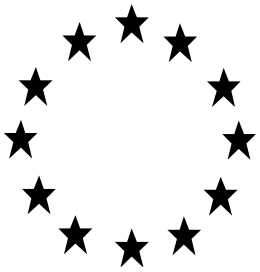
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



VANDAL Ameisen-Frühstück und VANDAL Ameisen-Kombiköder

Product type 18 (Insecticide)

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-WY023635-98

PUBLIC

Date: 23/08/2023 (Final)

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1 CONCLUSION

Austria was the Competent Authority responsible for evaluation of the biocidal product VANDAL Ameisen-Frühstück und VANDAL Ameisen-Kombiköder. The dossier submission date 28/4/2016 is to be taken into account for relevance of (new) guidance.

The ready-to-use product is a solid mixture which contains 3.87%(w/w) of the active substance permethrin. No substance of concern for human health or environment have been identified in the biocidal product.

The assessment considered:

- The conclusions and recommendations of the Assessment Report for the approval of the active substance permethrin including the "elements to be taken into account by Member States when authorisising products"
- The specific provisions from Inclusion Directive for the active substance permethrin [(EU) No 1090/2014]

Approval of the active substance:
The active substance permethrin is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance
- For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
- Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. Labels and, where provided, safety data sheets of products authorised shall indicate such measures required. In particular, products authorised for the application to textile fibres or other materials to control insect damage shall indicate that freshly treated fibres and other appropriate materials shall be stored to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
- For treated articles, the following condition applies: Where a treated article has been treated with or intentionally incorporates permethrin, and where necessary due to the possibility of skin contact as well as the release of permethrin under normal conditions of use, the person responsible for placing the article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

The fields of use are as follows:
Use # 1 – Ants (all stages) – non-professional user – RTU bait station with bait – indoor and outdoor

Identity and analytical methods were described in sufficient detail to meet the information requirements as laid down in annex III of regulation (EU) no. 528/2012. The physical-chemical properties and respective characteristics of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transport of the biocidal product.

Based on the authorised use including the general directions of use and any possibly defined risk mitigation measures and provided that there will be no misuse, the following can be concluded:

- Data on the biocidal product have demonstrated sufficient efficacy against the target organisms. No resistance is expected.
- The biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups or animals, directly or through drinking water, food, feed, air, or through other indirect effects.
- Also for the environment, the risk characterisation resulted in acceptable risks for all authorised uses in all exposed environmental compartments. The assessment of secondary poisoning has shown that no adverse effects for birds and mammals are to be expected.

The active substance permethrin is a candidate for substitution pursuant to Art. 10(1) BPR.

There is no indication of concern regarding ED properties of any of the co-formulants, hence the product is not an endocrine disruptor.

It can be concluded that the conditions of Article 19 1)-4) of regulation (EU) no. 528/2012 are fulfilled and that the product may be authorised.

The biocidal product will be authorised for a period not exceeding **5 years** in accordance with Article 23(6) of Regulation (EU) No 528/2012.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
VANDAL Ameisen-Frühstück und VANDAL Ameisen-Kombiköder	Austria

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Nifra Parfumerie Gesellschaft m. b. H.
	Address	Bräuhausgasse 68 1050 Wien Austria
Authorisation number	SEE AUTHORISATION LETTER	
Date of the authorisation	SEE AUTHORISATION LETTER	
Expiry date of the authorisation	SEE AUTHORISATION LETTER	

2.1.1.3 Manufacturer of the product

Name of manufacturer	Nifra Parfumerie Gesellschaft m.b.H.
Address of manufacturer	Bräuhausgasse 68 1050 Vienna Austria
Location of manufacturing sites	Norbert Neidlinger Gesellschaft m.b.H. Paschingerstrasse 76 4060 Leonding Austria

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

Active substance	Permethrin
Name of manufacturer	Limaru NV (Importeur) [agierend für Tagros Chemicals India Private Limited (India)]
Address of manufacturer	Tagros Chemicals India Pvt Limited, "Jhaver Centre", IV Floor, Rajha Annamalai Building, IV Floor, 72, Marshalls Road, Egmore Chennai-600 008 India
Location of manufacturing sites	Tagros Chemicals India Pvt. Ltd. A-4/1&2, Sipcot Industrial Complex Pachayankuppam 607 005 - Cuddalore Tamilnadu India

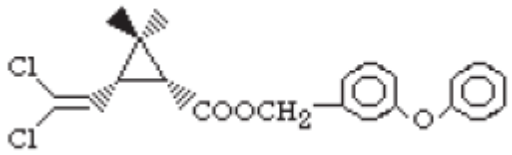
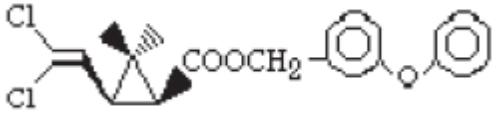
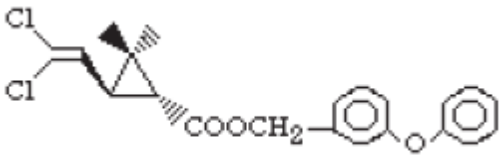
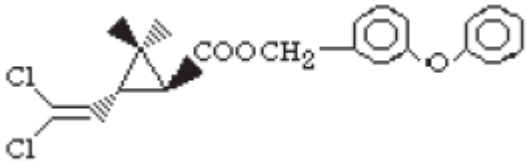
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content*	93.0 %
Structural formula	1R cis isomer –  1S cis isomer –  1R trans isomer –  1S trans isomer – 

*According to the REGULATION (EU) No 1090/2014

2.1.2.2 Candidate(s) for substitution

The active substance permethrin is a candidate for substitution in accordance with article 10(1) of the BPR. It is persistent and toxic, but not bio-accumulative. Permethrin is not classified as PBT.

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

Quantitative information on the biocidal product

Trade names: VANDAL Ameisen-Frühstück
VANDAL Ameisen-Kombiköder

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	3.871*

*Minimum amount of pure active substance without impurities: 3.6 % w/w

Qualitative information on the biocidal product

The biocidal product comprises a solid mixture which is a polymer ring containing the active substance primed for elimination of the target organisms. It is used together with a bait, both integrated separately inside the bait-station. For further information please confer to the confidential annex.

The rMS has concluded that the bait station is a special type of packaging, which contains a liquid bait formulation and a solid formulation (polymer ring incl. active substance) for the elimination of the target organisms. The solid formulation is regarded as biocidal product. The rationale behind the decision is depicted in depth in the confidential annex.

Rationale for differentiation between article and biocidal product

The biocidal product is a solid mixture (polymer ring incl. permethrin) according to Article 3(2) of the REACH Regulation in which according to Article 3(3) an **article is defined** as *"an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition".* The only function of the mixture is to deliver the active substance to the target organism via contact. The chemical composition of the active substance is the main driver for the activity of the biocidal product. The shape, design or surface of the polymer ring containing the active substance is not influencing the activity of the biocidal product.

Thus, following the decision tree under 2.3 (ECHA: Guidance on the Requirements for substances in articles):

Step 1	Identify the function of the object: The product contains an active substance which is transferred onto the target organisms only via contact, no other release is intended or observed.
Step 2	Are shape/surface/design more relevant for the function than the chemical composition? *If you can unambiguously conclude that the shape, surface or design of the object is more relevant for the function than its chemical composition, the object is an article. If the shape, surface or design is of equal or less importance than the chemical composition, it is a substance or mixture.* **No**, the shape, surface or design of the solid polymer ring are less important for the activity of the biocidal product than the chemical composition. Without the active substance no activity would occur. The design which poses an obstacle for the target organisms leads to the uptake of the active substance. The active substance may well be placed via other means in the vicinity of the target organisms inside the bait station. Activity would still be achieved in a less sophisticated way.
Conclusion	The object is a substance or mixture.

Following the definitions set out in document CA-Nov16-Doc.4.3 – Final, which describes how to handle "carrier" products the biocidal product can be seen as Type C product. The packaging of such products is designed in a way that it is not removed before use (i.e. to prevent contact with users). For type C biocidal products it has been agreed that only the composition of the biocidal mixture should be considered for the calculation of the active substance concentration to be indicated in the SPC. The carrier component (i.e. bait station) should not be considered as a part of the composition of the biocidal product. Furthermore, the hazard and precautionary statements as well as any other labelling elements deriving from the CLP Regulation, are based on the classification of the solid mixture (polymer incl. the active substance) only.

Thus, the eCA concludes that the solid polymer ring comprises the polymer and the active substance dissolved in it, in further consequence to be regarded as a mixture. Subsequently, the mixture is to be regarded as a biocidal product inside a specific type of packaging (i.e. ready to use bait station).

2.1.2.4 Information on technical equivalence

Is the source of permethrin the same as the one evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

Yes ☒
No ☐

2.1.2.5 Information on the substance(s) of concern

For the environmental and the human health part no SoC is identified in the biocidal product. For further details refer to the confidential Annex.

2.1.2.6 Type of formulation

XX (others)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1
Hazard statement	H317: May cause an allergic skin reaction H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Pictogram	
Signal words	Warning
Hazard statements	H317: May cause an allergic skin reaction. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read carefully and follow all instructions. 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 P391: Collect spillage P501: Dispose of contents/container according to national legislation
Note	P261 (Avoid breathing dust/fume/gas/mist/ vapours/spray) has been excluded based on the nature of the biocidal product P280 (as a result of H317) has been excluded, because skin contact with the biocidal product is not possible if it is not misused

2.1.4 Authorised use(s)

2.1.4.1 Use description

Use # 1 – Ants (all stages, nests) – non-professional user – RTU bait station – indoor and outdoor

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: all stages, nests (queen, adults, larvae)
Field of use	Indoor and outdoor use Field of Use description: Insecticide for use in households (indoor) and on hard surfaces in rain protected areas around houses (outdoor, e.g. terraces, balconies).
Application method(s)	Ready-to-use Bait station
Application rate(s) and frequency	Application rate: 1 bait station, containing 1.5 g biocidal product (corresponding to 3.87 % (w/w) permethrin), per ant trial or per nest Max. 1 single bait station per 15 m^2 Application frequency: Place the bait min. 2 weeks, max. 4 weeks If ants are still visible, repeat the treatment every 4 weeks during season of ant activity.
Category of users	Non-professional
Pack sizes and packaging material	Bait station: 6,9 x 7,3 x 2,4 cm, PP Outer packaging: 15,3 x 7 x 2,5 cm, paper, carton (1 or 2 bait station(s) per package)

2.1.4.2 Use-specific instructions for use

2.1.4.3 Use-specific risk mitigation measures

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

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

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

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2.1.5 General directions for use

2.1.5.1 Instructions for use

Take the bait station out of the packaging and place it horizontally on sheltered, paved and dry surfaces on preferred routes of the ants or as close as possible to the nest.

Place 1 bait station per ant run/nest (max. 1 bait station per 15 m^2).

First, open one of the two bait chambers by pressing down several times and empty by this way. After that, do not tilt to prevent the bait from leaking out.

Depending on the severity of the infestation, open the second chamber in the same way after 7 days to activate the trap with fresh bait.

N-172: Protect bait boxes from rain. Put the bait boxes only in places where they are protected from rainfall events to avoid release of the product into the environment.

N-119: Apply only in areas that are not liable to submersion or becoming wet, i.e protected from rain, floods and cleaning water.

The product should be applied in a way that pets, food, feedstuff and livestock do not come in contact with the product.

N-292: Remove the bait station at the end of the treatment.

Wash hands after placing the bait.

2.1.5.2 Risk mitigation measures

N-316: Keep out of the reach of children and non-target animals/pets.

N-335 (modified): Keep cats away. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats.

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

IF INHALED: not applicable.

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor

Measures to protect the environment:

Product and container shall not reach soil, water bodies and sewage system. In case of contamination notify the competent authorities.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents/container to a special waste collection point in accordance with local/national/international requirements.

Product residues must be collected and disposed of in accordance with the national waste disposal legislation and any regional and/or local authority requirements.

N-205: Do not re-use container for any purpose.

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

Store in a dry place in the original packaging.

Keep out of direct sunlight and moisture.

Shelf-life: 2 years

2.1.6 Other information

This biocidal product contains permethrin which is dangerous to bees.

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)
Bait station	6,9 x 7,3 x 2,4 cm	PP	Opening is not foreseen	Non-professional	yes
Box (including 1 or 2 bait boxes)	15,3 x 7 x 2,5 cm	Paper, carton	No closure. Carton is folded.	Non-professional	yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

A letter of access is available for Annex II data. The List of endpoints connected to the active substance approval is the basis for the a.s. data.

All Annex III data related to the biocidal product(s) are contained in the IUCLID dossier. Please cf. to annex 3.1. for the list of studies.

2.1.8.2 Access to documentation

A letter of access for the biocidal product satisfying the requirements set out in Annex II for the active substance in the biocidal product is available.

2.2 Assessment of the biocidal product

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

Intended use # 1 – name of the use

Product Type(s)	18
Where relevant, an exact description of the authorised use	---
Target organism (including development stage)	Ants (eggs, larvae, pupae, adults)
Field of use	Indoor use (outdoor only in areas well protected from rain, e.g covered terrace)
Application method(s)	Bait application
Application rate(s) and frequency	Ad libitum for at least 2-3 weeks
Category(ies) of user(s)	General public, non professional
Pack sizes and packaging material	Refer to relevant section.

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	100% biocidal product Batch no.: 0614	solid	Anonymous 2022a
Colour at 20 °C and 101.3 kPa	Visual inspection	100% biocidal product Batch no.: 0614	Milky white (polymer frame)	Anonymous 2022a
Odour at 20 °C and 101.3 kPa	olfactory inspection	100% biocidal product Batch no.: 0614	odourless	Anonymous 2022a
Acidity / alkalinity	---	---	Not Applicable. The water solubility of permethrin is 0.18 mg/L (20 °C). Permethrin does not show basic or acidic properties in water. The polymer content	CAR of permethrin

<table>
<tr><td></td><td></td><td></td><td>of the biocidal product is not soluble in water.</td><td></td></tr>
<tr><td>Relative density / bulk density</td><td>OECD 109</td><td>100% Biocidal product

Batch no.: APMT20E031</td><td>0.931</td><td>Anonymous 2022b</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC MT 46.3</td><td>100% Biocidal product

Batch no.: 0614</td><td>The results indicate that the biocidal product is stable for 2 weeks at 54°C.

The biocidal product was stored in its original packaging for 2 weeks at 54°C. The packaging remains intact and does not show any deficiencies after storage. No ballooning, panelling and leakages were observed.
<table>
<tr><th></th><th>T0</th><th>T2w</th></tr>
<tr><td>a.s. content (% w/w)</td><td>3.67</td><td>3.65</td></tr>
<tr><td>appearance</td><td>White PE-frame with white powder on the frame</td><td>White PE-frame with clear ossified liquid on the frame</td></tr>
<tr><td>Weight loss %</td><td>---</td><td>6 samples Weight loss from 1.77 to 1.83 %</td></tr>
<tr><td>packaging</td><td>Test samples were stored in original packaging. No deficiencies were observed.</td><td>Packaging remains intact. No deficiencies were observed (no ballooning, panelling and leakages).</td></tr>
</table></td><td>Anonymous 2022a</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>---</td><td>100% Biocidal product

Batch no.: 0614</td><td>The results indicate that the biocidal product is stable for 2 years when stored at 20°C in its original packaging.

Test items were stored in the original packaging at 20°C for 2 years. No changes of the packaging was observed during the whole storage test. No ballooning, no</td><td>Anonymous 2022a</td></tr>
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<td>panelling and no leakages were observed.
<table>
<tr><th></th><th>T0</th><th>T1y</th><th>T2y</th></tr>
<tr><td>a.s. content (% w/w)</td><td>3.67</td><td>3.47 (- 5.4 % from initial)</td><td>3.67</td></tr>
<tr><td>appearance</td><td>White PE-frame with white powder on the frame</td><td>White PE-frame with clear ossified liquid on the frame</td><td>White PE-frame with clear ossified liquid on the frame</td></tr>
<tr><td>Weight loss %</td><td>---</td><td>3 samples Weight loss from – 0.65 to 0.49 %</td><td>6 samples Weight loss from – 1.19 to 0.39 %</td></tr>
<tr><td>packaging</td><td>Test samples were stored in original packaging. No deficiencies were observed.</td><td>Packaging remains intact. No deficiencies were observed (no ballooning, panelling and leakages).</td><td>Packaging remains intact. No deficiencies were observed (no ballooning, panelling and leakages).</td></tr>
</table>
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<td></td>
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<tr>
<td>Storage stability test – low temperature stability test for liquids</td>
<td>---</td>
<td>---</td>
<td>Not applicable. The biocidal product consists of a solid mixture.</td>
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</tr>
<tr>
<td>Effects on content of the active substance and technical characteristics of the biocidal product – light</td>
<td>---</td>
<td>---</td>
<td>No exposition to light when stored in original packaging. The active substance is not susceptible to breakdown by light. For specific information on the active substance, please refer to the CAR.</td>
<td>---</td>
</tr>
</table>

Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	---	100% biocidal product Batch no.: 0614	The test items were stable at 54°C for 2 weeks. The effect of humidity was not investigated as the biocidal product and the active substance are insoluble in water and not hygroscopic.	Anonymous 2022a
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	---	100% biocidal product	No reactivity towards the packaging was observed during accelerated and long term storage for 2 years.	Anonymous 2022a
Wettability	---	---	Not applicable. Dispersing in water is not an intended use.	---
Suspensibility, spontaneity and dispersion stability	---	---	Not applicable. The biocidal product is no powder or granule which is dispersed in water.	---
Wet sieve analysis and dry sieve test	---	---	Not applicable. The biocidal product is a solid mixture and no powder, granule or suspension.	---
Emulsifiability, re-emulsifiability and emulsion stability	---	---	Not applicable. The biocidal product does not form an emulsion.	---
Disintegration time	---	---	Not applicable. The biocidal product is not a tablet.	---
Particle size distribution, content of dust/fines, attrition, friability	---	---	Not applicable. The biocidal product is not a powder or granule.	---
Persistent foaming	---	---	Not applicable. The product is not applied in water.	---
Flowability/Pourability/Dustability	---	---	Not applicable. The biocidal product is not a granule.	---
Burning rate — smoke generators	---	---	Not applicable. The biocidal product is not a smoke generator.	---

Burning completeness — smoke generators	---	---	Not applicable. The biocidal prodcut is not a smoke generator.	---
Composition of smoke — smoke generators	---	---	Not applicable. The biocidal prodcut is not a smoke generator.	---
Spraying pattern — aerosols	---	---	Not applicable. Spraying is not an intended use of the product.	---
Physical compatibility	---	---	The biocidal product is used together with a bait. Both are located on an article when used, but do not come in contact with each other due to the design of the bait station. Both products are sold in the same packaging.	---
Chemical compatibility	---	---	The biocidal product is used together with a bait. Both are located on an article when used, but do not come in contact with each other due to the design of the bait station. Both products are sold in the same packaging.	---
Degree of dissolution and dilution stability	---	---	Not applicable. The biocidal product is not a water soluble bag or tablet.	---
Surface tension	---	---	Not applicable. The biocidal product is solid and not liquid.	---
Viscosity	---	---	Not applicable. The biocidal product is solid and not liquid.	---

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

The bait station comprises the biocidal product (incl. the active substance permethrin) and a bait (in two sealed capsules). The biocidal product is a solid mixture which is odourless, milky white and has a relative density of 0.931.

The biocidal product is stable when stored in its original packaging at 20°C for 2 years. Shelf life: 2 years

The biocidal product shall be used in parallel with a bait. Both products are sold in the same packaging (ready to use bait station).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	---	---	Not explosive The active substance permethrin is not classified as explosive. There are no chemical groups present in the biocidal product that are associated with explosive properties.	---
Flammable gases	---	---	Not applicable. The biocidal product is a solid.	---
Flammable aerosols	---	---	Not applicable. The biocidal product is a solid and not an aerosol.	---
Oxidising gases	---	---	Not applicable. The biocidal product is a solid.	---
Gases under pressure	---	---	Not applicable. The biocidal product is a solid.	---
Flammable liquids	---	---	Not applicable. The biocidal product is a solid.	---
Flammable solids	---	---	The biocidal product is a solid mixture for which a test according to the CLP criteria of flammable solids is not feasible. In section 33.2.2.1 of the UN RTDG it is stated that Products should be classified according to the criteria in paragraphs 2.4.2.2.2 and 2.4.2.2.3 of the Model Regulations and paragraph 2.7.2 of the GHS, unless it is impracticable (e.g. because of the physical form) to perform the tests. Substances which cannot be tested should	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			be classified by analogy with existing entries (see paragraph 2.4.2.2.2.2 of the Model Regulations). The test method N.1 of the UN RTDG is referred to by CLP. UN test N.1 is applicable to granular, paste-like and powdery substances/mixtures.	
Self-reactive substances and mixtures	---	---	Not self-reactive. The active substance permethrin is not classified as self-reactive. There are no chemical groups present in the biocidal product, which are associated with self-reactive properties.	---
Pyrophoric liquids	---	---	Not applicable. The biocidal product is a solid.	---
Pyrophoric solids	---	---	Not pyrophoric The biocidal product is stable in air for prolonged periods of time and does not ignite when exposed to air.	---
Self-heating substances and mixtures			Not classified as self heating. The solid mixture has a melting point below 160°C.	---
Substances and mixtures which in contact with water emit flammable gases	---	---	Not classified The biocidal product does not contain any metals or metalloids. Therefore, the biocidal product is not classified as a mixture which in contact with water emits flammable gases.	---
Oxidising liquids	---	---	Not applicable.	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The biocidal product is a solid.	
Oxidising solids	---	---	Not oxidising The structure of the biocidal product does contain oxygen and halogens, which are chemically bonded only to carbon atoms.	---
Organic peroxides	---	---	Not applicable. The biocidal product does not contain any substance with a peroxide group (-O-O-) in the structure.	---
Corrosive to metals	---	---	Not applicable. The biocidal product is a solid mixture that does not become liquid below 55°C. Test is not applicable to solids.	---
Auto-ignition temperatures of products (liquids and gases)	---	---	Not applicable. The biocidal product is a solid.	---
Relative self-ignition temperature for solids	---	---	Permethrin: Auto-ignition temperature: >400 °C Flashpoint: >100 °C polyethylene: auto-ignition temperature: 330 - 410 °C	CAR International Chemical Safety Card: 1488 (https://inchem.org/documents/icsc/icsc/eics1488.htm)
Dust explosion hazard	---	---	No dust explosion hazard. The biocidal product does not form or produce dust if used as prescribed.	---

Conclusion on the physical hazards and respective characteristics of the product
The bait station comprises the biocidal product (incl. the active substance permethrin) and a bait (inside two sealed capsules). The biocidal product is a solid mixture which is not classified in any hazard category and is therefore neither flammable, nor oxidising, nor explosive, nor self-reactive.

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		
Permethrin (active substance)	GC-FID	100% 6 measurements	0.18 – 0.48 mg/mL R^2 > 0.99	No interference occurred. Method proved to be specific for the analyte.	96.5 – 106.2	100.8	3.4	Not determined. The method was developed to analyse the a.s. content in the biocidal product.	Anonymous 2016a

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin (active substance)									For more information on the active substance, please refer to CAR.

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin (active substance)									For more information on the active substance, please refer to CAR.

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin (active substance)									For more information on the active substance, please refer to CAR.

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin (active substance)									For more information on the active substance, please

									refer to CAR.

Analytical methods for animal and human body fluids and tissues									
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		
No data required. Permethrin is not classified as toxic or highly toxic. All other components of the biocidal product are also not classified as toxic or highly toxic. For details on the composition, please refer to the confidential annex. For more information on the active substance, please refer to CAR.									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
The biocidal products will not be used on any food or feed of plant and/or animal origin. Indirect exposure to permethrin as a result of contamination of food by the ants after contact with the bait station is theoretical possible but negligible, because in practice based on observations ants will go back to their nest after food intake in the bait station.									---

Conclusion on the methods for detection and identification of the product
The provided analytical method to determine the active substance content in the biocidal product could not be fully validated due to insufficient precision. The modified Horwitz ratio (HorRat) is above five for six independent measurements (usually a value below 2 is deemed acceptable). The complexity of the solid biocidal product and the analysis justify a higher HorRat in this case. The rMS is of the opinion, that the provided method is acceptable to analyse the active substance content in the biocidal product. Monitoring methods for the active substance permethrin in soil, air and water were provided in the CAR. Monitoring methods for animal and human body fluids and tissues as well as for the active substance and residues in food and feeding stuff are not deemed necessary.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The product is a ready-to-use bait station with a bait mixture against Black Garden ants (*Lasius niger*) for indoor use. Outdoor use is only in areas possible, which are well protected against rain, e.g. covered terrace.

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

Target organisms: Black Garden ants (all stages: eggs, larvae, nymphs, pupae, adults). The bait stations are set up indoors mainly for stored product protection and food protection. Also, restoring the well-being of people living in accommodations infested with ants is an important application aim. For outdoor applications the bait stations are set up mainly for material protection, for example on patios or terraces with hard surfaces.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The worker ants come in contact with the bait and thus also with the active substance permethrin, which is a contact insecticide that causes convulsions, paralysis and ultimately death in target organisms. The whole nest with all its developmental stages will be killed as the eggs and larvae are not cared for and die in consequence.
It should also be noted that permethrin may also exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is also common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lamdacyhalothrin) and is known as the "hot-foot effect" and may be relevant for some arthropods.
The repellent effect is dose related and for insecticidal products the repellent effect of permethrin is considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect.

2.2.5.4 Mode of action, including time delay

No time delay is expected. (Acute toxin: knock-down effect)
Permethrin it is a type I axonic poison which exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects. Pyrethroids act on the insect nervous system by slowing action potential decay and thereby initiating repetitive discharges in motor and sensory axons. Electrophysiological studies have suggested that these phenomena result from modification of the gating kinetics of neuronal, voltage-sensitive Na+ channels. Single channel studies have been conducted which have shown that pyrethroids slow the kinetics of opening and closing of Na+ channels. Type 1 pyrethroids produce a distinct poisoning syndrome characterised by progressive fine whole-body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. The effects are generated largely by effects in the central nervous system. Permethrin also induces hepatic microsomal enzymes.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide; Control of ants	*outdoor*	*VANDAL Ameisen-Frühstück/ Ameisen-Kombiköder*	*Lasius niger (nest)*	Field test	1 bait station per nest; 3 replicates, 3 controls; 1.5 g biocidal product (3.6% Permethrin). A product with a 2 chamber system (first activated at test start, second chamber activated after 1 week	Using 1 bait station per nest, achieved nest kill. After 1 to 2 weeks no more activity was observed. The effect was confirmed by excavation of the nests after 2 to 3 weeks.	*Anonymous 2015*
Insecticide Control of ants	*Indoor*	*VANDAL Ameisen-Frühstück/ Ameisen-Kombiköder*	*Black garden ants, Lasius niger, workers*	Lab test: Method no. BioGB 413-02 (modiifie d)	1 bait station per replicate/arena; 500 worker ants per replicate. 5 replicates/5 controls. 1.5 g biocidal product (3.6% Permethrin). A product with a 2 chamber system (first activated at test start, second chamber activated after 1 week	Mean values (% dead ants) of 5 replicates: After 1 week: 88% mortality 2: 98% 3: 99% 4: 99% Controls: week 1: 2% 2: 3% 3: 4% 4: 7%	*Anonymous 2020a*
Insecticide Control of ants	*Indoor*	*VANDAL Ameisen-Frühstück/ Ameisen-Kombiköder 4 years aged*	*Black garden ants, Lasius niger, workers*	Simulated use test	1 bait station per replicate/arena; 500 worker ants per replicate. 5 replicates/5 controls; 1.5 g	Mean values (% dead ants) of 3 replicates: After 1 week:	*Anonymous 2020b*

					biocidal product (3.6% Permethrin). A product with a 2 chamber system (first activated at test start, second chamber activated after 1 week	72% mortality 2: 83% 3: 91% 4: 94% Controls: Week 1: 5% 2: 5% 3: 9% 4: 10%	

Conclusion on the efficacy of the product
According to the BPR Guidance on Efficacy (Parts B+C, ECHA 2018), the following requirements have to be fulfilled for products intended for use as baits: A laboratory palatability choice test showing at least 95% mortality, a simulated-use test showing > 90% population reduction and a field test showing > 90% population reduction after a period of 2-4 weeks. The product tested in a laboratory test shows >95% mortality after 2 weeks. Since an alternative food source was also tested, the efficacy proofs sufficient palatability. A robust field trial was submitted showing nest kill after 2-3 weeks and thus a sufficient population reduction compared to untreated sites. A simulated-use test with the fresh product was waived since the field trial sufficiently fulfils the requirements, what is also in-line with the Efficacy Guidance ("*Sim-Use Tests can be waived if a robust field trial is submitted*"). A simulated use trial was submitted with a 4-years aged product showing > 90% population reduction. Thus, the efficacy (and palatability) is also sufficiently proven with the aged product and the claimed shelf-life of 2 years is supported. In each test, 1 ready-to-use bait station with a bait mixture per nest/arena was used. The presented efficacy studies sufficiently support the claims of the product and fulfil the requirements of the BPR Efficacy Guidance.

2.2.5.6 Occurrence of resistance and resistance management

Due to a high selection pressure through repetitive Insecticide treatments, this can educate arthropod pest's mechanisms leading to a genetically fixed reduced sensitivity (resistance) to insecticides. Target organisms can develop resistance with long-term use of a single active ingredient. Just like improper use that can also accelerate development of resistance, especially when under dosing, lack of follow-up treatments or incomplete deployment is applied.

For the use of permethrin against ants the probability of resistance is very low: The ants get unnoticed "dusted" with the active substance and transmit it to the rest of the ant conoly in the nest. As they still feed and care for the queen, they "contaminate" her and she dies in consequence. 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.

However, resistance of ants to permethrin, is not reported up to date in the scientific literature.

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

- Products should always be used in accordance with label recommendations
- The users should inform if the treatment is ineffective and report straightforward to the authorisation holder.

2.2.5.7 Known limitations

The bait station has to be placed in an absolutely dry area. Otherwise the bait will be washed out and the bait station has no more attracting effect.

2.2.5.8 Evaluation of the label claims

The following label claims are to be included:

- One single bait station shows sufficient efficacy after 2 weeks.
- Efficacious for up to 4 weeks.
- Kills ants (queen, eggs, larvae, adults) and their nests.

The mentioned label claims, as well as the field of application and the application rates and frequencies reflect the results of the efficacy tests.

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

According to the Applicant, the use with other biocidal products is not intended.

2.2.6 Risk assessment for human health

No new studies with the biocidal product have been performed, the effect on human health are calculated in sense of CLP Regulation No. 1272/2008 on basis of existing data.

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	The biocidal product does not require a classification as a skin irritant according to Regulation (EC) No. 1272/2008.
Justification for the value/conclusion	See table "Data waiving" below.
Classification of the product according to CLP and DSD	The biocidal product does not require a classification as a skin irritant according to Regulation (EC) No. 1272/2008.

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	No skin irritation/corrosion studies have been carried with the biocidal product. The potential to cause skin irritation can be deduced from the properties of the active substance (Ireland 2014) and co-formulants.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The biocidal product does not require a classification as an eye irritant according to Regulation (EC) No. 1272/2008.
Justification for the value/conclusion	See table "Data waiving" below.
Classification of the product according to CLP and DSD	The biocidal product does not require a classification as an eye irritant according to Regulation (EC) No. 1272/2008.

Data waiving	
Information requirement	Eye irritation
Justification	No eye irritation studies have been carried out for the biocidal product. The potential to cause eye irritation can be deduced from the properties of the active substance (Ireland 2014) and co-formulants.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	See table "Data waiving" below.
Classification of the product according to CLP and DSD	The biocidal product does not require classification as a respiratory tract irritant according to Regulation (EC) No. 1272/2008.

Data waiving	
Information requirement	Respiratory tract irritation
Justification	No respiratory tract irritation studies have been carried out for the biocidal product. There is no evidence that the active substance has irritative effects to the respiratory tract. Specific testing for respiratory irritation is not required.

Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The biocidal product require classification as a skin sensitiser according to Regulation (EC) No. 1272/2008.
Justification for the value/conclusion	According to the calculation procedure outlined in the CLP Regulation. The active substance permethrin is harmonised classified as Skin Sens. 1 H317.
Classification of the product according to CLP and DSD	Skin Sensitizer category 1 H317: May cause an allergic skin reaction.

Data waiving	
Information requirement	Skin sensitisation
Justification	No skin sensitisation studies have been carried out for the biocidal product. The potential to cause skin sensitisation can be deduced from the properties of the active substance permethrin, which is harmonised classified as Skin Sens. Cat. 1.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The biocidal product does not require classification as a respiratory sensitiser according to Regulation (EC) No. 1272/2008.
Justification for the value/conclusion	See table "Data waiving" below.
Classification of the product according to CLP and DSD	The biocidal product does not require classification as a respiratory sensitiser according to Regulation (EC) No. 1272/2008.

Data waiving	
Information requirement	Respiratory sensitisation
Justification	No respiratory sensitisation studies have been carried out for the biocidal product. Specific testing for respiratory sensitisation is not required and is not possible in the absence of any recognised and validated test method.

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
-	rat	Permethrin	-	480-1623 mg/kg bw		(Ireland 2014)

The active substance is harmonized classified for Acute Tox 4* H302+H332: Harmful if inhaled and swallowed.

Value used in the Risk Assessment – Acute oral toxicity	
Value	The biocidal product does not require classification for Acute Toxicity (oral) according to Regulation (EC) No. 1272/2008.
Justification for the selected value	ATE mix (calculated) > 13000 mg/kg bw
Classification of the product according to CLP and DSD	No acute toxicity studies are available with the biocidal product. According to the calculation method the biocidal product does not need to be classified for acute toxicity via the oral route.

Acute toxicity by inhalation

No detailed test data of permethrin are known. Data submitter has a Letter of Access.

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
-	rat	Permethrin	-	not exactly determined	-	(Irland 2014)

The active substance is harmonized classified for Acute Tox 4* H302+H332: Harmful if inhaled and swallowed.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	The biocidal product does not require classification for Acute Toxicity (inhalation) according to Regulation (EC) No. 1272/2008.Not acute toxic by inhalation
Justification for the selected value	ATE mix (calculated) > 290 mg/l
Classification of the product according to CLP and DSD	No acute toxicity studies are available with the biocidal product. According to the calculation method the biocidal product does not need to be classified for acute toxicity via the inhalation route.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
-	rat	Permethrin	-	> 2000 mg/kg bw	-	(Irland 2014)

Value used in the Risk Assessment – Acute dermal toxicity	
Value	The biocidal product does not require classification for Acute Toxicity (dermal) according to Regulation (EC) No. 1272/2008.
Justification for the selected value	ATE mix (calculated) > 50000 mg/kg bw
Classification of the product according to CLP and DSD	No acute toxicity studies are available with the biocidal product. According to the calculation method the biocidal product does not need to be classified for acute toxicity via the dermal route.

Information on dermal absorption

No detailed test data of permethrin are known. Data submitter has a Letter of Access.

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Permethrin		
Value(s)	25%		
Justification for the selected value(s)	The EFSA default value of 25% for concentrated products (EFSA, 2017) is used for accidental exposure calculations. According to APP the dermal absorption value of 3% set in the CAR of the active substance permethrin could be used for the risk assessment. The dermal absorption value set in the CAR for a liquid formulation (EC formulation) is considered as a worst case for the solid product Ameisen-Frühstück/Ameisen Kombiköder. Dermal exposure is not possible when the product is used as intended, since the biocidal product (PE frame) is protected by a polymer box, which should not be opened.		

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

No substance of concern was identified in the biocidal product.

Available toxicological data relating to a mixture

No data available.

2.2.6.2 Exposure assessment

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.	no	no
Dermal	n.a.	n.a.	no	n.a.	n.a.	no[1]	no
Oral	n.a.	n.a.	no	n.a.	n.a.	no[1]	no

[1] Exposure of the general public is considered to be not relevant. Nevertheless, dermal and oral exposure cannot be excluded fully assuming an activated bait station is tilted and bait (liquid) leaks out. A bait station might also get broken by accident. These cases will be discussed in the following risk assessment section.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Use	The biocidal product is contained in a polymer station, which should prevent any direct contact. If used as prescribed, no dermal or oral exposure to humans is expected. Inhalation exposure is considered to be negligible based on the low vapour pressure of the active substance ($2.155x10^{-6}$ Pa at 20°C).	Non-professional
2.	Exposure to contaminated bait	Exposure to the active substance cannot be excluded fully, if the bait station is tilted and bait leaks out. A bait station might also get broken by accident and release contaminated bait. Dermal and oral exposure cannot be excluded fully for adults, children or toddlers in such situations.	General public

Industrial exposure

Scenario

No industrial exposure foreseen.

Professional exposure

Scenario

No Professional exposure foreseen.

Non-professional exposure

Scenario 1: Use

Description of Scenario 1: Use
The biocidal product is sold as bait boxes. The polymer frame containing the active substance is hidden inside the bait station. Direct contact with the frame is considered to be not possible in common. On the upper part of the bait station there are two openings, which allow the user to open the bait capsules by squeezing down. The bait is then running down into the trap, which gets activated in this way. The user is expected to be not exposed to the bait. Exposure to contaminated bait might be only possible, if the bait station is tilted (and bait leaks out) or broken by accident. These situations are considered to be less likely and occur infrequently, cf. to scenario 2. Conclusion: Dermal and oral exposures of users are not expected in general, if the bait stations are used as envisaged. Inhalation exposure is considered to be negligible based on the low vapour pressure of the active substance (2.155×10^{-6} Pa at 20°C).

Calculations for Scenario [1]
Not relevant.

Further information and considerations on scenario [1]
None.

Exposure of the general public

Scenario 2: Exposure to contaminated bait

Description of Scenario 2: Exposure to contaminated bait

Assuming an adult steps on a bait station, it gets broken or a child/toddler shakes the bait station, contaminated bait (liquid) could be released. Therefore, dermal and oral exposure of the general public cannot be excluded fully.

Potential for risk via inhalation route

Inhalation exposure is considered to be negligible based on the low vapour pressure of the active substance (2.155×10^{-6} Pa at 20°C). In addition the polymer containing the active substance and the viscous bait offer no potential for aersol formation.

Potential for risk via dermal and oral route

Adults: Assuming an adult steps on a bait station and it gets broken, direct contact with the content of the bait station is possible (e.g. contaminated, liquid bait, polymer containing the active substance). Whereas oral exposure can be excluded for adults, dermal exposure is possible during disposal of bait station parts and cleaning the area.

A single bait station contains 1.5 g biocidal product (3.871% a.s.). This corresponds to 54 mg active substance. Considering a dermal absorption of 25% and a bodyweight of 60 kg, results in a maximum possible systemic exposure level 0.242 mg/kg bw/d. This value is considered to be conservative, as exposure to the full amount of active substance and full release and transfer from polymer to skin are assumed in this estimate. The polymer is not expected to release the full amount of active substance under real conditions in this case.

Toddlers, children: Toddlers might be unlikely to open/destroy a bait station, whereas this might be more likely for children. Toddlers might shake the bait station during playing with them and contaminated bait might be released via the openings. Assuming dermal exposure to the active substance content of one bait station like in the scenario for adults. higher systemic exposure levels are predicted for toddlers and children due to their lower bodyweights (10 kg[2], 15.6 kg[2]). The derived exposure levels for dermal exposure are: 1.452 mg/kg bw/d and 0.931 mg/kg bw/d.

The highest level of exposure is identified towards oral exposure assuming that a bait station is destroyed, and a toddler/child chews or even swallows the polymer containing the active substance, as oral absorption is expected to be 100% in the absence of any data.

The derived exposure levels are: 5.8 mg/kg bw/d and 3.7 mg/kg bw/d for toddlers and children.

	Parameters	Value
Tier 1 Adult	Biocidal product per bait station	1.500 mg
	Active substance content[1]	3.871%
	Active substance per bait station[1]	58.065 mg/box
	Dermal absorption	25%

	Bodyweight[2]	60 kg
	Dermal systemic exposure	0.242 mg/kg bw/d
Tier 1 Toddler, child	Biocidal product per bait station	1.500 mg
	Active substance content	3.871%
	Active substance per bait station	58.065 mg/ bait station
	Dermal absorption	25 %
	Bodyweight: toddler/child	10 kg/15.6 kg
	Dermal systemic exposure: toddler Dermal systemic exposure: child	1.452 mg/kg bw/d 0.931 mg/kg bw/d
	Oral systemic exposure: toddler Oral systemic exposure: child	5.8 mg/kg bw/d 3.7 mg/kg bw/d

1 Company statement
2 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products

Calculations for Scenario 2: Exposure to contaminated bait

Summary table: systemic exposure of general public					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated oral uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
Scenario 2: Adult	Tier 1 /no	n.r.	0.242	n.r.	0.242
Scenario 2: Toddler Child	Tier 1 /no	n.r.	1.452 0.931	5.8 3.7	5.8 3.7

Further information and considerations on scenario 2: *Exposure to contaminated bait*

None.

Combined scenarios

Not relevant.

Monitoring data

No data available.

Dietary exposure

The biocidal products will be not used on any food or feed of plants and/or animal origin.
Ants may crawl after contact with the biocidal product on food and as a result will contaminate it with permethrin, which is on their feet and feels. In practice it is negligible, because based on observations ants will go back to their nest after food intake in the bait station.
Contamination of foodstuff is highly unlikely, but for precautionary reasons use instruction is listed: The product should be applied so that pets, food, feedstuff and livestock do not come in contact with the product.

Information of non-biocidal use of the active substance

No non-biocidal use.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Livestock exposure is not foreseen.

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

Professional or industrial use is not intended.

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

Scenario

Indirect exposure to permethrin as a result of contamination of food by the ants is theoretical possible but unlikely, because in practice based on observations ants will go back to their nest after food intake in the bait station.

Conclusion.

Transfer of the active substance into food is considered to be negligible.

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

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR. It is assumed that the production is performed in conformity with national and European occupational safety and health regulations.
In addition, production or formulation of biocidal products are already covered by REACH legislation, where the registrants (manufacturers/importers) of substances are obliged to consider human hazard and exposure and to provide RMMs/exposure scenarios for ensuring safe use (e.g. via SDS in the supply chain). Moreover, it is assumed that industrial production

sites are subject to permit for installation. Therefore, it is not considered relevant to perform an additional exposure assessment under the biocide regime.

Aggregated exposure

Will be assessed once the methodology has been developed.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/d]**
1.	Non-professionals	Tier 1/no	N/A
2.	General public: Adult	Tier 1/no	0.242
2.	General public: Toddler	Tier 1/no	5.8
2.	General public: Child	Tier 1/no	3.7

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term Permethrin	Rat 2year oral study (acute effects)	59.43 mg/kg bw/d	100		0.5 mg/kg bw/d
AELmedium-term Permethrin	12 month dog study	172 mg/kg bw/d	100		0.05 mg/kg bw/d
AELlong-term Permethrin	12 month dog study		100		0.05 mg/kg bw/d
ARfD Permethrin					0.5 mg/kg bw/d
ADI Permethrin					0.05 mg/kg bw/d

[1] Please explain background and reason for assessment factor.

Risk for industrial users

Industrial use is not foreseen.

Risk for professional users

Professional use is not foreseen.

Risk for non-professional users

If used as prescribed, no dermal and oral exposures to humans are expected. (The biocidal product is kept in a polymer bait station, which should prevent any direct contact).
Inhalation exposure is considered to be negligible based on the low vapour pressure of the active substance (2.155×10^{-6} Pa at 20°C).

Risk for the general public

Human exposure of the general public is considered to be not relevant, if the bait station is applied correctly and no accidents occur.

Assuming an adult steps on a bait station or a child or toddler shakes the bait station, liquid bait might be released. Dermal and oral exposure of the general public and pets cannot be excluded fully in these cases. These potential scenarios have been assessed (Scenario 2), even if they are considered to be unlikely and not relevant in common.

Table: Risk characterisation*

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 2: exposure to contaminated bait (adult)	1	59.43 mg/kg bw d	0.5 mg/kg bw/d	0.242 mg/kg bw/d	48	YES
Scenario 2: exposure to contaminated bait (toddler) – dermal exposure	1	59.43 mg/kg bw d	0.5 mg/kg bw/d	1.452 mg/kg bw/d	290	NO
Scenario 2: exposure to contaminated bait (child) – dermal exposure	1	59.43 mg/kg bw d	0.5 mg/kg bw/d	0.931 mg/kg bw/d	186	NO
Scenario 2: exposure to contaminated bait (toddler) – oral exposure	1	59.43 mg/kg bw d	0.5 mg/kg bw/d	5.8 mg/kg bw/d	1160	NO
Scenario 2: exposure to contaminated bait (child) – oral exposure	1	59.43 mg/kg bw d	0.5 mg/kg bw/d	3.7 mg/kg bw/d	740	NO

* the presented scenarios are worst case scenarios based on the assumption that a.s. can be released by broken bait stations

If any exposure takes place accidently (destroying the bait station) and adults might be exposed dermally to the bait station content while throwing the contaminated bait box away and cleaning the contaminated area no unacceptable risk occurs.

The worst case scenario presented for toddlers and children, which open the bait station and come into contact dermally or orally with the content of the bait station, does imply a health risk. However, the scenario is considered very conservative since the default dermal absorption value might be too conservative and it is rather unlikely that contact to the whole a.s amount takes place.

Nevertheless following risk mitigation measure is provided: Keep out of the reach of children and non-target animals/pets.

Risk for consumers via residues in food

Contamination of foodstuff is highly unlikely, but for precautionary reasons following use instruction is listed: The product should be applied so that pets, food, feedstuff and livestock do not come in contact with the product.

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

Not applicable. The active substance is the only substance of concern in the biocidal product.

2.2.7 Risk assessment for animal health

The biocidal product is placed in a closed bait station which prevents direct contact of cats and dogs to the biocidal product. Inhalation is not considered to be relevant during application.

Nevertheless, low levels of permethrin might be carried out from the bait station by the ants.
Permethrin could stay on the tracks or remain on killed ants. Therefore, some exposure of cats and dogs cannot be ruled out. Regarding veterinary monitoring is that cats are more sensitive to permethrin than for dogs.

Therefore, the following risk mitigation measures are applied:
N-316: Keep out of the reach of children and non-target animals/pets.
N-335 (modified): Keep cats away. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats.

Furthermore following use instruction is applied: The product should be applied so that pets, food, feedstuff and livestock do not come in contact with the product.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The active substance permethrin has been evaluated according to the Regulation (EU) No 528/2012 for its use as insecticide (PT18). A final assessment report (AR) as agreed by the EU member states and the European Commission is available (Ireland 2014). An addendum to the CAR (Ireland 2017) with an agreed different $PNEC_{soil}$ for permethrin is available at ECHAs website. A full letter of access was submitted by the applicant. However only the risk for secondary poisoning for birds was calculated in the environmental risk assessment (refer to 2.2.8.3 risk characterisation).

The following PNECs for the active substance permethrin and its relevant metabolites are reported in the CAR for permethrin (Ireland 2014). Furthermore the following $PNEC_{soil}$ for permethrin is reported in the addendum to the CAR (Ireland 2017):

	Permethrin	DCVA	PBA
PNECsurface water	4.7E-07mg/L	1.5E-02mg/L	1.0E-02mg/L
PNEC sediment	2.17E-04mg/kg_{wwt}	1.2E-02mg/kg_{wwt}	9.0E-03mg/kg_{wwt}
PNEC STP	4.95E-03mg/L	-	-
PNEC soil	0.175mg/kg_{wwt}	4.6mg/kg_{wwt}	1.44mg/kg_{wwt}
PNECoral bird	16.7mg/kg food	-	-
PNECoral mammal	120mg/kg food	-	-

Bees:

In the CAR for permethrin (Ireland 2014) toxicity data for honeybees with an acute LD_{50} oral of 0.163 µg/bee and an LD_{50} contact of 0.02 µg/bee were reported.
Because the product is also used outdoor and the lowest reported LD_{50} contact for honeybees is below the discussed and agreed threshold of 11µg/bee (discussed and agreed at ENV WG-III 2021) the warning sentence "This biocidal product contains permethrin which is dangerous to bees" (in line with "CA-Dec20-Doc.4.1 Warning sentence and RMM for bees_finalrev2") will be included in the SPC. The warning sentence is an interim solution until the ECHA guidance for bees becomes available.

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

Valid data concerning the ecotoxicological effects of the components in the biocidal product are available. The ecotoxicological effects of the product are solely based on the active substance permethrin. Further effects or synergies between co-formulants and the active substance are not expected. Additional acute and/or chronic aquatic toxicity studies for the active substance or the biocidal product have not been submitted. According to the Reg. (EC) No 1272/2008 the harmonised classification and labelling of permethrin for its environmental effects is Aquatic Acute 1, H400 and Aquatic Chronic 1, H410 (M=1000). In the CAR for permethrin (Ireland 2014) a classification as Aquatic Acute 1 (M=100) and Aquatic Chronic 1 (M=10000) was proposed.
According to the content of permethrin in the biocidal product of 3.871 % (w/w) it has to be classified for environmental hazards as Aquatic Acute 1 (H400) and Aquatic Chronic 1

(H410). Therefore, the biocidal product has to be labelled with the hazard statement H410 Harmful to aquatic life with long lasting effects and the precautionary statements P273, 391 and P501.

Further Ecotoxicological studies

No new data were submitted, neither for the active substance nor for the biocidal product. The only relevant substance in the product is the active substance permethrin and the risk assessment is based on the data available from the CAR for permethrin (Ireland 2014) and the addendum to the CAR (Ireland 2017).

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

No new data were submitted, neither for the active substance nor for the biocidal product. The only relevant substance in the product is the active substance permethrin.

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

Supervised trials to assess risks to non-target organisms under field conditions are not available and not considered necessary as the product is used in a closed bait station which prevents the access to the bait for other pollinators or non-target organisms. Furthermore the product is used on terraces on hard surfaces which are artificial and unhospitable environments for any kind of non-target insects or arthropods.

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

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk are not available and not considered necessary as the product itself is no baits or granules. The product is furthermore used in a closed bait station.

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

Not regarded as necessary since no large proportion of a specific habitat will be treated.

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

Foreseeable routes of entry into the environment are described in detail in section Fate and distribution in exposed environmental compartments.

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

No new data were submitted, neither for the active substance nor for the biocidal product. The only relevant substance in the product is the active substance permethrin.

Leaching behaviour (ADS)

Not necessary for the biocidal product. No treated articles.

Testing for distribution and dissipation in soil (ADS)

No new data on distribution and dissipation of permethrin in soil are available.

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

No new data on distribution and dissipation of the active substance permethrin in water and sediment are available.

Testing for distribution and dissipation in air (ADS)

No new data on distribution and dissipation of the active substance permethrin in air are available.

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

Not applicable. The product is not intended to be sprayed near to surface waters.

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

Not applicable. The product is not intended to be applied as spray.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Indoor use and outdoor use (outdoor only on paved surfaces well protected from rain, e.g covered terrace)
ESD(s) used	OECD 2008: Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses. OECD series on Emission scenario documents, number 18; ENV/JM/MONO(2008)14; 17-Jul-2008 ECHA 2021: Technical Agreements for Biocides Environment (ENV), Release date: 9 November 2021
Approach	Average consumption
Distribution in the environment	For this product emissions are unlikely to occur
Groundwater simulation	For this product emissions are unlikely to occur
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	None

Environmental exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR. These life cycle steps are already covered by REACH legislation, where the registrants (manufacturers/importers) of substances are obliged to consider environmental hazard and exposure and to provide RMMs/exposure scenarios for ensuring safe use (e.g. via SDS in the supply chain). Moreover, it is assumed that industrial production sites are subject to permit for installation. Therefore, it is not considered relevant to perform an additional exposure assessment under the biocide regime.

The environmental exposure to permethrin is assessed for the use of the biocidal product as an insecticide (product type 18) for the non-professional use against ant infestation in and around buildings, in locations such as balconies and terraces. No further substances of environmental concern are present in the product in relevant concentrations. Therefore the provided environmental exposure assessment has only been performed for the active substance permethrin.
It should be noted that if emissions to water and soil accrue, an exposure assessment must also be conducted for the two identified relevant metabolites of permethrin, 3-(2,2-dichlorovinyl)-2,2-dimethyl (1-cyclopropane) carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA).

Emission estimation

In the following the main destination of the insecticide after application according to user´s instructions is identified by focusing on methods to estimate the emission rate of insecticides to the primary receiving environmental compartments.

The ESD for PT 18 for insecticides covers the following life-cycle steps as being potentially relevant for environmental emissions:

- Preparation step (mixing/loading)
- Application
- Releases from indoor treated surfaces by cleaning events and outdoor treated surfaces by weathering.

According to the applicant the ant trap is intended to be used indoors and outdoors on hard surfaces like terraces, but has always to be very protected from rain and humidity.
It is a "ready-to-use" bait station, a covered system, which has an inside polymer ring containing the active substance permethrin. The ants can easily get inside the bait station, and as the frame is covered by the lid emissions to the environment during use are prevented. In addition, permethrin is not able to evaporate out of the bait station, as the evaporation rate of permethrin is very low.
Due to this kind of formulation, the following release pathways can be excluded or can be identified to be relevant for environmental exposure:

Information regarding environmental exposure during mixing/loading of biocidal product

For this product there is no preparation step (as the stations are provided "ready-to-use").

Information regarding environmental exposure during application of biocidal product

Indoor:

The Emission Scenario Document for PT18 (OECD 2008) assumes that emission of the active substance after indoor application in bait stations is negligible.
Therefore releases arising from indoor use have not been considered further.

Outdoor:

It was agreed (Technical Agreements for Biocides, ENV 158; ECHA 2021) that no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment if the product is intended either for use in bait stations (general public and professionals) or for any professional use, but only used on paved surfaces, and not on bare soil and the product is to be applied in roof-covered areas, which cannot be affected by flooding, and which are protected from rain fall or cleaning wash, thus emissions are unlikely to occur. A risk assessment for primary/secondary poisoning according to Emission Scenario Document for PT18 however needs to be performed.
In line with the assessment report for permethrin (Ireland 2014) and based on the low vapour pressure (2.155×10^{-6} Pa at 20°C) and Henry constant (4.6×10^{-3} Pa m^3 mol^{-1}) of the active substance decontamination of air after exposure to the product is considered to be negligible.
Therefore releases arising from outdoor use have not been considered further.

Information regarding environmental exposure during cleaning step

For this product there is no loss from rinsing or cleaning as the bait station containing any remaining product can easily be picked up and disposed to disposed of according to local regulations for hazardous waste collection.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
	Surface water	**Sediment**	**STP**	**Air**	**Soil**	**Ground-water**	**Secondary poisoning**
Indoor use and outdoor use	no	no	no	no	no	no	yes

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Vapour pressure (at 20 °C)	2.155×10^{-6}	Pa	---
Log Octanol/water partition coefficient	4.67 (fish) 6.1 (earthworm)	Log 10	---
Henry's Law Constant	4.6×10^{-3}	$Pa/m^3/mol$	
Bioconcentration factor fish (BCF_{fish})	570	L/kg	
Bioconcentration factor earthworm ($BCF_{earthworm}$)	15108	L/kg	

Calculated PEC values

Summary table on calculated PEC values						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/m^3]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
Indoor use and outdoor use	Releases arising from outdoor use have been considered negligible. Therefore, no PECs have been calculated.					

Primary and secondary poisoning

Log K_{ow} values above 3 at pH 7 or higher indicate that bioaccumulation can occur. As reported in the Assessment Report of permethrin (Ireland 2014), the log Kow of permethrin was experimentally determined as 4.67 (fish) 6.1 (earthworm), indicating it is a fat-soluble molecule with a potential to bioaccumulate. Furthermore, the highest experimentally determined BCF was $BCF_{earthworm}$ = 15108 L/kg or BCF_{Fish} 570 L/kg, which is above the trigger value for bioaccumulation potential.
Therefore, for primary and secondary poisoning an assessment is made.

Primary poisoning

Primary poisoning via direct consumption of insecticide by birds or mammals
Primary poisoning is the direct consumption of insecticide by birds or mammals. The Emission Scenario Document for PT18 (OECD 2008) states that primary poisoning is only relevant for uses such as granules and concludes that other uses pose no risk via direct uptake. Therefore, primary poisoning of non-target organisms is considered not applicable since the biocidal product is placed in a polymer bait station, which should prevent any direct contact.

Primary poisoning via direct consumption of insecticide by bees
Permethrin is known to be toxic to bees. However, direct contact to permethrin is prevented if the biocidal product is used as prescribed (closed polymer bait station).
Furthermore, no guideline is available to calculate the risk for bees due to exposure from biocidal use of insecticides, as described in paragraph "2.2.8.1 Effect assessment on the environment".

Secondary poisoning

The Emission Scenario Document for PT18 (OECD 2008) states that during the outdoor use of insecticides, the most important route of exposition is the intake of contaminated feed. Non-target animals have potentially a risk of secondary poisoning in the following ways:
(1) By consumption of worms from contaminated soil,
(2) By consumption of contaminated vegetation and
(3) Through eating treated insects that have ingested the poison.

In consideration of the intended use of the biocidal product the assessment of secondary poisoning via consumption of contaminated insects (ants) is carried out (i.e. calculation of ETE for (3)). A risk for secondary poisoning by consumption of contaminated vegetation, earthworms or fishes is not considered applicable for insecticides use in bait stations only used on roof-covered paved surfaces, which cannot be affected by flooding, and which are protected from rain fall or cleaning wash.

Secondary poisoning via the consumption of contaminated ants:
For the assessment of secondary poisoning via the consumption of contaminated ants by insectivorous species, ETE is calculated form the ESD using the following equation:

$$\mathbf{ETE = C_{ant} \times (FIR/bw) \times AV \times PT \times PD}$$

In line with the ESD for PT 18, concentration of active substance in contaminated ants can be estimated on the basis of the following equation:

$$\mathbf{C_{ant} = RUD \times T_{appl} \times 10^{-4}}$$

The total application rate of biocidal product per square meter (T_{appl}) was calculated for 4 bait stations on a terrace with a size of 30 m². One bait station contains 1.5 g biocidal product, 3.87 % (w/w) of which correspond to the a.s permethrin.

	Calculation of the permethrin application rate	
	Definition	
Amount of product per baid station [g]	Q_{prod}	1.5
Fraction of active substance in product [-]	F_{AI}	0.0387
Number of application sites per terrace [-]	N_{sites}	4
Area of the treated terrace [m²]	$AREA_{terrace}$	30
Application rate [kg/m²]	**$T_{appl} = ((Q_{prod} \times F_{AI} \times N_{sites}) / AREA_{terrace}) / 1000)$**	**$7.7x10^{-6}$**

In a second step, the permethrin 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 birds).
In table 5.2-1 of the ESD for PT 18 insectivorous mammals are always assumed to eat large insects. Therefore an assessment for mammals is not considered applicable in this case. Small birds are assumed to prefer small insects, so the residues (RUD) for small insects are the default values in the case of birds in order to cover the worst case. According table 5.2-7 typical residues in contaminated small insects are 52 mg/kg wet weight for the acute situation and 29 mg/kg wet weight for the short term toxicity assessment.
Food intake rates per body weight (FIR /bw) for small insectivorous birds of 1.04 and 0.2 are listed in the table.
In a first tier the ETE values are calculated assuming the standardised worst-case scenario for the rest of the parameters.

Calculation of the Permethrin concentration in the fresh diet			
	Definition		
		Acute	**Short-term**
Application rate [kg x m^{-2}]	T_{appl}	$7.7x10^{-6}$	
Residue per unit dose [mg x kg^{-1}]	RUD	52	29
Predicted environmental concentration in ants [mg × kg^{-1}]*	C_{ant} = RUD x T_{appl} x 10^{-4}	$4.0 x10^{-8}$	$2.2 x10^{-8}$
Food intake rates per body weight-Small insectivorous bird I [d^{-1}]	FIR /bw	1.04	
Food intake rates per body weight-Small insectivorous bird II [d^{-1}]	FIR /bw	0.2	
Avoidance factor of contaminated food (AV=1, no avoidance) [-]	AV	1	
Proportion of diet obtained in treated area [-]	PT	1	
Proportion of food type (vegetation or insects) in the diet of specie of concern [-]	PD	1	
Estimated theoretical exposure- Small insectivorous bird I (e.g. Wren) [mg x kg_{bw}^{-1}x d^{-1}]	ETE= C_{ant} x (FIR/bw) x AV x PT x PD	$4.2x10^{-8}$	$2.3x10^{-8}$
Estimated theoretical exposure- Small insectivorous bird II (e.g. Tree sparrow) [mg x kg_{bw}^{-1}x d^{-1}]		$8.0x10^{-9}$	$4.4x10^{-9}$

* For household insecticides, the application rate is usually provided as kg/m². Therefore, an additional factor of 10^{-4} has to be added to convert T_{appl} into kg/ha.

Summary table on estimated theoretical exposition (ETE)				
	Small Insectivorous bird I		Small Insectivorous bird II	
	Acute	Short term	Acute	Short term
Estimated theoretical exposure [mg x kgbw-1x d-1]	**$4.2x10^{-8}$**	**$2.3x10^{-8}$**	**$8.0x10^{-9}$**	**$4.4 x10^{-9}$**

2.2.8.3 Risk characterisation

2.2.8.4 Risk characterisation for receiving compartments

A risk characterisation for the biocidal product for the aquatic and soil compartment is not considered as necessary, because no exposure due to its design and use is assumed and therefore no PECs were calculated (refer to 2.2.8.2 Exposure assessment, chapter Information regarding environmental exposure during application of biocidal product emission estimation of this report).

A risk assessment for primary poisoning was not assessed and secondary poisoning only for the ingestion of contaminated ants for birds.

Primary and secondary poisoning

Primary poisoning

The proposed uses of the product preclude any exposure via primary poisoning, given that the product does not occur in a form that would allow uptake by non-target organisms. Furthermore the product is placed inside a bait station only with small holes as entrance for ants on artificial environments, which are not attractant for any kind of non-target organisms. Therefore the risk for primary poisoning for birds and mammals and others (e.g. pollinators) can be considered negligible.

Birds and mammals

The product is enclosed in a bait station with only small holes as entrances for ants. Hence the risk of primary poisoning for birds and mammals from the outdoor use of the biocidal product is considered negligible.

Bees

The risk for bees was taken into account via the application of the warning sentence (for further information refer to section 2.2.8.1 Effect assessment on the environment.

Secondary poisoning

Secondary poisoning can occur when contaminated food (ants) are eaten up from birds. Hence a risk assessment for birds eating contaminated ants was conducted.

Secondary poisoning by contaminated feed (ants)

The risk ratios for secondary poisoning via the ingestion of contaminated ants were calculated for two small insectivorous bird species.

For the acute toxicity scenario the lowest reported oral acute LD_{50} for birds in the CAR for permethrin is 4640mg/kg bw (Ireland, 2014). For the short term scenario the lowest reported dietary LC_{50} value for birds (8-day dietary study, refer to Doc IIIA A7.5.3.1.2) is 10000ppm which corresponds to 10000mg/kg bw (CAR, IE 2014; Doc IIIA A7.5.3.1.2). In order to take into account the interspecific variation for birds for both scenarios an AF of 3000 was applied for both time frames (ECHA, 2017).

Summary table on secondary poisoning via contaminated ants				
Scenario	**ETE [mg/kg bw]**	**LD50 (acute) LC50 (short term) [mg/kg bw]**	**AF**	**ETE/LD_{50} or LC_{50}**
acute toxicity (small insectivorous bird I)	4.2E-08	4640	3000	2.72E-08
short term toxicity (small insectivorous bird I)	2.3E-08	10000	3000	6.90E-09
acute toxicity (small insectivorous bird II)	8.0E-09	4640	3000	5.17E-09
short term toxicity (small insectivorous bird II)	4.4E-09	10000	3000	1.32E-09

Conclusion:

The calculated risks for birds regarding secondary poisoning via the ingestion of contaminated ants for birds are acceptable.

Mixture toxicity

A mixture toxicity assessment was not considered as necessary since the biocidal product contains only one active substance. Moreover no substances of concern for the environment were identified (refer to confidential annex).

Aggregated exposure (combined for relevant emmission sources)

The guidance is still under development.

Conclusion:

Not applicable

Overall conclusion on the risk assessment for the environment of the product
For the biocidal product no exposure was assumed for its uses and hence no risk characterisation for any of the environmental compartments was performed. No substances of concern were identified for the environment (further details refer to confidential annex). Secondary poisoning

The risks for secondary poisoning via the consumption of contaminated ants for birds was calculated.

Conclusion

The calculated risks for the secondary poisoning for birds via consumption of contaminated ants are acceptable.

2.2.9 Measures to protect man, animals and the environment

Please cf. to chapter 2.1.4 and 2.1.5.

In case of fire:
Suitable extinguishing media:
CO_2, dry powder, foam, water spray.
In case of fire formation of toxic, irritant and/or corrosive gases is possible. For example HCl gas, CO_2.

2.2.10 Assessment of a combination of biocidal products

Not applicable. There is no intended co-use with other biocidal products.

2.2.11 Comparative assessment

The biocidal product „VANDAL Ameisen-Frühstück und VANDAL Ameisen-Kombiköder" contains the active substance permethrin, which meets the criteria for substitution pursuant to Article 10 (1) of the Biocides Regulation (EU) No 528/2012 (BPR) and thus it becomes a candidate for substitution (CFS). Permethrin is considered to be persistent (P) and toxic (T) but not bioaccumulative (B). Therefore it meets two of the three criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006.
Consequently, in line with Article 23(1) of the Biocides Regulation the Austrian Competent Authority has performed a comparative assessment for the biocidal product „VANDAL Ameisen-Frühstück und VANDAL Ameisen-Kombiköder", based on the *„Technical Guidance Note on comparative assessment of biocidal products*" (CA-May15-Doc.4.3.a).
For this comparative assessment the Austrian Competent Authority used the list of biocidal products authorised in Austria for PT 8 (in the version of 17.08.2022), accessible on https://www.biozide.at/, which is maintained by the Environment Agency Austria („Umweltbundesamt") on behalf of the Austrian Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology („BMK"). This was done due to the lack of a tool in the current version of R4BP3 to search SPCs, pursuant to the *„Technical Guidance Note on comparative assessment of biocidal products*"(CA-May15-Doc.4.3.a).

Authorised uses for the relevant biocidal product
The biocidal product „VANDAL Ameisen-Frühstück und VANDAL Ameisen-Kombiköder" is an insecticide (PT 18) which contains the active substance permethrin. The product is a ready to use bait station with bait mixture to be used by general public (non-professionals) in order to control black garden ants and its nests indoors and outdoors (*Lasius niger*; adults, larvae and queen).

Product Type	PT 18 (insecticides, acaricides and products to

	control other arthropods)
Where relevant, an exact description of the authorised use	---
Target organism(s), development stage	Common name: Black Garden Ant Scientific name: Lasius niger Development stage: all stages, nests (queen, adults, larvae)
Field of use	Indoor and outdoor use Field of Use description: Insecticide for use in households (indoor) and on hard surfaces in rain protected areas around houses (outdoor, e.g. terraces, balconies).
Category(ies) of users	Non-professional
Application method(s)	RTU bait station with bait. Application on hard surfaces near the ant run or nest at dry and sheltered places, where it is protected from rain and damage.

Authorised use of the biocidal product

Summary of the authorised uses:
PT18: Insecticide – *Lasius niger* (all stages, nests; queen, adults, larvae) – Indoor and outdoor use – Ready-to-use bait station – Non-professional user

As stated in CA-May15-Doc.4.3.a – Final, elements 1 to 5 in the table above should be considered as the critical ones. But the AT CA mentions, that in (33) of Note for Guidance it is stated that, if an *„eCA considers that an application method makes that the BP is used in practice for very different purposes or under very different circumstances […], some application methods could be considered as separate uses to be covered under the comparative assessment."* Furthermore, according to (57) *„at least three different and independent active substances/mode of action combinations should remain available through authorised BPs for a given use […] in order to consider that the chemical diversity is adequate."*
Therefore the application method has also been taken into consideration as the exposure differs depending on the application methods (example: exposure from a bait station is considered different from that of e.g. a liquid, powder or granules).

Mapping of existing alternatives to the relevant biocidal product in Austria:

Identified eligible alternative biocidal products:

For this comparative assessment the Austrian Competent Authority used the list of biocidal products authorised in Austria for PT 18 (in the version of 17.08.2022), as already mentioned above.
According to the information available, currently 28 biocidal products for non-professionals to control *Lasius niger* are obtainable (with various trade names). But just 11 of these are available as ready-to-use bait stations, which are considered to be the most appropriate application method for non-professionals. These products are based on the active substances fipronil, 1R-trans phenothrin, imidacloprid and spinosad. Note: Of the

aforementioned active substances only 1R-trans phenothrin is no candidate for substitution (CFS). Furthermore, in the list of biocidal products authorised in Austria for PT 18 only 3 biocidal products are mentioned for control of *Lasius niger* queens/all development stages. Two are based on spinosad, one on 1R-trans phenothrin.

Narrowing the situation down from another side, out of 28 biocidal products for non-professionals to control *Lasius niger*, just 7 are for the control of the queen/all development of stages *L. niger*. From these just 3 are in ready-to-use bait-boxes based on spinosad or 1R-trans phenothrin.

Identified eligible non-chemical alternatives
Eligible non-chemical alternatives are non-chemical means of control and prevention methods. These should already exist on the EU market and for which the eCA, on the basis of the available information, considers that there is robust evidence that the alternative does not give rise to concern in terms of safety for humans, animals or the environment and has demonstrated sufficient effectiveness under field conditions.
According to the AT CA, there are no such non-chemical alternatives that have sufficient efficiency and at the same time no significant economic or practical disadvantages to be applied on a large scale.

Screening phase
Description of the assessment of the adequate chemical diversity in authorised biocidal products to minimize the occurrence of resistance and conclusion.

Chemical diversity
Article 23(3)(b) BPR refers to the adequate chemical diversity of the available active substances within a given product type/use/target organism combination as one of the two sine qua non conditions to be met in order to allow a restriction or prohibition of a biocidal product subject to comparative assessment. During the screening phase, it shall be checked whether the diversity of the active substance, product type and mode of action combination in authorised biocidal products is adequate to minimize the occurrence of resistance in the target organisms. The screening phase shall allow through a simple assessment to judge whether it is required or not to perform a comprehensive comparative assessment. As proposed as general rule in ”CA-May15-Doc.4.3.a” at least three different and independent active substance/mode of action - combinations should be available through authorised biocidal products for a given use to provide adequate chemical diversity as stipulated by Article 23(3)(b) BPR.

Mode of action:
Permethrin belongs to the group of pyrethroids, which are sodium channel modulators. Their mode of action is to keep sodium channels open, causing hyperexcitation and, in some cases, nerve block.
Sodium channels are involved in the propagation of action potentials along nerve axons.

Consideration on whether the CFS(s) meet(s) at least one of the exclusion criteria listed in Article 5(1) but can benefit from derogation in accordance with Article 5(2) of the BPR
The active substance permethrin is neither carcinogenic, mutagenic or reprotoxic, nor is it a PBT or vPvB substance and therefore it does not meet any of the exclusion criteria in Article 5(1) of Regulation (EU) No 528/2012. But as mentioned before, it meets two of the three criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006 and thus it becomes a candidate substitution pursuant to Article 10(1) of the BPR.

Conclusion of the screening phase:

Stop comparative assessment. Taking into account the available information summarised here, three biocidal products based on two active substances for the given product type/use/target organism/application method for general public (non-professionals) are currently available, therefore (57) of CA-May15-Doc.4.3.a – Final (*„**at least three** different and independent active substances/mode of action combinations should remain available […] in order to consider that the chemical diversity is adequate.")* is not met. The AT CA concludes that with this low number of available biocidal products for the given combination the opportunity of an occurence of resistance is still high.

Two out of the just three authorised alternatives contain the CFS spinosad, and one 1R-trans phenothrin. As the three alternatives are seen to guarantee product availability and to ensure that retail competition encourages affordable prices, comparative assessment is stopped here.

In line with Article 23(3)(a) and (b) of the BPR, the Note for Guidance (CA-May15-Doc.4.3.a – Final) and since permethrin does not meet the exclusion criteria as outlined in Article 5(1) of the BPR, it is valid to conduct no further investigation at this point; comparative assessment is stopped and finalized at this stage.
The biocidal product „VANDAL Ameisen-Frühstück und VANDAL Ameisen-Kombiköder" will be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation (EU) No 528/2012.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No. in IUCLID	Refernece (Author, year)	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
3.1 3.4.1	Anonymous 2022a	Determination of physico-chemical Properties and Storage Stability Tests for Vandal Ameisen-Frühstück	BioGenius GmbH TechnologiePark Building 56, Friedrich-Ebert-Straße 51429 Bergisch Gladbach, Germany	Mo5409	yes	yes	Nifra Parfumerie Gesellschaft m.b.H.
5.1	Anonymous 2016a	Validation of Method: Bio AQ086-01: GC-Determination of Permethrin in Ameisen-Frühstück	BioGenius GmbH TechnologiePark Building 56, Friedrich-Ebert-Straße 51429 Bergisch Gladbach, Germany	Mo5408	no	yes	Nifra Parfumerie Gesellschaft m.b.H.
3.3	Anonymous 2022b	Certificate of Analysis	BioGenius GmbH TechnologiePark Building 56, Friedrich-Ebert-Straße 51429 Bergisch Gladbach, Germany	Mo7420	no	yes	Nifra Parfumerie Gesellschaft m.b.H.
6.7	Anonymous 2015	Efficacy of ant bait station "VANDAL Ameisen Frühstück" against Black ants, *Lasius niger*	BioGenius GmbH TechnologiePark Building 56, Friedrich-Ebert-Straße 51429 Bergisch Gladbach, Germany	BIO151a-15	yes	yes	Nifra Parfumerie Gesellschaft m.b.H.

Section No. in IUCLID	Refernece (Author, year)	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
6.7	Anonymous 2020a	Efficacy of an ant product (bait station) against black garden ants, *Lasius niger*	BioGenius GmbH TechnologiePark Building 56, Friedrich-Ebert-Straße 51429 Bergisch Gladbach, Germany	BIO027b-20	yes	yes	Nifra Parfumerie Gesellschaft m.b.H.
6.7	Anonymous 2020b	Efficacy of an ant product (bait station) against black garden ants, *Lasius niger*	BioGenius GmbH TechnologiePark Building 56, Friedrich-Ebert-Straße 51429 Bergisch Gladbach, Germany	BIO053b-20	yes	yes	Nifra Parfumerie Gesellschaft m.b.H.

3.2 Output tables from exposure assessment tools

Not available.

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)

Please refer to IUCLID 6.7 section.

3.6 Confidential annex

Please cf. to separate document.

3.7 Other

3.7.1 Reference list (excluding list of studies. cf. to chapter 3.1)

COM 2016, CA-Nov16-Doc.4.3.handling carriers_rev2_final

COM 2020, CA-Dec20-Doc.4.1 Warning sentence and RMM for bees_finalrev2

COM 2021, CA-March21-Doc.4.3_Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment

Ireland 2014, Chemical Assessment Report, Permethrin, Product type 18, EC no 258-067-9, CAS no 52645-53-1, February 2014.

Ireland 2017, Addendum to the Chemical Assessment Report, Permethrin, Product type 18, EC no 258-067-9, CAS no 52645-53-1, February 2017.

ECHA 2014, Guidance on the Biocidal Products Regulation, Volume I: Identiy/physico-chemical properties/analytical methodology – Part A: Information Requirements (Version 1.1, November 2014)

ECHA 2017a, Guidance on requirements for substances in articles, Version 4.0, June 2017.

ECHA 2017b, Guidance on the Biocidal Products Regulation, Volume IV: Environment - Assessment and Evaluation – Parts B+C (Version 2.0, October 2017)

ECHA 2017c, Guidance on the Biocidal Products Regulation, Vol III: Human Health – Assessment and Evaluation Part B+C

ECHA 2018, Guidance on the Biocidal Products Regulation, Volume II: Efficacy – Parts B+C (Version 3.0, April 2018)

ECHA 2021, Technical Agreements for Biocides Environment (ENV), Release date: 9 November 2021

EFSA 2017, Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp. https://doi.org/10.2903/j.efsa.2017.4873

OECD 2008, Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses. OECD series on Emission scenario documents, number 18; ENV/JM/MONO(2008)14; 17-Jul-2008