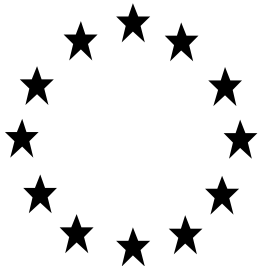
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	Ameisen-Mittel
Product type(s):	18 (Insecticides, acaricides and products to control other arthropods)
Active ingredient(s):	Permethrin
Case No. in R4BP	BC-YR023158-12
Asset No. in R4BP	DE-0015369-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/18.00018 710-05-18-00018-00-00-00-0000
Date	25.03.2019

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Overview of applications

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)	Page
NA-APP	DE	BC-YR023158-12 710-05-18-00018-00-00	25.03.2019	First authorisation	
NA-MIC	DE	BC-DB050185-65 710-05-18-00018-00-01	31.10.2019	Minor change (storage stability: 36 months)	

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product, Ameisen-Mittel with the active substance Permethrin (0.54 % w/w) is used as an insecticide (product-type 18) to knock down and subsequently kill black garden ants (*Lasius niger*) (all developmental stages) by non-professionals and professionals.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.

General directions for use of the product are summarised in chapter 2.5.

Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the Irish Assessment Report for the approval of the active substance Permethrin including the “elements to be taken into account by Member States when authorising products” as requested by the Irish CA.
2. The specific provisions from Inclusion Directive for the active substance Permethrin (Commission Implementing Regulation (EU) No 1090/2014).

Approval of the active substance

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

- 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

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

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.

Composition and formulation

The ready-to-use granule and soluble granule “Ameisen-Mittel” contains the active substance Permethrin. No substance of concern has been identified.

Please refer to chapter 2.2 (Composition and formulation) and 5.1 (Full composition of the product) for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.3).

Physical hazards and respective characteristics

Physical-chemical hazard(s) were not identified (please find more information in chapter 3.4).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.5. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.4. Please find more information on efficacy of the product in chapter 3.6.

Risk assessment for human health

Since no relevant substance of concern has been identified the human health risk assessment for this product is based on the active substance.

A human health risk assessment has been carried out for non-professional/professional use of the product (see chapter 3.7) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to non-professional/professional users, bystanders and residents. Regarding non-professional/professional users health protection, there are no objections against the intended uses if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

Since no substance of concern has been identified the risk assessment for the environment for this product is based on the active substance.
A risk assessment has been carried out for non-professional and professional users for the outdoor use of the product (see chapter 3.9) and all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk for the environment if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Comparative Assessment

A comparative assessment was not required (see chapter 3.11) since no candidates for substitution were identified (see chapter 2.2.4).

1 Summary of the product assessment

1.1 Administrative information

1.1.1 Identifier in R4BP

Ameisen-Mittel

1.1.2 Product type(s)

18 (Insecticides, acaricides and products to control other arthropods)

1.1.3 Manufacturer(s) of the product

Name of manufacturer	Detia Freyberg GmbH
Address of manufacturer	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach
Location of manufacturing sites	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach

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

Active substance	Permethrin
Name of manufacturer	Tagros Chemicals India Ltd.
Address of manufacturer	TAGROS CHEMICALS INDIA LTD, Jhaver Centre, Rajah Annamalai Building, IV Floor, 72, Marshalls Road, Egmore, Chennai-600.008, India
Location of manufacturing sites	A-4/1&2, Sipcot Industrial Complex Pachayankuppam Cuddalore - 607 005, Tamilnadu India

1.2 Composition and formulation

1.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.54[2]

- Information on the full composition is provided in the confidential[3] 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 ☒

- According to the information provided the product contains nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

1.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one 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 ☐ (The technical equivalence of the active substance from the new source was established by ECHA, see asset number EU-1234567-0000)

1.2.3 Information on the substance(s) of concern

No substance of concern was identified.

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[2] The purity of the active substance is > 93% w/w.

[3] Access level: “Restricted” to applicant and authority

1.2.4 Candidate(s) for substitution

No candidate for substitution was identified.

1.2.5 Type of formulation

Granule GR and soluble granule SG

1.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[4]

Besides the active substance Permethrin, the other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance Permethrin is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):

H302 – Harmful if swallowed
H317 – May cause allergic skin reaction
H332 – Harmful if inhaled
H400 – Very toxic to aquatic life
H410 – Very toxic to aquatic life with long lasting effects
M = 1000
Pictogram(s): GHS07, GHS09
Signal Word: Warning

Classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is required.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.5 and if applicable to chapter 2.4.

4 Regulation (EC) 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.

Table 2

Classification Hazard classes, Hazard categories	**Hazard statements**	
Aquatic Acute 1	H400 Very toxic to aquatic life.	
Aquatic Chronic 1	H410 Very toxic to aquatic life with long lasting effects.	
Labelling	**Code**	**Pictogram / Wording**
	GHS09	
Signal word	-	Warning
Hazard statements		
	H410	Very toxic to aquatic life with long lasting effects
Supplemental hazard information	EUH208	Contains Permethrin. May cause an allergic reaction
Supplemental label elements		
Precautionary statements	P273	Avoid release to the environment
	P391	Collect spillage
	P501	Dispose of contents/container to...
Note	-	

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.5 and 2.4.

Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.
It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

1.4 Use(s) appropriate for authorisation

1.4.1 Use 1 appropriate for authorisation – Non-professional use - Spreading

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide. Biocidal product knocks down and kills black garden ants of all development stages. There is a strong suppression of nest buildings activity and a rapid depression of the black garden ant population.
Target organism(s) (including development stage)	black garden ant (*Lasius niger*) (all developmental stages)

Field(s) of use	Around houses on paved ways, balconies and terraces.
Application method(s)	Spreading of the granulated product over the nests.
Application rate(s) and frequency	10 g product per nest. Up to 4 applications per year.
Category(ies) of users	Non-professional user
Pack sizes and packaging material	Single-dose sachets are limited to a size of 10 g. Pack sizes exceeding 10 g have to contain appropriate 10 g dosing equipment (e.g. measuring spoon). 1. Paper cardboard cans with an alu foil inside layer: 100 g – 600 g 2. PE-Cans: 100 g – 600 g 3. PE-Tubular bags placed in folding cartons: 10 g -500 g

1.4.1.1 Use-specific instructions for use

1. Resistance management advice: In the case of reduced efficacy or suspected development of resistance, the use of the product has to be discontinued immediately and a professional pest control operator needs to be contacted. Products should always be used in accordance with the label recommendations.

1.4.1.2 Use-specific risk mitigation measures

See chapter 1.5.2

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

See chapter 1.5.3

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

See chapter 1.5.4

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

See chapter 1.5.5

1.4.2 Use 2 appropriate for authorisation – Non-professional use - Pouring

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide Biocidal product knocks down and kills black garden ants of all development stages and has a complete nest kill effect.
Target organism(s) (including development stage)	black garden ant (*Lasius niger*) (all developmental stages)
Field(s) of use	Around houses on paved ways, balconies and terraces.
Application method(s)	Dissolve the product in tap water, stir well and pour immediately into the nest. The solution must be slowly added to open nests, crevices etc. If the product settles, it can be stirred again.
Application rate(s) and frequency	10 g product in 1L tap water and pouring it into the nests (1L/nest). Up to four applications per year.
Category(ies) of users	Non-professional user
Pack sizes and packaging material	Single-dose sachets and water soluble bags are limited to a size of 10 g. Pack sizes exceeding 10 g have to contain appropriate 10 g dosing equipment (e.g. measuring spoon). 1. Paper cardboard cans with an alu foil inside layer: 100 – 600 g 2. PE-Cans: 100g - 600 g 3. PE-Tubular bags placed in folding cartons: 10 -500 g 4. Water soluble PVA bags (10 g) in folding cartons (100 – 500 g) 5. Three-side sealed PE bags: 80 g

1.4.2.1 Use-specific instructions for use

1. After the outdoor watering application, rinse the watering can several times with a little water. Apply the rinse water on the ant nest. 2. Resistance management advice: In the case of reduced efficacy or suspected development of resistance, the use of the product has to be discontinued immediately and a professional pest control operator needs to be contacted. Products should always be used in accordance with the label recommendations.

1.4.2.2 Use-specific risk mitigation measures

See chapter 1.5.2

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

See chapter 1.5.3

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

See chapter 1.5.4

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

See chapter 1.5.5

1.4.3 Use 3 appropriate for authorisation – Professional use – Spreading

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide. Biocidal product knocks down and kills black garden ants of all development stages. There is a strong suppression of nest buildings activity and a rapid depression of the black garden ant population.
Target organism(s) (including development stage)	black garden ant (*Lasius niger*) (all developmental stages)
Field(s) of use	Around houses on paved ways, balconies and terraces.
Application method(s)	Spreading of the granulated product over the nests.
Application rate(s) and frequency	10 g product per nest. Up to 4 applications per year.
Category(ies) of users	Professional user
Pack sizes and packaging material	1. Paper cardboard cans with an alu foil inside layer: 100g - 600g 2. PE-Cans: 100g - 600 g

	3. PE-Buckets: 2.5kg - 10 kg

1.4.3.1 Use-specific instructions for use

1. The use of an applicator (e.g. spoon or beaker) is recommended when scattering the product from a bucket.

1.4.3.2 Use-specific risk mitigation measures

See chapter 2.5.2

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

See chapter 2.5.3

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

See chapter 2.5.4

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

See chapter 2.5.5

1.4.4 Use 4 appropriate for authorisation – Professional use - Pouring

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide, acaricide and products to control other arthropods Biocidal product knocks down and kills black garden ants of all development stages and has a complete nest kill effect.
Target organism(s) (including development stage)	black garden ant (*Lasius niger*) (all developmental stages)
Field(s) of use	Around houses on paved ways, balconies and terraces

Application method(s)	Dissolve the product in tap water, stir well and pour immediately into the nest. The solution must be slowly added to open nests, crevices etc. If the product settles, it can be stirred again.
Application rate(s) and frequency	10g product in 1L water and pouring it into the nests (1L/nest). Up to four applications per year
Category(ies) of users	Professional user
Pack sizes and packaging material	1. Paper cardboard cans with an alufoil inside layer: 100 g - 600 g 2. PE-Cans: 100 g - 600 g 3. PE-Tubular bags placed in the folding cartons: 10 g – 500 g 4. Water soluble PVA bags (10 g -100 g) in folding cartons (100-500 g) 5. PE-Buckets: 2.5kg - 10 kg

1.4.4.1 Use-specific instructions for use

1. After the outdoor watering application, rinse the watering can several times with a little water. Apply the rinse water on the ant nest.

1.4.4.2 Use-specific risk mitigation measures

1. The use of an applicator (e.g. spoon or beaker) is recommended when loading the product from a bucket into the watering can.
2. The use of waterproof footwear is recommended when applying the product.
3. The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:
   - Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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

See chapter 2.5.3

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

See chapter 2.5.4

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

See chapter 2.5.5

1.5 General directions for use

1.5.1 Instructions for use

1. Apply only around houses on paved ways, balconies and terraces. 2. Apply only outdoors in locations protected from rain.

1.5.2 Risk mitigation measures

1. Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water. 2. Do not use where release to drains (sewer) and/or surface water cannot be prevented. 3. Direct application to unpaved soil is not permitted. 4. Keep out of reach of children and pets. 5. Keep children and pets, particularly cats, away from treated surfaces. 6. Apply only in areas inaccessible to children and pets. 7. Do not re-enter before surface has dried. 8. Do not contaminate food, feed, eating utensils or food contact surfaces.

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

1. Pyrethroids and pyrethrines may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice

2. Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles, without contaminating yourself or others.

3. Eye exposure; ALWAYS check for and remove contact lenses, wash eyes with plenty of water with eye lids open for at least 15 minutes.

4. Skin contact; wash affected area with plenty of water and soap, NO scrubbing.

5. Inhalation/aspiration; Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.

6. Mouth contact/ingestion; Rinse mouth and drink plenty of water, do NOT induce vomiting unless indicated by medical or healthcare personnel and do NOT give anything by mouth to an unconscious individual.

7. If symptoms appear, persist or worsen seek medical attention IMMEDIATELY and bring the packaging or label whenever possible.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

- Symptomatic and supportive treatment.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER [INSERT LOCAL NUMBER HERE].

1.5.4 Instructions for safe disposal of the product and its packaging

1. Residues of the biocidal products must be disposed off in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations.
2. Leave biocidal products in original containers. Do not mix with other wastes. Containers containing residues of the product have to be handled accordingly. Waste entry on pesticides: 20 01 19 Waste entry on packaging containing residues of or contaminated by dangerous substances: 15 01 10

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

1. The product must be stored and transported without exposition to light.
2. Storage stability: 36 months for the following packages:

- Paper cardboard cans with an alu foil inside layer: 100 g – 600 g;
- PE-Cans: 100 g – 600 g;
- PE-Tubular bags placed in folding cartons: 10 g -500 g;
- Three-side sealed PE bags: 80 g;
- PE-Buckets: 2.5kg - 10 kg.

Storage stability:12 months for the following packages:

- Water soluble PVA bags (10-100 g) in folding cartons (100 – 500 g)

1.5.6 Other information

None

1.6 Packaging

Table 3

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Cardboard cans	100g - 600 g	paper(outside),Alu-foil(inside layer)	-	Professional, Non-professional	Yes
Cans	100g - 600 g	PE	PP/PE	Professional, Non-professional	Yes
Tubular bags (being placed in the folding cartons)	10 -500 g	PE	-	Professional, Non-professional	Yes
water soluble Bags	10-100 g (prof); 10g (non-	PVA = polyvinyl alcohol	-	Professional, Non-professional	Yes

(being placed in the folding cartons)	prof) 100-500 g				
three-side sealed Bags	80 g (110 x 210 mm)	PE	-	Professional, Non-professional	Yes
Buckets	2.5kg - 10 kg	PE	-	Professional	Yes

1.7 Documentation

1.7.1.1 Data submitted in relation to product application

Please refer to the reference list in Annex 4.1 of this PAR

1.7.1.2 Access to documentation

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC) of the active substance Permethrin for use in insecticides (product-type 18). Please, refer to the corresponding Assessment Report for a reference list.

2 Assessment of the product

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

Use	PT	Where relevant, an exact description of the use	Target organism(s) (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category(ies) of users	Pack sizes and packaging material
001	18	Insecticide, acaricide and products to control other arthropods. Biocidal product knocks down and kills ants of all development stages and has a complete nest kill effect. There is a string suppression of nest buildings activity and a rapid depression of the ant population.	Formicinae – Ants (all developmental stages)	Outdoor; Around houses on paved and not paved ways, balconies and terraces	Spreading of the granulated product over the nests	10g product per nest; up to 4 application per year	Non-professional user	1. Cardboard paper cans with an alu-foil inside layer: 100g - 600 g, 2. PE-Cans: 100g - 600 g 3. PE-Tubular bags 10 - 500 g (being placed in the folding cartons)

002	18	Insecticide, acaricide and products to control other arthropods Biocidal product knocks down and kills ants of all development stages and has a complete nest kill effect.	Formicinae – Ants (all development al stages)	Outdoor; Around houses on paved and not paved ways, balconies and terraces	Dissolving the product in tap water and pouring it into the nests, stir well and pour immediately into the nest. The solution must be slowly added to open nests, crevices etc. If the product settles, it can be stirred again.	10g product in 1L water and pouring it into the nests (1L/nest). Up to four applications per year	Non-professional user	1. Cardboard paper cans with an alu-foil inside layer: 100g - 600 g, 2. PE-Cans: 100g - 600 g 3. PE-Tubular bags 10 - 500 g (being placed in the folding cartons) 4. PVA water soluble bags 10-100 g, (being placed in the folding cartons, 100-500g) 5. PE three-side sealed bags: 80 g

003	18	Insecticide, acaricide and products to control other arthropods Biocidal product knocks down and kills ants of all development stages and has a complete nest kill effect. There is a string suppression of nest buildings activity and a rapid depression of the ant population.	Formicinae – Ants (all developmental stages)	Outdoor; Around houses on paved and not paved ways, balconies and terraces	Spreading of the granulated product over the nests	10g product per nest; up to 4 application per year	Professional user	1. Cardboard paper cans with an alu-foil inside layer: size 100g - 600 g, material paper 2. PE-Cans: 100g - 600 g 5. PE-Buckets: 2.5kg - 10 kg

004	18	Insecticide, acaricide and products to control other arthropods Biocidal product knocks down and kills ants of all development stages and has a complete nest kill effect.	Formicinae – Ants (all developmental stages)	Outdoor; Around houses on paved and not paved ways, balconies and terraces	Dissolving the product in tap water and pouring it into the nests, stir well and pour immediately into the nest. The solution must be slowly added to open nests, crevices etc. If the product settles, it can be stirred again.	10g product in 1L water and pouring it into the nests (1L/nest). Up to four applications per year	Professional user	1. Cardboard paper cans with an alu-foil inside layer: size 100g - 600 g, material paper 2. PE-Cans: 100g - 600 g 3. PE-Tubular bags 10 - 500 g (Nr.:205099) - (being placed in the folding cartons) 4. Water soluble bags 10-100 g, material PVA= polyvinyl alcohol (being placed in the folding cartons, 100-500g) 5. PE-Buckets: 2.5kg - 10 kg

2.2 Physical, chemical and technical properties

Table 4: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	visually	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	Homogenous solid	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113201204
Colour at 20 °C and 101.3 kPa	visually	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	white	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113201204
Odour at 20 °C and 101.3 kPa	olfactory	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	characteristic	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113201204
Acidity / alkalinity	CIPAC MT 75	Ameisenmittel 2015 Batch No.: 51013	Start value: pH = 9.8 (1% suspension)	Fieseler, A., 2016;

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		0.54% Permethrin	14 days/54°C: pH = 9.5 (1% suspension)	Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113201204
Relative density / bulk density	CIPAC MT 186	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	Start value: Pour density: 0.85 g/cm³ Tap density: 0.96 g/cm³ 14 days/54°C Pour density: 0.85 g/cm³ Tap density: 0.96 g/cm³	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113201204
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	Based on the obtained results of the study it can be concluded that the biocidal product Ameisen-Mittel is stable at accelerated storage for 14 days at 54 °C. Permethrin content: 0.6% before and after storage	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113201204

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 47.2 CIPAC MT 53.3 CIPAC MT 59.1 CIPAC MT 75.3 CIPAC MT 58.2 CIPAC MT 167 CIPAC MT 186 CIPAC MT 172.1 CIPAC MT 177 CIPAC MT 171 CIPAC MT 178.2 CIPAC MT 179 CIPAC MT 170	Ameisenmittel 2015 Batch No.: 20150615/591002 0.51% Permethrin	Ongoing 60 months study: following results are stated after 43 months Permethrin content: Start: 0.52% after 24 months: 0.48% (loss of 7.7%) after 43 months: 0.47% (loss of 9.6%) Packaging Stability: start: No signs of corrosion, distortion or deterioration were observed. Appearance: start: white solid with a characteristic odour. Permethrin Content: start: 5.24 g/kg	Fieseler, A., 2017; Final Interim Report ; Ameisenmittel 2015 (in sacks): Storage Stability at 20 °C Report no. 103259204

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			After 8, 16, 24 and 43 months the appearance did not change Persistent Foaming: start: No foam after 1 min of standing after 24 months: No foam after 1 min of standing after 43 months: No foam after 1 min of standing Wettability: start: without swirling: 8s with swirling: 3s after 24 months: without swirling: 7s with swirling: 3s after 43 months: without swirling: 8s with swirling: 3s	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Dry Sieving – Dusts: start: 98% residue on 0.25 to 0.85 mm sieves after 24 months: 91% residue on 0.25 to 0.85 mm sieves, additional 8.3% on a 0.15 mm sieve after 43 months: 96.4% residue on 0.25 to 0.85 mm sieves pH Value (1% solution) start: 9.0 after 24 months: 9.8 after 43 months: 9.9 Dust Content: start: 94% residue on 0.25 to 0.85 mm sieves	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			after 24 months: 97% residue on 0.25 to 0.85 mm sieves after 43 months: 95% residue on 0.25 to 0.85 mm sieves Wet Sieving: start: 0% remaining residue after 24 months: 0% remaining residue after 43 months: 0% remaining residue Pour Density: start: 0.882 g/cm³ after 24 months: 0.886 g/cm³ after 43 months: 0.889 g/cm³	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Tap Density: start: 0.994 g/cm³ after 24 months: 0.992 g/cm³ after 43 months: 0.981 g/cm³ Flowability: start: 0% residue after 24 months: 0% residue after 43 months: 0% residue Suspensibilty: start: 6 % after 24 months: 42.4% after 43 months: 16.1% Dustiness: 8 months: dust < 1 mg	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			attrition resistance: 8 months: 100% after 24 months: 100% after 43 months: 100% Degree of Dissolution: 8 months: –after 5 min: 0.7% After 18 h: 1.0% after 24 months: –after 5 min: 0% After 18 h: 0% after 43 months: –after 5 min: 0.2% After 18 h: 0.3% Dry Sieve Analysis: 16 months: main residue on sieve 125-500 µm	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			after 24 months: main residue on sieve 125-500 µm after 43 months: main residue on sieve 125-500 µm	
Storage stability test – **low temperature stability test for liquids**				Waiving[5]
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Ameisen-Mittel is stored and transported in the packaging without exposition to the light.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**				

[5] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Information about the packaging material is sufficient. BAM-No.: 10629 HDPE is resistant to Permethrin	Dangerous Goods Database http://www.dgg.bam.de/en/
Wettability	CIPAC MT 53.3	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	Start value: Without swirling: 6 s With swirling: 3 s 14 days/54°C Without swirling: 4 s With swirling: 5 s	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113201204
Suspensibility, spontaneity and dispersion stability	CIPAC MT 177	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	Start value: 30.4% in standard water C 14 days/54°C 40.1% in standard water C	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113201204
Wet sieve analysis and dry sieve test	CIPAC MT 167	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	The residue remaining on the 75 µm sieve was 1.0%.	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	CIPAC MT 59.1		(before and after storage of 14 days/54°C) Start value: < 0.25 mm: 4.9% > 0.25 mm: 93% 14 days/54°C < 0.25 mm: 0.4% > 0.25 mm: 98.9%	Stability; Report no. 113201204
Emulsifiability, re-emulsifiability and emulsion stability				Waiving[6]
Disintegration time				Waiving[7]
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 58.2	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	The calculated fractions of the material collected on the sieve (0.25 to 0.85 mm) was 91%.	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage

6 Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

7 Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

<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></td><td>Start value:
< 0.25 mm: 8.39%
< 0.15 mm: 1.1%
Loss on sieving: 0.1%
14 days/54°C
< 0.25 mm: 3.2%
< 0.15 mm: 0.03%
Loss on sieving: 0.05%</td><td>Stability; Report no. 113201204</td></tr>
<tr><td>Particle size distribution, content of dust/fines, attrition, friability</td><td>CIPAC MT 170 (Dry sieve analysis)</td><td>Ameisenmittel 2015
0.5% Permethrin</td><td>Results after 16 months storage (20°C):
<table>
<tr><th>sieve x [µm]</th><th>mass g_x [g]</th><th>residue r_x [%]</th></tr>
<tr><td>pan</td><td>0.05</td><td>0.0</td></tr>
<tr><td>75</td><td>1.73</td><td>1.3</td></tr>
<tr><td>125</td><td>10.75</td><td>7.8</td></tr>
<tr><td>250</td><td>47.88</td><td>34.7</td></tr>
<tr><td>500</td><td>75.55</td><td>54.8</td></tr>
<tr><td>1000</td><td>0.08</td><td>0.1</td></tr>
<tr><td>2000</td><td>0.00</td><td>0.0</td></tr>
<tr><td>3350</td><td>0.00</td><td>0.0</td></tr>
</table>
Sum of residues on all sieves: 98.7%</td><td>Non QAU audited data-Storage stability at 20°C after 16 months; Report No. 1032592204</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
content of dust/fines Dustiness	CIPAC MT 171	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	Start value: 0.2 mg dust 14 days/54°C 0.5 mg dust Thus the product is nearly dust free.	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113202204
Attrition resistance	CIPAC MT 178.2	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	Start and 14 days/54°C value: 100% attrition resistance	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113202204
Persistent foaming	CIPAC MT 47.2	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	No foam was observed in the cylinder after carrying the persistent foaming test. (before and after storage of 14 days/54°C)	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113201204
Persistent foaming (water soluble bags)	CIPAC MT 47.2	Ameisenmittel 2015 Batch No.: 20150615/591001 0.51% Permethrin	No foam was observed in the cylinder after carrying the persistent foaming test.	Fieseler, A., 2017; Ameisenmittel 2015 (in water soluble bags): Interim Report; Storage

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(after 9 months storage at 20°C)	Stability at 20 °C ; Report no. 113256204
Flowability/Pourability/Dustability	CIPAC MT 172.1	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	There were no residues found after the flowability test, therefore the test item is considered to be free-flowing. (before and after storage of 14 days/54°C)	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113201204
Burning rate — smoke generators				Waiving[8]
Burning completeness — smoke generators				Waiving[9]
Composition of smoke — smoke generators				Waiving[10]

[8] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

[9] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

[10] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Spraying pattern — aerosols				Waiving[11]
Physical compatibility				Waiving[12]
Chemical compatibility				Waiving[13]
Degree of dissolution and dilution stability	CIPAC MT 179	Ameisenmittel 2015 Batch No.: 51013 0.54% Permethrin	Start value: residue after 5 min: 2.0% residue after 18h: 1.0% 14 days/54°C residue after 5 min: 1.6% residue after 18h: 0.2%	Fieseler, A., 2016; Ameisenmittel 2015: Accelerated Storage Stability; Report no. 113202204
Degree of dissolution and dilution stability	CIPAC MT 179	Ameisenmittel 2015 Batch No.: 20150615/591001 0.51% Permethrin	Start value: residue after 5 min: 0.1% residue after 18h: 0.1%	Fieseler, A., 2017; Ameisenmittel 2015 (in water soluble bags): Interim Report; Storage Stability at 20 °C ; Report no. 113256204

11 Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

12 Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

13 Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Dissolution rate of water soluble bags	CIPAC MT 176	Ameisenmittel 2015 Batch No.: 20150615/591001 0.51% Permethrin	After 9 month storage at 20°C: max. time to reach the 950 mL mark – 14 sec	Fieseler, A., 2017; Ameisenmittel 2015 (in water soluble bags): Interim Report; Storage Stability at 20 °C ; Report no. 113256204
Surface tension			The product Ameisen-Mittel is a solid formulation. The measurement of the surface tension and viscosity is only required for liquid formulations.	
Viscosity				

Table 5

Conclusion on the physical, chemical and technical properties
The biocidal product is a white granular respectively a soluble granule which is applied directly or diluted. One of the packaging is a water soluble bag. The product has a pH of 9.5 and a tap density of 0.96 g/cm^3.The requested technical properties have been acceptable determined. The accelerated storage stability shows no decrease of the active substance. Unfortunately only a 16 months interim report is available for the long-term storage test with only a start value of the active substance content. Based on the provided data a shelf life of 36 months is acceptable. The Suspensibility (CIPAC MT 177) is determined in all measurements outside the acceptable range of < 60 and > 110%. To give respect to the low suspensibility the user is already advised to use the

solution immediately after preparation and also to mix respectively stir again if the products sediments.

The data provided by the applicant was acceptable.

2.3 Physical hazards and respective characteristics

Table 6: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	Regulation (EC) No 440/2008, EU Method A.14			No explosive properties according to EU test method A.14.	Krack, M., Ameisenmittel, Explosive properties A.14, Report No. 20150156.02 (2015)
Flammable gases	study scientifically unjustified			Waiver	IUCLID
Flammable aerosols	study scientifically unjustified			Waiver	IUCLID
Oxidising gases	study scientifically unjustified			Waiver	IUCLID
Gases under pressure	study scientifically unjustified			Waiver	IUCLID
Flammable liquids	study scientifically unjustified			Waiver	IUCLID

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Flammable solids	Regulation (EC) No 440/2008, EU Method A.10			Not classified based on GHS/CLP criteria	Krack, M., Ameisenmittel, Flammability (solids) A.10, Report No. 20150156.01 (2015)
Self-reactive substances and mixtures	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.	UCLID
Pyrophoric liquids	study scientifically unjustified			Waiver	IUCLID
Pyrophoric solids	study scientifically not necessary			Waiver: The study does not need to be conducted because the substance is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure does not need to be applied.	IUCLID
Self-heating substances and mixtures	study scientifically not necessary			Waiver: Due to the screening test according to EU Method A.16 no self-heating properties are expected. Therefore the study does not need to be conducted.	IUCLID
Substances and mixtures which in contact with water emit	study scientifically not necessary			Waiver: The study does not need to be conducted because the substance is known to be soluble in water to form a stable mixture.	IUCLID

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
flammable gases					
Oxidising liquids	study scientifically unjustified			Waiver	IUCLID
Oxidising solids	study scientifically not necessary			Expert statement	Rudolf, M., Lorenz, V. Oxidizing properties (A.17) of Ameisenmittel 2015 – Statement (2015)
Organic peroxides	study scientifically not necessary			Waiver	IUCLID
Corrosive to metals	study technically not feasible			Waiver: The study does not need to be conducted because there is no established suitable test method for solid substances.	IUCLID
Auto-ignition temperature (liquids and gases)	study scientifically unjustified			Waiver	IUCLID
Relative self-ignition temperature for solids	Regulation (EC) No 440/2008, Method A.16	Batch No.: 20150423/ 540011		No self-ignition observed under the test conditions up to the melting point.	Krack, M. Autoflammability (Solids – Determination of relative self-ignition temperature) A.16 (2015)

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
					Report No. 20150156.03 (2015)
Dust explosion hazard	study scientifically unjustified			Waiver: Due to the application method and the used amounts a dust explosion hazard is not to be expected.	IUCLID

Table 7

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. Acceptable studies were provided for: • explosive properties according to EU Method A.14 • flammability according to EU Method A.10 • relative self-ignition temperature according to EU Method A.16 Ameisen-Mittel is a homogeneous white solid. The product is not highly flammable. No self-ignition temperature was observed up to the melting point. It does not have explosive and oxidising properties. Therefore, no classification and labelling with regard to the physical hazards are proposed.

2.4 Methods for detection and identification

Table 8

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance Permerthin	HPLC method with UV detection	Specificity was established by comparison of the retention times of the analyte in the sample solutions and in the standard solutions prepared from the reference item. In addition the identity of the active substance was confirmed	20 to 80 mg reference item/L; R^2 = 1.000	80% (ca. 39 mg/L) and 120% (ca. 58 mg/L) of the original concentration; 5 measurements	80%	99% (of nominal) (38.7702 mg/L)	0.2	LOD = 0.06 mg reference item /L.	Fieseler, A, 2016; Ameisenmittel 2015: Development and Validation of the Analytical Method for the Determination of Permethrin; Report no: 103251101
					120%	99% (of nominal) (58.0534 mg/L)	0.2		

		by comparison of the UV-spectra of the reference item solutions with the UV-spectra of the sample solutions.							

Table 9

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	Permethrin	0.09 mg/kg	$PNEC_{soil}$ CAR Doc IIA combined; (PT08+PT18), 11/2013, 4.2.3.5
Drinking water	Permethrin	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	permethrin	0.47 ng/L	$PNEC_{water}$ based on NOEC *Daphnia magna*: 4.7 ng/L, AF: 10 CAR Doc IIA combined; (PT08+PT18), 11/2013, 4.2.1.6
Air	permethrin	15 µg/m³	medium+long-term AEL: 0.05 mg/kg bw/d; AR (PT08), 02/2014, LoEP, AR (PT18), 04/2014, LoEP,

Animal and human body fluids and tissues	no relevant residues expected		Waiver, CAR PT8 Tagros DocIIIA, 4.2.d; 12/2012
Food of plant origin	no relevant residues expected		Waiver; CAR PT8 Bayer/Sumitomo DocIIIA, 4.3; 12/2012 CAR PT8 Tagros DocIIIA, 4.3; 12/2012
Food of animal origin	no relevant residues expected		Waiver; CAR PT8 Bayer/Sumitomo DocIIIA, 4.3; 12/2012 CAR PT8 Tagros DocIIIA, 4.3; 12/2012

Table 10

Analytical methods for surface water – accepted for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	LC MS/MS Synergi 2µ Polar RP column; ESI+ m/z 408→183 m/z 408→ 355	confirmation included by second transition	0.04 – 10 ng/mL R^2=0.9995	m/z 408 →183 0.05 µg/L / 10 0.5 µg/L / 10 m/z 408 →355 0.05 µg/L / 10 0.5 µg/L / 10	99 – 105 % 92 – 95 % 91 – 104 % 90 – 101 %	102 % 93 % 98 % 95 %	2.0 % 1.8 % 4.2 % 3.3 %	0.05 µg/L validated for surface water, but LOQ >> MRL based on PNEC water Method is acceptable for drinking water.	Krebber & Braune, 2008 CAR PT8 Bayer/ Sumitomo DocIIIA, 4.2 (5); 12/2012

Table 11

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	LC MS/MS Synergi 2µ Polar RP column; ESI+ m/z 408→183 m/z 408→355	confirmation included by second transition	1 – 100 ng/mL R^2=0.9992 – 0.9999	m/z 408→183 silt loam 0.005 mg/kg / 5 0.05 mg/kg / 5 sandy loam 0.005 mg/kg / 5 0.05 mg/kg / 5 m/z 408→355 silt loam 0.005 mg/kg / 5 0.05 mg/kg / 5 sandy loam 0.005 mg/kg / 5	89 – 105 % 100 – 103 % 82 – 98 % 92 – 95 % 91 – 108 % 99 – 102 % 83 – 98 % 91 – 94 %	95 % 101 % 88 % 93 % 96 % 101 % 89 %	6.4 % 1.3 % 7.3 % 1.6 % 7.1 % 1.3 % 7.0 %	Permethrin	LC MS/MS Synergi 2µ Polar RP column; ESI+ m/z 408→183 m/z 408→355

				0.05 mg/kg / 5		93 %	1.5 %		

Table 12:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	LC MS/MS; ESI+ m/z 408→183 m/z 408→355	confirmation included by second transition	5 – 500 ng/mL R^2 > 0.997	m/z 408→183 ambient air 5 µg/m³/ 5 48 µg/m³/ 5 warm humid air 4.8 µg/m³/ 5 49 µg/m³/ 5 m/z 408→355 ambient air 5 µg/m³/ 5 48 µg/m³/ 5 warm humid air 4.8 µg/m³/ 5 49 µg/m³/ 5	Not given in DocIIIA	87 % 90 % 92 % 91 % 88 % 90 % 91 %	5 % 4 % 4 % 3 % 6 % 4 % 2 %	5 µg/m³	Bacher, 2008 CAR PT8 Bayer/Sumitomo DocIIIA, 4.2 (4); 12/2012

						90 %	4 %		
Permethrin	GC-ECD, DB-5 column	confirmation included by GC-MS m/z 127, 163, 183, but no validation data presented in CAR	0.05 – 10 mg/L R=1.0	0.1 µg/m³/ 5 1 µg/m³/ 5		72 % 74 %	1.9 % 3.4 %	0.1 µg/m³	Sathiyanarayanan, 2006 CAR PT8 Tagros DocIIIA, 4.2.b; 12/2012

Table 13

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product: 2. 5.2.1. Soil: No data waiving 3. 5.2.2. Air: Analytical methods for the determination of the active substance permethrin in air were not submitted for the biocidal product since this point is covered by the data set of the active substance permethrin in the corresponding CAR. Furthermore, the aerosol and vapour formation of the active substance permethrin is expected to be negligible in comparison to other exposure routes since the vapour pressure of the active substance permethrin is 2.15×10^{-6} Pa at 20°C and the product is not sprayed 4. 5.2.3. Water (including drinking water) and sediment: No data waiving 5. 5.2.4 Body fluids and tissues: Data waving was accepted. 6. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant: Data waiving was accepted
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 14

Conclusion on the methods for detection and identification

The method(s) provided regarding the active substance(s), residues and substances of concern was/were acceptable The method(s) provided regarding residues and substances of concern was/were not necessary. Please note: the method for determination of permethrin in surface water is not sufficient for monitoring the limit of 0.47 ng/L based on PNEC water. But the presented method was accepted in CAR. A method regarding a substance of concern was not necessary.

2.5 Efficacy against target organisms

2.5.1 Function and field of use

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

The biocidal product “Ameisenmittel” is a solid (granulate formulation) which can be applied in two different ways:

1) Spreading 10 g of the granular product directly to the ground on the entrances of the ant nest. In this case, it is a ready-to-use product.
2) Pouring into the nests after dilution of 10 g product with 1 l water.

The product contains 0.5% w/w of the insecticidal active substance Permethrin.
The biocidal product “Ameisenmittel” is intended to be used to knock down and subsequently kill ants. For the application method “spreading”, the claim is “suppression of nest building activity and fast decline of ant colonies”. For the application by “pouring”, “nest kill” is additionally claimed. No residual efficacy is claimed.
Application sites are paved and non-paved paths around houses, balconies and terraces.
The product is intended to be used by non-professionals and professional users.

The submitted studies are suitable to support the claim “knocks down and kills individuals of the black garden ant (*Lasius niger)”.* The claim “nest kill” is also supported outdoor for sprinkling application 2 weeks after the treatment and for pouring after 3 weeks. The product does not contain any preservative but studies with a- 3 years aged product have been submitted and supported a shelf life of 3 years.

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

The product “Ameisenmittel” is intended to be used to control ants (Formicinae; all developmental stages) around houses. However, as the product is applied as a bait and due to the specificity of baits, only effects against ant species that have been tested in the field can be claimed (TNsG 2012, chapter 4.2.3). Therefore, only the target organism black garden ant (*Lasius niger*) is supported by the submitted studies.

2.5.3 Effects on target organisms, including unacceptable suffering

The biocidal product acts by contact and ingestion. Due to its mode of action the active substance Permethrin causes paralysis and subsequent death by disrupting the nervous system of the insects.

2.5.4 Mode of action, including time delay

Permethrin is a synthetic pyrethroid which acts on ants by contact and ingestion and which causes convulsions, paralysis and ultimately death. The nervous system impairment occurs a few minutes to several hours after absorption of the biocide and is then followed by the insects´ death.
Permethrin is a type I axonic poison which exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects. Its effects are characterised by progressive whole body tremor, exaggerated responses, uncoordinated muscle twitching and hyperexcitability. 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 sodium channels. Single channel studies have been conducted, which have shown that pyrethroids slow the kinetics of opening and closing of sodium channels.
It should also be noted that permethrin may also exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is also common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lamda-cyhalothrin) and is known as the “hot-foot effect” and may be relevant for some arthropods. The repellent effect is dose related and for insecticidal products the repellent effect of permethrin is considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect.

2.5.5 Efficacy data

As the active substance Permethrin can enter the organism via two different ways, contact and ingestions, the actual mode of action of the product “Ameisenmittel” is unclear. It is therefore not possible to define whether the product functions as bait or as surface treatment. Therefore, the German CA decided to evaluate the efficacy on the basis of the requirements for bait products, as these are stricter, independently from the application methods (pouring and spreading).
The applicant submitted 9 studies (detailed study summary see table 15).

However, the German CA evaluates one field study (Heller 2015) as unreliable to prove the efficacy of the product “Ameisenmittel”. The study by Heller (2015) was conducted in June/July, even though in the TNsG (2012; chapter 4.2.2.4) it is stated that tests field tests should be conducted during early spring. Furthermore, pre-treatment monitoring of nests is missing and effects on the population is not proven by counting of ants. Consequently, in this study 100% population reduction was not demonstrated for the application method pouring, which would be necessary for the claim “nest kill”.
In the laboratory tests (Werner 2017a, b) with *Lasius niger*, the product was applied in the requested dosage for both application methods. For the sprinkle application, 100% mortality was observed after 24 hours. Watering application caused 92% mortality after 72 hours and total mortality after 120 hours. Mortality in the controls was 6% after 5 days. Therefore, both laboratory tests demonstrated a mortality of more than 95% as requested for bait products (TNsG 2012, chapter 4.3.1) and sufficiently prove the palatability of the product.

In both simulated-use studies (Linn 2017c, d) the product was applied by spreading or pouring in the requested dosage on the ant colonies. Both application methods lead to 100% population reduction in four of the five colonies, including no brood and complete colony kill, after 4 weeks. In the remaining two nests, the population was reduced and for the watering application also no brood was found. However, in both nests approximately 150 ants were found after excavation. For the controls no colony kill was observed and the activity of ants was similar to the beginning. In the TNsG (2012) “≥ 90% mortality within the test period, including ants in the nest” is required. This requirement was only meet in four out of five nests. Consequently, efficacy was not proven in all trials.

Four field trails with *Lasius niger* (Lüpkes 2015a, b, Linn 2017a, b) were submitted. In the studies by Lüpkes (2015a, b), for both applications, two out of three nests showed no ant activity, dead workers, no brood and no living queen two weeks after the treatment. In the remaining nest, even a second application two weeks after the first one was not successful. The applicant submitted the following explanation: “For these nests, already one day after treatment the recorded activity nearly ceased, while one week after treatment no more activity could be observed. The excavation two weeks after treatment confirmed the total nest kill. In one of the three nests in both trials by Lüpkes (2015a and b) activity of ants was reduced considerably, but did not completely cease. In one of these cases (Lüpkes 2015a, spreading application) the nest that could not be killed had a considerably higher initial infestation (>100 ants initially, compared to 20 and 30 ants). In the trial with pouring application (Lüpkes 2015b), the initial infestation was only slightly higher (50 ants, compared to 40 and 30 ants). It was assumed that in these nests the ants were able to avoid contact to the product and use only safe and untreated areas to continue their activities. This explanation seems very plausible considering the often intertwined and confusing construction of ant nests. Keeping this in mind it seems understandable that not always all parts and entrances of one nest can be found without excavation of the nest.” (IUCLID document “Doc IIB Ameisen-Mittel”)

The activity in the untreated control colonies did not vary during the assessment period. Controls were not treated neither with product nor with water. The applicant explained: “This is because past experience had shown that ants build their nests under protected areas and therefore the risk of drowning is not given. In addition to that ants withdraw in deeper nest areas when it comes to rain or take shelter in other ways. This point is supported by the fact that control groups in the field test were not destroyed or negatively impacted by heavy precipitation events.”
The German CA could accept the explanation by the applicant and evaluate both studies by Lüpkes (2015a, b) as supportive material.
In the field tests by Linn (2017a, b) nest kill, indicated by no ant activity, dead workers, no brood and no living queen, were observed in all three colonies two weeks after the treatment with the solid product (Linn 2017a) and 3 weeks after watering application (Linn 2017b). During the test period activity in the control colonies remain constant. In accordance to the TNsG (2012) the results with both application methods fulfil the requirements for the claim nest kill. The German CA is of the opinion that the results in the simulated-use studies are outweighed by these robust field studies (TNsG 2012, chapter 4.2.3).

To sum up the results of the submitted studies, it can be concluded that the product “Ameisenmittel” is effective against the black garden ant (*Lasius niger*) and the claim “nest kill” is supported for both application methods. As the product does not contain any preservative and studies with an aged product have not been submitted, only a shelf life of one year is supported.

Minor change - extension of shelf life from 1 to 3 years (Case number: BC-DB050185-65) :
The applicant submitted two simulated-use studies (Lüpkes 2018a, b) with black garden ant (*Lasius niger*) colonies. The fresh and the 3 years old product was applied by both spreading and pouring at the requested dosage. For the fresh and as well the 3 years old product both application methods led to 100% population reduction (no vital brood, colony kill) in four of the five colonies after 6 weeks. In the remaining nests, the population was reduced and approximately 150 ants were found after excavation. For the controls, the activity of ants was similar to the beginning. In the TNsG (2012) “≥ 90% mortality within the test period, including ants in the nest” is required. This requirement was only met in four out of five nests. Also in the simulated-use studies by Linn (2017c, d) with the fresh product, nest kill was only proven in four out of five treated colonies. Therefore, the German CA is of the opinion that the results of both studies by Lüpkes (2018a, b) are suitable to demonstrate that the efficacy of the product is not influenced by ageing, as the 3 years old product showed the same efficacy as the fresh product (independent of the application method).
However, as stated above, the results in the simulated-use studies are outweighed by robust field studies by Linn (2017a, b) (TNsG 2012, chapter 4.2.3).
Consequently, a shelf life of 3 years is supported for the applications “spreading” and “pouring”.

Table 15

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	Outdoors	Detia „Ameisen-mittel" 0.5% Permethrin	*Lasius niger* Common black garden ant, colonies, all development stages	Field trial	-Treatment of wild ant nests under fruit trees Application by 1) spreading and 2) pouring -Dose: 10g/ 1000 cm^2 -Location: Germany, Ingelheim -3 replicates per method -3 controls (2x pouring water, 1x no treatment at all) -Assessment intervals: 1 d, 10 d, 2 wk, 4 wk after application; complete opening of nests at final assessment -Effects investigated: behaviour of ants on surface of nests, inspection of nests	1) Application by spreading: Day 1: No activity in treated and untreated variants. Day 10: No activity in treated and untreated variants. Week 2: No activity in treated and untreated variants. Workers and brood present in treated and untreated nests. Week 4: No activity in treated and untreated variants. Workers and brood present in treated and untreated nests. 2) Application by pouring: Day 1: No activity in treated variants. Building activity and aggressive appearance of numerous ants after disturbance in control nests 7 and 8. Day 10:	Heller (2015)

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td>-Mean temp. 30°C±4°C, low precipitation during field trials, except 1d before end of trial (heavy precipitation)</td><td>No activity in treated and untreated variants due to dry weather period.
Week 2:
No activity in treated variants. No building activity in untreated. Presence of workers and brood in untreated nests.
Week 4:
No activity in treated variants. No building activity in untreated. Presence of workers and brood in untreated nests > 10 cm depth</td><td></td></tr>
<tr><td>PT 18</td><td>Outdoors</td><td>Ant powder (sprinkle appli-cation) 0.5% Perme-thrin</td><td>Lasius niger Common black garden ant, colonies, all develop-ment stages</td><td>Field trial</td><td>-Treatment of wild ant nests under stones/flower pots/on pavement (Germany)
-Weather: nearly cloudless, first rain 1 day to one week after application (13 mm)
-Application by spreading (ready to use product)
-Dose: 10g/ nest, application up to a radius of 50 cm onto/around the nests
-3 replicates (1-3 entrances per nest)</td><td>Table 1
Efficacy of Ant powder (powder product, sprinkled) against nests of Black ants, Lasius niger, in the field.
study: Mo5277 temperature: 17 - 26°C *
<table>
<tr><th rowspan="2">product</th><th rowspan="2">replicate/ nest</th><th rowspan="2">amount of product per nest</th><th colspan="6">Activity of ants (number [of movements] of ants / individuals)</th></tr>
<tr><th>1 minute before test start</th><th>1 day after test start</th><th>1 week after test start</th><th>2 weeks after test start</th><th>3 weeks after test start</th><th>3 1/2 weeks after test start</th></tr>
<tr><td rowspan="5">Ant powder
00.5 % Permethrin
Code: 2015-WA-1</td><td>1</td><td>10 gram</td><td>20</td><td>5</td><td>0</td><td>0**</td><td>0**</td><td>not tested</td></tr>
<tr><td>3</td><td>10 gram</td><td>30</td><td>5</td><td>0</td><td>0**</td><td>0**</td><td>not tested</td></tr>
<tr><td colspan="2">Ø</td><td>25</td><td>5</td><td>0</td><td>0</td><td>0</td><td>not tested</td></tr>
<tr><td colspan="2">range</td><td>20 - 30</td><td>---</td><td>---</td><td>---</td><td>---</td><td>not tested</td></tr>
<tr><td>2</td><td>10 gram</td><td>>100</td><td>>50</td><td>27</td><td>22***</td><td>>50</td><td>>50</td></tr>
</table>
* temperature at evaluations
** nest excavated
*** second treatment
note: all means rounded to integers

Evaluation of untreated nests of Black ants, Lasius niger, in the field.
study: Mo5277 temperature: 17 - 26°C *
<table>
<tr><th rowspan="2">product</th><th rowspan="2">replicate/ nest</th><th rowspan="2">amount of product per nest</th><th colspan="5">Activity of ants (number [of movements] of ants / individuals)</th></tr>
<tr><th>1 minute before test start</th><th>1 day after test start</th><th>1 week after test start</th><th>2 weeks after test start</th><th>3 weeks after test start</th></tr>
<tr><td rowspan="5">Untreated control</td><td>1</td><td>---</td><td>20</td><td>37</td><td>20</td><td>17</td><td>23</td></tr>
<tr><td>2</td><td>---</td><td>20</td><td>35</td><td>35</td><td>27</td><td>33</td></tr>
<tr><td>3</td><td>---</td><td>>100</td><td>>50</td><td>>50</td><td>>50</td><td>>100</td></tr>
<tr><td colspan="2">Ø</td><td>>47</td><td>41</td><td>35</td><td>31</td><td>52</td></tr>
<tr><td colspan="2">range</td><td>20 - >100</td><td>35 - >50</td><td>20 - >50</td><td>17 - >50</td><td>23 - >100</td></tr>
</table>
* temperature at evaluations
note: all means rounded to integers</td><td>Lüpkes, (2015a), report no.: BIO148a-15</td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td>-3 controls (2-3 entrances per nest)
-Assessment intervals: 1 d, 1, 2, 3 weeks, partly 3.5 weeks after application
-Effects investigated: activity of ants, number of individuals after short liftnig of nest coverage, determination of nest kill by excavation of nests</td><td></td><td></td></tr>
<tr><td>PT 18</td><td>Outdoors</td><td>Ant powder (watering appli-cation) 0.5% Perme-thrin</td><td>Lasius niger Common black garden ant, colonies, all develop-ment stages</td><td>Field trial</td><td>-Treatment of wild ant nests under stones/flower pots/on pavement (Germany)
-Weather: nearly cloudless, first rain 1 day to one week after application (13 mm)
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study: Mo5277 temperature: 17 - 26°C *
<table>
<tr><th rowspan="2">product</th><th rowspan="2">replicate/ nest</th><th rowspan="2">amount of product per nest</th><th rowspan="2">1 minute before test start</th><th colspan="5">Activity of ants (number [of movements] of ants / individuals)</th></tr>
<tr><th>1 day after test start</th><th>1 week after test start</th><th>2 weeks after test start</th><th>3 weeks after test start</th><th>3 1/2 weeks after test start</th></tr>
<tr><td rowspan="3">Ant powder
00.5 % Permethrin
Code: 2015-WA-1</td><td>1</td><td>10 gram</td><td>40</td><td>3</td><td>0</td><td>0**</td><td>0**</td><td>not tested</td></tr>
<tr><td>3</td><td>10 gram</td><td>50</td><td>12</td><td>0</td><td>0**</td><td>0**</td><td>not tested</td></tr>
<tr><td colspan="2">Ø</td><td>45</td><td>8</td><td>0</td><td>0</td><td>0</td><td>not tested</td></tr>
<tr><td colspan="2">range</td><td>40 - 50</td><td>3 - 12</td><td>---</td><td>---</td><td>---</td><td>not tested</td></tr>
<tr><td colspan="9"></td></tr>
<tr><td>2</td><td>10 gram</td><td>30</td><td>15</td><td>22</td><td>20***</td><td>13</td><td>35</td></tr>
</table>
* temperature at evaluations
** nest excavated
*** second treatment
note: all means rounded to integers</td><td>Lüpkes (2015b), report no.: BIO149a-15</td></tr>
</table>

<table>
<tr>
<td></td><td></td><td></td><td></td><td></td>
<td>-3 replicates (2-5 entrances per nest)
-3 controls (2-3 entrances per nest)
-Assessment intervals: 1 d, 1, 2, 3 weeks, partly 3.5 weeks after application
-Effects investigated: activity of ants, number of individuals after short lifting of nest coverage, determination of nest kill by excavation of nests</td>
<td>
<u>Evaluation of untreated nests of Black ants, Lasius niger, in the field.</u>
study: Mo5277 temperature: 17 - 26°C *
<table>
<tr><th rowspan="2">product</th><th rowspan="2">replicate/ nest</th><th rowspan="2">amount of product per nest</th><th colspan="5">Activity of ants (number [of movements] of ants / individuals)</th></tr>
<tr><th>1 minute before test start</th><th>1 day after test start</th><th>1 week after test start</th><th>2 weeks after test start</th><th>3 weeks after test start</th></tr>
<tr><td rowspan="3">Untreated control</td><td>1</td><td>---</td><td>20</td><td>37</td><td>20</td><td>17</td><td>23</td></tr>
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<tr><td>3</td><td>---</td><td>>100</td><td>>50</td><td>>50</td><td>>50</td><td>>100</td></tr>
<tr><td colspan="2">Ø</td><td>>47</td><td>41</td><td>35</td><td>31</td><td>52</td></tr>
<tr><td colspan="2">range</td><td>20 - >100</td><td>35 - >50</td><td>20 >50</td><td>17 - >50</td><td>23 - >100</td></tr>
</table>
* temperature at evaluations
note: all means rounded to integers
</td>
<td></td>
</tr>
<tr>
<td>PT 18</td><td>Outdoors</td><td>Detia „Ameisen-mittel” (sprinkle appli-cation) 0.5% Perme-thrin</td><td>Lasius niger Common black garden ant, workers</td><td>Labora-tory study</td>
<td>-Application by spreading (ready to use product)
-Arena: glass jar, Ø 9.5 cm filled with soil
-Temperature: 25 – 26°C
-Rel. humidity: 56 – 58%
-Dosage per arena: 0.64 g
-Acclimatisation: 1 d before treatment
-Starvation: no</td>
<td></td>
<td>Werner (2017a), report no.: BIO094a-17</td>
</tr>
</table>

					-Alternative food: sugar -5 replicates (5 controls) -20 workers per replicate -Assessment intervals: 4, 24, 48, 72, 120 hours after application -Effects investigated: % mortality	**Efficacy of an ant granular product via scattering application against Black ants, *Lasius niger* in test jars (Ø 9 cm)** Study: Mo5818 Method no.: BPD BioG B 955-01E (modified) 20 workers / replicate temperature: 25 - 26 °C rel. humidity: 56 - 58 % Note: All means are rounded to integer.	

Product	Replicate	% mortality out of 20 after hours (h)			
		24 h	48 h	72 h	120 h
Detia Ameisenmittel Batch: 52002.5 Granular product (ready to use) Active: 5 g / kg (0.5 %) Permethrin Expiry Date:02.2019	1	100	100	100	100
	2	100	100	100	100
	3	100	100	100	100
	4	100	100	100	100
	5	100	100	100	100
	Ø	**100**	**100**	**100**	**100**
Control	1	0	0	0	0
	2	0	0	0	10
	3	0	0	0	10
	4	0	0	0	0
	5	0	0	0	10
	Ø	**0**	**0**	**0**	**6**

PT 18	Outdoors	Detia „Ameisen-mittel” (watering appli-cation) 0.5% Perme-thrin	*Lasius niger* Common black garden ant, workers	Labora-tory study	-Application by **pouring** (after mixing with water; 10 g product in 100 ml water (10 times lower volume of water was used because the original volume of water would be to much)) -Arena: glass jar, Ø 9.5 cm filled with soil -Temperature: 25 – 26°C -Rel. humidity: 56 – 58%		Werner (2017b), report no.: BIO095a-17

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-Dosage per arena: 0.64 g
-Acclimatisation: 1 d before treatment
-Starvation: no
-Alternative food: sugar
-5 replicates (5 controls)
-20 workers per replicate
-Assessment intervals: 4, 24, 48, 72, 120 hours after application
-Effects investigated: % mortality</td>
<td>
<u>Efficacy of an ant granular product via watering application against Black ants, Lasius niger in test jars (Ø 9 cm)</u>
Study: Mo5818
Method no.: BPD BioG B 955-01E (modified) 20 workers / replicate
temperature: 25 - 26 °C
rel. humidity: 56 - 58 %
<table>
<tr><th>Product</th><th>Replicate</th><th colspan="4">% mortality out of 20 after hours (h)</th></tr>
<tr><th></th><th></th><th>24 h</th><th>48 h</th><th>72 h</th><th>120 h</th></tr>
<tr><td rowspan="7">Detia Ameisenmittel
Batch: 52002.5
Granular product (ready to use)
Active: 5 g / kg (0.5 %) Permethrin
Expiry Date:02.2019</td><td>1</td><td>0</td><td>80</td><td>95</td><td>100</td></tr>
<tr><td>2</td><td>0</td><td>95</td><td>95</td><td>100</td></tr>
<tr><td>3</td><td>0</td><td>50</td><td>80</td><td>100</td></tr>
<tr><td>4</td><td>0</td><td>50</td><td>90</td><td>100</td></tr>
<tr><td>5</td><td>0</td><td>50</td><td>100</td><td>100</td></tr>
<tr><td>Ø</td><td>0</td><td>65</td><td>92</td><td>100</td></tr>
<tr><td rowspan="7">Control</td><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>2</td><td>0</td><td>0</td><td>0</td><td>10</td></tr>
<tr><td>3</td><td>0</td><td>0</td><td>0</td><td>10</td></tr>
<tr><td>4</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>5</td><td>0</td><td>0</td><td>0</td><td>10</td></tr>
<tr><td>Ø</td><td>0</td><td>0</td><td>0</td><td>6</td></tr>
</table>
Note: All means are rounded to integer.
</td>
<td></td>
</tr>
<tr>
<td>PT 18</td>
<td>Outdoors</td>
<td>Detia „Ameisen-mittel” (sprinkle appli-cation) 0.5% Perme-thrin</td>
<td>Lasius niger Common black garden ant, colonies, all develop-ment stages</td>
<td>Simu-lated-use study</td>
<td>-Application by spreading (ready to use product)
-Arena: waxed card-board box (60 x 40 x 15 cm) filled with 12 cm soil
-Ant colonies „burrowed” in one half of the arena
-Temperature: 25 – 26°C
-Rel. humidity: 56 – 58%
-Dosage per arena: 10 g</td>
<td></td>
<td>Linn (2017c), report no.: BIO092a-17</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-Acclimatisation: 7 d before treatment
-Starvation: 4 d (only water)
-Alternative food: sugar honey mix in the untreated half of the arena
-5 replicates (5 controls)
-Assessment intervals: weekly after application
-Effects investigated: activity, determination of nest kill and killed queen by excavation of nests</td>
<td>
<u>Efficacy of an ant granular product via scattering application against Black ants, Lasius niger in test arenas (2400 cm²)</u>
Study: Mo5818
Method no.: BPD BioG B 407-05
1 colony / replicate
temperature: 25 - 26 °C
rel. humidity: 56 - 60 %
<table>
<tr><th rowspan="2">Product</th><th rowspan="2">Replicate</th><th colspan="5">Activity of ants
number of visible living ants on surface of test arena</th></tr>
<tr><th>1 day before application</th><th>1 week after application</th><th>2 weeks after application</th><th>3 weeks after application</th><th>4 weeks after application (incl. nest after excavation)</th></tr>
<tr><td rowspan="7">Detia Ameisenmittel
Batch: 52002.5
Granular product (ready to use)
Active: 5 g / kg (0.5 %) Permethrin
Expiry Date: 02.2019</td><td>1</td><td>2</td><td>0**</td><td>0**</td><td>0**</td><td>0** (0)</td></tr>
<tr><td>2</td><td>20</td><td>0</td><td>4</td><td>10</td><td>2 (150)</td></tr>
<tr><td>3</td><td>5</td><td>3*</td><td>0**</td><td>0**</td><td>0** (0)</td></tr>
<tr><td>4</td><td>5</td><td>0**</td><td>0**</td><td>0**</td><td>0** (0)</td></tr>
<tr><td>5</td><td>5</td><td>0**</td><td>0**</td><td>0**</td><td>0** (0)</td></tr>
<tr><td>Ø</td><td>7</td><td>1</td><td>1</td><td>2</td><td>0 (30)</td></tr>
<tr><td rowspan="7">Untreated Control</td><td>1</td><td>10</td><td>10</td><td>15</td><td>10</td><td>7 (500)</td></tr>
<tr><td>2</td><td>15</td><td>5</td><td>5</td><td>5</td><td>2 (300)</td></tr>
<tr><td>3</td><td>5</td><td>2</td><td>2</td><td>10</td><td>11 (300)</td></tr>
<tr><td>4</td><td>2</td><td>20</td><td>10</td><td>25</td><td>3 (300)</td></tr>
<tr><td>5</td><td>10</td><td>15</td><td>25</td><td>20</td><td>19 (600)</td></tr>
<tr><td>Ø</td><td>8</td><td>10</td><td>11</td><td>14</td><td>8 (400)</td></tr>
</table>
Note: All means are rounded to integer.
* = no brood
**= no brood and colony kill
Numbers in brackets ( ) depict amount of ants found in nest after excavation.
</td>
<td></td>
</tr>
<tr>
<td>PT 18</td>
<td>Outdoors</td>
<td>Detia „Ameisen-mittel” (watering appli-cation)</td>
<td>Lasius niger Common black garden ant, colonies,</td>
<td>Simu-lated-use study</td>
<td>- Application by pouring (after mixing with water)
-Arena: waxed card-board box (60 x 40 x 15 cm) filled with 12 cm soil
-Ant colonies „burrowed” in one half of the arena</td>
<td></td>
<td>Linn (2017d), report no.: BIO093a-17</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>0.5% Perme-thrin</td>
<td>all develop-ment stages</td>
<td></td>
<td>-Temperature: 25 – 26°C
-Rel. humidity: 56 – 58%
-Dosage per arena: 10 g
-Acclimatisation: 7 d before treatment
-Starvation: 4 d (only water)
-Alternative food: sugar honey mix in the untreated half of the arena
-5 replicates (5 controls)
-Assessment intervals: weekly after application
-Effects investigated: activity, determination of nest kill and killed queen by excavation of nests</td>
<td><u>Efficacy of an ant granular product via watering application against Black ants, Lasius niger in test arenas (2400 cm²)</u>
Study: Mo5818
Method no.: BPD BioG B 407-05
1 colony / replicate
temperature: 25 - 26 °C
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Granular product (ready to use)
Active: 5 g / kg (0.5 %) Permethrin
Expiry Date: 02.2019</td><td>1</td><td>5</td><td>30*</td><td>4*</td><td>30*</td><td>3* (150)</td></tr><tr><td>2</td><td>40</td><td>10*</td><td>2*</td><td>5*</td><td>0** (0)</td></tr><tr><td>3</td><td>10</td><td>0**</td><td>0**</td><td>0**</td><td>0** (0)</td></tr><tr><td>4</td><td>2</td><td>0**</td><td>0**</td><td>0**</td><td>0** (0)</td></tr><tr><td>5</td><td>5</td><td>0**</td><td>0**</td><td>0**</td><td>0** (0)</td></tr><tr><td>Ø</td><td>12</td><td>8</td><td>1</td><td>7</td><td>1 (30)</td></tr><tr><td rowspan="6">Untreated Control</td><td>1</td><td>10</td><td>10</td><td>15</td><td>10</td><td>7 (500)</td></tr><tr><td>2</td><td>15</td><td>5</td><td>5</td><td>5</td><td>2 (300)</td></tr><tr><td>3</td><td>5</td><td>2</td><td>2</td><td>10</td><td>11 (300)</td></tr><tr><td>4</td><td>2</td><td>20</td><td>10</td><td>25</td><td>3 (300)</td></tr><tr><td>5</td><td>10</td><td>15</td><td>25</td><td>20</td><td>19 (600)</td></tr><tr><td>Ø</td><td>8</td><td>10</td><td>11</td><td>14</td><td>8 (400)</td></tr></table>Note: All means are rounded to integer.
* = no brood
**= no brood and colony kill
Numbers in brackets ( ) depict amount of ants found in nest after excavation</td>
<td></td>
</tr>
<tr>
<td>PT 18</td>
<td>Outdoors</td>
<td>Ant powder (sprinkle appli-cation)</td>
<td>Lasius niger Common black garden ant, colonies,</td>
<td>Field trial</td>
<td>-Treatment of wild ant nests under stones/flower pots/on pavement (Germany)
-Application by spreading (ready to use product)
-Dose: 10g/nest
-3 replicates (3 controls)</td>
<td>Table 1
<u>Efficacy of ant product Detia Ameisenmittel (granular product, scattered) against nests of Black ants, Lasius niger in the field.</u>
Study: Mo5818
temperature at evaluations: 19 - 31°C
<table><tr><th rowspan="2">Product</th><th rowspan="2">Replicate/ nest</th><th rowspan="2">Amount of product per nest</th><th colspan="4">Activity of ants (number [of movements] of ants / individuals)</th></tr><tr><th>1 minute before test start</th><th>1 week after treatment</th><th>2 weeks after treatment</th><th>3 weeks after treatment</th></tr><tr><td rowspan="3">Detia Ameisenmittel scattered
Active: 5 g / kg (0.5 %) Permethrin
Batch: 52002.5
Expiry Date: 02.2019</td><td>1</td><td>10 gram</td><td>100</td><td>0</td><td>0**</td><td>0**</td></tr><tr><td>2</td><td>10 gram</td><td>100</td><td>0</td><td>0**</td><td>0**</td></tr><tr><td>3</td><td>10 gram</td><td>100</td><td>0</td><td>0**</td><td>0**</td></tr><tr><td>Ø</td><td></td><td>100</td><td>0</td><td>0</td><td>0</td></tr><tr><td>Range</td><td></td><td>no range</td><td>no range</td><td>no range</td><td>no range</td></tr></table>** excavation: no activity, dead workers, no brood, no living queen
note: all means rounded to integers</td>
<td>Linn, (2017a), report no.: BIO090a-17</td>
</tr>
</table>

		0.5% Perme-thrin	all develop-ment stages		-Assessment intervals: 1 d, 1, 2, 3 weeks -Effects investigated: activity of ants, number of individuals after short liftnig of nest coverage, determination of nest kill by excavation of nests	**Evaluation of untreated nests of Black ants, *Lasius niger* in the field** Study: Mo5818 temperature at evaluations: 19 - 31°C Activity of ants (number [of movements] of ants / individuals) Product / Replicate/ nest / Amount of product per nest / 1 minute before test start / 1 week after treatment / 2 weeks after treatment / 3 weeks after treatment Untreated control / 1 / - / 20 / 50 / 30 / 100 Untreated control / 2 / - / 100* / 100 / 100* / 100* Untreated control / 3 / - / 100* / 30 / 100 / 100 Ø / 73 / 60 / 77 / 100 Range / (20 - 100) / (30 - 100) / (30 - 100) / no range * with brood note: all means rounded to integers In case of high density of individuals the amount of ants was estimated. Lifting of stones, panels or other kind of shelter above the nests led to higher activity of the nests and therefore exact counting of individual organisms was not possible. When less activity occurred (e.g. at the end of the study) an exact counting was performed.	

PT 18	Outdoors	Ant powder (watering appli-cation) 0.5% Perme-thrin	*Lasius niger* Common black garden ant, colonies, all develop-ment stages	Field trial	-Treatment of wild ant nests under stones/flower pots/on pavement (Germany) -Application by **pouring** (after mixing with water) -Dose: 10g/nest -3 replicates (3 controls) -Assessment intervals: 1 d, 1, 2, 3 weeks -Effects investigated: activity of ants, number of individuals after short liftnig of nest coverage, determination of nest kill by excavation of nests	**Efficacy of ant product Detia Ameisenmittel (granular product, watered) against nests of Black ants, *Lasius niger* in the field.** Study: Mo5818 temperature at evaluations: 19 - 31°C Activity of ants (number [of movements] of ants / individuals) Product: Detia Ameisenmittel watered; Active: 5 g / kg (0.5 %) Permethrin; Batch: 52002.5; Expiry Date: 02.2019 Replicate/ nest; Amount of product per nest; 1 minute before test start; 1 week after treatment; 2 weeks after treatment; 3 weeks after treatment 1: 10 gram (diluted in 1 litre tap water): approx. 30; 0; 0**; 0** 2: 10 gram (diluted in 1 litre tap water): 100*; 0; 0**; 0** 3: 10 gram (diluted in 1 litre tap water): approx. 30; 3; 0; 0** Ø: 53; 1; 0; 0 Range: 30 - 100; 0 - 3; no range; no range * with brood ** excavation: no activity, dead workers, no brood, no living queen note: all means rounded to integers **Evaluation of untreated nests of Black ants, *Lasius niger* in the field** Study: Mo5818 temperature at evaluations: 19 - 31°C Activity of ants (number [of movements] of ants / individuals) Product: Untreated control Replicate/ nest; Amount of product per nest; 1 minute before test start; 1 week after treatment; 2 weeks after treatment; 3 weeks after treatment 1: -: 20; 50; 30; 100 2: -: 100*; 100; 100*; 100* 3: -: 100*; 30; 100; 100 Ø: 73; 60; 77; 100 Range: (20 - 100); (30 - 100); (30 - 100); no range * with brood note: all means rounded to integers In case of high density of individuals the amount of ants was estimated. Lifting of stones, panels or other kind of shelter above the nests led to higher activity of the nests and therefore exact counting of individual organisms was not possible. When less activity occurred (e.g. at the end of the study) an exact counting was performed.	Linn, (2017b), report no.: BIO091a-17

<table>
<tr>
<td>PT 18</td>
<td>Outdoors</td>
<td>Detia „Ameisen-mittel” (sprinkle appli-cation) 0.5% Perme-thrin; fresh and 3 years old</td>
<td>Lasius niger Common black garden ant, colonies, all develop-ment stages</td>
<td>Simu-lated-use study</td>
<td>-Application by spreading (ready to use product)
-Arena: waxed card-board box (60 x 40 x 15 cm) filled with 12 cm soil
-Ant colonies „burrowed” in one half of the arena
-Temperature: 25 – 26°C
-Rel. humidity: 55 – 60%
-Dosage per arena: 10 g
-Acclimatisation: 7 d before treatment
-Starvation: 4 d (only water)
-Alternative food: sugar honey mix in the untreated half of the arena
-5 replicates (5 controls)
-Assessment intervals: weekly after application
-Effects investigated: activity, determination of nest kill and killed queen by excavation of nests</td>
<td>Study: Mo6269 temperature: 25 - 26 °C
Method no.: BPD BioG B 407-05 1 colony / replicate rel. humidity: 55 - 60 %
<table>
<tr><th rowspan="2">Product</th><th rowspan="2">Replicate</th><th colspan="8">Activity of ants
number of visible living ants on surface of test arena, additional number of living ants after excavation of nest.</th></tr>
<tr><th>1 day before applic.</th><th>1 week after applic.</th><th>2 weeks after applic.</th><th>3 weeks after applic.</th><th>4 weeks after applic.</th><th>5 weeks after applic.</th><th>6 weeks after applic.</th><th>6 weeks after applic. after excavation of nest</th></tr>
<tr><td rowspan="7"><u>3 years aged</u>
Detia Ameisenmittel
Batch: 20150615/591002
Date of production: 04/2015
Date of analysis: 08/2018</td><td>1</td><td>3</td><td>0*</td><td>8*</td><td>0*</td><td>0*</td><td>0**</td><td>0**</td><td>0</td></tr>
<tr><td>2</td><td>12</td><td>0*</td><td>5*</td><td>0*</td><td>0*</td><td>4*</td><td>9*</td><td>ca. 100</td></tr>
<tr><td>3</td><td>10</td><td>0**</td><td>0**</td><td>---</td><td>---</td><td>---</td><td>---</td><td>0</td></tr>
<tr><td>4</td><td>11</td><td>0**</td><td>0**</td><td>---</td><td>---</td><td>---</td><td>---</td><td>0</td></tr>
<tr><td>5</td><td>8</td><td>0</td><td>0*</td><td>0*</td><td>0**</td><td>0**</td><td>---</td><td>0</td></tr>
<tr><td>Ø</td><td>9</td><td>0</td><td>3</td><td>0</td><td>0</td><td>1</td><td>2</td><td>20</td></tr>
<tr><td rowspan="7"><u>fresh</u>
Detia Ameisenmittel
Batch: 53186.14
Date of production: 07/2018
Date of analysis: 07/2018</td><td>1</td><td>6</td><td>0**</td><td>0**</td><td>---</td><td>---</td><td>--</td><td>---</td><td>0</td></tr>
<tr><td>2</td><td>18</td><td>0*</td><td>0**</td><td>0**</td><td>---</td><td>---</td><td>---</td><td>0</td></tr>
<tr><td>3</td><td>14</td><td>0</td><td>0</td><td>20</td><td>15</td><td>0</td><td>0</td><td>ca. 100</td></tr>
<tr><td>4</td><td>7</td><td>0</td><td>3</td><td>0</td><td>4</td><td>0**</td><td>0**</td><td>0</td></tr>
<tr><td>5</td><td>3</td><td>0</td><td>0</td><td>0</td><td>0**</td><td>0**</td><td>---</td><td>0</td></tr>
<tr><td>Ø</td><td>10</td><td>0</td><td>1</td><td>4</td><td>4</td><td>0</td><td>0</td><td>20</td></tr>
</table>
Note: All means are rounded to integer.
* = no brood
**= no brood and colony kill</td>
<td>Lüpkes (2018a), report no.: BIO112-18</td>
</tr>
</table>

Study: Mo6269 | temperature: 25 - 26 °C
Method no.: BPD BioG B 407-05 | 1 colony / replicate | rel. humidity: 55 - 60 %

Product	Replicate	Activity of ants number of visible living ants on surface of test arena, additional number of living ants after excavation of nest.							
		1 day before applic.	1 week after applic.	2 weeks after applic.	3 weeks after applic.	4 weeks after applic.	5 weeks after applic.	6 weeks after applic.	6 weeks after application (incl. nest after excavation)
Control untreated	1	15	ca. 200*	ca. 130*	ca. 150*	10*	10*	6*	ca. 300
	2	17	ca. 200*	ca. 65*	ca. 70*	ca. 30*	5*	13*	ca. 600
	3	4	5*	ca. 30*	ca. 30*	ca. 50*	17*	27*	ca. 500
	4	25	20*	ca. 50*	ca. 70*	20*	2*	5*	ca. 300
	5	14	0*	10*	ca. 30*	10*	7*	2*	ca. 700
	Ø	**15**	**ca. 85**	**ca. 57**	**ca. 70**	**ca. 24**	**8**	**11**	**ca. 480**

Note: All means are rounded to integer.
* = no brood
**= no brood and colony kill

<table>
<tr>
<td>PT 18</td>
<td>Outdoors</td>
<td>Detia „Ameisen-mittel” (watering appli-cation) 0.5% Perme-thrin; fresh and 3 years old</td>
<td>Lasius niger Common black garden ant, colonies, all develop-ment stages</td>
<td>Simu-lated-use study</td>
<td>- Application by pouring (after mixing with water)
-Arena: waxed card-board box (60 x 40 x 15 cm) filled with 12 cm soil
-Ant colonies „burrowed” in one half of the arena
-Temperature: 25 – 26°C
-Rel. humidity: 55 – 60%
-Dosage per arena: 10 g
-Acclimatisation: 7 d before treatment
-Starvation: 4 d (only water)
-Alternative food: sugar honey mix in the untreated half of the arena
-5 replicates (5 controls)
-Assessment intervals: weekly after application
-Effects investigated: activity, determination of nest kill and killed queen by excavation of nests</td>
<td>
Study: Mo6269
Method no.: BPD BioG B 407-05 1 colony / replicate temperature: 25 - 26 °C rel. humidity: 55 - 60 %
<table>
<tr><th rowspan="2">Product</th><th rowspan="2">Replicate</th><th colspan="8">Activity of ants
number of visible living ants on surface of test arena, additional number of living ants after excavation of nest.</th></tr>
<tr><th>1 day before applic.</th><th>1 week after applic.</th><th>2 weeks after applic.</th><th>3 weeks after applic.</th><th>4 weeks after applic.</th><th>5 weeks after applic.</th><th>6 weeks after applic.</th><th>6 weeks after applic. after excavation of nest</th></tr>
<tr><td rowspan="7"><u>3 years aged</u>
Detia Ameisenmittel
Batch: 20150615/591002
Date of production: 04/2015
Date of analysis: 08/2018</td><td>1</td><td>15</td><td>27*</td><td>3*</td><td>15*</td><td>9</td><td>16</td><td>23</td><td>ca. 100</td></tr>
<tr><td>2</td><td>3</td><td>0*</td><td>0**</td><td>0**</td><td>---</td><td>---</td><td>---</td><td>0</td></tr>
<tr><td>3</td><td>10</td><td>0*</td><td>0*</td><td>0*</td><td>0**</td><td>0**</td><td>---</td><td>0</td></tr>
<tr><td>4</td><td>10</td><td>0*</td><td>14*</td><td>0*</td><td>0*</td><td>0**</td><td>0**</td><td>0</td></tr>
<tr><td>5</td><td>1</td><td>0**</td><td>0**</td><td>---</td><td>---</td><td>---</td><td>---</td><td>0</td></tr>
<tr><td>Ø</td><td>8</td><td>5</td><td>3</td><td>3</td><td>2</td><td>3</td><td>5</td><td>ca. 20</td></tr>
<tr><td rowspan="7"><u>fresh</u>
Detia Ameisenmittel
Batch: 53186.14
Date of production: 07/2018
Date of analysis: 07/2018</td><td>1</td><td>7</td><td>15</td><td>0</td><td>12</td><td>0</td><td>1</td><td>0</td><td>ca. 150</td></tr>
<tr><td>2</td><td>26</td><td>4</td><td>0</td><td>0</td><td>0**</td><td>0**</td><td>---</td><td>0</td></tr>
<tr><td>3</td><td>6</td><td>0**</td><td>0**</td><td>---</td><td>---</td><td>---</td><td>---</td><td>0</td></tr>
<tr><td>4</td><td>5</td><td>2</td><td>0</td><td>0**</td><td>0**</td><td>---</td><td>---</td><td>0</td></tr>
<tr><td>5</td><td>8</td><td>0**</td><td>0**</td><td>---</td><td>---</td><td>---</td><td>---</td><td>0</td></tr>
<tr><td>Ø</td><td>10</td><td>4</td><td>0</td><td>2</td><td>0</td><td>0</td><td>0</td><td>ca. 30</td></tr>
</table>
Note: All means are rounded to integer.
* = no brood
**= no brood and colony kill
</td>
<td>Lüpkes (2018b), report no.: BIO113-18</td>
</tr>
</table>

Study: Mo6269 temperature: 25 - 26 °C
Method no.: BPD BioG B 407-05 1 colony / replicate rel. humidity: 55 - 60 %

Product	Replicate	Activity of ants number of visible living ants on surface of test arena, additional number of living ants after excavation of nest.							
		1 day before applic.	1 week after applic.	2 weeks after applic.	3 weeks after applic.	4 weeks after applic.	5 weeks after applic.	6 weeks after applic.	6 weeks after application (incl. nest after excavation)
Control untreated	1	15	ca. 200*	ca. 130*	ca. 150*	10*	10*	6*	ca. 300
	2	17	ca. 200*	ca. 65*	ca. 70*	ca. 30*	5*	13*	ca. 600
	3	4	5*	ca. 30*	ca. 30*	ca. 50*	17*	27*	ca. 500
	4	25	20*	ca. 50*	ca. 70*	20*	2*	5*	ca. 300
	5	14	0*	10*	ca. 30*	10*	7*	2*	ca. 700
	Ø	**15**	**ca. 85**	**ca. 57**	**ca. 70**	**ca. 24**	**8**	**11**	**ca. 480**

Note: All means are rounded to integer.
* = no brood
**= no brood and colony kill

2.5.6 Occurrence of resistance and resistance management

Permethrin is a synthetic pyrethroid, with the same mode of action as other members of the group, and is anticipated to be subjected to the same pressures regarding the potential development of resistance as the other synthetic pyrethroids. The resistance to pyrethroids has been found to varying degrees, depending on the pest species and location. A WHO review of Vector Resistance to Pesticides (2012) identified resistance among some species of flies and cockroach populations.
Cross-resistance of pest species within the group of pyrethroids is to be anticipated due to a common mode of action.
Resistance management advice for non-professional use on the label:

- In the case of reduced efficacy or suspected development of resistance, the use of the product has to be discontinued immediately and a professional pest control operator needs to be contacted.
- products should always be used in accordance with label recommendations

However, it is not likely that resistance will build up in ants nest with a queen who lays eggs for a long period. The product will affect other organisms in the treated area, and since resistance to Permethrin is known in other insects the product should be used with care.

2.5.7 Known limitations

No limitations and no undesirable or unintended side-effects have been observed during the efficacy studies.

2.5.8 Evaluation of the label claims

The submitted studies are suitable to support the claim “knock down and kills individuals of the black garden ant (*Lasius niger)*”. The claim “nest kill” is also supported outdoor for sprinkling application 2 weeks after the treatment and for pouring after 3 weeks. No residual efficacy is claimed. The product does not contain any preservative but studies with a 3 years old product have been submitted and supporta shelf life of 3 years

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

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

2.5.10 Data waiving and conclusion

Table 16

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.

Table 17

Conclusion on the efficacy
The intended label claim: “knocks down and kills individuals of the black garden ant (*Lasius niger*)” and also the claim “nest kill” are supported for both application methods outdoor (2 weeks or 3 weeks after the sprinkling or pouring application, respectively). Shelf life: 3 years

2.6 Risk assessment for human health

2.6.1 Assessment of effects of the active substance on human health

Table 18

Permethrin	Value	Study	Safety factor
AEL long-term	0,05 mg/kg bw/d[1]	12-month dog study. Bayer (Kalinowski *et al*, 1982)	100
AEL medium-term	0,05 mg/kg bw/d[1]	12-month dog study. Bayer (Kalinowski *et al*, 1982)	100
AEL acute	0,5 mg/kg bw[1]	Rat 2 year oral study (acute effect) Bayer (Ishmael and Litchfield, 1988)	100

[1] Assessment-Report (RMS IE (2014))

Table 19

Permethrin	Value	Reference
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Assessment-Report (RMS IE (2014))
Dermal absorption	3 %	Assessment-Report (RMS IE (2014)) Human dermal penetration study

2.6.2 Assessment of effects of the product on human health

2.6.2.1 Skin corrosion and irritation

Table 20

Data waiving was acceptable for the following information requirements	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	A skin irritation study performed with the product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III,

	section 8.1 “Skin corrosion or skin irritation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), testing on the biocidal products does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected. Sufficient information on skin-irritating/skin corrosion properties of the components of the biocidal product is available. Information on synergistic effects is not available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary.

Table 21

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin.
Justification for the value/conclusion	Evaluation and classification is based on the toxicological properties of the single components The content of components classified for skin irritation is below the limits for classification Pyrethroids like the active substance permethrin can cause paresthesia.
Classification of the product according to CLP	Classification for skin irritation/corrosivity is not required.

2.6.2.2 Eye irritation

Table 22

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	An eye irritation study performed with the product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.2 “Eye irritation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), testing on the biocidal products does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected. Sufficient information on eye-irritating/eye damage properties of the components of the biocidal product is available. Information on synergistic effects is not available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary.

Table 23

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not Irritating to the eyes.
Justification for the value/conclusion	Evaluation and classification is based on the toxicological properties of the single components. The biocidal product does not contain components classified for eye irritation or damage.
Classification of the product according to CLP	Classification for eye irritation/damage is not required.

2.6.2.3 Respiratory tract irritation

Table 24

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, “other endpoints”
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal product does not contain components classified for respiratory irritation.

Table 25

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract
Justification for the value/conclusion	Based on intrinsic properties of the individual components the biocidal product is not irritating to the respiratory tract.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

2.6.2.4 Skin sensitization

Table 26

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the biocidal product are not required.

	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.3 “Skin sensitisation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), testing on the biocidal products does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected. For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available from safety data sheets and other information for each of the individual components in the product. Information on synergistic effects is not available.

Table 27

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitising
Justification for the value/conclusion	The active substance of the biocidal product is classified for skin sensitisation according to Regulation (EC) No 1272/2008: Permethrin (0.54 %): Skin Sens. 1 [1)] (H317: C ≥ 1 %; EUH208: C > 0.1 %) [2)] [3)]
Classification of the product according to CLP	Classification for skin sensitisation is not required. Labelling with EUH208 (Contains permethrin. May produce an allergic reaction.)

[1)] According to Annex VI of Regulation (EC) No 1272/2008
[2)] According to Regulation (EC) No 1272/2008
[3)] According to the active substance evaluation permethrin is not skin-sensitising. A CLH intention to remove this entry has been submitted. However, a final decision is not available. Thus, the current classification is legally binding

2.6.2.5 Respiratory sensitization (ADS)

Table 28

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	Data on respiratory sensitisation for the biocidal product or its components are not available.

Table 29

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Respiratory sensitisation is not expected.
Justification for the value/conclusion	Data on respiratory sensitisation for the biocidal product or its components are not available.

Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

2.6.2.6 Acute toxicity

2.6.2.6.1 Acute toxicity by oral route

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	A study on acute oral toxicity of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected. For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available from safety data sheets and other information for each of the individual components in the products. Information on synergistic effects is not available. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 31

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route.
Justification for the selected value	Based on the oral LD_{50} available for the single components the oral LD_{50} of the biocidal product is estimated to be > 2000 mg/kg bw.
Classification of the product according to CLP	Classification for acute oral toxicity is not required.

2.6.2.6.2 Acute toxicity by inhalation

Table 32

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation

Justification	A study on acute inhalation toxicity of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected. For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available from safety data sheets and other information for each of the individual components in the products. Information on synergistic effects is not available. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 33

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on the inhalation LC_{50} available for the single components the inhalation LC_{50} of the biocidal product is estimated to be > 5 mg/L.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required

2.6.2.6.3 Acute toxicity by dermal route

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	A study on acute dermal toxicity of the biocidal product is not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available from safety data sheets and other information for each of the individual components in the products. Information on synergistic effects is not available. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in

	Regulation (EC) No 1272/2008 and testing of the biocidal product is not required

Table 35

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	Based on the dermal LD_{50} available for the single components the dermal LD_{50} of the biocidal product is estimated to be > 2000 mg/kg bw.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

2.6.2.7 Information on dermal absorption

Table 36

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving. 8.6. Information on dermal absorption
Justification	The applicant proposed to use the dermal absorption value derived during active substance evaluation in the CAR based on a study of Bartelt, N and Hubbell, J (1987). However, this value is not applicable for the biocidal product. According to the EFSA Guidance on Dermal Absorption (2012) the test formulation used in a dermal absorption study has to be sufficiently similar to the reviewed product. However, the identity of the test formulation in this study is not known. Probably, it is a solution of the pure active substance in a solvent. Hence, it cannot be proven whether the test formulation and the biocidal product (including the dilutions) are comparable. As a worst case the default in accordance with the EFSA Guidance on Dermal Absorption (2012) has to be used for human exposure and risk assessment.

Table 37

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	Permethrin (all scenarios and dilutions)
Value(s)	75 %
Justification for the selected value(s)	EFSA Guidance on Dermal Absorption (2012)

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

Not relevant

2.6.2.9 Available toxicological data relating to a mixture

Not relevant

2.6.2.10 Other

Not relevant

2.6.2.11 Summary of effects assessment

Table 38

Endpoint	Brief description
Skin corrosion and irritation	Not classified for skin irritation or corrosion. Skin exposure may cause paresthesia
Eye irritation	Not classified for eye irritation or damage.
Respiratory tract irritation	Not classified for respiratory tract irritation
Skin sensitisation	Not classified for skin sensitisation. However, labelling with EUH208 for permethrin is required.
Respiratory sensitization (ADS)	Not classified for respiratory sensitisation.
Acute toxicity by oral route	Not classified for acute oral toxicity. Oral LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw.
Acute toxicity by inhalation	Not classified for acute inhalation toxicity. Inhalation LC_{50} calculated from information on the ingredients: > 5.0 mg/L
Acute toxicity by dermal route	Not classified for acute dermal toxicity. Dermal LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw
Information on dermal absorption	Permethrin: concentrate, dilutions, residues: 75 %.
Available toxicological data relating to non-active substance(s)	Not relevant

Available toxicological data relating to a mixture	Not relevant
Other relevant information	Not relevant

2.6.3 Exposure assessment

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

Table 39

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	No	Yes	Yes	No	Not expected	Yes	
Dermal	No	Yes	Yes	No	Not expected	Yes	
Oral	n.a.	n.a.	No	n.a.	n.a.	Yes	

List of scenarios

Table 40

Summary table: scenarios (non-professional)			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Application	Primary acute exposure, application by scattering, dermal and inhalation exposure	Non-professional
2.	Mixing & loading and application	Primary acute exposure, mixing and loading of the biocidal product in watering can and application by pouring from a watering can, cleaning of equipment, dermal and inhalation exposure	Non-professional
3.	Post application	Secondary medium-term exposure, toddler crawling on the floor (representing also worst case for other age groups), oral, dermal and inhalation exposure	General public
4.	Post application	Secondary acute exposure, toddler ingesting the biocidal product orally by picking up granules applied by scatting, oral exposure, (reverse reference scenario)	General public
Summary table: scenarios (professional)			
1. (= Use 3)	Scattering granules	Primary exposure of workers resulting from scattering granules directly from the packaging or from a bucket using a spoon or beaker onto nests or trails. Secondary exposure of a professional bystander is not expected.	Professional, Trained professional
2. (= Use 4)	Pouring with watering can	Primary exposure of workers resulting from dissolving, application of the application liquid using a watering can or similar pouring device and cleaning of equipment. Secondary exposure of a professional bystander is not expected.	Professional, Trained professional

2.6.3.1.1 Professional exposure

Ameisen-Mittel is a granular insecticide. It is applied by pouring an aqueous application solution or scattering granules onto ant nests or trails outdoors on balconies, terraces or areas adjacent to buildings.

Ameisen-Mittel is a concentrate (for pour treatment) or ready-to-use (for scattering treatment) granular insecticide containing “permethrin” (CAS-No.: 52645-53-1; 0.54 % (w/w)).

The biocidal product is marketed in different package sizes: cardboard can (100-600 g), plastic (PE) scattering can (100-600 g), plastic (PE) bucket (2.5-10 kg), plastic (PE) tubular bag (10-500 g) or water soluble bags 10-100g packaged into carton boxes (100 - 500 g).

The exposure to the a.s. is assessed separately for the different application techniques and will thus be described in individual subsections of the current section. It is usually based on the harmonised document "Biocides Human Health Exposure methodology (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.
In Annex 3.3.1 the details of the exposure calculations to the a.s. for the professional user are laid out.

- **Scenario 1 – Scattering granules**

Description

The exposure assessment of scattering granules directly from a portable vessel is based on model data described in detail in the *Biocides Human Health Exposure Methodology Document Version 1 (October 2015).*
Ameisen-Mittel is a granular ready-to-use bait for the control of ants. The b.p. is sold in cardboard cans, scattering cans and buckets and is intended for spot application outdoors on balconies, terraces and area adjacent to buildings. The granules are scattered directly from the packaging or from a bucket by means of an applicator (e.g. spoon or beaker) onto insecticide nests or insecticide trails.

Dermal exposure

Exposure to hands is expected during the application phase when scattering the granules from the container. The dermal exposure is assessed using data from the "Consumer product spraying and dusting Model 2" (Biocides Human Health Exposure Methodology Document Version 1 (October 2015)). The model describes crack and crevice treatment in the kitchen (e.g. skirtings, shelves, horizontal laminate surfaces) and on furnishings and carpets by dusting powder (median, 45% of dust less than 75 µm) and scattering granules (median, > 95% of granules greater than 180 µm) directly from flexible and hard containers by non-professionals. The model provides data of potential "hand and forearm" and potential "legs, feet and face" exposure. For the present application, high dustiness is assumed to have an impact on exposure level. Due to the specified median particle sizes of the dusting powders and granules represented by the model, the dustiness of the b.p. can be considered to be of equal or even less level. Additionally, taking into account a similar kind of packaging and assuming that professional users have more experience in scattering treatment than non-professionals, the assessment may represent a worst-

case calculation for scattering granules directly from a portable vessel such as a shaker can or from a bucket by means of an applicator (e.g. spoon or beaker).

The product is used for spot application. According to the “OECD series on emission scenario documents Number 18 – emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses” an area of up to approx. $2m^2$ is expected to be treated per spot. According to the applicant, one spot per private house or ten spots per public building can be assumed to be treated by a professional. In accordance with the applicant’s information and the *Biocides Human Health Exposure Methodology Document Version 1 (October 2015)*, a total duration of 60 min per day was estimated for targeted spot application.

Beyond that, no separate calculation needs to be considered for the mixing and loading phase as well as the post-application phase as the product is ready to use, residues are not collected, containers are disposed of and other equipment does not need to be cleaned.

Exposure by inhalation

Inhalative exposure is expected to occur during the application phase (scattering granules) and is calculated for the a.s. using the values from “Consumer product spraying and dusting Model 2” (*Biocides Human Health Exposure Methodology Document Version 1 (October 2015)*).

Table 41

Details of Scenario 1	
Parameters	Value
Concentration of a.s. permethrin in b.p..	0.54 % (w/w)
Application duration	60 min

Calculations for Scenario 1

The results of the calculation for potential/actual inhalation and dermal exposure (Tier1 and Tier 2) are summarised in Table 43.

For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1. of this PAR.

For risk characterisation, see chapter 3.6.4.5.

Further information and considerations on scenario 1

Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking the use of protective gloves and a protective coverall into account.

The use of an applicator (e.g. spoon or beaker) is recommended when scattering the product from a bucket onto the nests. This is a technical measure to reduce dermal exposure in comparison to manual scattering of the product by hand.

- **Scenario 2 –Pouring with watering can**

Description

An approach for exposure assessment of pour treatment is described in the *Technical Agreements for Biocides* (September 2015). The assessment laid out in this PAR follows this approach.

Ameisen-Mittel is a water-soluble granular concentrate for control of ants. The b.p. is sold in cardboard cans, scattering cans, buckets and tubular or water soluble bags and has to be dissolved prior to application. Subsequently, the application liquid is applied onto insecticide nests or insecticide trails using a watering can. The b.p. is intended for spot application outdoors on balconies, terraces and area adjacent to buildings.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

During the mixing and loading phase, the hands are exposed to dust when the b.p. is transferred into a vessel. The calculation is based on data obtained from the "Mixing and Loading Model 5" (*Biocides Human Health Exposure Methodology Document Version 1 (October 2015)*). The model describes pouring a formulation (granules) from a container into a portable receiving vessel (e.g. knapsack type equipment) by professionals and provides measurement data for potential hand exposure.

During the application process exposure via skin seems likely, especially to the lower part of the work clothing (legs) and the hands of the operator. For the application method via watering can the dermal exposure is assessed using data from "Subsoil Treatment Model 2" (*Biocides Human Health Exposure Methodology Document Version 1 (October 2015)*) for professional treating soil by watering can. The model is the only model covering that type of application for professionals. The model is based on only 4 data points but provides data of potential body and actual hand exposure (measurements of hand exposure inside gloves).

The b.p. is used for spot application. According to the "OECD series on emission scenario documents Number 18 – emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses" an area of up to approx. $2m^2$ is expected to be treated per spot. According to the applicant, one spot per private house or ten spots per public building can be assumed to be treated by a professional. In accordance with the applicant's information and the *Biocides*

Human Health Exposure Methodology Document Version 1 (October 2015), a total duration of 60 min per day was estimated for targeted spot application.

In addition, exposure of hands during cleaning of the watering can is considered, although it represents only a minor part of the total dermal exposure. After application, cleaning is usually performed by filling tap water in the watering can and emptying the rinsing onto the treated area. As no suitable model is available to assess the cleaning of a watering can, the post-application phase is assessed using the indicative values given by *Marquart et al (Ann. Occup. Hyg., 2006, Vol. 50, No. 5, pp. 469-489)* for cleaning of spray guns.

Exposure by inhalation

Exposure to aerosols for the a.s. during the post-application phase is not expected, but has been calculated for the mixing and loading phase based on data from the “Mixing and Loading Model 5” (*Biocides Human Health Exposure Methodology Document Version 1 (October 2015)*) and for the application phase based on data from the ”Subsoil Treatment Model 2” (*Biocides Human Health Exposure Methodology Document Version 1 (October 2015)*).

Table 42

Details of Scenario 2	
Parameters	Value
Concentration of a.s. permethrin in b.p..	0.54 % (w/w)
Concentration of b.p. in application liquid	1 %
Total amount of b.p. used	0.3 kg
Application duration	60 min

Calculations for Scenario 2

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 42.

For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3of this PAR. For risk characterisation, see chapter 2.6.4.

Further information and considerations on scenario 2

The quantitative exposure assessment has indicated significant dermal exposure. As a consequence, a refined exposure assessment was performed, taking the following safety measures into account for Tier 2 to address systemic risks: protective gloves (EN 374).

Additionally, when pouring the application liquid with a watering can exposure to the feet is expected. Thus, waterproof footwear (e.g. rubber boots) is useful and recommended.
Further, the use of an applicator (e.g. spoon or beaker) is recommended when loading the product from a bucket into the watering can. This is a technical measure to reduce dermal exposure in comparison to manual loading of the product by hand.

Table 43

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.			
Exposure scenario	**Tier/PPE**	**a.s. 1**	
		Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**
Scenario 1 – Scattering granules	Tier 1:	1.67×10^{-3}	1.77
	Tier 2: • RMM: Protective gloves (EN 374) • RMM: Protective coverall (type 6, EN 13034) According to the calculation performed in Tier 1, additional specified protective equipment is not necessary; a risk for professional users is unlikely (for details see 3.6.4.5).	1.67×10^{-3}	0.18
Scenario 2 – Pouring with watering can	Tier 1:	3.38×10^{-5}	16.22
	Tier 2: • RMM: Protective gloves (EN 374)[1)]	3.38×10^{-5}	0.31

1) In addition to protective gloves (taking into account in the calculation) the use of waterproof footwear (e.g. rubber boots) is recommended.

2.6.3.1.2 Non-professional exposure

Two different types of application for non-professionals were described by the applicant. The biocidal product can be directly applied by spreading the granules or it can be dissolved in water and applied by pouring using a watering can. The biocidal product is for outdoor use.

- **<u>Scenario 1</u>**

Table 44

Description of Scenario 1		
The biocidal product is applied by scattering the granules directly from a cardboard box or a shaker. No models for the outdoor application of insecticides as granules directly to ant nests are available. However, models exist for similar application patterns of dusting powders against insects which can be seen as a worst case for outdoor application of granular products. The corresponding indicative exposure data are summarised in the Biocides Human Health Exposure Methodology (2015) and the TNsG on Human Exposure (2007). They are derived from a simulated volunteer study, in which insecticide powders against ants were applied to cracks and crevices, shelves or carpets. The powders were applied by scattering from a hand-held flexible duster/hand-held canister by non-professionals and professionals. Based on information by the applicant an application and exposure duration of 10 min is assumed. Note that for dusting powders an application duration of 5 min is proposed in the Biocides Human Health Exposure Methodology (2015). In this PAR, the applicant's duration value was used. The biocidal product is applied several times during the summer season when ants occur. Hence, medium-term exposure is expected.		
	Parameters	Value
Tier 1	Indicative exposure value hands and forearms (Biocidal product exposure methodology, 2015, p. 126 + 220)	2.73 mg/min
	Indicative exposure value legs, feet and face (Biocidal product exposure methodology, 2015, p. 126 + 220)	2.74 mg/min
	Indicative exposure value inhalation (Biocidal product exposure methodology, 2015, p. 126 + 220)	2.47 mg/m^3
	Protection by clothing or gloves	None
	Application/exposure duration (applicant)	10 min
	Concentration a.s. in the biocidal product	0.54 % (w/w)
	Dermal absorption (EFSA Guidance on Dermal Absorption, 2012)	75 %
	Inhalation absorption (CAR/AR, 2014)	100 %
	Body weight, adult (HEEG opinion No. 17, 2013)	60 kg
	Inhalation rate, short-term, adult (HEEG opinion No. 17, 2013)	1.25 m^3/h

Calculations for Scenario 1

Systemic exposure

$Exposure_{dermal}$ = (indicative exposure value hands, forearms x protection factor + indicative exposure value legs, feet, face x protection factor) x exposure duration x concentration a.s. x dermal absorption / body weight adult

= (2.73 mg BP/min x 100 % + 2.74 mg BP/min x 100 %) x 10 min x 0.54 % x 75 % / 60 kg
= 0.003692 mg/kg bw

$Exposure_{inhalation}$ = indicative exposure value inhalation x concentration a.s. x exposure duration x inhalation rate, short-term adult x inhalation absorption / body weight adult

$Exposure_{inhalation}$ = 2.47 mg/m^3 x 0.54 % x 10 min x 1.25 m^3 / 60 min x 100 % / 60 kg
= 0.000046 mg/kg bw

Total systemic exposure = 0.003739 mg a.s./kg bw

- **Scenario 2**

Table 45

Description of Scenario 2		
The biocidal product is dissolved in water and applied using a watering can. In the Biocides Human Health Exposure Methodology (2015) and in the TNsG on Human Exposure (2007) a model for exposure of professionals applying insecticides by means of a watering can directly to the soil including prior mixing and loading is described. This model gives default exposure values for actual hand exposure inside gloves, for potential body exposure of the rest of the body and for inhalation exposure. For calculation of potential hand exposure without gloves, the default value for hand exposure inside gloves is multiplied by 100 as suggested in the HEEG opinion No. 2 (2008) and in the Biocides Human Health Exposure Methodology (2015). Under these conditions the model is considered appropriate for non-professional exposure. Based on information by the applicant an application and exposure duration of 10 min is assumed. The calculation of the exposure of hands during cleaning of equipment (watering can) is based on the calculation for the professional user (please refer to 3.6.3.1.1, scenario 2). The usual cleaning is described as filling the watering can with tap water and emptying the rinsing onto the treated area. The biocidal product is applied several times during the summer season when ants occur. Hence, medium-term exposure is expected.		
	Parameters	Value
Tier 1	Indicative actual exposure value hands in gloves (Biocidal product exposure methodology,. 2015, p. 203)	48.8 mg/min
	Indicative actual exposure value hands without gloves (Biocidal product exposure methodology,. 2015, p. 203; HEEG opinion No. 2, 2008)	4880 mg/min
	Indicative exposure value body (Biocidal product exposure methodology, 2015, p. 203)	38.2 mg/min
	Indicative exposure value inhalation (Biocidal product exposure methodology, 2015, p. 203)	4.15 mg/m^3
	Indicative exposure value hand during cleaning without gloves (90th percentile; Marquart et al (Ann. Occup. Hyg., 2006, Vol. 50, No. 5, pp. 469-489))	210 mg
	Protection by clothing or gloves	None
	Application/exposure duration (applicant)	10 min
	Concentration a.s. in the biocidal product	0.54 % (w/w)
	Dilution factor (10 g b.p. in 1000 mL water)	100
	Dermal absorption (EFSA Guidance on Dermal Absorption, 2012)	75 %
	Inhalation absorption (CAR/AR, 2014)	100 %
	Body weight, adult (HEEG opinion No. 17, 2013)	60 kg
	Inhalation rate, short-term, adult (HEEG opinion No. 17, 2013)	1.25 m^3/h

Calculations for Scenario 2

Systemic exposure

$Exposure_{dermal\ Appl}$ = (indicative potential exposure value hands without gloves x protection factor + indicative exposure body x protection factor) x exposure duration x concentration a.s. / dilution factor x dermal absorption / body weight adult

= (4880 mg BP/min x 100 % + 38.2 mg BP/min x 100 %) x 10 min x 0.54 %/100 x 75 % / 60 kg

= 0.033198 mg/kg bw/d

$Exposure_{dermal\_Clean}$ = indicative potential exposure value hands during cleaning without gloves x concentration a.s. / dilution factor x dermal absorption / body weight adult

= 210 mg x 0.54 %/100 x 75 % / 60 kg

= 0.000142 mg/kg bw/d

$Exposure_{inhalation}$ = indicative exposure value inhalation x concentration a.s. / dilution factor x exposure duration x inhalation rate, short-term adult x inhalation absorption / body weight adult

$Exposure_{inhalation}$ = 4.15 mg/m^3 x 0.54 % / 100 x 10 min x 1.25 m^3 / 60 min x 100 % / 60 kg

= 0.000001 mg/kg bw/d

Total systemic exposure = 0.033341 mg a.s./kg bw/d

Table 46

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	1	0.000046	0.003692	-	0.003739
Scenario [2]	1	0.000001	0.0.033340	-	0.033341

- **Combined scenarios**

Not relevant

2.6.3.1.3 Secondary exposure of the general public

- **Scenario 3**

Table 47

Description of Scenario 3		
According to this scenario a toddler is crawling on a surface after treatment with the biocidal product. Exposure occurs by the dermal route and subsequently orally by hand-to-mouth contact. Also inhalation exposure was assessed based on the vapour pressure and the saturated vapour concentration with parameters and calculations as proposed in the HEEG opinion No. 13 - Assessment of inhalation exposure of volatilised biocide active substance (2011). This represents a very conservative approach since the estimation via the saturated vapour concentration generally represents an overestimation and since the biocidal product is applied outdoors. Ten grams of the biocidal product is normally applied to one nest. As proposed by the applicant it is assumed that this amount is evenly distributed to 1 m^2. According to the Consexpo Pest Control Fact Sheet the transfer coefficient for surface to skin transfer is 6000 cm^2/h. This value is based on data for adults and represents a worst case for smaller children. More recently, a value of 2100 cm^2/h for toddlers was estimated in the HEADhoc recommendation No. 12 - Default values for indoor Transfer Coefficient (2016). Although this value is for indoor application it is assumed that it is also applicable in this case where the biocidal product is applied around houses and exposure occurs most likely on terraces. For surface transferable residues the applicant proposed a value of 30 % from the CAR. However, this value from the Biocidal product exposure methodology (2015) and the TNsG on Human Exposure (2007) is for dried fluids on cotton, knitwear, plastic and wood. The more appropriate value is 55 % for dried fluid on smooth glazed tiles. It is assumed that the biocidal product is applied in maximum to 5 m^2 of a 30 m^2 terrace. Hence, the potential of dermal contact is reduced accordingly. It must be expected that toddlers are exposed daily during the summer season when the biocidal product is applied. Hence medium-term exposure is assumed. The exposure assessment for toddlers results in a human health risk. It should be noted that dermal exposure of adults using deviating parameters for transfer coefficient and body weight would result in an acceptable exposure level.		
	Parameters	Value
Tier 1	Application rate biocidal product (applicant)	10 g/m^2
	Application rate a.s. (applicant)	0.005 mg/cm^2
	Concentration a.s. in the biocidal product	0.54%
	Treated area	5 m^2
	Surface of a terrace	30 m^2
	Average surface loading (application rate x treated surface / surface terrace	8.33 x 10^{-4} a.s. mg/cm2
	Surface transferable residues (Biocidal product exposure methodology, 2015)	55 %
	Transfer coefficient (HEAdhoc recommendation No 12, 2016)	2100 cm^2/h
	Hand-to-mouth transfer, fraction of external dermal exposure (Consexpo Pest Control Fact Sheet, 2006)	10 %
	Exposure duration dermal and oral (Consexpo Pest Control Fact Sheet, 2006)	1 h

	Molecular weight (CAR/AR, 2014)	391.29 g/mol
	Vapour pressure (CAR/AR, 2014)	2.16x 10^{-6} Pa (20 °C)
	Gas constant (HEEG opinion No. 13, 2013)	8,314 J/mol/K
	Temperature (HEEG opinion No. 13, 2011)	293 K (20 °C)
	Saturated vapour pressure permethrin (calculated acc. to HEEG opinion No. 13, 2011)	3.46 x 10^{-4} mg/m^3
	Exposure duration inhalation (HEEG opinion No. 13, 2013)	1 d
	Inhalation rate, long-term toddler (HEEG opinion No. 17, 2013)	8 m^3/d
	Body weight toddler (HEEG opinion No. 17, 2013)	10 kg

Calculations for Scenario 3

Systemic exposure

$Exposure_{dermal}$ = application rate b.p. x concentration a.s. x treated area / surface terrace x surface transferable residues x transfer coefficient x exposure duration x dermal absorption / body weight toddler

= 10 g/m^2 x1000 / 10000 x 0.54 % x 5 m^2 / 30 m^2 x 55 % x 2100 cm^2/h x 1 h x 75 % / 10 kg

= 0.07796 mg/kg bw

$Exposure_{oral}$ = application rate b.p. x concentration a.s. x treated area / surface terrace x surface transferable residues x transfer coefficient x exposure duration x hand-to-mouth transfer x oral absorption / body weight toddler

= 10 g/m^2 x1000 / 10000 x 0.54 % x 5 m^2 / 30 m^2 x 55 % x 2100 cm^2/h x 1 h x 10 % x 100 % / 10 kg

= 0.01040 mg/kg bw

$Exposure_{inhalation}$ = saturated vapour concentration a.s. x inhalation rate x inhalation duration x inhalation absorption / body weight toddler

$Exposure_{inhalation}$ = 3.46 x 10^{-4} mg/m^3 x 8 m^3/d x 1 d x 100 % / 10 kg

= 0.00028 mg a.s./kg bw/d

Total systemic exposure = 0.08864 mg a.s./kg bw/d

Scenario 4

Table 48

Description of Scenario 4		
If the biocidal product is applied by scattering it must be assumed that the biocidal product is ingested orally by smaller children (toddlers) after picking up granules. A model for such an exposure is not available. Hence, a reverse reference scenario is calculated. It is expected that toddlers are normally supervised by their parents or other adults. Hence, such an exposure is expected to only occur occasionally and is considered as acute exposure.		
	Parameters	Value
Tier 1	Concentration a.s.	0.54 % (w/w) = 54 mg/g
	AEL_{acute} (CAR/AR, 2017)	0.5 mg/kg bw
	Body weight toddler (HEEG opinion No. 17, 2013)	10 kg

Acceptable amount of active substance, which can be ingested by a toddler:

= AEL_{acute} x body weight = 0.5 mg/kg bw x 10 kg = 5 mg a.s.

5 mg a.s are equivalent to 0.93 g biocidal product. Hence, a toddler can in maximum ingest 0.93 g of the biocidal product.

Table 49

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3]	1	0.00028	0.07796	0.001040	0.08864

2.6.3.2 Dietary exposure

Table 50

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	Permethrin
Type of formulation	Water-soluble granules

Substance(s) of concern	none
Field(s) of use	Outdoor use on paved and unpaved paths around the house, on balconies and terraces
Target organism(s)	black garden ant (*Lasius niger*) , all developmental stages
Application rate(s) and frequency	Biocidal product (containing 5 g permethrin/kg) is directly applied into ant nests, cracks and crevices by scattering of granules (10 g biocidal product per ant nest) or pouring of dissolved granules (10 g biocidal product per L water per ant nest), max 4 applications per year
Category(ies) of users	
Waiting periods after treatment	None
Further information	Outdoor use on paved and unpaved paths around the house, on balconies and terraces

Overall conclusion for dietary exposure

The biocidal product is to be used for control of ant pests by application to localised areas so that the biocidal product does not come into contact with food and feedstuff. Uptake of the active substance permethrin via the roots of adjacent plants used as food or feed crops is not expected.

In order to ensure that contact of the biocidal product with food or feed is avoided the following risk mitigation measures are proposed:

Do not contaminate food, feed, eating utensils or food contact surfaces.

2.6.3.3 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 BPD.

2.6.3.4 Aggregated exposure

2.6.3.5 Summary of exposure assessment

For summary of external exposure values please refer to section 3.6, Table 43

2.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in Table 18, 19, chapter 3.6.1.

2.6.4.2 Maximum residue limits or equivalent

Residue definitions

Definition of residue in food commodities of plant and animal origin (risk assessment and enforcement):

Permethrin (sum of isomers)

Table 51

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL	Reg. (EC) 839/2008	Food commodities of plant and animal origin	Variable

2.6.4.3 Specific reference value for groundwater

2.6.4.4 Risk for industrial users

No industrial applications are intended.

2.6.4.5 Risk for professional users

General considerations

The occupational risk assessment for the biocidal product Ameisen-Mittel takes into account systemic and local effects of the active substance permethrin (CAS No.: 52645-53-1).

Exposure of professional users to biocidal products generally takes place via the inhalation and/or dermal route and is usually assessed by means of external inhalation and/or dermal exposure values. For many substances (both active substances and substances of concern) external reference values such as occupational exposure limits (OELs) are available. By contrast, internal reference values (AELs) normally exist for active substances only. Therefore, external reference values will preferably be the basis for the risk characterisation of biocidal products as chemical mixtures. In case only internal reference values are available, they will be converted to external reference values in order to allow for a comparison with external exposure values.

- **Systemic effects**

The active substance permethrin, a synthetic pyrethroid, is a neurotoxin. The systemic reference value $AEL_{medium/long\text{-}term}$ of permethrin is based on adaptive hepatic changes associated with pyrethroid toxicity. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to permethrin resulting from use of the biocidal product.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from exposure of professional users to permethrin from the biocidal product Ameisen-Mittel, inhalation and dermal exposure to permethrin is assessed. For this, the systemic reference value $AEL_{medium/long\text{-}term}$ (0.05 mg/kg bw/d) of permethrin is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of permethrin, the corresponding $AEL_{medium/long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) and an external dermal reference value (RV_{derm}) according to the following equations:

RV_{inhal} (in mg/m^3) = $AEL_{medium/long\text{-}term}$ of permethrin (in mg/kg bw/d) x 60 kg / 10 m^3 x100 % / %-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{medium/long\text{-}term}$ of permethrin (in mg/kg bw/d) / %-dermal absorption x 100%.

By this means, RV_{inhal} equivalent to 0.30 mg/m^3 and RV_{derm} equivalent to 0.07 mg/kg bw/d are calculated for permethrin.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the active substance permethrin.

Dermal absorption rate

Valid data are not available for the biocidal product Ameisen-Mittel. Therefore, the default value of 75 % for active substance concentration below 5 % (according to the EFSA Guidance on Dermal Absorption, 2012) has to be taken into consideration for risk assessment.

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for the inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the active substance permethrin resulting from use of the biocidal product Ameisen-Mittel are determined according to the following equations:

RQ_{inhal} = inhalation exposure to permethrin (in mg/m³) / RV_{inhal} of permethrin (in mg/m³).

RQ_{derm} = dermal exposure to permethrin (in mg/kg bw/d) / RV_{derm} of permethrin (in mg/kg bw/d).

Dermal exposure to permethrin given in mg/kg bw/d is calculated from dermal exposure to permethrin given in mg/person through division by 60 kg/person.

The summation of RQ_{inhal} and RQ_{derm} for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 61 gives a detailed overview of the risk assessment results referring to the active substance permethrin for the biocidal product Ameisen-Mittel. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in table 61. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance permethrin resulting from the use of the biocidal product Ameisen-Mittel is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in table 61, the scenario ‘scattering granules’ yields a RI of less than 1 already in TIER 1. By contrast, the RI of the scenario ‘pouring with watering can’ exceeds the value of 1 after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenario. However, when risk reduction measures are implemented the risk characterisation result yields RI of less than 1 in TIER 2.

Table 52: Overview of detailed systemic risk assessment results referring to the active substance permethrin for the biocidal product Ameisen-Mittel

Scenario	inhalation external	dermal external	RI	concern

		potential/actual exposure mg/m³	RV_{inhal} mg/m³	RQ_{inhal}	potential/actual exposure mg/person	mg/kg bw/d	RV_{derm} mg/kg bw/d	RQ_{derm}		
Scattering granules	Tier 1	$1.67x10^{-3}$	0.30	0.01	1.77	0.03	0.07	0.44	0.45	**no**
Pouring with watering can	Tier 1	$3.38x10^{-5}$	0.30	$1.13x10^{-4}$	16.22	0.27	0.07	4.06	4.06	yes
	Tier 2	$3.38x10^{-5}$	0.30	$1.13x10^{-4}$	0.31	$5.18x10^{-3}$	0.07	0.08	0.08	**no**

Tier 1: no PPE; Tier 2: protective gloves and waterproof footwear (e.g. rubber boots)

RV_{inhal}: reference value for the inhalation route

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI: substance specific risk index

Conclusion

Based on the systemic risk assessment of the active substance permethrin via the inhalation and dermal route, a risk for professional users resulting from the intended uses ‘scattering granules’ and ‘pouring with watering can’ with the biocidal product Ameise-Mittel is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 at least after TIER 2 consideration. Regarding occupational safety, there are no objections against the aforementioned intended uses taking into account the provisions described in chapter 2.5 of this PAR.

- **Local effects**

The biocidal product Ameisen-Mittel contains the pyrethroid permethrin. Pyrethroids are known to cause paresthesia after dermal exposure, which are normally transient and do not persist. Hence, an appropriate labelling on the packaging is required to inform susceptible persons.

Overall Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product Ameisen-Mittel is unlikely for the intended uses ‘scattering granules’ and ‘pouring with watering can’. Risk reduction measures have to be taken into account in order to ensure safe use of the biocidal product Ameisen-Mittel.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

2.6.4.6 Risk for non-professional users

Table 53: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 / Application by scattering	1	5	0.05	0.003739	7.5	yes
2 / Application with watering can incl. Mixing and Loading and Cleaning	1	5	0.05	0,033341	67	yes

- **Local effects**

The biocidal product contains the pyrethroid permethrin. Pyrethroids are known to cause paresthesia, which are normally transient and do not persist. Hence, an appropriate labelling on the packaging is required to inform susceptible persons.

Conclusion

No human health risk was identified.

Hence, the biocidal product is considered safe for non-professional application if used as intended and if all safety advices are followed.

2.6.4.7 Risk for the general public

Table 54: 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)
3 / Toddler crawling on the floor	1	5	0.05	0.08864	177	Yes with appropriate labelling
4 / Toddler picking up and	1	50	5	Max. uptake: 5 mg a.s. =	100	Yes with appropriate

ingesting granules (reverse reference scenario)				0.93 g b.p. for a 10 kg toddler		labelling / bittering agent

- **Local effects**

The biocidal product contains the pyrethroid permethrin. Pyrethroids are known to cause paresthesia, which are normally transient and do not persist. Hence, an appropriate labelling on the packaging is required to inform susceptible persons.

Conclusion

A human health risk has been identified for toddlers crawling on treated surfaces. Hence contact to such surfaces by toddlers should be avoided. It is acknowledged that the exposure assessment is based on some very conservative assumptions.

1) The contact time (exposure duration) of 1 h, as adopted from Consexpo, is very long, particularly if it is taken into consideration that the biocidal product is only applied to a part of the terrace and the toddler will not stay permanently in vicinity of the ant nest.

2) The transfer coefficient for surface transferable residues of 55 % for smooth glaze tiles represents a worst case since the surface of terraces is normally rougher resulting in a lower transfer factor.

3) Since the biocidal product is applied outdoors it must be assumed that it at least partly degrades. Hence, exposure will be decrease with time.

4) The assumption of medium-term exposure is also very conservative since it assumes daily exposure over a longer time interval. In fact, intermittent exposure and at least transiently lowering exposure levels (until the next treatment) are more likely.

Considering these facts, it is expected that use of the biocidal product is safe if an additional labelling is provided and the user is advised to keep children away from treated surfaces and the biocidal product is applied only in areas inaccessible for children.

Normally, this exposure scenario for toddlers is considered as a worst case for older children and adults. It should be noted that the same exposure assessment with some adopted parameters for adults (transfer coefficient: 7800 cm^2/h, body weight: 60 kg, no oral exposure) leads to acceptable exposure levels. Hence, additional safety measures for adults are not required.

A reverse reference scenario was calculated for oral exposure of toddlers by picking up and ingesting scattered granules. Based on this scenario ingestion of up to 1 g is considered acceptable for acute exposure. The biocidal product contains an aversive agent and it is also labelled with an advice for the user to keep children away from treated surfaces and to use the biocidal product only in areas inaccessible to children (refer to scenario 3). Considering these risk mitigation measures ingestion of more than 0.9 g is considered unlikely if the biocidal product is stored out of the reach of children.

A specific exposure and risk assessment for contact to wet surfaces after watering was not provided by the applicant. Hence, treated surfaces should only be re-entered by adults when dried.

2.6.4.8 Risk for consumers via residues in food

Residues in food or feed from the intended use are not expected.

No acute or chronic exposure to residues in food resulting from the intended use is expected, and therefore a risk to consumers is unlikely.

Regarding consumer health protection, there are no objections against the intended uses.

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not required as the product contains only the active substance Permethrin and no substances of concern.

2.6.4.10 Summary of risk characterisation

2.6.4.10.1 Summary of risk characterisation for industrial user

No industrial applications are indented.

2.6.4.10.2 Summary of risk characterisation for professional user

For summary of risk characterisation for professional users refer to table 61 in section 3.6.4.5.

2.6.4.10.3 Summary of risk characterisation for non-professional user

For summary of risk characterisation for non-professional uses refer to Table 45 in section 3.6.4.6.

2.6.4.10.4 Summary of risk characterisation for indirect exposure

For summary of risk characterisation for the general public refer to Table 46 in section 3.6.4.7.

2.7 Risk assessment for animal health[14]

A specific risk assessment for pets and domestic animals was not performed. It general, it can be assumed that the secondary exposure and risk assessment for the general public is also valid for pets. Domestic animals are considered not relevant since the biocidal product is for use around private houses, on terraces and balconies. Hence, the same risk mitigation measures as for the general public are also applicable for pets with an appropriate extension of the concerned measures (e.g. Keep children and pets, particularly cats, away from treated surfaces; Keep out of reach of children and pets. Apply only in areas inaccessible to children and pets.). It is known that cats are more sensitive to pyrethroids than other pets (e.g. dogs). Hence, particular attention is required. However, since the proposed risk mitigation measures recommend to keep pets, in general, away from treated surfaces additional measures are not necessary.

2.8 Risk assessment for the environment

2.8.1 General information

The product (b.p.) ‘Ameisen-Mittel’ is used as insecticide (PT18) against black garden ants (*Lasius niger*, all developmental stages) and is applied directly on ant nests or on ant nest entrances on balconies, terraces and areas adjacent to buildings. The product contains 0.5 % w/w permethrin as active substance (0.54 % w/w technical a.s. with a purity of 93 % w/w), therefore the environmental risk assessment is based on the content of the pure a.s of 0.50 % w/w.

The following applications are intended for the product ‘Ameisen-Mittel’:

i) Pouring of dissolved granules directly into ant nests (non-professional use and professional use)
ii) Granular application by scattering granules on ant nest entrances (non-professional use and professional use)

The product ‘Ameisen-Mittel’ contains no substance of concern for the environment. As only one active substance is present in the product and the co-formulants do not significantly contribute to the ecotoxic profile and no synergistic effects between the components are expected, the environmental risk assessment for ‘Ameisen-Mittel’ is based on data on the active substance permethrin, including relevant metabolites. No new information for the assessment of fate and behaviour as well as of the effects of

[14] Pets and domestic animals. Regarding wild animals, please refer to chapter 2.8.

permethrin compared to the CAR has been provided within product authorisation for ‘Ameisen-Mittel’, so that the assessment is based upon data given in the CAR (2014) for permethrin.
The final CAR (2014) for permethrin combines ecotoxicological data from different applicants who originally submitted their data separately in the framework of active substance approval for PT8 and PT18 respectively. However, as the data set was identical for the different PTs, during a.s. approval it was decided to combine these data into one CAR (combined PT8 and PT18). The applicant applying for authorisation of the product ‘Ameisen-Mittel’ has a letter of access for the combined CAR (PT8 and PT18) and consequently all data contained therein were considered for product authorisation.

2.8.2 Effects assessment

Effects assessment is performed based on the active substance in the product ‘Ameisen-Mittel’. For the active substance permethrin, as well as its metabolites, the evaluation is adapted from the respective assessment reports in PT8 and PT18 (CAR 2014; Rapporteur: Ireland).
For permethrin in PT8 and PT18, a new effect study on other terrestrial non-target organisms (*Folsomia candida*) has been provided (November 2016) for the compartment soil, which is currently evaluated by eCA IE with regard to active substance approval. The outcome of the MS e-consultation concerning the derivation of $PNEC_{soil}$ is still pending. Therefore, the effect assessment of the product ‘Ameisen-Mittel’ is initially based on the data currently available in the CAR associated with the corresponding assessment factors.

2.8.2.1 Mixture toxicity

No ecotoxicological data is available for the biocidal product ‘Ameisen-Mittel’. For mixture toxicity assessment, active substances and substances of concern should be taken into account. As the product ‘Ameisen-Mittel’ contains only one active substance and no substance of concern, an assessment of mixture toxicity is not necessary.

2.8.2.2 Aquatic compartment (including sediment and STP)

- **Aquatic toxicity**

Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolites DCVA and PBA can be found in the CAR for PT8 and PT18 (2014). For risk assessment a $PNEC_{water}$ = 0.00047 µg/L was derived for permethrin. For the metabolites a $PNEC_{water}$ = 0.015 mg/L and $PNEC_{water}$ > 0.010 mg/L was derived for DCVA and PBA, respectively.

Table 55

Data waiving was acceptable for the following information requirements	
Information requirement	Tests on aquatic and terrestrial organisms with the product 'Ameisen-Mittel' are not provided.
Justification	As the biocidal product 'Ameisen-Mittel' contains only one active substance and no substance of concern, the risk assessment can be based on data of the active substance permethrin.

Table 56

Conclusion used in Risk Assessment – Aquatic toxicity	
Value/conclusion	permethrin: $PNEC_{water}$ = 0.00047 µg/L; DCVA: $PNEC_{water}$ = 0.015 mg/L; PBA: $PNEC_{water}$ > 0.010 mg/L.
Justification for the value/conclusion	The lowest NOEC value of 0.0047 µg/L was derived from a study with *Daphnia magna* (CAR 2014). An AF of 10 was applied as long-term tests with species from three trophic levels are available.

- **Sediment toxicity**

No effect data for sediment is available for the active substance permethrin as well as for its metabolites DCVA and PBA . For risk assessment of permethrin a $PNEC_{sed}$ = 0.001 mg/kg dwt (2.17×10^{-4} wwt) was derived on basis of the equilibrium partitioning method (EPM) as described in detail in the CAR for PT8 and PT18 (2014). For the metabolites DCVA and PBA a $PNEC_{sed}$ = 0.055 mg/kg dwt (0.012 mg/kg wwt) and $PNEC_{sed}$ = 0.042 mg/kg dwt (0.009 mg/kg wwt) was concluded via EPM, respectively.

Table 57

Conclusion used in Risk Assessment – Sediment toxicity	
Value/conclusion	permethrin: $PNEC_{sed}$ = 0.001 mg/kg dwt (= 2.17×10^{-4} wwt) DCVA: $PNEC_{sed}$ = 0.055 mg/kg dwt (= 0.012 mg/kg wwt) PBA: $PNEC_{sed}$ = 0.042 mg/kg dwt (= 0.009 mg/kg wwt)

- **Inhibition of microbial activity (aquatic)**

The effect of permethrin on aerobic biological sewage treatment processes was assessed according to OECD 209 by determining respiration inhibition of the micro-organisms present in activated sludge following 3 hours contact.

Since testing was conducted using concentrations above the water solubility and no inhibition was observed, the NOEC for permethrin is set equal to the water solubility of 4.95 µg/l. The $PNEC_{microorganisms\ (STP)}$ reported in the AR (2014) was 4.95 µg/l.

2.8.3 Terrestrial compartment (including groundwater)

Detailed data on the environmental effect assessment and PNEC derivation of the active substance permethrin and its metabolites DCVA and PBA are described in the CAR for PT8 and PT18 (2014). For risk assessment of permethrin a $PNEC_{soil}$ > 0.099 mg/kg dwt (> 0.0876 mg/kg soil wwt) was derived on basis of effect data for soil microorganisms and an AF of 100. For the metabolite DCVA a $PNEC_{soil}$ = 4.6 mg/kg wwt and for the metabolite 3-Phenoxybenzoic Acid (PBA) a $PNEC_{soil.}$ = 1.44 mg/kg wwt was derived on the basis of effect data for *Hypoaspis aculeifer* (CAR 2014).

For the active substance approval of permethrin in PT8/PT18 a new study has been provided for the terrestrial compartment (November 2016), which is currently evaluated by eCA IE. As the outcome of the evaluation is still pending, the effect assessment of the product 'Ameisen-Mittel' is initially based on the data currently available in the CAR associated with the corresponding AF.

Table 58

Conclusion used in Risk Assessment – Terrestrial compartment		
Value/conclusion	permethrin:	$PNEC_{soil}$ > 0.099 mg/kg dwt (> 0.0876 mg/kg soil wwt)
	DCVA:	$PNEC_{soil}$ = 4.6 mg/kg wwt
	PBA:	$PNEC_{soil.}$ = 1.44 mg/kg wwt

Bees:

Permethrin is toxic for bees (oral LD_{50} = 0.163 µg/bee), but has no systemic effects. Despite the fact that 'Ameisen-Mittel' in granular form contains 98% of sugar, the attractiveness and accessibility for honeybees has been considered as being rather low due to the granule-form and intended use around the house on paved terraces etc., i.e. that the product will not be applied on soil covered with plants.

For the application by pouring directly on ant nests also no significant uptake by bees can be expected, as the solution with the dissolved product contains only 1 % sugar. It can be expected that this is not sufficiently attractive as food source. Furthermore, the solution has to be poured directly into the entrances of ant nests and due to the low sugar content the solution will probably not exhibit sufficient viscosity to form droplets staying on the ground. Hence, only minor or no portions of the solution will remain at the soil surface until the solution has completely drained.

2.8.4 Atmosphere

Exposure to the atmosphere is not considered relevant for the biocidal product 'Ameisen-Mittel', due to low vapour pressure (2.16E-06 Pa×m³/mol at 20 °C) of permethrin, a low Henry's Law constant and a high adsorption potential. Calculations indicate that if permethrin was present in the atmosphere it would be expected to degrade rapidly, mainly via gas phase reaction with photo-chemically generated hydroxyl radicals (CAR 2014).

2.8.5 Non-compartment specific effects

- **Primary poisoning**

Permethrin may be hazardous to birds and small mammals following acute exposure. Primary poisoning is possible in case of granules when they are based on an organic carrier and have a nutritional value. This is the case for 'Ameisen-Mittel' as it consists mainly of sugar (98%). However, due to the small size of the granules (98 % are ≤ 0.5 mm) the attractiveness and accessibility for birds is reduced (smaller than 'small granules' used as grid according to EFSA guidance "Risk Assessment for Birds and Mammals", 2009). Nevertheless, as it cannot be excluded that single individuals might be exposed to the product and may be harmed or die, an initial assessment of primary poisoning was performed.

Sufficient data for toxicity of permethrin to birds and mammals is present in the permethrin CAR PT8 and PT18 (2014) for assessing primary poisoning. The acute oral toxicity is considered relevant for primary poisoning in accordance with CA-Nov06-Doc.4.3 (2006) and the lowest values are presented in the following table.

Table 59

Conclusion used in Risk Assessment – primary poisoning of birds and mammals		
Value/conclusion	birds:	LD_{50} > 4640 mg/kg bw
	mammals:	LD_{50} = 480 mg/kg bw

- **Secondary poisoning**

According to the BPR guidance Vol IV part B+C (2017) an assessment of secondary poisoning is performed if a substance shows bioaccumulation potential and has the potential to cause toxic effects if accumulated in higher organsims.

The log Kow = 4.7 reveals a potential for bioaccumulation for the active substance permethrin. Moreover, according to the CAR from 2014, some of the estimated BCF values indicate a potential of permethrin to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) and subsequently bioaccumulate through the food chain. As the product represents a bait for insects, secondary poisoning for insectivorous birds and mammals should also considered relevant in accordance to OECD ESD PT18 No. 18 (2008). According to CLP00 the active substance permethrin is classified as H302 (Acute Tox. 4), which indicates a potential to cause toxic effects if accumulated in higher organisms Therefore, the potential for secondary poisoning was assessed for the aquatic and terrestrial compartment.

For a summary of relevant BCF values taken into account for secondary poisoning reference is made to the permethrin CAR for PT8 and PT18 (2014). For risk assessment a $PNEC_{oral\ bird}$ = 16.7 mg a.s./kg food and a $PNEC_{oral\ mammal}$ = 120 mg a.s./kg food was derived.

Table 60

Conclusion used in Risk Assessment – secondary poisoning	
Value/conclusion	$PNEC_{oral\ bird}$ = 16.7 mg a.s./kg food $PNEC_{oral\ mammal}$ = 120 mg a.s./kg food
Justification for the value/conclusion	For the ecotoxicological studies taken into account for secondary poisoning reference is made to the respective assessment reports in PT8 and PT18 (CAR 2014; Rapporteur: Ireland)

2.8.5.1 Summary of effects assessment

For the active substance permethrin, as well as its metabolites, the evaluation is adapted from the assessment reports in PT8 and PT18 (CAR 2014; Rapporteur: Ireland). The PNEC values for permethrin and the relevant metabolites are summarized in the following table.

Table 61

Summary table on calculated PNEC values		
Compartment	**Active substance**	**PNEC (µg/L)**
STP	permethrin	4.95 µg/L
	DCVA & PBA	-
Surface water	permethrin	0.00047 µg/L
	DCVA	15 µg/L
	PBA	> 10 µg/L
Sediment	permethrin	0.001 mg/kg dwt
	DCVA	0.055 mg/kg dwt (0.012 mg/kg wwt)
	PBA	0.042 mg/kg dwt;
Soil	permethrin	> 0.099 mg/kg dwt (> 0.0876 mg/kg soil wwt)
	DCVA	4.6 mg/kg wwt
	PBA	1.44 mg/kg wwt
Bird	permethrin	≥ 16.7 mg a.s/kg food (LD_{50} > 4640 mg/kg bw)
	DCVA & PBA	-
Mammals	permethrin	120 mg a.s/kg food (LD_{50} = 480 mg/kg bw)
	DCVA & PBA	-

2.8.6 Fate and behaviour

Detailed information on the fate and behaviour of permethrin can be found in the CAR for the a.s. permethrin from April 2014. As in the b.p 'Ameisen-Mittel' the applicant relates to permethrin with two pairs of diastereomers in the isomeric ratio of 25:75 (*cis:trans*) only the data based on this permethrin composition from the CAR is taken into account for the environmental risk assessment.

- **Biodegradation**

Apart from the post approval submission of an aerobic water/sediment degradation study (OECD 308) for the permethrin metabolite DCVA for PT8 and PT18 no new data regarding biodegradation of permethrin were delivered for authorisation of the biocidal product "Ameisenmittel". However, since the new results are still awaiting the final outcome of the EU evaluation of the eCA IE and approval of BPC, they are not considered here for refinement of exposure assessment. No further data are required.

Permethrin is not readily biodegradable. For environmental exposure and risk assessment only results from aerobic laboratory degradation studies in soil were used. The range of reliable SFO DT50s in several soils ranged from 77 d to ~141 d at 12°C. The corresponding geomean DT50 was 106 d. The *cis* isomer degraded more slowly than the *trans*-isomer. The geomean DT50 is derived from permethrin samples containing 50-78% of the *trans*-isomer. It can be expected that a DT50 value of 106 days is conservative enough to represent the degradation in soil at 12°C of permethrin samples containing a *cis:trans* ratio of 25:75.

In the soil compartment permethrin breaks down to form DCVA (max 11.3 % AR, SFO DT50 33.1- ~175 d at 12°C) and PBA (max 15.0 % AR, 1.7-2.5 d at 12°C), and ultimately converts to CO_2. For risk refinement purposes worst case DT50 (12°C) values of 175 days resp. 2.5 days were used for the two metabolites DCVA resp. PBA.

- **Abiotic degradation**

Permethrin was observed to be hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50°C respectively. Only at pH 9.0/9.6 was permethrin observed to hydrolyse, with DT_{50} values for *cis*- and *trans*-permethrin estimated at 35 days and 42 days, respectively (at pH 9.6 and 25°C).

Slow photo-oxidative degradation of permethrin under aqueous photolysis was estimated using the ABIWAS computer program. Thus, it is concluded in the CAR that significant photolysis of permethrin in water will not occur under environmentally relevant pH and temperature conditions (12°C).

Volatilisation of permethrin is considered to be negligible in the CAR based on the vapour pressure (2.155×10^{-6} Pa at 20°C, 25:75 cis:trans) and Henry constant (4.6×0^{-3} Pa m^3 mol^{-1} (CAR)). Permethrin

volatilisation loss from a soil surface over 24 hours to the atmosphere was calculated to be 0.73% assuming a temperature of 25 °C.

The software AOPWIN v1.91, which utilises QSAR methods, was used to calculate an atmospheric half-life value of 0.701 d for the gas phase reaction of permethrin with photo-chemically produced hydroxyl radicals (24-hour day and a hydroxyl radical concentration of 5×10^5 radicals/cm^3). Based on the short half-life for this transformation pathway, it is concluded that permethrin is rapidly degraded and would not be transported over large distances in the atmosphere in gaseous phase.

- **Adsorption/Desorption**

Permethrin is strongly adsorbed to soil (mean K_{oc} 70,003 L/kg (n = 5), CAR LOEP). Therefore, leaching is not expected to occur. The two relevant soil metabolites are more mobile with a mean K_{oc} for DCVA of 32.3 L/kg (n = 2) and a mean K_{oc} of 118.3 L/kg (n = 3) for PBA (CAR LOEP).

2.8.6.1 Bioconcentration

- **Aquatic bioconcentration**

The reported Log Kow values for permethrin range from 4.6 to 6.1 (CAR April 2014 for PT8 and PT18), indicating it is a fat-soluble molecule with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms). The CAR 2014 for PT8 and PT18 provides a BCF value for fish (BCF 570). However the half-life for depuration of tissue residues in fish was approximately 4/5 days with approximately 80% of the accumulated residues depurated within 14 days. Therefore, it was concluded that bioconcentration in fish tissues would not significantly occur and any residues accumulated are readily eliminated.

Table 62

Summary table – Estimated aquatic bioconcentration					
Basis for estimation	**Log K_{ow} (measured)**	**Estimated BCF for fish (freshwater)**	**Estimated BCF for fish eating bird/predator**	**Remarks**	**Reference**
Permethrin	4.7	500 – 570 L/kg (fish) 166 L/kg (chironomid in water) (published study)	-	DT_{50} for depuration of tissue residues in fish = 4.7 ± 0.34 days	Permethrin LOEP Update 2016

		415 L/kg (chironomid in sediment) (published study) 166 L/kg (chironomid in porewater) (published study)			

Table 63

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	BCF_{fish} = 570 L/kg fish
Justification for the value/conclusion	The active substance Permethrin in the product 'Ameisen-Mittel' possesses a potential to bioconcentrate. In CAR 2014 for PT8 and PT18, it was concluded that bioconcentration in fish tissues would not significantly occur. Moreover, the instructions for use and risk mitigation measures for the product 'Ameisen-Mittel' should prevent any emissions to the aquatic compartment.

2.8.7 Exposure assessment

2.8.7.1 General information

The b.p. 'Ameisen-Mittel' differs from the representative product assessed in the CAR for permethrin. Hence, the environmental exposure assessment described in the CAR could not be translated, but was adapted to the field of use envisaged for the b.p. 'Ameisen-Mittel'. As the applicant declares to use permethrin produced by Tagros Chemicals, for exposure assessment the information and endpoints provided by Tagros were used preferably. In case of a.s. distribution in the STP the results from CAR Doc IIB Permethrin have been used.

The b.p 'Ameisen-Mittel' is a solid which can be applied directly on ant nests and in ant nest entrances by two application methods (outdoor spot application): spread as RTU granules or poured (granules diluted in tab water). The b.p. 'Ameisen-Mittel' is intended for non-professional and professional users. According to the OECD Emission Scenario Document PT18, No 18 (2008) for outdoor spot applications during the spot application the majority of the b.p is emitted to the environment (F_{spot}=0.9).

Life cycle steps

Production of the active substance permethrin takes place outside the EU, thus it is not necessary to specifically quantify the potential for environmental exposure associated with this stage of the product life cycle. Formulation of the b.p. 'Ameisen-Mittel' takes place in a manufacturing plant within the EU in Germany. Permethrin is received in closed drums and then sprayed as liquid into a mixture of other components in order to produce the granules. Then, the mixture is filled into the final packaging. All

production steps are performed under sufficient suction to avoid release of permethrin to the environment. Furthermore, emptied drums and all wastes are disposed as special waste according to local regulations. It is therefore considered acceptable that the environmental exposure during the formulation of b.p. is not assessed here. As the b.p. 'Ameisen-Mittel' evolves its specific effect against ants immediately after release and the insecticidal effect is continuous, the use and service life stages are considered to be inseparable. Thus, the releases are assigned to the use phase which is assessed below.

Table 64

Assessed PT	PT18
Assessed scenarios	Outdoor spot application on balconies, terraces and areas adjacent to buildings Scenario 0: Direct application (scattering and pouring) on ant nests on unpaved soil around domestic premises and large (commercial) buildings - professional and non-professional user Scenario 1: Direct application (scattering and pouring) on ant nests around domestic premises on paved soil (e.g. terraces) by non-professional user Scenario 2: Direct application (scattering and pouring) on ant nests around large (commercial) buildings on paved soil by professional user
ESD(s) used	OECD Emission Scenario Document for Product Type 18 No.18 (2006): for insecticides, acaricides and products to control other arthropods for household and professional uses, July 2008
Approach	10 g b.p. per ant nest application methods: spreading of granules or pouring of diluted granules (10 g diluted in 1L tab water in a watering can)
Distribution in the environment	Calculated based on Guidance on the BPR Volume IV ENV – Part B (April 2015)
Groundwater simulation	For Scenario 0, application on unpaved soil, simulation for leaching to groundwater using FOCUS PEARL model was performed.
Confidential Annexes	NO
Life cycle steps assessed	All Scenarios: Production: No Formulation No Use: Yes Service life: No
Remarks	

Table 65: Overview of receiving compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Soil	Ground-water	Air	Other
Scenario 0 Pouring	NO	NO	NO	NO	NO	YES	YES	NO	
Scenario 1 – non-professional	NO	NO	NO	NO	NO*	YES	YES	NO	
Scenario 2 - professional	YES	YES	NO	NO	YES	YES	YES	NO	

* According to TAB ENV 159 (version 2.0 August 2018) no release to sewer/STP is assumed for spot applications around domestic premises.

Table 66

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Permethrin			
Molecular weight	391.29	g/mol	
Vapour pressure (at 20°C)	2.16×10^{-6}	Pa	LOEP
Water solubility (at 20°C)	0.18	mg/L	LOEP
Log Octanol/water partition coefficient (at 25 °C)	4.67	Log 10	LOEP
Organic carbon/water partition coefficient (Kfoc)	70,003	L/kg	LOEP (1/n = 1.09)
Henry's Law Constant (at 12°C)	2.962×10^{-3}	Pa/(m^3×mol)	Calculated (CA)
Henry's Law Constant (at 20°C)	4.6×10^{-3}	Pa/(m^3×mol)	LOEP
Biodegradability	Not readily biodegradable		
DT_{50} for degradation in soil (at 12ºC)	106	d	geomean CAR
PBA			
Molecular weight	214.22	g/mol	
Vapour pressure (at 25°C)	0.000421	Pa	EPI Suite model
Water solubility (at 25°C)	16.91	mg/L	EPI Suite model

Organic carbon/water partition coefficient (Kfoc)	118.3	L/kg	LOEP (1/n=0.80)
Henry's Law Constant (at 12°C)	2.554×10^{-3}	Pa/(m³×mol)	Calculated (CA)
DT_{50} for degradation in soil (at 12ºC)	2.5	d	CAR
DCVA			
Molecular weight	209.07	g/mol	
Vapour pressure (at 25°C)	0.26	Pa	EPI Suite model
Water solubility (at 25°C)	127.6	mg/L	EPI Suite model
Organic carbon/water partition coefficient (Kfoc)	32.3	L/kg	LOEP (1/n = 0.65)
Henry's Law Constant (at 12°C)	0.205	Pa/(m³×mol)	Calculated (CA)
DT_{50} for degradation in soil (at 12ºC)	175	d	CAR

Table 67

Calculated fate and distribution in the STP*)		
Compartment	Percentage [%]	Remarks
	Permethrin	
Air	0.0	Model used: SimpleTreat 3.1
Water	27.6	
Sludge	72.4	
Degraded in STP	0	

* Distribution in STP was calculated according to Doc IIB of CAR Permethrin PT18, For the sake of completeness the results for distribution in STP applying the Koc from Tagros Chemicals India are provided here: F_{air} = 0.0%, $F_{surface\ water}$ = 16.7 %, F_{sludge} = 83.4%. Using this consistent (Tagros) data base for environmental exposure assessment would not affect the outcome in environmental risk assessment.

2.8.7.2 Outdoor use on ant nests on unpaved soil around domestic premises and large (commercial) buildings - Scenario 0

2.8.7.2.1 Release estimation

The spot application of the b.p. 'Ameisen-Mittel' to an ant nest on unpaved soil around domestic premises or large buildings is considered the worst case for the terrestrial compartment. An amount of 10 g biocidal product is applied by different application methods: spreading of granules or pouring of diluted granules (10 g diluted in 1 L tab water in a watering can). According to the OECD Emission Scenario Document PT18, No 18 (2008) for outdoor spot applications the majority (F_{spot} = 0.9) of the b.p is emitted to the

environment during application. In this scenario the receiving soil compartment is assumed to be a cube with dimensions of 0.5 × 0.5 × 0.5 m (ESD PT18, p. 133). The scenario is applicable to both, non-professional and professional users.

Table 68: Emission scenario for outdoor application of Ameisen-Mittel to ant nests on unpaved soil – direct release to soil

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 0: spot (scattering or pouring) application on unpaved soil			
Application rate of biocidal product	10	g/nest	
Fraction of active substance in product	0.005		ref. to chapter 3.9.1
Applied amount of a.s. permethrin	0.05	g/nest	
Number of application sites	1		
Fraction emitted to soil	0.9		(ref. to ESD No. 18 (2008) page 147)
Area exposed to a.s.	0.25	m^2	
Output			
Local direct emission rate of a.s. to soil	45	mg	

The application of the b.p. in a typical scenario results in a direct release of **45 mg** permethrin to soil.

2.8.7.2.2 Estimation of Predicted Environmental Concentrations for the terrestrial compartment

Using the above indicated input parameters the following predicted concentrations of permethrin in soil (ref. to ESD PT18 No. 18) and groundwater (ref. to Guidance BPR Vol. IV Env Part B (Version 1.0, April 2015)) were calculated following the application of b.p. “Ameisen-Mittel” outdoor on unpaved soil:

Table 69 Summary of PEClocal$_{soil}$ and PEClocal$_{groundwater}$

Calculated PEC values		
	PEC_{soil}	**PEC_{GW}**
	[mg/kg]	[µg/L]
Scenario 0	0.2120	0.1720

The estimated PEC for groundwater in Scenario 0 is above the ground water trigger value of 0.1 µg/L. In order to present a safe use for the groundwater compartment additional modelling with FOCUS PEARL (Version 4.4.4) were performed, details see in Chapter 4.3.
The use of FOCUS PEARL models for refinement of PEC groundwater resulted for all locations in PECs for permethrin which were < 0.001 µg/L.

2.8.7.2.3 Atmosphere

According to the OECD Emission Scenario Document PT18, No 18 (2008) outdoor spot applications with granules 'should be considered as spot applications to soil' (see page 132). Release to air is considered negligible due to the intended application methods for 'Ameisen-Mittel'. Furthermore volatilisation of permethrin is considered to be negligible in the CAR based on the vapour pressure (2.16×10^{-6} Pa at 20°C, 25:75 cis:trans) and Henry constant (2.96×10^{-3} Pa m^3 mol^{-1} at 12°C).

2.8.7.3 Outdoor use on ant nests on paved soil around domestic premises - Scenario 1

The application of the b.p. 'Ameisen-Mittel' around a domestic premise is assessed using the terrace scenario for bait boxes which was agreed at BPC-WG-V 2016. A private terrace was defined to have an area of 30 m^2 and a receiving soil compartment of 8.5 m^2×0.5 m. For this terrace the control of one ant nest is assumed to be realistic.

2.8.7.3.1 Release estimation

Table 70: Emission scenario for outdoor application of Ameisen-Mittel to ant nests on terraces

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: application on domestic terrace – non-professional user			
Application rate of biocidal product	10	g/nest	
Fraction of active substance in product	0.005		
Applied amount of a.s. permethrin	0.05	g/nest	
Number of application sites	1		
Number of applications	4	per year (max.)	according to information by applicant

Fraction emitted to soil	0.9		Scenario 1(s) (ref. to ESD No. 18 (2008) page 147)
Area exposed to a.s.	8.5	m^2	
Output			
Local direct emission rate of a.s. to soil	180	mg	

The application of the b.p. on ant nests around domestic premises results in a direct release of **180 mg** permethrin to soil without considering degradation processes in soil between the 4 applications (terrace scenario).

2.8.7.3.2 Estimation of Predicted Environmental Concentrations for the terrestrial compartment

Using the above indicated input parameters the predicted concentrations of permethrin for soil and groundwater were calculated:

Table 71: Summary of $PEClocal_{soil}$ and $PEClocal_{groundwater}$

	PEC_{soil}	PEC_{GW}
	[mg/kg]	[µg/L]
Scenario 1	0.0249	0.0202

2.8.7.4 Outdoor use on ant nests on paved soil around large (commercial) buildings - Scenario 2

The Emission Scenario Document does not specify the size of a terrace for a commercially used large building, thus the area around the larger building was derived from the set perimeter (250 m, ESD PT18, No.18 (2008) p.38) and a 0.5 m wide band, resulting in 125 m^2.

2.8.7.4.1 Release estimation

Estimation of release to sewage treatment plants

Table 72: Emission scenario for outdoor application of Ameisen-Mittel to ant nests on paved soil around larger buildings

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: spot application, commercial building, professional user			
Application rate of biocidal product	10	g/nest	
Fraction of active substance in product	0.005		
Applied amount of a.s. permethrin	0.05	g/nest	
Number of application sites	10		According to information by the applicant
Number of applications	4	per year	
Fraction released to environment (STP) during outdoor spot application	0.9		ref. to ESD No. 18 (2008) page 147
Number of large buildings connected to STP	300		ENV 87 (TAB, Dec. 2016)
Fsim = Simultaneity of treatment of buildings connected to the local STP	0.00815		4 times per year (ESD PT18, p.39)
Output			
Simultaneous emission to waste water:	1.10×10^{-3}	$kg\times d^{-1}$	

The application of the b.p. in a typical scenario around large commercial buildings results in a simultaneous release of **1.10×10^{-3} $kg\times d^{-1}$** permethrin to the STP. In Europe, estimates of potential exposures resulting from STPs are carried out according to the Guidance BPR Vol. IVB ENV (2015). According to this, the further receiving environmental compartments are surface water and sediment (after STP), soil and groundwater (from sludge application), and the outdoor air.

2.8.7.4.2 Estimation of Predicted Environmental Concentrations for the aquatic compartment (incl. sediment)

According to the intended use of 'Ameisen-Mittel' in scenario 2, indirect emission to surface water and sediment via output of the effluent from STP occurs. The predicted environmental concentrations for STP, surface water and sediment are estimated as follows:

PEC_{STP} (=$Clocal_{inf}$) and $Clocal_{eff}$ according to equation 32, 33 and 39, chapter 2.3.7.1, Guidance BPR Vol. IVB ENV (2015)
$PEClocal_{surfacewater}$ according to equation 48, chapter 2.3.8.3, Guidance BPR Vol. IVB ENV (2015)
$PEClocal_{sediment}$ according to equation 50, chapter 2.3.8.4, Guidance BPR Vol. IVB ENV (2015)

The results are summarised in Table 73.

Table 73: Summary of STP influent ($Clocal_{inf}$) and effluent ($Clocal_{eff}$), PEC_{STP}, $PEClocal_{surface\ water}$ and $PEClocal_{sediment}$

$Clocal_{inf}$ [µg×L^{-1}]	$Clocal_{eff}$ [µg×L^{-1}]	PEC_{STP} [µg×L^{-1}]	$PEClocal_{surface\ water}$ [µg×L^{-1}]	$PEClocal_{sediment}$ [mg×kg^{-1}]
5.501×10^{-1}	1.52×10^{-1}	5.501×10^{-1}	1.374×10^{-2}	2.09×10^{-2}

2.8.7.4.3 Estimation of Predicted Environmental Concentrations for the terrestrial compartment

The application of sludge from the STP onto agricultural and grassland soil provokes an indirect emission to soil, as well as the leaching of a.s. through soil following sludge application causes indirect emission to groundwater. The PEC_{soil} is estimated according to equation 66, chapter 2.3.8.5, Guidance BPR Vol. IV B ENV (2015). Additionally, the estimation of the local PECs for the terrestrial compartment includes also groundwater. The $PEC_{groundwater}$ is calculated according to equation 68, chapter 2.3.8.6, Guidance BPR Vol. IV B ENV (2015) as a first worst-case estimation. Table 85 indicates the PEC in soil and groundwater for permethrin according to the application scenario 2.

Table 74: Summary of C_{sludge}, $PEClocal_{soil}$ and $PEClocal_{groundwater}$ for indirect release to soil via sludge application

C_{Sludge} [µg×kg^{-1}]	$PEClocal_{soil}$ [mg×kg^{-1}]	$PEClocal_{Groudwater}$ [µg×L^{-1}]
1.008×10^{3}	1.48×10^{-3}	7.77×10^{-4}

2.8.7.4.4 Estimation of Predicted Environmental Concentrations for the atmosphere

In view of the limited volatility of permethrin (vapour pressure 2.16×10^{-6} Pa at 20°C, 25:75 cis:trans) emissions to air are expected to be not significant in relation to the intended use pattern. The annual average predicted environmental concentration in air was estimated to 5.732×10^{-11} mg×m^{-3}.

2.8.7.4.5 Estimation Predicted Environmental Concentrations for primary and secondary poisoning

Primary poisoning:

According to OECD ESD PT18, No. 18 (2008) primary poisoning, i.e. the direct consumption of insecticide by birds or mammals may mainly occur in 2 cases: either the insecticide is applied together with a food attractant, or the insecticide is applied as granular formulation. In case of 'Ameisen-Mittel' both conditions apply. Furthermore, as ESD PT18 makes reference to ESD PT14, the exposure can be assessed in a

similar way as for rodenticide baits. Thus, the approach described in ESD PT14 (EUBEES 2 (2003)) will be followed for estimation PECs for primary poisoning following the use of 'Ameisen-Mittel'.

The qualitative first tier assessment (short-term situation) assumes that non-target animals are directly exposed to the insecticide granules, without considering avoidance and assuming that the non-target animal obtains the diet exclusively in the treated area. The estimation of daily uptake (ETE) of permethrin by non-target animals is calculated according to equation 19 of ESD PT14. In the second tier assessment, the avoidance factor and the fraction of diet obtained in the treated area are set to 0.9 and 0.8, respectively. The summary of input values is presented in Table 86. The values for ETE in the selected non-target animals are shown in Table 87.

Table 75: Parameters used for estimation of daily uptake and of expected concentration in non-target animals

Determinants of the emission scenario	**Symbol**	**Value**		**S/D/O/P**
		Tier 1	**Tier 2**	
Fraction of active compound in fresh diet (insecticide granules)	C	5 g/kg		S
Avoidance factor (1 = no avoidance, 0 = complete avoidance)	AV	1	0.9	S/D
Fraction of diet obtained in treated area	PT	1	0.8	S/D
Fraction of food type in diet	PD	1	1	S/D

Table 76: Expected daily uptake (ETE), following ESD PT14

Species		**ETE** [$mg \times kg_{bw}^{-1}$]	
		Tier 1	**Tier 2**
Dog	*Canis familiaris*	**300**	**216**
Pig	*Sus scrofa*	37.5	27
Pig, young	*Sus scrofa*	120	86.4
Tree sparrow	*Passer montanus*	**1727**	**1244**
Chaffinch	*Fringilla coelebs*	1500	1080
Wood pigeon	*Columba palumbus*	541.8	390.1
Pheasant	*Phasianus colchicus*	538.8	387.9

The maximum values of expected permethrin concentration for short-term (poisoning) situation due to primary poisoning are calculated for dogs (mammals) and tree sparrow (birds) (cf. bold values in Table 88). It should be noted that the situation around a typical house or commercial building will be limited by

the amount of treated ant nests and for big mammals as recommended in ESD PT14 the required amount of the product will not be available for consumption by one animal.

As the mammalian species given in ESD PT14 are not appropriate indicator species for the treatment of ants around the house, the calculation was also performed for a small mammal (BW = 25 g; FIR = 5.7 g):

Table 77: Expected daily uptake (ETE), following ESD PT14

Species	**ETE** [mg×kg$_{bw}^{-1}$]	
	Tier 1	**Tier 2**
Small mammal (BW = 25 g)	**1140**	**820.8**

The ETE for such a small mammal will be significantly higher than for those species suggested in ESD PT14 and will be already covered by one treated ant nest. For slightly bigger mammals like hedgehogs, the ETE would in practice already be limited by the amount of treated ant nests around the building.

Secondary poisoning:

In the permethrin CAR (April 2014) the log Kow of permethrin was calculated as 4.67 (99 % technical a.s. 25:75) indicating it as a fat-soluble molecule with a potential to bioconcentrate following uptake via water/porewater (e.g. in fish/worms) leading to secondary poisoning.

Predatory birds and mammals are especially susceptible for indirect poisoning effects caused by the intake of already accumulated substances with their prey. Two different accumulation pathways have to be distinguished:

The bioaccumulation of permethrin via the aquatic food chain in fish and consequently in fish-eating birds or mammals: The concentration of permethrin in food (fish) of fish eating predators ($PEC_{oral,\ predator}$) is calculated according to eq. 80 in chapter 3.8.3.6 of BPR Vol. IV Part B ENV (2015) from the PEC in surface water, the bioconcentration factor BCF (570 L×kg^{-1}) for fish and the biomagnification factor (BMF = 1). The PEC in surface water (1.37×10^{-2} µg×L^{-1}) was taken from the PEC calculations for application scenario 2.

PEC_{oral} for fish eating predators = 3.904×10^{-3} mg·kg^{-1}

The bioaccumulation of permethrin via the terrestrial food chain in earthworms (BPR Vol. IV Part B ENV (2015)) and consequently in worm eating birds or mammals. Additional, the OECD ESD PT18 (2008) states that the risk of secondary poisoning is considered at the local scale and non-target animals (birds and mammals) 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 product 'Ameisen-Mittel' as well as the realistic emission path of the a.s. into the environment (here: soil compartment) the assessment of secondary poisoning via consumption of contaminated worms or insects is carried out (i.e. calculation of ETE for (1) and (3)). A risk for secondary poisoning by consumption of contaminated vegetation is only applicable for spray application of insecticides. The procedure for ETE calculation is described in chapter 5.2.3.4 of OECD ESD PT18 (2008). The estimated theoretical exposure (ETE) will be calculated for indicator species among mammals and birds, and ETE corresponds to the PEC_{oral} per day. The ETE resulting from application scenario 0 is used for the risk assessment as this scenario represents the worst case for risk of secondary poisoning by consumption of worms from contaminated soil. The relevant input parameters are presented in Table 89. The values taken from the pick lists of the ESD PT18 (2008; Table 5.2-5, 5.2-7) are not repeated here.

Table 78: Parameters used for estimation of daily uptake of a compound

Determinants of the emission scenario according to chapter 5.2.3.4, OECD ESD PT18 No. 18 (2008)	Symbol	Value	S/D/O/P
Application rate of a.s.	T_{appl}	1.8×10^{-4} kg×m^{-2}	S
Concentration of a.s. in fresh diet	$c_{earthworm}$	1.15×10^{-1} mg×kg^{-1}	S
Avoidance factor	AV	1	S/D
Fraction of diet obtained in treated area	PT	1	S/D
Fraction of food type in diet	PD	1	S/D

The values of the expected daily uptake ETE for assessment of secondary poisoning via consumption of contaminated worms and insects (acute and short term) for selected indicator species are shown in Table 90.

Table 79: Expected daily uptake (ETE) of permethrin for selected indicator species following application of Ameisen-Mittel in ant nests on unpaved soil

Species		ETE_{worm} [mg×(kg×d)$^{-1}$]	ETE_{insect} [mg×(kg×d)$^{-1}$]	
			Acute	Short term
Pipistrelle	*Pipistrellus pipistrellus*	-	**1.72×10^{-3}**	**6.28×10^{-4}**
Shrew	*Sorex araneus*	7.22×10^{-2}	1.59×10^{-3}	5.78×10^{-4}
Mole	*Talpa europaea*	**8.25×10^{-2}**	-	-
Hedgehog	*Erinaceus europaeus*	3.90×10^{-2}	3.94×10^{-4}	1.44×10^{-4}

Species		ETE_{worm} [mg×(kg×d)$^{-1}$]	ETE_{insect} [mg×(kg×d)$^{-1}$]	
			Acute	Short term
Badger	*Meles meles*	2.03×10^{-2}	2.05×10^{-4}	7.47×10^{-5}
Tree sparrow	*Passer domesticus*	-	**7.66×10^{-3}**	**4.27×10^{-3}**
Blackbird	*Turdus merula*	8.83×10^{-2}	1.94×10^{-3}	7.08×10^{-4}
Black-billed Magpie	*Pica pica*	**1.02×10^{-1}**	1.03×10^{-3}	3.77×10^{-4}

The maximum values of expected daily uptake of permethrin via contaminated worms are calculated for moles (mammals) and black-billed magpie (birds). The maximum values of expected daily uptake of permethrin via contaminated insects are calculated for pipistrelle (mammals) and tree sparrow (birds) for acute and for short-term (poisoning) situations (cf. Table 90). Bold values (ETE_{worm} and ETE_{insect}) are used as PEC_{oral} for the first tier risk characterisation of secondary poisoning for birds and mammals, respectively.

2.8.7.5 Predicted environmental concentrations for the metabolites for permethrin

Major relevant metabolites of permethrin in soil and water/sediments are 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA), and 3-phenoxybenzyl alcohol to 3-phenoxybenzoic acid (PBA).

Predicted environmental soil metabolite concentrations can be calculated by multiplying the PECsoil of the parent by a correction factor for the molecular weight and considering the highest percentage of metabolite occurrence (from soil degradation studies).

From those PEC_{soil} of the metabolites, the PEC_{gw} for the expected groundwater concentrations were calculated according to the Guidance BPR Vol. IV Env Part B (eq. 67) using $K_{soil\text{-}water}$ coefficients calculated for each metabolite.

Table 80: Parameters for calculation of PEC metabolites

	DCVA	PBA
Molecular weight [g/mol]	209.07	214.22
Molecular correction factor	0.534	0.548
Max. occurrence in soil degradation studies	11.3 %	15.0 %
$K_{soil\text{-}water}$ (m^3/m^3)	1.17	3.75

2.8.7.6 Calculated PEC values

Table 81: Summary table on calculated PEC_{soil} values for PERMETHRIN

	PEC_{soil}
	[mg/kg]
Scenario 0	0.2120
Scenario 1	0.0249
Scenario 2	0.00148

Table 82: Summary table on calculated PEC values for DCVA

	PEC_{soil}	PEC_{GW}
	[mg/kg]	[µg/L]
Scenario 0	1.28×10^{-2}	1.86×10^{1}
Scenario 1	1.502×10^{-3}	2.18×10^{0}
Scenario 2	8.94×10^{-5}	1.30×10^{-1}

Table 83: Summary table on calculated PEC values for PBA

	PEC_{soil}	PEC_{GW}
	[mg/kg]	[µg/L]
Scenario 0	1.74×10^{-2}	7.90×10^{0}
Scenario 1	2.05×10^{-3}	9.28×10^{-1}
Scenario 2	1.22×10^{-4}	5.53×10^{-2}

The estimated PEC for groundwater for both metabolites is above the ground water trigger value of 0.1 µg/L in several scenarios, except for PBA in scenario 2. In order to present a safe use for the groundwater compartment for all scenarios additional modelling with FOCUS PEARL (Version 4.4.4) were performed, details see in Chapter 4.3. The use of FOCUS PEARL models for refinement of PEC groundwater resulted in PECs for the metabolites below the trigger value of 0.1 µg/L for all locations.

2.8.7.7 Aggregated exposure (combined for relevant emission sources)

Biocidal active substances (a.s.) are used in various applications and are often contained in many different products. The environmental exposure assessment of single uses may therefore underestimate the actual concentrations of a.s. to be found in the environment.

According to the “Decision tree on the need for estimation of aggregated exposure” (Figure 1), it is checked if aggregated exposure estimations are required for permethrin which is the active substance in the b.p. ‘Ameisen-Mittel’.

The present exposure and risk assessment does not consider the whole amount of permethrin which the environment could be exposed to due to the use of different insecticidal applications and biocidal products containing permethrin. Furthermore, transformation of permethrin in the environment leads to the major metabolites DCVA (3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate and PBA (3-phenoxybenzyl alcohol to 3-phenoxybenzoic acid) which are common transformation products of several active substances of the group of pyrethroids. As pyrethroids are common insecticides, therefore, future risk assessments of permethrin containing b.p. should take the possible aggregated exposure not only of the parent but also of the transformation products into account.

For the assessed b.p. ‘Ameisen-Mittel’ as described in all authorised uses, due to the application method directly into the ant nest entrances and only on the defined local spot of the ant nest, an overlap in time and space seems not likely. Thus for those scenarios no aggregated exposure estimation is required for the b.p. ‘Ameisen-Mittel’.

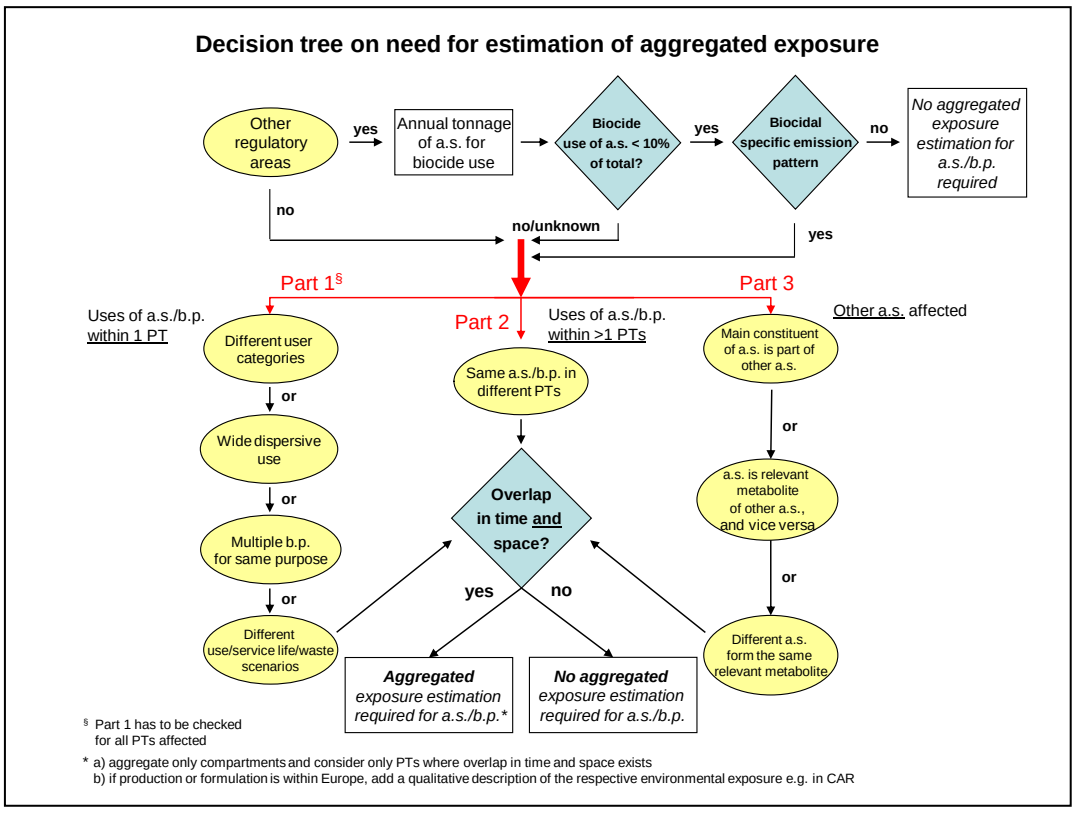

Figure 1: Decision tree on the need for estimation of aggregated exposure

Conclusion

The present exposure and risk assessment does not consider the whole amount of permethrin which the environment could be exposed to due to the use of different biocidal products containing permethrin or

other pyrethroids, which form the same major metabolites. Therefore, future risk assessments of pyrethroid-containing biocidal products should take the possible aggregated exposure into account.
However, if the b.p. 'Ameisen-Mittel' is to be applied around the house only sheltered from rain, so that b.p. granules run-off into the sewer system is prevented, no overlap of emissions in space would occur for 'Ameisen-Mittel' with other permethrin-containing b.p. and no aggregated exposure estimation would be required.

2.8.8 Risk characterisation

For the risk characterisation, the active substance permethrin and the transformation products DCVA and PBA have been considered. A risk assessment has been performed for water, soil, groundwater, primary and secondary poisoning, based on the intended use of the product 'Ameisen-Mittel'.

2.8.8.1 Aquatic compartment (sediment and STP)

Application directly on unpaved soil – non-professional use and professional use (scenario 0):
An application on unpaved soil would not lead to emissions to the aquatic compartment.
Conclusion: Due to a lack of exposure, no unacceptable risk for the aquatic environment is expected.

Application on paved ground (e.g. terraces) – non-professional use (scenario 1) and professional use (scenario 2):
An emission to the aquatic compartment is possible only indirectly via STP. As this is most likely around large commercial buildings, only the application on paved soil by professionals (scenario 2) has been considered as relevant.

Table 84: Risk characterisation for the aquatic compartment for indirect emissions (*via* the STP) following application on unpaved and paved soil

Calculated PEC/PNEC values			
	PEC/PNEC$_{STP}$	**PEC/PNEC$_{surface\ water}$**	**PEC/PNEC$_{sediment}$**
Permethrin			
Scenario 0: unpaved soil	no emission expected	no emission expected	no emission expected
Scenario 1: paved soil – non-professionals	no emission expected	no emission expected	no emission expected
Scenario 2: Paved soil – professionals	0.111	**29.2**	**20.9**

The PEC/PNEC ratios for surface water and sediment are exceeding the trigger value of 1, indicating an unacceptable risk for the aquatic environment for indirect emissions via STP. Therefore any release to the STP has to be excluded.

The applicant has therefore specified that the application of 'Ameisen-Mittel' in areas that are exposed to rainfall or wet cleaning with subsequent wash-off to the STP is not permitted. In addition, the instructions for use should state that the rinsing water from cleaning should not be disposed into the sewage. Furthermore, the b.p. shall only be applied in areas where it is protected from floods that might lead to run-off to sewer systems and STP.

Conclusion: Due to a lack of exposure, no unacceptable risk for the aquatic environment is expected.

2.8.8.2 Terrestrial compartment (Soil/Groundwater)

Three scenarios are considered for the terrestrial compartment. The results of the environmental risk assessment for soil and groundwater are presented in the following table.

Table 85: Risk characterisation for the terrestrial compartment

Calculated PEC/PNEC values and groundwater assessment			
	$PEC/PNEC_{soil}$	**PEC_{GW} [µg/L]**	**refined PEC_{GW} [µg/L]**
Permethrin			
Scenario 0: unpaved soil	**2.42**	**0.172**	< 0.1
Scenario 1: paved soil – non-professionals	0.28	0.02	< 0.1
Scenario 2: Paved soil – professionals	0.017	0.00078	< 0.1
DCVA			
Scenario 0: unpaved soil	0.0028	**18.6**	< 0.1
Scenario 1: paved soil – non-professionals	0.00033	**2.2**	< 0.1
Scenario 2: Paved soil – professionals	1.9×10^{-5}	**0.13**	< 0.1
PBA			
Scenario 0: unpaved soil	0.012	**7.9**	< 0.1
Scenario 1: paved soil – non-professionals	0.0014	**0.93**	< 0.1
Scenario 2: Paved soil – professionals	8.3×10^{-5}	0.055	< 0.1

Application directly on unpaved soil – non-professional use and professional use (scenario 0):

The direct application of the b.p. on unpaved soil is the worst case scenario for the terrestrial compartment, because regardless of the application method (granules or diluted) or user category 10 g b.p. per nest are

applied. Both application methods result in the same PEC value and therefore pose an identical risk to the environment. The PEC/PNEC ratio for soil exceeds 1, showing that already the treatment of one nest with one application per year leads an unacceptable risk for soil. However, as a dose of 10 g b.p./application and nest are necessary in order to ensure efficacy, there are no risk management options available that can reduce the risk to an acceptable level.

Conclusion: The intended application of the b.p. on unpaved soil cannot be authorised due to an unacceptable risk for soil that cannot be mitigated by other management options.

Application on paved ground (e.g. terraces) – non-professional use (scenario 1) and professional use (scenario 2):

When the b.p. is used on paved ground like e.g. terraces there is no unacceptable environmental risk for the active substance permethrin, neither for the non-professional user nor for the professional users. However, an unacceptable groundwater risk was identified for the transformation products DCVA and PBA. Therefore, a groundwater risk refinement was calculated.

Groundwater refinement – non-professional and professional uses (scenario 0, 1 and 2):

For the active substance permethrin the intended use according to scenario 0 will exceed the maximum permissible concentration of 0.1 µg/L as laid down by Directive 98/83/EC. Furthermore, the relevant transformation products DCVA and PBA will exceed the maximum permissible concentration for scenarios 0 and 1, and for DCVA also for scenario 2. To demonstrate that under relevant field conditions the trigger concentration set by directive 98/8/EC will not be exceeded, calculations based on FOCUS PEARL models were applied (see Chapter 4.3) for all scenarios. The use of FOCUS PEARL for refinement of PEC groundwater resulted in PECs for permethrin and PBA which were < 0.001 µg/L for all scenarios and for DCVA in PEC_{gw} < 0.1 µ/L for all scenarios.

Conclusion: The application of the b.p. ‘Ameisen-Mittel’ can be authorised for the use on paved ground like e.g. terraces (scenario 1 and 2).

Note from RefMS (2017-07-31): New effect data for soil for the active substance permethrin in PT8 and 11 have been submitted to the RMS IE. An e-consultation on the new data has been initiated by IE in the end of 2016, however no agreement on the use of the new data has been made until now, therefore the new folsomia study was not used for the risk assessment of 'Ameisen-Mittel'. Based on our evaluation, the new data would not change the lowest NOEC for derivation of $PNEC_{soil}$, but could lower the AF from 100 to 50. This would not significantly change the outcome of the soil risk assessment: based on a changed AF the risk ratio would still exceed 1 for scenario 0.

2.8.8.3 Atmosphere

Exposure of the air compartment is not be expected, due to the low volatility of the active substance.

2.8.8.4 Non-compartment specific

- **Primary poisoning**

Direct exposure of birds and small mammals could be relevant in case of a granular application of the b.p. (solid granules, 98 % are ≤ 0.5 mm), considering the product is applied in accordance with its authorised use on paved soil only. If the solved product is poured on ant nests, no significant amounts of the product will remain sufficiently long on the paved soil surface and significant uptake by birds or mammals can be excluded. Therefore an initial assessment of primary poisoning of birds and small mammals with regard to the granular product is required. The following qualitative risk assessment is in principle based on the concept and default values from ESD PT14 (EUBEES, 2003, and CA-Nov06-Doc.4.3, 2006).

According to the intended use, 10 g of the b.p. “Ameisen-Mittel” will be applied on one ant nest around houses or commercial buildings. Based on an a.s. content of 0.5 %, this corresponds to 50 mg permethrin/nest. It cannot be excluded that more than one ant nest will be treated at the same time.

Birds:

For a first tier, qualitative acute risk assessment for birds, the calculated daily intake of 1727 mg a.s./kg bw/d estimated for tree sparrow is directly compared with the acute LD_{50} of > 4640 mg/kg bw, assuming a relevant time frame of 1 day. The resulting PEC does not exceed the LD_{50}, indicating that a risk for primary poisoning of birds can be excluded. In addition, due to a size of the granules of < 500 µm it is not likely that birds will consider the granules as feed or grid.

An acute effect can therefore be excluded and an acceptable risk for primary poisoning of birds was demonstrated.

Mammals

The b.p. mainly consists of sugar and could therefore attract small mammals. The bittering agent present in the b.p. is not considered to have a repellent effect to small mammals.

For an initial first tier assessment, it is assumed that a mammal meets its daily feed intake by consumption of granules only. As the recommended mammalian species from ESD PT14 cannot be considered as worst case for the treatment of ants at a small scale, the assessment was performed instead for a small

mammal of 25 g body weight and a Food Intake Rate (FIR) of 5.7 g feed/mammal/d (or 230 g feed/kg bw/d) resulting in a ETE of 1140 mg a.s./kg bw.

For a first tier, qualitative acute risk assessment for mammals, the calculated daily intake of 1140 mg a.s./kg bw is directly compared with the acute LD_{50} of 480 mg/kg bw, assuming a relevant time frame of 1 day. The resulting PEC exceeds the LD_{50}, indicating that a risk for primary poisoning of mammals cannot be excluded. The LD_{50} is already reached if a small mammal will consume 2.4 g of the b.p., which corresponds to 24 % of the amount for the treatment of one ant nest.

According to ESD PT14 a second tier assessment can be performed with slightly refined values for AV, PT and PD. This results in a refined ETE of 820.8 mg a.s./kg bw, still exceeding the LD_{50}. The risk for mammals exceeding 104 g bw would be acceptable, as the treatment of ant nests will only occur as a spot treatment, limiting the total amount available for one individual.

Unlike for birds, for mammals there is no readily available data regarding the attractiveness of granules based on their size. However, with regard to the very small size of the granules (< 500 µm), it may be considered that although the sugar base could be attractive to e.g. mice, they may find handling the small granules difficult, reducing attractiveness and exposure. In addition to this, the granules have a tendency to soften and become adherent once they contact moisture following application. Consequently, the b.p. will tend to adhere to the treated surface, making the granules even less available for ingestion. Therefore, the assumption, that a small mammal meets its daily feed intake by consumption of granules only, is rather unrealistic.

It has to be considered that the tier 2 refinement for the primary poisoning scenario is developed for PT14 products that are mainly based on cereals and can only be transferred in parts to sugar based baits in PT18. As opposed to PT14, no elimination factor was considered for the refined risk assessment in tier 2.

The granular b.p. represents a bait formulation, which will be applied directly on the ant nest entrances. It is therefore expected that ants will quickly begin to carry the product into the nest, hence making the collected product inaccessible to mammals. Although considered as relevant, this reduction will depend on the size of the ant colony and probably also on environmental conditions (e.g. climatic conditions and time of day during application) and therefore cannot be considered for the assessment of primary poisoning.

Considering the limitation of the assessment as presented above, it can be assumed that the risk will be lower in reality.

Conclusion for primary poisoning

An unacceptable risk for single small mammals could not be excluded in tier 1 and 2 of the qualitative risk assessment. However, based on the composition and size of the granules, the lack of elimination processes considered and that ants will collect the baits from the nest entrance, it can be assumed the risk for primary poisoning can be considered acceptable even at the level of single species, especially with regard to populations.

- **Secondary poisoning**

The K_{ow} and calculated BCF values indicate a potential of secondary poisoning for birds and small mammals. The main routes of secondary poisoning for birds and mammals are the consumption of food items containing residues such as insects that may have eaten the bait, fish that may have been exposed to residues in surface water, and earthworms that may have been exposed to residues in soil. As application scenario 0 represents the worst case with regard to secondary poisoning, only this scenario was considered in detail below. Worst-case (acute) ETE_{worm} and ETE_{insect} for birds and small mammals are used as PEC_{oral} for first tier risk characterisation.

Birds: The risk to birds was calculated as the ratio between the concentration in their food ($PEC_{oral, predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral, predator\ bird}$). Based on a **$PNEC_{oral, bird}$ of 16.7 mg a.s./kg food** the risk for secondary poisoning for birds was calculated.

Mammals: The risk to mammals was calculated as the ratio between the concentration in their food ($PEC_{oral, predator}$) and the no-effect-concentration for oral intake ($PNEC_{oral}$). Based on a **$PNEC_{oral, mammal}$ of 120 mg/kg food** the risk for secondary poisoning for small mammals was calculated.

Table 86

Scenario	Species	$PEC_{oral\ predator}$	PEC/ PNEC
0	insectivorous birds (Tree sparrow)	7.66×10^{-3} mg/kg/d	4.59×10^{-4}
0	insectivorous mammals (Pipistrelle)	1.72×10^{-3} mg/kg/d	1.43×10^{-5}
0	earthworm-eating birds (Black-billed Magpie)	1.02×10^{-1} mg/kg/d	6.11×10^{-3}
0	earthworm-eating mammals (Mole)	8.25×10^{-2} mg/kg/d	6.88×10^{-4}
0	fish-eating birds	3.90×10^{-3} mg/kg	2.34×10^{-4}
0	fish-eating mammals	3.90×10^{-3} mg/kg	3.25×10^{-5}

Insectivorous birds and mammals: The ETE for indicator species of birds and mammals was calculated to be **7.47×10^{-5} – 7.66×10^{-3} mg/kg/d**, which is below the PNEC for both birds and mammals. Therefore the risk to birds and mammals from the consumption of insects is considered acceptable.

Earthworm-eating birds and mammals: The ETE for indicator species of birds and mammals was calculated to be **2.03×10^{-2} – 0.102 mg/kg/d**, which is below the PNEC for both birds and mammals. Therefore the risk to birds and mammals from the consumption of earthworm is considered acceptable.

Fish-eating birds and mammals: The PEC_{oral} for fish-eating predators was calculated according to BPR Vol. IV Part B as **3.90×10^{-3} mg/kg**, which is below the PNEC for both birds and mammals. Therefore the risk to birds and mammals from the consumption of fish is considered acceptable.

In conclusion, the intended use of the b.p. ‘Ameisen-Mittel does not indicate an unacceptable risk for primary or secondary poisoning.

2.8.8.5 PBT assessment

P criterion

Permethrin as the isomeric mixture 25:75 cis:trans is not persistent in aquatic systems, on the basis that its whole system DT50 (12 ºC) values do not fulfil the P criterion for sediment. However, a constituent of permethrin (the cis isomer) may have the potential to be persistent. For further detailed information please refer to Permethrin CAR 2014, PT8/PT18; Rapporteur: Ireland; April 2014.
Permethrin (25:75) **is not considered to fulfil the P or vP criteria**.

B criterion

Permethrin does **not fulfil the B** criterion. BCF_{fish} and $BCF_{chironomid}$ values are < 2000. For further detailed information please refer to permethrin CAR 2014 for PT8/PT18; Rapporteur: Ireland.

T criterion

Permethrin **meets the criteria for T**. The measured NOEC values aquatic organisms are all lower than the specified T criterion trigger value of 0.01 mg/L.

Conclusion

Permethrin does not fulfil P, vP, not B, however it fulfils the T criterion. Furthermore the biocidal product ‘Ameisen-Mittel’ does not contain co-formulants which fulfil PBT criteria.

2.8.8.6 Endocrine disrupting properties

Active substance: Permethrin is currently not considered classified as an identified ED substance to have endocrine disrupting properties under Regulation (EU) 528/2012 in wildlife. and has not been assessed according to the new ED criteria . With reference to current guidance for application of these criteria the evaluating body should not evaluate endocrine disrupting properties nor request additional data in the context of product authorisation procedures. It is therefore concluded that the active substance does not possess endocrine disruptive properties which should be taken into account for the authorisation of 'Ameisen-Mittel'. For further details, please refer to CAR from 2014.

Non-active substances: Based on existing knowledge and the available scientific information from the submitted SDSs for the non-active substances there are no indications of endocrine disruption for any of the co-formulants. Furthermore, there are no indications of the need to evaluate any of the co-formulants regarding ED properties in detail the biocidal product 'Ameisen-Mittel' does not contain any substance known to exhibit endocrine disrupting properties.

Conclusion: With regard to the environment the biocidal product 'Ameisen-Mittel' is not considered as having endocrine disrupting properties according to current guidance.

2.8.8.7 Summary of risk characterisation

The biocidal product 'Ameisen-Mittel' with the active substance permethrin contains no substance of concern for the environment. Therefore, the environmental risk assessment for the product is based on the active substance permethrin.

Application of 'Ameisen-Mittel' on paved areas would imply the potential exposure of the connected sewage treatment plant (STP) after rain events and wash-off of the product, which could result in unacceptable risks for the aquatic compartment. During assessment of the b.p., the applicant has therefore restricted the intended use to areas that are not exposed to rainfall or wet cleaning with a subsequent wash-off to the STP. In addition, the rinse water from the cleaning of the watering can should not be disposed into the sewage. Therefore emissions to STP are considered negligible.

The use of 'Ameisen-Mittel' on unpaved soil would result in unacceptable local risks for soil based on PEC/PNEC for the a.s. permethrin (scenario 0). The use of the b.p. by non-professional and professional users on paved soil will not result in unacceptable risks for soil (scenario 1 and 2). For the a.s. and relevant transformation products DCVA and PBA, refinement based on FOCUS PEARL models demonstrated that none of these substance would exceed the trigger values for groundwater according to directive 98/8/EC.

The b.p. does not contain substances of concern with regard to the environment, no BPT or ED substances.

Based on the assessment presented above, the following risk mitigation measures are required to ensure acceptable risks for the environment:

- N-121: “Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.”
- N-143: “Do not use where release to drains (sewer) and/or surface water cannot be prevented.”
- “Direct application to unpaved soil is not permitted.” (based on N-166)

Furthermore, the instructions for use have to describe the intended use accordingly:

- “Apply only around houses on paved ways, balconies and terraces.”
- N-29: “Apply only outdoors in locations protected from rain.” (general)
- N-120: “After the outdoor watering application, rinse the watering can several times with a little water. Apply the rinse water on the ant nest.”

The risk mitigation measures and use instructions are based on the recently published list of harmonised phrases “Frequently used sentences in the SPC and translations” (https://echa.europa.eu/documents/10162/13566/frequently_used_sentences_spc_translations.xlsx/d217b817-ddcd-1f95-286d-ffa648ceb3f9).

The product is formulated as ‘granule’ (including ‘soluble granule’). It can be assumed that professional users are able to ensure proper dosing of the product. However, for non-professional users it shall be required that appropriate dosing equipment will be attached to the product and that ‘ready-to-use’ packages (e.g. single-dose sachets, water soluble bags) are limited to an amount of the product for the treatment of one ant nest:

- Pack sizes exceeding 10 g have to contain appropriate 10 g dosing equipment (e.g. measuring spoon) and both single-dose sachets and water soluble bags are limited to a size of 10 g.

Therefore it can be concluded that the intended use of ‘Ameisen-Mittel’ up to 4 times per year, in conjunction with these risk mitigation measures and conditions concerning packaging will result in acceptable risks for the environment.

2.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

2.10 Comparative assessment

No candidate for substitution was identified (see chapter 2.2.4), hence a comparative assessment is not necessary.

3 Annexes

3.1 List of studies for the biocidal product

Table 87

Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
3.1. 3.2 3.3 3.4.1.1	Ameisenmittel 2015: Accelerated Storage Stability	Fieseler, A	2016a	
3.4.1.2	Ameisenmittel 2015: Storage Stability at 20°C	Fieseler, A	2015a-g	
3.5.1 3.5.2 3.5.3 3.5.6 3.5.7 3.5.8	Ameisenmittel 2015: Accelerated Storage Stability	Fieseler, A	2016a	
3.4.1.2	Ameisenmittel 2015 (in sacks): Storage Stability at 20 °C Final Interim Report	Fieseler, A	2017	
4.1	Ameisenmittel Batch No.: 20150423/540011 Explosive properties A.14	Krack, M	2015a	
4.7	Ameisenmittel Batch No.: 20150423/540011 Flammability (Solids) A.10	Krack, M	2015b	
4.14	Oxidising properties (A.17) of Ameisenmittel 2015 Statement	Rudolf, M.and Lorenzen, V.	2015	
4.17.2	Ameisenmittel Batch No.: 20150423/540011 Auto-flammability (Solids-Determination of Relative Self-Ignition Temperature) A.16	Krack,M	2015c	
5.1	Ameisenmittel 2015: Development and Validation of the Analytical Method for the Determination of Permethrin	Fieseler A	2016b	
6.7	FELDSTUDIE ZUR WIRKSAMKEIT DES AMEISENSTREU- UND GIESSMITTELS (0,5 % Permethrin): ; Efficacy of an ant product against Black garden ants, Lasius niger; Efficacy of an ant product against Black garden ants, Lasius niger	Heller, G. (2015); Luepkes, K.-H. (2015a); Luepkes, K.-H. (2015b)	2015	

3.2 List of studies for the active substance(s)

3.2.1 Permethrin

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).

3.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[15]) of the active substance Permethrin for use in insecticides (product-type 18). Please, refer to the corresponding Assessment Report for a reference list.

15 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

3.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

3.3.1 Safety for professional users

Overview of professional exposure:

Overview

Scenario 1 - scattering granules:

Scenario 1 - scattering granules

Scenario 2 – pouring with watering can:

Scenario 2 - pouring with watering can

Output tables from environmental exposure assessment tools

3.3.2 Modelling the PEC groundwater for scenario 0 (non-professional and professional use on unpaved soil) as well as for scenario 1 (non-professional use on paved soil (terraces))

Scenario 0 describes the outdoor spot treatment on unpaved soil and is thus applicable for domestic as well as for commercial buildings. Thus the application rate for the modelling with FOCUS PEARL 4.4.4 was derived assuming maximum 10 nests (number of spots used by the applicant for modelling) per large building and three large buildings (area of a large building according to the ESD PT18, p 37 is defined as 3280 m^2) per hectare. This is worst case in comparison to application for domestic buildings as the application rate of a.s. is estimated to be 0.0009 kg/ha (application of 'Ameisen-Mittel' to one nest; 20 domestic premises per hectare). Concerning the application timing, ants will most probably occur during spring and summer months. Thus four applications between May and August were considered. The transformation scheme for permethrin in soil considered 100 % transformation to PBA and DCVA in accordance with the decisions of the AHEE-meeting 2016.

Table 88

Input parameters for modelling with FOCUS PEARL			
Input	**Value**	**Unit**	**Remarks**
Application rate of a.s. permethrin	4 times 0.0014	kg/ha	Scenario 0
Number of applications	4		May-August
Crop	Alfalfa		grass
FOCUS PEARL Parameters	**Permethrin**	**DCVA**	**PBA**
Molecular weight [g/mol]	391.29	209.07	214.22

Water solubility [mg/L]	0.18 (20°C)	127.6 (25°C)	16.91 (25°C)
Vapour pressure [Pa]	2.16E-06 (20°C)	0.26 (°25)	0.000421 (°25)
Transformation			
half life DT_{50} [d]	106 (12°C)	175 (12°C)	2.5 (12°C)
plant uptake factor	0	0	0
Interception by plants	No	No	no
Koc [mL/g]	70003	32.3	118.3
Kom=Koc/1.724	40604.99	18.74	68.62
Freundlich exponent	1.09	0.80	0.65

The resulting concentrations for permethrin and its metabolites DCVA and PBA (80th percentile at 1 m soil depth) following the application of Ameisen-Mittel in scenario 0 and 1 are all below the groundwater trigger value of < 0.1 µg/L (Council Directives 2006/118/EC and 98/83/EC) for all EU locations.

Table 89: Predicted 80th percentile concentration for permethrin, DCVA and PBA in the percolate at 1 m soil depth calculated for a period of 20 annual applications for application of Ameisen-Mittel in scenario 0 and 1

RUN_ID	RESULT_TEXT	SUBSTANCE	PERME	DCVA	PBA	LOCATION	APPLICATION_SCHEME	CROP_CALENDAR	SOIL_TYPE	METEO_STATION	IRI
193	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.018833	0.000000	CHATEAUDUN	ants_around_domestic_premises	CHAT-GRASS	CHAT-S_Soil	CHAT-M	
194	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.032824	0.000000	HAMBURG	ants_around_domestic_premises	HAMB-GRASS	HAMB-S_Soil	HAMB-M	
195	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.012144	0.000000	JOKIOINEN	ants_around_domestic_premises	JOKI-GRASS	JOKI-S_Soil	JOKI-M	
196	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.018201	0.000000	KREMSMUENSTER	ants_around_domestic_premises	KREM-GRASS	KREM-S_Soil	KREM-M	
197	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.028298	0.000000	OKEHAMPTON	ants_around_domestic_premises	OKEH-GRASS	OKEH-S_Soil	OKEH-M	
198	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.030826	0.000000	PIACENZA	ants_around_domestic_premises	PIAC-GRASS	PIAC-S_Soil	PIAC-M	
199	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.019316	0.000000	PORTO	ants_around_domestic_premises	PORT-GRASS	PORT-S_Soil	PORT-M	
200	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.005852	0.000000	SEVILLA	ants_around_domestic_premises	SEVI-GRASS	SEVI-S_Soil	SEVI-M	
201	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.014837	0.000000	THIVA	ants_around_domestic_premises	THIV-GRASS	THIV-S_Soil	THIV-M	

3.3.3 Modelling the PEC groundwater for scenario 2 (professional use on paved soil)

The simulation model FOCUS PEARL 4.4.4 is also used for the refinement of the environmental exposure assessment of permethrin and of the metabolites DCVA and PBA in the groundwater in case of application scenario 2. For the calculation of PEClocalgroundwater following the application scheme is used: Sewage Sludge Application on soil. In case of running sewage sludge application scenarios in FOCUS groundwater models it was agreed at WG-II-2014 that both grassland (alfalfa) and agricultural land (maize) should be used. In case of grassland application the scenario considers one sewage sludge application per year on 1st of March (absolute application) and 10 cm incorporation depth. In case of agricultural land application the scenario considers one sewage sludge application per year to maize 20 days before crop event “emergence” (relative application) and 20 cm incorporation depth. The application rate of the active substance was calculated to 1.008×10^{-3} kg/ha and 5.04×10^{-3} kg/ha for grassland and arable land, respectively.

Table 90: Predicted 80th percentile concentration for permethrin, DCVA and PBA in the percolate at 1 m soil depth calculated for a period of 20 annual applications for application of Ameisen-Mittel in scenario 2 for grassland

RUN_ID	RESULT_TEXT	SUBSTANCE	PERME	DCVA	PBA	LOCATION	APPLICATION_SCHEME	CROP_CALENDAR	SOIL_TYPE	METEO_STATION	IRRIG
202	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.000745	0.000000	CHATEAUDUN	application_STP_sludge_grassland_soil	CHAT-GRASS	CHAT-S_Soil	CHAT-M	
203	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.001896	0.000000	HAMBURG	application_STP_sludge_grassland_soil	HAMB-GRASS	HAMB-S_Soil	HAMB-M	
204	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.000466	0.000000	JOKIOINEN	application_STP_sludge_grassland_soil	JOKI-GRASS	JOKI-S_Soil	JOKI-M	
205	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.001180	0.000000	KREMSMUENSTER	application_STP_sludge_grassland_soil	KREM-GRASS	KREM-S_Soil	KREM-M	
206	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.001675	0.000000	OKEHAMPTON	application_STP_sludge_grassland_soil	OKEH-GRASS	OKEH-S_Soil	OKEH-M	
207	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.001938	0.000000	PIACENZA	application_STP_sludge_grassland_soil	PIAC-GRASS	PIAC-S_Soil	PIAC-M	
208	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.000827	0.000000	PORTO	application_STP_sludge_grassland_soil	PORT-GRASS	PORT-S_Soil	PORT-M	
209	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.000058	0.000000	SEVILLA	application_STP_sludge_grassland_soil	SEVI-GRASS	SEVI-S_Soil	SEVI-M	
210	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.000503	0.000000	THIVA	application_STP_sludge_grassland_soil	THIV-GRASS	THIV-S_Soil	THIV-M	

Table 91: Predicted 80th percentile concentration for permethrin, DCVA and PBA in the percolate at 1 m soil depth calculated for a period of 20 annual applications for application of Ameisen-Mittel in scenario 2 for agricultural soil

RUN_ID	RESULT_TEXT	SUBSTANCE	PERME	DCVA	PBA	LOCATION	APPLICATION_SCHEME	CROP_CALENDAR	SOIL_TYPE	METEO_STATION	IRRI
211	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.028362	0.000000	CHATEAUDUN	application_STP_sludge_arable_land	CHAT-MAIZE	CHAT-S_Soil	CHAT-M	
212	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.049186	0.000000	HAMBURG	application_STP_sludge_arable_land	HAMB-MAIZE	HAMB-S_Soil	HAMB-M	
213	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.036871	0.000000	KREMSMUENSTER	application_STP_sludge_arable_land	KREM-MAIZE	KREM-S_Soil	KREM-M	
214	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.049524	0.000000	OKEHAMPTON	application_STP_sludge_arable_land	OKEH-MAIZE	OKEH-S_Soil	OKEH-M	
215	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.039479	0.000000	PIACENZA	application_STP_sludge_arable_land	PIAC-MAIZE	PIAC-S_Soil	PIAC-M	
216	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.016853	0.000000	PORTO	application_STP_sludge_arable_land	PORT-MAIZE	PORT-S_Soil	PORT-M	
217	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.000696	0.000000	SEVILLA	application_STP_sludge_arable_land	SEVI-MAIZE	SEVI-S_Soil	SEVI-M	
218	Concentration closest to the 80th percentile (ug/L)	Perme	0.000000	0.017787	0.000000	THIVA	application_STP_sludge_arable_land	THIV-MAIZE	THIV-S_Soil	THIV-M	

The resulting concentrations for permethrin and its metabolites DCVA and PBA (80th percentile at 1 m soil depth) following the application of ‘Ameisen-Mittel’ in scenario 2 are all below the groundwater trigger value of < 0.1 µg/L (Council Directives 2006/118/EC and 98/83/EC) for all EU locations.