Application type	refMS/eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	*NL*	BC-PD019500-58	07.07.2017	Initial assessment	
NA-AAT	*NL*	BC-PA042045-61	23.08.2018	*Post-authorisation requirement: final data to support a shelf-life of 2 years*	
NA-MIC	*NL*	BC-VF071989-10	26.04.2022	*Change in the shelf-life from 2 years to 4 years*	See addendum '20220512_NL-0013401-0000_Addendum'

This PAR has not been amended following a minor change. For changes to the original evaluation please see the respective addendum.

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)

COMPO Mierenlokdoos

Insectex Mierenlokdoos

Product type 18

1R-trans-phenothrin

Case Number in R4BP: BC-PD019500-58

Evaluating Competent Authority: The Netherlands

Date: 07-07-2017
Date: 12-05-2022

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1 CONCLUSION

The overall conclusion from the evaluation of the biocidal product, COMPO Mierenlokdoos / Insectex Mierenlokdoos, containing 0.1% w/w of the active substance 1R-trans-phenothrin, is that the biocidal product will not present an unacceptable risk to humans or animal health when using the product according to the conditions as stated in the SPC.
Furthermore, the environmental risk assessment for the biocidal product containing the active substance 1R-trans-phenothrin has demonstrated a safe use for the environment. The assessment of secondary poisoning of birds by the ingestion of contaminated ants showed that no adverse effects for insectivorous bird species are to be expected.
Data on the biocidal product have demonstrated sufficient efficacy against different species of ants (*Lasius niger, Lasius emarginatus, Tetramorium caespitum, Tapinoma erraticum, Linepithema humile, Monomorium pharaonis*).

The physico-chemical properties of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. A condition for authorisation is that the final shelf-life data are provided in the fourth quarter of 2017 for evaluation by the eCA, enabling confirmation of the claimed shelf-life of 2 years in the proposed packaging.

Update 12-7-2018:
Long term stability studies for the product COMPO Mierenlokdoos NL-0013401-000 were submitted in December 2017. The conclusion of the eCA is that the data support a shelf-life of 2 years. Hence, the condition in the original authorisation is fulfilled, and the storage stability period of the COMPO Mierenlokdoos of 2 years at 20°C as indicated in the SPC is fully supported.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
COMPO Mierenlokdoos	Netherlands*
Insectex Mierenlokdoos	Netherlands
Reinex Ameisenköder	Austria
degro Ameisenköder	Austria
Insectex Ameisenköder	Austria
Ameisen-Köderdose	Austria
Ameisenköder	Austria
Gardol Myrelokkedåse	Denmark
Substral Myrelokkedåse	Denmark
Myrelokkedåse	Denmark
Tanaco Myrelokkedåse	Denmark
Garden Myrelokkedåse	Denmark
Insectex Myrelokkedåse	Denmark
Lotus Myrelokkedåse	Denmark
Bonus Myrelokkedåse	Denmark
COOPER MUURAHAISRASIA	Finland
Muurahaisrasia	Finland
Muurahainen-syöttitölkki	Finland
LASIUS MAX	France
Insectex Appât á fourmis	France
Appât a fourmis étain	France
Reinex Ameisenköder	Germany
Dehner Ameisenköder	Germany
Insectex Ameisenköder	Germany
Rubin Ameisenköder	Germany
Grüner Jan Ameisenköder	Germany
Pritex Ameisen-Köderdose	Germany
Ameisen-Köderdose	Germany
Ameisenköder	Germany
Degro hangyák csali	Hungary
Hangyák csali	Hungary
Insectex hangyák csali	Hungary
Maur-agnboks	Norway
Insectex mauragn	Norway

Identifier	**Country (if relevant)**
Rubin pryznęta na mrówki	Poland
Expel Pułapka na MRÓWKI	Poland
Przynęta na mrówki	Poland
Insectex przynęta na mrówki	Poland
Przynęta na mrówki - puszka	Poland
Degro Vaba za mravlje	Slovenia
Vaba za mravlje	Slovenia
Mravlje vaba kositer	Slovenia
Anticimex Myrdosa	Sweden
Snip Myrdosa	Sweden
Myragndosa	Sweden
Myr-agndosa	Sweden
Insectex Myragn	Sweden
Optimum Ameisenköder	Switzerland
Optimum Appât á fourmis	Switzerland
Optimum Esca antiformiche	Switzerland
Ameisen-Köderdose	Switzerland
Fórmicha-Escascatola	Switzerland
Fourmis-Appâtboîte	Switzerland
Insectex Ameisenköder	Switzerland
Insectex Appât á fourmis	Switzerland
Insectex Esca antiformiche	Switzerland
Degro Ameisenköder	Switzerland
Degro Appât á fourmis	Switzerland
Degro Esca antiformiche	Switzerland
Martec Ameisenköder	Switzerland
Martec Appât á fourmis	Switzerland
Martec Esca antiformiche	Switzerland
Neocid EXPERT Ameisenköder	Switzerland
Neocid EXPERT Appât á fourmis	Switzerland
Neocid EXPERT Esca antiformiche	Switzerland

*In this Product Assessment Report the first trade name is used to indicate the product.

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	terrasan Haus- + Gartenbedarf GmbH
	Address	Rosenweg 2 - 4 86641 Rain am Lech Germany
Authorisation number	NL-0013401-0000	
Date of the authorisation	7-7-2017	

Expiry date of the authorisation	7-7-2027

2.1.1.3 Manufacturer of the products

Name of manufacturer	terrasan Haus- + Gartenbedarf GmbH
Address of manufacturer	Rosenweg 2 - 4 86641 Rain am Lech Germany
Location of manufacturing sites	Please refer to address above.

2.1.1.4 Manufacturer of the active substance

Active substance	1R-trans-phenothrin
Name of manufacturer	Sumitomo Chemical (UK) PLC
Address of manufacturer	77-85 Fulham Palace Road W6 8JA London United Kingdom
Location of manufacturing sites	See above

2.1.2 Product composition and formulation

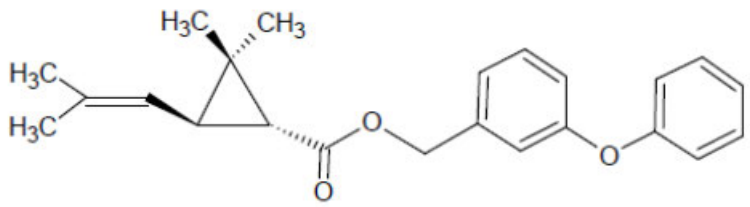
The full composition of the product according to Annex III Title 1 is provided in the confidential annex.

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 X

2.1.2.1 Identity of the active substance

Main constituent	
ISO name	1R-trans-phenothrin
IUPAC or EC name	3-Phenoxybenzyl (1R,3R)-2,2-dimethyl- 3-(2-methylprop-1-enyl) cyclopropanecarboxylate
EC number	247-431-2
CAS number	26046-85-5
Index number in Annex VI of CLP	Not allocated
Minimum purity / content	min. 890 g/kg (95.5% as sum of all isomers)

Structural formula	

2.1.2.2 Candidates for substitution

The active substance does not fulfil the criteria listed in article 10 of the BPR (EU) 528/2012 and is not considered a candidate for substitution.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
1R-trans-phenothrin	3-phenoxybenzyl (1R,3R)-2,2-dimethyl- 3-(2-methylprop-1-enyl)cyclopropanecarboxylate	Active Substance	26046-85-5	247-431-2	**Pure content**: 0.10%w/w **TGAI*:** 0.11%w/w (91% pure)

* TGAI: technical grade of active ingredient
FAO/WHO tolerances are +/-15% for this product: 0.085 – 0.115%w/w.

2.1.2.4 Information on technical equivalence

The source of active substance was the same as was evaluated for inclusion in the Union list of approved active substances.

2.1.2.5 Information on the substances of concern

The product contains no substances of concern.

2.1.2.6 Type of formulation

RB, Bait (ready for use)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Skin Sens. 1A Aquatic Chronic 2
Hazard statement	H317: May cause an allergic skin reaction H411: Toxic to aquatic life with long lasting effects.
Labelling	
Signal words	warning
Hazard statements	H317: May cause an allergic skin reaction H411: Toxic to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P103: Read label before use. P264: Wash … thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P302+P352: IF ON SKIN: Wash with plenty of water/... P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P501: Dispose of contents/container to ...
EUH statements	-

2.1.4 Authorised use

2.1.4.1 Use description

Table 1. Use # 1 – Bait application

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Ants and tropical ants Scientific name: *Lasius niger* Common name: Black garden ant Development stage: adults and nymphs Scientific name: *Lasius emarginatus* Common name: Black ant Development stage: adults and nymphs Scientific name: *Tetramorium caespitum* Common name: Pavement ant Development stage: adults and nymphs

	Scientific name: *Tapinoma erraticum* Common name: Tapinoma ant Development stage: adults and nymphs Scientific name: *Linepithema humile* Common name: Argentine Ant Development stage: adults and nymphs Scientific name: *Monomorium pharaonis* Common name: Pharaoh antDevelopment stage: adults and nymphs
Field of use	Indoor, outdoor Areas of use are in-house and terraces.
Application method	**Method of application:** Bait application **Detailed description of the method:** The product is a ready-to-use insecticide formulated as a paste and distributed in a bait station containing 0.1 % (w/w) (1 g/L) 1R-trans phenothrin as active substance (1 bait box contains 2 gr of biocidal product, i.e. 0.002g 1R-trans phenothrin). The product is an insecticide intended for in-house treatment and on terraces. The product is applied as a bait box and should be placed in the close vicinity of ant nests or trails. The bait box needs to be protected from moisture and rainfall.
Application rate and frequency	**Application rate:** 1 bait box (2 g biocidal product)/ nest, with a maximum of 1 bait boxes per 7.5 m^2 No dilution **Number and timing of application:** At the same time one or more applications at different locations depending on the extent of ant infestation. Complete nest kill can be expected in 2 to 4 weeks.
Category of users	General public
Pack sizes and packaging material	White screw-top bait station made of HDPE containing 2 g of the biocidal product. Black thermoformed bait box made of polystyrene high impact containing 2 g of the biocidal product. Green screw-top bait station made of polypropylene, homopolymer containing 2 g of the biocidal product.

2.1.4.2 Use-specific instructions for use

See 2.1.5.1

2.1.4.3 Use-specific risk mitigation measures

See 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 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 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 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Instruction for use

The product is a bait paste provided in a bait box that kills ants in the house and on terraces. The product contains attractive bait combined with the active ingredient, which is collected by the ants and transported into their nests. The uptake of the bait is improved by removing other food sources in the vicinity of the bait box.

- The product is packed in two different bait box designs, a thermoformed station and a screw-top station. In order to open the thermoformed bait box, the bait box must be broken from its attachment. Thereby entrances to the bait box will be opened. In order to open the screw-top bait box the top part of the station must be screwed to the left as far as it will go.
- Place the bait station in an area that is protected from moisture and rainfall and near the nest or ant trail.
- Apply the product away from direct sunlight or heat sources (e.g. do not place it under a radiator).
- Apply bait box on hard surfaces only.
- No or only a few dead ants will be visible because the product does not start to act until it has entered the ant nest.
- Place the station in the area of infestation for at least eight to fourteen days. Remove the product when ants are no longer visible. To close the screw-top station, the top part of the station must be screwed to the right as far as it will go.
- If the treatment is ineffective, users should report possible development of resistance directly to the registration holder.

2.1.5.2 Risk mitigation measures

Risk mitigation measures:

- The product must be protected from moisture and rainfall.
- The product and its residues, empty containers or packaging must not enter water.
- Avoid any unnecessary contact with the product. Misuse may cause harm to health. Keep away from children and pets.
- Avoid any direct or indirect contact with food, feed and drinks.
- Do not use force when opening the bait stations.
- Dispose of product residues in the original packaging at a collection point for household chemicals. Dispose of empty bait stations and folding carton at a collection point for recyclable materials.
- Do not re-use original packaging or empty containers.

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

Particulars of likely direct or indirect effects: None known when the product is used properly according to the product label.

First aid instructions:

Description of first aid measures

In case of skin contact: After contact with skin, wash immediately with plenty of water.

In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

If swallowed: If swallowed, seek medical advice immediately and show this container or label.

Indication of any immediate medical attention and special treatment needed.

Treatment: Treat symptomatically.

Emergency measures to protect the environment:

Environmental precautions: Do not let product enter drains, surface water or subsoil water.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Product: Disposal together with normal waste is not allowed. Special disposal required according to local regulations.

Contaminated packaging: Observe national and local legal requirements.

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

Requirements for storage areas and containers: Store protected against frost.

Further information on storage conditions: Keep container tightly closed in a cool place.

Advice on common storage: Keep away from food, drink and animal feed.

The shelf life of the biocidal product is two years at 20 °C.

Storage temperature: 0 - 30 °C

2.1.6 Other information

-

2.1.7 Packaging of the biocidal product

Type of packaging	Size / volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
White screw-top bait box	2 g	HDPE	HDPE*	non-professional	Yes
Black thermoformed bait box	2 g	Polystyrene high impact	Polystyrene high impact*	non-professional	Yes
Green screw-top bait box	2 g	Propylene, homopolymer	Propylene, homopolymer*	non-professional	Yes**

** *by extrapolation from HDPE data*

Secondary packaging: 2 bait boxes are packed in a carton reinforced blister pack.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the product or on the active substace have been submitted.

2.1.8.2 Access to documentation

The applicant has submitted a letter of access from Sumitomo Chemical Company Limited. Data access is granted to the dossier that supported the approval of the active substance 1R-trans-phenothrin.

2.2 Assessment of the biocidal product

2.2.1 Intended use as applied for by the applicant

Table 2. Intended use # 1 – Bait application

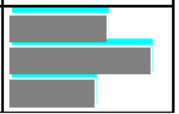
Product Type	PT 18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide

Target organism (including development stage)	Scientific name: *Lasius niger* Common name: Black garden ant Development stage: Adults and nymphs Scientific name: *Lasius emarginatus* Common name: Black ant Development stage: Adults and nymphs Scientific name: *Tetramorium caespitum* Common name: Pavement ant Development stage: Adults and nymphs Scientific name: *Tapinoma erraticum* Common name: Tapinoma ant Development stage: Adults and nymphs Scientific name: *Linepithema humile* Common name: Argentine Ant Development stage: Adults and nymphs Scientific name: *Monomorium pharaonis* Common name: Pharao ant Development stage: Adults and nymphs
Field of use	Indoor and outdoor use
Application method	Method of application: Ready to use bait box Detailed description of the method: The product is an insecticide intended for in-house treatment and on terraces. The product is applied as a bait box in the close vicinity of ant nests or trails. The bait box needs to be protected from moisture and rainfall.
Application rate and frequency	The application rate: 2 g biocidal product (1 bait box)/ 10 m^2. Number and timing of application: At the same time one or more applications at different locations depending on the extent of ant infestation.
Category of users	General public (non-professional)
Pack sizes and packaging material	Bait box containing 2 g biocidal product. The white and green boxes are screw-top stations and the black box is a thermoformed station. The boxes are made of HDPE (white box), polystyrene high impact (black box), and polypropylene, homopolymer (green box).

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 inspection	Content 1R-trans-phenothrin: 0.1% Batch 12/064	Before and after storage for 2 weeks at 54 °C: Paste	
Colour at 20 °C and 101.3 kPa	Visual inspection	Content 1R-trans-phenothrin: 0.1% Batch 12/064	Before for 2 weeks at 54 °C: Beige After storage for 2 weeks at 54 °C: Brown-orange	
Odour at 20 °C and 101.3 kPa	Olfactory inspection	Content 1R-trans-phenothrin: 0.1% Batch 12/064	Before and after storage for 2 weeks at 54 °C: Odourless	
Acidity / alkalinity	CIPAC method 75.3	Content 1R-trans-phenothrin: 0.1% Batch 12/064	Results of pH, concentration 1% w/v: Before for 2 weeks at 54 °C: 6.9 After storage for 2 weeks at 54 °C: 6.7 **eCA remark:** The temperature was not reported. This is considered a minor deficiency.	
Relative density / bulk density	SOP-PR-028 based on the weight of a product sample in air and its weight in Isopar V, a low viscosity auxiliary liquid	Content 1R-trans-phenothrin: 0.1% Batch 12/064	Result for density: Before storage for 2 weeks at 54 °C: 1.327 g/mL After storage for 2 weeks at 54 °C: 1.309 g/mL **eCA remark:** The temperature was not reported. This is considered a minor deficiency.	
			The bulk density must be determined for solids. Since the biocidal product is a paste formulation this test does not apply.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **accelerated storage**	CIPAC method MT 46.3 The test was performed with commercial packages of the formulation (black thermoformed box).	Content 1R-trans-phenothrin: 0.1% Batch 12/064	The formulation is stable at 54 °C for 2 weeks. No significant changes of physico-chemical properties occurred during the tests. The a.s. content was 0.122% before and after the storage. The appearance, pH, density and viscosity were measured before and after storage at 54°C for 2 weeks. Results for these tests were considered acceptable before and after storage and are discussed under the relevant section points. **eCA remark:** The black box consists of polystyrene.	[redacted]
	CIPAC method MT 46.3 The test was performed with commercial packages of the formulation (white screw-top box).	Content 1R-trans-phenothrin: 0.1% Batch 12/083	The formulation is stable at 54 °C for 2 weeks. No significant changes of physico-chemical properties and packaging stability occurred during the tests. The a.s. content was 0.102% before and 0.083% after the storage. **eCA remark:** The white box consists of high density polyethylene. The accelerated data show a significant decrease of the active substance content after storage (~19%). The applicant has provided a statement to address the issue. The laboratory performing the test indicate that the decrease may be caused by migration of the active substance to the container wall. HDPE is suggested to soften at higher temperature, allowing the active substance to attach or migrate into its surface. Considering the active substance is dispersed in a relatively polar matrix, this clarification is accepted by the eCA as breakdown by means of hydrolysis or thermal sensitiveness is not expected.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			In addition, 2 CoAs were provided, with data of the active substance content after 6 and 12 months at RT. These CoAs show no significant decrease in active substance content. The possibility of migration of the active substance into the packaging would depend on the grade of HDPE and its composition (additives). As there is no information on this subject, the eCA restricts the product to be stored at temperatures equal to or lower than 30°C, as was proposed by the applicant.	
			The appearance and pH were measured before and after storage. The density was measured once at the beginning of the study. Results for these tests were considered acceptable and described in the following.	
			Appearance: Before storage at 54 °C for 2 weeks: Beige paste with odour like caramel. After storage at 54 °C for 2 weeks: Brown-orange paste with odour like caramel.	
			The pH value was 6.4 before and 6.0 after storage at 54 °C for 2 weeks.	
			The density was 1.199 g/mL.	
			eCA remark: The polypropylene green bait box was not tested. Considering the type of product and the similarity of this polymer to HDPE, it is considered acceptable to extrapolate stability data to PP.	
Storage stability test – **long term**	Storage stability for 2 years at 20 °C (comparable	Content 1R-trans-phenothrin: 0.1%	The determination of storage stability of the biocidal product in its commercial packaging (black and white	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
storage at ambient temperature	to GIFAP Monograph No. 17) The test was performed with commercial packages of the formulation (black thermoformed and white screw-top box)		box) at 20 °C for 48 months is still in progress. Interim results after 6, 12, 20, 21, 24 and 28 months storage are provided and summarised below. available. **eCA remark** Interim data provided in HDPE, generated using a HPLC-ESTD method (certificate of analysis, no method description or validation): Initial active substance content: 0.102% Active substance after 6m storage: 0.107% Active substance after 12m storage: 0.0096% Active substance after 20m storage: 0.104% Active substance after 21m storage: 0.101% Active substance after 24m storage: 0.087% Active substance after 28m storage: 0.109% Overall a slight increase in the active substance of 6.9% is observed, which is still considered acceptable. The pH value of the biocidal product slowly decreases over time: Initial pH(1% solution): 6.5 pH(1% solution) after 6 months: 5.6 pH(1% solution) after 12 months: 5.1 pH(1% solution) after 24 months: 4.7 pH(1% solution) after 28 months: 4.7 The decrease of pH seems to stabilize after two years. The appearance before and after 28 months remains unchanged: beige pasta with weak caramel/sugar odour. The packaging material (HDPE) showed no sign of degradation and is considered stable for 28 months.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Based on these interim results of the long term storage stability study it is concluded that the shelf-life of the biocidal product is two years at 20°C.	
			eCA remark: The polypropylene green bait box was not tested. Considering the type of product and the similarity of this polymer to HDPE, it is considered acceptable to extrapolate.	
Storage stability test – **low temperature stability test for liquids**	–	–	Although the biocidal product is a paste which may be considered as a liquid, its low temperature stability does not need to be tested due to the label claim "protect the product from frost".	–
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	–	–	Not applicable as the packaging is light-proof (non-transparent). Therefore, the formulation is not exposed to light during storage.	–
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	–	–	Not applicable because according to the label instructions the biocidal product has to be stored tightly closed in a cool place. **eCA remark:** The product's stability is not expected to be affected by humidity as it is a paste containing a significant amount of water.	–

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**	Accelerated storage at 54 °C for 2 weeks (black box)	Content 1R-trans-phenothrin: 0.1% Batch 12/064	The formulation is stable at 54 °C for 2 weeks. No significant changes of packaging stability occurred during the test. The packaging of the biocidal product was in sound condition, sealed and without leakages before and after storage. The weight loss of the test item was less than 2.04%.	[redacted]
	Accelerated storage at 54 °C for 2 weeks (white box) Interim results of long term storage stability study at 20°C (white box)	Content 1R-trans-phenothrin: 0.1% Batch 12/083	The formulation is stable at 54 °C for 2 weeks. No significant changes of packaging stability occurred during the test. The packaging of the biocidal product was in sound condition, sealed and without leakages. The weight loss was less 0.3% except one test item which showed a weight loss of 2.47%. The formulation is stable at 20°C for 28 months. The packaging (HDPE) of the biocidal product was in sound condition, sealed and without leakages before and after storage. The weight loss of the test item stored for up to 28 months was less then 0.35%.	[redacted]
Wettability	–	–	Since the biocidal product is a paste formulation not intended to be dispersed in water this test does not need to be performed.	–
Suspensibility, spontaneity and dispersion stability	–	–	Since the biocidal product is a ready-to-use paste formulation these tests do not need to be performed.	–
Wet sieve analysis and dry sieve test	–	–	Since the biocidal product is not solid, no dispersable concentrate and no suspension, these tests do not need to be performed.	–

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Emulsifiability, re-emulsifiability and emulsion stability	–	–	Since the biocidal product is a ready-to-use product these tests do not need to be performed.	–
Disintegration time	–	–	Since the biocidal product is a paste formulation this test does not need to be performed.	–
Particle size distribution, content of dust/fines, attrition, friability	–	–	Since the biocidal product is a liquid formulation these tests do not need to be performed.	–
Persistent foaming	–	–	Since the biocidal product is not intended for dilution with water before use, this test does not need to be performed.	–
Flowability/Pourability/Dustability	–	–	Since no equipment is needed for the application of the biocidal product and since the biocidal product is no suspension, emulsion, or dust these tests do not need to be performed.	–
Burning rate — smoke generators	–	–	Since the biocidal product is not a smoke generator this test does not need to be performed.	–
Burning completeness — smoke generators	–	–	Since the biocidal product is not a smoke generator this test does not need to be performed.	–
Composition of smoke — smoke generators	–	–	Since the biocidal product is not a smoke generator this test does not need to be performed.	–
Spraying pattern — aerosols	–	–	Since the biocidal product is not an aerosol this test does not need to be performed.	–

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical compatibility	–	–	Not applicable	–
Chemical compatibility	–	–	Not applicable	–
Degree of dissolution and dilution stability	–	–	Since the biocidal product is not a water soluble bag, tablet or a water-soluble preparation these tests do not need to be performed.	–
Surface tension	–	–	Since the biocidal product is a paste formulation aspiration of it can be excluded. Therefore the surface tension of the formulation does not need to be tested.	–
Viscosity	CIPAC method MT 192	Content 1R-trans-phenothrin: 0.1% Batch 12/064	Results at 20 °C and a shear rate of 20 1/s: Before storage at 54 °C for two weeks: 44804 mPa*s After storage at 54 °C for two weeks: 51067 mPa*s **eCA remark** Five shear rates were investigated (20, 40, 60, 80, 100 1/s). The viscosity proved to be shear dependent. At 100 1/s, the viscosity was: Before storage at 54 °C for two weeks: 15995 mPa*s After storage at 54 °C for two weeks: 17987 mPa*s. The guidance on information requirements requires a determination at 40°C for liquids, but considering the product is a paste, the viscosity data is considered supplementary and the eCA does not require additional data.	[redacted]

Conclusion on the physical, chemical and technical properties of the product

eCA conclusion

The physical and chemical properties are adequately reported. The product is considered stable for 2 years when stored in the proposed packaging materials (PS, HDPE and PP) at temperatures between 0 and 30°C. As there is no low temperature storage data, the applicant has included the recommendation to protect the product from frost in the SPC.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	–	–	The biocidal product does not contain components which are known to confer explosivity or to enhance explosibility properties. None of its ingredients is classified as explosive. Therefore the biocidal product does not present any risk for explosion and this test does not need to be performed.	–
Flammable gases	–	–	The parameter flammable gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed.	–
Flammable aerosols	–	–	The parameter flammable aerosols must be determined for biocidal products that are supplied as aerosols. Since the biocidal product is not an aerosol this test does not need to be performed.	–
Oxidising gases	–	–	The parameter oxidising gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed.	–
Gases under pressure	–	–	The parameter gases under pressure must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed.	–
Flammable liquids	–	–	The flash point must be determined for liquid biocidal products. Since the biocidal product is a paste formulation the flash point does not need to be investigated.	–
Flammable solids	–	–	The biocidal product does not contain components that are classified as flammable. It is therefore incapable of exothermic reaction and it is not necessary to perform corresponding tests.	–
Self-reactive substances and mixtures	–	–	There are no ingredients with explosive or self-reactive properties present in the biocidal product. Therefore the formulation is not self-reactive.	–

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Pyrophoric liquids	–	–	Pyrophoric properties have to be determined for liquid biocidal products. Since the biocidal product is a paste formulation this test does not need to be performed.	–
Pyrophoric solids	–	–	The study does not need to be conducted as based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected.	–
Self-heating substances and mixtures	–	–	From the composition of the biocidal product it can be concluded that it is stable in air at room temperature and is not self-heating.	–
Substances and mixtures which in contact with water emit flammable gases	–	–	The biocidal product contains water. Therefore an emission of flammable gases is not expected when the preparation comes in contact with water.	–
Oxidising liquids	–	–	Oxidising properties must be determined for liquid biocidal products. Since the biocidal product is not a liquid this test does not need to be performed.	–
Oxidising solids	–	–	The biocidal product does not contain components which are known to enhance oxidising properties. None of its ingredients is classified as oxidising. Therefore the formulation does not have oxidising properties and tests do not need to be performed.	–
Organic peroxides	–	–	Since the biocidal product is not an organic peroxide, tests do not need to be performed.	–
Corrosive to metals	–	–	The product has been known since many years. It has never been reported any significant corrosion with tank or applicability material which are partially made of metal. In addition, the active substance and all the co-formulants of the recipe are not known to be corrosive to metals. In conclusion, the product is not significantly corrosive to metals.	–
Auto-ignition temperatures of products	–	–	The auto-ignition temperature must be determined for liquid biocidal products and gases. Since the biocidal product is a paste formulation these tests do not need to be performed.	–

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
(liquids and gases)				
Relative self-ignition temperature for solids	–	–	The biocidal product does not contain components that are classified as flammable or self-igniting. It is therefore incapable of exothermic reaction and it is not necessary to perform corresponding tests.	–
Dust explosion hazard	–	–	The dust explosion hazard must be determined for powders or biocidal products containing, or able to produce, dust. Since the biocidal product is a paste formulation this test does not need to be performed.	–

Conclusion on the physical hazards and respective characteristics of the product
The product is not classified with regard to physical and chemical 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	HPLC-UV, chiral column	Three placebo samples were prepared for each fortification level. Each sample was measured twice.	Six concentration levels over the range 0.06 mg/mL to 0.16 mg/mL were measured. Each	No interference greater than 3% occurred at the retention time of 1R-	The mean recovery rates ranged from 100.0% to 104.8% (n = 3). The overall mean recovery was 102.0% (n = 9). The relative standard deviations ranged from 0.9% to 5.5% (n = 3). The overall relative			Limit of quantification and detection are not required because the method will only be used for testing of	

		Fortification levels: 0.07, 0.10 and 0.13%, corresponding to 70, 100 and 130%.	concentration was measured three times. Correlation coefficient: 1.00	trans-phenothrin.	standard deviation was 3.6% (n = 9).	specification limits.	

Conclusion on the methods for detection and identification of the product

The method validated is the same as used in the storage stability studies and employs a chiral column, allowing the specific determination of 1R-trans-phenothrin. Method validation is considered acceptable.
System precision is also addressed. Six samples were prepared and injected twice resulting in an RSD of 3.67%. The Horwitz RSDr is 3.79%, meaning the RSD is acceptable. Linearity: slope and intercept of the calibration curve: 10497 and -3.1.

The high retention time of the active in this normal phase HPLC-UV method of 50 minutes means the method is not state of art and would most likely not be used by enforcement labs. In addition, the eluent, n-hexane, is not preferable. However, the method is accepted as there is no agreed upper limit on retention times for monitoring methods and n-hexane is not yet prohibited.

Residue analytical methods

Analytical methods for the determination of 1R-trans-phenothrin residues in relevant environmental media (soil, air and water) as well as in animal and human body fluids and tissues were not submitted for the biocidal product since this point is covered by the data set of the active substance. Please refer to the dossier submitted for the active substance. Analytical methods for the determination of active substance residues in/on food or feedstuffs are required if the active substance or the material treated with it is to be used in a manner which may cause contact with food or feedstuffs, or is intended to be placed on, in or near soils in agricultural or horticultural use. The active substance 1R-trans-phenothrin is not intended for direct application to foods or feedingstuffs or to surfaces and areas where foods or feedingstuffs are prepared or stored. An exposure of 1R-trans-phenothrin to food and feedstuffs can be excluded when applied according to the recommended use. An analytical method for the determination of active substance residues in/on food and feedstuffs is therefore not necessary.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The biocidal product is a ready-to-use bait formulation insecticide (PT18) and is applied by using bait boxes. The product is sold in three different bait boxes containing 2g of the formulation, respectively. The bait boxes will be used by the general public (non-professional users). The product kills garden ants and other ant species at terraces and indoor locations within two to four weeks. The ready-to-use product combines attractive bait paste mixed with an active substance. The bait is collected by the ants and transported into their nests. At the same time, the active ingredient is dispersed in the nests of the ants, which is released after contact and ingestion by the insects which hereupon die.
It is intended to be applied by the general public directly on the target area where the ants occur (in the close vicinity of ant nests or trails). The areas to be protected from infestation are in and around domestic premises like terraces.

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

Target organisms to be controlled are garden ants and other ant species *(Lasius niger*, *Lasius emarginatus*, *Tetramorium caespitum*, *Tapinoma erraticum*, *Linepithema humile*, *Monomorium pharaonis*).

2.2.5.3 Effects on target organisms, including unacceptable suffering

1R-trans-phenothrin may cause paralysis or death by disrupting the nervous system of insects. The active substance acts by contact and by ingestion at very low doses.
Due to incorporation of the active ingredient in a gel, the product is intended to be released only upon contact and ingestion by the target organism. It remains stable over several weeks and therefore provides a long-lasting protection (depending on the magnitude of infestation with ants and the type of surface) and is therefore deemed to be left until no ants appear any longer.

2.2.5.4 Mode of action, including time delay

Pyrethroids modify the gating characteristics of voltage-sensitive sodium channels in mammalian and invertebrate neuronal membranes to delay their closure. 1R-trans-phenothrin acts by being absorbed by invertebrate neuronal membranes and binding to the sodium channels. This results in severe disturbances of synaptic transmission. The prolonged opening of sodium channels produces a protracted sodium influx which leads to repetitive firing of sensory nerve endings which may progress to hyper-excitation of the entire nervous system. At high pyrethroid concentrations conduction block can occur and the insects will die.

These effects on sodium channels are common to all pyrethroids although specific effects of type I pyrethroids such as 1R-trans-phenothrin have been clarified in experimental studies. These show that type I compounds keep sodium channels open. There is no significant time delay in the action of 1R-trans-phenothrin.By contact or ingestion, ants are knocked-down and killed. However, for ants the effect does not appear immediately but after a few hours. Since a great part of worker ants will not be able to transfer food to the nest colony after contamination, this will lead to nest killing within 2-4 weeks. Furthermore, ants which might

be able to reach the nest with the paste containing the active ingredient, adhered to their body, can contribute to nest killing.

Pest species	**Knockdown after direct application on pest species**	**Time until 100% control (treatment of surface area)**
Ants	Not tested. Product was applied by using bait boxes.	4 to 7 days in laboratory arena trials. 2 to 4 weeks in field studies

2.2.5.5 Efficacy data

The product used in the efficacy tests, THG 128 01 IRB, is identical in composition to the product for which authorization is requested.

Experimental data on the efficacy of the biocidal product against target organism(s)

<table>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin)

(additionally at rates of 0.08, 0.06, and 0.04% a.s.)</td><td><u>Insects:</u>
Lasius niger</td><td>Laboratory test (exposure time 7 days) of the efficacy of the product intended to control ants in garden and house environment. The study was conducted as dose range test.
The tests were carried out in 30 cm × 30 cm × 15 cm plastic arenas with 5 cm ground retrieved from the nest with competition food.
2 g bait gel per bait box (containing 1, 0.8, 0.6, or 0.4 g d-phenothrin (=1R-trans-phenothrin)/kg product)</td><td>Arena trial with food: % of mortality of ants along time
<table>
<tr><th></th><th colspan="7">Days of exposure</th></tr>
<tr><th></th><th>1</th><th>2</th><th>3</th><th>4</th><th>5</th><th>6</th><th>7</th></tr>
<tr><td>Untreated control</td><td>0</td><td>0</td><td>0</td><td>0.2</td><td>0.7</td><td>1</td><td>1</td></tr>
<tr><td>THG 128 01 IRB 0.10% a.i.</td><td>0</td><td>1.8</td><td>56</td><td>100</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>THG 128 02 IRB 0.08% a.i.</td><td>0</td><td>0.8</td><td>52</td><td>98</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>THG 128 03 IRB 0.06% a.i.</td><td>0</td><td>1</td><td>47</td><td>82</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>THG 128 04 IRB 0.04% a.i.</td><td>0</td><td>0.3</td><td>17</td><td>62</td><td>87</td><td>100</td><td>100</td></tr>
</table>
Conclusion: Under the conditions of the trail, THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin), THG 128 02 IRB 0.08% d-phenothrin (=1R-trans-phenothrin), THG 128 03 IRB 0.06% d-phenothrin (=1R-trans-phenothrin), and THG 128 04 IRB 0.04% d-phenothrin (=1R-trans-phenothrin), in white bait standard stations, have proved a complete and fast lethal efficacy against Lasius niger. The sample THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin) gave the faster results but this is not very significant for this kind of product which is intended to conduct to a secondary poisoning of the ants in the nest, and not to kill too quickly before this contamination.</td><td></td></tr>
</table>

<table>
<tr><th colspan="4">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin)</td><td><u>Insects:</u>
Lasius niger</td><td>Laboratory test (exposure time 5 days) of the efficacy of the product intended to control ants in garden and house environment. Aim of the test was to evaluate possible differences in the efficacy when the product is provided in different coloured bait boxes. The boxes are similar to those described in chapter 2.2.4 B (packaging) above.
The tests were carried out in 30 cm × 30 cm × 15 cm plastic arenas with 5 cm ground retrieved from the nest with competition food.
2 g bait gel per bait box (containing 1 g d-phenothrin (=1R-trans-phenothrin)/kg product)</td><td>Arena trial with food: % mortality of ants along time
<table>
<tr><th></th><th colspan="4">Days of exposure</th></tr>
<tr><th></th><th>2</th><th>3</th><th>4</th><th>5</th></tr>
<tr><td>Untreated control</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>White COMPO bait box - THG 128 01 IRB</td><td>1.3</td><td>58</td><td>96</td><td>100</td></tr>
<tr><td>Black bait box - THG 128 01 IRB</td><td>2.3</td><td>70</td><td>100</td><td>100</td></tr>
<tr><td>Green bait box - THG 128 01 IRB</td><td>2.8</td><td>63</td><td>100</td><td>100</td></tr>
</table>
Conclusion: Under the conditions of the trail, THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin), gave equal results for the three types of bait boxes and has proved a complete lethal efficacy against Lasius niger. The ants were killed in less than 5 days of exposure.</td><td></td></tr>
</table>

Experimental data on the efficacy of the biocidal product against target organism(s)

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: effects	Reference
THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin)	Insects: *Lasius niger,* *L.emarginatus,* *Tetramorium caespitum,* *Tapinoma erraticum,* *Linepithema humile,* *Monomorium pharaonis*	Laboratory test (exposure time 7 days) of the efficacy of the product intended to control ants in garden and house environment. **Aim of the test was to test the efficacy on different ant species**. The tests were carried out in 30 cm × 30 cm × 15 cm plastic arenas with 5 cm ground retrieved from the nest with competition food. 2 g bait gel per bait box (containing 1 g d-phenothrin (=1R-trans-phenothrin)/kg product)	Arena trial with food: % mortality of ants along time	

		1 D	2 D	3 D	4 D	5 D	6 D	7 D
Lasius niger	Untreated control	0	0	0	0	0	1	1
	THG 128 01 IRB 0.10% a.i.	0	2	68	99	100	100	100
Lasius emarginatus	Untreated control	0	0	0	0	0	0	1
	THG 128 01 IRB 0.10% a.i.	0	2	71	100	100	100	100
Tetramorium caespitum	Untreated control	0	0	0	0	1	1	1
	THG 128 01 IRB 0.10% a.i.	0	1	91	95	100	100	100
Tapinoma erraticum	Untreated control	0	0	0	0	0	0	1
	THG 128 01 IRB 0.10% a.i.	0	2	71	100	100	100	100
Linepithema humile	Untreated control	0	0	0	0	0	0	0
	THG 128 01 IRB 0.10% a.i.	0	0	25	67	90	100	100
Monomorium pharaonis	Untreated control	0	0	0	0	0	0	0
	THG 128 01 IRB 0.10% a.i.	0	1	17	65	80	99	100

Conclusion: Under the conditions of the trail, THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin), in white bait boxes has proved a complete lethal efficacy against ants. For all species, the ants were killed in less than 7 days of exposure.

Experimental data on the efficacy of the biocidal product against target organism(s)

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: effects	Reference
THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin)	Insects: *Lasius niger,* *L. emarginatus,* *Tetramorium caespitum,* *Tapinoma erraticum,* *Linepithema humile,* *Monomorium pharaonis*	Field test (exposure time 4 weeks) of the efficacy of the product intended to control ants in garden and house environment. Aim of the test was to measure the frequency of ants passage in a 1 m² surface around the main nest entry before and after the treatment, then to open the nest after 4 weeks to check any alive insects. Results were compared to those with a registered standard product. 2 g bait gel per bait box (containing 1 g d-phenothrin (=1R-trans-phenothrin)/kg product). The trial was conducted in France, area: 64, Pyrénées-Atlantiques, South West of France, on orchards, meadows, terraces or lawns in the cities/areas of Anglet, Bayonne, St. Jean, Macay, Tamos, Biarritz,	Field trial: % of reduction of the Frequency of Crossing in Surface of the ants in comparison with the activity before the treatment (means of 4 replicates)	

		1 D	3 D	7 D	14 D	21 D	28 D
LASIUS NIGER	Untreated	-5,7	-9,7	1.2	0,0	-5,3	-6.7
	THG 128 01 IRB 0.10% d-phenothrin	0.2	64.2	90.9	100	100	100
	Standard AFOURMI® F	1.4	23.5	82.7	100	100	100
LASIUS EMARGINATUS	Untreated	1,4	11,2	-8.6	-11.2	-11.8	-20.4
	THG 128 01 IRB 0.10% d-phenothrin	8.9	72.9	93.2	100	100	100
	Standard AFOURMI® F	5.4	31.8	78.9	100	100	100
TETRAMORIUM CAESPITUM	Untreated	9.9	-2.0	4.7	3.3	2.2	-8.0
	THG 128 01 IRB 0.10% d-phenothrin	-2.4	70.8	87.8	100	100	100
	Standard AFOURMI® F	-1.0	35.8	87.0	100	100	100
TAPINOMA ERRATICUM	Untreated	-2.4	-2.1	6.0	-3.8	-4.9	-6.5
	THG 128 01 IRB 0.10% d-phenothrin	1.9	40.5	72.0	99.2	100	100
	Standard AFOURMI® F	0.6	38.2	67.7	96.2	99.5	100
LINEPITHELMA HUMILE	Untreated	-12.9	-12.2	-4.6	-12.2	-10.2	-16.8
	THG 128 01 IRB 0.10% d-phenothrin	-0.8	57.3	89.3	100	100	100
	Standard AFOURMI® F	-2.4	40.2	63.2	95.7	100	100
MONOMORIUM PHARAONIS	Untreated	7.8	-3.2	-17.9	-17.0	-19.1	-16.5
	THG 128 01 IRB 0.10% d-phenothrin	1.2	32.7	68.5	94.1	98.3	100
	Standard AFOURMI® F	-2.5	19.0	51.4	81.6	96.6	100

Conclusion: under the conditions of the trail, THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin), in white bait boxes has proved a good efficacy for the destruction of ants' nests.

Experimental data on the efficacy of the biocidal product against target organism(s)				
Test substance	**Test organism(s)**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		Mendionde and Bidart. Dose: one bait box per nest entry. *Lasius niger*: 4 outdoor nests *Lasius emarginatus*: 3 outdoor nests / 1 indoor nests *Tetramorium caespitum*: 4 outdoor nests *Tapinoma erraticum*: 2 outdoor nests / 2 indoor nests *Linepithema humile*: 1 outdoor nests / 3 indoor nests *Monomorium pharaonis*: 1 outdoor nest / 3 indoor nests		

Conclusion on the efficacy of the product
In the available laboratory and field studies efficacy of the biocidal product was sufficiently demonstrated, according to criteria laid out in guidance documents, against the species *Lasius niger*, *Lasius emarginatus*, *Tetramorium caespitum*, *Tapinoma erraticum*, *Linepithema humile*, *Monomorium pharaonis*. The ability of the product to achieve nest kill within a 2-4 week period was demonstrated in laboratory and field tests and no differences in efficacy performance were observed between the three types of bait boxes. Based on the ant species used in the available tests, efficacy of the product against both ants and tropical ants was sufficiently demonstrated.

2.2.5.6 Occurrence of resistance and resistance management

No development of resistance is expected although the specific mode of action (sodium channel modulation) of the active substance might indicate there is a risk of resistance formation.
In the case of THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin), the treatment is very localised and targeted (no massive or big areas treated). The use of bait boxes avoids dispersing the substance into the environment. This further reduces the risk of resistance developing.
For the biocidal use of THG 128 01 IRB 0.10% d-phenothrin (=1R-trans-phenothrin) against *Lasius* spp. (garden ants) and other ant species the probability of resistance is very low due to the eusocial lifestyle of ants. The individuals of this species are social insects from which only the queen can reproduce. A great part of worker ants will not be able to transfer food to the nest colony after contamination whereas other ants might be able to reach the nest with the product. Therefore, even if some worker ants would survive, the colony would disappear if the queen is dead, i.e. the resistance could then not be passed on to offspring.

Resistance to pyrethroid insecticides has been reported for a number of pests both in agriculture and public health. However, as explained above no development of resistance is expected here.

2.2.5.7 Known limitations

The product should be applied in areas which are protected from moisture and rainfall throughout the service period.

2.2.5.8 Evaluation of the label claims

Based on the provided efficacy studies, it can be concluded that the biocidal product containing 0.10% d-phenothrin is effective in controlling ants of the species *Lasius niger, Lasius emarginatus, Tetramorium caespitum, Tapinoma erraticum, Linepithema humile* and *Monomorium pharaonis* when used in bait boxes containing 2g of the biocidal product.
The dose used in the field test (one bait box per nest entrance) corresponds to a dose of one bait box per nest. Since no data was provided to support the use of additional bait boxes in case of heavy infestations, this claim was not included in the SPC.

The ability of the product to achieve nest kill within a 2-4 week period was demonstrated in laboratory tests (with alternative food; 100% mortality within 7 days) and field tests (100% mortality within 4 weeks), thus meeting the guidance document criteria for both bait

products and nest kill, and no differences in efficacy performance were observed between the three types of bait boxes in laboratory tests. Therefore it is considered that it is not necessary to carry out field studies with the three types of bait boxes.

Based on the ant species used in the available tests, efficacy of the product against both ants and tropical ants was sufficiently demonstrated.

It can be concluded that the label claims reflect the efficacy of the biocidal product. The requested dose (1 bait box per 10 m^2) was adapted to "1 bait box (2 g biocidal product) per nest, with a maximum of 1 bait boxes per 7.5 m^2" as the field test was performed at a dose of 1 bait box per nest and no argumentation was provided to convert this to 1 bait box per 10 m^2. Furthermore, the maximum of 1 bait boxes per 7.5 m^2 was included as this was the maximum dose at which no risk was found in the environmental risk assessment.

A stability test is still ongoing, this study will be provided when ready (Q3 2019). In the assessment of physical-chemical properties of the product it was concluded that the product is considered to be stable for up to two years with regard to active substance content and physical properties. As the attractants in the product are protected against microbial decay by the presence of a preservative, it is concluded that the product will be palatable after up to two years of storage, in line with the conclusions of the physical-chemical assessment and in line with the conclusions of the Efficacy Working Group e-consultation that a 2-year shelf-life can be granted for baitboxes without providing palatability data. To demonstrate a shelf-life exceeding two years, both a stability test and a test demonstrating efficacy of aged product (according to the claim) should be provided.

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

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

2.2.6 Risk assessment for human health

The toxicological properties of the active substance in COMPO Mierenlokdoos, 1R-trans-phenothrin, are summarised in the respective CA report (RMS IE, 2013).

Acute toxicity tests as well as tests for skin or eye irritation and skin sensitisation have not been performed. The criteria for the classification of mixtures according to the Regulation 1272/2008 (CLP) were followed. According to CLP, COMPO Mierenlokdoos does not need to be classified for Acute Toxicity, Skin or Eye Irritation, but needs to be classified for Skin Sensitisation.

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	Not irritating to skin.
Justification for the value/conclusion	A skin irritation study with COMPO Mierenlokdoos has not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	According to CLP, no classification for skin irritation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product (biocidal product) can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

For skin corrosion and irritation no human data is available.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to eyes.
Justification for the value/conclusion	An eye irritation study with COMPO Mierenlokdoos has not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	According to CLP, no classification for eye irritation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product (biocidal product) can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

For eye damage and eye irritation no human data is available.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the conclusion	No experimental data on respiratory irritation of COMPO Mierenlokdoos is available. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	According to CLP, no classification for respiratory tract irritation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product (biocidal product) can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

For respiratory tract irritation no human data is available.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	A skin sensitisation study with COMPO Mierenlokdoos has not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

Classification of the product according to CLP and DSD	According to CLP, classification for skin sensitisation is necessary

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Based on the concentration of the co-formulant 2-methylisothiazol-3(2H)-one and the SCL for H317 as stated in the RAC opinion (6/3/2016), the product needs to be classified with H317

For skin sensitisation no human data is available.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising.
Justification for the value/conclusion	No data on respiratory sensitisation is available for COMPO Mierenlokdoos. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	According to CLP no classification for respiratory sensitisation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not harmful.
Justification for the selected value	Acute toxicity studies with COMPO Mierenlokdoos have not been conducted. Toxicological properties and classification of the biocidal

	product was deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	According to CLP, no classification for acute oral toxicity is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

For acute oral toxicity no human data is available.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not harmful
Justification for the selected value	Acute toxicity studies with COMPO Mierenlokdoos have not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	According to CLP, no classification for acute inhalation toxicity is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

For acute inhalation toxicity no human data is available.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not harmful.
Justification for the selected value	Acute toxicity studies with COMPO Mierenlokdoos have not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the active

	substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP and DSD	According to CLP, no classification for acute dermal toxicity is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).

For acute dermal toxicity no human data is available.

Information on dermal absorption

Value used in the Risk Assessment – Dermal absorption	
Substance	1R-trans-phenothrin
Value	5%
Justification for the selected value	The dermal absorption value of 4.5% 1R-trans-phenothrin as set by the RMS Ireland was adopted for the biocidal product. According to the Guidance on Dermal Absorption (EFSA Journal, 2012; 10(4):2665) dermal absorption values between 1% and 9% should be rounded to one significant figure. Therefore, the absorption value of 4.5% as reported in the CAR was rounded up to 5%.

Data waiving	
Information requirement	Other justification.

Justification	The biocidal product is a gel like bait preparation which contains 0.1% 1R-trans-phenothrin. Data of the active substance 1R-trans-phenothrin were evaluated by the Rapporteur Member State (RMS) Ireland. In an *in vitro* human dermal absorption study with 1% w/v formulation of 1R-trans-phenothrin in ethanol, a dermal penetration of 4.5% was determined when skin samples were exposed for 24 hours. Only 0.86% of test material was found in the receptor fluid. The amount of 3.65% of test material remained in the skin after 24 hours, being thus not absorbed after one day. The dermal absorption of 4.5% 1R-trans-phenothrin in a 1% formulation is considered suited for the biocidal product COMPO Mierenlokdoos containing 0.1% 1R-trans-phenothrin. This assumptions is based on i) the gel like formulation of COMPO Mierenlokdoos, ii) the 24 hours exposure period in the dermal absorption study and iii) the conservatism included in the dermal absorption value. Absorption from a gel-like formulation is in principle lower compared to a liquid formulation leading to a decreased dermal absorption for COMPO Mierenlokdoos compared to the dummy product. Furthermore, based on its poor solubility in water, the test was performed with the a.s. solved in ethanol, which can be seen as a skin permeability enhancer. In the CAR the value was also considered suitable for lower concentration products with the following reasoning (page 24, doc IIA): The aforementioned value of '4.5%' for dermal absorption was deemed appropriate for higher concentration (5.25%) products and lower concentration products (0.04%). It is accepted that the 1 % solution may be suboptimal as a surrogate for 0.04% concentration products and conservative for higher concentration products. However, the substance has a Pow of 6.8 and a relatively high molecular weight of 350. In the context of having data from a study and the conduct of the study (ethanol as solvent [a skin permeability enhancer] ethanol water 50:50 as a receptor) a value of approximately half a standard default is regarded as suitably conservative and appropriate. Additionally the exposure period of 24 hours represent a clear worst case for the intended use of COMPO Mierenlokdoos, where only occasionally exposure may occur. This infrequent exposure is, if any occurs, limited to a short period during handling of the bait box. Even if hands are not washed directly after potential exposure, the hands will be washed during the course of the day therefore shortening the exposure duration compared to the in vitro study situation. Finally, the dermal absorption value of 4.5% contains 3.65% 1R-trans-phenothrin detected in the skin samples. In fact only 0.86% 1R-trans-phenothrin was absorbed through human skin when exposed for 24 hours. The 3.65% detected in the skin tissue was not absorbed through the skin within 24 hours. Thus addition of the amount detected in the skin samples confers further conservatism to the dermal absorption value established in the CAR.

	Therefore the dermal absorption of 4.5% given in the CAR of 1R-trans-phenothrin can be adopted. To assess systemic exposure to the active substance in the biocidal product a dermal absorption value of 5% was used, obtained by rounding up.

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

An Occupational Exposure Limit (OEL) for dust and aerosol is established for two co-formulants making these ingredients potential substances of concern. However, taking into account the intended application of the biocidal product (place bait station, no spraying) these ingredients in the biocidal product are of no concern for human health.

The biocidal product contains no further non-active substances that are classified in Annex VI of CLP at concentrations leading to a classification of the biocidal product
In conclusion, the biocidal product does not contain substances of concern according to Article 3(f) of Regulation (EU) 528/2012.

Available toxicological data relating to a mixture

Toxicological data relating to a mixture that a substance of concern is a component of are not required.

Other

One of the co-formulants contains a compound that is classified for germ cell mutagenicity. It is classified as Muta. 2, H341 according to CLP. No specific concentration limits are specified for this component in Annex VI of CLP, so that the generic concentration limit of the CLP applies. Since, the concentration of this compound is present at a concentration significantly lower than the concentration limit of 0.1%, the biocidal product does not need to be classified for germ cell mutagenicity.

The biocidal product is intended for the use in bait stations against ants. Other test(s) related to the exposure to humans are not available for the proposed biocidal use pattern. Exposure estimates and risk characterisations are given in the human risk assessment. The risk characterisation, showed no concern when the biocidal product is handled and applied. Therefore no other test related to the exposure to humans is necessary.

The biocidal product is not intended for direct application to foods or feeding stuff or to surfaces and areas where foods or feeding stuff are prepared or stored. Hence, an exposure of food and feeding stuff to a.s. can be excluded when applied according to the recommended uses. Additional food or feeding stuffs studies are not required.

2.2.6.2 Exposure assessment

COMPO Mierenlokdoos is an insecticidal bait preparation which contains 0.1% of the insecticidal active substance, 1R-trans-phenothrin (product type 18). The biocidal product is efficacious against ants.
The biocidal product is sold in three different bait boxes containing 2 g of the formulation, respectively. The bait boxes will be used by non-professional users (general public).
According to the instructions for use as applied for by the applicant one bait box per 10 m²

will be used.

There is no dermal exposure to the insecticidal formulation since it is safely contained in a tamper-proof casing. The bait boxes cannot be opened easily, so that small children cannot ingest the contents of the bait box. Nonetheless, incidental dermal and oral exposure will be addressed.
The vapour pressure of 1R-trans-phenothrin is only 2.37×10^{-5} Pa at 20°C so that exposure to vapours can be ruled out. Consequently exposure estimates differentiating between indoor and outdoor use are not required.
Ants are intended to carry parts of the bait material into their nests. In doing so, some of the carried bait material might contaminate the path between the location of the bait box and the nest. However, this amount is going to be minute and hard to quantify.

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Place bait station	Primary exposure during set-up and use of the bait box	Non-professionals

Industrial exposure
No industrial exposure is foreseen.

Professional exposure
No professional exposure is foreseen.

Non-professional exposure
Scenario [1]

Place bait station

Description of Scenario [1]
Users are not exposed to the active substance during the intended use of the biocidal product. Due to the very low vapour pressure only the dermal route of exposure is relevant, irrespective from the usage indoors or outdoors. However, to provide an estimate for a worst-case risk assessment, the default scenario for mouse bait boxes is adopted from ConsExpo 4.1. This scenario assumes 40 g bait per bait station and that the total dermal exposure will be maximally 0.5% of the applied amount (0.5% of 40 g = 0.2 g) during set-up and use of the bait. Cleary this is a very conservative assumption since COMPO Mierenlokdoos contains maximally only 2 g bait per bait station. Therefore, this assumption covers the usage of more than one bait station per day (i.e. 20 times). The bait material contains 0.1% 1R-trans-phenothrin. According to the CAR (RMS IRL, 2013), a worst case dermal absorption of 4.5% was determined for a 1% w/v formulation of 1R-trans-phenothrin which is thought to represent the worst case for the gel like bait formulation. To assess systemic exposure to the active substance in the biocidal product a dermal absorption value of 5% was used as according to the Guidance on Dermal Absorption (EFSA Journal, 2012; 10(4):2665) dermal absorption values between 1% and 9% should be rounded to one significant figure. For a 60-kg user, the worst-case systemic dose on the day of use is estimated to be I_D = 200 mg × 0.1% × 5% / 60 kg bw = 1.67×10^{-4} mg/kg bw/day. For details on the exposure assessment please refer to Annex 3.2.

	Parameters	Value
Tier 1	Product amount[1]	40 g
	Total dermal exposure of product amount[1]	0.5%
	Dermal absorption[2]	5%
	Body weight[3]	60 kg

[1] default scenario for mouse bait boxes from ConsExpo 4.1
[2] see above: Information on dermal absorption; CAR (RMS IRL, 2013)
[3] HEEG opinion no. 17, 2013

Calculations for Scenario [1]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		mg/kg bw/day			
Scenario [1]	1 / none	-	0.000167	-	0.000167

Exposure of the general public

Secondary exposure to biocidal product contained inside the box is virtually excluded. Some material may be removed from the box by ants that attempt to carry feed to their nest and

lost in transit. Exposure to this material is hard to quantify. It is unlikely that ants lose a significant amount of the attractive bait material in transit to their nest. This exposure route is not expected to be of toxicological significance.
Additionally, the three types of bait boxes are very robust and it is unlikely that children are able to open the boxes. Due to the used material and the design it is not possible for children to open the box or to reach the product through the openings. However, the black box might be opened to a certain extend when pulling apart top and bottom of the box with great strength. The force needed to partly open the box is rather high and it is unlikely that a child is able to open it. However, even when a child is able to open the box, it is very unlikely that it is able to remove the lid completely. Therefore, contact to the whole biocidal product within the box can be excluded. To prove that no unacceptable risk for children needs to be expected, even when being able to tear away the lid of the box partly, a reverse risk assessment is performed. The acute AEL of 1R-trans-phenothrin is 0.18 mg/kg bw/d. A 10 kg child, which is most likely not able to open the box, can therefore theoretically be exposed to an internal dose of 1.8 mg 1R-trans-phenothrin per day. Considering an oral absorption of 60% the external dose could be as high as 3 mg 1R-trans-phenothrin per day. The amount of biocidal product in the box is 2 g. The concentration of 1R-trans-phenothrin is 0.1%. Thus, even when ingesting the whole biocidal product of the bait station, the child will be ingest 2 mg 1R-trans-phenothrin (i.e. 0.1% * 2 g product) (internal dose 2mg x 60% oral absorption / 10kg = 0.12 mg/kg bw/day). Calculation of the exposure/AEL_{acute} results in 67% of the AEL. In conclusion, this reverse risk assessment clearly shows that no risk needs to be expected even when children might come into contact with the biocidal product

Monitoring data
No further information on surveys or studies with the actual product or with a surrogate is submitted.

Dietary exposure
Food, drinking water or livestock exposure of 1R-trans-phenothrin can be excluded when applied according to the recommended uses.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	plant protection products*	MRL in crops and in products of animal origin	0.05 mg/kg[1]
		ADI (evaluated by JMPR)	0.07 mg/kg[2]

* not approved under Reg. (EC) No 1107/2009

Estimating Livestock Exposure to Active Substances used in Biocidal Products

1 EU – Maximum Residues Level, EU Pesticides data base (http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.CurrentMRL&language=EN&pestResidueId=351)

2 Evaluation by JMPR (Joint FAO/WHO Meetings on Pesticide Residues), 1988 (http://www.inchem.org/documents/jmpr/jmpmono/v88pr09.htm)

Food, drinking water or livestock exposure of 1R-trans-phenothrin can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)
Food, drinking water or livestock exposure of 1R-trans-phenothrin can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of non-professional use
Food, drinking water or livestock exposure of 1R-trans-phenothrin can be excluded when applied according to the recommended uses.

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Food, drinking water or livestock exposure of 1R-trans-phenothrin can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)
Food, drinking water or livestock exposure of 1R-trans-phenothrin can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of non-professional use
Food, drinking water or livestock exposure of 1R-trans-phenothrin can be excluded when applied according to the recommended uses.

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

Exposure during the production and formulation of the active substance and the biocidal product should be addressed under other EU legislation (e.g. REACH) and not repeated under Regulation EU (No.) 528/2012. The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for 1R-trans-phenothrin which is an existing biocidal active substance within the EU.

Aggregated exposure
Significant combination of direct and indirect scenarios is unrealistic.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake** [mg/kg bw/day]
1.	Non-professionals	1 / None	0.000167

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL** [mg/kg bw/day]	**AF**[1]	**Correction for oral absorption**	**Value** [mg/kg bw/day]
ADI (acceptable daily intake, external long-term reference dose)	52 wk study in dog	8.2	100	-	0.08
ARfD (acute reference dose)	rabbit oral development toxicity study	30 mg/kg bw/day	100	-	0.3
AEL_{acute}	rabbit oral development toxicity study	30 mg/kg bw/day	100	60 %	0.18
AEL_{medium} (AOEL-S (Operator Exposure))	52 wk study in dog	8.2 mg/kg bw/day	100	60 %	0.05
Professional user ($AEL_{chron\ c}$)	52 wk study in dog	8.2 mg/kg bw/day	100	60 %	0.05

[1] compensating for inter/intra species variations (10 for interspecies and 10 for intraspecies)

Specific reference value for groundwater

No specific reference value for groundwater was established. Thus, the European standard value of 0.1 µg/L for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC) does apply.

Exposure through drinking water should account for no more than 10% of the ADI. If it is assumed that the average daily consumption of water amounts to 2 L per person (60 kg bw), a drinking water limit of ((60 kg bw x 0.08 mg/kg bw/d) / 10) / 2 L = 0.24 mg/L can be established.

Risk for industrial users

Not relevant

Risk for professional users

Not relevant

Risk for non-professional users

The biocidal product will be used by non-professional users in the domestic / residential area. The use pattern indicates short- or medium-term exposure of the non-professional user. Therefore a medium-term AEL is established. The AEL for medium-term exposure is based on the NOAEL of 8.2 mg/kg bw/day from the oral 52-week study in the dog. For establishment of an internal AEL a safety factor of 100 is used. For correction of incomplete oral absorption a factor of 0.6 is used. This results in an internal systemic medium-term AEL of 0.05 mg/kg bw/day.

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)
[1] Place bait station	1	8.2	0.05	0.000167	0.33	yes

Combined scenarios
No combined exposure is foreseen. The product contains only one active substance.

Local effects
The biocidal product is classified for skin sensitisation (H317). Therefore, risk characterisation for local effects is presented in the table below.

Table: Primary exposure

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Conclusion on risk**
High	Skin Sens. 1A	-	18	General public	Opening and placing an bait box against ants	Skin	When placing the bait station and when it is removed	-	The thermoformed bait box is opened by breaking it from its attachment. Thereby entrances to the bait box will be opened. In order to open the screw-top bait box the top part of the station must be screwed to the left as far as it will go. Due to the technical specifications of the bait boxes, no direct contact can take place with the active substance. The exposure is considered negligible. **The following P-statements are included in the label** P264 Wash … thoroughly after handling. P302+P352 IF ON SKIN: Wash with plenty of water/... P333+313: If skin irritation or rash occurs: Get medical advice/attention	Acceptable: Negligible exposure P-statements related to H317 on the label

Conclusion
The AEL is neither reached nor exceeded by the estimated exposures. The local risk is considered acceptable in the view of negligible exposure. The use of COMPO Mierenlokdoos in bait boxes is safe for human health.

Risk for the general public
Secondary exposure to biocidal product contained inside the box is virtually excluded. This exposure route is not expected to be of toxicological significance.
Additionally, the three types of bait boxes are very robust and it is unlikely that children are able to open the boxes. To prove that no unacceptable risk for children needs to be expected, even when being able to tear away the lid of the box partly, a reverse risk assessment is performed. The acute AEL of 1R-trans-phenothrin is 0.18 mg/kg bw/d. A 10 kg child, which is most likely not able to open the box, can therefore theoretically be exposed to an internal dose of 1.8 mg 1R-trans-phenothrin per day. Considering an oral absorption of 60% the external dose could be as high as 3 mg 1R-trans-phenothrin per day. The amount of biocidal product in the box is 2 g. The concentration of 1R-trans-phenothrin is 0.1%. Thus, even when ingesting the whole biocidal product of the bait station, 2 mg 1R-trans-phenothrin (0.1% x 2 g product) is ingested. Calculation of the exposure/AEL_{acute} results in 67% of the AEL. In conclusion, this reverse risk assessment clearly shows that no systemic risk needs to be expected even when children might come into contact with the biocidal product

Risk for consumers via residues in food
Food, drinking water or livestock exposure of 1R-trans-phenothrin can be excluded when applied according to the recommended uses. Therefore no unacceptable risk to consumer health via residues in food needs to be expected.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product
No substances of concern were identified. Therefore exposure to several active substances or substances of concern within the product is not relevant.

2.2.6.4 Risk assessment for animal health

Food, drinking water or livestock exposure of 1R-trans-phenothrin can be excluded when applied according to the recommended uses. Therefore no unacceptable risk to animal health needs to be expected.

2.2.7 Risk assessment for the environment

COMPO Mierenlokdoos is an insecticidal bait preparation which contains 0.1% of the insecticidal active substance, 1R-trans-phenothrin (product type 18). The biocidal product is efficacious against ants (Lasius spp.). The biocidal product is sold in a bait box containing 2 g of the formulation and will be used by non-professional users (general public). One bait box per 10 m² for at least eight to fourteen days is sufficient.
The environmental risk assessment was based on the use of 2 bait boxes per 12 m^2, since the applicant proposed to place additional bait boxes in case of heavy infestations.

Emissions of the active ingredient 1R-trans-phenothrin to the environment from indoor treatment are excluded due to the form of the product (bait station).
Emissions to the environmental compartments soil and groundwater may occur due to outdoor application. In the course of outdoor applications in areas that are not protected from water (only for the bait box form), releases may arise from the transport of the product by contaminated insects or following flooding from rain events. The ESD considers 20% remains in the bait station being emitted to the environment, i.e. this portion reaches the surrounding garden soil following wash-off of the terrace by rainfall.
Furthermore, secondary poisoning is to be considered due to the potential ingestion of contaminated ants by birds and mammals or by the consumption of earthworms from contaminated soils.

2.2.7.1 Effects assessment on the environment

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

Regarding ecotoxicological properties, the formulation is toxic to aquatic organisms with long-lasting adverse effects in the aquatic environment. The proposed classification/labelling of the biocidal product according to GHS is Aquatic Chronic 2, and the hazard statement H411.

Further Ecotoxicological studies

Data waiving	
Information requirement	No further ecotoxicological studies are required
Justification	The biocidal product COMPO Mierenlokdoos contains the active substance 1R-trans-phenothrin. The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, ecotoxicological properties and classification of the biocidal product (biocidal product) can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in Directive 1999/45/EC (DPD) and the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Data of the a.s. 1R-trans-phenothrin were evaluated by the Rapporteur Member State (RMS) Ireland and published as Competent Authority Report (CAR 2013). The product is used by non-professionals, dealing with commercially available household amounts of the biocidal product, not intended to be employed extensively. Moreover, the biocidal product is designed in such a way that the active substance remains in the gel and does not diffuse or leave the bait mix. Therefore, the a.s. is inaccessible for non-target animals and primary poisoning of birds and mammals can be excluded. A consumer activates it by just twisting the box so that slits open or the bait box must be broken from its attachment. Thereby entrances to the bait box will be opened, allowing ants to feed on the bait formulation. The outdoor

	use of the product is limited to ants-pathways on paved surfaces of terraces and it is not directly applied to the soil. The indoor use of the product of the biocidal product does not lead to noteworthy emissions of 1R-trans-phenothrin to the environment. During outdoor use the bait box should be deposited outdoor protected from moisture to avoid release of the a.s. However, applying the biocidal product outdoors can result in residues reaching terraces where the baits have been placed. These residues can be washed-off after rainfall, ending up in the surrounding garden soil and groundwater. Therefore, only the outdoor use was considered within the environmental exposure assessment. No risk was identified for the terrestrial compartment and groundwater in case the product is used according to the label instructions (PEC/PNEC << 1). During the utilisation of the biocidal product, birds and mammals may be poisoned secondarily through the ingestion of contaminated ants or by the consumption of earthworms from contaminated soils. Risk characterisation ratios were << 1 calculated for secondary poisoning for all non-target organisms excluding earthworms. For those non-target organisms with a PEC/PNEC << 1 there is no unacceptable risk. With regards to the secondary poisoning – earthworm, the PEC/PNEC value was slightly above 1 indicating unacceptable risk during a worst case scenario (i.e. a wash off event). As a risk mitigation measure, the following statement must be entered on the product label: "Product must be protected from rainfall". Thus, the emission of a.s. to soil is prohibited as no 1R-trans-phenothrin is released during flooding after a rain event.
	The eCA, accepts the non-submission of ecotoxicity studies, considering the available data are sufficient to carry out a risk assessment. The proposed mitigation measure, however, is inappropriate considering that the product is used outdoors and it is considered as not realistic that non-professionals will remove the bait box in case of a rain event. The adapted risk assessment presented below, however, indicates no unacceptable risks for secondary poisoning. Therefore from risk assessment perspective the risk mitigation measure is not a requirement, just a recommendation.

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

Data waiving	
Information requirement	Information on effects on any other specific, non-target organisms (flora and fauna) believed to be at risk is not required for the biocidal product.
Justification	The biocidal product is used in the bait box. Thus, a primary poisoning of non-target organisms is no matter of concern. The bait box is only having small slits making the insecticide inaccessible for non-target animals. An effect assessment for non-target animals

	primary exposed to 1R-trans-phenothrin is therefore not deemed reasonable.
	The eCA, accepts the non-submission of ecotoxicity studies to non-target organisms. The product in the bait Box is expected to be accessible only for ants. There is sufficient data in the dossier to perform a risk assessment for non-target animals

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

Data waiving	
Information requirement	Information on the risks to non-target organisms under field conditions is not required.
Justification	The biocidal product is used in the bait box. Thus, a primary poisoning of non-target organisms is no matter of concern. The bait box is only having small slits making the insecticide inaccessible for non-target animals. An effect assessment for non-target animals primary exposed to 1R-trans-phenothrin is therefore not deemed reasonable.
	The eCA agrees with the justification statement

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

Data waiving	
Information requirement	Information on the acceptance by ingestion of the biocidal product by any non-target organisms is not need required.
Justification	The biocidal product is used in the bait box. Thus, a primary poisoning of non-target organisms is no matter of concern. The bait box is only having small slits making the insecticide inaccessible for non-target animals. An effect assessment for non-target animals primary exposed to 1R-trans-phenothrin is therefore not deemed reasonable.
	The eCA agrees with the justification statement

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

The bait box containing the product is applied outdoors on hard, paved surfaces such as terraces or paths close to habitation entrances and not on bare soil. This type of use is not expected to cause secondary ecological effects. No additional information is required.

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

The bait box contains 2 g of the formulation COMPO Mierenlokdoos. One bait box per 10

m^2 for at least eight to fourteen days is sufficient. The environmental risk assessment was based on the use of 2 bait boxes per 12 m^2, since the applicant proposed to place additional bait boxes in case of heavy infestations.

A consumer activates the bait box by just twisting the box so that slits open or the bait box must be broken from its attachment. Thereby entrances to the bait box will be opened, allowing ants to feed on the bait formulation.
Indoor and outdoor applications are considered for this product form. The product is used by non-professionals, dealing with commercially available household amounts of the biocidal product, not intended to be employed extensively. Furthermore, the product use is limited to paved surfaces of terraces, paths or the like and is not directly applied to the soil.

In summary, the indoor use of the biocidal product COMPO Mierenlokdoos does not lead to noteworthy emissions of 1R-trans-phenothrin to the environment.

Applying the biocidal product outdoors can result in residues reaching terraces where the box baits have been placed. These residues can be washed-off, ending up in the surrounding garden soil. Predicted Environmental Concentrations for this primary target of emissions will be calculated. For safety reasons, the soil pore water concentration as an indicator for potential concentrations in groundwater is also assessed. Primary poisoning of non-target organisms is not a topic since 1R-trans-phenothrin is inaccessible for other organisms. However, during the utilisation of the biocidal product, birds and mammals may be poisoned secondarily through the ingestion of contaminated ants or by the consumption of earthworms from contaminated soils. Hence, potential concentrations in earthworms and ants will be calculated.

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

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment are not required.
Justification	Additional data concerning abiotic and biotic degradation or distribution of the product are not required as its environmental behaviour can be extrapolated from data on its active ingredient 1R-trans-phenothrin.
	The eCA agrees with the justification statement

Leaching behaviour (ADS)

Data on the leaching behaviour was considered unreasonable and thus, is not available.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	Information on distribution and dissipation in soil is not required
Justification	There are no indications for a widespread distribution of substances in environmental compartments caused by the use of the biocidal product. Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.
	The eCA agrees that sufficient data is available to perform the risk assessment for the soil compartment.

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

Data waiving	
Information requirement	Information on distribution and dissipation in water and sediment is not required.
Justification	There are no indications for a widespread distribution of substances in environmental compartments caused by the use of the biocidal product. Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.
	The eCA agrees that sufficient data is available to perform the risk assessment for the water and compartment.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Information on distribution and dissipation in air is not required.
Justification	There are no indications for a widespread distribution of substances in environmental compartments caused by the use of the biocidal product. Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.
	The eCA agrees with the justification statement

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)

Data waiving	
Information requirement	Information on risks to aquatic organisms or plants under field conditions is not required.
Justification	This formulation is applied in a bait box having only small slits and making the insecticide inaccessible for non-target animals. A risk assessment for spray application is therefore deemed unreasonable..
	The eCA agrees with the justification statement

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)

This formulation is applied in a bait box having only small slits and making the insecticide inaccessible for non-target animals. A risk assessment for spray application is therefore considered not relevant.

2.2.7.2 Exposure assessment

General information

Assessed PT	PT18
Assessed scenarios	Scenario 1: indoor use in form of a bait box Scenario 2: outdoor use in form of a bait box along ants-pathways on hard surfaces such as terrace
ESD(s) used	Emission Scenario Document for Product Type 18: Insecticides, acaricides and products to control other arthropods (ENV/JM/MONO(2008)14)
Approach	Scenario 1: Average consumption Scenario 2: Average consumption
Distribution in the environment	Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). Emissions to the environmental for outdoor treatment occur to soil by wash-off of the terrace by rainfall and also to ground water and were calculated according to the ESD PT 18 (OECD, 2008). The secondary poisoning to biota is assessed according to the ESD PT18 (OECD, 2008).
Groundwater simulation	Not necessary
Confidential Annexes	No confidential Annexes
Life cycle steps assessed	*Scenario n: 1 + 2* *Production: No* *Formulation No* *Use: Yes* *Service life: Yes*
Remarks	No remarks

Emission estimation

Emissions of the active substance to the environment for indoor treatment are excluded due to the application form (bait box). The ESD for PT 18 (OECD, 2008) states (at page 34) that "for these products, emissions to the environment during the treatment are negligible. The only possible emission is when the box is eliminated to waste during indoor uses". Supposing a proper waste disposal according to national legislation and municipal capabilities, the disposal of the empty bait box should not pose a risk for the environment. Therefore, the assessment of the environmental risk from indoor use of the bait box containing 1R-trans-phenothrin is irrelevant.

Emissions to the environmental for outdoor treatment occur to soil by wash-off of the terrace by rainfall and also to ground water. The secondary poisoning to biota is assessed.

As developed above, emissions of 1R-trans-phenothrin to the environment may occur when the biocidal product product in the form of bait box is applied outdoors, i.e., bait stations

are placed on ant pathways, generally on terraces or patios close to habitation entrance. Residues reaching terraces can be washed off by rainwater and may reach the adjacent soil. In the ESD for PT 18 (OECD, 2008) typical buildings are defined and their dimensions are determined. In the case of outdoor applications of ant bait stations, only private houses are considered relevant. For private houses, the size of the terrace is assumed to amount to 12 m^2. In line with scenarios used for other BPR product authorisations for similar uses.. Two bait stations will be taken in this assessment for a 12 m^2 terrace. As outlined above, industrial buildings are no matter of concern.

Emission scenario for calculating the release of 1R-trans-phenothrin when used as bait box insecticide within COMPO Mierenlokdoos.		
Parameter	Definition	Value Private house
Amount of product used for each bait box [g]	Qprod	2
Fraction of active substance in product [-]	FAI	0.001
Number of application sites [-]	Nsites	2
Number of application [-]	Nappl	1
Fraction emitted to soil during outdoor application [-]	Foutdoor, soil	0.2
Emission rate of the active substance to soil from a campaign [g]	**Espot, soil = Qprod x FAI x Nsites x Nappl x Foutdoor, soil**	**0.0008**

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
	Fresh-water	Freshwater sediment	STP / rainwater	Air	Soil	Ground-water	Earthworm
Scenario 1 (Indoors)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
Scenario 2 (Outdoors)	Not relevant*	Not relevant*	Not relevant*	Not relevant	Relevant	Relevant	Relevant

* The ESD states at page 130 that "Although exposure of STP is possible, it is thus considered that the relevant scenario for outdoor use of baits is the exposure of surrounding garden soil following wash-off of the terrace by rainfall".

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	350.46	g/mol	
Melting point	-41.1	°C	
Boiling point	>301	°C	
Vapour pressure (at 20° C)	2.372×10^{-5}	Pa	

Water solubility (at 20 °C)	2	µg/L	
Log Octanol/water partition coefficient	6.8	Log 10	
Organic carbon/water partition coefficient (Koc)	125,892.5	L/kg	
Henry's Law Constant	4.2	$Pa/m^3/mol$	
Biodegradability	No readily biodegradable		
Rate constant for STP	n.d.	h^{-1}	
DT_{50} for biodegradation in surface water	n.d.	d or hr (at 12°C)	
DT_{50} for hydrolysis in surface water	301	d (at 25°C /pH 5)	
DT_{50} for photolysis in surface water	n.d.	hr (at 24.5°C/pH 5)	
DT_{50} for degradation in soil	27.2	d (at 12°C)	
DT_{50} for degradation in air	3.63	hr	
Bioconcentration factor for earthworm	75700	L/kg wwt	

Calculated fate and distribution in the STP			
Compartment	Percentage [%]		Remarks
	Scenario 1	Scenario 2	
Air	-	-	Not relevant
Water	-	-	Not relevant
Sludge	-	-	Not relevant
Degraded in STP	-	-	Not relevant

- not applicable as the product is not released to the sewer.

Calculated PEC values

PEC in soils

The relevant scenario for the outdoor use of the bait box is the exposure of the surrounding garden soil following wash-off of the terrace by rainfall (OECD, 2008).

The ESD defines the directly exposed area when spots of insecticides are placed e.g. on soil surfaces, however a definition of the receiving compartment for the current scenario is not worked out. In line with other already authorised products under the BPR with similar use it is presumed that a terrace with the dimensions 3 m x 4 m is located at one side along the house and that the run-off process following flooding after a rain event occurs in one direction (worst-case: shortest terrace side with a length of 3 m). Thus, the receiving soil area $AREA_{exposed}$ is considered to be 3 m x 0.5 m (50 cm distance from the terrace). As to the soil depth at WG-V-2014 it was agreed to harmonise the procedure with other product types and use a soil depth of 50 cm, but only in restricted areas (e.g. for the soil adjacent to the building, i.e. 50 cm distance from the treated wall, terraces, etc.). The receiving soil volume therefore is calculated at 0.75 m^3. At WGV 2016 an adapted scenario was agreed. Although the dosage increases maximal 2 times (from 2 sites to 4 sites), the receiving soil volume also increases by an factor of 11 times (from 0.75 m^2 to 8.5 m^2), which consecuently

results in a PEC 6 times lower. The values in the table below were not adapted further Considering that the present assessment is worst case but leads to a product authorisation.

Predicted Environmental Concentrations in soil for 1R-trans-phenothrin, when used as insecticide within COMPO Mierenlokdoos (outdoor application, private house scenario)		
Parameter	Definition	Value
Emission rate of the active substance to soil from a campaign [g]	$E_{spot, soil}$	0.0008
Area directly exposed to insecticide [m²]	$AREA_{exposed}$	1.5
Depth of exposed soil [m]	DEPTHsoil	0.5
Density of exposed soil [kg/m³ ww]	RHOsoil	1700
Local concentration in soil due to direct release [mg/kg wwt]	**Cspot, soil = Espot, soil / (AREAexposed x DEPTHsoil x RHOsoil)**	**6.27×10^{-4}**

PEC in groundwater

According to the ESD, the exposure of groundwater is considered negligible during the use of bait box stations. In addition the sorption characteristics of 1R-trans-phenothrin indicate a strong sorption to soil components and a very low potential for mobility. However, for reasons of completeness the soil pore water concentration will be assessed as an indicator of potential residues occurring in groundwater.

Most of the parameters used for the PEC calculation in soil pore water have default values, which are provided in the TGD (TGD, 2003). For characterisation of the adsorption potential in soils, the lowest K_{oc}-value, which was determined for 1R-trans-phenothrin (125,892.5 L/kg), has been used to calculate the solid-water partition coefficient according to TGD equation 23. For the calculation of the air-water partitioning coefficient (TGD equation 22), the Henry´s Law constant for 1R-trans-phenothrin of 4.2 Pa x m³ x mol^{-1} has been used. As result, a soil-water partitioning coefficient of 3777 m³/m³ is calculated according to TGD equation 24 and used to calculate the local pore water concentration (PECgw) according to TGD equation 67.

Summary table on calculated PEC values							
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{gw}**	**$PEC_{earthworm}$**	**PEC_{air}**
	[mg/m³]	[mg/l]	[mg/kg_{wwt}]	[$\mu g/kg_{wwt}$]	[µg/l]	[mg/kg_{wwt}]	[mg/m³]
Scenario 1 Indoors	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
Scenario 2 Outdoors	Not relevant	Not relevant	Not relevant	0.627	0.0003	0.0192*	Not relevant

* Calculated from half the PEC_{soil} applying the default TGD formulas

Leaching to groundwater is assessed semi-qualitatively on basis of the PECs available in the AR of 1R-trans-phenothrin. The use assessed in the AR leads to the following PECs groundwater for active and metabolites: 0.000272 µg/L and 0.000122 µg/L for 1R-trans-phenothrin and total metabolites (HO-PHN + PBalc + PBacid), respectively. Considering that these PECs are well below the 0.1 µg/L trigger value and the PEC calculated for the active presented in the table above (0.0003 µg/L) is in the same range, the PECs for the metabolites formed from bait box emissions also will be well below the 0.1 µg/L trigger value.

Primary and secondary poisoning

Primary poisoning

Primary poisoning is the direct consumption of insecticide by birds or mammals. According to the ESD for PT 18 (OECD, 2008), in the case of the biocidal product in the bait box, primary poisoning of non-target organisms is no matter of concern. This formulation is applied in a bait box having only small slits and making the insecticide inaccessible for non-target animals. A risk assessment for non-target animals' primary exposed to 1R-trans-phenothrin is therefore not deemed reasonable.

Secondary poisoning

During the utilisation of COMPO Mierenlokdoos in the form of bait box, birds and mammals may be poisoned secondarily through the ingestion of contaminated ants, insects and/or by the consumption of earthworms from contaminated soils (bait box stations release via wash-off).

Mammals and birds may consume contaminated worms and insects from the adjacent soil. The concentration of the active substance in the earthworm is calculated according to the TGD (2003). As input parameter the concentrations in the receiving soil compartment are included (without considering degradation of 1R-trans-phenothrin) as well as the BCF in earthworms, the concentration in pore water, the fraction of gut loading in worm and the conversion factor for soil concentration wet-dry/weight soil. For calculating the bioconcentration factor, the octanol/water partition coefficient is needed. A log Pow for 1R-trans-phenothrin of 6.8 at pH 7 was taken for the calculation (TGD equation 82b-d). For the concentration (C) of active substance in insects the ESD is in line with document (SANCO/4145 2002), distinguishing residue concentrations in large insects and small insects as a result of an application rate by spraying of 1 kg active substance per hectare (RUD = Residue per Unit Dose). Consequently, these figures have to be multiplied by the actual application rate (T_{appl}) to obtain the concentration per wet weight. Depending on the time scale (acute or short term) either arithmetic means or 90th percentiles are used. The calculations were adapted in line with the approaches agreed at WGV 2016.
T_{appl} is calculated in line with the ESD as follows: =(Qprod_g/box (2 g)*Fai (0.001)/1000) * Number_of_boxes (4)*fraction_released_from_Bait_box (0.2) / surface (8.5 m^2) = 1.882E-07 kg a.s./m^2. The formula $\mathbf{C_{insects} = RUD \times T_{appl} \times 10^{-4}}$. is used to calculate the concentration in insects. Concentration in earthworms was calculated according to $BCF_{earthworm}*C_{porewater} + C_{soil}*F_{gut}*CONV_{soil})/(1+F_{gut}*CONV_{soil})$, where C_{soil} is set to 0.5 of the calculated PEC_{soil}.

The species presented below are derived from the ESD.

Residue values per unit dose (mg a.s./kg bw at a dosage of 1 kg a.s./ha area) and relevant food sources derived from the ESD PT18, used for calculating the concentration (C) in indicator species			
Species	**Main food**	**Residue value per unit dose (RUD)**	
Mammals		Acute (90%)	Short-term (mean)
Pipistrelle	Large insects	14	5.1
Shrew	Large insects and worms	14	5.1
Mole	Worms		
Hedgehog	Large insects	14	5.1
Badger	Large insects and worms	14	5.1
Bird			
Tree sparrow	small insects	52	29
Blackbird	Large insects and worms	14	5.1
Magpie	Large insects and small mammals	14	5.1

Tier 1 calculations Predicted Environmental Concentrations in food for insect, earthworm and mammal eating birds and mammals for 1R-trans-phenothrin, when used as insecticide within COMPO Mierenlokdoos (outdoor application, private house scenario)			
Species	**PECinsects (mg a.s./kg ww food)**		**PECearthworm* (mg a.s./kg ww food)**
	Acute	short term	
Mammals			
Pipistrelle	2.64E-10	9.60E-11	
Shrew	2.64E-10	9.60E-11	1.92E-02
Mole			1.92E-02
Hedgehog	2.64E-10	9.60E-11	1.92E-02
Badger	2.64E-04	9.60E-11	1.92E-02
Bird			
Tree sparrow	9.79E-10	5.46E-10	
Blackbird	2.64E-10	9.60E-11	1.92E-02
Magpie	2.64E-10	9.60E-11	1.10E-02*

** Magpies eat insects and small mammals. Therefore the acute and short term ETE values for shrews were used in this instead of the concentration in earthworm.

In the ESD for PT 18 (OECD, 2008) a refinement is incorporated, where the calculated active substance in the earthworm $C_{earthworm}$ ($PEC_{earthworm}$) have to be replaced by the estimated theoretical exposure (ETE). For the food chain from earthworm to earthworm-eating mammals and birds, the estimated residues in earthworm is converted to daily dose in the predator by multiplying a factor that relates the food intake rates and the body weight (FIR/bw). This factor corresponds to 1.4 for mammals and 1.1 for birds and it is derived from the exposure scenario established for plant protection products in the EU (European Commission, 2002). The ETE values are calculated as a function of the content of the active substance 1R-trans-phenothrin in worms and assuming the standardised worst-case scenario for the rest of the parameters.

For insectivorous species, the estimated theoretical exposure (ETE) is calculated, representing the estimated daily intake and corresponding to the PEC_{oral} per day (expressed as mg a.s./kg bw of the pray species/day of mg a.s./kg food/day).

ETE = (FIR / BW) * C * AV * PT * PD (mg.kg^{-1} bw/d)

Where:

Variable/parameter	Symbol	Unit	default
Food intake rate of insectivorous or worm eating species (fresh weight)	FIR	g.d-1	
Body weight of insectivorous or worm eating species	BW	g	
Concentration of active compound in fresh diet (insects or worms)	C*	mg. kg-1	
Avoidance factor (1 = no avoidance, 0 = complete avoidance)	AV	-	1
Fraction of diet obtained in treated area (value between 0 and 1)	PT	-	1
Fraction of food type in diet (number between 0 and 1; one type or more types)	PD	-	1

Food intake rate (FIR) en body weights for indicator species of lawn/garden Derived from table 5.2-5 of ESD18			
	FIR (g/d)		Body weight (g)
	insect	earthworm	
Mammals			
Pipistrelle	5.2	-	7.6
Shrew	6.8*	5.7**	10
Mole	-	61.2	85
Hedgehog	172.1	374.2	1100
Badger	822	1786.7	10100
Bird			
Tree sparrow	18	-	22
Blackbird	72.6***	87.1	113
Magpie	92.4	200.9	225

*: Extrapolated from FIR/BW data on pipistrelle eating insects;
**: extrapolated from FIR insects correcting for percentage moisture (70.5/84.6)
***: reasonable estimate

The theoretical exposure of predators is a function of the estimated concentration of the insecticide found in food sources (insectivorous birds and mammals). Concentrations are derived from the exposure scenario established for plant protection products in the EU (European Commission, 2002).
The total application rate of biocidal product per m² is 1 bait box of 2 g of b.p per 10 m². As a first step, the actual application rate is calculated. As done above, it is assumed that two bait stations are placed on a terrace, having an area of 12 m². In a second step, the 1R-trans-phenothrin concentration in the fresh diet is assessed for acute and short-term exposure, and the estimated theoretical exposure is calculated for the corresponding indicator species (insectivorous bird).

Tier 2 calculations of Predicted Environmental Concentrations (in insect and earthworm eating birds and mammals) for 1R-trans-phenothrin, when used as insecticide within COMPO Mierenlokdoos (outdoor application, private house scenario)			
Species	**ETEinsectivorous (mg/kg/d)**	**ETEworm eater (mg/kg/d**	**ETE combined**

	acute	short term		acute	short term
Mammals					
Pipistrelle	1.80E-10	6.57E-11		1.80E-10	6.57E-11
Shrew	1.80E-10	6.57E-11	1.10E-02	1.10E-02	1.10E-02
Mole	-	-	1.38E-02	1.38E-02	1.38E-02
Hedgehog	4.12E-11	1.50E-11	6.54E-03	6.54E-03	6.54E-03
Badger	2.14E-11	7.81E-12	3.40E-03	3.40E-03	3.40E-03
Bird					
Tree sparrow	8.01E-10	4.47E-10		8.01E-10	4.47E-10
Blackbird	1.69E-10	6.17E-11	1.48E-02	1.48E-02	1.48E-02
Magpie	1.08E-10	3.94E-11	1.72E-02*	3.94E-11	3.76E-02

* Magpie eats insects and small mammals. Therefore the acute and short term ETE combined values for shrews were used as C* instead.

Note that due to the imbalance in the calculations for insects and earthworms, risk assessment is driven by the exposure to earthworms.

2.2.7.3 Environmental effects assessment

Risk assessment is based on Predicted No-Effect Concentrations (PNECs) for the different compartments which are derived from ecotoxicity data and applying assessment factors. The assessment factor depends on the type of test performed (acute or chronic), the toxicological endpoint (effect concentrations (ECs), no-observed effect concentrations (NOECs), etc), and the number of data and is determined according to Volume IV Part B. The ecotoxicological data and PNECs used for the current risk assessment are derived from the AR of 1R-trans-phenothrin version March 2013.

PNECs endpoints and Assessment factors of 1R-trans-phenothrin				
Compartment	**Lowest endpoint**	**AF**	**PNEC**	**Test/species**
STP	NOEC: 100 mg/L	10	10 mg/L	respiration inhibition test
fresh water	NOEC: 0.47 µg/L	10	0.047 µg/L	*Daphnia magna*
sediment	NOEC: 1.29 mg/kg ww	10	0.129 mg/kg	EP
soil	NOEC: 0.104 mg/kg wwt	10	0.0104 mg/kg wwt	EP
birds	LC50 of 5620 mg/kg food	3000	1.87 mg/kg food	Test was performed with drinking water
mammals	NOEC: 300 mg/kg food NOAEL=8.2 mg/kg bw/day	30	10 mg/kg food 0.27 mg/kg bw	52 weeks dog

* EP: PNEC derived from equilibrium

In the AR PNEC for the metabolites were not derived with the following reasoning: On basis of QSARs "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 acceptable that the PNECaquatic value derived for d-trans-Phenothrin will provide a sufficient level of protection".

2.2.7.4 Risk characterisation

Atmosphere

Conclusion: The active substance is virtually not volatile and even when entering the atmosphere, the compound is rapidly degraded by photochemical processes and neither accumulation in the air nor transport over longer distances is to be expected.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values for 1R-trans-phenothrin	
	PEC/PNEC$_{STP}$
Scenario 1 (Indoors)	Not relevant
Scenario 2 (Outdoors)	Not relevant

Conclusion: Emissions of the biocidal product to the aquatic environment due to indoor and outdoor use are excluded and the calculation of emission rates is therefore deemed unreasonable. A risk assessment for sewage treatment plants is therefore not indicated.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1 (Indoors)	Not relevant	Not relevant
Scenario 2 (Outdoors)	Not relevant	Not relevant

Conclusion: Emissions of the biocidal product to the aquatic environment due to indoor and outdoor use are excluded and the calculation of emission rates is therefore deemed unreasonable. A risk assessment for surface water is therefore not indicated.

Terrestrial compartment

Calculated PEC/PNEC values for 1R-trans-phenothrin	
	PEC/PNECsoil
Scenario 1 (Indoors)	Not relevant
Scenario 2	0.06

(Outdoors)	

Conclusion: Risk ratios for Scenario 2 were << 1 indicating no unacceptable risk for soil.

Groundwater

Calculated PEC/PNEC values for 1R-trans-phenothrin	
	PEC/groundwater standard
Scenario 1 (Indoors)	Not relevant
Scenario 2 (Outdoors)	0.003

Conclusion: Risk ratios for Scenario 2 were << 1 indicating no unacceptable risk for groundwater for both the active substance and its metabolites.

Primary and secondary poisoning

Primary poisoning

Due to the use as a bait station, primary poisoning of birds or mammals is not relevant.

Secondary poisoning

Tier 1: concentrations in insect and worm eating birds and mammals tested against the PNEC food

Summary table on secondary poisoning					
Risk assessment for insect and worm eating birds and mammals – indicator species					
Species	**PECinsects**		**PECearthworm**	**PEC/PNEC combined**	
Mammals	Acute	short term		Acute	short term
Pipistrelle	2.64E-10	9.60E-11		2.64E-11	9.60E-12
Shrew	2.64E-10	9.60E-11	1.92E-02	1.92E-03	1.92E-03
Mole			1.92E-02	1.92E-03	1.92E-03
Hedgehog	2.64E-10	9.60E-11	1.92E-02	1.92E-03	1.92E-03
Badger	2.64E-04	9.60E-11	1.92E-02	1.95E-03	1.92E-03
Bird					
Tree sparrow	9.79E-10	5.46E-10		9.79E-11	5.46E-11
Blackbird	2.64E-10	9.60E-11	1.92E-02	1.92E-03	1.92E-03
Magpie	2.64E-10	9.60E-11	1.10E-02	5.86E-03	5.86E-03

Summary table on secondary poisoning
Risk assessment for insect and worm eating birds and mammals

Exposure scenario	PECoral [mg/kg]*	PECoral [mg/kg]*	PEC/PNEC	
	Acute	short term	Acute	short term
Birds feeding on worms	1.92E-02		1.03E-02	
Mammals feeding on worms	1.92E-02		1.92E-03	
Birds feeding on insects	9.79E-10	5.46E-10	5.23E-10	2.92E-10
Mammals feeding on insects	5.46E-10	9.60E-11	5.46E-11	9.60E-12

* mg/kg insects or earthworms;

Tier 2: At WGV 2016 it was clarified that the Tier 2 refinement in the ESD where food concentrations are transformed to concentrations based on body weights (ETE) at the PEC side induces that also at the PNEC side the units should be transformed to body weight. It should be noted, however, that this approach is not a higher tier, but only another way to do the risk assessment.

Summary table on secondary poisoning					
Species	ETEinsect (mg/kg/d)		ETEworm(mg/kg/d)	PEC/PNEC combined	
	Acute	short term		Acute	short term
Mammals					
Pipistrelle	1.80E-10	6.57E-11		6.68E-10	2.43E-10
Shrew	1.80E-10	6.57E-11	1.10E-02	4.06E-02	4.06E-02
Mole	-	-	1.38E-02	5.13E-02	5.13E-02
Hedgehog	4.12E-11	1.50E-11	6.54E-03	2.42E-02	2.42E-02
Badger	2.14E-11	7.81E-12	3.40E-03		
Bird					
Tree sparrow	8.01E-10	4.47E-10		2.97E-09	1.65E-09
Blackbird	1.69E-10	6.17E-11	1.48E-02	5.49E-02	5.49E-02
Magpie	1.08E-10	3.94E-11	1.72E-02	6.36E-02	6.36E-02

*A PNEC on body weight is lacking for birds. Therefore the PNECmammals was used

Summary table on secondary poisoning				
Exposure scenario	PECoral [mg/kg]	PECoral [mg/kg]	PEC/PNEC	
	Acute	short term	Acute	short term
Birds feeding on worms	1.72E-02		6.36E-02	
Mammals feeding on worms	1.38E-02		5.13E-02	
Birds feeding on insects	8.01E-10	4.47E-10	2.97E-09	1.65E-09
Mammals feeding on insects	1.80E-10	6.57E-11	6.68E-10	2.43E-10

Conclusion: During the utilisation of the biocidal product, mammals and birds may be poisoned secondarily by the ingestion of insects and/or earthworms from contaminated soils. All scenarios indicate PEC/PNEC values below 1 indicating no unacceptable risk (i.e. due to a wash off event).

Mixture toxicity

Mixture toxicity is not relevant since the biocidal product contains only the active substance 1R-trans-phenothrin and no substance of concern.

Aggregated exposure (combined for relevant emmission sources)

Summary table on calculated ΣPEC/PNEC values					
$\Sigma PEC/PNEC_{STP}$	$\Sigma PEC/PNEC_{water}$	$\Sigma PEC/PNEC_{sed}$	$\Sigma PEC/PNEC_{soil}$	ΣPEC_{GW}	ΣPEC_{air}
Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant

Conclusion: Aggregated exposure is not relevant for the PT 18 use of the biocidal product.

PBT and endocrine disruption assessment

PBT

In the Assessment report, 1R-trans-phenothrin was identified as potential P, potential B and T and incorporated like that on the CLH and PBT status list for approved existing and new active substances of January 2016.

The substance has been discussed in the PBT_EG in 2015 and it may be discussed again after Ireland has reviewed the data. At present, however, there is no further information available. The substance is not to be regarded PBT (as it appears in the AR) until a formal decision is being made.

Endocrine Effects

On the basis of the evaluation by the Irish CA for Biocides of toxicology/eco-toxicology studies using d-Phenothrin, no determination of endocrine disruption effects could be ascertained in the test organisms dosed with d-Phenothrin.

However, work carried out under the EU Strategy for Endocrine Disruptors has included R 1R-trans-phenothrin in Group III (No sufficient data) of a list of 553 candidate substances with the potential to be substances 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 1R-trans-phenothrin when EU harmonised guidelines are established for test methods and risk assessment. The substance is not to be regarded as endocrine disrupter until a formal decision is being made.

POP Conclusion

d-Phenothrin does not fulfil the POP criteria.

Overall conclusion on the risk assessment for the environment of the product
The environmental risk assessment for the biocidal product containing the active substance 1R-trans-phenothrin has demonstrated a safe use for the environment. The assessment of secondary poisoning of birds by the ingestion of contaminated ants showed that no adverse effects for insectivorous bird species are to be expected.

2.2.8 Measures to protect man, animals and the environment

Handling:
Advice on safe handling: Misuse can be harmful to health. Keep away from children and pets.
Do not use force when opening the bait stations.

Storage:
Requirements for storage areas and containers: Store protected against frost.
Further information on storage conditions: Keep container tightly closed in a cool place.
Advice on common storage: Keep away from food, drink and animal feed.
The shelf life of the biocidal product is two years at 20 °C.
Storage temperature: 0 - 30 °C

Transport:
The product is classified in class 9 (environmentally hazardous substance) for ADR/RID, packaging group III.

Disposal:
Product: Disposal together with normal waste is not allowed. Special disposal required according to local regulations.
Contaminated packaging: Observe national and local legal requirements.

Fire:
Suitable extinguishing media: Water spray jet, sand, dry powder, foam, carbon dioxide (CO_2)
Unsuitable extinguishing media: Water jet
Specific hazards during firefighting: Heating can release hazardous gases.
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.
Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Description of first aid measures
In case of skin contact: After contact with skin, wash immediately with plenty of water.
In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
If swallowed: If swallowed, seek medical advice immediately and show this container or label.
Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically.

Emergency measures to protect the environment:
Do not let product enter drains, surface water or subsoil water.

2.2.9 Assessment of a combination of biocidal products

According to the instruction of use, the biocidal product is not intended to be used with other biocidal products.

2.2.10 Comparative assessment

The active substance does not fulfil the criteria of article 10 of Regulation (EU) 528/2012 and therefore, a comparative assessment is not relevant.

3 ANNEXES

3.1 List of studies for the biocidal product

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
[redacted]	2015a	Determination of physico-chemical properties and storage stability test for THG 128 01 I RB. Date: 2015-07-29	[redacted]	Mo5263	No	No	Yes	COMPO GmbH	3.1 3.2 3.3 3.4.1_01 3.9
[redacted]	2015b	Determination of physico-chemical properties and storage stability test for THG 128 01 I RB. Date: 2015-09-04	[redacted]	Mo5262	No	No	Yes	COMPO GmbH	3.4.1_02
[redacted]	2015c	Study plan: Determination of physico-chemical properties and storage stability test for THG 128 01 I RB. Date: 2015-08-13	[redacted]	Mo5265	No	No	Yes	COMPO GmbH	3.4.1_03

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
[redacted]	2015d	Study plan: Determination of physico-chemical properties and storage stability test for THG 128 01 I RB. Date: 2015-08-13	[redacted]	Mo5264	No	No	Yes	COMPO GmbH	3.4.1_04
[redacted]	2015e	Validation of method MV121: COM: HPLC - Determination of 1R-trans-phenothrin in THG 128 01 I RB. Date: 2015-07-28	[redacted]	Mo5261	Yes	No	Yes	COMPO GmbH	5
[redacted]	2018	Determination of Physico-Chemical Properties and Storage Stability Test for THG 128 01| RB	[redacted]	Mo5264	No	No	Yes	COMPO GmbH	
[redacted]	2014	Laboratory assessment of the efficacy of an insecticidal ant bait. Arena trial - dose range test. Date: 2014-12-10	[redacted]	1869-1/1214	No	No	Yes	COMPO GmbH	6.7_01

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
[redacted]	2015a	Laboratory assessment of the efficacy of an insecticidal ant bait. Arena trial - bait boxes comparison. Date: 2015-03-04	[redacted]	1869-2/1214	No	No	Yes	COMPO GmbH	6.7_02
[redacted]	2015b	Laboratory assessment of the efficacy of an insecticidal ant bait. Arena trial - broad spectrum (6 species). Date: 2015-03-20	[redacted]	1869-3/1214	No	No	Yes	COMPO GmbH	6.7_03
[redacted]	2015c	Field assessment of the efficacy of an ant bait station. Date: 2015-05-28	[redacted]	1869-4/1214	No	No	Yes	COMPO GmbH	6.7_04

3.2 Output tables from exposure assessment tools

Scenario [1]: Place bait station

	ConsExpo 4.1 report	
Product	COMPO Mierenlokdoos	
Compound		
Compound name :	1R-trans-phenothrin	
CAS number :	26046-85-5	
General Exposure Data		
exposure frequency	8	1/year
body weight	60	kilogram
Dermal model: Direct dermal contact with product : instant application		
weight fraction compound	0.1	%
applied amount	0.2	gram
Uptake model: fraction		
uptake fraction	5	%
Output		
Dermal : point estimates		
dermal load :	-	mg/cm2
dermal external dose :	0.00333	mg/kg
dermal acute (internal) dose :	0.000167	mg/kg
dermal chronic (internal) dose :	3.65E-06	mg/kg/day
Integrated (point estimates)		
total external dose:	0.00333	mg/kg
total acute dose (internal):	0.000167	mg/kg
total chronic dose (internal):	0.00000365	mg/kg/day

3.3 New information on the active substance

Not applicable.

3.4 Residue behaviour

Not applicable.

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

For summaries of the efficacy studies please refer to the table shown in Chapter 2.3.4 E and to the IUCLID file.

3.6 Confidential annex

Please refer to the separate document.