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 Ameisenfalle neu

Product type 18

Permethrin
Piperonyl butoxide

Case Number in R4BP: BC-PY039493-99

Evaluating Competent Authority: AT

04/08/2023 (FINAL)

PUBLIC

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1 CONCLUSION

Austria was the Competent Authority responsible for evaluation of the biocidal product VANDAL Ameisenfalle neu. The dossier submission date 07/05/2018 is to be taken into account for relevance of (new) guidance.

The ready-to-use product VANDAL Ameisenfalle neu is a contact trap which contains 6.989%(w/w) of the active substance permethrin and 0.851%(w/w) of the active substance piperonyl butoxide. No substances of concern were identified.

The assessment considered:

- The conclusions and recommendations of the Assessment Reports for the approval of the active substances permethrin and piperonyl butoxide including the "elements to be taken into account by Member States when authorising products"
- The specific provisions from Inclusion Directive for the active substance permethrin [(EU) No 1090/2014] and piperonyl butoxide [(EU) 2016/2288]

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

- The authorisations of biocidal products are subject to the following conditions:

- The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.
- In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
  a) surface water and sediment compartments for products used indoor for fogging;
  b) surface water, sediment and soil for products used outdoor for fogging.
- For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (2) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (3) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
- The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating piperonyl butoxide shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

The fields of use are as follows:
Use # 1 – Insecticide - Ants (adults, forager ants) – non-professionals – ant trap – 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 substances permethrin is a candidate for substitution pursuant to Art. 10(1) BPR.

The product has no indications for endocrine-disrupting properties.

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[1]	**Country (if relevant)**
VANDAL Ameisenfalle neu	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 Vienna Austria
Authorisation number	AT-0019780-0000	
Date of the authorisation	SEE AUHTORISATION LETTER	
Expiry date of the authorisation	SEE AUHTORISATION LETTER	

2.1.1.3 Manufacturer(s) of the products of the family

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 Manufacturers of the active substances

Active substance 1	Permethrin
Name of manufacturer	Limaru NV (Importer) [Acting for Tagros Chemicals India Private Limited (India)]
Address of manufacturer	Paalsesteenweg 170 Bus 7 3583 BERINGEN Belgium
Location of manufacturing sites	Tagros Chemicals India Ltd. A-4/1&2, Sipcot Industrial Complex Pachayankuppam Cuddalore - 607 005

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

	Tamilnadu India

Active substance 2	Piperonyl butoxide
Name of manufacturer	ENDURA S.p.A.
Address of manufacturer	Viale Pietramellara, 5 40121 Bologna Italy
Location of manufacturing sites	Via Baiona, 107-111, 48123 Ravenna, Italy

2.1.2 Product composition and formulation

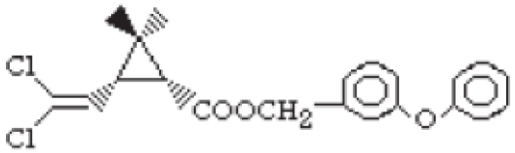
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

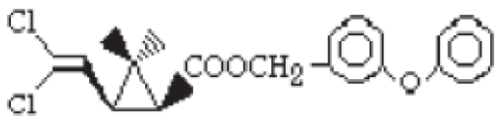
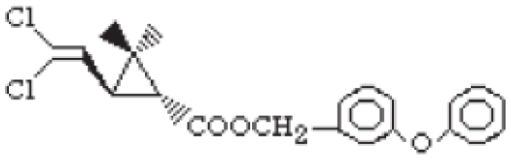
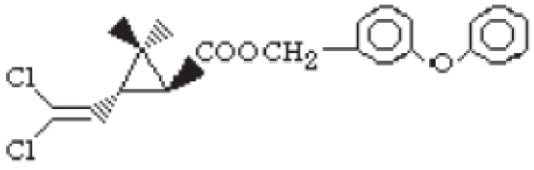
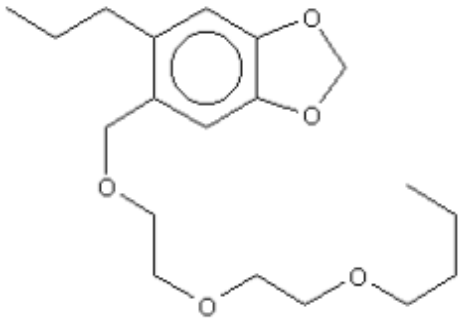
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituents	
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	1Rcis isomer – 

	1Scis isomer –  1Rtrans isomer –  1Strans isomer – 
ISO name	Piperonyl butoxide
IUPAC or EC name	5-[2-(2-butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxole
EC number	200-076-7
CAS number	51-03-6
Index number in Annex VI of CLP	-
Minimum purity / content	94.0 %
Structural formula	

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. The active substance is persistent and toxic, but not bio-accumulative. It is not classified as PBT.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product2

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	6.989*
Piperonyl butoxide	5-[2-(2-butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxole	Active substance	51-03-6	200-076-7	0.851**

*Minimum amount of pure active substance permethrin without impurities: 6.5 % w/w
**Minimum amount of pure active substance piperonyl butoxide without impurities: 0.8 % w/w

Absolute mass of the biocidal product: 2.6 g

Qualitative information on the biocidal product

The product comprises a polymer frame (i.e. article) which carries a polyethylene ring (i.e. solid mixture containing active substances primed for elimination of the target organisms). The article consists of polypropylene and allows for an easier handling, application and delivery of the biocidal product. On the underside of the article are teeth which are arranged in small distances as a double row, so that ants can get into the inside of the trap. The distance is so small, that no larger insects can get into the trap. The biocidal product (polyethylene ring) is located inside the serrated row. For further information on the biocidal product, please confer to the confidential annex.

Rationale for differentiation between article and biocidal product

The biocidal product is a solid mixture (a.s. and polyethylene ring) 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 solid mixture is to deliver the active substance to the target organism (ants) 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 frame

2 Please delete as appropriate.

allows an easier handling, application and delivery of the biocidal product and is not influencing the activity of the biocidal product.

Applying the decision tree as given in chapter 2.3 of the Guidance on requirements for substances in articles (ECHA 2017a) gives the following results:

Step 1	Identify the function of the object: The object consists of a solid polypropylene frame with a polyethylene ring which contains the active substances. The function is to kill ants. The target organisms are killed by contact with active substances permethrin and piperonyl butoxide.
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.* It is not possible to unambiguously conclude. Without its specific and highly sophisticated shape the function of the object may not be observed.
Step 3	Does the object contain a substance/mixture that can be separated from the object? Yes, the PE ring can be separated from the object and the active substances are consumed by contact with target organisms.
Question 4a	If the substance/mixture were to be removed or separated from the object and used independently from it, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function defined above? Yes
Question 4b	Does the object act mainly (i.e. according to the function defined under step 1) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products? Yes
Question 4c	Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life? Yes
Conclusion	**Object consists of a substance or mixture and an article**

Following the definitions set out in document CA-Nov16-Doc.4.3 – Final, which describes how to handle "carrier" products the product can be seen as Type A product. For type A biocidal products it has been agreed that the carrier component should not be considered as a part of the composition of the biocidal product. Therefore, it should not be considered

for the calculation of the active substance concentration to be indicated in the SPC. 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 (incl. the active substances) used in the product only.

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 ☐

Is the source of piperonyl butoxide 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 ☐

An assessment of technical equivalence of the active substances is therefore not required.

2.1.2.5 Information on the substance(s) of concern

In the biocidal product no substances of concern for human health were identified according to Article 3, 1 (f) of Reg. (EU) No. 528/2012.

2.1.2.6 Type of formulation

XX – Others (ready to use contact trap)

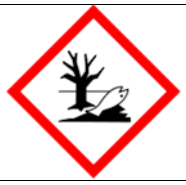
2.1.3 Hazard and precautionary statements[3]

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

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.

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

Labelling		
Pictogram		
	GHS07	GHS09
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. P302 + P352: IF ON SKIN: Wash with plenty of water. P333 + P313: If skin irritation or rash occurs: Get medical advice. P273: Avoid release to the environment P501: Dispose of contents/ container in accordance with local/ regional/national/international regulation (to be specified).	
Note		

In fact H317 would trigger P280 (Wear protective gloves/protective clothing/eye protection/face protection.). However, for non-professional use correct application of personal protective equipment cannot be assumed. Based on a qualitative risk assessment the additional RMMs "N-383 modified: Avoid contact with the contents of the trap." and "N-209 modified: Wash hands after opening and placing the trap." are considered sufficient to protect the non-professional user from the corresponding risk.
H317 also triggers P261 (Avoid breathing dust/fume/gas/mist/vapours/spray). This precautionary statement is not required since the active substances are implemented in a polyethylene ring and therefore exposure to dust/fume/gas/mist/vapours/spray cannot be assumed. Furthermore, based on a quantitative risk assessment, inhalation of volatised residues can be neglected due to the low volatility of the active substances.
P362 + P364 is not required because contamination of clothes is not expected for the biocidal product.
According to the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (2016) the precautionary statement P272 (Contaminated work clothing should not be allowed out of the workplace), which is triggered by H317, is not intended to be used for the general public.
P321 is not recommended since no specific treatment for the active substance permethrin is known.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Use # 1 – Insecticide - ants (adults, forager ants) – non-professionals – ant trap – indoor and outdoor

Product Type	PT 18
Where relevant, an exact description of the authorised use	insecticide
Target organism (including development stage)	Common name: Black Garden Ant Scientific name: *Lasius niger* Development stage: adults; forager ants
Field of use	Indoor and outdoor use on paved surfaces (Outdoor only in rain protected, dust free places, e.g. terraces)
Application method(s)	Bait free ant trap to be placed crosswise over an ant trail in infested areas.
Application rate(s) and frequency	One single trap per ant run. 100% mortality of forager ants is achieved within 24h. One trap remains efficacious for up to 3 months
Category(ies) of users	Non-professional
Pack sizes and packaging material	2.6 g per trap, one trap per package (carton box, trap wrapped in cellulose-foil)

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 trap out of the packaging and place it crosswise over the ant trails.
Place the trap either indoor or outdoor on paved surfaces (only in rain protected places, e.g. terraces)
Attention: Dust or sand can strongly reduce the effect.
Therefore, make sure you have a dust-free environment, then the ant trap works up to 3 months.

N-292 (modified): Remove the trap at the end of the treatment.

2.1.5.2 Risk mitigation measures

Apply the product so that pets and food do not come in contact with the product.
N-335 modified: Keep cats away from the trap. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats.
N-383 modified: Avoid contact with the contents of the trap.
N-209 modified: Wash hands after opening and placing the trap.
This biocidal product contains permethrin which is dangerous to bees.

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

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

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

IF ON SKIN: 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.

N-318: Pyrethroids (including permethrin) may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

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 and cool place in the original packaging. Provide adequate ventilation. Shelf-life: 2 years

2.1.6 Other information

2.1.7 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Ant trap Foil Box	8.4 x 5.3 x 1.4 cm 12.5 x 6 cm 13 x 8 x 1.5 cm	PP Cellulose-foil Paper, carton	Trap is wrapped in cellulose-foil. No closure. Carton is folded. One trap per box.	Non-professional	yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

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

2.1.8.2 Access to documentation

A letter of access for the biocidal product satisfying the requirements set out in Annex II BPR for each 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

Please refer to the DRA submitted by the applicant.

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.: 0318	solid	Anonymous 2022a
Colour at 20°C and 101.3 kPa	Visual inspection	100% biocidal product Batch no.: 0318	Milky white	Anonymous 2022a
Odour at 20°C and 101.3 kPa	Olfactory inspection	100% biocidal product Batch no.: 0318	Weak odour of active substances odourless	Anonymous 2022a Applicant statement
Acidity / alkalinity	---	---	N.A. The biocidal product is a solid and not applied as aqueous dilution or dispersion.	---
Relative density / bulk density	OECD 109	Qualitative and quantitative composition of the test formulation is stated in the conf. annex under 3.6.2. Batch no.: APMT20E031	0.931	Anonymous 2022b
Storage stability test – **accelerated storage**	CIPAC MT 46.3	100% biocidal product Batch no.:	The biocidal product is stable when stored for 2 weeks at 54°C in its original packaging. No changes in the	Anonymous 2022a

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td>0318</td><td>appearance and the packaging stability were observed.

<table><tr><th></th><th>T0</th><th>T2w</th></tr><tr><td>Permethrin content (% w/w)</td><td>7.08</td><td>7.00 (- 1.1 % from T0)</td></tr><tr><td>Piperonyl butoxide (% w/w)</td><td>0.882</td><td>0.851 (- 3.5 % from T0)</td></tr><tr><td>Weight loss</td><td>---</td><td>From - 0.06 % to 0.15 %, 6 samples</td></tr><tr><td>appearance</td><td>Milky white</td><td>Milky white</td></tr><tr><td>packaging</td><td>Original packaging. No deficiencies are observed.</td><td>Original packaging. No deficiencies are observed.</td></tr></table>
Packaging size: The test items used for storage for 2 weeks at 54 ° C had a larger packaging.
Length: 12.7 cm
Width: 11.2 cm
Height: 0.7 cm</td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>---</td><td>100% biocidal product

Batch no.: 0318</td><td>The biocidal product is stable when stored for 2 years in its original packaging at 20°C.

The test items were stored in the original packaging. No changes in the appearance and the packaging stability were observed after storage for 24 months at 20 °C and ambient humidity.

<table><tr><th></th><th>T0</th><th>T12 m</th><th>T24 m</th></tr><tr><td>Permethrin content</td><td>7.08</td><td>7.14 (+ 0.85</td><td>6.64 (- 6.2 %</td></tr></table></td><td>Anonymous 2022a</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(% w/w) | | % from T0) | from T0) Piperonyl butoxide (% w/w) | 0.882 | 0.899 (+ 1.93 % from T0) | 0.865 (- 1.93 % from T0) Weight loss | --- | From 0.11 % to 0.16 %, 6 samples | From 0.18 % to 0.27 %, 21 samples appearance | Milky white | Milky white | Milky white packaging | Original packaging | Original packaging. No deficiencies are observed. | Original packaging. No deficiencies are observed.	
Storage stability test – **low temperature stability test for liquids**	---	---	N.A. The biocidal product is a solid and not a liquid.	---
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	---	---	The biocidal product is protected from direct sunlight when stored in its original packaging.	---
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	---	---	The biocidal product is stable for 2 weeks at 54°C as well as for 2 years at 20°C with ambient humidity. The biocidal product is not hygroscopic and the original packaging is watertight.	Anonymous 2022a
Effects on content of the active substance and technical	---	---	The active substances content is stable and no reactivity towards container material was observed in	Anonymous 2022a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
characteristics of the biocidal product - **reactivity towards container material**			the storage stability studies. The packaging remain intact and does not show any signs of panelling, ballooning, leakage.	
Wettability	---	---	N.A. The biocidal product is a solid which is not dispersed in water for use.	---
Suspensibility, spontaneity and dispersion stability	---	---	N.A. The biocidal product is a solid and not a suspension and does not form a suspension upon use.	---
Wet sieve analysis and dry sieve test	---	---	N.A. The biocidal product is a solid but not a powder or granule and is not wetted for use.	---
Emulsifiability, re-emulsifiability and emulsion stability	---	---	N.A. The biocidal product is a solid and not an emulsion and does not form an emulsion upon use.	---
Disintegration time	---	---	N.A. The biocidal product is a solid but not a tablet and is not intended to be dissolved in water.	---
Particle size distribution, content of dust/fines, attrition, friability	---	---	N.A. The biocidal product is a solid but not a powder or granule.	---
Persistent foaming	---	---	N.A. The product is a solid and not applied in water for use.	---
Flowability/Pourability/Dustability	---	---	N.A. The biocidal product is a solid but not granular and is not to be dispersed.	---
Burning rate — smoke generators	---	---	N.A. The biocidal product is not a smoke generator.	---
Burning completeness — smoke generators	---	---	N.A. The biocidal product is not a smoke generator.	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Composition of smoke — smoke generators	---	---	N.A. The biocidal product is not a smoke generator.	---
Spraying pattern — aerosols	---	---	N.A. Spraying is not an intended use of the biocidal product.	---
Physical compatibility	---	---	N.A. The biocidal product is not applied together with any other substances, mixtures, products.	---
Chemical compatibility	---	---	N.A. The biocidal product is not applied together with any other substances, mixtures, products.	---
Degree of dissolution and dilution stability	---	---	N.A. Biocidal product is a solid and not intended to be diluted in water.	---
Surface tension	---	---	N.A. Biocidal product is a solid and not a liquid.	---
Viscosity	---	---	N.A. Biocidal product is a solid and not a liquid.	---

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

The biocidal product is a solid mixture, which is affixed onto a carrier, functioning as contact trap for the control of target pests. It contains the active substances permethrin and piperonyl butoxide.

The biocidal product is milky-white, with a weak odour of active substances to odourless and with an approximate relative density of 0.931. The relative density was measured for a similar formulation (see confidential annex for further information). Furthermore, the density of polyethylene varies from 0.90 to 0.95 when manufactured. Therefore, the certificate of analysis on a similar formulation was accepted be the eCA.

The biocidal product is stable when stored for two weeks at 54°C in its original packaging and when stored for two years in its original packaging at 20°C.

Shelf life: 2 years

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	---	---	Not classified as explosive. The active substances permethrin and piperonyl butoxide are not classified as explosive. Apart from the a.s., the biocidal product consists of polymers (C-H or C=H groups) which are not regarded as explosive. No other chemical groups are present in the biocidal product, which are associated with explosive properties.	---
Flammable gases	---	---	N.A.	---
Flammable aerosols	---	---	N.A.	---
Oxidising gases	---	---	N.A.	---
Gases under pressure	---	---	N.A.	---
Flammable liquids	---	---	N.A.	---
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 be classified by analogy with existing entries (see paragraph 2.4.2.2.2.2 of the Model Regulations). The test	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			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	---	---	The biocidal product does not contain chemical groups that are associated with self-reactive properties.	---
Pyrophoric liquids	---	---	N.A.	---
Pyrophoric solids	---	---	Not classified pyrophoric. Experience in manufacture and handling as well as data on storage stability shows that the biocidal product is stable for elongated time periods and does not ignite when coming into contact with air.	---
Self-heating substances and mixtures	---	---	Not classified as a self heating mixture. The biocidal product is packed according to the ADR, as limited quantity UN 3077. Large amounts (kilograms) can never stick together. No data are required for substances with a melting point below 160°C. All substances of the mixture except calcium stearate have a melting point below 160°C.The product does not contain any self heating substance. Moreover, the biocidal product does not consist of small particles like powders or granules, organometallic	For further details on the active substances, please refer to the CAR of permethrin and piperonyl butoxide.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			compounds and metals beside calcium.	
Substances and mixtures which in contact with water emit flammable gases	---	---	Not classified as a mixture which in contact with water emit flammable gases. The biocidal product does not contain metals or metalloids and is therefore exempted from testing.	---
Oxidising liquids	---	---	N.A.	---
Oxidising solids	---	---	Not classified as oxidising solid. The biocidal product does contain oxygen, chlorine or fluorine but only bonded to carbon and hydrogen and is therefore exempted from testing.	---
Organic peroxides	---	---	N.A. The biocidal product does not contain a bivalent oxygen structure (-O-O-) and is therefore exempted from testing.	---
Corrosive to metals	---	---	Not classified as corrosive to metals. The test is only applicable to liquids and solids that may become liquid (melting point lower than 55°C or by dissolution). The melting range of the biocidal product is well above 100°C and does not melt up to 55°C and does not dissolve in water.	---
Auto-ignition temperatures of products (liquids and gases)	---	---	N.A. The biocidal product is a solid and not a liquid. Permethrin: Relative self-ignition temperature: >400°C	For further details on the active substances, please refer to the CAR of permethrin and

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Flashpoint: >100°C Piperonyl butoxide: Relative self-ignition temperature: 265°C Flashpoint: 179.25°C	piperonyl butoxide.
Relative self-ignition temperature for solids	---	---	The biocidal product consists mainly of polyethylene. polyethylene: 330-410°C	International Chemical Safety Card, ICSC: 1488
Dust explosion hazard	---	---	No dust explosion hazard. The biocidal product is a solid but not powdery or granular and does not form dust. Therefore, it is exempted from testing.	---

Conclusion on the physical hazards and respective characteristics of the product
The biocidal product is a solid mixture, which is affixed onto a carrier, functioning as contact trap for the control of target pests. It contains the active substances permethrin and piperonyl butoxide. The biocidal product is not classified as explosive, flammable, self-reactive, oxidising or corrosive to metals.

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		
Active substance *Permethrin*	GC-FID AQ089	3 samples in 3 concentrations 70% 0.5702 mg/mL 100% 0.8146 mg/mL	Working range 0.4808-1.282 mg/mL r=1.00	Specific, interference from other substances <3% of total peak	97.3 - 100.0	98.3	1.48	0.5702 mg/ml	Anonymous 2018a

		130% 1.042 mg/mL							
Active substance *Piperonyl butoxide*	GC-FID AQ089	3 samples in 3 concentrations 70% 0.06946 mg/mL 100% 0.09923 mg/mL 130% 0.1325 mg/mL	Working range 0.06114-0.1630 mg/mL r =1.00	Specific, interference from other substances <3% of total peak	98.7 - 101.8	99.8	1.46	0.0695 mg/ml	Anonymous 2018a

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		
Active substance *Permethrin*	Please refer to the CAR of permethrin for detailed information on the active substance.								
Active substance *Piperonyl butoxide*	Please refer to the CAR of piperonyl butoxide for detailed information on the active substance.								

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

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		
Active substance *Permethrin*	Please refer to the CAR of permethrin for detailed information on the active substance.								
Active substance *Piperonyl butoxide*	Please refer to the CAR of piperonyl butoxide for detailed information on the active substance.								

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		
Active substance *Permethrin*	Please refer to the CAR of permethrin for detailed information on the active substance.								
Active substance *Piperonyl butoxide*	Please refer to the CAR of piperonyl butoxide for detailed information on the active substance.								

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
No data required. Permethrin is not classified as toxic or highly toxic.									
No data required. Piperonyl butoxid is not classified as toxic or highly toxic.									

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 product will not be used on any food or feed of plant and/or animal origin. Indirect exposure to permethrin and piperonyl butoxide as a result of contamination of food by the ants after contact with the ant trap is theoretical possible but negligible, because in practice based on observations ants show a clear effect when they pass through the ant trap and will brake up to track the food source or try to return to the nest.									

Conclusion on the methods for detection and identificationof the product
The analytical methods for the analysis of the active substances permethrin and piperonyl butoxide in the biocidal product were validated successfully. The methods for both active substances are linear, specific, precise and accurate and are therefore suitable to analyse the active substances in the biocidal product. Monitoring methods for the active substances are given in the respective assessment reports. For detailed information on the active substances, please refer to the respective CARs.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The PT 18 product (insecticide) is a bait-free ant trap against forager ants (workers) for indoor and outdoor use for non-professional users. Outdoor use is only possible in areas, which are well protected against rain and dust, e.g. on a covered terrace. The product controls ants on their trails running below or touching the insecticide frame of the trap. Ants are getting killed within when in contact with the insecticide.

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

The target organisms are the forager ants (workers) of the Black Garden Ant *Lasius niger*.

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

Mortality of ants (forager ants, adults). Permethrin is a contact insecticide which causes convulsions, paralysis and ultimately death in target organisms. First signs appear after certain minutes, followed soon by knockdown and rapid death (from CAR of Permethrin). The second active substance piperonyl butoxide (PBO) mainly acts by inhibiting a number of enzymes present in the insects' body.

2.2.5.4 Mode of action, including time delay

Permethrin is a type I axonic poison which exerts its effects by means of hyper excitation of both the peripheral and central nervous systems of target insects. Its effects are characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyper excitability. Permethrin also induces hepatic microsomal enzymes. 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 (from CAR of Permethrin).
Piperonyl butoxide mainly acts by inhibiting a number of enzymes present in the insects' body. It is widely recognized as an inhibitor of Mixed Function Oxidases (MFOs), but recent studies prove that piperonyl butoxide can also act on other enzymes, such as esterases. PBO stabilises the co-applied insecticide in the target insect body and potentiates more toxins to reach their target molecules (from CAR of piperonyl butoxide)

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT 18	Lab study	VANDAL Ameisenfalle neu	*Lasius niger (adults, forager ants)*	C.E.B 196 (adapted)	One single trap (6.5% Permethrin, 0.8% PBO) per arena. 4 replicates; 100 ± 2 forager ants per replicate; Recording of deads every hour on the	- 100% mortality after 2 hours. - This efficacy was confirmed after 24h and 48h.	Anonymus 2017

					first day, then every day until 8 days if necessary.		
PT 18	Sim-use trial	VANDAL Ameisenfalle neu	*Lasius niger (adults, forager ants)*	C.E.B 196 (adapted)	One single trap (6.5% Permethrin, 0.8% PBO) per arena. 4 replicates; 100 ± 2 forager ants per replicate. Recording deads after 1, 2, 4, 8, 24, 48 hours. The same procedure was applied with the product open 3 months before and let in outside climatic conditions (protected from rain, dust and direct sun).	FRESH PRODUCT-100% of the forager ants were killed within 24 hours - this efficacy was confirmed after 48 hours AGED PRODUCT-100% of the forager ants (workers) were killed within 24 hours - this efficacy was confirmed after 48 hours	Anonymus 2021

Conclusion on the efficacy of the product

Since the PT 18 product is neither a spray nor a bait product, it is an ant trap suited to be regarded as general surface treatment for consumers according to the Guidance in force at the submission date (ECHA 2017b). Moreover, no nest-kill is claimed. The product is intended to be used exclusively on ant trials to reduce the number of forager ants. To demonstrate the efficacy accordingly, a lab trial and a simulated-use trial were submitted, which is also in-line with the requirements from the efficacy Guidance in force at submission date.

The Efficacy Guidance states the following: If no guidelines are available or the guidelines are not suitable, the applicant can use his own methods. Therefore, the efficacy studies were conducted according to C.E.B 196 with modifications, which are also stated in the test protocols.

The product fulfils the respective requirements (preferably ≥90% mortality after 24h) in dependence on the efficacy guidance for general surface treatments against ants. In the lab-test, 100% mortality was shown after 2 hours, in the Simulated Use Trial the product has proved a complete lethal efficacy (100%) against forager ants (workers) of *Lasius*

niger. This efficacy was confirmed after 24 and 48 hours (No recoveries were observed). Since the simulated use trial was also conducted with an aged product, it is confirmed that the efficacy is lasting up to 3 months after opening.

Justification concerning the submitted efficacy studies:
In the valid Guidance on the BPR at the time of dossier submission (ECHA 2017b) examples and possibilities (5.6.4.4.2 Dossier requirements, ff.) are listed which generally fit to the products concerned. In the dossier requirements there are 3 obvious categories for the target organism "ant":

- Bait products
- Direct surface treatment without nest kill
- Direct surface treatment with nest kill

The eCA agreed to the applicant that the product is rather unfit to be covered by the mentioned claims/categories. However, the product is suited to be regarded as general surface treatment for consumers (non-professional users). Under this category also other products are collected which are intended to be used exclusively on ant trails to reduce the number of forager ants. To demonstrate the efficacy accordingly a lab trial and a simulated use trial were submitted, which is in-line with chapter 5.6.4.4.2.3 (requirements for products intended for use as general surface treatment for consumers) of the respective Guidance. Considering this, the eCA assessed the criteria according to section 5.6.4.4.3.1 of the BPR Efficacy Guidance as fulfilled and thus defined the notation "ant trap" (for general surface treatment without nest-kill) in the Authorised Use section as suitable.

2.2.5.6 Occurrence of resistance and resistance management

No known resistance in the target species has been observed to-date for this active substance in the given concentration.

Management strategies to avoid resistance:
Use the product only in the approved concentration, duration and frequency. Change used biocides regularly. Do not alternate between products containing active substances showing the same molecular mode-of-action.

2.2.5.7 Known limitations

The trap has to be placed in an absolutely dry area. A dustfree area will also keep a full efficacy over the 3 months.

2.2.5.8 Evaluation of the label claims

The following label claims are proposed for the product VANDAL Ameisenfalle neu:

- Kills forager ants (worker ants) in desired areas within 24h.
- Elimination of ant trails indoors and outdoors (outdoor only in rain protected, dust free places)
- Efficacious after opening for up to 3 months

The label claims are successfully supported by the efficacy studies described in 2.2.5.5.

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

Use with other biocidal products is not intended.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

The assessment of human health effects is based on the Competent Authority Report (CAR) and assessment report (AR) of permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2017). For the human health effect assessment of AQUA LIGNEX I products data on a tested mixture for some endpoints were submitted by the applicant. The effects of the product on human health for other endpoints can be derived from information on the individual co-formulants and the active substance in the mixture.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The biocidal product does not cause skin corrosion/irritation.
Justification for the value/conclusion	A skin corrosion/irritation study with the biocidal product has not been conducted. Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008. Co-formulants or active substances are either not classified themselves for this endpoint or are present in the product at a concentration below the cut off value.
Classification of the product according to CLP	Not classified. Pyrethroids (including permethrin) may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Data waiving	
Information requirement	8.1 Skin irritation or corrosion
Justification	A study is scientifically unjustified. Valid data on each of the components in the product is available and no synergistic effects between any of the co-formulants or active substance are expected. This allows classification of the mixture according to CLP Regulation 1272/2008.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The biocidal product does not cause eye irritation.
Justification for the value/conclusion	An eye irritation study with the biocidal product has not been conducted. Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008. Co-formulants or active substances are either not classified themselves for this endpoint or are present in the product at a

	concentration below the cut off value.
Classification of the product according to CLP	Not classified.

Data waiving	
Information requirement	8.2 Eye irritation
Justification	A study is scientifically unjustified. Valid data on each of the components in the product is available and no synergistic effects between any of the co-formulants or active substance are expected. This allows classification of the mixture according to CLP Regulation 1272/2008.

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	The biocidal product does not cause respiratory tract irritation.
Justification for the value/conclusion	Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008. Co-formulants or active substances are either not classified themselves for this endpoint or are present in the product at a concentration below the generic and specific concentration limit.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Not a core data requirement.
Justification	Valid data on each of the components in the product is available and no synergistic effects between any of the co-formulants or active substance are expected. This allows classification of the mixture according to CLP Regulation 1272/2008.

Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Sensitizing to skin.
Justification for the value/conclusion	A skin sensitisation study with the biocidal product has not been conducted. The potential to cause skin sensitization can be deduced from the properties of the active substances and co-formulants and their concentrations in the product as set out in the CLP Regulation 1272/2008. On the basis of the information provided in the Assessment

	Reports for the active substances the biocidal product is classified as skin sensitising. For additional information please refer to the Confidential annex.
Classification of the product according to CLP and DSD	Skin sens. 1, H317

Data waiving	
Information requirement	8.3 Skin sensitisation
Justification	A study is scientifically unjustified. Valid data on each of the components in the product is available and no synergistic effects between any of the co-formulants or active substance are expected. This allows classification of the mixture according to CLP Regulation 1272/2008.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The biocidal product does not cause respiratory sensitisation.
Justification for the value/conclusion	Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008. Co-formulants or active substances are either not classified themselves for this endpoint or are present in the product at a concentration below the cut off value.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	8.4 Respiratory sensitization
Justification	Valid data on each of the components in the product is available and no synergistic effects between any of the co-formulants or active substance are expected. This allows classification of the mixture according to CLP Regulation 1272/2008.

Acute toxicity

Acute toxicity by oral route

Value used in Risk Assessment – Acute inhalation toxicity	
Value	The biocidal product is not acutely toxic via the oral route.
Justification for the value/conclusion	Classification of the mixture was conducted by calculation according to the CLP Regulation 1272/2008 Annex I: 3.1.3.6. Information from submitted MSDS and information provided in the Assessment Reports for the active substances were used for classification by calculation resulting in an ATE_{mix} of 4805.29 mg/kg bw which is above 2000 mg/kg bw, therefore no classification for acute oral toxicity is required. For more information on the classification calculations refer to the Confidential Annex.
Classification of the product according to CLP and DSD	Not classified

Acute toxicity by inhalation

Value used in Risk Assessment – Acute inhalation toxicity	
Value	The biocidal product is not acutely toxic via inhalation.
Justification for the value/conclusion	Classification of the mixture was conducted by calculation according to the CLP Regulation 1272/2008 Annex I: 3.1.3.6. Information from submitted MSDS and information provided in the Assessment Reports for the active substances were used for classification by calculation resulting in an ATE_{mix} of 66.36 mg/l which is above 20 mg/l, therefore no classification for acute inhalation toxicity is required. For more information on the classification calculations refer to the Confidential Annex.
Classification of the product according to CLP and DSD	Not classified

Acute toxicity by dermal route

Value used in Risk Assessment – Acute dermal toxicity	
Value	The biocidal product is not acutely toxic via the dermal route.
Justification for the value/conclusion	Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008. Co-formulants or active substances are either not classified themselves for this endpoint or are present in the product at a

	concentration below the cut off value.
Classification of the product according to CLP and DSD	Not classified

Additional information on the classification of the active substances

The classification of piperonyl butoxide has been recently discussed in RAC-53 (RAC, 2020). The agreed classification (Eye irritation, Cat. 2, H319; STOT SE Cat. 3, H335; EUH066) has been incorporated in the toxicological hazard assessment of the biocidal product.

Information on dermal absorption

If no dermal absorption studies exist with the specific formulation of the biocidal product, either a default value from the *Guidance on dermal absorption* (EFSA, 2017) is applied for a first worst-case exposure estimate or read across with data from the CAR of the active substance or other product formulations similar to the biocidal product to be authorized is performed.
There are no dermal absorption studies available with the specific formulation of AQUA LIGNEX I. In the Assessment Report for permethrin in PT18 (Ireland, 2014) it is stated that product specific studies should be submitted for product authorisation. Therefore, an absorption value of 70 % used for ready-to-use (RB) bait formulations, which are diluted, should be applied as a default for permethrin according to Guidance on dermal absorption (EFSA, 2017). According to the Assessment Report for piperonyl butoxide (Greece, 2017) the absorption values in the Assessment Report were established from a study in human volunteers where a solution of 3% w/w piperonyl butoxide in isopropanol and an aqueous formulation (4% w/w) were tested. As a worst case, a value of 2.4% for the concentrate was set and 4.8% for in-use dilutions. However, according to the EFSA Guidance on Dermal Absorption (EFSA, 2017) the test substances used in a dermal absorption study and the biocidal product are considered not sufficiently similar to the reviewed product. Therefore, a default absorption value of 70 % used for ready-to-use (RB) bait formulations, which are diluted, should be considered for permethrin.

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Permethrin	Piperonylbutoxide
Value(s)*	70%	70%
Justification for the selected value(s)	Default value for ready-to-use (RB) bait formulations according to according to Guidance on dermal absorption (EFSA, 2017).	Default value for ready-to-use (RB) bait formulations according to according to Guidance on dermal absorption (EFSA, 2017).

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

Please see section 2.1.2.5 and the confidential appendix for further information on substances of concern.

Available toxicological data relating to a mixture
Not applicable.

Other
Certificates of compliance of the polymer are attached in IUCLID.

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	no
Oral	n.a.	n.a.	no	n.a.	n.a.	yes	no

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.	Mouthing of trap	Secondary Exposure, acute: A toddler picks up a trap and sucks on it	General public
2.	Inhalation of volatilised residues indoors	Secondary Exposure, chronic: Inhalation of volatilised residues indoors released in the living area of a domestic house.	General public

Industrial exposure

No industrial exposure foreseen.

Professional exposure

No Professional exposure foreseen.

Non-professional exposure

No non-professional exposure is expected if the biocidal product is used as prescribed.

Exposure of the general public

Description of Scenario [1]
VANDAL Ameisenfalle neu is an ant trap for indoor use. The polyethylene ring which contains the active substances is properly placed in-between a double row PP frame. This PE frame is fenced in by 2 rows of plastic teeth, so that people – even toddlers - do not come into direct contact with the PE frame. A width of 3 mm in between the teeth of the row and also in between the 2 rows is considered to keep a solid safety level. Another support for safety are the plastic teeth themselves. The plastic teeth have a flat end with sharp edges, so these feel uncomfortable when touched directly. Thus it is concluded, that if the biocidal product is used as prescribed there is no dermal exposure to humans. Nevertheless, as toddlers love to chew on everything, an estimation of oral exposure is performed. Even if it is highly expected, that the plastic teeth might feel uncomfortable so the toddler would immediately let go of or spit out the trap. Tier 1: Extraction from the polyethylene ring can be assumed to be in the range of the water solubility of the substances as well as by the saliva produced by toddler per day. It is assumed that the mouthing takes place during 1 hour (very conservative assumption).

	Parameters	Value
Tier 1	Frequency	1/day
	Body weight toddler[1]	10 kg
	Water solubility of substance[2]	4.95 µg/l → 0.0045 mg/L (Permethrin) 28.9 mg/L (PBO)
	Salvia produced by toddler per day[3]	0.2 L
	Duration of chewing	1 h / day
	Oral absorption	100% (Permethrin) 100% (PBO)

[1] ECHA 2017c, HEAdhoc recommendation no 14, Appendix A
[2] Ireland 2014, Assessment report page 47; Greece 2017, Assessment report page 43,
[3] Austria 2013, Doc II-B, page 29.

Calculations for Scenario [1]

$$Oral\ systemic\ exposure, tier\ 1\ \left[\frac{mg}{kg\ bw\ day}\right] = water\ solubility\ of\ substance\ \left[\frac{mg}{L}\right] * Salvia\ production\ \left[\frac{L}{day}\right] * \frac{1}{24}\left[\frac{day}{h}\right] * \frac{Duration\ of\ chewing\ [h\,]}{day} * \frac{1}{body\ weight\ [kg]}$$

Summary table: systemic exposure for general public given in [mg/kg bw/day]						
Scenario	**Tier/PPE**	**Estimated uptake**				
			inhalation	**dermal**	**oral**	**total**
Scenario [1]	Tier 1 / no PPE	**Permethrin**	n.a.[1]	n.a.[1]	0.0000	**0.0000**
		PBO			0.0241	**0.0241**

[1]n.a. not assessed

Scenario [2] - Secondary exposure via inhalation of volatilised residues

Description of Scenario [2] Inhalation of volatilised residues

Inhalation of volatilised residues: toddler inhaling volatilised residues from treated timber indoors. As worst case 24h/day of inhalation exposure is assumed. This scenario also covers children and adults.

According to the HEEG Opinion 13 (EC 2011) endorsed at TM IV 2011 and amended after TM III 2013 long-term exposure to volatilised residues can be neglected if the following tier 1 screening tool which is based on the toddler (inhalation rate of 8 m³/24 h and body weight of 10 kg) representing the worst case, is ≤1:

$$0.328 \bullet \frac{MW(g/mol) \bullet VP(Pa)}{AEL_{long-term}} \leq 1$$

This is true for permethrin (0.0055) and piperonylbutoxide (0.0074). Therefore long-term exposure to volatilised residues is negligible for adults, infants and children for this a.s. and no further calculations are performed.

Further information and considerations on scenarios [1] and [2]

Please see detailed description of scenarios.

Combined scenarios

Not applicable.

Monitoring data

No data available.

Dietary exposure

The biocidal products are not intended to be used on any food or feed of plant and/or animal origin. In case the ants' way back to the nest after contact with the biocidal product may cross any food or feed following exposure is highly considered negligible.

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

Indirect relevant exposure to Permethrin and piperonyl butoxide as a result of contamination of food by the ants is only of theoretical nature. Additionally observations show ants will go back to their nest after food intake in the bait box. Even if any exposure would occur, amounts would be minimal.

Conclusion
Transfer of the active substance into food is 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.

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
$AEL_{short\text{-}term}$	Piperonyl butoxid: developmental study rabbit Permethrin: Rat 2 year oral study (acute effect)	Piperonyl butoxid: 100 mg/kg bw/day Permethrin: 59.46 mg/kg bw/day	Piperonyl butoxid: 100 Permethrin: 100	Piperonyl butoxid: No[2] Permethrin: No[2]	Piperonyl butoxid: 1 mg/kg bw/day Permethrin 0.5 mg/kg bw/day
$AEL_{medium\text{-}term}$	Piperonyl butoxid: 1-year dietary dog Permethrin: 12-month dog study	Piperonyl butoxid: 16 mg/kg bw/day Permethrin: 5 mg/kg bw/day	Piperonyl butoxid: 100 Permethrin: 100	Piperonyl butoxid: No[2] Permethrin: No[2]	Piperonyl butoxid: 0.2 mg/kg bw/day Permethrin 0.05 mg/kg bw/day
$AEL_{long\text{-}term}$	Piperonyl	Piperonyl	Piperonyl	Piperonyl	Piperonyl

	butoxid: 1-year dietary dog Permethrin: 12-month dog study	butoxid: 16 mg/kg bw/day Permethrin 50 mg/kg bw/day	butoxid: 100 Permethrin: 100	butoxid: No[2] Permethrin: No[2]	butoxid: 0.2 mg/kg bw/day Permethrin 0.05 mg/kg bw/day

[1] Inter/Intra species variation.

[2] According to the respective CARs: Piperonyl butoxid: 100% based on the results of the ADME studies; Permethrin: Extensive and rapid. Only between 3 and 6% of the administered dose is being recovered unmetabolised in faeces resulting in an estimated oral absorption of about 95%. The Guidance on BPR: Volume III Parts B+C (ECHA, 2017b) states that "… when oral absorption rate exceeds 80%, the default value of 100% should be applied for the derivation of AELs and internal exposure levels." Consequently, oral absorption is assumed to be 100% for permethrin.

Maximum residue limits or equivalent

MRLs are not relevant for this biocidal product as the product will not come into contact with food or animal feeding stuffs when used in compliance with the authorised use. For permethrin MRLs for certain food items can be found in Regulation (EU) 2017/623.

Local effects

According to the Guidance on BPR: Volume III Parts B+C (ECHA, 2017) risk characterisation (RC) for local effects is only required when the biocidal product is classified for local effects. The biocidal product contains 6.989% (w/w) permethrin which is classified as a skin sensitizer. As a result VANDAL Ameisenfalle neu is classified Skin sens 1, H317 and a qualitative risk assessment has to be performed.

The trap consists of a polyethylene ring containing the active substance, which is placed in-between a double row PP frame. Because of this design dermal exposition to the PE ring containing the active substances is minimized and considered negligible.

The biocidal product is for non-professional users and regular contact with the contact trap is not expected since one single trap is required per ant run and once placed the trap remains efficacious for up to 3 months.

Even tough dermal contact with the active substance is not expected due to the design of the biocidal product it cannot be ruled out completely (e.g. during opening of the product) and therefore the RMMs "N-383 modified: Avoid contact with the contents of the trap." and "N-209 modified: Wash hands after opening and placing the trap." are prescribed for precautionary reasons to reduce a possible risk for local effects.

According to a recent discussion of piperonyl butoxide in RAC-53 (RAC, 2020) a harmonized classification of the active substance piperonyl butoxide with Eye irritation, Cat. 2, H319; STOT SE Cat. 3, H335; EUH066 was proposed. The amendment to Regulation (EC) No 1272/2008 to include the harmonised classification of piperonyl butoxide in Annex VI of the CLP Regulation shall apply from 23 November 2023 according to COMMISSION DELEGATED REGULATION (EU) 2022/692. Nevertheless, the CLP Guidance (ECHA, 2017e) states that the opinion adopted by the ECHA Risk Assessment Committee (RAC) on the harmonised C&L should already be taken into consideration and substances and mixtures may be classified and labeled in accordance with this revision before this date.

Piperonyl butoxide is classified for EUH066. According to the Guidance on BPR: Volume III Parts B+C (ECHA, 2017e) "Substances of Concern – Proposed Human Health (Toxicology)

Assessment Scheme for Authorisation of Biocidal Products" classification with EUH066 is assigned to Band A.
The active substance is incorporated in a polyethylene ring (i.e. solid mixture containing active substances) and repeated contact on a regular basis with the biocidal product is not expected when complying with the instructions for use.
Regarding the design of the biocidal product dermal contact with the PE ring containing the active substance is not expected. Furthermore, the active substance is present at a low concentration of 0.851% in the biocidal product.
Considering this, labelling of the biocidal product with EUH066 can be omitted.

Risk for industrial users

There are no industrial exposure scenarios relevant to the use of the product No risk assessments are required.

Risk for professional users

There are no professional exposure scenarios relevant to the use of the product. No exposure assessments are required.

Risk for non-professional users

The product is a ready-to-use formulation intended for non-professional use only. The trap consists of a polyethylene ring containing the active substance, which is placed in-between a double row PP frame. A width of 3 mm between the teeth of the row and also in-between the two rows as well as the sharp edges of the teeth row are considered to keep a solid safety level. Due to this design dermal contact is considered negligible. Once used, the biocidal product is disposed and dermal contact is not expected. No mixing or refilling occurs. Dermal exposure of users is therefore not predicted at any stage.
An assessment of exposures in non-professional users is therefore not considered to be relevant.

Risk for the general public

Secondary (indirect) exposures in members of the public are unlikely due to the design of the product.

Nevertheless, toddlers may chew on the biocidal product. Even though it is very likely, that the plastic teeth might feel uncomfortable and toddlers are rarely left unattended, an estimation of oral exposure is performed (Scenario 1).

For risk characterisation, it is considered that the extraction by saliva is in the range of the water solubility of the substances. To cover possible uncertainties of components of the saliva which may improve extraction of the active substances from the PE ring a very conservative extraction time of one hour was assumed.

Additionally, inhalation of volatilised residues released from the biocidal product was assessed. According to the result obtained by using the equation proposed by HEEG opinion 13 for the active substances permethrin and piperonyl butoxid long-time exposure to volatised residues can be neglected due to the low volatility.

The quantitative estimate to determine the potential risk for active substance exposure is depicted below:

Systemic effects

Task/ Scenario		Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [1] Mouthing of trap	Permethrin	1 / no PPE	59.46	0.5[1]	0.0000	0.00	Yes
	Piperonyl butoxid	1 / no PPE	16	0.2[1]	0.0241	12.05	Yes

[1] $AEL_{short\ term}$

Conclusion

Based on the risk characterisation for health effects, secondary (indirect) exposures to the active substances permethrin and piperonyl butoxid in members of the public arising from the consumer use of the biocidal product to control ants in the home is not considered to pose an unacceptable risk to human health. In addition, P phrase P102: "Keep out of reach of children" shall prevent these unintentional accidents.

Risk for consumers via residues in food

The insect bait box product will not be used in areas relevant to the processing or manufacturing of food and do not have any applications relevant to farm animals or livestock. Contamination of foodstuff is highly unlikely, but for precautionary reasons following risk mitigation measure is listed: "Apply the product so that pets and food 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

The Guidance on Human health risk assessment (ECHA, 2017e) describes a tiered approach for the risk assessment for products containing multiple active substances. In Tier 1 the risk assessment is performed for each individual active substance separately, as described in the above sections.

Tier 2 implements the worst case scenario in combining the exposures for all the active substances in the product. The approach uses assessment of combined exposure to mixture by concentration or dose-addition. The hazard index (HI) is calculated by addition of the individual hazard quotient (HQ, the ratio of exposure-to-reference value) for each active substance.

In Tier 2 the HQ is determined (HQ = internal exposure/ AEL) for each active substance and the HQ of the individual active substances added up resulting in the HI for the mixture/product.

HI = ∑ HQa.s.

If HI ≤ 1 the risk related to use of the mixture will be considered acceptable;

If HI > 1 the risk related to use of the mixture will be considered unacceptable and refinement of the cumulative risk assessment is performed in Tier 3.

Scenarios	**Permethrin**	**Piperonyl butoxide**	**Conclusion**
Scenario [1] Mouthing of trap			
Without PPE			
%AEL	0.00	12.05	Acceptable
HQ	0.0000	0.1205	Acceptable
	HI = 0.1205		

Conclusion
The calculations in the table above result in a HI ≤ 1 and therefore show an acceptable risk from mixture toxicity.

2.2.7 Risk assessment for animal health

Based on the specific construction of the biocidal product and the intended use, contact of pets or domestic animals to the biocidal product is not expected. Hence, a specific exposure and risk assessment is not required, but for precautionary reasons following risk mitigation measure is listed: "Apply the product so that pets and food do not come in contact with the product."

Please note that cats are more sensitive to pyrethroids like permethrin due to a slower metabolisation of these substances. Therefore, the access of cats to the biocidal product has to be avoided and the following RMM has been added: "N-335 modified: Keep cats away from the trap. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats."

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The active substances permethrin and piperonyl butoxide (PBO) have been approved according to the Regulation (EU) No 528/2012 for their use as insecticides (PT18). Final CARs as agreed by the EU member states and the European Commission are available for permethrin (IE, 2014) and piperonyl butoxide (Greece, 2017). An addendum to the CAR (Ireland, 2017) for permethrin with an agreed different $PNEC_{soil}$ compared is available on ECHAs website. Full letter of access are available to the active substances by the applicant. However, for secondary poisoning only for birds a risk assessment was performed (refer to 2.2.8.3 risk characterization).

The following endpoints for the active substance permethrin and its relevant metabolites are reported in the CAR (Ireland, 2014):

	Permethrin	**DCVA**	**PBA**
$PNEC_{sw}$	4.7E-07 mg/L	1.5E-02 mg/L	1.0E-02 mg/L
$PNEC_{sed}$	2.17E-04 mg/kg_{wwt}	1.2E-02 mg/kg_{wwt}	9.0E-03 mg/kg_{wwt}
$PNEC_{STP}$	4.95E-03 mg/L	-	-
$PNEC_{soil}$	0.175 mg/kg_{wwt}[4]	4.6 mg/kg_{wwt}	1.44 mg/kg_{wwt}
$PNEC_{oral\ bird}$	16.7 mg/kg food	-	-
$PNEC_{oral\ mammal}$	120 mg/kg food	-	-

The following endpoints for the active substance piperonyl butoxide and its relevant metabolites are reported in the CAR (Greece, 2017):

	Piperonyl butoxide	**M1**	**M2**	**M12**	**F**
$PNEC_{sw}$	1.48E-03 mg/L	2.8E-03 mg/L	3.3E-03 mg/L	2.3E-03 mg/L	-
$PNEC_{sed}$	4.0E-05 mg/kg_{wwt}	Covered by aquatic risk assessment	Covered by aquatic risk assessment	Covered by aquatic risk assessment	-
$PNEC_{STP}$	2.89 mg/L	-	-	-	-
$PNEC_{soil}$	9.8E.02 mg/kg_{wwt}	Covered by the parent	Covered by the parent	Covered by the parent	Covered by the parent
$PNEC_{oral\ bird}$	10 mg/kg food	-	-	10 mg/kg food[5]	-

4 According to the addendum to the CAR for permethrin (Ireland, 2017)
5 Worst case approach (Greece, 2017)

$PNEC_{oral}$ mammal	20mg/kg food	-	-	20mg/kg food[9]	-

Bees:

In the CAR for permethrin (Ireland, 2014) toxicity data for honeybees with an acute $LD50_{oral}$ of 0.163 µg/bee and an $LD50_{contact}$ of 0.02 µg/bee were reported.
As the product is also used outdoor and since the $LD50_{contact}$ for honeybees for permethin is below the discussed and agreed threshold of 11 µg/bee (for further details refer to the final minutes of ENV WG-III 2021) the warning sentence "This biocidal product contains (an active substance) which is dangerous to bees" (in line with "CA-Dec20-Doc.4.1 Warning sentence and RMM for bees_finalrev1") will be included as a RMM 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 substances permethrin and PBO. Further effects from other components are not expected.
Further 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 (0.ATP) of permethrin for its environmental effects is Aquatic Acute 1, H400 (M=1000) and Aquatic Chronic 1, H410. In the Assessment report for permethrin (IE, 2014) a classification as Aquatic Acute 1 (M=100) and Aquatic Chronic 1 (M=10000) was proposed.

For piperonyl butoxide no harmonised classification is available. In the CAR (GR, 2017) a classification as Aquatic Acute 1 (M=1) and Aquatic Chronic 1 (M=1) according to Reg. (EC) No 1272/2008 was proposed. A RAC opinion from June 2020 for piperonyl butoxide is available, where it was concluded to classify it as Aquatic Acute 1 (M=1) and Aquatic Chronic 1 (M=1). This classification was reflected in the 18.ATP to the CLP regulation.

According to the content of permethrin of 6.989% (w/w) and PBO of 0.851% (w/w) in the biocidal product (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 H400 Harmful to aquatic life (may be omitted) and H410 Harmful to aquatic life with long lasting effects and the precautionary statements P273, 391 and P501.

Further Ecotoxicological studies

New data was neither submitted, for the active substances nor for the biocidal product. The relevant substances in the product are the active substances permethrin and piperonyl butoxide (PBO). The risk assessment is based on the data available from the CARs for permethrin (Ireland, 2014) and piperonyl butoxide (Greece, 2017).

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

No new data was submitted, neither for the active substances nor for the biocidal product. The product does not contain a food attractant and 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 products are no baits or granules.

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 was submitted, neither for the active substances nor for the biocidal product. The only relevant substances in the product are the active substances permethrin and PBO.

Leaching behaviour (ADS)

Not necessary for the biocidal product. No treated articles.

Testing for distribution and dissipation in soil (ADS)

No new data was submitted, neither for the active substances nor for the biocidal products.

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

No new data was submitted, neither for the active substances nor for the biocidal products.

Testing for distribution and dissipation in air (ADS)

No new data was submitted, neither for the active substances nor for the biocidal products.

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 sprayed.

2.2.8.3 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 the active substances in the biocidal product, permethrin and piperonyl butoxide, 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 substances permethrin and piperonyl butoxide.
It should be noted that for emissions to water and soil, an exposure assessment must also be conducted for the identified relevant metabolites of permethrin and piperonyl butoxide, which are:

Metabolites of permethrin
- DCVA: 3-(2,2-dichlorovinyl)-2,2-dimethyl (1-cyclopropane) carboxylate
- PBA: 3-phenoxybenzoic acid ().

Metabolites of piperonyl butoxide
- M1: [(6-propyl-1,3-benzodioxol-5-yl)methoxy]acetic acid
- M2: {2-[(6-propyl-1,3-benzodioxol-5-yl)methoxy]ethoxy}acetic acid

- M8: 6-{[2-(2-butoxyethoxy)ethoxy](hydroxy)methyl}-1,3-benzodioxole-5-carboxylic acid
- M12: 6-propylbenzo[d][1,3]dioxole-5- carboxylic acid
- EN-1-101-/4: (2-{2-[(6-propyl-1,3-benzodioxol-5-yl)methoxy]ethoxy}ethoxy) acetic acid (Metabolite F)

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 well protected from rain and dust.
Hence, the biocidal product consists of a polyethylene ring retaining the active substances permethrin and piperonyl butoxide. This ring is part of the "ready-to-use" contact trap and contains the active substance (evenly) distributed therein. A small percentage of the active substances diffuses to the surface of the polymer ring and is transferred to the ants via contact.
The ants can easily get inside the trap, while the biocidal product is well protected by double row PP frame avoiding contact to the surface underneath the trap. Hence, emissions to the environment during use are prevented. In addition, permethrin and piperonyl butoxide are not able to evaporate out of the ant trap, as the evaporation rate of permethrin and piperonyl butoxide 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 ant traps are provided "ready-to-use").

Information regarding environmental exposure during application of biocidal product
The biocidal product is part of a chemical bait free ant trap to be placed crosswise over an ant trial in infested areas. Although this kind of ant trap is not a bait station in a strict sense, it is suited to be regarded as such and to use corresponding emission models.

Indoor:
The Emission Scenario Document for PT18 (OECD 2008) assumes that emission of the active substance after indoor application in bait boxes is negligible. Similar to the bait

boxes the biocidal product is contained in a resistant plastic frame. At the end of the efficacy period, traps containing any remaining product can easily be picked up and disposed to solid waste.
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.
For the already mentioned reasons, the ant trap is suited to be treated like a bait box. In addition and in line with the assessment report for permethrin (Ireland 2014) based on the low vapour pressure (2.155 x 10^{-6} Pa at 20°C) and Henry constant (4.6x10^{-3} Pa m^3 mol^{-1}) of permethrin decontamination of air after exposure to the product is considered to be negligible. As reported in the Assessment Report of piperonyl butoxide (Greece 2017) and based on the vapour pressure (2.11 x 10^{-5} Pa at 60°C, the calculated vapour pressure at 25°C will be less than 1.33 x 10^{-5} Pa) and the Henry's law constant (1.648 x 10^{-4} Pa m^3 mol^{-1}) decontamination of air is also considered to be negligible for the active substance piperonyl butoxide.
Therefore releases arising from outdoor use have not been considered further.

Information regarding environmental exposure during cleaning step
The only possible emission pathway to the environmental compartments via disposing of to waste does not result in considerable emissions, as the empty bait station has to be disposed of according to local regulations for 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	**Permethrin**	**Piperonyl Butoxide**	**Unit**	**Remarks**
Vapour pressure (at 20°C)	2.155 x 10^{-6}	2.11 x 10^{-5} Pa at 60°C, the calculated vapour pressure at 25°C will be less than 1.33 x 10^{-5} Pa	Pa	---
Log Octanol/water	4.67 (fish	4.8	Log 10	---

Input parameters (only set values) for calculating the fate and distribution in the environment				
Input	**Permethrin**	**Piperonyl Butoxide**	**Unit**	**Remarks**
partition coefficient	6.1 (earthworm))			
Henry's Law Constant	4.6×10^{-3}	1.648×10^{-4} Pa m^3 mol^{-1}	Pa/m^3/mol	
Bioconcentration factor fish (BCF_{fish})	570	290	L/kg	
Bioconcentration factor earthworm ($BCF_{earthworm}$)	15108	757	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 indoor and 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 determined as 4.67 (fish) and 6.1 (earthworm), indicating that it is a fat-soluble molecule with a potential to bioaccumulate. Furthermore, the highest experimentally determined BCF values were a $BCF_{earthworm}$ =15108 L/kg and a BCF_{Fish} 570 L/kg, which are both above the trigger value for a bioaccumulation potential of permethrin. The log octanol:water partition coefficient (log K_{OW}) of piperonyl butoxide, 4.8, suggests that it may have significant potential for bioconcentration in both the aquatic and terrestrial environment, with the possibility of bioaccumulation leading to secondary poisoning (Greece 2017). The experimentally determined BCF values ($BCF_{earthworm}$ =757 L/kg and BCF_{Fish} =290 L/kg also indicate bioaccumulation of piperonyl butoxide.
Therefore, for secondary poisoning an overall worst case approach 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. This assumption is supported by the fact that the biocidal product is placed in a polymer frame, which should prevent direct contact to the biocidal product.

Primary poisoning via direct consumption of insecticide by bees
Permethrin and piperonyl butoxide are known to be toxic to bees. However, direct contact to permethrin and piperonyl butoxide is prevented if the biocidal product is used as prescribed (The biocidal product is protected by double row PP frame.).
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 Effects 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 fish 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 may be calculated using the following equation:

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

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:

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

The total application rate of biocidal product per square meter (T_{appl}) was calculated for 4 bait boxes on a terrace with a size of 30 m². One ant trap contains 2.6 g biocidal product, 6.989%(w/w) and 0.851%(w/w) of which correspond to the active substances permethrin and piperonyl butoxide, repectivly.

Calculation of the *p*ermethrin application rate			
	Definition	**Permethrin**	**Piperonyl Butoxide**
Amount of product per baid box [g]	Q_{prod}	2.6	
Fraction of active substance in product [-]	F_{AI}	0.065989	0.00851
Number of application sites per terrace [-]	N_{sites}	4	
Area of the treated terrace [m²]	$AREA_{terrace}$	30	
Application rate [kg/m²]	**$T_{appl} = ((Q_{prod} \times F_{AI} \times N_{sites}) / AREA_{terrace}) / 1000)$**	**2.29×10^{-5}**	**2.95×10^{-6}**

In a second step, the permethrin and piperonyl butoxide concentrations in the fresh diet are 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	**Permethrin**		**Piperonyl Butoxide**	
		Acute	**Short-term**	**Acute**	**Short-term**
Application rate [kg x m^{-2}]	T_{appl}	$2.29x10^{-5}$		$2.95x10^{-6}$	
Residue per unit dose [mg x kg^{-1}]	RUD	52	29	52	29
Predicted environmental concentration in ants [mg × kg^{-1}]*	C_{ant} = RUD x T_{appl} x 10^{-4}	$1.19x10^{-7}$	$6.64x10^{-8}$	$1.53x10^{-8}$	$8.55x10^{-9}$
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	$1.24x10^{-7}$	$6.91x10^{-8}$	$1.59x10^{-8}$	$8.89x10^{-9}$
Estimated theoretical exposure- Small insectivorous bird II (e.g. Tree sparrow) [mg x kg_{bw}^{-1}x d^{-1}]		$2.38x10^{-8}$	$1.33x10^{-8}$	$3.06x10^{-9}$	$1.71x10^{-9}$

* 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 Tappl into kg/ha.

Summary table on estimated theoretical exposition (ETE)				
	ETE [mg x kg_{bw}^{-1}x d^{-1}]			
	Small insectivorous bird I		Small insectivorous bird II	
	Acute	Short term	Acute	Short term
Permethrin	$1.24x10^{-7}$	$6.91x10^{-8}$	$2.38x10^{-8}$	$1.33x10^{-8}$
Piperonyl butoxide	$1.59x10^{-8}$	$8.89x10^{-9}$	$3.06x10^{-9}$	$1.71x10^{-9}$

2.2.8.4 Risk characterization

2.2.8.5 Risk characterization for receiving compartments

A risk characterization for the biocidal product for any environmental compartment is not considered necessary, since no exposure due to its use is assumed and therefore no PECs were calculated (refer to 2.2.8.2 Exposure assessment, chapter emission estimation of this report). 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.

Bees

Referring to the risk for bees the agreed warning sentence was applied (refer to 2.2.8.1 Effect assessment).

Secondary poisoning

Secondary poisoning can occur when contaminated ants are eaten up from birds.

Secondary poisoning by contaminated ants

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

For the acute toxicity scenario the lowest reported oral acute LD50 for birds in the CAR for permethrin is 4640 mg/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 10000 ppm which corresponds to 10000 mg/kg bw (Ireland, 2014).

For the acute toxicity scenario the lowest reported acute LD50 for birds in the CAR for piperonyl butoxide is >2250 mg/kg bw (Greece, 2017). For the short term scenario the lowest reported LD_{50} dietary value (5-day) for birds is >5620 mg/kg bw (Greece, 2017).

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, 2017d).

Summary table on secondary poisoning via contaminated ants				
Scenario	**ETE [mg/kg bw]**	**LD50 (acute) LC50/LD50 (short term) [mg/kg bw]**	**AF**	**ETE/LD50 or LC50**
Permethrin				
acute toxicity (small insectivorous bird I)	1.24E-07	4640	3000	8.02E-08

short term toxicity (small insectivorous bird I)	6.91E-08	10000	3000	2.07E-08
acute toxicity (small insectivorous bird II)	2.38E-08	4640	3000	1.53E-08
short term toxicity (small insectivorous bird II)	1.33E-08	10000	3000	3.99E-09
Piperonyl butoxide				
acute toxicity (small insectivorous bird I)	1.59E-08	2250	3000	2.12E-08
short term toxicity (small insectivorous bird I)	8.89E-09	5620	3000	4.75E-09
acute toxicity (small insectivorous bird II)	3.06E-09	2250	3000	4.08E-09
short term toxicity (small insectivorous bird II)	1.71E-09	5620	3000	9.13E-10

Mixture toxicity

A mixture toxicity assessment was not deemed necessary, since no exposure was assumed (refer to 2.2.8.2 Exposure assessment, emission estimation page 54). Moreover, no substances of concern for the environment were identified (refer to Confidential Annex).

Aggregated exposure (combined for relevant emission sources)

This part of the PAR will be further elaborated as soon as the guidance on aggregated exposure is available.

Overall conclusion on the risk assessment for the environment of the product
For the biocidal product no exposure was assumed and hence no risk characterisation for any of the environmental compartments was performed. No substances of concern were identified for the environment. Secondary poisoning The risk ratios for secondary poisoning via the consumption of contaminated ants by birds were calculated. <u>Conclusion:</u> An acceptable risk for the secondary poisoning via consumption of contaminated ants for birds was demonstrated.

2.2.9 Measures to protect man, animals and the environment

Please refer to section 2.1.4 and 2.1.5 and IUCLID Point 11

In Case of fire:
Suitable extinguishing media:

CO2, dry powder, foam, water spray.
In case of fire formation of toxic, irritant and/or corrosive gases is possible. For example HCl gas, CO2

2.2.10 Assessment of a combination of biocidal products

Not applicable. No intended concomitant use with other biocidal products.

2.2.11 Comparative assessment

The biocidal product „VANDAL Ameisenfalle neu" 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 Ameisenfalle neu", 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 authorized in Austria for PT 8 (in the version of 12.05.2022), 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 Ameisenfalle neu" is an insecticide (PT 18) which contains the active substance permethrin. The product is a ready-to-use bait free contact trap to be used by general public (non-professionals) in order to control black garden ants indoors and outdoors (*Lasius niger;* adults; forager ants). The product controls ants on their trails running below or touching the insecticide frame of the trap.

Product Type	PT 18
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s), development stage	Common name: Black Garden Ant Scientific name: *Lasius niger* Development stage: adults; forager ants
Field of use	Indoor and outdoor use on paved surfaces (Outdoor only in rain protected, dust free places, e.g. terraces)
Category(ies) of users	Non-professional user
Application method(s)	Bait free ant trap to be placed crosswise over an ant trial in infested areas.

Authorised use of the biocidal product

Summary of the authorised uses:
PT18: Insecticide – *Lasius niger* (all stages, adults; forager ants) – Indoor and outdoor use – Ready-to-use bait free contact trap – 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 authorized 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 box 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 12.05.2022), as already mentioned above.
According to the information provided in the list, currently 28 biocidal products for non-professionals to control *Lasius niger* are obtainable (with various trade names). Eleven of these are available as ready-to-use bait boxes, but no trap is currently authorised. In our point of view traps and bait boxes are considered to be a very appropriate way of biocidal use – especially for non-professional use. Additionally the trap is free of bait, therefore it is considered to be less attractive for non-target organisms. Thus the present biocidal is seen as a unique use.

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 authorized 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 authorized 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 authorized 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 spinosad 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, to our understanding the product represents a unique use.
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 Ameisenfalle neu” 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	Reference (Author, year)	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
3.1 3.2 3.4.1 3.4.2	Anonymous 2022a	**Determination of physico-chemical Properties and Accelerated Storage Stability Tests for VANDAL Ameisenfalle neu: 2 weeks at 54 °C and up to 60 months at 20 °C**	BioGenius GmbH Analytics 51429 Bergisch Gladbach Germany	Mo6117	no	no	Nifra Parfumerie Ges.m.b.H.
3.3	Anonymous 2022b	**Certificate of analysis**	BioGenius GmbH Analytics 51429 Bergisch Gladbach Germany	Mo7420	no	no	Nifra Parfumerie Ges.m.b.H.

Section No. in IUCLID	Reference (Author, year)	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
5.1	Anonymous 2018a	**Validation of Method Bio AQ089: NIR: GC-Determination of Permethrin and Piperonyl butoxide in VANDAL Ameisenfalle neu**	BioGenius GmbH Analytics 51429 Bergisch Gladbach Germany	Mo6116	yes	no	Nifra Parfumerie Ges.m.b.H.
6.7	Anonymus 2017	Laboratory assessment of the efficacy of insecticidal plaquettes against ants	T.E.C. Laboratory ZAC Maignon 64600 Anglet	2261/1017	yes	no	Nifra Parfumerie Ges.m.b.H.
6.7	Anonymus 2021	Simulated-use trial of the efficacy of insecticidal plaquettes against ants	T.E.C. Laboratory ZAC Maignon 64600 Anglet	2261b/1017	yes	no	Nifra Parfumerie Ges.m.b.H.

3.2 Output tables from exposure assessment tools

None

3.3 New information on the active substance

Not available

3.4 Residue behaviour

Not available

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

A IUCLID file is available and the summaries are considered sufficient.

3.6 Confidential annex

Please refer to the confidential annex provided as a separate document.

3.7 Other

Austria 2013, Assessment Report Cu-HDO, Product type 8, 13th December 2013; Available at: https://echa.europa.eu/documents/10162/8aa74693-d291-9eb7-ecfe-1a21a4f41cf2)

EC 2011 HEEG: Opinion 13 *HEEG opinion on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance*

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

ECHA 2017b: Guidance on the biocidal products regulation, Vol. II Efficacy – Parts B+C, version 1.0, February 2017.

ECHA 2017c HEAdhoc Recommendation no. 14 *Default human factor values for use in exposure assessments for biocidal products*

ECHA 2017d, Guidance on the Biocidal Products Regulation, Volume IV: Assessment and Evaluation – Parts B+C, Version 2.0, October 2017.

ECHA 2017e: Guidance on the Biocidal Products Regulation, Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0

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

EFSA 2017: Guidance on dermal absorption, European Food Safety Authority. EFSA Journal 2017;15(6):4873

Greece 2017, SUBSTANCE EVALUATION REPORT, Piperonyl Butoxide, EC Number: 200-076-7, CAS Number: 51-03-6, January 2017.

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

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

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

RAC 2020, 53rd Meeting of the Committee for Risk Assessment (RAC-53), 26 June 2020

LEGAL NORMS

Regulation (EC) No 1272/2008: Commission Regulation (EU) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R1272-20170101

Regulation (EU) 2017/623: Commission Regulation (EU) 2017/623 of 30 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, amitraz, coumaphos, diflufenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin in or on certain products; Available at: ELI https://eur-lex.europa.eu/eli/reg/2017/623/oj

Regulation (EU) 2022/692: Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance); Available at: ELI https://eur-lex.europa.eu/eli/reg_del/2022/692/oj