) /batch Exp.time: 4h	100% mortality after 24h	IUCLID/Sec. 6.7/endpoint 002
					Laboratory, residual efficacy Dose: 10 mL/m^2 textile Exp.time: 4h	100% mortality after 24h KT100 <4 h (up to 4 months after application) Controls: <10% mortality	
Acaricide	Household textiles	Sanytol Antiácaros (1R-trans-phenothrin 0.45%)	*D. farinae* *D. pteronyssinus* (mixed adults and nymphs; 1000±50 mites/batch)*;*	BPD TNsG PT18 (2012) GLP compliant 4 replicates/treatm.	Simulated-use study Dose: 10 g/m^2 textiles Direct effect (day 0)/residual (day 120) effects Exp.time: 4h	Direct/residual: 100% mortality after 24h Residual efficacy: up to. 4 months	IUCLID/Sec. 6.7/endpoint 003

				Untreated controls included. Choice test, no harbourages. Application by trigger spray on floor of test chamber (6 m^2) covered with treated/untreated tiles (0.25 m^2) of cotton, wool, polyester and polyamide fabrics (total treated area 3 m^2). Mites set on untreated half with food/water.	Observations: mortality after 24h and at day 7.	Controls: <4% mortality	

Conclusion on the efficacy of the product
SANYTOL ANTIÁCAROS has demonstrated sufficient efficacy in laboratory tests against two species of house dust mites (Dermatophagoides pteronyssinus and Dermatophagoides farinae) and bed bugs (Cimex lectularius) following direct exposure to the product. In addition, residual effect was also demonstrated by exposing the target organisms to treated textiles at the dose rate of 10 g/m^2 (=10 mL/m^2). According to the results of the laboratory and simulated use trials, residual efficacy lasts up to 3 months against bed bugs and up to 4 months against mites. SANYTOL ANTIÁCAROS will produce 100% knockdown and kill of target organisms 24h after exposure to the product applied onto common household textiles.

2.2.5.6 Occurrence of resistance and resistance management

1R-trans-fenothrin is the active ingredient of SANYTOL ANTIACAROS. 1R-trans-fenothrin belongs to the class of pyrethroid insecticides. Pyrethroid insecticides belong to the Group 3A (Sodium channel modulators) of the insecticide mode of action classification developed by the Insecticide Resistance Action Committee (IRAC).

According to the Applicant, resistance is considered unlikely to occur as a result of the proposed uses of 1R-transphenothrin. As a result of the scale of the proposed uses the proportion of the target population treated is small and selection pressure for the development of resistance is consequently low. The applicant claimed that no adverse effects on performance attributable to the development of resistance have been recorded during commercial use in Japan.

Resistance against pyrethroids has been demonstrated in a variety of insects. It is conveyed through a number of mechanisms, the two most common of which are modification of the (single) target site in the insect (Kdr knockdown resistance and super Kdr resistance) and enhanced degradation by increased enzyme activity. Accordingly, development of resistance to pyrethroids has been quite well documented (Cochran, 1999). Therefore, the existence should be considered of an inherent risk of resistance developing against the a.s. in target species.

Resistance against pyrethroids has also been confirmed for bed bugs in the recent years, as a result of the intensive use of this type of insecticides after the resurgence of this species. Before, organochlorine and organophosphate insecticides were mostly used. The high effectiveness against insects and low mammalian toxicity of pyrethroids has been the key for them to be in the market. However, to our knowledge, there are not studies considering the resistance of bed bugs to the active substance 1R-trans-fenothrin. Nevertheless, because the a.s. is a pyrethroid, adequate measures should be taken to avoid the development of resistance to the product.

Management strategies to avoid resistance

The principles of strategies for managing the development of resistance are similar for 1R-trans-phenothrin as they are for other synthetic pyrethroids:

- where possible, application treatments should be recommended to be combined with non-chemical measures
- products should always be used in accordance with label recommendations
- complete elimination of insect pests should be attempted in infested areas
- the users should inform if the treatment is ineffective.

2.2.5.7 Known limitations

Regarding the use as an insecticide against bed bugs, it should be considered that these organisms harbour themselves in very confined areas in wall cracks, furniture joints, along lining of mattresses, behind pictures and in seams of furnishings. Therefore even if a biocidal product is used to treat the mattresses, all the other areas around the beds should also be examined and treated with specific products in order to control bed bugs pests. In addition, other textiles that may be cleaned should be washed at temperatures higher than 60ºC to kill adults and juveniles bed bugs.

2.2.5.8 Evaluation of the label claims

The product SANYTOL ANTIÁCAROS is formulated as an aqueous solution containing 0.45% w/w of the active substance 1R-trans-phenothrin. The solution is a ready-to-use liquid packaged in a HDPE plastic bottle with a trigger sprayer. The trigger sprayer delivers 0.9 mL of product in each spray containing 0.9 g of product.

SANYTOL ANTIÁCAROS is intended to be used as an acaricide against house dust mites and as an insecticide to control common bed bugs. The product is intended to be applied onto household textiles that are not frequently washed, where the target organisms live or harbour.

SANYTOL ANTIÁCAROS should be used at a dose rate of 10 mL/m^2 (equivalent to ca. 10 g/m^2) as recommended by the Applicant. The direct efficacy tests were conducted with a dose of 3 mL sprayed onto a batch of mites and bed bugs. Efficacy in terms of knowdown/mortality was achieved with KT100 of 5-10 minutes. The residual efficacy studies were conducted by spraying the product at the rate of 10 mL/m^2 onto textile pieces that were allowed to dry. The product resulted to be sufficiently efficacious up to 3 or 4 months after treatment against bed bugs and mites, respectively. Therefore the recommended dose rate was considered adequate by the eCA.

The following label claims were assessed:

Claim: 'Acaricide'

A general claim for acaricides includes ticks and mites, according to the TNsG. Studies with mites were submitted to support this claim. The general claim 'Acaricide' is not included in the label as such but it is included in the product's name (i.e. 'antiácaros' means 'against mites'). Therefore the main intended use is as an acaricide to control mites. The CA did not request studies against ticks and therefore ticks will not be considered in the label claims.

Since the product is intended to be used to treat textiles in households, the mites' species selected for the trials should be among the common species found in homes, i.e., house dust mites.

According to the TNsG, when mites are the main pest to control, laboratory and simulated use efficacy studies with more than one mite species are required. Efficacy studies with the most common house dust mite species were submitted and evaluated. The two most

common species in Europe are *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*. These studies support the claim 'Acaricide'. Efficacy against house dust mites was demonstrated in two laboratory studies and one simulated-use test in terms of knockdown and mortality.

The label claims that SANYTOL ANTIACAROS eliminates 100% mites instantly. This was demonstrated with the available study when direct efficacy was tested. According to the results, the KT100 for knockdown/mortality of the mites is <5 minutes.

Claim: 'Efficacy against bed bugs'

The use as insecticide against bed bugs is a secondary pest claim. The TNsG requires a test with one species for products against bed bugs. The common bed bug (*Cimex lectularius*) was tested and the eCA considered it sufficient to support the authorisation of the product.

For the general public, the TNsG requires only a laboratory study showing mortality/knockdown and/or residual efficacy according to the label claim. A laboratory test showing mortality/knockdown and/or residual efficacy was submitted by the Applicant.

The label claims that SANYTOL ANTIACAROS eliminates 100% bed bugs instantly. This was demonstrated with the available study when direct efficacy was tested. According to the results, the KT100 for knockdown/mortality of the bed bugs is <10 minutes.

Claim: 'Residual efficacy until 4 months against mites and bed bugs'

The residual efficacy laboratory studies against mites and bed bugs were conducted by spraying the product at the rate of 10 mL/m^2 onto textile pieces that were allowed to dry.

Sufficient efficacy was demonstrated in terms of mortality of the mites (100% kill) after contact with the product residues deposited on textiles treated up to 4 months before.

In the trial against bed bugs, sufficient efficacy was demonstrated in terms of mortality of the mites (100% kill) 24 hours after contact with the product residues deposited on textiles treated up to 3 months before. Textiles aged up to 4 months yielded 56% mortality after 24 hours. This is not considered a sufficient efficacy to support the claim. Therefore residual efficacy up to 3 months for bed bugs may be claimed on the product label.

Knockdown was also recorded during the trial and this is a requirement of the TNsG for consumers. The guidance requires ≥90% knockdown after contact with the product, direct after application and at the end of the residual period, according to the label claim. In the study 100% knockdown was obtained after 4 h with exposure to treated textiles aged 1 day and 1 month, after 6 h in 2-month ageing trial and after 24 h in 3-month ageing trial.

Claim: 'use in household textiles'

The TNsG requires for mites and bed bugs that the product is applied on representative surfaces at the recommended label rate. SANYTOL ANTIÁCAROS was applied onto textile surfaces for residual effects evaluation since the product is intended to be used only for the treatment of textiles not frequently washed. This is considered adequate.

Four types of textile materials (i.e. wool, cotton, polyamide, polyester) were used in the tests. These are considered representative types of household textiles normally found in private houses.

The studies were conducted by spraying the product at the rate of 10 mL/m^2 onto textile pieces that were allowed to dry before the exposure period of 4 hours.

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

The product is not intended to be authorised for use with other biocidal product(s)

2.2.6 Risk assessment for human health

The concentration of the active ingredient, Sumithrin® in the biocidal product SANYTOL ANTIÁCAROS is 0.5%. Sumithrin® is a mixture of diverse isomers of d-Phenothrin (CAS 188023-86-1), and the main component is 1R-trans phenothrin (CAS 26046-85-5). Taking into account that:

- The purity of Sumithrin ® fulfils the criteria established for 1R-trans phenothrin and
- The toxicological and environmentar studies were mainly conducted on product containing 80% trans isomer.

In the following section we consider that the biocidal product SANYTOL ANTIÁCAROS contains 0.45% w/w of 1R-trans phenothrin (CAS 26046-85-5).

No studies were submitted for the risk assessment for human health of the biocidal product SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation).

According to Guidance on the Biocidal Products Regulation (Volume III: Human health Part A: Information Requirements Version 1.1 November 2014, III. Dossier Requirements For Biocidal Products, pp 82), testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

The toxicological end points of the active substance as listed in the Final Assessment Report 1R-trans phenothrin, March 2013, as well as the classification and labelling for human health of the co-formulants (see information in Annex VI of CLP Regulation, C&L Inventory of ECHA and/or data sheets of coformulants) are used for the risk assessment for human health of the biocidal product. Synergistic effects between any of the components are not expected. In addition, the active substance is not classified for human health hazards.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	SANYTOL ANTIÁCAROS is not skin corrosive or irritant to skin.
Justification for the value/conclusion	Based on the classification of the active substance 1R-trans phenothrin and the coformulants and their respective content in the final formulation.
Classification of the	The biocidal product SANYTOL ANTIÁCAROS is not classified.

product according to CLP and DSD	

Data waiving	
Information requirement	Skin corrosion and irritation studies on SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation).
Justification	Several substances in the biocidal product are classified as irritating or corrosive to skin. Some substances have harmonized classification in Annex VI of CLP regulation but other substances are included in the C&L inventory of ECHA. However, their concentration in the product do not exceed the limit for classification of the mixture according to Regulation (EC) Nº 1272/2008 and the biocidal product is not classified with regard to their presence in the product.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	SANYTOL ANTIÁCAROS is not irritant to eyes.
Justification for the value/conclusion	Based on the classification of the active substance 1R-trans phenothrin and the coformulants and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The biocidal product SANYTOL ANTIÁCAROS is not classified.

Data waiving	
Information requirement	Eye irritation studies on SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation).
Justification	Several substances in the biocidal product are classified as irritating or damaging to eye. Some substances have harmonized classification in Annex VI of CLP regulation but other substances are included in the C&L inventory of ECHA. However, their concentration in the product do not exceed the limit for classification of the mixture according to Regulation (EC) Nº 1272/2008 and the biocidal product is not classified with regard to their presence in the product.

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	SANYTOL ANTIÁCAROS is not irritant to respiratory tract.
Justification for the value/conclusion	Based on the classification of the active substance 1R-trans phenothrin and the coformulants and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The preparation SANYTOL ANTIÁCAROS is not classified as "specific target organ toxicity - single exposure, H335".

Data waiving	
Information requirement	Respiratory tract irritation studies on SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation).
Justification	Some substances in the biocidal product are classified as STOT SE 1; H335 according to the C&L Inventory of ECHA. However, their

	concentration in the product do not exceed the limit for classification of the mixture according to Regulation (EC) Nº 1272/2008 and the biocidal product is not classified with regard to their presence in the product.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	SANYTOL ANTIÁCAROS is not skin sensitizer.
Justification for the value/conclusion	Based on the classification of the active substance 1R-trans phenothrin and the coformulants and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The preparation SANYTOL ANTIÁCAROS is not classified.
Remarks: labelling requirements	

Data waiving	
Information requirement	Skin sensitisation studies on SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation).
Justification	There are several substances in the biocidal product which are classified as Skin Sens. 1; H317. Some substances have harmonized classification in Annex VI of CLP regulation but other substances are included in the C&L inventory of ECHA. However, their concentration in the product do not exceed the limit for classification of the mixture according to Regulation (EC) Nº 1272/2008 and the biocidal product is not classified with regard to their presence in the product.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	SANYTOL ANTIÁCAROS is not respiratory sensitiser.
Justification for the value/conclusion	Based on the classification of the 1R-trans phenothrin and the coformulants and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The preparation SANYTOL ANTIÁCAROS is not classified.

Data waiving	
Information requirement	Respiratory sensitisation studies on SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation).
Justification	No substance is classified with this property. No information and evidence was found.

Acute toxicity

Data waiving	
Information requirement	Acute toxicity studies on SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation) were not submitted.
Justification	Point 8.5 of Annex III to the BPR states that classification using the tiered approach to classification of mixtures for acute toxicity in

	Regulation (EC) No 1272/2008 is the default approach. Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. The biocidal product is not acutely toxic by any route according to Regulation (EC) Nº 1272/2008 since all the ingredients which classify as acutely toxic by the oral/dermal/inhalation routes are in a percentages lower than the applicable values in the biocidal product. ATE $_{mix}$ were calculated by oral, dermal and inhalation route taking into account the data/information of active substances and coformulants and the results confirms the no classification of the biocidal product by acute toxicity.

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	SANYTOL ANTIÁCAROS is not harmful by the oral route.
Justification for the selected value	Based on the classification of the 1R-trans phenothrin and the coformulants and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The biocidal product SANYTOL ANTIÁCAROS is not classified.

Data waiving	
Information requirement	Acute toxicity studies on SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation)
Justification	Several substances in the biocidal product are classified as Acute Tox. Via oral route according to Annex VI of CLP, C&L Inventary of ECHA and/or data sheets. However, taking into account their concentration in the product and, in some cases, the LD_{50} of them the biocidal product is not classified.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	SANYTOL ANTIÁCAROS is not harmful by the inhalation route.
Justification for the selected value	Based on the classification of the 1R-trans phenothrin and the coformulants and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The preparation SANYTOL ANTIÁCAROS is not classified.

Data waiving	
Information requirement	Acute toxicity studies on SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation)

Justification	Several substances in the biocidal product are classified as Acute Tox. Via inhalation route according to Annex VI of CLP, C&/L Inventary of ECHA and/or data sheets. However, taking into account their concentration in the product, and, in some cases, the LC_{50} of them, the biocidal product is not classified.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	SANYTOL ANTIÁCAROS is not harmful bu the dermal route.
Justification for the selected value	Based on the classification of the 1R-trans phenothrin and the coformulants and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The preparation SANYTOL ANTIÁCAROS is not classified.

Data waiving	
Information requirement	Acute toxicity studies on SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation)
Justification	Several substances in the biocidal product are classified as Acute Tox. Via dermal route according to Annex VI of CLP, C&/L Inventary of ECHA and/or data sheets. However, taking into account their concentration in the product, and, in some cases, the LC50 of them, the biocidal product is not classified.

Information on dermal absorption

According to the risk and exposure assessment for human health, no risk is envisaged for non-professional users considering the following values for dermal absorption.

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	SANYTOL ANTIÁCAROS	SANYTOL ANTIÁCAROS
Value(s)*****	75% for primary exposure	75% for secondary exposure
Justification for the selected value(s)	Guidance on Dermal Absorption[a], EFSA Journal 2012;10(4):2665	Guidance on Dermal Absorption[a], EFSA Journal 2012;10(4):2665

***** No dermal absorption study on SANYTOL ANTIÁCAROS is submitted.

[a] In absence of data on the formulation into consideration, a default value of 75% should be used for products or in use dilutions containing ≤ 5% active substance.

Data waiving	
Information requirement	Dermal absorption studies on SANYTOL ANTIÁCAROS (1R-trans phenothrin 0.45% formulation).
Justification	The applicant justified the no submission of data taking into account the information about dermal absorption included in the assessment report of the active substance. The absorption of 1R-trans phenothrin from a nominal 1% w/v 1R-trans phenothrin formulation, (actual content 10g 1R-trans phenothrin/Litre) was measured in vitro through human epidermis. A dermal absorption of 4.5% of the applied dose was found in the study submitted for Annex I entry [Please refer to the letter of access granted by Sumitomo (notifier and having on all the data included in the dossier for 1R trans phenothrin presented by

	Sumitomo), based in the information reported in the Assessment Report (March 2013)]. According to EFSA guidance pp. 18, data generated with the active substance should only be used when the formulation under evaluation is very closely related to the vehicle used in the study with the active substance, in terms of solvent, surfactant content, skin irritancy and active substance content. This equivalence has not been demonstrated, hence the use of a dermal absorption value of 4.5% is not supported. In absence of data on the product SANYTOL ANTIÁCAROS, the use of default value of 75% following EFSA guidelines on dermal absorption, is believed to represent a sufficient conservative approach for human exposure.

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

The biocidal product contains 0.45% (w/w) of the active substance 1R trans phenothrin and other co-formulants. Several components of the biocidal product carry toxicological hazard classification; (see confidential Annex, section 2.2.6.1 Assessment of effects on Human Health).

SANYTOL ANTIÁCAROS contains two substances currently in the review program of active substances for biocidal uses as PT6 (in can preservatives). The data related to these substances shall be taken into account in the evaluation after their approvals at European level, at product's renewal stage. These substances have a concentration which does not exceed the limit for classification according to Regulation (EC) Nº 1272/2008 and the biocidal product is not classified with regard to their presence in the product. Hence, these co-formulants are not considered to be substances of concern.

Available toxicological data relating to a mixture

Not applicable. The uses of this product do not consider the combination with any other product or active ingredient.

ED Assessment

<u>- Assessment of the ED properties of the active substance:</u>

El biocidal product contains 1R-trans phenothrin On the basis of the evaluation of toxicology/eco-toxicology studies when the active substance was approved, The CAR of active substance indicates: "*no determination of endocrine disruption effects could be ascertained in the test organisms dosed with 1R-trans Phenothrin.*

However, d-Phenothrin is listed in the Annexes of the EU Commission document on implementation of the Community Strategy for Endocrine Disruptors as a substance with the potential to be a substance that cause endocrine disruption in both humans and animals. With this in mind, further information may be required to assess the potential for endocrine disruption of both d-Phenothrin and 1R-trans phenothrin when EU harmonised guidelines are established for test methods and risk assessment".

Nevertheless, according to *List compilation exclusion or substitution criteria (Version. January 2019)*, 1R-trans phenothrin there is no concern for endocrine disruption.

<u>- Assessment of the ED properties of non-active substances (co-formulants):</u>

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disruption assessment of co-formulants is mandatory according to the article 19. Pending a

standardized procedure is made available at EU level, the following sources were considered to check the potential endocrine disrupting properties of the co-formulants contained in the biocidal product:

Substance identified as ED under the BPR: https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d

Substance identified as ED under the PPPR: https://ec.europa.eu/food/sites/food/files/pesticides_ppp_app-proc_cfs_database-201501.xlsx

ECHA Candidate List of substances of very high concern for Authorisation: https://echa.europa.eu/candidate-list-table

ECHA's Endocrine disruptor assessment list: https://echa.europa.eu/ed-assessment

EU Community rolling action plan (CoRAP): https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table.

Regarding this, no ED properties have been detected in co-formulants when the search has been performed. This information can be included in the PAR.

- Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the data provided by the applicant, there is no indication of concern regarding the ED properties of the substances used in the biocidal product SANYTOL ANTIACAROS.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

Other

No other additional tests relating to exposure of 1R-trans phenothrin or the formulated product SANYTOL ANTIÁCAROS, are considered necessary due to the lack of risk of the different population groups that are exposed as a consequence of the intended uses.

2.2.6.2 Exposure assessment

The product SANYTOL ANTIÁCAROS is marketed as ready-to-use water solutions in plastic trigger spray bottles. It is only for use in domestic small-scale. Therefore, exposures from professional operators have not been assessed.

The primary and secondary exposure scenarios considered in the risk assessment from the use of SANYTOL ANTIÁCAROS are described below.

There are no substances of concern.

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

Summary table: application by trigger spray, relevant paths of human exposure		
Exposur	**Primary (direct) exposure**	**Secondary (indirect) exposure**

e path	Trained professional use	Professional use	Non-professional use*	Trained professional use	Professional use	General public	Via food [3]
Inhalation	n.a.	n.a.	Yes	n.a.	n.a.	No[1]	No
Dermal	n.a.	n.a.	Yes	n.a.	n.a.	Yes[2]	No
Oral	n.a.	n.a.	Yes	n.a.	n.a.	Yes[2]	No

n.a. = not applicable;
1R-trans phenothrin and the biocidal product are produced in Japan /the EU respectively. The exposure during the production of the active substance and the formulation of the biocidal product are not assessed by the rapporteur under the requirements of the BPR. However, the rapporteur assumes that the production is performed in conformity with national and European occupational safety and health regulations.
** Use by the general public. The product is not intended for professional use.*
[1] secondary exposure via inhalation route is considered negligible due to the low vapour pressure of the active substance (2.37E-5Pa, 20ºC).
[2] via dermal and/or hand to mouth contact (e.g., infants) with treated textiles after application of b.p.
[3] food contamination and exposure of animals is not expected using the product according to label instructions.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Application: spraying	Primary exposure Application of ready to use product using a trigger spray.	Non professional
2.	Post application: sleeping in a treated mattress	Secondary exposure Dermal contact with treated textiles.	Bystander (infant/ adult)
3.	Post application: crawling on treated carpet	Secondary exposure Dermal and hand to mouth contact with treated textiles.	Bystander (infant)

Industrial exposure

1R-trans phenothrin and the biocidal product are produced in Japan /the EU respectively. The exposure during the production of the active substance and the formulation of the biocidal product are not assessed by the rapporteur under the requirements of the BPR. However, the rapporteur assumes that the production is performed in conformity with national and European occupational safety and health regulations.

Professional exposure

Not applicable. The product is not intended for professional uses.

Non-professional exposure

Scenario [1] spray application of SANYTOL ANTIÁCAROS

Description of Scenario [1] spray application of SANYTOL ANTIÁCAROS

SANYTOL ANTIÁCAROS is specifically designed for small-scale use in residential properties and is to be marketed solely for the non-professional worker market. Potential exposure via dermal and inhalation route is expected during the spray application of SANYTOL ANTIÁCAROS. Also part of the inhaled product (non-respirable fraction) could be ingested by the oral way.
This is a ready-for-use indoor product, no dilution is required. The product is applied spraying onto the home textiles that are not frequently washed (mattresses, carpets, upholsteries…).
The application rate is 10 g product/m^2. Spray preferably in the morning to allow drying for 8 hours and vacuum the applied surface. Hoover again the surfaces to remove the dead insects. The mattress must be enclosed in a protective cover.
According to the efficacy, re-apply the product every 3-4 months.
In absence of appropriate product-specific data (such as amount of product delivered per trigger pull or aerodynamic particle size mean distribution of the spray), the default scenario in ConsExpo: Pest Control Products /Sprays /Application (trigger spray) is used to estimate the exposure to the consumer.
The inhalation exposure 'spray' model and the dermal exposure model 'constant rate' from ConsExpo are used to describe the scenario. The oral exposure is handled in the inhalation exposure model. ConsExpo assumes that the non-respirable fraction is taken in orally.
Either ConsExpo 4.1 software or the ConsExpo Web version are used to estimated exposure using the following input parameters:

	Parameters	Value
Tier 1	weight fraction substance	0.45%
	Dermal absorption[1]	75%
	Exposed body surface area[2]	1948.8 cm^2
	Contact rate[2]	46 mg/min
	Oral absorption[3]	60%
	Inhalation absorption	100%
	Density of non-volatile[2]	1 g/cm^3
	Weight fraction non-volatile[4]	0.012
	Airborne fraction[4]	0.008
	Spray duration[2]	6 min
	Mass generation rate[4]	0.8 g/sec
	Aerosol diameter distribution [4] Median diameter Arithmetic coefficient of variation Maximum diameter Inhalation cut off diameter	Log Normal 7.7 µm 1.9 50 µm 15 µm
	Room volume[5] Ventilation rate	20 m^3 0.6 hr^{-1}
	Body weight[6]	60 kg

[1] Guidance on Dermal Absorption, EFSA Journal 2012;10(4):2665.
[2] Default area of hands and lower arms and body weight for adult in HEEG opinion 17
[3] considered for exposure assessment purposes in Tier 1 assessment. The oral absorption of the a.s. is 60% (Final Assessment Report of 1R-trans phenothrin, 2013)

[4] RIVM Report 320104005/2009, 'The ConsExpo spray model. Modelling and experimental validation of the inhalation exposure of consumers to aerosols from spray cans and trigger sprays'
[5] RIVM report 090013003/2014; General Fact Sheet Updated version 2014: defaults for unspecified room
[6] HEEG Opinion 17.

Calculations for Scenario [1] spray application of SANYTOL ANTIÁCAROS

See calculations in Annex 3.2

Summary table: systemic exposure for Scenario [1] [mg/kg bw]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1/ none	3.6E-3	1.6E-2	1.2E-4	1.97E-2

Further information and considerations on scenario [1]

ConsExpo assumes that the application takes place 9 times per year and the exposure during the day of application lasts for 4 hours. According to the specific instructions for use of SANYTOL ANTIÁCAROS, the treatment of textile surfaces is done once every three-four months and the textile is left to dry for 8 hours after the spray application. Hence it is considered that the exposure is short term. In addition given the pattern of use it is assumed that the duration of exposure is 60 min.

Taking into account that the product is applied occasionally, the primary exposure scenario presented here is considered short term and will be compared to AEL $_{\text{short term}}$ for risk assessment purposes.

Using the default values from ConsExpo, by multiplying the mass generation rate and the spray duration (set at 6 min), the total amount of sprayed formulation can be calculated (0.8 g/sec x 360 sec = 288 g).

The recommended application rate of SANYTOL ANTIÁCAROS is 10 g/m^2 surface and one application is every 3-4 months. Therefore, 288 g/day allow the treatment of:

$$288 \text{ g/day} / 10 \text{ g/m}^2 = 28.8 \text{ m}^2\text{/day}$$

Assuming a double size mattress (surface area: 135 cm * 191 cm * 2 (sides) = 5.2 m^2), this application is equivalent to two sides of five mattresses. Therefore, the default CONSEXPO parameters can be considered as very conservative. However, no refinements of the model inputs related to the application rate have been done.

Accidental exposure by application of the product directly on the skin

An incidental contact of the product with the skin of the applicator during the application of the product is not included in the exposure estimation. Accidents (swallowing, children who open the container) do not form a part of a standard assessment.

Combined scenarios

Not applicable.

Exposure of the general public: Indirect exposure as a result of use of the active substance in biocidal product

Scenario [2] Dermal exposure of infant/adult sleeping in a treated mattress

Description of Scenario [2] Dermal exposure of infant/adult sleeping in a treated mattress

The model in **US EPA SOP October 2012; *Standard Operating Procedures for Residential Pesticide Exposure Assessment,* Section 7 Indoor Environments; 7.2.2.2 Post-Application Dermal Exposure Algorithm (mattresses) 7-35**, is used to estimate exposure.

Post-application dermal exposure can occur as a result of insecticide applications to mattresses, such as those directed for the control of bedbugs. Exposure to treated mattresses is dependent on a number of exposure factors. The algorithm to calculate the absorbed dose is as follows:

$$D = DR * SA/BW * F * Fai * PF * AF * CF1$$

where:

- D = Dermal dose (mg/kg-day);
- DR = Deposited residue (mg/cm^2);
- SA/BW = Surface area / Body Weight Ratio (cm^2/kg);
- F = Fraction of body that contacts residue;
- CF1 = Conversion factor (mg/µg);
- AF = Absorption factor;
- Fai = fraction of ai available for transfer from treated mattress; and
- PF = Protection factor to account for the presence of a single layer of fabric (e.g. bed sheet) between the treated material and individual.

The dermal contact with the treated surfaces is the main route of exposure after the product is applied to textile products. The residues of 1R-trans phenothrin in surfaces can be removed from the textiles during diverse activities: sleeping in treated mattress, crawling in carpets, sitting in sofa and handling other treated textiles.

Taking into account people usually sit dressed on chairs and sofas, we have not taken into account the exposure derived from these situations because we have considered it negligible.

The specific scenario that can be associated to a major exposure is during the sleeping in a treated mattress, because the surface and the contact time are larger than in other indirect exposure scenarios.

According to the label instructions, the mattress will be dried and vacuumed after treatment but there are no data available quantifying the amount of residues that will remain on the surface. It is reasonable to admit that the product available on the mattress will be reduced. If we assume that after vacuuming 10 % of the used amount of product remains on the surface, the deposited residue (DR) can be calculated as:

DR = 10 g/m^2 (application rate) * 10% (residual fraction) *0.45%sa =0.45µg sa/cm^2

The following parameters are used to estimate exposure:

	Parameters	Value
Tier 1	DR[1]	0.45 µg/cm^2
	SA[2]	4100 cm^2 infant 16600 cm^2 adult
	BW[3]	8 kg infant 60 kg adult
	SA/BW[4]	512.5 cm^2/kg infant 276.7 cm^2/kg adult

	F[5]	100%
	Fai[6]	30% Tier 1 15% Tier 2
	PF[7]	50%
	AF[8] (Dermal absorption)	75%
	CF1[9]	0.001 mg/µg

[1] Surface residue concentration of a.i.; from application rate: 10g/m^2 * 0.0045 g ai/g prod *10E6 µg/g*10E-4 m^2/cm^2*10%(residual fraction after vacuuming)
[2] body surface area HEEG Opinion 17
[3] body weight HEEG Opinion 17
[4] body surface area to body weight ratio. Infant 6 < 12 months old is chosen as worst case (highest SA/BW ratio)
[5] Fraction of body that contacts residue (whole body, worst case)
[6] Fraction of ai available for transfer (Tier 1 Transfer coefficients – dislodgeable residues BHHEM pg 351(355); Tier 2 see explanations below)
[7] Protection factor (default)
[8] EFSA Guidance on dermal absorption
[9] conversion factor (default)

Calculations for Scenario [2] Dermal exposure of infant/adult sleeping in a treated mattress

See calculations in Annex 3.2

Summary table: systemic exposures for Scenario [2] _ Tier 1 Short Term Exposure [mg/kg bw]					
Exposure scenario	**Tier/ population**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1/ infant	-	0.0259	-	0.0259
Scenario [2]	Tier 1/ adult	-	0.0140	-	0.0140

Further information and considerations on Scenario [2]

The Scenario includes the following assumptions:

- 100% of the surface of the mattress is treated (USEPA model).
- Whole of the body is in contact with the mattress (100% of body surface area) (worst case).
- The fraction of residue available for transfer from mattresses is assumed to be similar to that for cotton 30% (dislodgeable residue) (Transfer coefficients – dislodgeable residues BHHEM pg 351(355)).
- A protection factor is included to account for the presence of a single layer of fabric (e.g., bed sheet) between the treated material and the individual (0.5) (USEPA model).

The USEPA model estimates an approach to the exposure in the first day after the application. It must be noted that according to the label instructions the mattress will be left to dry for 8 hours after treatment and vacuumed. There are no experimental data available quantifying the amount of residues that will stay on the textile after drying and vacuuming, but, taking into account RIVM 320104003/2006 reports 10% for powder products containing water, solvents and sufactants and the application method is spraying, and also that the

transfer coefficients for carpet are the same for dried fluids and powders in the BHHEM, it is reasonable to admit that 10% is a good approach for effectiveness of mattress vacuuming.

Hence, this secondary exposure scenario is considered the worst case acute exposure (taking place the day of the application). The exposure thus estimated is compared to $AEL_{short\ term}$ for risk assessment purposes.

Tier 2 Estimation of medium term exposure for Scenario [2]

According to USEPA (Residential SOP Oct 2012, 7-38) post-application dermal exposure following applications indoors is generally considered short-term in duration, but is dependent on the dissipation/degradation properties of the active ingredient. The treatment of textile surfaces is recommended to be done once every three months for bed bugs or four months for mites. Therefore the residues remaining will vanish between applications by several mechanisms and the long term mean daily exposure would be lower than the exposure on the day of application. For longer-term assessments, chemical-specific information on removal/degradation processes that can decrease the amount of residue found would allow for better characterization of potential exposure.

Secondary exposure will be medium term if we consider that the residues will be available for transfer until the dissipation of the substance is complete between applications. The medium term exposure could be estimated using a % of transferable residue that reflects an averaged value during that period.

Literature provides a certain number of studies where residues of pyretroids on textiles are measured. Several examples are shown below:

- Snodgrass H.L., (J. Toxicol. Environ. Health., 1992; 35 (2):91-105), quantified leaching from pyretroid-treated clothing and results showed that fabric treated with permethrin at a rate of 0.125 mg/cm^2 lost the substance to the skin surface at an average rate of 0.49%/d.
- Williams, R.L., (J. Expo. Anal. Environ. Epidemiol., 2003; 13: 112-119), reported results of carpet and surface residue monitoring following an indoor application of cyfluthrin to nylon carpet and found that percent of transferable residues varied from 8%, 3 hr after application, to 1% of applied dose, approx. 15 days after application; (application rate of 5% (w/v)).
- Also Williams, R.L., (J. Environ. Sci. & Health Part B, 2008; 43 , 675–679) in a study measuring the dislodgeable residues of cyfluthrin from carpet (at application rate of 0.05% (w/v) or 4 µg/cm^2) found that the residue transferability decreased during the study period (21 days). Transferable chemical residue declined from day 1 =0.08 µg/cm^2 (2% of applied dose) to day 7 =0.04 µg/cm^2 and day 21 =0.02 µg/cm^2 (0.5% of applied dose).

From these studies, we could observe that the reduction of transferable residues with time is around 80/75% in 15/21 days. Being conservative and applying a reduction of 50% to the fraction of transfer residue available as an average value during the period of medium term exposure, we would have a Transfer coefficient – dislodgeable residues of 15% for a Tier 2 exposure assessment in this scenario.

The same input parameters as in Scenario [2] for short term exposure are used except for the value of Fai = 15% 1R-trans phenothrin.

Calculations for Scenario [2] Dermal exposure of infant/adult sleeping in a treated mattress _ Tier 2 Medium Term Exposure

See calculations in Annex 3.2

Summary table: systemic exposures for Scenario [2] _ Tier 2 medium term exposure [mg/kg bw/d]					
Exposure scenario	**Tier/ population**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 2/ infant	-	0.013	-	0.013
Scenario [2]	Tier 2/ adult	-	0.007	-	0.007

Scenario [3] Infant crawling on treated carpet and hand to mouth contact

Description of Scenario [3] Infant crawling on treated carpet and hand to mouth contact		
In the EU Biocide Products Regulation, infants (>6 to 12 months) are considered as the worst case exposed population in the rubbing off scenario for playing on indoor treated surfaces. The scenario of an infant crawling on a treated carpet includes not only the dermal exposure as a consequence of the residues rubbed off but also includes the ingestion of the residues due to hand to mouth transference. The model in **RIVM report 320005002/2006 Pest Control Products Fact Sheet pp 28**, is used to estimate exposure. The model assumes that an infant is crawling on a treated carpet during an hour. Exposure after application is described using the dermal exposure model 'rubbing off' and the oral exposure, due to hand-mouth contact, with the 'constant rate' model. The following parameters are used to estimate exposure: • The dislodgeable amount (DA) is the amount of substance on the treated textile that can be brushed off. • The transfer coefficient (TC) is the surface that is wiped per unit time due to skin contact. • Dermal exposure of children can take place on any uncovered skin, that is, on the head, the arms and hands, and on the legs and feet. • The ingestion rate (IR) can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth contact.		
	Parameters	Value
Tier 1	Content in a.s.	0.45%
	Rubbed floor surface[1]	22m^2 (living room)
	Transfer coefficient[2] (TC)	0.2 m^2/hr
	Exposed body area[3]	2410 cm^2
	Body weight[3]	8kg
	Dermal absorption[4]	75%
	Oral uptake[5]	60%
	Dislodgeable amount[6] (DA) 6%	0.6 g bp/m^2
	Ingestion rate (IR)[6] = 10%*DA*TC	0.2 mg bp/min
	Duration of exposure[1]	1hr/day
Tier 2	Dislodgeable amount[7] (DA) 3%	0.3 g bp/m^2

	Ingestion rate (IR)[7] = 10%*DA*TC	0.1 mg bp/min

[1] RIVM Report 320005002 & RIVM Report 090013003/2014, (General Fact Sheet - Updated version 2014)
[2] Recommendation 12 of Ad hoc Working Group on Human Exposure New default values for indoor Transfer Coefficient
[3] Default area of hands, head, arms, legs and feet and body weight for infant 6 to <12 months old in HEEG opinion 17
[4] EFSA Guidance on Dermal Absorption
[5] Assessment Report 1R-trans phenothrin March 2013
[6] US EPA Residential SOPs, October 2012, 7-32 https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide#sops
Dislodgeable amount 6% of applied product; DA = 10g/m^2 * 6% =0.6 g bp/m^2
Ingestion rate; IR = 0.6 g bp/m^2 * 0.2 m^2/hr * 10% = 0.012 g bp/hr = 0.2 mg/min
[7] refinement: after vacuuming 10% of the applied product remains on carpet, see explanations below
Dislodgeable amount 3% of applied product; DA = 10g/m^2 * 3% = 0.3 g bp/m^2
Ingestion rate; IR = 0.3 g bp/m^2 * 0.2 m^2/hr * 10% = 0.006 g bp/hr = 0.1 mg/min

Calculations for Scenario [3] Infant crawling on treated carpet and hand to mouth contact

See calculations in Annex 3.2

Summary table: systemic exposure for Scenario [3] as [mg/ kg bw/ d]					
Exposure scenario	**Tier/ population**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	Tier 1/infant	-	5.1E-2	4.1E-3	5.51E-2
Scenario [3]	Tier 2/infant	-	2.5E-2	2.0E-3	2.7E-2

Further information and considerations on Scenario [3]

USEPA Residential SOPs Oct 2012 sets a default value of 6% of dislodgeable residue from carpets: in Table 7-8: Chemical-specific Fraction transferred (Fai) for Carpets (7-32) the measured value for Permethrin is 6% (arithmetic mean).

Hence the dislodgeable amount (DA) is:

Tier 1: DA = 10 g/m^2 (application rate) * 6% (dislodgeable fraction) = 0.6 g/m^2.

According to the label instructions, the textile will be vacuumed after treatment but there are no data available quantifying the amount of residues that will remain on the carpet. It is reasonable to admit that the product available on the carpet will be reduced. If we assume that after vacuuming 10 % of the used amount of the product remains on the carpet from which a certain fraction is dislodgeable (as considered in ConsExpo RIVM report 320104003, pp 97) and using the more conservative value of 30% of dislodgeable fraction (the default value for the dislodgeable amount from general surfaces is set at 30% by ConsExpo), the amount of product that is transferable (DA) can be calculated as:

Tier 2: DA = 10 g/m^2 (application rate) * 10% (residual fraction) * 30% (dislodgeable fraction) = 0.3 g/m^2.

The value of DA = 0.3 g/m^2, is used in the assessment presented as Tier 2 in table above and it is considered a realistic refinement of the scenario.

ConsExpo defines 14 days as the total contact time for children who are exposed orally and dermally after the treatment. The use frequency is 3 times per year, hence the default

value for the frequency that children are exposed after the treatment is set at (14 x 3 =) 42 days per year. On this basis, medium term exposure is expected.

It must be noted that ConsExpo gives an averaged year dose taking into account that exposure takes place only for 42 days per year (averaged year dose = daily dose * 42 days/year * 1 year/365 days).

However, it is not common practice to average the doses over a year in EU biocides evaluation. Hence the exposure estimated using the ConsExpo model (which represents the internal dose on the day of exposure) is compared to $AEL_{medium\ term}$ for risk assessment purposes.

Combined scenarios

Combined scenario for short term exposure of adults.

Non-professionals will be exposed to the product during the application and after the product is applied. The scenarios that can be combined considering the time frame used to estimate exposures are: Scenario [1] spray application of SANYTOL ANTIÁCAROS and Scenario [2] Dermal exposure of adult sleeping in a treated mattress _ Short Term Exposure.

The combined systemic exposure is shown in table below.

Summary table: combined systemic exposure for Scenarios [1] + [2] [mg/kg bw]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1] + [2]	Tier 1/ none	3.6E-03	3.0E-02	1.21E-04	3.37E-02

Combined scenarios for medium term exposure of infants.

Infants will be exposed after the product is applied. Taking into account the time frame used to estimate exposure, there are two scenarios that can be combined: Scenario [2] Dermal exposure of infant sleeping in a treated mattress (Tier 2 Medium Term Exposure) + Scenario [3] Infant crawling on treated carpet and hand to mouth contact. The Scenario [3] allows for a refinement of exposure in Tier 2.

The resulting combined systemic exposures are shown in the table below.

Summary table: systemic exposure for Scenarios [2] & [3] [mg/ kg bw/ d]					
Exposure scenario	**Tier/ population**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2] + [3]	Tier 2 [2] and Tier 1 [3]/ infant	-	6.4E-2	4.1E-3	6.8E-2
Scenario [2] + [3]	Tier 2 both / infant	-	3.8E-02	2.0E-03	4.0E-02

Monitoring data

Not applicable.

Dietary exposure

Food contamination as result of use

The biocidal product is applied spraying on textiles not usually washed (courtains, mattresses,..). This precise mode of application prevents the contamination of surfaces where food is stored or prepared; it is unlikely that there could be transference of residues to food.

In addition, the label must include restrictions/instructions to preclude food contamination:

- Keep away and avoid any direct or indirect contact from food/feedingstuff, eating utensils or food/feed contact surfaces.

Conclusion

Dietary risk does not have to be further considered.

Information of non-biocidal use of the active substance
Not applicable. There is no non-biocidal use of the active substance

Estimating Livestock Exposure to Active Substances used in Biocidal Products

The biocidal product is applied spraying on textiles not usually washed (courtains, mattresses,..). This precise mode of application prevents the contamination of surfaces where feed is stored or prepared; it is unlikely that there could be transference of residues to feed. The product should be applied in spaces inaccessible to animals; hence, exposure of livestock to residues of the biocidal product is not expected.

In addition, the label must include restrictions/instructions to preclude feed contamination:

- Keep away from food/feedingstuff, eating utensils or food/feed contact surfaces.

Conclusion

Livestock exposure does not have to be further considered.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)
Not applicable. The product is intended for non-professional uses.

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

Transference of residues of the biocidal product into foods as a result of non professional uses is not expected due to the intended uses and the mode of application.

In addition, the label must include restrictions/instructions to preclude food contamination:

- Keep away from food/feedingstuff, eating utensils or food/feed contact surfaces.

Exposure associated with production, formulation and disposal of the biocidal product
Not applicable.

Summary of exposure assessment

Scenarios and values to be used in risk assessment

Scenario number*	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/remarks**	**Estimated total uptake [mg/kg bw-d]**
1.	Non-professional	Tier 1/ no PPE Short term exposure	0.0197
2.	Bystander/ Infant	Tier 1/ Short term exposure	0.0259
2.	Bystander/ Adult	Tier 1/ Short term exposure	0.0140
2.	Bystander/ Infant	Tier 2/ Medium term exposure	0.013
2.	Bystander/ Adult	Tier 2/ Medium term exposure	0.007
3.	Bystander/ Infant	Tier 1/ Medium term exposure	0.0551
3.	Bystander/ Infant	Tier 2/ Medium term exposure	0.027
1 + 2	Non-professional	Tier 1 both scenarios/ combined scenario for short term exposure	0.0337
2 + 3	Bystander/ Infant	Tier 2 [2] and Tier 1 [3]/ combined scenario for medium term exposure	0.068
2 + 3	Bystander/ Infant	Tier 2 both / combined scenario for medium term exposure	0.04

* Scenario [1] spray application of SANYTOL ANTIÁCAROS; Scenario [2] Dermal exposure of infant/adult sleeping in a treated mattress; Scenario [3] Infant crawling on treated carpet and hand to mouth contact

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	rabbit oral development toxicity study	30 mg/kg bw/day	100	60%	0.18 mg/kg bw/day
AELmedium-term	dog chronic toxicity study	8.2 mg/kg bw/day	100	60%	0.05 mg/kg bw/day
AELlong-term	dog chronic toxicity study	8.2 mg/kg bw/day	100	60%	0.05 mg/kg bw/day
ARfD	rabbit oral development toxicity study	30 mg/kg bw/day	100	*	0.3 mg/kg bw/day
ADI	chronic dietary toxicity study in dogs	8.2 mg/kg bw /day	100	*	0.08 mg/kg bw/day

[1] A safety factor of 100 (10 for interspecies and 10 for intraspecies) is considered sufficient

* oral absorption correction value is not normally applied to the ARfD/ADI

Maximum residue limits or equivalent

Residue definitions: not applicable.

The active substance is not approved under Reg. (EC) No 1107/2009 (plant protection products), hence the MRLs are set at the lower limit of analytical determination (see Reg. (EU) 2015/868).

The active substance is only EU - approved for biocidal PT18 uses.

Risk for professional users

Not applicable. The product is intended for non-professional uses

Risk for non-professional users

According to the specific instructions for use of SANYTOL ANTIÁCAROS, the treatment of textile surfaces by spraying is done once every three-four months. Hence it is considered that the exposure associated with the application of the product is short term.

The secondary exposure Scenario [2] Tier 1 'sleeping in a treated mattress', is considered a worst case acute exposure (taking place the day of the application) where the effect of the vacuuming and the dissipation of residues over time in the residue level are not considered. The USEPA model used was developed for the assessment of the short term exposure in the first day post-application. A Tier 2 assessment for this secondary exposure scenario, where the dislodgeable residue is refined to account for medium term exposure, is also presented.

Systemic effects

Task/	Tier	Systemic	AEL	Estimated	Estimated	Acceptable

Scenario		NOAEL mg/kg bw/d	mg/kg bw/d	uptake mg/kg bw/d	uptake/ AEL (%)	(yes/no)
Application: spraying/ Scenario [1]	1	30	0.18	0.0197	11	Yes
Post application: sleeping in treated mattress/ Scenario [2]	1	30	0.18	0.0140	8	Yes
Post application: sleeping in treated mattress/ Scenario [2]	2	8.2	0.05	0.007	14	Yes

Considering the time frame of the exposure scenarios presented for non-professionals, the combined exposure for adults as results of both primary and secondary scenarios for short term exposure is compared to AEL $_{\text{short term}}$ for risk assessment purposes.

Combined scenarios

Scenarios combined	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] & [2] combined for short term exposure	1	30	0.18	0.0337	19	Yes

Local effects

Not applicable.

Conclusion

The short term exposure assessment for non-professional users under worst case assumptions yields potential exposures leading to systemic doses from 0.0140 to 0.0337 mg/kg bw-d during the application and postapplication tasks and the combined scenarios. The estimated uptakes represents 8 to 19 % of the proposed AEL of 0.18 mg/kg bw/day.

The medium term exposure assessment for non-professional users under worst case assumptions shows that the exposure associated to the scenario 'sleeping in a treated mattress' is below concern. The estimated uptake represents 14% of the proposed AEL of 0.05 mg/kg bw/day.

Assessment indicates an acceptable risk for non-professional users. No risk is envisaged for the use of SANYTOL ANTIÁCAROS by non-professional users.

Risk for indirect (secondary) exposure for the general public

Systemic effects

The secondary exposure Scenario [2] Tier 1, 'sleeping in a treated mattress', is considered a worst case acute exposure (taking place the day of the application) where the dissipation of residues over time in the residue level are not considered. The USEPA model used was developed for the assessment of the short term exposure in the first day post-application. Hence, exposure is compared to $AEL_{short\ term}$ for risk assessment purposes. A Tier 2 assessment for this secondary exposure scenario, where the dislodgeable residue is refined to account for medium term exposure, is also presented.

The ConsExpo model used to estimate the exposure associated to Scenario [3], 'infant crawling on treated carpet', defines 14 days as the total contact time for children who are exposed orally and dermally after the treatment. However, SANYTOL ANTIÁCAROS is used 3 times per year, hence the default value for the frequency that children are exposed after the treatment is set at (14 x 3 =) 42 days per year. On this basis, medium term exposure is expected. Considering that it is not common practice to average the doses over a year in EU biocides evaluation, the exposure estimated on the day of application will be compared to $AEL_{medium\ term}$ for risk assessment purposes. A Tier 2 assessment for this secondary exposure scenario, where the dislodgeable residue is refined, is also presented.

Systemic effects

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] infant sleeping in treated mattress	1	30	0.18	0.0259	14	Yes
Scenario [2] infant sleeping in treated mattress	2	8.2	0.05	0.013	26	Yes
Scenario [3] infant crawling on treated carpet and hand to mouth contact	1	8.2	0.05	0.0551	110	No
Scenario [3] infant crawling on treated carpet and hand to mouth contact	2	8.2	0.05	0.027	54	Yes

Combined scenarios

Medium term exposure scenarios can be combined for infants as shown below.

Scenarios	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
2 + 3	Tier 2 [2] and Tier 1 [3]	8.2	0.05	0.068	136	No
2 + 3	Tier 2 both	8.2	0.05	0.04	80	Yes

Local effects

Not applicable.

Conclusion

The short term exposure assessment for indirect exposure of infants under worst case assumptions yields a potential exposure leading to a systemic dose of 0.0259 mg/kg bw. The estimated uptake represents 16% of the proposed AEL of 0.18 mg/kg bw/day. The acute indirect exposure of infants is below concern.

The medium term exposure assessment for indirect exposure of infants under worst case assumptions yields a potential exposure leading to systemic doses from 0.068 to 0.04 mg/kg bw-d, (considering Scenario [2] Tier 2, Scenario [3] both Tier 1 and Tier 2, and the combined scenarios). The estimated uptakes represent from 136 to 80% of the proposed AEL of 0.05 mg/kg bw/day. The results for Tier 2 assessments shows that the medium term indirect exposure of infants is below concern (including the exposure estimated for the combined scenarios).

Assessment indicates an acceptable risk for the indirect exposure of infants. No risk is envisaged for the use of SANYTOL ANTIÁCAROS by the general public.

In addition, the following label restrictions must be included to preclude or minimise the exposure of children and the general public:

- After application allow drying for 8 hours and vacuum the applied surface.
- Avoid contact of children with treated surfaces until the surfaces are dry.
- Do not perform the operation in presence of people.
- Product must be securely applied in a way so as to minimize the risk of consumption by children.
- The product contains a bitter substance that makes it repulsive to people.

Risk for consumers via residues in food

The biocidal product is intended to be used as a spray application on textiles (mattresses, courtains, carpets,..) three times per year. In addition, the label includes intructions/ restrictions of use to preclude the transference of residues to food.

The mode of use of SANYTOL ANTIÁCAROS makes food contamination unlikely.

No risk for consumers via residues in food is envisaged.

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

Not applicable.

2.2.7 Risk assessment for animal health

The label must include restrictions and instructions of use to preclude exposure of animals. The following label restrictions preclude the exposure of animals:

- Do not perform the operation in presence of pets.
- Product must be securely applied in a way so as to minimize the risk of consumption by other animals.
- The product contains a bitter substance that makes it repulsive to pets.
- "Contain a pyrethroid, may be lethal to cats. Cats must avoid contact with treated object/area".

No risk is envisaged for animal health

2.2.8 Risk assessment for the environment

The acaricide SANYTOL ANTIACAROS is a ready-to-use water solution marketed in plastic trigger spray bottles. It is only for use in domestic small-scale to control house dust mites and bed bugs in textiles not frequently washed (mattresses, carpets, upholsteries…), with an application rate of 10 g of product per 1 m^2 of surface. The concentration of the active ingredient, Sumithrin ®, is 0.5% (technical grade). The active substance is a mixture of isomers of d-Phenothrin (CAS 188023-86-1), and the main component is 1R-trans phenothrin (CAS 26046-85-5). Taking into account that:

- The purity of Sumithrin ® fulfils the criteria established for 1R-trans phenothrin and
- The toxicological and environmental studies were mainly conducted on product containing 80% trans isomer.

ES CA has considered that SANYTOL ANTIACAROS contains 0.5% of 1R-trans phenothrin (CAS 26046-85-5).

SANYTOL ANTIACAROS has several other co-formulants in the formulation. ES CA analised the information available on the co-formulants (i.e. Safety Data Sheets, C&L Inventory, REACH Registration dossiers, and CAR of approved biocidal active substances). Most of the co-formulants are not classified for environmental hazards and therefore do not contribute to the classification or possible risks of the mixture. In addition, there are four co-formulants included in the Review Program of BPR but the evaluations for approval of three of them are still in progress. Three active substances are classified for environmental hazards, however their concentrations in the biocidal product are so low (i.e.<0.001%) that they do not contribute to the toxicity of mixture.

Therefore the biocidal product SANYTOL ANTIACAROS contains no substances of concern for the environment. Consequently, all the information concerning the environmental risk assessment for this product is based on data of the active substance 1R-trans phenothrin as reported in the CAR document. The applicant, GRUPO AC MARCA, S.L., has a full letter of access to the data from the active substance dossier. The Annex I assessment of this active substance, 1R-trans phenothrin, was supported by the formulation Sumithrin® 10 SEC (10.5% w/w "sum of all isomers"), intended for indoor use only by professional operators, to control crawling and flying insects through targeted spot application to cracks and crevices in areas such as trains, trucks, hospitals, hotels and other public buildings. Application was carried out using either a knapsack sprayer or ultralow volume (ULV) sprayer. Therefore, an environmental exposure assessment has to be carried out for SANYTOL ANTIACAROS on the basis of the ECHA Guidance on the Biocidal Products Regulation (April 2015), the updated emission scenario for PT18, OECD PT18 emission scenario document (ESD) for household and professional uses (OECD Series on Emission Scenario Documents, Number 18 (ENV/JM/MONO(2008)14), 17-Jul-2008, and the ECHA Technical Agreements for Biocides (TAB) (ECHA, 2018).

In addition to the CAR, the definitive study on the bioaccumulation potential of *d-trans*-Phenotrin was conducted for the purpose of clarification and discussion by the PBT Expert Group in September 2015. The study, Kang, S. (2015), allowed for an unambiguous conclusion on this point. While the study was considered acceptable by the group, it was agreed that growth correction needed to also be conducted in order to derive a reliable BCF. BCFs (kinetic, 5% lipid-normalized, growth corrected) are 1878 L/kg for the low concentration and 1623 L/kg for the high concentration. Neither of the BCF values met the

B criteria in the PBT assessment. This results in an overall conclusion that d-Phenotrin is not bioaccumulative.

Within product authorisation for the product SANYTOL ANTIACAROS, no new information compared to the CAR has been provided.

2.2.8.1 Effects assessment on the environment

All the studies supporting environmental fate and toxicity properties of the product SANYTOL ANTIACAROS are based on the active substance 1R-trans phenothrin as reported in the CAR document. In addition, no substances of concern regarding the environment are contained in the biocidal product in such quantity as to lead to classification and therefore this assessment is based only on the properties of the active substance 1R-trans phenothrin as reported in the CAR, as well as specific characteristics related with product application.

The following PNEC values were derived in the Assessment Report of 1R-trans phenothrin:

$PNEC_{water}$ = 0.000047 mg/l, based on the application of an assessment factor of 10 to the NOEC value obtained in the Reproduction and Growth Rate in Invertebrates (21 day NOEC in Daphnia magna = 0.00047 mg/l), as regards BPR Guidance on Risk Assessment.

$PNEC_{microorganisms}$ (STP) = 10 mg/l. According to BPR Guidance, the PNEC for micro-organisms in a STP is derived by dividing the NOEC or EC10 from a respiration inhibition test (OECD 209) by a factor of 10. An aqueous solution of 100 mg d-Phenothrin/l had no effect on the respiration of activated sludge micro-organisms (Grutzner I.(2002b)). In accordance with the strategy set out in the BPR Guidance, the value PNECmicro-organisms is derived by applying an assessment factor of 10.

$PNEC_{sediment}$ = 0.129 mg/kg wwt (0.59 mg/kg dwt). Specific data on the toxicity of 1R-trans phenothrin to sediment-dwelling organisms are not available. However, assuming equal susceptibility of sediment-dwelling and aquatic organisms to the given chemical, the PNEC was determined by the equilibrium partitioning method (Ksusp-water = 31528.93). Considering the high logKoc of 5.1 (i.e. >5.0), an additional factor of 10 should be added to the PEC/PNEC ratio.**$PNEC_{soil}$ = 0.0104 mg/kg wwt (0.0117 mg/kg dwt).** No study was performed on the acute toxicity to earthworms or other soil non-target organisms, as the proposed use of the test substance in CAR does not result in direct release to soil (the product is intended for indoor use only). However, the PNEC soil can be determined using the equilibrium partitioning method. Considering the high logKoc of 5.1 (i.e. >5.0), an additional factor of 10 should be added to the PEC/PNEC ratio. Please note that the PNECsoil of the CAR of the a.s. already included the additional factor of 10, therefore there is no need to add the factor to the PEC/PNEC ratio.

The Q(S)AR model, ECOSAR contained within the US-EPA EPISuite program - version 4.10, has been used in CAR to assess d-trans-Phenothrin and its major environmental metabolites, PBalc, PBacid and HO-trans-PHN, with respect to the ecosystem. From the results summarised in CAR it can be seen that the PBalc and PBacid metabolites are significantly (>100x) less toxic than the parent compound and the HO-trans-PHN metabolite is also less toxic than the parent compound. Therefore it is considered that the PNECaquatic value derived for d-trans-Phenothrin (0.000047 mg/L) will provide a sufficient level of protection. No further ecotoxicity testing was considered necessary.

$PNEC_{secondary\ poisoning}$:

$PNEC_{oral,mammals}$ = 10.0 mg/kg food. PNEC calculated applying an assessment factor of 30 to a determined NOEC value of 300 mg/kg food in the 52 week dog study (Cox R. (1987)), which represents the most sensitive species (NOAEL=8.2 mg/kg bw/day).

$PNEC_{oral,birds}$ = 1.87 mg/kg food. PNEC derived from the LC50 of 5620 ppm on the 5 day dietary study (Grimes J, 1988), and the appropriate assessment factor of 3000.

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

Based on the toxicity of d-Phenothrin to aquatic organisms, 1R-trans phenothrin was proposed to be classified in the CAR (RMS: Ireland. 2013) as Aquatic Acute Category 1(H400), Aquatic Chronic Category 1 (H410) (H410 for labelling purposes). In the Classification and Labelling Inventory this substance has a notified classification as Acute 1 (M factor = 100) and Chronic 1 (M factor = 10). This classification will be harmonised by the ECHA RAC, but so far only the notified classification is available.

The ES CA has revised the information included in the CAR in order to use the appropriate Multiplication factors. The lowest acute ecotoxicity endpoint (fish 96h LC50 0.0027 mg/L) leads to an acute M factor = 100 (0.001<L(E)C50≤0.01). The lowest chronic ecotoxicity endpoint (Daphnia 21h NOEC 0.00047 mg/L) leads to a chronic M factor = 100 (0.0001<NOEC≤0.001; not rapidly degradable). Therefore this M factors are used for the classification of the biocidal product.
The biocidal product SANYTOL ANTIACAROS contains 0.5% 1R-trans phenothrin as the only ingredient to contribute to the classification regarding environmental properties. Most of the co-formulants are not classified for environmental hazards and therefore do not contribute to the classification of the mixture.

In addition, there are four co-formulants included in the Review Program of BPR but the evaluations for approval of three of them are still in progress. One co-formulant has harmonised classification as Aquatic Acute 1 (M=10) and Aquatic Chronic 1 (M=1). Another co-formulant has harmonised classification as Aquatic Acute 1 (with no M-factor set so far, but a proposal was made in the CAR as Acute 1 M= 10 and Chronic 2). Another co-formulant is currently under evaluation by the RAC (proposed as Aquatic Acute 1 (M= 100) and Aquatic Chronic 2). Another co-formulant is registered under REACH and notified as not fulfilling the criteria to be classified for environmental hazards.
However these four co-formulants do not contribute to classification on acute and chronic hazards because their individual concentrations in the mixture are well below 0.1% (w/w).

The active substance 1R-trans phenothrin is classified as Aquatic Acute (H400) Category 1 with M factor of 100 and Aquatic Chronic Category 1 (H410) with an M factor of 100. The concentration of the active substance in the product (i.e. 0.5% w/w) leads to classification of the mixture according to the procedure as set out in Regulation EC 1272/2008.
In conclusion, the biocidal product SANYTOL ANTIACAROS is classified as Aquatic Acute Category 1(H400), Aquatic Chronic Category 1 (H410); H410 for labelling purposes.

Further Ecotoxicological studies

No further data are available. Ecotoxicological data have been extrapolated from the active substance as reported in the CAR of the a.s.

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

No further data are available. Ecotoxicological data have been extrapolated from the active substance as reported in the CAR.

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

No additional trials to assess risk to non-target organisms have been conducted.

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

No additional studies on acceptance of ingestion of the biocidal product by non-target organisms have been performed. The biocidal product SANYTOL ANTIACAROS is an insecticide to be used indoors and therefore this study is not required.

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

Not relevant.

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

The biocidal product belongs to PT-18 (Insecticides, acaricides and other biocidal products against arthropods) and is intended to be used indoors by non-professional users against bed bugs and house dust mites in order to protect human health.The product is applied by spraying in a rate of 10g/m^2 onto the home textiles that are not frequently washed (mattresses, carpets, upholsteries...). This dose rate is effective for the purpose of knocking-down and killing the insects by blocking their nervous system. The product is effective both at the moment of application and during the next 3 or 4 months thanks to its residual efficacy against bed bugs and house dust mites . As a consequence, the worst-case frequency of application is 4 times per year. A waiting period of 8 hours after the spray application onto household textiles is necessary followed by a vacuum-cleaning process of the treated surface are required before its use.

Exposure to the receiving environmental compartments such as soil, water and air depends on the physical-chemical properties of the active substance as well as its formulation type, mode of application, use and disposal. For the environmental risk assessment, the relevant compartments for emissions have to be defined and a numerical assessment of the potential residues in each area of importance has to be conducted. The emission scenario document (ESD) for PT18 provided models to calculate emission to the environment and concentration in the receiving compartment at a local scale. The ESD for PT18 covers the following life-cycle steps as being potentially relevant for the environmental emissions:

- Mixing/loading

- Application
- Releases from indoor treated surfaces by cleaning.

SANYTOL ANTIACAROS is a ready-to-use product, thus, emissions from mixing and loading steps are not expected and therefore not assessed. Depending on the product properties, the product can be released to air, target surfaces, applicator and floor during the application stage. Therefore, the intermediate receiving compartments consist of indoor air, floors, applicator, treated surfaces (textiles), and wastewaters.

The intended use of SANYTOL ANTIACAROS was according to the label claims the application by spraying onto home textiles not frequently washed. The Applicant proposed a scenario based on emissions from a reduced treated area such as the scenario of application in 'cracks and crevices', which considers a treated area of $2m^2$ and cleaning efficiency of 0.2. In order to better represent the exposure derived from this use, ES CA has calculated the emissions to compartments following the 'Scenario for spraying application to treat against cat fleas or bedbugs (indoor)' agreed by the MS CA and included in TAB v.2.0 (ENV#147). According to this scenario the spray products to treat against cat fleas or bedbugs are applied on soft furnishings and carpeted areas, for which the general surface area is 22 m^2 according to the ESD PT18 (non-professional use in private houses). However these surfaces are not expected to be subject to regular wet cleaning. So an area of 5.9 m^2 should be used to reflect the area wet cleaned in a domestic home (barrier) and use the default cleaning efficiency of 20% for a surface application. Hence ES CA assumes that a treated area of 5.9 m^2 and a cleaning efficiency of 0.2 adequately represents the area of household textiles not frequently washed that are treated in a private house.

. According to ESD for PT18 and the Guidance on the Biocidal Products Regulation, indoor application may result in indirect environmental exposure via the sewage system (i.e. during a cleaning operation following treatment). This poses a risk of the product entering sewage treatment plants (STPs) and subsequently being released via effluent into surface water. Consequently, final receiving compartments in the environment are outdoor air (atmosphere), STP, surface water (after effluent emission), soil (after sludge application) and groundwater (after leaching from agricultural soil). Emissions to these environmental compartments result from the cumulative emission from the application and cleaning steps indoors following a treatment of SANYTOL ANTIACAROS.

Metabolite exposure to the environment was also estimated (for identified metabolites exceeding 10% of applied radioactivity) for the final relevant scenarioincluded in this PAR . The following metabolites were included:

- 3-phenoxybenzoic acid (PBacid) (max. formation (aquatic) = 18.6% in a water-sediment study) (mwt. = 214.22).
- 3-phenoxybenzyl (1R, 3R)-2,2-dimethyl-3-[(1RS)-hydroxy-2-methyl prop-2-enyl]cyclopropanecarboxylate (HO-PHN) (max. formation (aquatic) = 21.1% in a photolysis study) (mwt. = 366.46).
- 3-phenoxybenzyl alcohol (PBalc) (max. formation (aquatic) = 20.0% in a photolysis study) (max. formation (terrestrial) = 12.9% in an aerobic soil) (mwt. = 200.24).

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

No new environmental fate & behaviour or leaching data on 1R-trans phenothrin or product specific data are available as they have not been considered necessary. All agreed endpoints have been taken from the PT 18 CAR for 1R-trans phenothrin.

Leaching behaviour (ADS)

Not relevant.

Testing for distribution and dissipation in soil (ADS)

Not relevant.

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

Not relevant.

Testing for distribution and dissipation in air (ADS)

Not relevant.

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)

The product is not going to be sprayed near surface waters. For more information about aquatic toxicity, please refer to 1R-trans phenothrin CAR document.

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)

Based on the use pattern of the biocidal product SANYTOL ANTIACAROS, no outdoor use is intended and therefore, no risk to bees or other non-target arthropods is anticipated. Therefore, no additional studies performed with bees or other arthropods are deemed necessary.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Indoor spray application; barrier treatment on not frequently washed household textiles;
ESD(s) used	Emission Scenario Document for Insecticides, Acaricides and Products to Control other Arthropods for Household and Professional Users (OECD Series of Emission Scenario Documents No. 18). TAB v.2.0 ENV 147. Scenario for spraying application to treat against cat fleas or bedbugs (indoor)
Approach	A consumption based approach has been used as a suitable protective measure at the local level
Distribution in the environment	Calculated according to the Guidance on Biocidal Products Regulations, Vol. IV Environment – Part B Risk Assessment

	(Version 1.0, April 2015).
Groundwater simulation	Tier 1 Screening. No higher tier modelling has been performed.
Confidential Annexes	No
Life cycle steps assessed	Production: No, as the active substance 1-R trans Phenothrin is manufactured outside the EU. Formulation: No. Use: Yes. Scenario 1, following the ESD. Service life: Yes. Scenario 1, following the ESD.
Remarks	None

Emission estimation

Scenario [1]

SANYTOL ANTIACAROS is a ready-to-use product intended to be used indoors by non-professional users against bed bugs and house dust mites. The product is applied by spraying in a rate of 10g/m^2 onto the home textiles that are not frequently washed (mattresses, carpets, upholsteries...). According to the scenario included in the TAB v.2.0, a treated surface of 5.9 m^2 should be considered, such as in case of barrier treatment. It is assumed that only soft furnishings not expected to be subject to regular wet cleaning will be treated.
Due to the proposed use pattern of the b.p., the application mode can be described as a indoor spray application for the treatment of surfaces. Emissions of 1-R trans Phenothrin to the environment may arise either due to washing of contaminated clothes from the applicator or due to wet cleaning of the treated surface and its surrounding floor surface, considering that cleaning events result only in emissions to waste water as a worst-case approach. Therefore the exposed environmental compartments comprise outdoor air, STP, surface waters, sediment, soil and groundwater.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Indoor spray application; surface treatment on household textiles not frequently cleaned ;			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	10	*g/m^2*	
Concentration of active substance in the product	5	*g/Kg*	
Application Step			
Number of applications per day	1	*d^{-1}*	
Fraction emitted to air during application	0.02	-	Default value

Fraction emitted to floor during application	0.11	-	Default value
Fraction emitted to treated surfaces during application	0.85	-	Default value
Fraction emitted to applicator during application	0.02	-	Default value
Area treated with the product	5.9	m^2	Default value for the treatment of surfaces (barrier application)
Cleaning step			
Fraction emitted to waste water during cleaning	1	-	Default value
Fraction emitted to waste water from applicator - washable coveralls	1	-	Default value
Fraction of cleaning efficiency of wet cleaning	0.2	-	Default value
Simultaneity factor	0.00815	-	Default value for 3-11 applications per year
Number of houses	4000	-	Default value

Calculations for Scenario [*1*]

Release estimation during application

The input values for determining releases to the environment during application of SANYTOL ANTIACAROS as well as the calculated emission rates are summarised in **Table 1**. An application frequency of 1 application per day in households is proposed by ESD PT 18 (OECD, 2008). Moreover, the ESD PT 18 (OECD, 2008) and TAB (ENV 147) states that 85% of the emissions are released to the target surface (household textiles), 11% reach the surrounding floor surface due to drift during spray application and 2% of the emission release to the applicator clothes and the surrounding air, respectively (Tier 1A). TAB v.2 (ENV 147) also sets a default value of 5.9 m^2 for the treated area of not frequently washed textiles by spray application when treating surfaces.

Since, according to the instructions for use, the product should be sprayed on textiles and left to dry for 8 hours before use, the fraction emitted to air during application events is summed up to the fraction going to the surrounding floor.

Table 1: Emission scenario for indoor spray application of SANYTOL ANTIACAROS during application (Tier 1A)

Determinants of the emission scenario	**Value**
Quantity of b.p. applied [Q_{prod}]	0.01 $kg.m^{-2}$
Fraction of a.s. in the product [F_{AI}]	0.005
Area treated and cleaned with the product [$AREA_{treated}$] - Spray application on textiles (household)	5.9 m^2

Number of applications per day per household [$N_{appl, building}$]	1 d^{-1}
Fraction emitted to air [$F_{application, air}$]	0.02
Fraction emitted to treated area [$F_{application, treated area}$]	0.85
Fraction emitted to applicator [$F_{application, applicator}$]	0.02
Fraction emitted to floor [$F_{application, floor}$]	0.11
Emission rates due to application of SANYTOL ANTIACAROS in households	
Local emission rate to air $E_{application, air} = N_{appl, building} \times F_{application, air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$	5.90E-06 $kg.d^{-1}$
Local emission rate to floor $E_{application, floor} = N_{appl, building} \times F_{application, floor} \times Q_{prod} \times F_{AI} \times AREA_{treated}$	3.25E-045 $kg.d^{-1}$
Local emission rate to treated area $E_{application, treated area} = N_{appl, building} \times F_{application, treated area} \times Q_{prod} \times F_{AI} \times AREA_{treated}$	2.51E-04 $kg.d^{-1}$
Local emission rate to applicator $E_{application, applicator} = N_{appl, building} \times F_{application, applicator} \times Q_{prod} \times F_{AI} \times AREA_{treated}$	5.90E-06 $kg.d^{-1}$

Release estimation during cleaning

According to the ESD PT 18 (OECD, 2008), it is assumed that the application and cleaning steps take place at the same day. In addition, in a first approach the degradation of the product is not taken into acount. Two cleaning methods are considered:

1. dry cleaning by vacuum/broom and disposable clothes of the applicator resulting in emission to solid wastes,
2. wet cleaning of washable surfaces and applying of washable coveralls resulting in emission to waste water.

Inthis case, the cleaning step will therefore lead to releases either to solid wastes and to waste water. Considering the application of b.p. in the above mentionedtextiles, it might be realistic that residues of SANYTOL ANTIACAROS could be removed by dry cleaning methods (spray fraction from treated textiles which is left to dry and then cleaned by vacuum). However, the exposure pathway of solid waste to municipal landfill will not be further evaluated.

Furthermore, according to the TAB v.2.0 (ENV 147) a default cleaning efficiency of 20 % is used for the envisaged application to target and non-target surfaces (treated textiles, the surrounding floor and the applicator coveralls (clothes)) which will be wet cleaned or washed.

In adition, since according to the instructions for use, the product should be sprayed on textiles and left to dry for 8 hours before use, the fraction of product emitted to air during application events should be summed up to the fraction going to treated textiles and the surrounding floor. Therefore the estimation of emissions during cleaning will include the fraction of deposited product after application. However neither additional emissions to air nor deposition on surfaces is foreseen during the cleaning event, according to the ESD.

The local emission rates to floor, as further required input values, are taken from results in Table 1.

The input and output values for SANYTOL ANTIACAROS are summarised in Table 2.

Table 2: Emission scenario for indoor spray application of SANYTOL ANTIACAROS during cleaning.

Determinants of the emission scenario	**Value**
Fraction emitted to air during cleaning	0
Cleaning efficiency [F_{CE}]	0.2
Fraction emitted during cleaning step	
Fraction emitted to waste water from applicator - washable coveralls [$F_{applicator, ww}$]	1
Fraction emitted to waste water during cleaning step [$F_{floor, ww}$]	1
Emission rates	
Local emission rate to air [$E_{cleaning, air}$]	0 $kg.d^{-1}$
Local emission rate to waste water during cleaning step from applicator $E_{applicator, ww}$ = $E_{application, applicator} \times F_{applicator, ww}$	5.90E-06 $kg.d^{-1}$
Local emission rate to waste water during cleaning step from floor and treated area $E_{floor/treated\ area, ww}$ = ($E_{application, floor}$ + $E_{application, treated\ area}$+ $E_{application, air}$) × $F_{floor, ww} \times F_{CE}$	5.78E-05 $kg.d^{-1}$

Release estimation to sewage treatment plant

It is supposed that product residues removed through wet cleaning may potentially be emitted to the sewer and subsequently to the sewage treatment plant (STP). According to the ESD PT 18 (OECD, 2008) the STP is considered as one of the main "receiving compartment" in which insecticides will be released through wet cleaning events. In Europe, estimates of potential exposures resulting from STPs are carried out according to the Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015). According to this, the further receiving environmental compartments are surface water and sediment (after STP), soil and groundwater (from sludge application), and the outdoor air.

According to ESD PT 18 (OECD, 2008), 4000 houses are connected to one STP (Nhouses). Furthermore, a simultaneity factor (F_{sim}) was implemented in the ESD PT18 that considers the simultaneity of treatments by the houses connected to the STP. For indoor applications, the ESD presumes per default a daily application of the biocidal products, leading to a simultaneity factor of 5.5% (F_{sim} = 0.055). However, according to the intended use of SANYTOL ANTIACAROS, a maximum of 4 applications per year is assumed. Therefore, the simultaneity factor is calculated without taking into account the frequency of insecticide used on a daily, weekly and monthly basis:

$$F_{sim} = \frac{1.9 \times 32.15 + 0.54 \times 37.82}{100} = 0.815\%$$

$$E_{ww\_sim} = (E_{floor/treated\ area, ww} + E_{applicator, ww}) \times N_{houses} \times F_{Sim}$$

The application of the b.p. in a typical scenario results in release of **2.08E-03 kg d^{-1}** (Tier 1A) and **4.42E-04 kg d^{-1}** (Tier 1B) 1-R trans Phenothrin to STP.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	2.08E-03	
Air	5.90E-06	Tier 1A and 1B

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	Yes	Yes	No	No	Yes	Yes	Yes	Yes	

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	350.5	g/mol	
Melting point	-41.4	°C	
Boiling point	301	°C	
Vapour pressure (at 25 ºC)	4.17E-05	Pa	
Water solubility (at 21°C)	2	µg/l	
Log Octanol/water partition coefficient	6.8	Log 10	
Organic carbon/water partition coefficient (Koc)	1.26E+05	l/kg	
Henry's Law Constant (at 20 ºC	4.2	$Pa/m^3/mol$	
Biodegradability	Not ready biodegradable		OECD 301F
Bioconcentration factor in fish	1,878	L/kg	
DT_{50} for biodegradation in surface water	19.15	d (at 12ºC)	
DT_{50} for hydrolysis in surface water	1635	d (at 12ºC /pH 7)	
DT_{50} for photolysis in surface water	13.9	hr	
DT_{50} for degradation in soil	27.2	d (at 12ºC)	
DT_{50} for degradation in air	3.63	hr	

Calculated fate and distribution in the STP *[if STP is a relevant compartment]*		
Compartment	Percentage [%]	Remarks
	Scenario 1	

Air	0.271	
Water	12.9	
Sludge	86.8	
Degraded in STP	0	

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{soil,30d}$**[1]	**$PEC_{soil,180d}$**[2]	**$PEC_{soil,30d,grass}$**[3]	**PEC_{GW}**	**PEC_{air}**
	[mg/m³]	[mg/l]	[mg/kg_{wwt}]	[mg/m³]	[mg/m³]	[mg/m³]	[µg/l]	[mg/m³]
Scenario 1	1.3E-04	1.1E-05	3.1E-02	2.35E-03	7.2E-04	2.9E-04	3.2E-04	4.3E-12

[1] Local PEC in agricultural soil averaged over 180 days.

[2] Local PEC in grassland averaged over 180 days.

[3] Annual average local PEC values in air following emission to waste water.

Emission rates of 1-R trans Phenothrin and resulting predicted environmental concentrations (PECs) were calculated in accordance with ESD assumptions for primary receiving environmental compartments (e.g. STP) and also for secondary compartments (e.g. surface water, sediment and soil). From local initial emission rates and concentrations, local PEC values were generated using EUSES v.2.1.2. The PEC_{local} value normally incorporates a background concentration for use in the regional scale assessment ($PEC_{regional}$). However, in the case of d-Phenothrin, regional and continental environmental concentrations are generally regarded as insignificant.

As it is stated in the CAR, metabolite exposure to the environment was also estimated (for identified metabolites exceeding 10% of applied radioactivity) for each relevant scenario covered in the ESD. The following metabolites were included:

- 3-phenoxybenzoic acid (PBacid) (max. formation (aquatic) = 18.6% in a water-sediment study) (mwt. = 214.22);
- 3-phenoxybenzyl (1R, 3R)-2,2-dimethyl-3-[(1RS)-hydroxy-2-methyl prop-2-enyl]cyclopropanecarboxylate (HO-PHN) (max. formation (aquatic) = 21.1% in a photolysis study) (mwt. = 366.46) and
- 3-phenoxybenzyl alcohol (PBalc) (max. formation (aquatic) = 20.0% in a photolysis study) (max. formation (terrestrial) = 12.9% in an aerobic soil) (mwt. = 200.24).

PEC values for the metabolites of d-Phenothrin were calculated directly from the estimated PEC values for d-phenothrin, taking into account the molecular weight difference between parent and metabolites and the maximum observed levels of the metabolites. The values for each metabolite of d-Phenothrin were calculated individually and also on a simultaneous basis assuming additivity.

$PEC_{metab} = PEC_{s.a.} \times F_{metab} \times (Mw_{metab}/Mw_{s.a.})$

PEC_{STP} values			
	F_{metab} (%)	**Mw (g/mol)**	**PEC_{STP} [mg/L]**
Phenotrin		350.5	1.34E-04

PBacid	18.6	214.22	1.52E-05
HO-PHN	21.1	366.46	6.29E-06
PBalc	20	200.24	3.26E-06

PEC_{water} values			
	F_{metab} (%)	**Mw (g/mol)**	**PEC_{water} [mg/L]**
Phenotrin		350.5	1.13E-05
PBacid	18.6	214.22	1.28E-06
HO-PHN	21.1	366.46	2.49E-06
PBalc	20	200.24	1.29E-06

PEC_{sed} values			
	F_{metab} (%)	**Mw (g/mol)**	**PEC_{sed} [mg/kg_{wwt}]**
Phenotrin		350.5	3.09E-02
PBacid	18.6	214.22	3.51E-03
HO-PHN	21.1	366.46	6.82E-03
PBalc	20	200.24	3.53E-03

$PEC_{soil\ 30\ d,\ agricultural}$ values			
	F_{metab} (%)	**Mw (g/mol)**	**PEC_{soil} [mg/ kg_{wwt}] Tier 1A**
Phenotrin		350.5	2.35E-03
PBacid	18.6	214.22	2.67E-04
HO-PHN	21.1	366.46	5.18E-04
PBalc	20	200.24	2.69E-04

$PEC_{soil,\ 180\ d,\ agricultural}$ values			
	F_{metab} (%)	**Mw (g/mol)**	**PEC_{soil} [mg/ kg_{wwt}]**
Phenotrin		350.5	7.22E-04
PBacid	18.6	214.22	8.21E-05
HO-PHN	21.1	366.46	1.59E-04
PBalc	20	200.24	8.25E-05

$PEC_{soil,\ 180\ d,grassland}$ values			
	F_{metab} (%)	**Mw (g/mol)**	**PEC_{soil} [mg/ kg_{wwt}]**
Phenotrin		350.5	2.88E-04
PBacid	18.6	214.22	3.27E-05
HO-PHN	21.1	366.46	6.35E-05
PBalc	20	200.24	3.29E-05

PEC_{GW} values			
	F_{metab} (%)	Mw (g/mol)	PEC_{GW} [µg/l]
Phenotrin		350.5	3.25E-04
PBacid	18.6	214.22	3.69E-05
HO-PHN	21.1	366.46	7.17E-05
PBalc	20	200.24	3.71E-05

PEC_{air} values			
	F_{metab} (%)	Mw (g/mol)	PEC_{air} [mg/m^3]
Phenotrin		350.5	4.28E-12
PBacid	18.6	214.22	4.87E-13
HO-PHN	21.1	366.46	9.44E-13
PBalc	20	200.24	4.89E-13

Summary table on calculated PEC values (d-Phenothrin and metabolites)					
	PEC_{STP} [mg/L]	PEC_{water} [mg/L]	PEC_{sed} [mg/kg_{wwt}]	PEC_{GW} [µg/L]	PEC_{air} [mg/m^3]
Phenotrin	1.34E-04	1.13E-05	3.09E-02	3.25E-04	4.28E-12
PBacid	1.52E-05	1.28E-06	3.51E-03	3.69E-05	4.87E-13
HO-PHN	6.29E-06	2.49E-06	6.82E-03	7.17E-05	9.44E-13
PBalc	3.26E-06	1.29E-06	3.53E-03	3.71E-05	4.89E-13
Total PEC metabolites	2.48E-05	5.07E-06	1.39E-02	1.46E-04	1.92E-12

Summary table on calculated PEC values (d-Phenothrin and metabolites)			
	$PEC_{soil,30,ag}$ [mg/kg_{wwt}]	$PEC_{soil,180,ag}$ [mg/kg_{wwt}]	$PEC_{soil,180,grass}$ [mg/kg_{wwt}]
Phenotrin	2.35E-03	7.22E-04	2.88E-04
PBacid	2.67E-04	8.21E-05	3.27E-05
HO-PHN	5.18E-04	1.59E-04	6.35E-05
PBalc	2.69E-04	8.25E-05	3.29E-05
Total PEC metabolites	1.05E-03	3.24E-04	1.29E-04

Primary and secondary poisoning

Primary poisoning

Acording to the ESD for type 18 products, Primary poisoning, *i.e.* the direct consumption of insecticide by birds or mammals may mainly occur in the following cases:

- Insecticides are applied together with food attractant, or
- Insecticides are applied as granular formulation.

Neither of these scenarios apply in this case and the product is for indoor use only so exposure via this route is considered to be negligible.

Secondary poisoning

Non-target animals are potentially at risk of secondary poisoning via:

- consumption of worms from contaminated soil
- consumption of contaminated fish
- consumption of contaminated vegetation, and
- eating treated insects that have accumulated the poison

Exposure via consumption of contaminated vegetation and treated insects can be ruled out as the formulation is to be applied indoors only. However, $PEC_{oral,\ predator}$ values were determined for fish-eating and earthworm-eating predators/scavengers, given the high log octanol/water partition coefficient of d-Phenothrin (6.8) and results of previous bioconcentration studies, which suggest that it may have significant potential for bioaccumulation in soil-dwelling organisms (e.g. earthworms). New testing data on the bioconcentration in fish was included in an updated CAR of the a.s. The BCF (kinetic, 5% lipid-normalized, growth corrected) is 1878 L/kg, which indicates that the a.s. cannot be considered a bioaccumulative substance. Nevertheless a quantitative risk characterisation of secondary poisoning is included in this PAR for the sake of completeness.

PEC estimations for fish eating organisms:

The concentration in fish is a result of uptake from the aqueous phase and intake of contaminated food (aquatic organisms). Thus, a $PEC_{oral,\ predator}$ is calculated from the PEC for surface water(50% of annual PEC water, assuming emissions for 365 d/y), the measured or estimated BCF for fish and the biomagnification factor (BMF). As a measured BCF value (1,878 l/kg) is available, this value has been used as follows. A default BMF value of 1 was taken from Table 24 of the Guidance for substances having a BCF <2,000 L/kg.

$$\mathbf{PEC_{oral,\ predator} = PEC_{water} * BCF_{fish} * BMF}$$
$$\mathbf{PEC_{oral,\ predator} = 1.20E\text{-}06 * 1{,}878 * 10}$$
$$\mathbf{PEC_{oral,\ predator} = 1.06E\text{-}02\ mg/kg_{\ wet\ fish}}$$

PEC estimations for earthworm eating organisms:

As no study was conducted, the calculation method described in the TGD was used to determine the $PEC_{oral,\ predator}$ for earthworm eating predators as follows:

According to the TGD, the most likely route of uptake of organic substances will be via the interstitial water and data suggest that the Jager (1998) model often overestimates uptake as it does not account for adsorption. It is acknowledged that substances adsorbed to soil particles can be ingested and may bioaccumulate in worms, however they may also pass directly through the organism. Since birds and mammals consume worms and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the quantity of active substance that is present in this soil. The $PEC_{oral,\ predator}$ is calculated as follows:

$$\mathbf{PEC_{oral,\ predator} = C_{earthworm}}$$

where $C_{earthworm}$ is the total concentration of the substance in the worm as a result of bioaccumulation in worm tissues and the adsorption of the substance to the soil present in the gut.

The total concentration in a full worm can be calculated as the weighted average of the worm's tissues (through BCF and porewater) and gut contents (through soil concentration):

$C_{earthworm}=BCF_{earthworm} * C_{porewater} * W_{earthworm} + C_{soil} * W_{gut} / W_{earthworm} + W_{gut}$ (Eq. 81)

The weight of the gut contents can be rewritten using the fraction of gut contents in the total worm:

$W_{gut} = W_{earthworm} * F_{gut} * CONV_{soil}$ Eq. (82a)

where:

$CONV_{soil} = RHO_{soil} / F_{solid} * RHO_{solid}$ Eq. (82b)

Using this equation, the concentration in a full worm can be written as:

$C_{earthworm} = ((BCF_{earthworm} * C_{porewater}) + (C_{soil} * F_{Gut} * CONV_{soil})) / (1 + (F_{Gut} * CONV_{soil}))$
where $C_{porewater}$ is 50% of $PEC_{soil,porewater}$ value and C_{soil} is 50% of $PEC_{soil, 180d}$

$C_{earthworm}$ = ((75700 * 1.63E-07) + (3.61E-04* 0.1 * 1.13)) / (1 + (0.1 * 1.13))
$C_{earthworm}$ = 1.11E-02 mg/kg wet earthworm = $PEC_{oral, predator}$

2.2.8.3 Risk characterisation

Predicted No Effect Concentrations (PNECs) for Phenothrin:

PNEC	Value
$PNEC_{STP}$	10 mg/l
$PNEC_{freshwater}$	0.000047 mg/l (4.70E-05 mg/l)
$PNEC_{sediment,freshwater}$	0.129 mg/kg wwt (1.29E-01 mg/kg wwt)
$PNEC_{soil}$	0.0104 mg/kg wwt (1.04E-02 mg/kg wwt)

Atmosphere

Exposure of the atmospheric compartment to d-Phenothrin is expected from the spray application of SANYTOL ANTIACAROS. However, exposure to the air is expected to be negligible since SANYTOL ANTIACAROS is applied indoors and, hence, is unlikely to generate significant levels of particulates to the air outside. If exposed to the atmosphere d-Phenothrin is expected to degrade quickly in the air based on the calculated DT_{50} value of 3.63 h, determined using the US EPA AOPWIN model. Furthermore, volatilisation is unlikely to be a major route of entry into the atmospheric compartment of the environment based on a vapour pressure of 2.372×10^{-5} Pa (at 20 °C, *trans*:*cis* d-phenothrin). The emissions from spray indoor use of SANYTOL ANTIACAROS have, however, been calculated using EUSES to be 4.3E-12 mg/m^3.

Aquatic compartment

Summary of Local aquatic PECs		
Assessment		**PEC**
Scenario 1. Use in textiles not frequently whashed	PEC for micro-organisms in the STP (mg/L)	1.34E-04
	Local PEC in surface water during emission episode (dissolved) (mg/L)	1.13E-05
	Local PEC in fresh-water sediment during emission episode (mg/kg wwt)	3.09E-02
	Local PEC in groundwater under agricultural soil (µg/L)	3.25E-04

Summary table of calculated PEC/PNEC values for the aquatic compartment				
Assessment		**PEC**	**PNEC**	**PEC/ PNEC**
Scenario 1. Use in textiles not frequently whashed	PEC for micro-organisms in the STP (mg/L)	1.34E-04	10	1.34E-05
	Local PEC in surface water during emission episode (dissolved) (mg/L)	1.13E-05	4.70E-05	2.40E-01
	Local PEC in fresh-water sediment during emission episode (mg/kg wwt)	3.09E-02	1.29E-01	**2.40E+00(*)**
	Local PEC in groundwater under agricultural soil (µg/L)	3.25E-04		

(*)An additional factor of 10 has been considered as PNECsed was defined using the EPM method and LogKow is >5

Conclusion: The risk characterisation step is carried out by comparing the PEC derived for each exposure scenario with the relevant PNEC value. Scenarios for which the PEC/PNEC value is <1.0 are considered to pose no unacceptable risk to the aquatic environment.

The PEC/PNEC ratios indicate that the indoor use of SANYTOL ANTIACAROS poses unacceptable risk to organisms of the aquatic compartment.

Terrestrial compartment

Summary of Local Terrestrial PECs		
Assessment		**PEC**
Scenario 1. Use in textiles not frequently whashed	Local PEC in agricultural soil (total) averaged over 30 days (mg/m^3)	2.35E-03
	Local PEC in agricultural soil (total) averaged over 180 days (mg/m^3)	7.22E-04
	Local PEC in grassland (total) averaged over 180 days (mg/m^3)	2.88E-04

Summary table of calculated PEC/PNEC values for the terrestrial compartment

Assessment		PEC	PNEC	PEC/PNEC
Scenario 1. . Use in textiles not frequently whashed	Local PEC in agricultural soil (total) averaged over 30 days (mg/ kg wwt)	2.35E-03	1.04E-02	2.26E-01
	Local PEC in agricultural soil (total) averaged over 180 days (mg/ kg wwt)	7.22E-04		6.94E-02
	Local PEC in grassland (total) averaged over 180 days (mg/ kg wwt)	2.88E-04		2.77E-02

Conclusion: The risk characterisation step is carried out by comparing the PEC derived for each exposure scenario with the relevant PNEC value. Scenarios for which the PEC/PNEC value is <1.0 are considered to pose no unacceptable risk to the terrestrial environment.

The PEC/PNEC ratios indicate that the indoor use of SANYTOL ANTIACAROS poses acceptable risk to organisms of the terrestrial environment.

Groundwater

The local PEC in groundwater under agricultural soil calculated by EUSES v. 2.1.2 is 3.25E-04µg/L which is less than the maximum permissible concentration of 0.1 µg/L laid down by Directive 98/83/EC. This demonstrates that there is no cause of concern for groundwater

Risk characterisation for the metabolites of d-Phenothrin

Risk characterisation for aquatic compartment:

Maximum additive PEC values calculated for the metabolites of d-Phenothrin, HO-PHN, PBalc and PBacid, in the aquatic system (including groundwater) are presented in the Table below.

Additive PEC values of d-Phenothrin for STP, surface water, sediment and groundwater .	
Compartment	**Scenario 1**
Total metabolites (HO-PHN + PBalc + PBacid) PEC_{STP} [mg/L]	2.48E-05
Total metabolites (HO-PHN + PBalc + PBacid) PEC_{SW} [mg/L]	5.07E-06
Total metabolites (HO-PHN + PBalc + PBacid) PEC_{SED} [mg/kg wwt]	1.39E-02
Total metabolites (HO-PHN + PBalc + PBacid) PEC_{GW} [mg/L]	1.46E-04

As is it stated in the CAR, the Q(S)AR model, ECOSAR contained within the US-EPA EPISuite program - version 4.10, has been used to assess d-trans-Phenothrin and its major environmental metabolites, PBalc, PBacid and HO-trans-PHN, with respect to the ecosystem. From the results it can be seen that the PBalc and PBacid metabolites are

significantly (>100x) less toxic than the parent compound and the HO-trans-PHN metabolite is also less toxic than the parent compound. Therefore it is considered that the PNECaquatic value derived for d-trans-Phenothrin (4.7E-05 mg/L) will provide a sufficient level of protection. No further ecotoxicity testing was considered necessary.

The major metabolites of d-trans-Phenothrin, PBalc, PBacid and HO-trans-PHN, have low Q(S)AR calculated BCF values (EPI Suite - BCFBAF module) indicative of low potentials to bioaccumulate. The Log BCF values for PBalc, PBacid and HO-trans-PHN are 1.48, 0.50 and 2.84, respectively.

PEC/PNEC ratios for d-Phenothrin metabolites (HO-PHN, PBalc and PBacid added together) for aquatic exposure (including groundwater)			
Compartment	**PNEC**	**PEC**	**PEC/PNEC**
Micro-organisms in the STP [mg/L]	1.0E+01	2.48E-05	2.48E-06
Surface water during emission episode (dissolved) [mg/L]	4.7E-05	5.07E-06	1.08E-01
Fresh-water sediment during emission episode [mg/kg wwt]	1.29E-01	1.39E-02	1.07E+00(*)
Groundwater under agricultural soil [µg/L]	1.0E-02	1.46E-04	-

(*) An additional factor of 10 has been considered as PNECsed was defined using the EPM method and LogKow is >5

The risk quotients for the d-phenothrin metabolites (HO-PHN, PBalc and PBacid added together) indicate that there is no risk to the aquatic environment from metabolites during an emission episode following spray application of SANYTOL ANTIACAROS.

Overall, the risk to the aquatic environment from the use of SANYTOL ANTIACAROS is considered unacceptable

Risk characterisation for terrestrial compartment:

The pattern of use of the formulated product as an indoor spray application excludes direct contamination of soil. However, exposure to soil may arise from the use of sewage sludge in agriculture. Maximum additive PEC values calculated for the metabolites of d-Phenothrin, HO-PHN, PBalc and PBacid, in the terrestrial system are presented in the table below.

Additive PEC values of d-Phenothrin metabolites (HO-PHN, PBalc and PBacid) for terrestrial exposure	
Compartment	**Scenario 1**
HO-PHN	
Local PEC in agric. soil averaged over 30 days [mg/kg wwt]	5.18E-04

PBalc	
Local PEC in agric. soil averaged over 30 days [mg/kg wwt]	2.69E-04
PBacid	
Local PEC in agric. soil averaged over 30 days [mg/kg wwt]	2.67E-04
Total metabolites PEC_{soil}	
Local PEC in agric. soil averaged over 30 days [mg/kg wwt]	1.05E-03

The PNEC value for the active substance is used for risk characterisation for the metabolites.

PEC/PNEC ratios for d-Phenothrin metabolites (HO-PHN, PBalc and PBacid added together) for terrestrial exposure			
Compartment	**PNEC**	**PEC**	**PEC/PNEC**
Local PEC in agric. soil (total) averaged over 30 days [mg/kg wwt]	1.04E-02	1.05E-03	**1.01E-+01**

For the metabolites, acceptable risk was identified for the soil compartment where contaminated sludge (via waste water emissions) is spread onto agricultural soil and the concentration is averaged over 30 days.

Overall, the risk to the terrestrial environment from the use of SANYTOL ANTIACAROS is considered acceptable

Primary and secondary poisoning

Primary poisoning

It is considered that the possibility of primary poisoning for SANYTOL ANTIACAROS is very unlikely. Even if a wild bird or mammal did gain access to the product the exposure would only be localised and would not result in widespread (population level) exposure.

Secondary poisoning

Aquatic Compartment

The log octanol/water partition coefficient of d-Phenothrin (6.8) suggests that it may have significant potential for bioconcentration in the aquatic environment, with the possibility of bioaccumulation leading to secondary poisoning. This theoretical potential is further reflected in a calculated bioconcentration factor (BCF) for fish of 46100 (estimated using the QSAR method of Veith et al 1979, as presented in the Technical Guidance Document on Risk Assessment (TGD, 2003)) and a default biomagnification factor (BMF) of 10 (determined as set out in TGD, 2003).

In the CAR of the a.s. the results of a bioconcentration study with d-Phenothrin in bluegill sunfish show an average steady-state BCF value of 2506-3192 L/kg at Day 28 of the exposure phase. In 2016 the CAR was updated with the definitive study on the

bioaccumulation potential of *d-trans*-Phenotrin. The study was conducted for the purpose of clarification and discussion by the PBT Expert Group in September 2015. The study, Kang, S. (2015), allowed for an unambiguous conclusion on this point. While the study was considered acceptable by the group, it was agreed that growth correction needed to also be conducted in order to derive a reliable BCF. BCFs (kinetic, 5% lipid-normalized, growth corrected) are 1,878 L/kg for the low concentration and 1,623 L/kg for the high concentration. Neither of the BCF values met the B criteria in the PBT assessment. This results in an overall conclusion that d-Phenotrin is not bioaccumulative.
Nonetheless, quantitative risk characterisations associated to emissions calculated have been performed below for completeness sake.

$PNEC_{oral,\ predator}$, mammal derivation:
A predicted no effect oral concentration ($PNEC_{oral}$) can be calculated based on the results of the mammalian repeat dose toxicity tests and toxicity data for mammals (LC50 dietary). The result of these calculations gives a predicted no-effect concentration in food that should be protective to other mammalian species.
The 52 week dog study (Cox R. (1987)) represents the most sensitive species (NOAEL=8.2 mg/kg bw/day) with a determined NOEC value of 300 mg/kg food. Applying an assessment factor of 30 to this value gives:

$PNEC_{oral,\ predator}$=10.0 mg/kg food or $PNEC_{oral,\ predator}$ of 10.09 bw/day.

$PEC_{oral,\ predator}$ derivation:
The concentration of d-phenothrin in fish is a result of uptake from the aqueous phase and intake of contaminated food (aquatic organisms). The $PEC_{oral,\ predator}$ for fish-eating organisms has been determined from the bioconcentration factor (BCF) and a biomagnification factor (BMF) as:

$PEC_{oral,\ predator}$ = 1.06E-02 mg/kg wet fish
Risk characterisation for fish-eating mammals and birds:
The risk to the fish-eating predators/scavengers (mammals) is calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:

$PEC_{oral,\ predator}$/ $PNEC_{oral\ mammals}$ = 1.06E-02 / 10.00 = **1.06E-03**

The risk to fish-eating birds was calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral,\ predator\ bird}$). In this case, the $PNEC_{oral}$ was derived from the LC50 of 5620 ppm and the appropriate assessment factor of 3000 was then applied to this value resulting in a **$PNEC_{oral,\ predator}$ of 1.87 mg/kg food**.

The $PEC_{oral,\ predator}$ for fish-eating organisms was determined from the bioconcentration factor (BCF) and a biomagnification factor (BMF) as **$PEC_{oral,\ predator}$ = 1.06E-02 mg/kg wet fish**.

The resulting risk quotient (**$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 1.06E-02 / 1.87 = 5.67E-03**) is less than 1, confirming the fact that there is no risk of secondary poisoning to fish-eating birds arising from d-Phenothrin use.

The resulting risk quotient (<1) confirms the fact that there is no risk of secondary poisoning to fish-eating predators/scavengers arising from d-Phenothrin use.

Terrestrial Compartment

As discussed above, the log octanol/water partition coefficient of d-Phenothrin (6.8) suggests that it may have significant potential for bioconcentration in soil-dwelling organisms, with the possibility of bioaccumulation leading to secondary poisoning. This theoretical potential is further reflected in a calculated BCF for earthworms of 75,700 (estimated using the QSAR method of Jager et al 1998, as presented in the Technical Guidance Document on Risk Assessment (TGD, 2003)) and a default BMF of 10 (determined as set out in TGD, 2003).

However, as discussed above, bluegill sunfish have been shown to rapidly eliminate residues of d-phenothrin from their tissues, once exposure ceases, thereby mitigating any perceived potential for biomagnification through the food chain that may otherwise lead to secondary poisoning. Given that the uptake of a chemical from soil pore water by soil-dwelling organisms is analogous to that by aquatic organisms, it is reasonable to extrapolate the conclusions of this study to the terrestrial environment also. The use pattern of products that contain d-Phenothrin will further act to ensure that the potential for secondary poisoning is negligible. When used as instructed on the label, there is essentially no potential for contamination of the soil compartment to occur. Even in the rare event that accidental contamination does occur (for example in the event that contaminated sludge is spread on agricultural land), the infrequent nature of such emissions, will not give rise to a realistic possibility of significant bioconcentration in exposed organisms.

Nonetheless, a quantitative risk characterisation for secondary poisoning in the terrestrial compartment (for the food chain soil → earthworm → worm-eating birds or mammals) has been performed below for completeness sake.

$PNEC_{oral,\ predator\ mammal}$ derivation:
A predicted no effect oral concentration ($PNEC_{oral}$) can be calculated based on the results of the mammalian repeat dose toxicity tests and toxicity data for birds (LC_{50} dietary). The result of this calculation gives a predicted no-effect concentration in food that should be protective to other mammalian and avian species.
The 52 week dog study (Cox R. (1987)) represents the most sensitive species (NOAEL=8.2 mg/kg bw/day) with a determined NOEC value of 300 mg/kg food. Applying an assessment factor of 30 to this value gives:

$PNEC_{oral,\ predator}$ = 10.0 mg/kg food

$PEC_{oral,\ predator}$ derivation:
The calculation method described in the TGD was used to determine the $PEC_{oral,\ predator}$ for earthworm eating predators as:

$PEC_{oral,\ predator}$ = 1.11E-02 mg/kg wet earthworm ($C_{earthworm}$)

Risk characterisation for earthworm-eating mammals:
The risk to the earthworm-eating mammals is calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:

$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 1.11E-02/10 = 1.11E-03

$PNEC_{oral,\ predator,\ bird}$ derivation:

A predicted no effect oral concentration ($PNEC_{oral\ bird}$) can be calculated based on the results of the 5 day dietary study (Grimes J, 1988). The result of this calculation gives a predicted no-effect concentration in food that should be protective to other avian species.
The 5 day dietary study, using an assessment factor of 3000 was calculated to give a PNECoral of 1.87 mg/kg food.

$PNEC_{oral,\ bird\ predator}$ =1.87 mg/kg food.

$PEC_{oral,\ predator}$ derivation:
The calculation method described in the TGD was used to determine the $PEC_{oral,\ predator}$ for earthworm eating predators as:

$PEC_{oral,\ predator}$ = 1.11E-02 mg/kg wet earthworm ($C_{earthworm}$)

Risk characterisation for earthworm-eating birds:
The risk to the earthworm-eating birds is calculated as the ratio between the concentration in their food ($PEC_{oral,\ predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$) as follows:

$PEC_{oral,\ predator}$/ $PNEC_{oral}$ = 1.11E-02/ 1.87 = 5.93E-03

The resulting risk quotient (<1) confirms the fact that there is no risk of secondary poisoning to earthworm-eating organisms arising from d-Phenothrin use.

Conclusion: It may be concluded that there are no unacceptable risks to fish eating predators or worm eating predators from the use of SANYTOL ANTIACAROS

Mixture toxicity

Mixture toxicity is not relevant for SANYTOL ANTIACAROS. The co-formulants present in the biocidal product are not considered relevant substances for mixture assessment.
SANYTOL ANTIACAROS contains one active substance providing insecticidal effect to the product. It is the only substance contributing to the b.p. classification regarding environmental hazards.

There are however several other co-formulants in the product. Most of them are not classified for environmental hazards and therefore are not considered substances of concern. Hence they are not relevant for mixture assessment.

Nevertheless, there are four co-formulants that are active substances and are included in the Review Program of BPR. One co-formulant has harmonised classification as Aquatic Acute 1 (M=10) and Aquatic Chronic 1 (M=1). This substance was approved for some product types and other types are still in progress. From the data available in the CARs, it can be concluded that only the PNECstp is lower than the one of d-phenothrin. However the concentration of this substance is so low (i.e. <0.000001%) that it is not expected it contributes significantly to the risks of the mixture.
Another active substance has not been evaluated so far but it has harmonised classification as Aquatic Acute 1 (with no M-factor set so far since it comes from Directive 67/548/EEC; a proposal was made in the draft CAR as Acute 1 M= 10 and Chronic 2). The concentration of this a.s. in the product is <0.01%. In the absence of agreed harmonised classification and of approved PNEC values, this substance has not been considered relevant for mixture toxicity assessment.

Another active substance is currently under evaluation by the RAC (proposed as Aquatic Acute 1 (M= 100) and Aquatic Chronic 2). In addition it has not been approved in the Review Program, therefore PNEC values have not been agreed so far. The substance has a REACH Registration dossier but no PNEC values are available. Moreover this substance is present in the product in concentration below 0.01%. Hence this substance has not been considered relevant for mixture toxicity assessment.

The forth co-formulant is registered under REACH and notified as not fulfilling the criteria to be classified for environmental hazards. It is also included in the Review Program, but the evaluation for approval is still in progress. This substance is present in the product in concentration of ca. 0.001%. Hence this substance has not been considered relevant for mixture toxicity assessment.

Aggregated exposure (combined for relevant emmission sources)

Aggregated exposure is not relevant for SANYTOL ANTIACAROS.

Overall conclusion on the risk assessment for the environment of the product
In conclusion, ES CA has estimated that when SANYTOL ANTIACAROS is used in not frequently washed textiles there is cause for concern for the environmental compartments. In summary: Atmosphere: The maximum PEC in air is negligible (4.28E-12 mg/m^3 for Phenothrin and 1.92E-12 for total metabolites) therefore, there is no concern for the atmospheric compartment following use of SANYTOL ANTIACAROS. STP: There is no concern for the STP microorganisms following the indoor use of SANYTOL ANTIACAROS. Aquatic compartment: Unacceptable risks in sediment has been found for the use of the product SANYTOL ANTIACAROS Terrestrial compartment: The PEC/PNEC values for soil show acceptable risks for the use of the product SANYTOL ANTIACAROS Secondary poisoning: The $PEC_{oral,predator}/PNEC_{oral}$ ratios determined for fish-eating predators/scavengers (5.67E-03 mg/$kg_{wet\ fish}$) and for earthworm eating organisms (5.93E-03 mg/$kg_{wet\ earthworm}$) indicate that there is no unacceptable risk of secondary poisoning following the use of SANYTOL ANTIACAROS. ES CA concludes that the authorisation of SANYTOL ANTIACAROS should only be granted when the following RMMs are included on the label instructions and the SPC: "Do not apply to wet washable textiles" and "During application, protect the adjacent surfaces with a non-washable plastic sheet".

2.2.9 Measures to protect man, animals and the environment

Handling: Do not smoke, eat or drink while you are using the product.
Avoid contact with eyes and skin.
Use: Protection of man and animals
After application allow drying for 8 hours and vacuum the applied surface.
Avoid contact of children with treated surfaces until the surfaces are dry.
Keep away from food/feedingstuff, eating utensils or food/feed contact surfaces.
Do not perform the operation in presence of people and/or pets.

Product must be securely applied in a way so as to minimize the risk of consumption by other animals or children.
The product contains a bitter substance that makes it repulsive to people or pets.

2.2.10 Assessment of a combination of biocidal products

Not relevant for the assessment of SANYTOL ANTIACAROS, since the Applicant has not informed ES CA that this product is intended to be authorised for the use with other biocidal products.
[

2.2.11 Comparative assessment

Not applicable for SANYTOL ANTIACAROS.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
2.2.2	[redacted]	2015	Study Plan Title: Determination of physico-chemical properties and storage stability test for SANYTOL ANTIÁCAROS. Study No.: Mo5058 - Amendments 2 & 3. Test facility: BioGenius GmbH, Analytics, 51429, Bergisch Gladbach, Germany
2.2.2	[redacted]	2017	Study Plan Title: Determination of physico-chemical properties and storaging for SANYTOL ANTIÁCAROS. Study No.: Mo5820 Test facility: BioGenius GmbH, Analytics, 51429, Bergisch Gladbach, Germany
2.2.2	[redacted]	2017	Study Plan Title: Determination of particle size distribution for SANYTOL ANTIÁCAROS. Study No.: 12376. Test facility: WestRock
2.2.4	[redacted]	2015	Study Plan Title: Validation of method "BioG AQ392: ACM: HPLC-Determination of 1R-trans Phenothrin in SANYTOL ANTIÁCAROS". Study No.: Mo5057. Test facility: BioGenius GmbH, Analytics, 51429, Bergisch Gladbach, Germany
2.2.5 (IUCLID/Sec. 6.7/endpoint 001)	[redacted]	2015	Title: Laboratory assessment of an insecticide speciality intended to control house dust mites and bed bugs. Test facility: Laboratory T.E.C., 1, rue Jules Védrines, ZAC Maignon – F- 64600 Anglet (France) Report no. 1763/0414R G.E.P.
2.2.5 (IUCLID/Sec. 6.7/endpoint 002)	[redacted]	2016	Title: Laboratory assessment of an insecticide speciality intended to control house dust mites *Dermatophagoides farinae*. Test facility: Laboratory T.E.C., 1, rue Jules Védrines, ZAC Maignon – F- 64600 Anglet (France) Report no. 2031-LAB/1215R G.E.P.
2.2.5	[redacted]	2016	Title: Simulated-use trial of the effectiveness of a product intended for the control of house dust mites in household environment. Test facility: Laboratory T.E.C., 1, rue Jules Védrines, ZAC Maignon – F- 64600 Anglet (France)

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
			Report no. 2031-SIM/1215R G.E.P.

3.2 Output tables from exposure assessment tools

Scenario [1] Non- professional exposure Spraying (trigger spray)

ConsExpo Web Report

Substance Name	1R-trans phenothrin
CAS	26046-85-5
Molecular weight	350 g/mol
K_{OW}	6.8 10Log
Pvap	2.37E-5 Pa at 20ºC
Product Name	SANYTOL ANTIÁCAROS
Weight fraction substance	0.45 %
Population Name	general public
Frequency	1 per day
Body weight	60 kg

Inhalation[1, 2]

Exposure model	Exposure to spray - Spraying
Spray duration	6 minute
Exposure duration	60 minute
Weight fraction substance	0.45 %
Room volume	20 m³
Room height	2.5 m
Ventilation rate	0.6 per hour
Inhalation rate	20.8 l/min
Spraying towards person	No
Mass generation rate	0.8 g/s
Airborne fraction	0.008
Density non volatile	1 g/cm³
Inhalation cut off diameter	15 µm
Aerosol diameter distribution	Log normal
Median diameter	7.7 µm
Arithmetic coefficient of variation	1.9
Maximum diameter	50 µm
Include oral non-respirable material exposure	Yes
Absorption model	Fixed fraction
Absorption fraction	1

Dermal[3]

Exposure model	Direct contact - Constant rate
Exposed area	1950 cm²
Weight fraction substance	0.45 %
Contact rate	46 mg/min
Release duration	6 minute
Absorption model	Fixed fraction
Absorption fraction	0.75

Oral

Exposure model Non-respirable spray model

No parameters Parameters are set in Inhalation exposure route.

Absorption model Fixed fraction

Absorption fraction 1

[1] New default values for the spray model RIVM, March 2010: Table 1: mass generation rate trigger spray 0.8g/sec; airborne fraction 0.008; initial droplet size distribution P_{50} 7.7; CV (1.9) (Pesticide Trigger spray, ready to use on surfaces).
[2] General Fact Sheet General default parameters for estimating consumer exposure - Updated version RIVM report 090013003/2014: room volume 20m^3 (unspecified room), Ventilation rate 0.6 hr-1 (unspecified room).
[3] Pest Control Products Fact Sheet RIVM report 320005002/2006 for trigger sprays the default value for contact rate is set at 46 mg/min.

Results for scenario Spraying (trigger spray)

Inhalation

Mean event concentration	1.7×10^{-1}mg/m^3
Peak concentration (TWA 15 min)	2.7×10^{-1}mg/m^3
Mean concentration on day of exposure	7.2×10^{-3}mg/m^3
Year average concentration	7.2×10^{-3}mg/m^3
External event dose	3.6×10^{-3}mg/kg bw
External dose on day of exposure	3.6×10^{-3}mg/kg bw
Internal event dose	3.6×10^{-3}mg/kg bw
Internal dose on day of exposure	3.6×10^{-3}mg/kg bw/day
Internal year average dose	3.6×10^{-3}mg/kg bw/day
Dermal	
Dermal load	6.4×10^{-4}mg/cm^2
External event dose	2.1×10^{-2}mg/kg bw
External dose on day of exposure	2.1×10^{-2}mg/kg bw
Internal event dose	1.6×10^{-2}mg/kg bw
Internal dose on day of exposure	1.6×10^{-2}mg/kg bw/day
Internal year average dose	1.6×10^{-2}mg/kg bw/day
Oral	
External event dose	1.2×10^{-4}mg/kg bw
External dose on day of exposure	1.2×10^{-4}mg/kg bw
Internal event dose	1.2×10^{-4}mg/kg bw
Internal dose on day of exposure	1.2×10^{-4}mg/kg bw/day
Internal year average dose	1.2×10^{-4}mg/kg bw/day
Integrated	
Internal event dose	1.9×10^{-2}mg/kg bw
Internal dose on day of exposure	1.9×10^{-2}mg/kg bw/day
Internal year average dose	1.9×10^{-2}mg/kg bw/day

Scenario [2] Adult/Infant sleeping in a treated mattress

Model: US EPA Standard Operating Procedures for Residential Pesticide Exposure Assessment, October 2012. Section 7 Indoor Environments; 7.2.2.2 Post-Application Dermal Exposure Algorithm (mattresses) 7-35

The algorithm to calculate absorbed dose is (see definitions in table below):

$$D = DR * SA/BW * F * Fai * PF * AF * CF1$$

Parameters introduced to the model:

parameter	value	definition	comments
DR	0.45 µg/cm^2	Surface residue concentration a.i.	From application rate: 10g/m^2 * 0.005 g ai/g prod *10E6 µg/g*10E-4 m^2/cm^2*10% (residual fraction after vacuuming)
SA	4100 cm^2 16600 cm^2	body surface area infant adult	HEEG Opinion 17
BW	8 kg 60 kg	body weight infant adult	HEEG Opinion 17
SA/BW	512.5 cm^2/kg 276.7 cm^2/kg	body surface area to body weight ratio infant adult	Note: infants 6 < 12 months old
F	100%	Fraction of body that contacts residue	Whole body (worst case)
Fai	30% Tier 1 15% Tier 2	Fraction of ai available for transfer	Tier 1 Transfer coefficients (cotton) – dislodgeable residues – BHHEM pg 351 (355) Tier 2 refinement to account for longer exposure
PF	50%	Protection factor	default
AF	75%	Dermal absorption	EFSA Guidance on dermal absorption
CF1	0.001 mg/µg	conversion factor	default

Absorbed dermal dose (ADD):

Tier 1 _ Short Term Exposure

Infant ADD = 0.45 µg/cm^2 * 512.5 cm^2/kg * 1* 0.30 * 0.5 * 0.75 * 0.001 mg/µg = 0.0259 mg/kg bw/d

Adult ADD = 0.45 µg/cm^2 * 276.7 cm^2/kg * 1 * 0.30 * 0.5 * 0.75 * 0.001 mg/µg = 0.0140 mg/kg bw d

Tier 2 _ Medium Term Exposure

Infant ADD= 0.45 µg/cm^2 * 512.5 cm^2/kg * 1 * 0.15 * 0.5 * 0.75 * 0.001 mg/µg = 0.013 mg/kg bw

Adult ADD = 0.45 µg/cm^2 * 276.7 cm^2/kg * 1 * 0.15 * 0.5 * 0.75 * 0.001 mg/µg = 0.007 mg/kg bw

Scenario [3] Infant crawling on a treated carpet & hand to mouth contact Tier 1

ConsExpo Web - Report

Substance Name	1R trans phenothrin
Molecular weight	350 g/mol
KOW	6.8 10Log
Product Name	Sanytol antiácaros
Weight fraction substance	0.45 %
Population Name	infant
Body weight	8 kg
Frequency	42 days per year
Description	Infant crawling on treated carpet

Inhalation

Exposure model	n.a.
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Rubbing off
Exposed area	2410 cm²
Weight fraction substance	0.45 %
Transfer coefficient	0.2 m²/hr
Dislodgeable amount	0.6 g/m²
Contact time	60 minute
Contacted surface	22 m²
Release duration	–
Absorption model	Fixed fraction
Absorption fraction	0.75

Oral

Exposure model	Direct product contact - Constant rate
Weight fraction substance	0.45 %
Ingestion rate	0.012 g/hr
Exposure duration	60 minute
Absorption model	Fixed fraction
Absorption fraction	0.6

Results for scenario Infant crawling on a treated carpet & hand to mouth contact Tier 1

Dermal

Dermal load	2.2×10^{-4}mg/cm²
External event dose	6.8×10^{-2}mg/kg bw
External dose on day of exposure	6.8×10^{-2}mg/kg bw
Internal event dose	5.1×10^{-2}mg/kg bw

Internal dose on day of exposure	5.1×10^{-2}mg/kg bw/day
Internal year average dose	5.8×10^{-3}mg/kg bw/day
Oral	
External event dose	6.8×10^{-3}mg/kg bw
External dose on day of exposure	6.8×10^{-3}mg/kg bw
Internal event dose	4.1×10^{-3}mg/kg bw
Internal dose on day of exposure	4.1×10^{-3}mg/kg bw/day
Internal year average dose	4.7×10^{-4}mg/kg bw/day
Integrated	
Internal event dose	5.5×10^{-2}mg/kg bw
Internal dose on day of exposure	5.5×10^{-2}mg/kg bw/day
Internal year average dose	6.3×10^{-3}mg/kg bw/day

Scenario [3] Infant crawling on a treated carpet & hand to mouth contact Tier 2

ConsExpo Web - Report

Substance Name	1R trans phenothrin
Molecular weight	350 g/mol
KOW	6.8 10Log
Product Name	sanytol
Weight fraction substance	0.45 %
Population Name	infant
Body weight	8 kg
Frequency	42 days per year

Scenario Infant crawling on a treated carpet & hand to mouth contact Tier 2

Inhalation

Exposure model	n.a.
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Rubbing off
Exposed area	2410 cm²
Weight fraction substance	0.45 %
Transfer coefficient	0.2 m²/hr
Dislodgeable amount	0.3 g/m²
Contact time	60 minute
Contacted surface	22 m²
Release duration	–
Absorption model	Fixed fraction
Absorption fraction	0.75

Oral

Exposure model	Direct product contact - Constant rate
Weight fraction substance	0.45 %
Ingestion rate	0.006 g/hr
Exposure duration	60 minute
Absorption model	Fixed fraction
Absorption fraction	0.6

Results for scenario Infant crawling on a treated carpet & hand to mouth contact Tier 2

Dermal

Dermal load	1.1×10^{-4} mg/cm²
External event dose	3.4×10^{-2} mg/kg bw
External dose on day of exposure	3.4×10^{-2} mg/kg bw
Internal event dose	2.5×10^{-2} mg/kg bw

Internal dose on day of exposure	2.5×10^{-2}mg/kg bw/day
Internal year average dose	2.9×10^{-3}mg/kg bw/day
Oral	
External event dose	3.4×10^{-3}mg/kg bw
External dose on day of exposure	3.4×10^{-3}mg/kg bw
Internal event dose	2.0×10^{-3}mg/kg bw
Internal dose on day of exposure	2.0×10^{-3}mg/kg bw/day
Internal year average dose	2.3×10^{-4}mg/kg bw/day
Integrated	
Internal event dose	2.7×10^{-2}mg/kg bw
Internal dose on day of exposure	2.7×10^{-2}mg/kg bw/day
Internal year average dose	3.1×10^{-3}mg/kg bw/day

3.3 New information on the active substance

New information on the active substance has not been submitted.

3.4 Residue behaviour

The biocidal product is intended to be used as a spray application on textiles (mattresses, courtains, carpets,..) three times per year. This precise mode of use makes surface and food/feed contamination unlikely. In addition, the label includes instructions/ restrictions of use that precludes transference of residues to food or feed.

No risk for consumers via residues in food is envisaged.

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

The Applicant submitted three efficacy studies to demonstrate the biocidal effect of SANYTOL ANTIACAROS against bed bugs and house dust mites.

In a laboratory study (IUCLID file, Section 6.7/endpoint 001) SANYTOL ANTIACAROS was tested against bed bugs (*Cimex lectularius*) and house dust mites (*Dermatophagoides pteronyssinus*) according to C.E.B. No. 135 (2007) protocol. Direct and residual efficacy were tested by hand-held spraying the product onto a 7 cm diameter parcel of treated and untreated material. Four material types were included in the trial (wool, cotton, polyamide, polyester). Efficacy was assessed in terms of knockdown (until 4 hours of exposure) and lethal effects recorded 24h after treatment and 4 h of exposure. There were 4 replicates, each with 300±30 mites (mixed adults and nymphs) and 20 bed bugs (adults). Untreated controls were also included in the trial, which resulted in death rates <10%.

Direct efficacy was conducted by directly spraying 3 mL (aprox. 3 sprays) of SANYTOL ANTIACAROS onto batches of insects. This dose seems to be higher than that recommended in the label (11 sprays per square metre). KT100 was <5 minutes for dust mites and <10 minutes for bed bugs. The guidance requires ≥90% knockdown within a few minutes; therefore the direct efficacy is considered to be valid.

Residual activity was assessed the day of spraying at the label dose of 10 g/m^2 (after drying the tested material) and every month until the sixth month. For dust mites, 100% knockdown was obtained in <24 h and 100% mortality after 24 h until the fourth month. The Applicant indicated that the mites would not have time to reproduce in less than 24 h. This is considered adequate by the eCA. Therefore the residual activity for dust mites is valid until 4 months.

For bed bugs, 100% knockdown was obtained in less than 24h and 100% mortality after 24h until the third month of ageing. 100% knockdown was obtained in <48h until the fourth month. The Applicant indicated that the bed bugs would not have time to reproduce in less than 48h. However at the fourth month, 56% mortality was achieved. This is not considered adequate enough by the eCA. Therefore the residual activity for bed bugs is valid until 3 months. Please see below a table showing the results of residual efficacy tests.

Date	Target	Knockdown (100% in less than)	Mortality after 24 h
Day0	House dust mite	30 min	100%
	Bed bug	4 h	100%
Day0 + 1 month	House dust mite	1 h	100%
	Bed bug	4 h	100%
Day0 + 2 months	House dust mite	3 h	100%
	Bed bug	6 h	100%
Day0 + 3 months	House dust mite	8 h	100%
	Bed bug	24 h	100%
Day0 + 4 months	House dust mite	24 h	100%
	Bed bug	48h	56%
Day0 + 5 months	House dust mite	48 h	43%
	Bed bug	72 h	27%
Day0 + 6 months	House dust mite	5 days	8%
	Bed bug	7 days	4%

In another laboratory study (IUCLID file, Section 6.7/endpoint 002), SANYTOL ANTIACAROS was tested against a different species of house dust mites (*Dermatophagoides farinae*). The testing conditions were identical to those explained in Serrano 2015. In the direct efficacy test, KT100 was <5 minutes. In the residual activity trial, until the fourth month of ageing 100% knockdown was obtained in less than 4h and 100% mortality after 24h. Untreated controls resulted in death rates <10%. Therefore the residual activity for *D. farinae* mites is valid until 4 months. Please see below a table showing the results of residual efficacy tests.

Date	Target	Knockdown (100% in less than)	Mortality after 24 h
Day0	*D. farinae*	30 min	100%
Day0 + 4 months	*D. farinae*	4 hours	100%

In a simulated use trial (IUCLID file, Section 6.7/endpoint 003) SANYTOL ANTIACAROS was tested against two species of house dust mites, i.e. *D. farinae* and *D. pteronyssinus* in compliance with GLP. Four replicates of 1000+/-50 mites (adults and nymphs) were exposed to the product; untreated controls were included.
It was a choice test where mites were set on the untreated half with food and water and covered with a Petri lid. There were no harbourages available for mites but they could reach the untreated area.

As the application method of this product is not in cracks and crevices we consider that the simulated used test does not have to include harbourages.

The product was applied with the trigger spray provided by the App. at the dose rate of 10 g/m^2 (average measured 9.98 g/m^2 [SD 0.08 g/m^2]) onto half of fabric tiles (i.e. 3 m^2 made of cotton, wool, polyester and polyamide fabrics typical of bed sheets, mattress ticking, carpets, etc.) placed in the floor of a test chamber of 6 m^2. The tiles were left to dry for 2 h. It was a choice test where mites were set on the untreated half with food and water and covered with a Petri lid. The exposure time was 4 h. Mites were tested in tiles treated 2 h before (direct effect) and in tiles treated 4 months before (stored at conditions similar to domestic premises) (residual effect). Mortality was assessed after 24 h (visual assessment only to avoid deletion of test system) and after 7 d (accurate count under binocular microscope) after exposure.

The results of the trials with direct effect (day 0 after treatment and drying) and residual activity (day 0 + 4 months) were 100% mites of both species killed after 24h (no visible alive mites) which was also confirmed after 7 days with accurate count. The mortality of the untreated control series was lower than 10%, in every replicate. Therefore direct and residual efficacy up to 4 months of SANYTOL ANTIACAROS were adequately demonstrated in this trial against both *D. farinae* and *D. pteronyssinus* at the recommended dose rate of 10 g/m^2.

3.6 Confidential annex

See confidential document

3.7 Other