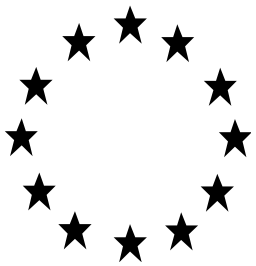
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Ameisenköder N

Product type 18

Active substance: Spinosad

Case Number in R4BP: BC-JY063227-08

Evaluating Competent Authority: Austria

Date: **04/01/2024 (Final)**

PUBLIC

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1 CONCLUSION

Austria was the Competent Authority responsible for evaluation of the biocidal product Ameisenköder N. The dossier submission date 09/12/2020 is to be taken into account for relevance of (new) guidance.

The ready-to-use product Ameisenköder N is a liquid, water-based formulation which contains 0.089%(w/w) of the active substance spinosad. 1,2-Benzisothiazol-3(2H)-one was identified as substance of concern and is present in a concentration of 0.002%(w/w).

The assessment considered:

- The conclusions and recommendations of the Assessment Report for the approval of the active substance spinosad including the "elements to be taken into account by Member States when authorising products"
- The specific provisions from Inclusion Directive for the active substance spinosad (Reg.2010/72/EU)

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

- When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the EU level risk assessment. Member States shall ensure that authorisations are subject to the following conditions:
  — Authorisations shall be subject to appropriate risk mitigation measures. In particular, products authorised for professional use by spraying shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by others means.
  — For products containing spinosad that may lead to residues in food or feed, Member States shall verify the need to set new and/or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 and/or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.'

The field of use is as follows:
Use # 1 – Insecticide - ants (all stages, nests) – non-professional users – ready to use bait station - indoor and outdoor

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

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

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

The product contains spinosad which is a candidate for substitution.

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

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

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

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
Ameisenköder N Trade names: Ameisenköder N Ameisen – Köder plus Nestwirkung	Austria

2.1.1.2 Authorisation holder

Name and address of the applicant	**Name**	Evergreen Garden Care Poland Sp. z o. o.
	Address	ul. Ostrobramska 101A 04-041 Warszawa Poland
Name and address of the authorisation holder	**Name**	Evergreen Garden Care Österreich GmbH
	Address	Franz Broetzner Str. 11-13 5071 Wals Siezenheim Austria
Authorisation number	See authorisation letter	
Date of the authorisation	See authorisation letter	
Expiry date of the authorisation	See authorisation letter	

2.1.1.3 Manufacturer of the product

Name of manufacturer	Evergreen Garden Care France S.A.S
Address of manufacturer	4 Allée des Séquoias Limonest 69760 France
Location of manufacturing sites	Evergreen Garden Care France S.A.S Usine de Fourneau Bourth 27580 France

2.1.1.4 Manufacturer of the active substance

Active substance	Spinosad (ISO)
Name of manufacturer	Corteva Agriscience France S.A.S.
Address of manufacturer	Corteva Agriscience France S.A.S. 78280 Guyancourt France

Location of manufacturing sites	305 North Huron Avenue Harbor Beach Michigan 48441 USA

2.1.2 Product composition and formulation

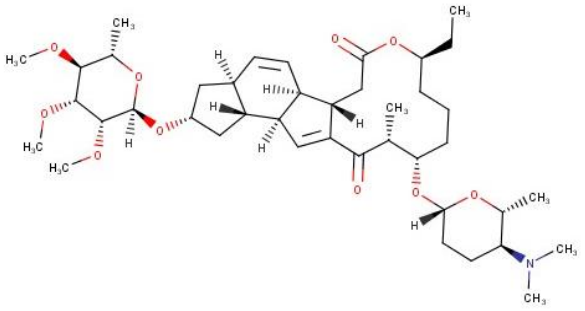
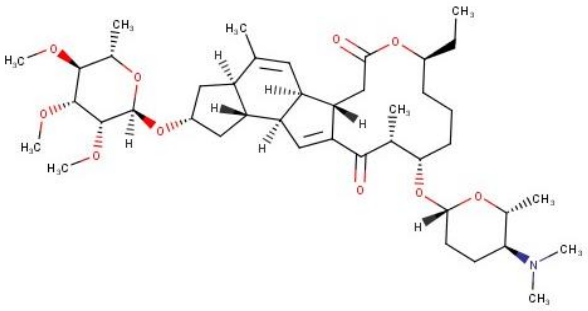
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Spinosad
IUPAC or EC name	Spinosad: Mixture of spinosyn A: (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-Derythropyranosyloxy)- 9-ethyl- 2,3a,5a,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-14-methyl-1H-8-oxacyclododeaca[b]as-indacene-7,15-dione and spinosyn D: (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2.3.4.6-tetradeoxy-β-Derythropyranosyloxy)- 9-ethy- 2,3,3a,5a,6,7,9,10,11,12,13,14,15,16a,16bhexadecahydro-4,14-dimethyl-1H-8-oxacyclododeaca[b]as-indacene-7,15-dione
EC number	434-300-1
CAS number	Spinosad: 168316-95-8 Spinosyn A: 131929-60-7 Spinosyn D: 131929-63-0
Index number in Annex VI of CLP	603-209-00-0
Minimum purity / content	85%(w/w) (850 g/kg) spinosad Spinosad typically contains spinosyn A and spinosyn D in a ratio of 85:15(w/w) and range between 95:5(w/w) and 50:50(w/w)

Structural formula	Spinosyn A:  Spinosyn D: 

2.1.2.2 Candidate(s) for substitution

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

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Spinosad (ISO)	A mixture of: Spinosyn A: (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3a,5a,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-14-methyl-1H-8-oxacyclododeaca[b]as-indacene-7,15-dione; Spinosyn D: (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2.3.4.6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethy-2,3,3a,5a,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-4,14-dimethyl-1H-8-oxacyclododeaca[b]as-indacene-7,15-dione	Active substance	168316-95-8	434-300-1	0.089 *
1,2-Benzisothiazol-3(2H)-one	1,2-Benzisothiazol-3(2H)-one	Preservative of co-formulant	2634-33-5	220-120-9	0.002

*Minimum content of pure active substance (without impurities): 0.07565%(w/w)

The biodidal product is a liquid formulation (gel) that contains the active substance spinosad. The liquid is soaked onto a fibre tamponade, which is enclosed in a bait station.

The full composition of the biocidal product is provided in the confidential annex.

2.1.2.4 Information on technical equivalence

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

Yes ☒
No ☐

2.1.2.5 Information on the substance(s) of concern

The biocidal product contains one substance of concern (the biocidal active substance 1,2-Benzisothiazol-3(2H)-one (BIT), approved for PT6 and 13, CAR ES Spain) with regard to the

environment according to the criteria defined in the "guidance on the BPR Vol IV Part B+C" (ECHA, 2017a).
For further information refer to the confidential annex.

2.1.2.6 Type of formulation

RB bait (ready for use)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Chronic 3
Hazard statement	H412: Harmful to aquatic life with long lasting effects.
Labelling	**Pictograms**
	None
Signal words	None.
Hazard statements	H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P273: Avoid release to the environment. P501: Dispose of contents/container according to national legislation.
Note	none

2.1.4 Authorised use(s)

2.1.4.1 Use description

Use # 1 – Insecticide - ants (all stages, nests) – non-professional users – ready to use bait station - indoor and outdoor

Product Type	PT 18
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Common name: Black Garden Ant Scientific name: *Lasius niger* Development stage: all stages, nests (queen, adults, larvae)
Field of use	indoor and outdoor use **Field of use description**: Insecticide for use in households (indoor) and private areas around the houses on hard surfaces (outdoor, e.g. terraces, balconies)
Application method(s)	ready-to-use bait station
Application rate(s) and frequency	One bait station contains 10 g of the product which corresponds to 8.9 mg of the active substance Spinosad. Number and timing of application (indoor and outdoor use): One single bait station per ant run or nest. Maximum 2 bait stations per 15 m^2, placed at separate sites. The bait station may be replaced after 4 weeks, if ants are still visible, but maximum 11 applications per year.
Category(ies) of users	non-professional user
Pack sizes and packaging material	Pre-filled bait box made of polystyrene, 10 g per bait box (dimensions 77.8 x 19.35 mm). Sold as 1 – 2 – 4 bait boxes per blister.

2.1.4.2 Use-specific instructions for use

2.1.4.3 Use-specific risk mitigation measures

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

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

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

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2.1.5 General directions for use

2.1.5.1 Instructions for use

Comply with the instructions for use.

Apply one bait station near each ant trail found, with a maximum of two bait stations per 15 m^2. If two bait stations are used they must be placed at separate sites (separate ant runs/nests).

N-290 (modified): Before treatment, remove all natural sources of food for ants from the infested area.

N-289 (modified): Do not expose bait boxes to sunlight or heat (i.e radiator).

Only apply the bait station on hard surfaces near the ant nest or ant runs in dry and sheltered places.

N-172 (modified): Put the bait boxes only in places where they are protected from submersion or becoming wet (i.e protected from rainfall events, floods and cleaning water) and damage to avoid release of the product into the environment

N-134: Do not force open the bait box.

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

N-293 (modified): Retreat in case of new infestation without exceeding the maximum number of treatment authorised per year (i.e. 11 applications).

If the infestation persists despite following the instructions on the label, contact a professional pest controller.

2.1.5.2 Risk mitigation measures

This biocidal product contains spinosad which is dangerous to bees.

N- 224: Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.

N-298: Place bait stations away from food, drink and feed, as well as from utensils or surfaces that have contact with these.

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

2.1.5.4 If medical advice is needed, have product container or label at hand

Likely direct or indirect effects: None known.

First aid instructions:

IF INHALED: not applicable
IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

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

2.1.5.5 Instructions for safe disposal of the product and its packaging

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

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

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

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

2.1.5.7 Keep out of reach of children and non-target animals/pets

Store in original container and in a dry place.

Store at temperatures not exceeding 35°C.

Shelf life: 2 years.

2.1.6 Other information

None.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bait box; pre-filled bait station made of polystyrene (the gel formulation is soaked onto a fibre tamponade)	10 g bait box dimensions: Diam 77.8 x 19.35 mm Opening slots (ellipse shape): 11.04 x 3.75 mm; sold as either 1, 2 or 4 bait stations per blister	polystyrene	n.a.	non-professional	yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

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

2.1.8.2 Access to documentation

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

2.2 Assessment of the biocidal product

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

Please cf. to the DRAs in the respective IUCLID files, section 13.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20°C and 101.3 kPa	Visual inspection	100% biocidal product UKS 171 K Batch no: 01-12 33719	slightly viscous liquid cloudy liquid, no signs of separation	Anonymous 2012a Anonymous 2022a
Colour at 20°C and 101.3 kPa	Visual inspection	100% biocidal product UKS 171 K Batch no: 01-12 33719	dark yellow, turbid cloudy liquid, allowing light to pass through	Anonymous 2012a Anonymous 2022a
Odour at 20°C and 101.3 kPa	Olfactory inspection	100% biocidal product UKS 171 K Batch no: 01-12 33719	weak fusty smell no discernible odour	Anonymous 2012a Anonymous 2022a

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td>Acidity/alkalinity</td><td>CIPAC MT 75.3</td><td>100% biocidal product

UKS 171 K

Batch no: 33719</td><td>pH measured at 20°C using neat formulation and a 1% dilution before and after twelve week accelerated storage at 35°C; average of two results

<table><tr><td></td><td>Neat formulation</td><td>1% dilution</td></tr><tr><td>Before storage</td><td>5.51</td><td>6.56</td></tr><tr><td>After storage – Bait box</td><td>4.86</td><td>6.49</td></tr></table></td><td>Anonymous 2020a</td></tr>
<tr><td>Acidity/alkalinity</td><td>CIPAC MT 75.3</td><td>100% biocidal product

UKS 171 K

Batch no: 33719</td><td>pH measured at 20°C using neat formulation and a 1% dilution after 6 months, 1 year, 18 months and 24 months storage at ambient temperature; average of two results

<table><tr><td></td><td>Neat formulation</td><td>1% dilution</td></tr><tr><td>Post 6 months</td><td>4.90</td><td>6.77</td></tr><tr><td>Post 1 year</td><td>4.84</td><td>6.59</td></tr><tr><td>Post 18 months</td><td>5.25</td><td>6.50</td></tr><tr><td>Post 24 months</td><td>4.91</td><td>6.78</td></tr></table></td><td>Anonymous 2022a</td></tr>
<tr><td>Relative density / bulk density</td><td>EU Method A.3</td><td>100% biocidal product

UKS 171 K

Batch no: 01-12

33719</td><td>1.2395 at 20°C

1.2258 at 20°C</td><td>Anonymous 2012a

Anonymous 2020a</td></tr>
</table>

<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>Storage stability test – accelerated storage

35°C for 12 weeks</td><td>in-house method equivalent to CIPAC MT 46.3

Active substance content: validated method (cf. to Section 2.2.4, Anonymous 2020b)</td><td>100% biocidal product

UKS 171 K

Batch no: 33719</td><td>The biocidal products were stored in the commercial packaging (bait box) at 35°C for 12 weeks.
<table>
<tr><th>Test</th><th>Prior to storage</th><th>After storage 12 weeks</th></tr>
<tr><td>Appearance (Bait box)</td><td>Cloudy liquid, allowing light to pass through; no signs of separation into oil, cream, sediment or suspended solid. No discernable odour.</td><td>The appearance of the liquid formulation remained unchanged.</td></tr>
<tr><td>Stability of packaging (Bait box)</td><td>No signs of leakages, panelling or ballooning.</td><td>No signs of leakages, panelling or ballooning.</td></tr>
<tr><td>Active substance content (Bait box)</td><td>0.7162 g/kg (=89.5% of declared 0.8 g/kg)</td><td>0.6976 g/kg (=87.2% of declared 0.8 g/kg)</td></tr>
</table></td><td>Anonymous 2020a</td></tr>
<tr><td>Storage stability test – accelerated storage

54°C for 14 days</td><td>CIPAC MT 46.3

Active substance content: validated method (cf. to Section 2.2.4, Anonymous 2012a)</td><td>100% biocidal product

UKS 171 K

Batch no.: 12182</td><td>The biocidal products were stored in the commercial packaging at 54°C for 2 weeks. The packaging (polystyrene bait boxes) of the biocidal product is not stable under tested conditions.
<table>
<tr><th>Test</th><th>Prior to storage</th><th>After storage 14 days</th></tr>
<tr><td>Appearance</td><td>Dark yellow, turbid, slightly viscous liquid</td><td>No change</td></tr>
</table></td><td>Anonymous 2012a</td></tr>
</table>

<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>
<table>
<tr><td></td><td>with a weak fusty smell</td><td></td></tr>
<tr><td>Active content (%w/w) – storage on a fibre tamponade in polystyrene bait station</td><td>0.0646</td><td>0.0636</td></tr>
<tr><td>pH (1%)</td><td>7.6</td><td>7.8</td></tr>
<tr><td>Stability of bait box (polystyrene)</td><td>Stable pack</td><td>Cracked at joints, bait had leaked out; weight loss: 6.58%</td></tr>
</table>
</td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature

2 years</td><td>UK Pesticides Safety Directorate Guidelines for the Generation of Data on the Physical, Chemical and Technical Properties of Active Substances (01 May 2002)</td><td>UKS 171 B

batch no.: 568/SR2077</td><td>The test items were stored in the commercial packaging (polystyrene bait boxes) for 2 years at ambient temperature.
<table>
<tr><th>Test</th><th>Prior to storage</th><th>After storage</th></tr>
<tr><td>Appearance</td><td>Off white opaque viscous liquid with no odour</td><td>no change</td></tr>
<tr><td>Active substance content (%w/w)</td><td>0.0802</td><td>0.0822</td></tr>
<tr><td>pH (1%)</td><td>6.75</td><td>6.81</td></tr>
<tr><td>Stability of pack</td><td>---</td><td>Some dry and sticky gel on the outside of the lids of all packs

Weight loss: 0.57%</td></tr>
</table>
</td><td>Anonymous 2008

(supporting study)</td></tr>
</table>

<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>It is noted that a small build up of the biocidal product occurred on the lid.</td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature – 24 months</td><td>GIFAP monograph no. 17

Active substance content: validated method (cf. to Section 2.2.4, Anonymous 2020b)</td><td>100% biocidal product

UKS 171 K

Batch no.: 33719</td><td>The biocidal product is stable when stored in its original packaging for 2 years at ambient temperature. The active substance content is stable as well as the other parameters concerning the appearance, the packaging, the pH and the relative density.

The Samples were stored for 2 years at ambient temperature in sealed green PS bait boxes, measuring 7.5 cm x 2cm (i.e. original packaging). The bait boxes contained a single fibre tamponade soaked in formulation.
<table>
<tr><th>Test</th><th>T0</th><th>T6m</th><th>T12m</th><th>T18m</th><th>T24m</th></tr>
<tr><td>Appearance</td><td colspan="5">The sample was a cloudy liquid, allowing light to pass through the sample. The sample remained free flowing and coated the walls of a beaker. There were no signs of separation into oil, cream, sediment, claying or suspended solids. The sample retained no discernible odour. The sample appearance remained unchanged after storage.</td></tr>
<tr><td>Stability of packaging</td><td colspan="5">The bait boxes showed no signs of leaks, visual seepage or panelling.
The sample packaging remained unchanged after storage.</td></tr>
<tr><td>Sample weight</td><td>---</td><td>overall mean weight change of -3.089% compared to the pre storage weight</td><td>overall mean weight change of -5.976% compared to the pre storage weight</td><td>overall mean weight change of -8.472% compared to the pre storage weight</td><td>overall mean weight change -9.779 % compared to the pre storage weight</td></tr>
<tr><td>a.s. content (X % of declared concentration)</td><td>0.7162 g/kg (89.53%)</td><td>0.7194 g/kg (89.92%)</td><td>0.7246 g/kg (90.58%)</td><td>0.7288 g/kg (91.10%)</td><td>0.7163 g/kg (89.93%)</td></tr>
<tr><td>pH average of two results</td><td>1% dilution: 6.56 at 20°C</td><td>1% dilution: 6.77 at 20.1°C</td><td>1% dilution: 6.59 at 20.0°C</td><td>1% dilution: 6.50 at 20.0°C</td><td>1% dilution: 6.78 at 20.0°C</td></tr>
</table></td><td>Anonymous 2022a

(key study)</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			<table><tr><td></td><td>neat formulation: 5.51 at 20.0°C</td><td>neat formulation: 4.90 at 20.0°C</td><td>neat formulation: 4.84 at 20.0°C</td><td>neat formulation: 5.25 at 20.1°C</td><td>neat formulation: 4.91 at 20.0°C</td></tr><tr><td>**Relative density**</td><td>1.2258 at 20°C</td><td>1.2258 at 20.1°C</td><td>1.2258 at 20.1°C</td><td>1.2250 at 19.9°C</td><td>1.2243 at 20.1°C</td></tr></table>	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	100% biocidal product UKS 171 K Batch no: 01-12	No visible changes to the appearance of the test item on storage at 0°C for seven days. No separated material and no phase separation was observed.	Anonymous 2012a
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	---	---	The active substance degrades when exposed to sunlight (conf. to CAR). The packaging of the biocidal product protects the liquid formulation from direct exposure to sunlight.	---
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	---	---	The effect of temperature was investigated in the accelerated storage stability study. The biocidal product is stable when stored at 35°C for 12 weeks, when stored at 54°C for 2 weeks the packaging leaked. The effect of humidity was not investigated as the biocidal product consists of a water-based liquid formulation.	---
Effects on content of the active substance and technical characteristics of the biocidal product -	---	---	The content of active substance as well as the container material are stable for 2 years as proved by the ambient storage stability study. No reactivity towards the container material was observed.	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
reactivity towards container material				
Wettability	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no solid preparations which are to be dispersed in water.	---
Suspensibility, spontaneity and dispersion stability	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no suspension.	---
Wet sieve analysis and dry sieve test	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no solid or suspension.	---
Emulsifiability, re-emulsifiability and emulsion stability	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no emulsion.	---
Disintegration time	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no tablet.	---
Particle size distribution, content of dust/fines, attrition, friability	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no powder or granule.	---
Persistent foaming	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and not intended to be applied in water for use.	---
Flowability/Pourability/Dustability	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no solid or suspension.	---
Burning rate — smoke generators	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no smoke generator.	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning completeness — smoke generators	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no smoke generator.	---
Composition of smoke — smoke generators	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no smoke generator.	---
Spraying pattern — aerosols	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no aerosol.	---
Physical compatibility	---	---	The biocidal product is a ready-to-use bait station which is not intended to be applied together with other products.	---
Chemical compatibility	---	---	The biocidal product is a ready-to-use bait station which is not intended to be applied together with other products.	---
Degree of dissolution and dilution stability	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no water soluble bag, no water soluble preparation or tablet.	---
Surface tension	OECD 115 EC method A.5	100% biocidal product UKS 171 K Batch no: 01-12	25°C: 40.4 mN/m	Anonymous 2012a
Surface tension	OECD 115 EC method A.5	100% biocidal product UKS 171 K	Mean corrected Surface Tension at 20°C: 45.69 mN/m (SD=0.481) Mean corrected Surface Tension at 25°C: 46.37 mN/m (SD=0.260)	Anonymous 2020a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Batch no: 33719		
Viscosity	OECD 114	100% biocidal product UKS 171 K Batch no: 01-12	Non-Newtonian liquid Dynamic viscosity (lowest values given) 25°C: 24.7 mPa*s 40°C: 18.5 mPa*s Kinematic viscosity 40°C: 1.5*10^-9 m2/s	Anonymous 2012a
Viscosity	OECD 114	100% biocidal product UKS 171 K Batch no: 33719	Non-Newtonian liquid Dynamic viscosity 20°C: from 2.5 rpm 1255.4 mPa*s to 100 rpm 149.2 mPa*s 40°C: from 6 rpm 473.7 mPa*s to 100 rpm 100.6 mPa*s	Anonymous 2020a

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

The biodidal product is a liquid formulation (gel) that contains the active substance spinosad. The liquid is soaked onto a fibre tamponade, which is enclosed in a bait station.

The biocidal product is a cloudy and slightly viscous liquid formulation (gel) with the active substance spinosad. The smell of the formulation is weak fusty to not discernible. The pH of the undiluted liquid is 5.51 with a relative density around 1.23. The surface tension ranges from 40.4 to 46.37 mN/m at 25°C. The liquid formulation is a non-Newtonian liquid.

The biocidal product is stable when stored in its original packaging for 2 years at ambient temperature and when stored for 7 days at 0°C. When stored for 2 weeks at 54°C the bait boxes leaked. When stored for 12 weeks at 35°C the container and the active substance content remain stable. Therefore, the biocidal product shall not be stored above 35°C.

Shelf life: 2 years

The qualitative and quantitative composition of the formulation UKS 171 B is included in the confidential annex.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	---	---	The biocidal product is not classified as explosive. For further details please refer to confidential annex.	Anonymous 2010a
Flammable gases	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no gas.	---
Flammable aerosols	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no aerosol.	---
Oxidising gases	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no gas.	---
Gases under pressure	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no gas.	---
Flammable liquids	EC method A.9	100% biocidal product UKS 171 K Batch no: 01-12	The biocidal product is not classified as flammable. No flash was observed up to 115°C. Vapours from the test item extinguished the flame from as low as 56°C.	Anonymous 2012a
Flammable solids	---	---	N.A.	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The biocidal product is a liquid formulation contained in a bait station ready for use and no solid.	
Self-reactive substances and mixtures	---	---	The biocidal product is not classified as self-reactive. For further details please refer to confidential annex.	Anonymous 2010a
Pyrophoric liquids	---	---	Not pyrophoric. The formulation does not contain any chemical groups which are associated with pyrophoric properties. The product shows no pyrophoric properties in contact with surfaces and air. Also, the auto-ignition temperature of the product was determined to be 410°C. The liquid does not ignite spontaneously on coming into contact with air at normal temperatures. The liquid is known to be stable at room temperature for prolonged periods of time.	---
Pyrophoric solids	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no solid.	---
Self-heating substances and mixtures	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no solid.	---
Substances and mixtures which in contact with water emit flammable gases	---	---	Not classified as a substance and mixture which in contact with water emits flammable gases. Based on the many years of experience in handling the product, it is not to be	---

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			assumed that the product or the formulation, emits flammable gases when in contact with water. Experience in handling and use shows that the mixture does not react with water. Furthermore, the formulation is manufactured with water.	
Oxidising liquids	---	---	The biocidal product is not classified as oxidising. None of the components of the formulation contain oxygen, fluorine and chlorine chemically bonded to other atoms beside carbon and hydrogen.	Anonymous 2010
Oxidising solids	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and no solid.	---
Organic peroxides	---	---	N.A. The biocidal product is a liquid formulation contained in a bait station ready for use and does not contain organic peroxides.	---
Corrosive to metals	UN Test C1 using aluminum and low carbon grade steel, 28 day test	100% biocidal product UKS 171 K batch number: 02/21	The biocidal product is not classified as corrosive to metals. The test duration was 28 days at 55°C. The steel samples exposed to the gase phase showed signs of corrosion and all three samples lost their lustre. The Al samples exposed to the gase phase showed discolouration and the other samples remain unchanged. The criteria for classification are not met for uniform and localised corrosion.	Anonymous 2022b

<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>
<table>
<tr><th>Steel</th><th>T0</th><th>T28d</th><th>Mass loss [%]</th></tr>
<tr><td>Immersed</td><td>22.8012 g</td><td>22.7931 g</td><td>0.04%</td></tr>
<tr><td>Half way immersed</td><td>22.8248 g</td><td>22.8182 g</td><td>0.03%</td></tr>
<tr><td>Gas phase</td><td>22.8486 g</td><td>22.9635 g</td><td>- 0.50%</td></tr>
<tr><td colspan="4">Al</td></tr>
<tr><td>Immersed</td><td>5.3682 g</td><td>5.3681 g</td><td>0.00%</td></tr>
<tr><td>Half way immersed</td><td>5.3482 g</td><td>5.3481 g</td><td>0.00%</td></tr>
<tr><td>Gas phase</td><td>5.3554 g</td><td>5.3634 g</td><td>- 0.15%</td></tr>
</table>
</td><td></td></tr>
<tr><td>Auto-ignition temperatures of products (liquids and gases)</td><td>EC method A.15</td><td>100% biocidal product

UKS 171 K

Batch no: 01-12</td><td>410°C</td><td>Anonymous 2012a</td></tr>
<tr><td>Relative self-ignition temperature for solids</td><td>---</td><td>---</td><td>N.A.
The biocidal product is a liquid formulation contained in a bait station ready for use and no solid.</td><td>---</td></tr>
<tr><td>Dust explosion hazard</td><td>---</td><td>---</td><td>N.A.
The biocidal product is a liquid formulation contained in a bait station ready for use and no solid and does not contain dust.</td><td>---</td></tr>
</table>

Conclusion on the physical hazards and respective characteristics of the product
The biocidal product is not explosive, flammable, oxidising, self-reactive or corrosive to metals. The biocidal product is not classified in any physical hazard class according to the criteria set out in Annex I to CLP.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Spinosad[1)] *(UKS 171 K (gel formulation containing 0.08% w/w Spinosad))*	CIPAC 636 RP-HPLC-UV at 250 nm	active substance concentration 0.06% w/w 0.08% w/w 0.1% w/w *4 independent measurements at each fortification level*	0.15-0.35 mg/mL (63–146% w/v of nominal active substance content in calibration solution) Single determination at 5 concentrations R^2=0.9992	Method is specific to analyse the active substance in the biocidal product. No interference is observed in the chromatograms.	72.2–104.4	93	10.5	N.A. Method is used to determine the active substance concentration in the biocidal product.	Anonymous 2012a
					Precision: Fortification level: 0.08% w/w n=5 RSD =1.86%				
Spinosad[1)] *(gel formulation containing 0.08% w/w Spinosad)*	RP-HPLC-UV at 250 nm	active substance concentration 0.08% w/w *6 independent measurements*	0.005–0.50 mg/ml (6.25–625% w/v of nominal active substance content in calibration solution) Duplicate determination at 7 concentrations R^2=1.0000	Method is specific to analyse the active substance in the biocidal product. No interference is observed in the chromatograms.	99.1 – 101.1	*99.7*	0.63	0.005 mg/ml (LOQ recovery =99.7 RSD=2.63 n=6)	Anonymous 2020b
					Precision: Fortification level: 0.07% w/w n=6 RSD =0.627% Hr=0.157				

Substance of concern: ***1,2-Benzisothiazol-3(2H)-one***	Study is not deemed to be necessary, as 1,2-Benzisothiazol-3(2H)-one cannot possibly increase on manufacture or storage of the biocidal product.

[1)] Sample preparation: Spinosad is extracted with methanol.

Analytical methods for monitoring								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
For detailed information on the active substance spinosad, please refer to the CAR.									Netherlands, Competent Authority Report, Spinosad (May 2010)

Analytical methods for soil								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
For detailed information on the active substance spinosad, please refer to the CAR.									Netherlands, Competent Authority Report, Spinosad (May 2010)

Analytical methods for air								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
For detailed information on the active substance spinosad, please refer to the CAR.									Netherlands, Competent Authority Report, Spinosad (May 2010)

Analytical methods for water								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
For detailed information on the active substance spinosad, please refer to the CAR.									Netherlands, Competent Authority Report, Spinosad (May 2010)

Analytical methods for animal and human body fluids and tissues								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
For detailed information on the active substance spinosad, please refer to the CAR.									Netherlands, Competent Authority Report, Spinosad (May 2010)

Analytical methods for monitoring of active substances and residues in food and feeding stuff								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
For detailed information on the active substance spinosad, please refer to the CAR.									Netherlands, Competent Authority Report, Spinosad (May 2010)

Conclusion on the methods for detection and identification of the product

The analytical methods for the analysis of the active substance spinosad in the biocidal product is considered to be satisfactorily validated in accordance with SANCO/3029/99 rev.4. The presented analytical methods are linear, specific, precise and accurate. Analytical methods for soil, air, water, human body fluids and tissues and for monitoring in food and feeding stuff are available from the Competent Authority Report of the active substance spinosad (May 2010, Netherlands). Further monitoring methods are not required.

Study Anonymous 2012a:
The HPLC-method used to determine spinosad in the biocidal product has been validated for the determination of the active substance in SC and GR formulations, but not in gels. Here, the applicant has provided validation data. Approximately 20 g of the biocidal product were accurately weighed out and 66.7 mL of methanol was added. Additionally, the fibre tamponade of two bait boxes was analysed. Final determination was by HPLC-UV (isocratic elution on a C18 column). Quantification was at 250 nm using external standards.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The biocidal product is an insecticide (PT 18) intended to be used indoors and outdoors by non-professional users to control *Lasius niger* (Black Garden ant) in and around their houses on hard surfaces. For indoor and outdoor use a maximum of two bait stations can be placed per 15 m² at the same time, but at separate sites (separate ant runs/nests).

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

The product is used to control Black Garden ants (*Lasius niger*). The bait stations are set up indoors mainly for stored product protection and food protection. Also, restoring the well-being of people living in accommodations infested with ants is an important application aim. For outdoor applications the bait stations are set up mainly for material protection, for example on patios or terraces with hard surfaces.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The worker ants (female adults) are attracted by the sugar component in the formulation of the biocidal product contained in the bait stations. They ingest the product and take it back to the nest to feed the brood. The whole nest with all its developmental stages will be killed as the eggs and larvae are not cared for and die.

2.2.5.4 Mode of action, including time delay

Spinosad kills ants by ingestion or by contact exposure. For the present biocidal product the mode of action by ingestion is more relevant since the ants are attracted by the sugary component in the product and ingest it. Spinosad leads to an activation of the acetylcholine nervous system through nicotine receptors. This continuous activation leads to involuntary muscle contractions, prostration with tremors and paralysis which in turn leads to death by exhaustion within one or two days. The active substance is a short-acting toxin and has no residual effect. Nevertheless, the whole ant nest dies because the female worker ants die and the brood is not cared for any longer. The area is ant-free until a new nest is built.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	indoor and outdoor use; non-professional user	Bait Stations containing 0.089% spinosad (w/w) UKS 171K bait station (corresponding to Ameisenköder N, which is the product to be authorised)	*Lasius niger* (Black Garden Ant)	General method n° 1 and specific method n° 196 of the CEB (Commission des Essais Biologiques) of the Association Française pour la Protection des Plantes (AFPP)	Test system: Laboratory based simulated use arena test involving the treatment of artificial nests. A total of four replicates and four untreated controls were conducted. 100 ants (adults) per replicate. Alt. Food source: 2% saccharose syrup. Temperature: 23.6°C Humidity: 75.0% relative humidity Application: one bait station applied per nest (arena), corresponding to 0.008 g active substance per nest	99% mortality within 7 days, 100% within 8 days Mortality in untreated controls: max. 3.5 % (at the end of the trial)	Anonymous 2009
Insecticide	indoor and outdoor use; non-professional user	Spinosad Bait Station (UKS 171K) containing 0.089% spinosad (w/w)	*Lasius niger* (Black Garden ant)	not stated	Test system: Laboratory based simulated use arena test involving the treatment of artificial nests. A total of four replicates and four untreated controls were conducted. 250-490 ants (adults) per replicate. Alt. Food source: sugar. Temperature: 19.0–27.4°C	94.4 % affected (knockdown and dead) ants within 7 days Affected ants in untreated controls: max. 4.2 % (at the end of the trial), **Supportive information** since	Anonymous 2012b

Experimental data on the efficacy of the biocidal product against target organism(s)							
					Humidity: 20.0% relative humidity Application: one bait station applied per nest (arena), corresponding to 0.008 g active substance per nest	no Test method is described definitely.	
Insecticide	indoor and outdoor use; non-professional user	Spinosad Bait Station (UKS 171K) containing 0.089% spinosad (w/w)	*Lasius niger* (Black Garden Ant)	General Method n° 1 and specific method n° 196 of the CEB (Commission des Essais Biologiques) of the Association Française pour la Protection des Plantes (AFPP)	Test system: Laboratory based simulated use arena test involving the treatment of artificial nests (vivarium trial). A total of four replicates and four untreated controls were conducted. Mean 5100 ants were tested per replicate (treated and untreated). Alt. Food source: honey. Temperature: 20.0–30.0°C Humidity: 45.0–85.0% relative humidity Application: one bait station applied per nest, corresponding to 0.008 g active substance per nest	97% (FPS) and 100% (FPD) efficacy within three weeks Anthills opened at the end of the trial (32 days after application): Alive ants in control: 2625 Alive ants in treated nests: 0	Anonymous 2010b
Insecticide	indoor and outdoor use; non-professional user	Spinosad Bait Station (UKS 171K) containing 0.089% spinosad (w/w)	*Lasius niger* (Black Garden Ant)	BioG B 413-02 (modified)	Test system: Laboratory based simulated use arena test involving the treatment of artificial nests. A total of four replicates and four controls were conducted. 1 colony per arena: relevant	63.2% reduction in worker ants within six weeks; 2 out of 4 nests > 90% efficacy after 6 weeks. Untreated controls: in all 4 cases the	Anonymous 2012c

Experimental data on the efficacy of the biocidal product against target organism(s)							
					queen, brood of all stages, approx. 2000 workers. Alt. Food source: powdered sugar/honey. Temperature: 25.0–26.0°C Humidity: 60.0-62.0% relative humidity Application: one bait station applied per nest, corresponding to 0.008 g active substance per nest	relevant queen was found alive with a lot of brood and approx. 2000 workers alive. Supportive study. Note: The result is not enough to support the efficacy of the product since only 2 out of 4 replicates show >90% mortality, but it provides an answer regarding the capability of the product to destroy a nest and thus supporting the claim "can kill the nest". See also the explanations in the efficacy conclusion.	
Insecticide	indoor and outdoor use; non-professional user	Spinosad Bait Station (UKS 171K) containing 0.089% spinosad (w/w)	*Lasius niger* (Black Garden Ant)	General Method n° 1 and specific method n° 196 of the CEB (Commission des Essais Biologiques) of the Association Française pour la Protection	Test system: Laboratory based simulated use arena test involving the treatment of artificial nests (vivarium trial). A total of four replicates and four untreated controls were conducted. Alt. Food source: sugar/honey. Initial average number of ants per vivarium: 3965 (adults + brood) Temperature: 20.0–22.0°C	Efficacy (FPS and FPD results in comparison to untreated controls): 80% efficacy within four weeks (FPS results) and 96% efficacy within two weeks (FPD results) Mortality: >90% mortality in treated nests at the end of the trial (opening of the nest	Anonymous 2012d

Experimental data on the efficacy of the biocidal product against target organism(s)							
				des Plantes (AFPP)	Humidity: 72.4–79.2% relative humidity Application: one bait applied per nest, corresponding to 0.008 g active substance per nest	– 41 DAA) in comparison to untreated control. Alive ants in control: 2225 (after 41 days) Alive ants in treated nests: 0 (after 41 days)	
Insecticide	indoor and outdoor use; non-professional user	Spinosad Bait Station (UKS 171K) containing 0.089% spinosad (w/w)	*Lasius niger* (Black Garden Ant)	CEB method n° 196 CEB method MG1 EPPO Guideline n° 135	Test system: Field trial involving treatment of four separate nests. Four untreated nests were used as a control. Locations of the nests were indoor and outdoor (house garden/terrace; buildings; industrial zone). After 28 days the nests are opened in order to count dead/living ants. Temperature: 15.0-25.0°C Application: one or two baits applied per nest, corresponding to 0.008 or 0.016 g active substance per nest	96% reduction in *Lasius niger* populations within 14 days, and 100% reduction after 28 days; no alive ants nor alive brood present after 28 days	Anonymous 2010c
Insecticide	indoor and outdoor use; non-professional user	Spinosad Bait Station (UKS 171K) containing 0.089% spinosad (w/w)	*Lasius niger* (Black Garden Ant)	CEB method n° 196 CEB method MG1 EPPO Guideline n° 135	Test system: Field trial involving treatment of four separate nests. Four untreated nests were used as a control. Locations of the nests were indoor and outdoor (lawn, terraces, pavements) After 90 days the nests are opened in order to count dead/living ants.	93% reduction in *Lasius niger* populations within 14 days, and 100% reduction after 28, 60 and 90 days; no alive ants, larvae or nymphs present after 90 days	Anonymous 2010d

Experimental data on the efficacy of the biocidal product against target organism(s)							
					Temperature: 15.0–25.0°C Application: one or two baits applied per nest, corresponding to 0.008 or 0.016 g active substance per nest		
Insecticide	indoor and outdoor use; non-professional user	Spinosad Bait Station containing 0.089% spinosad (w/w)	*Lasius niger* (Black Garden Ant)	CEB method n° 196 CEB method MG1 EPPO Guideline n° 135	Test system: Field trial involving treatment of four separate nests. Four untreated nests were used as a control. Locations of the nests were indoor and outdoor (house garden/terrace; buildings; industrial zone; roads). After 28 days the nests are opened in order to count dead/living ants. Temperature: 15.0 – 25 °C Application: one or two baits applied per nest, corresponding to 0.008 or 0.016 g active substance per nest	93% reduction in *Lasius niger* populations within 14 days, and 100% reduction after 28 days; no alive ants, larvae or nymphs present after 28 days	Anonymous 2012e
Insecticide	indoor and outdoor use; non-professional user	Bait stations (UKS 171K) containing 0.8 g/kg spinosad, fresh product, as well as 2 year aged and 4 year aged product	*Lasius niger*	BioG B 407-04	Test system: Laboratory based simulated use arena test involving the treatment of artificial nests. A total of four replicates and four controls were conducted. 100 worker ants per replicate. Alt. food source: sugar cube. Temperature: 25°C	Fresh product: 100% efficacy after 7 and 14 days 2 years aged product: 100% efficacy after 7 and 14 days	Anonymous 2016

Experimental data on the efficacy of the biocidal product against target organism(s)							
					Relative humidity: 52-55% Application: 1 bait station per test arena	4 years aged product: 98% efficacy after 7 days; 100% efficacy after 14 days Mortality in untreated controls: 10% after 14 days.	

Conclusion on the efficacy of the product

The presented trials demonstrate the efficacy of the product containing 0.089% spinosad against *Lasius niger* (Black Garden ant). The requirements according to Efficacy Guidance are fulfilled accordingly: The palatability is successfully shown (100% efficacy after 7 and 14 days) and the required population reduction of >90% is achieved as well in laboratory and simulated-use trials. The field trials also show the required reduction in ant population of >90% in the claimed period. Furthermore, a palatability study is submitted that demonstrates the efficacy of the aged product, with efficacy values of 100% after 7 and 14 days for the two years aged product and 98% and 100% after 7 and 14 days for the four years aged product, respectively.

There is one efficacy trial (Anonymous 2012c) that wouldn't be enough to support alone the authorisation of the product as the efficacy wasn't high enough in all replicates during this trial, but it does provide an answer regarding the capability of the product to destroy the nest and by that supporting the claim "can kill ant nests". Considering the results of the field trials and the mode of action of Spinosad (worker ants die and consequently the whole nest might die because the brood and also the queen is not cared for any longer), whole ant nests can be eradicated by application of the product. One explanation of the low efficacy of the product in test report Anonymous 2012c may be linked to the status of the colony. The ants are bread internally, and fed with a mixture of powdered sugar +honey ad libitum plus frozen houseflies weekly. It can be imagined that their behaviour of searching new food alternative was soften due to the feeding routine (the alternative food source during the trial is their normal food source). It has to be noted at this point, that nestkill is not achieved each time applying the product. The claim "kills ants" is sufficiently fulfilled anyway. The eCA supports this adoption.

The study of Anonymous (2009) excludes the influence of co-formulants (preservative, bittering agent) on the efficacy of the product.

Justification regarding the application rates and frequencies:

Research made by Brian, et al. in 1965 determined that ant species similar to *Lasius niger* have respectively a territory depending of the size of the nest with an average of 336 workers per m^2 and 430 workers per m^2.
Beckers et al. in 1989 have determined that the average nest size of the *Lasius niger* is 5500 workers. If one divides the 5500 workers by a 383 workers/m^2 (mean of 336 and 430), this results in an average territory of 14.36 m^2 for a *Lasius niger* nest.
The expectation is that a nest will not be directly under a house, so a room might be in an edge of their territory. If an ant infestation occurs in several areas of a 15 m^2 room it can be from two different nests. By placing two bait stations the separate baiting of the nests will be allowed. In order to avoid an overuse of the product, the applicant recommended that the consumer should apply one bait station near each ant trail found, with a maximum of 2 bait stations per 15 m^2.

For Anonymous 2010d, the trial showed an efficacy of 100% from 28 days up to 90 days (the end of the trial) indicating a destruction of the nest (which is confirmed by the absence of ants and cocoons at the opening). But, as there was no tentative of reinfestation, it is unknown if the absence of ants after 28 days is coming from a continuous protection of the product or if it's just the consequence of the nest destruction. Therefore, the applicant recommends the consumer to reapply the product after 4 weeks if ants can still be seen running because at that time the product should have reached its maximum efficacy.

The eCA accepts the justifications. Thus the claims, the application rate and frequency is successfully supported by the presented efficacy trials.

2.2.5.6 Occurrence of resistance and resistance management

There is no evidence for resistance of ants against spinosad. Resistance should be monitored on a continuous basis. Should the authorisation holder become aware of reports of resistance this should be reported to the competent authorities.

2.2.5.7 Known limitations

To ensure good efficacy, the following restrictions should be noted:

- Do not place the bait station on warm or heating objects (e.g. a radiator)
- Use only on hard surfaces and sheltered places; keep the bait station dry
- Remove all other sources of food from the area

2.2.5.8 Evaluation of the label claims

The following label claims are to be included:

- Effective for up to 4 weeks
- Kills ants and can kill their nests

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

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

The product is not intended to be authorised for use with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

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

Data waiving	
Information requirement	Skin corrosion and irritation
Justification	No skin irritation and corrosivity studies have been carried out for the biocidal product. The potential to cause skin irritation can be deduced from the properties of the active substance and co-formulants and their concentrations in the biocidal product. On the basis of the information provided in the Assessment Report for the active substance spinosad (NL, 2010), the biocidal product does not meet the criteria for classification for skin irritation and corrosivity.

Eye irritation

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

Data waiving	
Information requirement	Eye irritation
Justification	No eye irritation studies have been carried out for the biocidal product. The potential to cause eye irritation can be deduced from the properties of the active substance and co-formulants and their concentration in the product. On the basis of the information provided in the Assessment Report for the active substance spinosad (NL, 2010), the biocidal product does not meet the criteria for classification for eye irritation.

Respiratory tract irritation

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

Data waiving	
Information requirement	Respiratory tract irritation
Justification	No respiratory tract irritation studies have been carried out for the biocidal product. The potential to cause respiratory tract irritation can be deduced from the properties of the active substance and co-formulants and their concentrations in the product. On the basis of the information provided in the Assessment Report for the active substance spinosad (NL, 2010), the biocidal product does not meet the criteria for classification for respiratory tract irritation.

Skin sensitization

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

Data waiving	
Information requirement	Skin sensitization
Justification	No skin sensitization studies have been carried out for the biocidal product. The potential to cause skin sensitization can be deduced from the properties of the active substance and co-formulants and their concentrations in the product. On the basis of the information provided in the Assessment Report for the active substance spinosad (NL, 2010), the biocidal product does not meet the criteria for classification as a skin sensitizer.

Respiratory sensitization (ADS)

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

Data waiving	
Information requirement	Respiratory sensitization
Justification	No respiratory sensitization studies have been carried out for the biocidal product. The potential to cause respiratory sensitization can be deduced from the properties of the active substance and co-formulants and their concentrations in the product. On the basis of the information provided in the Assessment Report for the active substance spinosad (NL, 2010), the biocidal product does not meet the criteria for classification as a respiratory sensitizer.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	The biocidal product does not require classification for acute oral toxicity according to Regulation (EC) No. 1272/2008.
Justification for the selected value	See table "Data waiving" below.
Classification of the product according to CLP and DSD	The biocidal product does not require classification for acute oral toxicity according to Regulation (EC) No. 1272/2008.

Data waiving	
Information requirement	Acute oral toxicity
Justification	No acute toxicity studies have been carried out for the biocidal product. The acute toxicity and human health classification can be deduced from the properties of the active substance and co-formulants and their concentrations in the product. On the basis of the information provided in the Assessment Report (NL, 2010) which states that acute oral toxicity is low (LD50 > 2000 mg/kg bw), the biocidal product does not meet the criteria for classification for acute toxicity.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	The biocidal product does not require classification for acute inhalation toxicity according to Regulation (EC) No. 1272/2008.
Justification for the selected value	See table "Data waiving" below.
Classification of the product according to CLP and DSD	The biocidal product does not require classification for acute inhalation toxicity according to Regulation (EC) No. 1272/2008.

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	No acute toxicity studies have been carried out for the biocidal product. The acute toxicity and human health classification can be deduced from the properties of the active substance and co-formulants and their concentrations in the product. On the basis of the information provided in the Assessment Report for the active substance spinosad (NL, 2010), which states that acute inhalation toxicity is low (LC50 >5.18 mg/L), the biocidal product does not meet the criteria for classification for acute toxicity.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	The biocidal product does not require classification for acute dermal toxicity according to Regulation (EC) No. 1272/2008.
Justification for the selected value	See table "Data waiving" below.
Classification of the product according to CLP and DSD	The biocidal product does not require classification for acute dermal toxicity according to Regulation (EC) No. 1272/2008.

Data waiving	
Information requirement	Acute dermal toxicity
Justification	No acute toxicity studies have been carried out for the biocidal product. The acute toxicity and human health classification can be deduced from other properties of the active substance and co-formulants and their concentrations in the biocidal product. On the basis of the information provided in the Assessment Report (NL, 2010) which states that acute dermal toxicity is low (LD50 > 5000 mg/kg bw), the biocidal product does not meet the criteria for classification for acute toxicity.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	-
Value(s)	70% (default value)
Justification for the selected value(s)	See table "Data waiving" below.

Data waiving	
Information requirement	Dermal absorption
Justification	Studies on the dermal absorption of the active substance of the biocidal product have not been conducted. A read-across to the dermal absorption values in the List of End Points (0.1% for concentrated products and 2% for dilutions) was proposed. These values were established from toxicology studies in which a water-based formulation, containing approx. 50% active substance, and a 1000-fold aqueous dilution (approx. 0.05% active substance) were tested. These values were considered worst-case estimated for the active substance approval representative product (a granular product containing 1% spinosad). However, against the background that there is a new guidance for skin absorption, where extrapolation of dermal absorption values between different formulation types is difficult and considering that the exact composition of the reference formulation is not known to the applicant, in the calculation for the biocidal product the default value for dermal absorption of gel formulations 70% is considered.

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

No potential substances of concern that require evaluation have been identified. Since the toxicological properties and human health hazard classification of the biocidal product can be predicted from the known properties of the active substance and information of co-formulants, additional toxicological studies with the biocidal product are not justified.

Available toxicological data relating to a mixture

Not applicable.

Other

None.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance from the use of the biocidal product are listed below. No substances of concern are identified for human health.

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	n.a.	n.r.	n.a.	n.a.	n.r.	n.r.
Dermal	n.a.	n.a.	n.r.	n.a.	n.a.	yes	n.r.
Oral	n.a.	n.a.	n.r.	n.a.	n.a.	yes	n.r.

n.a. not applicable
n.r. not relevant

Inhalation exposure:
Inhalation exposure to gaseous releases of the active substance is not considered to be relevant, as the active substance reveals low vapour pressures at room temperature (spinosyn A=3 x 10^{-8} Pa at 25°C; spinosyn D=2 x 10^{-8} Pa at 25°C). Formation of aerosols (fine liquid droplets or fine solid particles) is not considered to be relevant, as the biocidal product (10 g gel formulation per box, η at 25°C: 24.7 mPa*s) is soaked onto a fibre tamponade in a ready-to-use bait box. The openings of the bait box are small limiting any significant potential for aerosol release (4 openings, ellipse shaped with the following dimensions: 11.04 mm x 3.75 mm).

Dermal exposure:
The bait box is robust and nearly fully closed. The biocidal product (liquid gel formulation) is soaked onto a fibre tamponade and considered to be significantly immobilised via this measure. To demonstrate that the formulation is not dropping out of the bait box, the applicant positioned the bait box upside down and upright on a piece of paper. None of the product came out of the bait station after 15 minutes. The tamponade is situated in the middle at the bottom of the box and not in contact with the openings. The openings are small and allow only minor potential for dermal contact of users and general public (4 openings, ellipse shaped with the following dimensions: 11.04 mm x 3.75 mm). The holes are even too small for a toddler's fingertip to get through. There is a distance of nearly 1 cm between the hole and the bottom of the bait station. Due to the distance between tamponade and openings direct dermal contact is even more unlikely. Potential contact with biocidal product is expected to be limited to parts of fingertips only.

Oral exposure:
Oral exposure of adult users and general public are expected to be limited or even not relevant, if the bait box is applied following the use instructions. Considering that fingertips might be exposed and get contaminated, the potential for oral exposure via hand-to-mouth contact cannot be excluded fully. In addition, it should be taken into account that the gel contains a bittering agent to prevent repeated human ingestion of the biocidal product.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Installation of bait stations	Primary exposure Setting up of the ready-to-use bait stations (dermal exposure)	Non-professional user
2.	Post application	Secondary exposure General public being exposed to the product after the setting up of bait stations (dermal, oral exposure)	General public

Industrial exposure

Industrial use is not intended for the biocidal product. Thus, industrial exposure is not foreseen.

Professional exposure

Professional use is not intended for the biocidal product. Thus, professional exposure is not foreseen.

Non-professional exposure

Scenario 1 – Installation of bait stations

Description of Scenario 1
Ameisenköder N is meant for the control of ants. The biocidal product is a liquid gel formulation soaked on a fibre tamponade contained in a ready-to-use bait station. The bait stations are placed indoors or outdoors (around the building). Up to two bait stations are installed per household. They are replaced after 4 weeks, if needed. As the bait stations are ready-to-use any pre-application phases leading to potential exposure like "mixing or loading" or "refilling of bait station" are not applicable. Tasks leading to potential primary exposure are opening and placing the bait station and disposal of stations after use. Use of protective clothing like gloves is not assumed when handling the bait stations.

Discussion and results

The exposure potential for the three exposure routes has been discussed at the top of this section. The semi-quantitative arguments are considered to be sufficient to substantiate the

qualitative estimate of no relevant primary exposure for adult, non-professional users. This conclusion is based on the intrinsic properties of the a.s. and the biocidal product, the design of the bait station and use pattern limiting highly the level of exposure. Nevertheless, quantitative estimates are provided for secondary exposure describing the upper order of magnitude of potential exposure. The levels for adults are considered to cover primary exposure of adults as well and to represent the upper possible level, if human exposure occurs.

Exposure of the general public

Scenario 2 – General public being dermally and orally exposed to the product after application

Description of Scenario 2
Children, toddlers and infants but also adults may be exposed to the product after application. Children, toddlers and infants might try to put their fingers into the bait station leading to potential exposure of parts of the fingertips. Inhalation exposure of active substance is considered to be unlikely referring to the previous sections. Oral exposure might happen via hand-to-mouth transfer.

Discussion and results

As the openings of the bait box are small (4 openings, ellipse shaped with the following dimensions: 11.04 mm x 3.75 mm), it is unlikely that a finger can be pressed deeply into one opening. Exposure of parts of the fingertip is most likely. Furthermore, the biocidal product is soaked on the fibre tamponade revealing limited mobility and potential for transfer.

Quantitative exposure assessment:

Assuming a rectangular shape of the ellipse shaped openings, the dimensions correspond to an area of 0.414 cm^2 (1.104 cm x 0.375 cm). Although the biocidal product is described as gel, it reveals a low viscosity (η at 25°C: 24.7 mPa*s, water at 25°C: 0.891 mPa*s, olive oil at 25°C: ~ 100 mPa*s). Considering the opening of the bait station of 3.75 mm and assuming a droplet-like, semi-circular shape of the deposited liquid on skin, this would result in a radius of approximately 2mm (2 mm corresponds to approximately half of the width of the opening). Higher heights of the film (3mm, 4mm, 5mm, …) are expected to be less likely considering the width of the opening (3.75mm) and the viscosity of the product. Therefore, deposition of a 2 mm thick layer of b.p. on skin in contact with the b.p. is considered to be a conservative estimate. Using these values, the deposited volume on the fingertip results in 0.083 cm^3 (0.414 cm^2 x 0.2 cm) equal to 102.4 mg b.p. (density of b.p.: 1237.3 mg/cm^3 at 25°C).

Considering the biocidal product contains 0.089%w/w a.s, this results in 0.091 mg active substance deposited on skin per event.
Considering the bodyweight of the exposed person, this corresponds to the following external exposure levels on skin:

- 0.011 mg/kg bw/d for infants (8 kg)
- 0.009 mg/kg bw/d for toddlers (10 kg),
- 0.006 mg/kg bw/d for children (15.6 kg, 2-6 years),
- 0.004 mg/kg bw/d, children (23.9 kg, 6-12 years) and
- 0.002 mg/kg bw/d for adults (60 kg).

Assuming one event per day and the whole amount of substance is taken up dermally or orally, the following internal exposures levels are derived for 70% dermal and 50% oral absorption. Oral exposure is expected to happen via hand-to-mouth transfer. As the dermal absorption value (70%) is higher than the oral absorption value (50%)[1], the dermal exposure values corresponds to the reasonable worst case total exposure levels:

Population (body weight, age)*	Dermal exposure 70% absorption [mg/kg bw/d]	Oral exposure 50% absorption [mg/kg bw/d]	Total estimated exposure [mg/kg bw/d]
infants (8 kg)	7.7E-03	5.5E-03	7.7E-03
toddlers (10 kg)	6.3E-03	4.5E-03	6.3E-03
children (15.6 kg, 2-6 years)	4.2E-03	2.9E-03	4.2E-03
children (23.9 kg, 6-12 years)	2.8E-03	1.9E-03	2.8E-03
adults (60 kg)	1.4E-03	7.6E-04	1.4E-03

*Bodyweights and ages taken from ECHA 2017d

Combined scenarios

Since the dermal exposure of the general public to the biocidal product formulation is considered to be unlikely no combined scenarios are assessed.

Combined scenarios

Since the oral exposure of the general public to the biocidal product formulation is considered to be unlikely no combined scenarios are assessed.

[1] The oral absorption value of 50% is taken from the CAR of the active substance spinosad (NL, 2010)

Monitoring data

Not available.

Dietary exposure

The biocidal product will be applied indoors and outdoors near ant runs or nests. The product will not get in contact with food and feeding stuff. Also, the product formulation is applied on a fibre tamponade and enclosed within a bait station which further minimizes the risk of food and feeding stuff to get contaminated. Dietary exposure is not relevant.

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

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

Aggregated exposure

Aggregated exposure is not relevant.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELmedium-term	subchronic (90 days) oral study, dogs	4.89 mg/kg bw/day	100	50%	0.024 mg/kg bw/day
AELlong-term	2-year oral study, rats	2.4 mg/kg bw/day	100	50%	0.0012 mg/kg bw/day
ADI	24 month rats	2.5 mg/kg bw/day	100	--	0.024 mg/kg bw/day

AEL acute not necessary (no acute effects). In case of acute exposure the medium-term AEL is used. The drinking water limit is 0.1 µg/L according to Document 8064/VI/79 of the European Commission, the EU drinking water limit for pesticides of 0.1 µg/L is applicable for spinosad (NL, 2010).

The active substance spinosad is also authorised for the use in plant protections products. The MRLs in the product type - FRUITS, FRESH or FROZEN; TREE NUTS - range from 0,02 to 60 mg/kg bw (Annexes II Regulation (EC) No 396/2005). Details on MRLs are provided at the EU pesticide database (link: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database)

Risk for industrial users

The biocidal product is not intended to be used by industrial users. Thus, the risk for industrial users is not relevant.

Risk for professional users

The biocidal product is not intended to be used by professional users. Thus, the risk for professional user is not relevant.

Risk for non-professional users

The product is a ready-to-use bait box against ants which contains a fibre tamponade with the product formulation. Primary exposure of non-professional users is not considered to be relevant as described in the corresponding human exposure section. Low potential for human exposure exists during the opening and placing the bait station and disposal of station after use. Conservative quantitative exposure level estimates are provided for secondary exposure (see below) describing the upper order of magnitude of potential exposure to active substance released from the bait station. The primary exposure levels are not expected to exceed the exposure levels for secondary exposure. Based on qualitative and semi-quantitative estimations, the exposure due to the use of such bait stations is considered to be not relevant.

Risk for the general public

After application children, toddlers and infants but also adults may be exposed to the active substance. Children, toddlers and infants might try to put their fingers into/onto openings of the the bait station leading to potential exposure of parts of the fingertips. Also for adults a dermal exposure scenario dipping the finger on the opening is considered.

Inhalation exposure of active substance is considered to be unlikely referring to the previous sections. Oral exposure might happen via hand-to-mouth transfer.

For risk characterisation, it is considered that the amount of active substance deposited on the fingertip is either taken up fully via the dermal or oral route. Total dermal uptake (in contradiction to full or partial oral uptake) results in the highest internal exposure levels, as dermal absorption is assumed with 70% as a default value, whereas 50% oral absorption is anticipated[1]. These levels are taken forward for risk characterisation for toddlers, infants, children and adults.

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

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 2: General public being dermally and orally exposed to the product after application						
infants (8 kg)	1	4.89	0.024	7.7E-03	32%	yes
toddlers (10 kg)	1	4.89	0.024	6.3E-03	26%	yes
children (15.6 kg, 2-6 years)	1	4.89	0.024	4,2E-03	18%	yes
children (23.9 kg, 6-12 years)	1	4.89	0.024	2,8E-03	12%	yes
adults (60 kg)	1	4.89	0.024	1,4E-03	6%	yes

No unacceptable risk is expected; the risk ratios are below 1.

It needs to be considered, that for risk characterisation, only one exposure event per day (finger-tipping on the opening) is considered. Referring to the exposure scenario description, it is assumed that a film of active substance remains on the skin, when the fingertip is pressed on the opening, although direct contact between finger and treated tamponade should not be possible because of the design of the box- preventing the potential for dermal transfer. Therefore, the assumption of a single event per day is still considered to be conservative and to cover even several events per day, when the fingertip is pressed on the openings, but without any direct contact between skin and tamponade as intended.

Nevertheless, as the bait station contains a high amount of a.s. and represents a potential source of poising for children independent from the likeliness of exposure, the provided N-224 sentence (Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals applies) address this remaining concern.

For adults the risk ratio (0.06) is low and more than one event (up to 17 events) would still lead to acceptable risk. For adults no risk is anticipated having dermal contact to the opening of the bait box.

Risk for consumers via residues in food

The biocidal product will be placed near ant runs and nests in around the houses of non-professional users. The product will not get into contact with food or feeding stuff. Also, the product formulation is contained in the bait station on a fibre tamponade which further minimizes the risk of contamination of food and feeding stuff. Contamination of foodstuff is highly unlikely, but for precautionary reasons following instruction of use is considered: Place bait stations away from food, drink and feed, as well as from utensils or surfaces that have contact with these

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

Not relevant.

2.2.7 Risk assessment for animal health

Non-target animals such as companion animals (e.g. kittens and puppies) are not likely to come into contact with the biocidal product. The product marketed is a ready-to-use bait station containing the gel bait on a fibre tamponade, so there should be little opportunity for companion animals to access the gel bait. Also, the gel contains a bittering agent to deter the ingestion of the bait.
Nevertheless following RMM is set: Place bait stations away from food, drink and feed, as well as from utensils or surfaces that have contact with these.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The toxicity of the biocidal product can be predicted from the information available for the active substance spinosad and the other components of the formulation. The risk for the environment is driven by the active substance and the identified substance of concern BIT (for further details please refer to the confidential Annex).

The PNECs for spinosad and its relevant metabolites are available from the CAR (Netherlands 2010).
However, during product authorisation of another biocidal product containing spinosad as active substance DE and FR revealed minor mistakes in the PNEC conversion from dry weight to wet weight for sediment and in the $PNEC_{EP}$ calculation for soil. As up to now no updated CAR with the corrected PNEC values is available on the ECHA dissemination website, we discuss the calculation of the original PNECs and present the corrected PNECs. The later were used in the RA presented below. AT decided to use the corrected PNEC values since all data needed are available and were chosen for further calculations in the CAR on spinosad PT 18 (Netherlands 2010), which by mistake did not happen.

The **$PNEC_{sediment}$** of **spinosad** for freshwater sediment has been calculated in the CAR (Netherlands 2010) based on the NOEC of 60 µg/kg dwt for *Chironomus riparius*, with an assessment factor of 100. The resulting $PNEC_{sediment}$ was 0.06 µg/kg dwt and thereof erroneously a wet weight PNEC of 0.23 µg/kg was calculated. The correct wet weight PNEC is **0.13 µg/kg wwt**, which was used in the risk assessment.

The **$PNEC_{soil,EP}$** value for **spinosad** was calculated in the CAR (Netherlands 2010) using the equilibrium partitioning method. By mistake wrong input values were used in that calculation, ignoring the arithmetic mean Kp_{soil} of 137.6 L/kg, which was chosen for further calculations in Doc. IIA to the CAR. The $PNECs_{soil,EP}$ presented was 2.27 µg/kg wwt.
Based on the correct Kp_{soil} of 41.3 L/kg a $PNEC_{soil,EP}$ of **7.53 µg/kg wwt** was calculated, which was used in the RA.
For the **metabolites (spinosyn B and N-demethylated spinosyn D)** in Doc. IIA to the CAR (Netherlands 2010) $PNEC_{soil,EP}$ values of 1.43 and 0.35 µg/kg wwt were presented.
On basis of a corrected arithmetic mean Kp_{soil} soil value of 51.4 L/kg for both substances $PNEC_{soil,EP}$ values of **4.32 µg/kg wwt for spinosyn B** and **1.05 µg/kg wwt for N-demethylated spinosyn D** were calculated, which were used in the risk assessment below.

The following PNECs for the active substance spinosad were used in the environmental risk assessment:

	Spinosad	Spinosyn B	Spinosyn D
PNECsurface water	6.2E-05 mg/L	-	-
PNEC sediment	1.3E-04 mg/kg_{wwt}	-	-
PNEC STP	10 mg/L	-	-
PNEC soil	7.53E-03 mg/kg_{wwt}	4.32E-03 mg/kg_{wwt}	1.05E-03 mg/kg_{wwt}

PNECoral bird (primary and secondary poisoning)	18.3 mg/kg feed or 2.2 mg/kg bw/d	-	-
PNECoral mammal (primary and secondary poisoning)	3.33 mg/kg feed or 0.33 mg/kg bw/d	-	-

Secondary poisoining spinosad

Due to the reported log KoW of 4.01 at pH 7 for spinosyn A, 4.53 for spinosyn D and the highest BCF of 115 L/kg (Netherlands 2010) there is a potential for bioaccumulation via the food chain.

Bees

In the CAR for spinosad (Netherlands 2010) toxicity data for honeybees with an acute $LD50_{oral}$ of 0.163 µg/bee and an $LD50_{contact}$ of 0.02 µg/bee were reported.
As the product is also used outdoor and since the $LD50_{contact}$ for honeybees for spinosad is below the discussed and agreed threshold of 11 µg/bee (for further details refer to the final minutes of ENV WG-III 2021) the warning sentence "This biocidal product contains spinosad which is dangerous to bees" (in line with CA-Dec20-Doc.4.1) will be included in the SPC. The warning sentence is an interim solution until the ECHA guidance for bees becomes available.

SoC BIT

The risk for the STP was quantitatively assessed (refer to 2.2.8.3 risk characterisation). The other environmental compartments were qualitatively assessed (refer to confidential annex).

The following PNECs were reported in the CAR for BIT (Spain 2022):

	BIT
PNECsurface water	2.6E-03 mg/L
PNEC sediment	1.32E-02 mg/kg_{wwt}
PNEC STP	5.5E-02 mg/L
PNEC soil	3.3E-01 mg/kg_{wwt} (indirect exposure via sludge application and direct application without degradation) 4.3E-03 mg/kg_{wwt} (direct exposure to soil with degradation)

Secondary poisoning BIT

Due to the reported low log KoW of 0.7 and very low BCF of 6.96L/kg for BIT (Spain 2022) the potential for bioaccumulation via the food chain can be regarded as negligible.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

There is no harmonised classification for spinosad yet available. The proposed classification of the active substance spinosad (Netherlands, 2010) in accordance with Regulation (EC) No. 1272/2008 is Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) (M=10). The identified SoC and all other co-formulants in the biocidal product do not contribute to the overall classification of the biocidal product. Based on the concentration of the active substance of 0.089% (w/w) the biocidal product is classified as Aquatic Chronic 3, H412: Harmful to aquatic life with long lasting effects including the precautionary statements P273 and P501.

Further Ecotoxicological studies

No further ecotoxicology data were submitted.

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

No further ecotoxicology data were submitted.

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

No further ecotoxicology data were submitted.

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

No further ecotoxicology data were submitted.

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

No further ecotoxicology data were submitted.

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

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

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

No new data were submitted, neither for the active substances nor for the biocidal product.

Leaching behaviour (ADS)

Not relevant.

Testing for distribution and dissipation in soil (ADS)

No further testing on distribution and dissipation has been conducted for the biocidal product.

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

No further testing on distribution and dissipation has been conducted for the biocidal product.

Testing for distribution and dissipation in air (ADS)

No further testing on distribution and dissipation has been conducted for the biocidal product.

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

No further ecotoxicology data were submitted. The product is used in a bait station.

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

No further ecotoxicology data were submitted. The product is used in a bait station.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios*	Scenario [1]: Direct emission to soil following outdoor application of the biocidal product on hard surfaces like terraces Scenario [2]: Release to STP following outdoor application of the biocidal product on hard surfaces like terraces
ESD(s) used	OECD 2008: Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses. OECD series on Emission scenario documents, number 18; ENV/JM/MONO(2008)14; 17-Jul-2008 ECHA 2021: Technical Agreements for Biocides Environment (ENV), Release date: 9 November 2021
Approach	Average consumption
Distribution in the environment	Calculated in EUSES 2.1.2
Groundwater simulation	Groundwater assessment is performed on pore water concentrations
Confidential Annexes	NO
Life cycle steps assessed	Scenarios [1] and [2]: Production: No Formulation No Use: Yes Service life: No
Remarks	none

** The ESD for PT 18 assumes that emission of the active substance after indoor application in bait boxes is negligible. Therefore releases arising from indoor use have not been considered further.*

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

The environmental exposure to spinosad is assessed for the use of the biocidal product as an insecticide (product type 18) for the non-professional use against ant infestation in and around buildings, in locations such as balconies and terraces. The co-formulant 1,2-Benzisothiazol-3(2H)-on (BIT) is a substance of environmental concern due to the fact that the $PNEC_{STP}$ is lower than then the one of the active substance spinosad. Therefore the provided environmental exposure assessment has been performed for the active substance spinosad and the co-formulant BIT.

It is important to note that spinosad is a naturally derived bacterial fermentation product containing a mixture of two structurally similar molecules which are both active insecticides and have been designated spinosyn A and spinosyn D. The Competent Authority Report for spinosad establishes that spinosad generally contains spinosyn A and spinosyn D in a ratio of 85:15(w/w). Amounts of spinosyn A and spinosyn D are calculated assuming this ratio. In addition PECs for the terrestrial compartment for the two identified relevant metabolites of spinosyn A and spinosyn D, spinosyn B and N demethylated spinosyn D, are calculated assuming complete formation from their relevant parent factors.
For the identified substance of concern BIT only the risk for the STP was quantitatively assessed in this part of the report, for the other environmental compartments a qualitative assessment was performed (for further details refer to the confidential annex). Due to low log Kow of 0.7 and very low BCF of 6.96 L/kg (Spain, 2022) the potential for bioaccumulation of BIT via the food chain can be regarded as negligible. Therefore, primary and secondary poisoning of non-target organisms is considered not applicable and no assessment is performed.

Emission estimation

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

The ESD for PT (OECD 2008) covers the following life-cycle steps as being potentially relevant for environmental emissions:

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

For the biocidal product Ameisenköder N indoor and outdoor use by non-professional users in and around their houses on hard surfaces like terraces is intended. It is an insecticidal product in the form of ready-to-use bait boxes. The bait boxes will be placed in or near the ant runs when applied indoor and near the nest or the ant runs when applied outdoors. Maximum two bait stations shall be applied per 15 m².

Information regarding environmental exposure during mixing/loading of biocidal product
For this product there is no preparation step (as the stations are provided "ready-to-use").

Information regarding environmental exposure during use and wash-off from treated surfaces by weathering.

Indoor application:
The ESD for PT 18 states that for ready-to-use bait boxes emissions to the environment during the treatment are negligible (OECD 2008). No emission model is proposed in the ESD for indoor use.

Outdoor application:
The use of insecticides on paved surfaces in rural or urban area leads to different assumptions:

- Rural area (Scenario [1]): In rural area; it is considered that possible run-off and wash-off though rainwater go into the soil. Soil as primarily exposed environmental compartment is followed by groundwater as secondarily affected compartment.
- Urban area (Scenario [2]): In urban area possible run-off and wash-off though rainwater will be added to the concentration in STP. With STP as primarily exposed environmental compartment, surface water and groundwater are secondarily exposed after passing the STP. The sewage sludge sometimes is distributed on the arable farmland; therefore agricultural soil is stated as secondarily exposed compartment.

Release to air is potentially possible, but considered in the ESD as negligible. Furthermore, spinosad has a vapour pressure between 2.0 to 3.0×10^{-8} Pa (for spinosyn A and spinosyn D) and therefore is considered a non-volatile substance.

In the ESD it is further assumed that 80% of the product are consumed by the insects, whereas 20% of the product remain in the bait station and can be emitted to the environment. In line with the Technical Agreement for Biocides (TAB) (ECHA 2021) the 80% of a product taken up by ants are not considered in this assessment.

Information regarding environmental exposure during cleaning step
The product in the bait stations is not exposed to cleaning, neither wet nor dry method (OECD 2008), therefore, there is no emission to soil or sewage treatment plant and secondary environmental compartments such as surface water or soil/groundwater.

Scenario [1]: Direct emission to soil following outdoor application of the biocidal product on hard surfaces like terraces

A scenario under the name "spot application" is proposed in the ESD for PT 18 (OECD 2008), chapter 4.4.5, which is meant to cover a variety of situations in which local applications of insecticides (gel, powder, bait station…) are used on insect paths or nests.
It is indicated that local soil is the primary compartment for emission of insecticides from outdoor bait boxes and two emissions pathways can be considered: (i) direct exposure of soil as a result of flooding bait boxes on hard surfaces like treated terraces (ii) targeted spot applications to bare soil.
However, the bait stations must not be placed on bare soil but on hard surfaces such as terraces which are usually covered with cobblestones or something similar. Therefore releases arising from targeted spot applications to bare soil have not been considered further.

The number of bait boxes used during treatment on terraces is indicated by the applicant with 1 or 2 boxes (each 10 g product) placed per 15 m² depending on the level of ant pressure. The Technical Agreement for Biocides (TAB, ENV 154; ECHA, 2021) recommends that a default value of 4 bait boxes should be used on one terrace per house if no data on

the application is provided by the applicant, substantiated with efficacy tests. Therefore, the assessment was conducted for both cases, two and 4 boxes.
The ESD further establishes that about 80% of the product is consumed by the target pests whereas 20% may be left in the bait station and can be emitted into soil.

Input parameters for calculating the direct emission to soil as a result of flooding bait boxes on treated terraces				
Input		**Value**	**Unit**	**S/D/O* Origin**
Amount of product in one bait box	Q_{prod}	10	g	S
Fraction of active substance in product	F_{AI}	0.00089	-	S
Number of application sites	N_{sites}	2	-	S
Number of applications per site[a]	N_{appl}	1-2	-	S
Fraction emitted during outdoor bait application	$F_{spot,bait}$	0.2	-	D
*Set, Default, Output				

[a]1-2 bait stations per 15 m²

Calculations for Scenario [1]
The following model (OECD 2008; equation 58) was used to calculate the emission to soil:

$$E_{spot,soil} = Q_{prod} \times F_{AI} \times N_{sites} \times N_{appl} \times F_{spot,bait}$$

$$E_{spot,soil} = 10\ g \times 0.00089 \times 2 \times 1 \times 0.2$$

Using the emission model, the direct emission rate of active substance to soil from a campaign was calculated to be:

$$E_{spot,soil} = 0.0036\ g$$

A typical terrace could be assumed to have an area up to 30 m^2 (ECHA 2021; ENV 154). Although the placement of 2 bait stations is intended by the applicant, calculations for a default value of four bait stations (2 bait stations per 15 m²) is also presented.

Considering the equation above, emission from 4 bait stations would be:

$$E_{spot,soil} = 10\ g \times 0.00089 \times 2 \times 2 \times 0.2$$

$$E_{spot,soil\ (4\ bait\ stations)} = 0.0071\ g$$

Resulting local emission to soil				
Parameters		**Value**	**Unit**	**Remarks**
Direct emission rate of active ingredient to soil from a campaign	$E_{spot,soil}$	3.6	mg	
Direct emission rate of active ingredient to soil from from 4 bait stations	$E_{spot,soil\ (4\ bait\ stations)}$	7.1	mg	

Scenario [2]: Release to STP following outdoor application of the biocidal product on hard surfaces like terraces

Environmental exposure following bait boxes use outdoor on hard surfaces like terraces may arise due to flooding events which could wash out the active substance (e.g. during a rain event) to a rainwater/sewage system. Releases can then occur to surface water and sediment from STP discharge, to agricultural soil from sludge application and eventually to groundwater.
For the estimation of emissions to sewage systems the emission scenario "spot application" from ESD for PT 18 (OECD 2008), chapter 4.4.5 was used.

The number of bait boxes used during treatment on terraces is indicated by the applicant with 1 or 2 boxes (each 10 g product) placed on one terrace per house depending on the level of ant pressure. The Technical Agreement for Biocides (TAB, ENV 154; ECHA, 2021) recommends that a default value of 4 bait boxes should be used if no data on the application is provided by the applicant, substantiated with efficacy tests. Therefore, the assessment was conducted for both cases, 2 and 4 boxes.
The ESD further establishes that about 80% of the product is consumed by the target pests whereas 20% may be left in the bait station and can be emitted into the STP. The ESD also outlines that the simultaneity factor to be used will be 0.03 for outdoor uses. As the application frequency is not expected to be more than once every 3 weeks during season of ant activity, the simultaneity factor could be refined to 0.00815 (adapted for a number of applications between 3 to 11 times a year). Following the Technical Agreement for Biocides (ECHA 2021) the number of houses per STP (N house) was assumed to be 2500 for outdoor use.

Input parameters for calculating the local emission to STP as a result of flooding bait boxes					
Input		**Value**		**Unit**	**S/D/O* Origin**
		Spinosad	**BIT**		
Amount of product in one bait box	Q_{prod}	10		g	S
Fraction of active substance in product	F_{AI}	0.00089	0.00002	-	S
Number of application sites	N_{sites}	2		-	S
Number of applications per site[a]	N_{appl}	1-2		-	S
Fraction emitted during outdoor bait application	$F_{spot,bait}$	0.2		-	D
Number of houses connected to the STP	N_{house}	2500		-	D
Simultaneity factor	$F_{simultaneity}$	0.00815		-	D
*Set, Default, Output					

[a] 1-2 bait stations per 15 m²

Calculations for Scenario [2]
The following model (OECD 2008; equation 58) was used to calculate the emission to STP:

$$E_{spot,water} = Q_{prod} \times F_{AI} \times N_{sites} \times N_{appl} \times F_{spot,bait}$$

The total emissions to the STP from all households within the STP catchment are then calculated according to the following equation:

$$Elocal_{water} = E_{spot,water} \times F_{simultaneity} \times N_{house}$$

Using these equations combined the emissions to water soil from a campaign were calculated as follows:

$Elocal_{water,spinosad}$ = (10 g x 0.00089 x 2 x 1 x 0.2) x 0.00815 x 2500 = 0.0725 g/d
$Elocal_{water, BIT}$ = (10 g x 0.00002 x 2 x 1 x 0.2) x 0.00815 x 2500 = 0.00163 g/d

As a typical terrace could be assumed to have an area up to 30 m^2 (ECHA 2021; ENV 154). Although the placement of 2 bait stations is intended by the applicant, calculations for a default value of four bait stations (2 bait stations per 15 m^2) is also presented.

Considering the equation above, emission from 4 bait stations would be:

$Elocal_{water,spinosad\ (4\ bait\ stations)}$ = (10 g x 0.00089 x 2 x 2 x 0.2) x 0.00815 x 2500 = 0.145g/d
$Elocal_{water,BIT\ (4\ bait\ stations)}$ = (10 g x 0.00002 x 2 x 2 x 0.2) x 0.00815 x 2500 = 0.0033 g/d

The relative quantities of spinosyn A and spinosyn D emitted to the STP were determined based on the 85:15w/w ratio specified above.

Resulting local emission to STP				
Parameters		**Value**	**Unit**	**Remarks**
from a campaign				
Local emission rate to wastewater – spinosad	$Elocal_{water}$	72.5	mg/d	
Local emission rate to wastewater – spinosyn A	$Elocal_{water}$	61.6	mg/d	Value is 85% of the previously calculated emission of spinosad to wastewater (i.e. 0.85 x 72.5 mg/d)
Local emission rate to wastewater – spinosyn D	$Elocal_{water}$	10.9	mg/d	Value is 15% of the previously calculated emission of spinosad to wastewater (i.e. 0.15 x 72.5 mg/d)
Local emission rate to wastewater – BIT	$Elocal_{water}$	1.6	mg/d	

Resulting local emission to STP				
Parameters		**Value**	**Unit**	**Remarks**
from 4 bait stations				
Local emission rate to wastewater – spinosad	$Elocal_{water}$ (4 bait stations)	145.1	mg/d	
Local emission rate to wastewater – spinosyn A	$Elocal_{water}$ (4 bait stations)	123.3	mg/d	Value is 85% of the previously calculated emission of spinosad to wastewater (i.e. 0.85 x 145.1 mg/d)
Local emission rate to wastewater – spinosyn D	$Elocal_{water}$ (4 bait stations)	21.7	mg/d	Value is 15% of the previously calculated emission of spinosad to wastewater (i.e. 0.15 x 145.1 mg/d)
Local emission rate to wastewater – BIT	$Elocal_{water}$ (4 bait stations)	3.3	mg/d	

Fate and distribution in exposed environmental compartments

The biocidal product is a ready-to-use bait box. No mixing and loading steps are considered. Also, there is no spillage during setting of insecticide in a bait box. Release during the treatment may occur following flooding from a rain event (EST PT for 18; OECD 2008).

Identification of relevant receiving compartments based on the exposure pathway							
	Fresh-water	Freshwater sediment	STP	Air	Soil	Ground-water	Primary and secondary poisoning
Rural area (Scenario [1])	-	-	-	yes$^{(Q)}$	yes^{++}	yes^{+}	(secondary poisoning)
Urban area (Scenario [2])	yes^{+}	yes^{+}	yes^{++}	yes$^{(Q)}$	yes^{+}	yes^{+}	(secondary poisoning)

$^{++}$ Compartment directly exposed, $^{+}$ Compartment indirectly exposed, - Compartment not exposed, $^{(Q)}$ Qualitative assessment, depending on application or substance-specific properties

Input parameters for calculating the fate and distribution in the environment*			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	A: 731.98 D: 746 B: 718 N: 732 BIT: 151.18	g/mol	A = Spinosyn A D = Spinosyn D B = Spinosyn B N = N demethylated Spinosyn D BIT = 1,2-Benzisothiazol-3(2H)-one
Melting point	A: 84 D: 161.5 BIT: 160	°C	
Vapour pressure (at 25°C)	A: $3x10^{-8}$ D: $2x10^{-8}$ BIT: $1.1x10^{-4}$	Pa	
Water solubility (at 20°C)	A: 89.4 D: 0.495 BIT: 1200	mg/L	
Log octanol/water partition coefficient	A: 3.91 D: 4.38 BIT: 0.7	Log 10	
Organic carbon/water partition coefficient (Koc)	35024** BIT: 197.87	L/kg	It is assumed that Spinosyn D has sorption characteristics equal to Spinosyn A BIT = 1,2-Benzisothiazol-3(2H)-one
Henry's Law Constant (at 25°C)	A: $1.89x10^{-7}$ D: $2.32x10^{-5}$ BIT: $1.45x10^{-5}$	$Pa/m^3/mol$	A = Spinosyn A D = Spinosyn D B = Spinosyn B N = N demethylated Spinosyn D BIT = 1,2-Benzisothiazol-3(2H)-one
Biodegradability***	persistent		
Bioconcentration factor for earthworms	A: 98 D: 229	L/kg_{ww}	
Bioconcentration factor for fish	A: 114 D: 115	L/kg_{ww}	

**Endpoints are taken from the Assessment Report for spinosad, Product Type 18, May 2010 (Netherlands, 2010) and for 1,2-BENZISOTHIAZOL-3-(2H)-ONE (BIT), Product Type 18, February 2022 (Spain, 2022), respectively.*

***The LoEP of the Assessment Report for spinosad gives a $K_{oc,}$ but this value is not used in the assessment of the leaching potential. The arithmetic mean K_F 137.6 L/kg (=Kp_{soil}) of spinosyn A and the arithmetic mean K_F 51.4 L/kg (=Kp_{soil}) of spinosyn B also presented in the LoEP are used in the risk assessment.*

****Specific degradation DT_{50} values in soil, water and air as presented in the CAR were not included. Based on these data spinosad fulfils the criteria for being P according to Annex XIII of Reg. (EC) No 1907/2006. Therefore a worst-case assessment was assumed.*

The elimination of spinosad in the environment after release to the sewer system was simulated using SimpleTreat module of EUSES 2.1.2. Output reports concerning the release pathway via sewage treatment plant (STP) are reported in Annex 3 under chapter 3.2.1

Environmental Exposure Assessment. The distribution in the STP is summarised in the following table:

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
	Spinosyn	
Air	A: 3.12×10^{-8} D: 3.83×10^{-6}	Source: Calculated by SimpleTreat module of EUSES 2.1.2 A = Spinosyn A D = Spinosyn D
Water	23.8	
Sludge	76.2	
Degraded in STP	0	

Calculated PEC values

PEC for the aquatic compartment (incl. sediment)

According to the ESD for PT 18 (OECD 2008) emissions to the STP resulting from indoor uses are not considered likely as bait stations will be committed to solid waste following use and are not designed to be opened or rinsed in any way. Consequently, indoor emissions to the STP are not considered.
The ESD states that the primary potential receiving compartments for outdoor use of bait stations (on patios or terraces) are local soil and groundwater. Emissions to surface water, sediment, and the wastewater treatment plant (STP) are considered negligible for outdoor use due to the limited scale and scope of bait stations. However, a risk assessment has been run for flood driven emissions to the STP resulting from outdoor uses.
The calculation of emissions to sewer systems are discussed in chapter "Emission estimation" of this document. A short summary of the resulting local emission to the STP are summarised here:

Resulting local emission to sewer system following bait boxes use outdoor on hard surfaces like terraces			
Parameters	**Value**	**Unit**	**Remarks**
from a campaign (2 bait stations)			
Local emission rate to wastewater – spinosyn A	6.16×10^{-5}	kg/d	Value is 85% of the previously calculated emission of spinosad to wastewater (i.e. 0.85 x 72.5 mg/d)
Local emission rate to wastewater – spinosyn D	1.09×10^{-5}	kg/d	Value is 15% of the previously calculated emission of spinosad to wastewater (i.e. 0.15 x 72.5 mg/d)
Local emission rate to wastewater – BIT	1.6×10^{-6}	kg/d	
from 4 bait stations			
Local emission rate to wastewater – spinosyn A	1.233×10^{-4}	kg/d	Value is 85% of the previously calculated emission of spinosad to wastewater (i.e. 0.85 x 145.1 mg/d)
Local emission rate to wastewater – spinosyn D	2.17×10^{-5}	kg/d	Value is 15% of the previously calculated emission of spinosad to wastewater (i.e. 0.15 x 145.1 mg/d)
Local emission rate to wastewater – BIT	3.3×10^{-6}	kg/d	

The values spinosyn A and spinosyn D were entered into EUSES 2.1.2 as the "local emission rate to wastewater" ($Elocal_{water}$) along with the physicochemical properties of the substance

to determine the PEC_{STP} and subsequently the predicted environmental concentrations in freshwater, sediment, soil (after sewage sludge application) and groundwater.
The PECs for spinosyn A and spinosyn D were calculated separately to allow for a more accurate determination of the potential concentrations of the constituents in the environment. The PECs of spinosyn A and spinosyn D presented by EUSES 2.1.2 were also summed to give PECs for spinosad.

In water/sediment studies of spinosad, no major metabolites were formed in the water phase. Therefore, no assessment for metabolites needs to be provided for the aquatic compartment.

EUSES Output reports on the release pathway via STP are presented in Annex 3 under Chapter 3.2.1 Environmental Exposure Assessment. A summary of the predicted environmental concentrations in wastewater treatment plants, surface water, and sediment is located later in this chapter under the heading "Summary table on calculated PEC values".

In addition, predicted environmental concentrations in the STP are calculated for the substance of concern contained in the biocidal product (the biocidal active ingredient 1,2-benzisothiazol-3(2H)-one (BIT)). The input parameters necessary for calculation are taken from the assessment report for BIT and the PEC_{STP} is calculated in line with the Equations 35, 36 and 41 of the Guidance on BPR Vol IV Part B+C:

$$Clocal_{inf} = Elocal_{water} \times 10^6 / EFFLUENT_{stp}$$
$$Clocal_{eff} = Clocal_{inf} \times F_{stp,water}$$
$$PEC_{stp} = Clocal_{,eff}$$

The fraction of emission directed to water by STP is reported as 30.88 % (Spain 2022) and for the effluent discharge rate of STP a default value of $2x10^6$ l/d is recommended (ECHA 2017a)

Thus PEC_{stp} becomes:

$PEC_{STP,BIT\ (2\ bait\ stations)}$ = $(1.6x10^{-6}$ kg/d x 10^6 / $2x10^6$ l/d) x 0.3088= **$2.47x10^{-7}$ mg/L**
$PEC_{STP,BIT\ (4\ bait\ stations)}$ = $(3.3x10^{-6}$ kg/d x 10^6 / $2x10^6$ l/d) x 0.3088= **$5.10x10^{-7}$ mg/L**

PEC for the terrestrial compartment (incl. groundwater)

Indirect exposure via sludge application
The application of sewage sludge from the treatment plants onto agricultural and grassland soils results in indirect emissions to soil, and the subsequent leaching of the active substance through the soil results in indirect emissions to groundwater. The PECs of spinosyn A and spinosyn D in the soils and ground water were determined using EUSES 2.1.2 and summed to obtain the PECs for spinosad.

EUSES Output reports on the release pathway via STP are presented in Annex 3 under Chapter 3.2.1 Environmental Exposure Assessment. A summary of the predicted

environmental concentrations in soil and ground water is located later in this chapter under the heading "Summary table on calculated PEC values".

In addition, major metabolites of spinosyn A and spinosyn D were identified. Predicted environmental concentrations of these metabolites, spinosyn B and N-demethylated spinosyn D, were calculated assuming complete formation of metabolite from the corresponding parent, using the molecular weight conversions in the table "Input parameters for calculating the fate and distribution in the environment" above.
The PECs in soil and groundwater for the metabolites are also listed below in the summary table under the heading " Summary table on calculated PEC values."

Direct exposure of soil as a result of flooding bait boxes on treated terraces:
According to use instructions the bait stations must not be placed on bare soil but on hard surfaces such as terraces which are usually covered with cobblestones or something similar. Therefore release arising from targeted spot applications to bare soil have not been considered in this assessment. The terrace scenario for assessment of spot applications on paved surfaces is used.

Equation 60 from the emissions scenario document for PT18 (OECD 2008), Chapter 4.4.5, is used to calculate the local predicted environmental concentration in soil (PEC_{soil} = $C_{spot,soil}$):

$$C_{spot,soil} = \frac{E_{spot,soil}}{AREA_{exposed} \times DEPTH_{soil} \times RHO_{soil}}$$

For bait box application scenarios on terraces, it was agreed in the Technical Agreements for Biocides (ECHA 2021) to assume a default receiving area of 8.5 m^2 (taking into account three sides of a terrace), coupled with the default depth stated in the ESD of 0.5 m. The RHO_{soil} (mass of soil for a given volume) is the ESD default of 1700 kg/m^3ww. Using the above calculated direct emission rates of spinosad to soil (3.6 mg for two bait stations; 7.1 for 4 bait stations), the concentration in the soil around the terrace after direct release can be estimated by the following equation:

$C_{spot,soil\ (2\ bait\ stations)}$ = 3.6 mg / (8.5 m^2 x 0.5m x 1700 kg/m^3)
$C_{spot,soil\ (2\ bait\ stations)}$ = 0.50 µg/kg_{wwt} soil

$C_{spot,soil\ (4\ bait\ stations)}$ = 7.10 mg / (8.5 m^2 x 0.5m x 1700 kg/m^3)
$C_{spot,soil\ (4\ bait\ stations)}$ = 0.98 µg/kg_{wwt} soil

The $C_{spot,soil}$ values stated above should be used for the soil risk assessment for the parent molecule spinosad. For the risk assessment of the metabolites the following should be considered.

Based on the 85:15 ww ratio the above $C_{spot,soil}$ values for spinosad equates to the following soil concentrations for spinosyn A and D:

Spinosyn A:
$C_{spot,soil\ (2\ bait\ stations)}$ = 0.43 µg/kg_{wwt} soil
$C_{spot,soil\ (4\ bait\ stations)}$ = 0.83 µg/kg_{wwt} soil

Spinosyn D:

$C_{spot,soil\ (2\ bait\ stations)}$ = 0.08 µg/kg_{wwt} soil
$C_{spot,soil\ (4\ bait\ stations)}$ = 0.15 µg/kg_{wwt} soil

Assuming complete formation of the relevant metabolites in soil (worst case assumption) and using the molecular weight conversions in table "Input parameters for calculating the fate and distribution in the environment" above the following metabolite concentrations are derived:

Spinosyn B:

$C_{spot,soil\ (2\ bait\ stations)}$ = 0.43 µg/kg_{wwt} soil
$C_{spot,soil\ (4\ bait\ stations)}$ = 0.81 µg/kg_{wwt} soil

Spinosyn D:

$C_{spot,soil\ (2\ bait\ stations)}$ = 0.08 µg/kg_{wwt} soil
$C_{spot,soil\ (4\ bait\ stations)}$ = 0.15 µg/kg_{wwt} soil

The following inconsistencies were noted: In the table 4.3-17 of the ESD for PT 18 it is indicated that emission to groundwater from outdoor application in bait stations occurs but in the text below this emission route is considered negligible.
It was agreed (TAB, ENV 157; ECHA 2021) that for insecticides in bait stations a groundwater assessment should be performed on tier 1 level in order to show that the exposure is negligible. If in the light of experience it is shown that the exposure is not negligible a scenario for a tier 2 assessment should be developed.

To estimate the concentrations in groundwater the soil PECs calculated above have been manually entered into EUSES for Spinosyn A and D and its metabolites. EUSES has then calculated the concentrations in pore water. The PECs in soil and groundwater are reported below in the summary table under the heading " Summary table on calculated PEC values."

PEC in air

In view of the limited volatility of both substances, spinosyn A and D, emissions to the air are regarded to be insignificant. Furthermore the ESD for PT 18 indicates that loss to air from enclosed bait stations is generally considered minimal. As such no emission to air is considered and so PECs in air are not determined.

Summary table on calculated PEC values

Summary table on calculated PEC values								
Main-scenario	**Sub-scenario**		**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
			[mg/L]	[µg/L]	[µg/kg_{wwt}]	[µg/kg_{wwt}]	[µg/L]	
Scenario [1] Rural area	2 bait stations	Spinosyn A	-	-	-	0.43	3.52E-03	has not been predicted
		Spinosyn D				0.08	1.61E-03	
		Spinosad				0.50	5.13E-03	
		Spinosyn B	-	-	-	0.43	9.46E-03	
		N-demethylated Spinosyn D	-	-	-	0.08	1.76E-03	
	4 bait stations	Spinosyn A	-	-	-	0.83	7.05E-03	
		Spinosyn D	-	-	-	0.15	3.20E-03	
		Spinosad	-	-	-	0.98	1.03E-02	
		Spinosyn B	-	-	-	0.81	1.78E-02	
		N-demethylated Spinosyn D	-	-	-	0.15	3.30E-03	
Scenario [2]) Urban area	2 bait stations	1,2-Benzisothiazol-3(2H)-one	2.47E-07	-	-	-	-	
		Spinosyn A	7.34E-06	7.33E-04	2.25E-02	0.86*	7.04E-03*	
		Spinosyn D	5.45E-06	1.30E-04	1.55E-03	0.15*	3.22E-03*	
		Spinosad	1.28E-05	8.63E-04	2.41E-02	1.00*	1.03E-02*	
		Spinosyn B	-	-	-	0.84*	6.90E-03*	
		N-demethylated Spinosyn D				0.14*	3.16E-03*	
	4 bait stations	1,2-Benzisothiazol-3(2H)-one	5.1E-07	-	-	-	-	
		Spinosyn A	1.47E-05	1.47E-03	4.50E-02	1.71*	1.41E-02*	
		Spinosyn D	1.09E-05	2.58E-04	3.09E-03	0.29*	6.41E-03*	
		Spinosad	2.56E-05	1.73E-03	4.81E-02	2.00*	2.05E-02*	
		Spinosyn B	-	-	-	1.67*	1.38E-02*	
		N-demethylated Spinosyn D	-	-	-	0.28*	6.29E-03*	

- Compartment not exposed; *PEC via release to the STP by treatment on hard surfaces

The biocidal product is a ready-to-use bait box used indoors and in private areas around the houses on hard surfaces, e.g. terraces, balconies. Therefore, and in line with the ESD for PT 18 (OECD 2008) emission of the active substance after indoor application are considered negligible and no mixing and loading steps are considered.

Primary and secondary poisoning

The partition coefficient log K_{ow} at 23°C is 4.01 at pH 7 for spinosyn A and 4.53 for spinosyn D (3.91 and 4.38 in un-buffered water for spinosyn A and spinosyn D, respectively). Log K_{ow} values above 3 at pH 7 or higher indicate that bioaccumulation can occur. Furthermore, the highest experimentally determined BCF was 115 L/kg, which is above the trigger value for bioaccumulation potential.
Therefore, for primary and secondary poisoning an assessment is made.

Primary poisoning

Primary poisoning via direct consumption of insecticide by birds or mammals
Primary poisoning is the direct consumption of insecticide by birds or mammals. According to the Emission Scenario Document for PT18 (OECD 2008), it is not believed that powder, gels or any other insecticide are in the form that could be sufficiently appetent to birds and mammals so they would be at risk. In the case of this ant trap, the product is even enclosed in a bait box and also contains a bittering agent to avoid accidental animal feeding. Therefore, primary poisoning of non-target organisms is considered not applicable.

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

Secondary poisoning

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

In consideration of the intended use of the biocidal product the assessment of secondary poisoning via consumption of contaminated worms, fish and insects (ants) is carried out (i.e. calculation of ETE for (1) and (3)). A risk for secondary poisoning by consumption of contaminated vegetation is not considered applicable for insecticides use in bait stations (spot application).

Secondary poisoning via the consumption of contaminated ants:
The Risk Assessment was conducted for the intended use of two bait boxes with 10 g product per 15 m², corresponding to 0.0178 g spinosad/15 m², which can be converted to 1.187×10^{-6} kg spinosad/m² ($=T_{appl}$).

ETE calculation followed ESD PT18, Chapter 5 using the representative species and the proposed data for body weight and FIR.

$$ETE = C \times (FIR/bw) \times AV \times PT \times PD$$

Following parameters were used for the calculation of the daily intake:

Variable/parameter	Symbol	Unit
Concentration of substance in fresh diet	C	mg/kg
Food intake rate of indicator species	FIR	g fresh weight per day
Body weight	bw	g
Avoidance factor	AV	--
Fraction of diet obtained in treated area	PT	--
Fraction of food type in diet	PD	--

with $C = RUD \times T_{appl} \times 10^{-4}$

Following parameters were used for the calculation of substance in the fresh diet:

Variable/parameter	Symbol	Unit
Concentration of substance in fresh diet	C	mg/kg
Residue per unit dose	RUD	mg/kg
Application rate	T_{appl}	kg a.s./m²

Herbivorous species have not been considered since there is no contamination of plants from the use of the biocidal product.

Acute risk

The following table shows ETE calculations for birds and mammals from application of the biocidal product against ants on terraces and on pathways.

Tier 1 acute risk assessment for birds and mammals regarding spinosad after the use of the biocidal product					
Indicator species	**FIR/bw** [g]	**Category**	**RUD (90%)** [mg/kg]	**AV*PD*PT** [-]	**ETE** [mg/kg/d]
Small insectivorous mammal 1	0.68	large insects	14	1.00	1.14×10^{-9}
Small insectivorous mammal 2	0.63	large insects	14	1.00	1.05×10^{-9}
Medium insectivorous mammal	0.18	large insects	14	1.00	3.00×10^{-10}
Large insectivorous mammal	0.18	large insects	14	1.00	3.00×10^{-10}
Small herbivorous mammal	1.39	short grass	142	1.00	--
Medium herbivorous mammal	0.32	leafy crops	87	1.00	--

Small insectivorous bird 1	1.04	small insects	52	1.00	$6.41x10^{-9}$
Small insectivorous bird 2	0.2	small insects	52	1.00	$1.24x10^{-9}$
Medium insectivorous bird	0.44	large insects	14	1.00	$7.32x10^{-10}$
Omnivorous bird	0.2	small insects	14	1.00	$3.32x10^{-10}$
Medium herbivorous bird	0.76	leafy crops	87	1.00	--
Large herbivorous bird	0.44	short grass	142	1.00	--

FIR – food intake rate per unit bodyweight, RUD – residue unit per dose, ETE – estimated theoretical expose, "--" - not calculated because there is no contamination of plants

Short-term risk

The following table shows the ETE calculations for birds and mammals from application of the biocidal product against ants on terraces and on pathways.

Tier 1 short-term risk assessment for birds and mammals regarding spinosad after the use of the biocidal product

Indicator species	**FIR/bw** [g]	**Category**	**RUD (mean)** [mg/kg]	**AV*PD*PT** [-]	**ETE** [mg/kg/d]
Small insectivorous mammal 1	0.68	large insects	5.1	1.00	$4.12x10^{-10}$
Small insectivorous mammal 2	0.63	large insects	5.1	1.00	$3.82x10^{-10}$
Medium insectivorous mammal	0.18	large insects	5.1	1.00	$1.09x10^{-10}$
Large insectivorous mammal	0.18	large insects	5.1	1.00	$1.09x10^{-10}$
Small herbivorous mammal	1.39	short grass	76	1.00	--
Medium herbivorous mammal	0.32	leafy crops	40	1.00	--
Small insectivorous bird 1	1.04	small insects	29	1.00	$3.57x10^{-9}$
Small insectivorous bird 2	0.2	small insects	29	1.00	$6.88x10^{-10}$
Medium insectivorous bird	0.44	large insects	5.1	1.00	$2.66x10^{-10}$
Omnivorous bird	0.2	small insects	5.1	1.00	$1.21x10^{-10}$
Medium herbivorous bird	0.76	leafy crops	40	1.00	--

Tier 1 short-term risk assessment for birds and mammals regarding spinosad after the use of the biocidal product					
Indicator species	**FIR/bw** [g]	**Category**	**RUD (mean)** [mg/kg]	**AV*PD*PT** [-]	**ETE** [mg/kg/d]
Large herbivorous bird	0.44	short grass	76	1.00	--

FIR – food intake rate per unit bodyweight, RUD – residue per unit dose, ETE – estimated theoretical exposure, "--" – not calculated because no contamination of plants

Secondary poisoning via the consumption of contaminated worms
The ESD for PT18 usually calculates the estimated daily exposure (ETE) by the following equation:

$$ETE = C \times (FIR/bw) \times AV \times PT \times PD$$

Parameters for the calculation of the daily intake		
Variable/parameter	**Symbol**	**Unit**
stimated daily exposure	ETE	[mg/kg$_{bw}$/d]
Concentration of the active substance in the diet	C	[mg/kg]
Food intake rate of indicator species	FIR	g fresh weight per day
Body weight of the indicator species	BW	g
avoidance factor	AV	[-]
fraction of diet obtained in treated area	PT	[-]
fraction of the food type in the diet	PD	[-]

In this case C is the concentration in earthworms and as a first estimate (tier 1) avoidance (AV), fraction of diet from treated area (PT) and fraction of food type in diet (PD) are all set at 1.

As the Assessment Report for spinosad (Netherlands 2010) has derived $PNEC_{oral}$ values based on concentrations in food the ETE can be set equal to C_{worm}. A risk assessment can then be carried out by calculating the exposure of birds and mammals who may consume contaminated earthworms as a function of the concentration of spinosad in those earthworms. As a worst case assumption it is considered that birds and mammals would fulfil their complete dietary requirements with contaminated worms (which is a very worst case assumption based on the limited scale of use).

The predicted concentration of residues in earthworms is calculated in line with the Equation 99 and 103c of the Guidance on BPR Vol IV Part B+C (ECHA 2017a):

$$PEC_{oral,predator} = C_{earthworm} = [(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})] \div [1 + (F_{gut} \times CONV_{soil})]$$

For PEC_{soil} worst case estimates of concentrations in the receiving soil compartment after direct and indirect exposure are included. The BCF for earthworms estimated from the log K_{ow} is presented in the Assessment Report for spinosad (Netherlands 2010). The estimated BCF for earthworms is given as 98 L/kg for spinosyn A and 229 L/kg for spinosyn D. For this secondary poisoning risk assessment the higher value of 229 L/kg is used for spinosad itself.

Thus C_{worm} becomes:

Calculation of the predicted environmental concentration in worm			
Parameter	**Definition**	**Value**	
		Exposure via STP	**Direct exposure of soil**
Predicted environmental concentration in soil [mg/kg$_{wwt}$]	PEC_{soil}	2.00×10^{-3}	0.98×10^{-3}
Concentration in porewater [mg/L]	$C_{porewater}$	2.05×10^{-5}	1.03×10^{-5}
Fraction of gut loading in worm [kg$_{dwt}$/kg$_{wwt}$]	F_{gut}	0.1	
Conversion factor for soil concentration wet-dry weight soil [kg$_{wwt}$/kg$_{dwt}$]	$CONV_{soil}$	1.13	
Bioconcentration factor for earthworm on wet weight basis [L/kg$_{wet\ earthworm}$]	$BCF_{earthworm}$	229	
Predicted Environmental Concentaration in earthworm [mg/kg$_{wet\ earthworm}$]	$C_{earthworm} = [(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})] \div [1 + (F_{gut} \times CONV_{soil})]$	4.42×10^{-3}	2.22×10^{-3}

Secondary poisoning via the consumption of contaminated fish

The concentration of contaminant fish of fish-eating predators ($PECoral_{predator}$) is calculated from the BCF for fish and the biomagnification factor (BMF) proposed in the Assessment Report for spinosad (Netherlands 2010).

Calculation of the predicted environmental concentration in fish			
Parameter	**Definition**	**Value**	
		2 bait stations	**4 bait stations**
Predicted environmental concentration of a.s. in surface water [mg/L]	PEC_{water}	8.63×10^{-7}	1.73×10^{-6}
Bioconcentration factor for fish on wet weight basis [L/kg$_{wet\ fish}$]	BCF_{fish}	115	
biomagnification factor in fish [-]	BMF	1	
Predicted Environmental Concentaration of a.s. in fish [mg/kg$_{wet\ fish}$]	$PEC_{oral,\ predator} = PEC_{water} \cdot BCF_{fish} \cdot BMF$	9.93×10^{-5}	19.90×10^{-5}

2.2.8.3 Risk characterisation

SoC BIT:

For the identified SoC BIT a quantitative assessment for the STP was performed, for the other receiving compartments a qualitiative one (refer to confidential annex).

Atmosphere

In the ESD for PT 18 (OECD 2008) it is stated that the release to air from bait stations is considered negligible. Furthermore, spinosad has a reported vapour pressure between 2.0 x 10^{-8} Pa and 3.0 x 10^{-8} Pa and is therefore considered a non-volatile substance (Netherlands 2010).

Conclusion:

The risk through release to the atmosphere for the active spinosad is considered to be negligible.

Sewage treatment plant (STP)

The risk characterisation for the STP was calculated for direct exposure to STP (scenario 2, urban environment). The PNEC for the risk characterisation for spinosad is 10 mg/L and for the SoC BIT 0.055 mg/L (refer to 2.2.8.1 Effect assessment on the environment). The PEC values were taken from the table "Summary table on calculated PEC values".

Summary table on calculated PEC/PNEC values for spinosad and the SoC BIT		
$PEC/PNEC_{STP}$		
	Spinosad	BIT
Urban area (scenario 2) 2 bait stations	1.28E-06	4.49E-06
Urban area (scenario 2) 4 bait stations	2.56E-06	9.27E-06

Conclusion:

The PEC/PNEC ratios for spinosad and the SoC BIT are <1 for the calculated scenario 2 urban area (2 and 4 bait stations) indicating acceptable risk for micro-organisms.

Aquatic compartment

The risk characterisation for the aquatic compartment was calculated for indirect exposure to surface water and sediment representing the urban environment (scenario 2).
The $PNEC_{water}$ and $PNEC_{sed}$ for the risk characterisation are 6.2E-05 mg/L and 1.3E-04 mg/kg_{wwt} respectively (refer to 2.2.8.1 Effect assessment on the environment).
The PEC values were taken from the table "Summary table on calculated PEC values".

Summary table on calculated PEC/PNEC values for spinosad		
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**
Urban area (scenario 2) 2 bait stations	1.39E-02	1.85E-01
Urban area (scenario 2) 4 bait stations	2.79E-02	3.70E-01

Conclusion:
The PEC/PNEC ratios for the aquatic compartment are <1 for the calculated scenario 2 (2 and 4 bait stations) indicating acceptable risk for surface water and sediment dwelling organisms.

Terrestrial compartment

The risk characterisation for the terrestrial compartment was calculated for direct exposure (rural environment) and indirect exposure via sludge application (urban environment). The $PNEC_{soil}$ for the risk characterisation is 7.53E-03 mg/kg wwt for spinosad and 4.32E-03 mg/kg wwt for the metabolites spinosyn B and 1.05E-03 mg/kg wwt for spinosyn D respectively (refer to 2.2.8.1 Effect assessment on the environment). The PEC values were taken from the table "Summary table on calculated PEC values".

Summary table on calculated PEC/PNEC values for spinosad and its relevant metabolites spinosyn B and spinosyn B			
	$PEC/PNEC_{soil}$ (spinosad)	**PEC/PNECsoil (spinosyn B)**	**$PEC/PNEC_{soil}$ (spinosyn D)**
Rural area (scenario 1) 2 bait stations	6.64E-02	9.95E-02	7.62E-02
Rural area (scenario 1) 4 bait stations	1.30E-01	1.88E-01	1.43E-01
Urban area (scenario 2) 2 bait stations	1.33E-01	1.94E-01	1.33E-01

Urban area (scenario 2) 4 bait stations	2.66E-01	3.86E-01	2.67E-01

Conclusion: The resulting PEC/PNEC ratios are <1, indicating acceptable risk for soil organisms.

Groundwater

The PEC values were taken from the table "Summary table on calculated PEC values". The indirect exposure to soil via sludge application (scenario 1, rural environment and scenario 2, urban environment) for spinosad and its relevant metabolites spinosyn B and spinosyn D were assessed. All calculated values are below the generic groundwater limit value of 0.1 µg/L. Hence an acceptable risk for groundwater is demonstrated.

Primary and secondary poisoning

Primary poisoning

Birds and mammals

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

Effects on honeybees (and non-target organisms)

Spinosad was shown to be highly toxic for honeybees with reported LD_{50} values (contact and oral) of 0.057 µg/bee and 0.0036 µg/bee, respectively (Netherlands, 2010).

The product is attractive to honeybees due to its sugar based composition (46%). With respect to the high toxicity of spinosad the mortality of honeybees which consume the biocidal product cannot be excluded.

However the biocidal product is placed in a bait box which is not accessible for bees. Furthermore the bait boxes are placed on hard surfaces which are not attractive to bees and other non-target insects and contains a bittering agent. In order to take into account the risk for honeybees the warning sentence "This biocidal product contains spinosad which is dangerous to bees" (in line with CA-Dec20-Doc.4.1 and agreed discussions at ENV WG-III 2021) will be included as a RMM in the SPC (for further information please refer to 2.2.8.1 Effect assessment on the environment).

Secondary poisoning

Secondary poisoning can occur when contaminated food (ants) and earthworms or fish are eaten up from birds or mammals.

Secondary poisoning by contaminated feed (ants)

The risk ratios for secondary poisoning via the ingestion of contaminated ants were calculated for two small insectivorous birds and mammals, one medium insectivorous mammal and bird and one large insectivorous mammal (acute and short term toxicity).

For the acute toxicity scenario the lowest reported oral acute LD_{50} for birds and mammals in the CAR for spinosad is 2000 mg/kg bw (Netherlands 2010). In order to take into account the interspecific variation for birds and mammals an AF of 3000 was applied (ECHA 2017a).

For the short term scenario the lowest reported NOEC for birds is 66.2 mg/kg bw and for mammals 10 mg/kg bw (Netherlands 2010). In order to take into account the interspecific variation for birds and mammals an AF of 30 was applied (ECHA, 2017a).

Summary table on secondary poisoning via contaminated ants for mammals and birds (acute and short term)				
Scenario	**ETE [mg/kg bw]**	**LD_{50} (acute) NOEC (short term) [mg/kg bw]**	**AF**	**ETE/LD_{50} or NOEC**
acute toxicity (small insectivorous mammal 1)	1.14E-09	2000	3000	1.71E-09
short term toxicity (small insectivorous mammal 1)	4.12E-10	10	30	1.24E-09
acute toxicity (small insectivorous mammal 2)	1.05E-09	2000	3000	1.58E-09
short term toxicity (small insectivorous mammal 2)	3.82E-10	10	30	1.15E-09
acute toxicity (medium insectivorous mammal)	3.00E-10	2000	3000	4.50E-10
short term toxicity (medium insectivorous mammal)	1.09E-10	10	30	3.27E-10
acute toxicity (large insectivorous mammal)	3.00E-10	2000	3000	4.50E-10

short term toxicity (large insectivorous mammal)	1.09E-10	10	30	3.27E-10
acute toxicity (small insectivorous bird 1)	6.41E-09	2000	3000	9.61E-09
short term (small insectivorous bird 1)	3.57E-09	66.2	30	1.62E-09
acute toxicity (small insectivorous bird 2)	1.24E-09	2000	3000	1.86E-09
short term (small insectivorous bird 2)	6.88E-10	66.2	30	3.12E-10
acute toxicity (medium insectivorous bird)	7.32E-10	2000	3000	1.10E-09
short term (medium insectivorous bird)	2.66E-10	66.2	30	1.20E-10
acute toxicity (omnivorous bird)	3.32E-10	2000	3000	4.98E-10
short term (omnivorous bird)	1.21E-10	66.2	30	5.48E-11

Conclusion:

The calculated risks for secondary poisoning for spinosad via contamination of ingested ants for birds and mammals are acceptable.

Secondary poisoning by contaminated earthworms and fish

Based on the concentration in earthworms and fish (as food for birds and mammals) derived previously and considering the derived $PNEC_{oral}$ for birds and mammals of 18.3 mg/kg feed and 3.3mg/kg feed respectively the following PEC/PNEC ratios are calculated for spinosad:

PEC/PNEC ratios for the terrestrial compartment				
Exposure scenario	**Species**	**C_{worm} mg/kg**	**$PNEC_{oral}$ mg/kg feed**	**PEC/PNEC**
Exposure via STP	**Birds**	4.42E-03	18.3	2.41E-04
Exposure via STP	**Mammals**	4.42E-03	3.3	1.34E-03
Direct exposure of soil	**Birds**	2.22E-03	18.3	1.21E-04
Direct exposure of soil	**Mammals**	2.22E-03	3.3	6.72E-04

PEC/PNEC ratios for the aquatic compartment			
Species	**C_{fish} mg/kg**	**$PNEC_{oral}$ mg/kg feed**	**PEC/PNEC**
Birds (2 bait stations)	9.93E-05	18.3	5.43E-06
Birds (4 bait stations)	1.99E-06	18.3	1.09E-07
Mammals (2 bait stations)	9.93E-05	3.3	3.01E-05
Mammals (4 bait stations)	1.99E-06	3.3	6.03E-07

Conclusion:

The calculated risks for secondary poisoning via the consumption of contaminated earthworms and fish for birds and mammals are acceptable.

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

For the following environmental compartments an exposure is likely: STP, surface water (including sediment), soil and GW (for further details refer to 2.2.8.2 Exposure assessment chapter "Fate and distribution in exposed environmental compartments").

Screening Step 2: Identification of relevant substances

According to the "Guidance on the BPR, Vol IV ENV, Part B+C (ECHA, 2017a)" the following substances need to be considered as relevant for the mixture assessment:

1. active substance
2. substances of concern (SoC)

Beside the active substance one substance of concern, namely BIT was identified (for further information refer to the confidential annex).

Screening Step 3: Screen on synergistic interactions

There are no indications for synergistic effects.

Screening step		
1	Significant exposure of environmental compartments?	**Yes**
2	Number of relevant substances >1?	**Yes**
3	Indication for synergistic effects for the product or its constituents in the literature?	**No**

Conclusion:

A mixture toxicity assessment (tier 1 PEC/PNEC summation according to the "guidance on the BPR Vol IV Part B+C" (ECHA, 2017a)) was performed for the STP (active substance and the SoC BIT). For the other compartments a qualitative assessment was performed (refer to confidential annex).
The environmental mixture toxicity assessment is based on the active substance spinosad and the substance of concern BIT.

Tiered approach

As tier 1 approach PEC/PNEC summation the active substance and the SoC BIT for the STP was performed.

Tier 1. PEC/PNEC summation

Tier 1		
RQ product	Acceptable risk for the environment? (Y/N)	Yes

Summary table PEC/PNEC values for spinosad and BIT for STP	
SCENARIO	**PEC/PNEC summation**
Urban area (scenario 2) 2 bait stations	5.77E-06
Urban area (scenario 2) 4 bait stations	1.18E-05

Conclusion:

The cumulative risk ratios (Tier 1 PEC/PNEC summation) of the active substance spinosad and the SoC BIT <1 indicating acceptable risk for micro-organisms.

Aggregated exposure (combined for relevant emission sources)

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

Overall conclusion on the risk assessment for the environment of the product
For the use of spinosad as active substance in the biocidal product (PT 18) risk ratios <1 were calculated for STP, freshwater (including sediment), soil and secondary poisoning for birds and mammals. For the groundwater all calculated tier 1 concentrations for spinosad and its relevant metabolites are <0.1 µg/L which is the generic trigger value. For the SoC BIT the calculated risk ratios for the STP were <1. For the other compartments a qualitative discussion was performed (refer to the confidential annex). The risk ratios for the mixture toxicity assessment for spinosad and BIT (tier 1, PEC/PNEC summation) were <1. In order to take into account the toxicity for bees the warning sentence "This biocidal product contains spinosad which is dangerous to bees" was applied to the SPC. **Conclusion:** The active substance spinosad and the SoC BIT presents acceptable risk for all discussed scenarios and all environmental compartments.

2.2.9 Measures to protect man, animals and the environment

Please cf. to chapter 2.1.4 and 2.1.5.

2.2.10 Assessment of a combination of biocidal products

The biocidal product is not intended to be authorised for use with other biocidal products.

2.2.11 Comparative assessment

Background:
The biocidal product „Ameisenköder N" contains the active substance spinosad, which meets the criteria for substitution pursuant to Article 10(1) of the Biocides Regulation (EU) No 528/2012 (BPR). Spinosad is considered to be persistent (P) and toxic (T), but not bioaccumulative (B). Therefore, it meets two of the three criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006.
Consequently, in line with Article 23(1) of the Biocides Regulation the Austrian Competent Authority has performed a comparative assessment for the biocidal product „Ameisenköder N", based on the „Technical Guidance Note on comparative assessment of biocidal products" (CA-May15-Doc.4.3.a).
For this comparative assessment the Austrian Competent Authority used the list of biocidal products authorized in Austria for PT 18 (in the version of 12.05.2022), accessible on https://www.biozide.at/, which is maintained by the Environment Agency Austria („Umweltbundesamt") on behalf of the Austrian Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology („BMK"). This was done due to the lack of a tool in the current version of R4BP3 to search SPCs, pursuant to the „Technical Guidance Note on comparative assessment of biocidal products"(CA-May15-Doc.4.3.a).

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

Product Type	PT 18
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s), development stage	Common name: Black Garden Ant Scientific name: *Lasius niger* Development stage: all stages, nests (queen, adults, larvae)
Field of use	Indoor and outdoor use **Field of use description:** Insecticide for use in households (indoor) and private areas around the houses on hard surfaces (outdoor, e.g. terraces, balconies)
Category(ies) of users	Non-professional user
Application method(s)	Ready-to-use bait station

Authorised uses of the biocidal product

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

As stated in CA-May15-Doc.4.3.a – Final, elements 1 to 5 in the table above should be considered as the critical ones. But the AT CA mentions, that in (33) of Note for Guidance it is stated that, if an *„eCA considers that an application method makes that the BP is used in*

practice for very different purposes or under very different circumstances […], some application methods could be considered as separate uses to be covered under the comparative assessment." Furthermore, according to (57) *„at least three different and independent active substances/mode of action combinations should remain available through authorized BPs for a given use […] in order to consider that the chemical diversity is adequate."*
Therefore the application method has also been taken into consideration as the exposure differs depending on the application methods (example: exposure from a bait box is considered different from that of e.g. a liquid, powder or granules).

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

Identified eligible alternative biocidal products:

For this comparative assessment the Austrian Competent Authority used the list of biocidal products authorised in Austria for PT 18 (in the version of 12.05.2022), as already mentioned above.
According to the information available, currently 28 biocidal products for non-professionals to control *Lasius niger* are obtainable (with various trade names). But just 11 of these are available as ready-to-use bait boxes, which are considered to be the most appropriate application method for non-professionals. These products are based on the active substances fipronil, 1R-trans phenothrin, imidacloprid and spinosad, which is object of the current investigation. Note: Of the aforementioned active substances only 1R-trans phenothrin is no candidate for substitution (CFS). Furthermore, in the list of biocidal products authorised in Austria for PT 18 only 3 biocidal products are mentioned for control of *Lasius niger* queens/all development stages. Two are based on spinosad, one on 1R-trans phenothrin.

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

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

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

Chemical diversity
Article 23(3)(b) BPR refers to the adequate chemical diversity of the available active substances within a given product type/use/target organism combination as one of the two sine qua non conditions to be met in order to allow a restriction or prohibition of a biocidal product subject to comparative assessment. During the screening phase, it shall be checked whether the diversity of the active substance, product type and mode of action combination

in authorized biocidal products is adequate to minimize the occurrence of resistance in the target organisms. The screening phase shall allow through a simple assessment to judge whether it is required or not to perform a comprehensive comparative assessment. As proposed as general rule in "CA-May15-Doc.4.3.a" at least three different and independent active substance/mode of action - combinations should be available through authorized biocidal products for a given use to provide adequate chemical diversity as stipulated by Article 23(3)(b) BPR.

Mode of action:
Spinosad causes excitation of the insect nervous system. The active substance leads to long lasting opening of sodium channels of nerve cells. A continuous sodium influx leads to hyperactivity of motor neurons, tremor of the muscles, and as a consequence to paralysis and death.
Worker ants will carry bait (nutrient solution) containing spinosad to the nest and feed it to colony members, including larvae, adults and the queen, which is the only reproductive individual. A drop of ant activity becomes apparent after a few days. Two up to three weeks after application the treated colony dies off.

Active substance	**Mode of action**
Spinosad	Disturbance of neuro-transmittance by effecting on nicotinic acetylcholine receptors primarily and secondarily GABA-gated ion channels
1R-trans phenothrin	Disturbance of neuro-transmittance by effecting the sodium channels

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

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

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

In line with Article 23(3)(a) and (b) of the BPR, the Note for Guidance (CA-May15-Doc.4.3.a – Final) and since spinosad does not meet the exclusion criteria as outlined in Article 5(1)

of the BPR, it is valid to conduct no further investigation at this point; comparative assessment is stopped and finalized at this stage.
The biocidal product "Ameisenköder N"will be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation (EU) No 528/2012.

2.2.12 ED assessment of co-formulants

The ED assessment was carried out in line with "CG-49-2021-15 AP 16.7 ED assessment of co-formulants by applicants" and assessed according to CA-March21_Doc.4.3 - Proposal to bridge the endocrine disruptor assessment of biocidal non-active substances with REACH screening and assessment. There are no indications of endocrine disrupting properties, hence the product is not an endocrine disruptor. Further details on the performance of the assessment are given in the confidential annex.

3 ANNEXES

3.1 List of studies for the biocidal product

Reference point in IUCLID 6	Author	Year	Title, Source (where different from company, Report no., GLP (where relevant), Published / not published	Test facility	Report number	Data protection claimed (yes/no)	Owner
3.1 3.2 3.3 3.4.1 3.4.2.2 3.8 3.9 4.2 4.17.1 5	Anonymous	2012a	Spinosad Gel UKS 171 K Physical Chemical Analysis, 0 °C, 54 °C & 5a RT Storage Stability & Method Validation Content of Active Ingredient, GLP not published	Spectral Service AG, Köln, Germany	SSL03012	yes	EGC
3.2 3.3 3.4.1 3.4.2 3.8 3.9	Anonymous	2020a	Determination of Storage Stability and Shelf Life Specification Data for a Gel Formulation containing 0.8 g/kg Spinosad, stored at 54°C ± 2°C for Two Weeks and 35 °C ± 2 °C for twelve weeks, in Compliance with Good Laboratory Practive GLP Not published	David Norris Analytical Laboratories Ltd., Kent, UK	DNA5176	yes	EGC
4.1 4.4	Anonymous	2010a	Oxidizing and explosive properties UKS 171K	DHD-Consulting	CEL-2010-02	yes	EGC

Reference point in IUCLID 6	Author	Year	Title, Source (where different from company, Report no., GLP (where relevant), Published / not published	Test facility	Report number	Data protection claimed (yes/no)	Owner
			Non-GLP not published	GmbH, Hildesheim, Germany			
3.4.1	Anonymous	2008	24 months ambient storage stability and pack compatibility study for UKS 171 B stored in polystyrene packs GLP not published	CEM Analytical Services Limited (CEMAS), North Ascot, Berkshire, UK	PC06/SP1001	yes	EGC
5	Anonymous	2020b	Validation of the Methods for Determination of spinosad in a Gel Formulation containing 0.8 g/kg Spinosad, in Compliance with Good Laboratory Practice GLP Not published	David Norris Analytical Laboratories Ltd., Kent, UK	DNA5179	yes	EGC
3.1 3.2 3.3 3.4.1.2	Anonymous	2022a	Determination of Storage Stability and Shelf Life Specification Data for a Gel Formulation containing 0.8g/kg spinosad, stored at ambient temperature for 2 years, in Compliance with Good Laboratory Practice GLP Not published	David Norris Analytical Laboratories, Kent, UK	DNA5177	yes	EGC
4.16	Anonymous	2022b	Analysis of the Corrosivity of a Gel Formulation containing	David Norris Analytical	DNA6529	yes	EGC

Reference point in IUCLID 6	Author	Year	Title, Source (where different from company, Report no., GLP (where relevant), Published / not published	Test facility	Report number	Data protection claimed (yes/no)	Owner
			0.8g/kg spinosad, in Compliance with Good Laboratory Practice GLP Not published	Laboratories Limited, Kent, UK			
6.7.1	Anonymous	2009	UKS 171 K – Efficacy trial in arena against *Lasius niger* GEP not published	Scotts France S.A.S, Ecully, France	Report no. FRIN0924W1	yes	EGC
6.7.2	Anonymous	2012b	Laboratory bioassay to determine the efficacy of bait formulations against black ants, *Lasius niger* (E12OAE093) GEP not published	i2LResearch Ltd., Cardiff, UK	Report no. E12PAE093	yes	EGC
6.7.3	Anonymous	2010b	UKS 171 K – Efficacy trial in vivarium against *Lasius niger* GEP not published	Scotts France S.A.S., Ecully, France	Report no. FRIN1014W1	yes	EGC
6.7.4	Anonymous	2012c	Biological Test Report, Efficacy of various products against colonies of black ants Non-GEP not published	BioGenius GmbH, Bergisch-Gladbach, Germany	Report no. BIO033a-12	yes	EGC

Reference point in IUCLID 6	Author	Year	Title, Source (where different from company, Report no., GLP (where relevant), Published / not published	Test facility	Report number	Data protection claimed (yes/no)	Owner
6.7.5	Anonymous	2012d	UKS 171 K – Efficacy trial against Lasius niger in vivarium GEP not published	Scotts France S.A.S., Ecully, France	Report no. FRIN1216M1	yes	EGC
6.7.6	Anonymous	2010c	UKS 171 K – Field assessment of the efficacy of a bait station against garden ants GEP not published	Laboratoire T.E.C., Anglet, France	Report no. 1390b/0710R	yes	EGC
6.7.7	Anonymous	2010d	UKS 171 K – Field assessment of the efficacy of a bait station against garden ants GEP not published	Laboratoire T.E.C., Anglet, France	Report no. 1390c/0710R	yes	EGC
6.7.8	Anonymous	2012e	UKS 171 K – Field assessment of the efficacy of the gel bait and a bait station against garden ants GEP not published	Laboratoire T.E.C., Anglet, France	Report no. 1515/0612R	yes	EGC
6.7.9	Anonymous	2016	Efficacy of ant bait station against Black ants, Non-GLP not published	BioGenius GmbH, Bergisch Gladbach, Germany	Report no. BIO080c-16	yes	EGC

3.2 Output tables from exposure assessment tools

3.2.1 Environmental Exposure Assessment

3.2.1.1 Scenario [2] - Spinosyn A; 2 bait stations – EUSES OUTPUT FILE

IDENTIFICATION OF THE SUBSTANCE		
General name	Spinosyn A	S
CAS-No	131929-60-7	S
EC-notification no.		D
EINECS no.		D
Molecular weight	731.98	[g.mol-1] S
PHYSICO-CHEMICAL PROPERTIES		
Melting point	84	[oC] S
Boiling point	??	[oC] D
Vapour pressure at test temperature	3E-08	[Pa] S
Vapour pressure at 25 [oC]	3E-08	[Pa] O
Water solubility at test temperature	89.4	[mg.l-1] S
Temperature at which solubility was measured	20	[oC] S
Water solubility at 25 [oC]	95.8	[mg.l-1] O
Octanol-water partition coefficient	3.91	[log10] S
Henry's law constant at 25 [oC]	1.89E-07	[Pa.m3.mol-] O

ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
Tonnage of substance in Europe	0	[tonnes.yr-1]
	O	
Regional production volume of substance	0	[tonnes.yr-1]
	O	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
[1 "EMISSION TO STP", IC=15/UC=39]		
Industry category	15/0	
Others		D
Use category	39 Biocides, non-agricultural	
	D	
Fraction of tonnage for application	1	[-]
	D	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
[INDUSTRIAL USE]		
Use specific emission scenario	Yes	
	D	
Emission tables	A3.16 (general table), B3.14 (general table)	
	S	
Emission scenario	Local wastewater emission, application soil concentration	
	S	
Main category industrial use	III Non-dispersive use	
		D
Scenario choice for biocides	(18)	
Insecticides		S
Additional scenario information	(18.3.5) Outdoor, spot application	
	S	
Fraction of tonnage released to air	1E-03	[-]
	O	
Fraction of tonnage released to wastewater	0.1	[-]
	O	
Fraction of tonnage released to surface water	0	[-]
	O	
Fraction of tonnage released to industrial soil	1E-02	[-]
	O	
Fraction of tonnage released to agricultural soil	0	[-]
	O	
Fraction of the main local source	1	[-]
	O	
Number of emission days per year	1	[-]
	O	
Local emission to air during episode	0	[kg.d-1]
	O	
Local emission to wastewater during episode	6.16E-05	[kg.d-1]
	S	
Intermittent release	No	
	D	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
TOTAL REGIONAL EMISSIONS TO COMPARTMENTS		
Total regional emission to air	0	[kg.d-1]
	O	
Total regional emission to wastewater	0	[kg.d-1]
	O	
Total regional emission to surface water	0	[kg.d-1]
	O	
Total regional emission to industrial soil	0	[kg.d-1]
	O	
Total regional emission to agricultural soil	0	[kg.d-1]
	O	

ENVIRONMENT-EXPOSURE
PARTITION COEFFICIENTS

Organic carbon-water partition coefficient	3.5024E+04	[l.kg-1]

ENVIRONMENT-EXPOSURE
PARTITION COEFFICIENTS
SOLIDS-WATER PARTITION COEFFICIENTS

Solids-water partition coefficient in soil	137.6	[l.kg-1]
Solids-water partition coefficient suspended matter	137.6	[l.kg-1]

ENVIRONMENT-EXPOSURE
DEGRADATION AND TRANSFORMATION

Characterization of biodegradability	Not biodegradable	
Degradation calculation method in STP tests	First order, standard OECD/EU	
Rate constant for biodegradation in STP	0	[d-1]
Rate constant for biodegradation in surface water (12[oC])	0	[d-1]
Rate constant for biodegradation in bulk soil (12[oC])	6.93E-07	[d-1]
Rate constant for biodegradation in aerated sediment (12[oC])	6.93E-07	[d-1]
Rate constant for hydrolysis in surface water (12[oC])	6.93E-07	[d-1]
Rate constant for photolysis in surface water	6.93E-07	[d-1]

ENVIRONMENT-EXPOSURE
SEWAGE TREATMENT
LOCAL STP [1 "EMISSION TO STP", IC=15/UC=39][INDUSTRIAL USE]
OUTPUT

Fraction of emission directed to air by STP	3.12E-08	[%]
Fraction of emission directed to water by STP	23.8	[%]
Fraction of emission directed to sludge by STP	76.2	[%]
Fraction of the emission degraded in STP	0	[%]
Concentration in untreated wastewater	3.08E-05	[mg.l-1]
Concentration of chemical (total) in the STP-effluent	7.34E-06	[mg.l-1]
Concentration in effluent exceeds solubility	No	
Concentration in dry sewage sludge	0.0594	[mg.kg-1]
PEC for micro-organisms in the STP	7.34E-06	[mg.l-1]

ENVIRONMENT-EXPOSURE
DISTRIBUTION
LOCAL SCALE
[1 "EMISSION TO STP", IC=15/UC=39][INDUSTRIAL USE]

Concentration in air during emission episode	5.34E-18	[mg.m-3]
Annual average concentration in air, 100 m from point source	1.46E-20	[mg.m-3]
Concentration in surface water during emission episode (dissolved)	7.33E-07	[mg.l-1]
Annual average concentration in surface water (dissolved)	2.01E-09	[mg.l-1]
Local PEC in surface water during emission episode (dissolved)	7.33E-04	[ug.l-1]
Annual average local PEC in surface water (dissolved)	2.01E-06	[ug.l-1]
Local PEC in fresh-water sediment during emission episode	0.0225	[ug.kgwwt-1]
Concentration in seawater during emission episode (dissolved)	3.07E-07	[mg.l-1]
Annual average concentration in seawater (dissolved)	8.42E-10	[mg.l-1]
Local PEC in seawater during emission episode (dissolved)	3.07E-07	[mg.l-1]
Annual average local PEC in seawater (dissolved)	8.42E-10	[mg.l-1]
Local PEC in marine sediment during emission episode	9.43E-06	[mg.kgwwt-1]
Local PEC in agric. soil (total) averaged over 30 days	0.856	[ug.kgwwt-1]
Local PEC in agric. soil (total) averaged over 180 days	0.855	[ug.kgwwt-1]
Local PEC in grassland (total) averaged over 180 days	0.335	[ug.kgwwt-1]
Local PEC in groundwater under agricultural soil	7.04E-03	[ug.l-1]

3.2.1.2 Scenario [2] - Spinosyn A; 4 bait stations – EUSES OUTPUT FILE

IDENTIFICATION OF THE SUBSTANCE

General name	Spinosyn A	S
CAS-No	131929-60-7	S
EC-notification no.		D
EINECS no.		D
Molecular weight	731.98	[g.mol-1] S

PHYSICO-CHEMICAL PROPERTIES

Melting point	84	S	[oC]
Boiling point	??	D	[oC]
Vapour pressure at test temperature	3E-08	[Pa]	S
Vapour pressure at 25 [oC]	3E-08	[Pa]	O
Water solubility at test temperature	89.4	S	[mg.l-1]
Temperature at which solubility was measured	20	S	[oC]
Water solubility at 25 [oC]	95.8	O	[mg.l-1]
Octanol-water partition coefficient	3.91	S	[log10]
Henry's law constant at 25 [oC]	1.89E-07	O	[Pa.m3.mol-]

ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
Tonnage of substance in Europe	0	[tonnes.yr-1]
	O	
Regional production volume of substance	0	[tonnes.yr-1]
	O	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
[1 "EMISSION TO STP", IC=15/UC=39]		
Industry category	15/0	
Others		D
Use category	39 Biocides, non-agricultural	
	D	
Fraction of tonnage for application	1	[-]
	D	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
[INDUSTRIAL USE]		
Use specific emission scenario	Yes	
	D	
Emission tables	A3.16 (general table), B3.14 (general table)	
	S	
Emission scenario	Local wastewater emission, application soil concentration	
	S	
Main category industrial use	III Non-dispersive use	
		D
Scenario choice for biocides	(18)	
Insecticides		S
Additional scenario information	(18.3.5) Outdoor, spot application	
	S	
Fraction of tonnage released to air	1E-03	[-]
	O	
Fraction of tonnage released to wastewater	0.1	[-]
	O	
Fraction of tonnage released to surface water	0	[-]
	O	
Fraction of tonnage released to industrial soil	1E-02	[-]
	O	
Fraction of tonnage released to agricultural soil	0	[-]
	O	
Fraction of the main local source	1	[-]
	O	
Number of emission days per year	1	[-]
	O	
Local emission to air during episode	0	[kg.d-1]
	O	
Local emission to wastewater during episode	1.233E-04	[kg.d-1]
	S	
Intermittent release	No	
	D	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
TOTAL REGIONAL EMISSIONS TO COMPARTMENTS		
Total regional emission to air	0	[kg.d-1]
	O	
Total regional emission to wastewater	0	[kg.d-1]
	O	
Total regional emission to surface water	0	[kg.d-1]
	O	
Total regional emission to industrial soil	0	[kg.d-1]
	O	
Total regional emission to agricultural soil	0	[kg.d-1]
	O	

ENVIRONMENT-EXPOSURE
PARTITION COEFFICIENTS

Organic carbon-water partition coefficient	3.5024E+04	[l.kg-1]
	S	

ENVIRONMENT-EXPOSURE
PARTITION COEFFICIENTS
SOLIDS-WATER PARTITION COEFFICIENTS

Solids-water partition coefficient in soil	137.6	[l.kg-1]
	S	
Solids-water partition coefficient suspended matter	137.6	[l.kg-1]
	S	

ENVIRONMENT-EXPOSURE
DEGRADATION AND TRANSFORMATION

Characterization of biodegradability	Not biodegradable	D
Degradation calculation method in STP tests	First order, standard OECD/EU	D
Rate constant for biodegradation in STP	0	[d-1]
	O	
Rate constant for biodegradation in surface water (12[oC])	0	[d-1]
	O	
Rate constant for biodegradation in bulk soil (12[oC])	6.93E-07	[d-1]
	O	
Rate constant for biodegradation in aerated sediment (12[oC])	6.93E-07	[d-1]
	O	
Rate constant for hydrolysis in surface water (12[oC])	6.93E-07	[d-1]
	O	
Rate constant for photolysis in surface water	6.93E-07	[d-1]
	O	

ENVIRONMENT-EXPOSURE
SEWAGE TREATMENT
LOCAL STP [1 "EMISSION TO STP", IC=15/UC=39][INDUSTRIAL USE]
OUTPUT

Fraction of emission directed to air by STP	3.12E-08	[%] O
Fraction of emission directed to water by STP	23.8	[%] O
Fraction of emission directed to sludge by STP	76.2	[%] O
Fraction of the emission degraded in STP	0	[%] O
Concentration in untreated wastewater	6.17E-05	[mg.l-1] O
Concentration of chemical (total) in the STP-effluent	1.47E-05	[mg.l-1] O
Concentration in effluent exceeds solubility	No	O
Concentration in dry sewage sludge	0.119	[mg.kg-1] O
PEC for micro-organisms in the STP	1.47E-05	[mg.l-1] O

ENVIRONMENT-EXPOSURE
DISTRIBUTION
LOCAL SCALE
[1 "EMISSION TO STP", IC=15/UC=39][INDUSTRIAL USE]

Concentration in air during emission episode	1.07E-17	[mg.m-3]
Annual average concentration in air, 100 m from point source	2.93E-20	[mg.m-3]
Concentration in surface water during emission episode (dissolved)	1.47E-06	[mg.l-1]
Annual average concentration in surface water (dissolved)	4.02E-09	[mg.l-1]
Local PEC in surface water during emission episode (dissolved)	1.47E-03	[ug.l-1]
Annual average local PEC in surface water (dissolved)	4.02E-06	[ug.l-1]
Local PEC in fresh-water sediment during emission episode	0.045	[ug.kgwwt-1]
Concentration in seawater during emission episode (dissolved)	6.15E-07	[mg.l-1]
Annual average concentration in seawater (dissolved)	1.69E-09	[mg.l-1]
Local PEC in seawater during emission episode (dissolved)	6.15E-07	[mg.l-1]
Annual average local PEC in seawater (dissolved)	1.69E-09	[mg.l-1]
Local PEC in marine sediment during emission episode	1.89E-05	[mg.kgwwt-1]
Local PEC in agric. soil (total) averaged over 30 days	1.71	[ug.kgwwt-1]
Local PEC in agric. soil (total) averaged over 180 days	1.71	[ug.kgwwt-1]
Local PEC in grassland (total) averaged over 180 days	0.671	[ug.kgwwt-1]
Local PEC in groundwater under agricultural soil	0.0141	[ug.l-1]

3.2.1.3 Scenario [2] - Spinosyn D, 2 bait stations - EUSES OUTPUT FILE

IDENTIFICATION OF THE SUBSTANCE

General name	Spinosyn D	S
CAS-No	131929-63-0	S
EC-notification no.		D
EINECS no.		D
Molecular weight	746	[g.mol-1] S

PHYSICO-CHEMICAL PROPERTIES

Melting point	161.5 S	[oC]
Boiling point	?? D	[oC]
Vapour pressure at test temperature	2E-08	[Pa] S
Vapour pressure at 25 [oC]	2E-08	[Pa] O
Water solubility at test temperature	0.495 S	[mg.l-1]
Temperature at which solubility was measured	20 S	[oC]
Water solubility at 25 [oC]	0.53 O	[mg.l-1]
Octanol-water partition coefficient	4.38 S	[log10]
Henry's law constant at 25 [oC]	2.32E-05 O	[Pa.m3.mol-1]

ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
Tonnage of substance in Europe	0	[tonnes.yr-1]
	O	
Regional production volume of substance	0	[tonnes.yr-1]
	O	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
[1 "EMISSION TO STP", IC=15/UC=39]		
Industry category	15/0	
Others		D
Use category	39 Biocides, non-agricultural	
	D	
Fraction of tonnage for application	1	[-]
	D	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
[INDUSTRIAL USE]		
Use specific emission scenario	Yes	
	D	
Emission tables	A3.16 (general table), B3.14 (general table)	
	S	
Emission scenario	Local wastewater emission, application soil concentration	
	S	
Main category industrial use	III Non-dispersive use	
		D
Scenario choice for biocides	(18)	
Insecticides		S
Additional scenario information	(18.3.5) Outdoor, spot application	
	S	
Fraction of tonnage released to air	1E-03	[-]
	O	
Fraction of tonnage released to wastewater	0.1	[-]
	O	
Fraction of tonnage released to surface water	0	[-]
	O	
Fraction of tonnage released to industrial soil	1E-02	[-]
	O	
Fraction of tonnage released to agricultural soil	0	[-]
	O	
Fraction of the main local source	1	[-]
	O	
Number of emission days per year	1	[-]
	O	
Local emission to air during episode	0	[kg.d-1]
	O	
Local emission to wastewater during episode	1.09E-05	[kg.d-1]
	S	
Intermittent release	Yes	
	S	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
TOTAL REGIONAL EMISSIONS TO COMPARTMENTS		
Total regional emission to air	0	[kg.d-1]
	O	
Total regional emission to wastewater	0	[kg.d-1]
	O	
Total regional emission to surface water	0	[kg.d-1]
	O	
Total regional emission to industrial soil	0	[kg.d-1]
	O	
Total regional emission to agricultural soil	0	[kg.d-1]
	O	

ENVIRONMENT-EXPOSURE
PARTITION COEFFICIENTS

Organic carbon-water partition coefficient	3.5024E+04	[l.kg-1]
	S	

ENVIRONMENT-EXPOSURE
PARTITION COEFFICIENTS
SOLIDS-WATER PARTITION COEFFICIENTS

Solids-water partition coefficient in soil	51.4	[l.kg-1]
	S	
Solids-water partition coefficient suspended matter	51.4	[l.kg-1]
	S	

ENVIRONMENT-EXPOSURE
DEGRADATION AND TRANSFORMATION

Characterization of biodegradability	Not biodegradable	D
Degradation calculation method in STP tests	First order, standard OECD/EU	D
Rate constant for biodegradation in STP	0	[d-1]
	O	
Rate constant for biodegradation in surface water (12[oC])	0	[d-1]
	O	
Rate constant for biodegradation in bulk soil (12[oC])	6.93E-07	[d-1]
	O	
Rate constant for biodegradation in aerated sediment (12[oC])	6.93E-07	[d-1]
	O	
Rate constant for hydrolysis in surface water (12[oC])	6.93E-07	[d-1]
	O	
Rate constant for photolysis in surface water	6.93E-07	[d-1]
	O	

ENVIRONMENT-EXPOSURE
SEWAGE TREATMENT
LOCAL STP [1 "EMISSION TO STP", IC=15/UC=39][INDUSTRIAL USE]
OUTPUT

Fraction of emission directed to air by STP	3.83E-06 [%]	O
Fraction of emission directed to water by STP	23.8	[%]
	O	
Fraction of emission directed to sludge by STP	76.2	[%]
	O	
Fraction of the emission degraded in STP	0	[%]
	O	
Concentration in untreated wastewater	5.45E-06	[mg.l-1]
	O	
Concentration of chemical (total) in the STP-effluent	1.3E-06	[mg.l-1]
	O	
Concentration in effluent exceeds solubility	No	
	O	
Concentration in dry sewage sludge	0.0105	[mg.kg-1]
	O	
PEC for micro-organisms in the STP	5.45E-06	[mg.l-1]
	O	

ENVIRONMENT-EXPOSURE
DISTRIBUTION
LOCAL SCALE
[1 "EMISSION TO STP", IC=15/UC=39][INDUSTRIAL USE]

Concentration in air during emission episode	1.16E-16	[mg.m-3]
Annual average concentration in air, 100 m from point source	3.18E-19	[mg.m-3]
Concentration in surface water during emission episode (dissolved)	1.3E-07	[mg.l-1]
Annual average concentration in surface water (dissolved)	3.56E-10	[mg.l-1]
Local PEC in surface water during emission episode (dissolved)	1.3E-04	[ug.l-1]
Annual average local PEC in surface water (dissolved)	3.56E-07	[ug.l-1]
Local PEC in fresh-water sediment during emission episode	1.55E-03	[ug.kgwwt-1]
Concentration in seawater during emission episode (dissolved)	5.45E-08	[mg.l-1]
Annual average concentration in seawater (dissolved)	1.49E-10	[mg.l-1]
Local PEC in seawater during emission episode (dissolved)	5.45E-05	[ug.l-1]
Annual average local PEC in seawater (dissolved)	1.49E-07	[ug.l-1]
Local PEC in marine sediment during emission episode	6.51E-04	[ug.kgwwt-1]
Local PEC in agric. soil (total) averaged over 30 days	0.147	[ug.kgwwt-1]
Local PEC in agric. soil (total) averaged over 180 days	0.146	[ug.kgwwt-1]
Local PEC in grassland (total) averaged over 180 days	0.0556	[ug.kgwwt-1]
Local PEC in groundwater under agricultural soil	3.22E-03	[ug.l-1]

3.2.1.4 Scenario [2] - Spinosyn D, 4 bait stations - EUSES OUTPUT FILE

IDENTIFICATION OF THE SUBSTANCE

General name	Spinosyn D	S
CAS-No	131929-63-0	S
EC-notification no.		D
EINECS no.		D
Molecular weight	746	[g.mol-1] S

PHYSICO-CHEMICAL PROPERTIES

Melting point	161.5 S	[oC]
Boiling point	?? D	[oC]
Vapour pressure at test temperature	2E-08	[Pa] S
Vapour pressure at 25 [oC]	2E-08	[Pa] O
Water solubility at test temperature	0.495 S	[mg.l-1]
Temperature at which solubility was measured	20 S	[oC]
Water solubility at 25 [oC]	0.53 O	[mg.l-1]
Octanol-water partition coefficient	4.38 S	[log10]
Henry's law constant at 25 [oC]	2.32E-05 O	[Pa.m3.mol-1]

ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
Tonnage of substance in Europe	0	[tonnes.yr-1]
	O	
Regional production volume of substance	0	[tonnes.yr-1]
	O	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
[1 "EMISSION TO STP", IC=15/UC=39]		
Industry category	15/0	
Others		D
Use category	39 Biocides, non-agricultural	
	D	
Fraction of tonnage for application	1	[-]
	D	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
[INDUSTRIAL USE]		
Use specific emission scenario	Yes	
	D	
Emission tables	A3.16 (general table), B3.14 (general table)	
	S	
Emission scenario	Local wastewater emission, application soil concentration	
	S	
Main category industrial use	III Non-dispersive use	
		D
Scenario choice for biocides	(18)	
Insecticides		S
Additional scenario information	(18.3.5) Outdoor, spot application	
	S	
Fraction of tonnage released to air	1E-03	[-]
	O	
Fraction of tonnage released to wastewater	0.1	[-]
	O	
Fraction of tonnage released to surface water	0	[-]
	O	
Fraction of tonnage released to industrial soil	1E-02	[-]
	O	
Fraction of tonnage released to agricultural soil	0	[-]
	O	
Fraction of the main local source	1	[-]
	O	
Number of emission days per year	1	[-]
	O	
Local emission to air during episode	0	[kg.d-1]
	O	
Local emission to wastewater during episode	2.17E-05	[kg.d-1]
	S	
Intermittent release	Yes	
	S	
ENVIRONMENT-EXPOSURE		
RELEASE ESTIMATION		
TOTAL REGIONAL EMISSIONS TO COMPARTMENTS		
Total regional emission to air	0	[kg.d-1]
	O	
Total regional emission to wastewater	0	[kg.d-1]
	O	
Total regional emission to surface water	0	[kg.d-1]
	O	
Total regional emission to industrial soil	0	[kg.d-1]
	O	
Total regional emission to agricultural soil	0	[kg.d-1]
	O	

ENVIRONMENT-EXPOSURE
PARTITION COEFFICIENTS

Organic carbon-water partition coefficient	3.5024E+04	[l.kg-1]
	S	

ENVIRONMENT-EXPOSURE
PARTITION COEFFICIENTS
SOLIDS-WATER PARTITION COEFFICIENTS

Solids-water partition coefficient in soil	51.4	[l.kg-1]
	S	
Solids-water partition coefficient suspended matter	51.4	[l.kg-1]
	S	

ENVIRONMENT-EXPOSURE
DEGRADATION AND TRANSFORMATION

Characterization of biodegradability	Not biodegradable	
	D	
Degradation calculation method in STP tests	First order, standard OECD/EU	
	D	
Rate constant for biodegradation in STP	0	[d-1]
	O	
Rate constant for biodegradation in surface water (12[oC])	0	[d-1]
	O	
Rate constant for biodegradation in bulk soil (12[oC])	6.93E-07	[d-1]
	O	
Rate constant for biodegradation in aerated sediment (12[oC])	6.93E-07	[d-1]
	O	
Rate constant for hydrolysis in surface water (12[oC])	6.93E-07	[d-1]
	O	
Rate constant for photolysis in surface water	6.93E-07	[d-1]
	O	

ENVIRONMENT-EXPOSURE
SEWAGE TREATMENT
LOCAL STP [1 "EMISSION TO STP", IC=15/UC=39][INDUSTRIAL USE]
OUTPUT

Fraction of emission directed to air by STP	3.83E-06	[%]
		O
Fraction of emission directed to water by STP	23.8	[%]
		O
Fraction of emission directed to sludge by STP	76.2	[%]
		O
Fraction of the emission degraded in STP	0	[%]
		O
Concentration in untreated wastewater	1.09E-05	[mg.l-1]
	O	
Concentration of chemical (total) in the STP-effluent	2.59E-06	[mg.l-1]
	O	
Concentration in effluent exceeds solubility	No	
	O	
Concentration in dry sewage sludge	0.0209	[mg.kg-1]
	O	
PEC for micro-organisms in the STP	1.09E-05	[mg.l-1]
	O	

ENVIRONMENT-EXPOSURE
DISTRIBUTION
LOCAL SCALE
[1 "EMISSION TO STP", IC=15/UC=39][INDUSTRIAL USE]

Concentration in air during emission episode	2.31E-16	[mg.m-3]
Annual average concentration in air, 100 m from point source	6.32E-19	[mg.m-3]
Concentration in surface water during emission episode (dissolved)	2.58E-07	[mg.l-1]
Annual average concentration in surface water (dissolved)	7.08E-10	[mg.l-1]
Local PEC in surface water during emission episode (dissolved)	2.58E-04	[ug.l-1]
Annual average local PEC in surface water (dissolved)	7.08E-07	[ug.l-1]
Local PEC in fresh-water sediment during emission episode	3.09E-03	[ug.kgwwt-1]
Concentration in seawater during emission episode (dissolved)	1.08E-07	[mg.l-1]
Annual average concentration in seawater (dissolved)	2.97E-10	[mg.l-1]
Local PEC in seawater during emission episode (dissolved)	1.08E-04	[ug.l-1]
Annual average local PEC in seawater (dissolved)	2.97E-07	[ug.l-1]
Local PEC in marine sediment during emission episode	1.3E-03	[ug.kgwwt-1]
Local PEC in agric. soil (total) averaged over 30 days	0.292	[ug.kgwwt-1]
Local PEC in agric. soil (total) averaged over 180 days	0.291	[ug.kgwwt-1]
Local PEC in grassland (total) averaged over 180 days	0.111	[ug.kgwwt-1]
Local PEC in groundwater under agricultural soil	6.41E-03	[ug.l-1]

3.3 New information on the active substance

Not relevant.

3.4 Residue behaviour

Not relevant.

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

Please refer to the provided IUCLID-file.

3.6 Confidential annex

Please confer to separate document.

3.7 Other

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

Beckers, R. et al. (1989): Colony size, communication and ant foraging strategy. Psyche: A Journal of Entomology 96 (3-4).

Brian, M.V. et al. (1965): Ant Pattern and Density in a Southern English Heath. Journal of Animal Ecology, Vol. 34, No. 3, p. 545 – 555.

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

ECHA (2017b): Guidance on the Application of the CLP Criteria (Version 5.0, July 2017)

ECHA (2017c): Guidance on the Biocidal Products Regulation, Volume III: Assessment and Evaluation – Parts B+C (Version 4.0, December 2017)

ECHA (2017d): Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)

ECHA (2018): Guidance on the Biocidal Products Regulation, Volume I: Identity of the active substance/physico-chemical properties/analytical methodology - Information Requirements, Evaluation and Assessment. Parts A+B+C (Version 2.0, May 2018)

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

OECD (2008): Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses. OECD series

on Emission scenario documents, number 18; ENV/JM/MONO(2008)14; 17-Jul-2008

Netherlands (2010): Assessment Report Spinosad, Product Type 18, May 2010

Spain (2022): Assessment Report 1,2-BENZISOTHIAZOL-3-(2H)-ONE (BIT), Product Types 6 and 13, February 2022

LEGAL NORMS

COMMISSION DIRECTIVE 2010/72/EU of 4 November 2010 amending Directive 98/8/EC of the European Parliament and of the Council to include spinosad as an active substance in Annex I thereto. Available at: ELI http://data.europa.eu/eli/dir/2010/72/oj