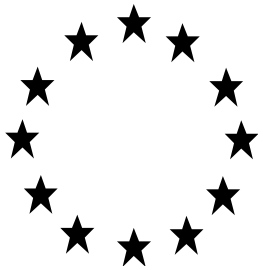
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	Ameisen-Köderdose
Product type(s):	18 (Insecticides, Acaricides and products against other arthropods)
Active ingredient(s):	Spinosad
Case No. in R4BP	BC-PH036377-32
Asset No. in R4BP	DE-0006715-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/18.00004 710-05-18-00004-01-00-00-0000
Date	05.03.2020

Overview of applications

Table 1 - Overview regarding all relevant applications

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	DE	No case number, application submitted unter BPD 98/8/EC	03.07.2014	First authorisation
NA-AAT	DE	BC-YH008688-18	23.09.2014	Amendment by CA (SoC, addition of Risk mitigation measures, additional tradename)
NA-ADC	DE	BC-AW016472-29	26.05.2016	Adminstrative change (additional tradename)
NA-AAT	DE	BC-TT021854-09	25.01.2016	Amendment by CA (change of expiry date to 02.07.2019)
NA-ADC	DE	BC-YW034535-99	16.10.2017	Adminstrative change (change of a tradename)
NA-AAT	DE	BC-PH051680-40	14.05.2019	Amendment by CA (Extension of the expiry date to 31.12.2019)
NA-AAT	DE	BC-JT055504-20	03.12.2019	Amendment by CA (Extension of the expiry date to 31.03.2020)
NA-RNL	DE	BC-PH036377-32	05.03.2020	Renewal 2020

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1 Conclusion

The German Competent Authority (DE CA) proposes to renew the authorisation of the biocidal product Ameisen-Köderdose for use as an insecticide (PT 18) against black garden ants for professional and non-professional use. The product is a bait solution soaked on a cellulose pad and placed on the market in a bait box. The product is supposed to be used indoor and outdoor around buildings, on balconies and terraces. Ameisen-Köderdose contains 0.08% w/w spinosad.

At the time of the first authorisation, the whole bait box was considered the biocidal product. Meanwhile an agreement concerning “Carrier-based products” (CA-Nov16-Doc.4.3 – Final) has been reached. Following this agreement, the liquid is the biocidal product and has to be evaluated.
Consequently, the DE CA has requested some additional data concerning physical-chemical data and data on physical hazards from the applicant. The applicant has submitted the necessary data and the results have been included into the respective sections of the PAR.
Furthermore, the applicant submitted additional laboratory, simulated-use and field tests with *Lasius niger* (Lüpkes 2017a, b, c) (detailed study summary see Table 19).
No further new data were submitted.

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product, Ameisen-Köderdose with the active substance spinosad (0.08 % w/w) is used as an insecticide (product-type 18) for the control of black garden ants in and around buildings.

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

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.
General directions for use of the product are summarised in chapter 2.4.2.

A classification according to Regulation (EC) No 1272/2008[2] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

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

2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

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: The approval of the active substance spinosad has not been renewed until now.

Composition and formulation

The ready-to-use bait box Ameisen-Köderdose contains the active substance spinosad.

No substance of concern has been identified.

Please refer to chapter 2.2 (Composition and formulation) and the Confidential Annex for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

Physical hazards were not identified. (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.4. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

No substance of concern has been identified. However two potential substances of concern are present in the product. For details see the Confidential Annex.

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3).

A human health risk assessment has been carried out for non-professional and professional use of the product (see chapter 3.6) for all intended uses (see chapter 3.1).

In summary, a risk for professional users resulting from the use of the biocidal product Ameisen-Köderdose is unlikely. Risk mitigation measures according to chapter 2.4 have to be taken into account in order to ensure safe use of the biocidal product Ameisen-Köderdose.
Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to non-professional users, bystanders and residents. Regarding non-professional users health protection, there are no objections against the intended uses if the directions for use according to chapter 2.4.2 and if applicable to 2.4 are followed.

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

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3 and 3.8.4.6).

A risk assessment for the environment has been carried out for non-professional, professional and trained professional use of the product in and around buildings (see chapter 3.8) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk for the environment if the directions for use according to chapter 2.4.2 and if applicable to 2.4 are followed.

Comparative Assessment
Since the active substance spinosad has been identified as a candidate for substitution (see also chapter 2.2.5) a comparative assessment has been necessary (see chapter 3.10). The corresponding Comparative Assessment Report was forwarded to ECHA on 05.03.2020.
The German CA concludes that without spinosad based products there is not an adequate chemical diversity.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Ameisen-Köderdose

2.1.2 Manufacturer(s) of the product

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

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

Active substance	Spinosad
Name of manufacturer	Dow AgroSciences L.L.C.
Address of manufacturer	305 North Huron Avenue 48441 Harbor Beach Michigan United States of America
Location of manufacturing sites	305 North Huron Avenue 48441 Harbor Beach Michigan United States of America

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Spinosad technical	Mixture of 50-95 % spinosyn A and 5-50 % spinosyn D **Spinosyn A:** (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-.alpha.-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-.beta.-D-erythropyranosyloxy)-9-ethyl-2,3a,5a,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-14-methyl-1H-as-indaceno(3,2-d)oxacyclododecin-7,15-dione **Spinosyn D**: 2-((6-Deoxy-2,3,4-tri-O-methyl-.alpha.-L-mannopyranosyl)oxy)-13-((5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl)oxy)-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-as-indaceno(3,2-d)oxacyclododecin-7,15-dione	active substance	168316-95-8	434-300-1	0.08[3]

- Information on the full composition (including the carrier) is provided in the confidential[4] 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 ☒

[3] *technical grade spinosad, considerng the purity of technical grade spinosad (94%) the exact content of pure spinosad in the formulation is 0.0752%*

[4] Access level: "Restricted" to applicant and authority

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

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☒
  No ☐

2.2.3 Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.

2.2.4 Information on the substance(s) of concern

With respect to human health two potential substances of concern are present in the biocidal product. For details see the Confidential Annex.

2.2.5 Candidate(s) for substitution

The following candidate for substitution was identified:

- Spinosad

Spinosad is not considered as a candidate meeting the exclusion criteria according to Article 5(1) BPR.

Spinosad does meet the following criteria for substitution:

- Persistent and Toxic

2.2.6 Type of formulation

Bait solution (absorbed on a cellulose pad)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008

Besides the active substance spinosad (reaction mass of spinosyn A and spinosyn D in ratios between 95:5 to 50:50), the other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance spinosad is based on Commission Regulation (EU) No. 790/2009 (1st ATP to CLP regulation):

H400

H410

M = 10

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

Classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 for human health is not required.
Since the biocidal product has no classification for human health, no labelling according to Regulation (EC) No 1272/2008 is required.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.4.2 and if applicable to chapter 2.4.

Table 3

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Chronic 3	H412 – Harmful to aquatic life with long lasting effects

Table 4

Labelling	**Code**	**Pictogram / Wording**
Signal word	-	
Hazard statements	H412	Harmful to aquatic life with long lasting effects
Supplemental hazard information		
Supplemental label elements		
Precautionary statements	P273	Avoid release to the environment
	P501	Dispose of contents/container according to national legislation.
Note	-	

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.4.2 and 2.4.

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

2.4 Use(s) appropriate for authorisation

2.4.1 Use 1 appropriate for authorisation – Use of bait stations against ants – professional user, trained professional user

Product Type(s)	18
Where relevant, an exact description of the use	Insecticides, acaricides and products against other arthropods
Target organism(s) (including development stage)	black garden ant (*Lasius niger)*, Larvae, Adults
Field(s) of use	In and around buildings
Application method(s)	Covered application in metal tin containing a cellulose pad soaked with ant bait solution Place the ready-to-use product directly on the runway of the ants and leave it there for 6-8 weeks, or until no more ants are visible.
Application rate(s) and frequency	Low infestation: 1 bait station per 12m^2 High infestation: 2 bait station per 12m^2
Category(ies) of users	Trained professional users, professional users
Pack sizes and packaging material	1-2 bait stations, ready-to-use with pre-filled liquid bait on cellulose pad in cardboard blister pack

2.4.1.1 Use-specific instructions for use

See chapter 2.5

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.4.2 Use 2 appropriate for authorisation – Use of bait stations against ants, non- professional user

Product Type(s)	18
Where relevant, an exact description of the use	Insecticides, acaricides and products to control other arthropods
Target organism(s) (including development stage)	black garden ant *(Lasius niger)*, Larvae, Adults
Field(s) of use	In and around buildings
Application method(s)	Covered application in metal tin containing a cellulose pad soaked with ant bait solution Place the ready-to-use product directly on the runway of the ants and leave it there for 6-8 weeks, or until no more ants are visible.
Application rate(s) and frequency	Low infestation: 1 bait station per 12m^2 High infestation: 2 bait station per 12m^2

Category(ies) of users	Non-professional users
Pack sizes and packaging material	1-2 bait stations, ready-to-use with pre-filled liquid bait on cellulose pad in cardboard blister pack

2.4.2.1 Use-specific instructions for use

See chapter 2.5

2.4.2.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.5 General directions for use

2.5.1 Instructions for use

1) Avoid any unnecessary contact to the preparation. 2) Do not force open the bait station.

3) Apply up to 2 bait boxes per of 12 m² and do not exceed 11 of such treatments per year. *4)* Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.

2.5.2 Risk mitigation measures

1) Do not use bait stations on surfaces likely to be in contact with food, feed or drinks. 2) If medical advice is needed, have product container or label at hand. 3) Keep out of reach of children.

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

In case of accident: Call a poison centre or a doctor. If on skin: Rinse with water. If in eyes: Rinse with water for several minutes. If swallowed: Call a poison centre or a doctor.

2.5.4 Instructions for safe disposal of the product and its packaging

1) Residues of the biocidal products must be disposed of in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations. 2) Leave biocidal products in original containers. 3) Do not mix with other wastes. 4) Containers containing residues of the product have to be handled accordingly.

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

1) Keep away from food, drinks and animal feeding stuffs. 2) Store the product in a cool and dry place. 3) Shelf-Life: 24 months

2.5.6 Other information

<u>Resistance management:</u>

- In the case of reduced efficacy or suspected development of resistance, the use of the product has to be discontinued immediately and a professional pest control operator needs to be contacted.
- To reduce the risk of resistance development different products containing various active substances (with different mode of actions) should be used alternately.
- Products should always be used in accordance with label recommendations.

As the product will affect other organisms in the treated area, and since resistance to Spinosad is known in other insects the product should be used with care.

2.6 Packaging

Table 5

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Box (aluminium) containing a cellulose pad impregnated with a spinosad liquid formulation. The cover and the bottom part of the bait are sealed with a rubber sealant.	Ant bait 5 g Cover: diameter 78.8 ± 0.3 mm Bottom: diameter 82.45 ± 0.2 mm Height: 20.5 ± 0.3 mm	Aluminium	rubber	Professional and non-professional users	Yes

3 Assessment of the product

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

3.1.1 Intended use 1 – bait against ants to be used by trained professional, professional

Product Type(s)	18
Where relevant, an exact description of the use	18 (Insecticides, Acaricides and products against other arthropods)
Target organism(s) (including development stage)	Ants (*Formicidae*), Larvae, Adults
Field(s) of use	In and around buildings Aim: Food protection, stored product protection, health protection, material protection
Application method(s)	Covered application in metal tin containing a cellulose pad soaked with ant bait solution
Application rate(s) and frequency	Low infestation: 1 bait station per 12m^2 High infestation: 2 bait station per 12m^2
Category(ies) of users	Trained professional, professional,
Pack sizes and packaging material	1-2 bait station ready-to-use with pre-filled liquid bait on cellulose pad

3.1.1 Intended use 2 – bait against ants to be used by non-professional user

Product Type(s)	18
Where relevant, an exact description of the use	18 (Insecticides, Acaricides and products against other arthropods)
Target organism(s) (including development stage)	Ants (*Formicidae*), Larvae, Adults
Field(s) of use	In and around buildings Aim: Food protection, stored product protection, health protection, material protection
Application method(s)	Covered application in metal tin containing a cellulose pad soaked with ant bait solution
Application rate(s) and frequency	Low infestation: 1 bait station per 12m^2 High infestation: 2 bait station per 12m^2
Category(ies) of users	Non-professional user
Pack sizes and packaging material	1-2 bait station ready-to-use with pre-filled liquid bait on cellulose pad

3.2 Physical, chemical and technical properties

Table 6: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual		The product is a colourless water bait solution with a slightly perfumed, synthetic odour which is absorbed on a cellulose pad which is tightly sealed in a metal tin.	Voigt, 2012
	Visual after 54°C for 2 weeks after 40°C for 8 weeks after RT for 24 month	Detia Ant Bait Tin RB Batch Kai-01-119 4mg Spinosad per tin	During storage stability studies the product absorbed on the cellulose pad was investigated. Tin with white pad inside Tin with white pad inside Tin with white pad inside Tin with white pad inside	Rodriguez, 2012: Study No.: Mo4363
Colour at 20 °C and 101.3 kPa	Visual	Detia Ant Bait Tin RB Batch Kai-01-119 4mg Spinosad per tin	During storage stability studies the product absorbed on the cellulose pad was investigated.	Rodriguez, 2012: Study No.: Mo4363

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Tin with white pad inside	
	after 54°C for 2 weeks		Tin with white pad inside	
	after 40°C for 8 weeks		Tin with white pad inside	
	after RT for 24 month		Tin with white pad inside	
	Visual		The product is a colourless water bait solution with a slightly perfumed, synthetic odour which is absorbed on a cellulose pad which is tightly sealed in a metal tin.	Voigt, 2012
Odour at 20 °C and 101.3 kPa	Visual	Detia Ant Bait Tin RB Batch Kai-01-119 4mg Spinosad per tin	Slightly perfumed, synthetic	Rodriguez, 2012: Study No.: Mo4363
	after 54°C for 2 weeks		Moderate perfumed, synthetic	
	after 40°C for 8 weeks		Slightly perfumed, synthetic	
	after RT for 24 month		Slightly perfumed, synthetic	
Acidity / alkalinity	CIPAC MT 75.3	Detia Ant Bait Tin RB Batch Kai-01-119 4mg Spinosad per tin	pH value of a 1% dilution was: 5.8 at 21.5-21.8°C	Rodriguez, 2012: Study No.: Mo4363
	CIPAC MT 191		The acidity respectively alkalinity was not determined because the pH value of the formulation was > 4 and < 10.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	after 40°C for 8 weeks after RT for 24 month		pH value of a 1% dilution was: 5.5 at 21.5°C pH value of a 1% dilution was: 5.6 at 22.1-22.7°C	
Relative density / bulk density	A.3 ; OECD 109 Oscillating densiometer	Ameisenköder Batch 54027-1 0.072 % Spinosad (liquid)	D_4^{20}= 1.26	Winkler, 2019: Study No.: PS20190017-1
Storage stability test – **accelerated storage**	Accelerated storage at 54 °C for 2 weeks CIPAC MT 46.3	Detia Ant Bait Tin RB Batch Kai-01-119 4mg Spinosad per tin	3.44 mg/tin (corresponding to a loss of 10.65 % of initial content) A loss in weight of 0.04% was found after storage Further effects of temperature on the following technical characteristics are given at the individual endpoints: Appearance,	Rodriguez, 2012: Study No.: Mo4363
	Accelerated storage at 40 °C for 8 weeks CIPAC MT 46.3	Detia Ant Bait Tin RB Batch Kai-01-119 4mg Spinosad per tin	3.61 mg/tin (corresponding to a loss of 6.23 % of initial content) A loss in weight of 0.06% was found after storage	Rodriguez, 2012: Study No.: Mo4363

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Further effects of temperature on the following technical characteristics are given at the individual endpoints: Appearance, Acidity/ Alkalinity	
Storage stability test – **long term storage at ambient temperature**	storage at 20°C/Roomtemperatur (RT) °C for 24 months	Detia Ant Bait Tin RB Batch Kai-01-119 4mg Spinosad per tin	Before storage: Time 0: 3.85 mg/tin After 24 month storage: 3.58 mg/tin (corresponding to a loss of 7.02 % of initial content) No significant chemical or physical changes occur in this test. Therefore the product complies with the shelf life specification of 2 years.	Rodriguez, 2012: Study No.: Mo4363
Storage stability test – **low temperature stability test for liquids**			The product is a colourless water bait solution with a slightly perfumed, synthetic odour which is absorbed on a cellulose pad which is tightly sealed in a metal tin. Based on the Carrier document (CA-Nov16-Doc.4.3 – Final) stirage stability test should be done on the product as supplied to the user. This is the liquid absorbed on a	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			cellusose pad. Thus the test is not required.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Please, see accelerated storage stability test.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Please, see accelerated storage stability test. The biocidal product is a water based liquid. Therefore, effects of humidity are not expected.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The packaging material is proper.	Study Rodriguez 2012,(CIPAC MT 46.3), Document IIB, chapter III.3.7: *[…the aspect of the test item and the packaging material was considered to be stable…]*
Wettability			Not applicable as the ant bait consists of a water bait solution absorbed on a cellulose pad which is tightly sealed in a metal tin. Furthermore it is a ready to use product and is not intended for use with water or as a smoke generator. Therefore the technical characteristics are waived (not applicable).	
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Persistent foaming				
Flowability/Pourability/Dust ability				
Burning rate — smoke generators				
Burning completeness — smoke generators				
Composition of smoke — smoke generators				
Spraying pattern — aerosols				
Physical compatibility			The product is ready-to-use and is not intended to be added to or mixed with any other product.	
Chemical compatibility				
Degree of dissolution and dilution stability			Not applicable as the ant bait consists of a water bait solution absorbed on a cellulose pad which is tightly sealed in a metal tin. Furthermore it is a ready to use product and is not intended for use with water or as a smoke generator. Therefore the technical characteristics are waived (not applicable).	
Surface tension	A.5 ; OECD 115 Ringmethod	Ameisenköder Batch 54027-1 0.072 % Spinosad (liquid)	70.2 mN/m , concentration 1g/L	Winkler, 2019: Study No.: PS10290017-2

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Viscosity	OECD 114 Capillary viscosimeter	Ameisenköder Batch 54027-1 0.072 % Spinosad (liquid)	22.2 mm²/s at 20°C 9.4 mm²/s at 40°C	Winkler, 2019: Study No.: PS20190017-3

Table 7

Conclusion on the physical, chemical and technical properties
The biocidal product is the spinosad liquid formulation. The physical chemical properties are mainly tested in combination with the cellulose pad, thus as the product is supplied to the user. The pad is packaged in an entirely closed (aluminium) tin. The cover and the bottom part of the bait are sealed with a rubber sealant. The pH of a 1% dilution of the spinosad liquid formulation is 5.8. The product indicates effects of temperature because of the high loss of active substance after storage at 54°C and 40°C. Therefore it should be stored dry and cool. As active substance decreases is < 10% (7.02 %) after two years storage a shelf life of two years is granted.

3.3 Physical hazards and respective characteristics

Table 8: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives				Expert statement: None of the components of the preparation are considered to have explosive or oxidising properties. It is noted that the preparation is an aqueous liquid and therefore the sugar, present at 60.00% w/w, would be dissolved within the aqueous solution. It is concluded that Detia Spinosad ant bait formulation is unlikely to undergo a rapid chemical decomposition with the production of gases or release of heat sufficient to cause damage to the surroundings, and therefore does not present a risk of explosion.	Curl and Wright, 2012: Report no: TSGE_04-15-05_Spinosad_Exp
Flammable gases			:	Not applicable Product is a liquid (aqueous solution)	
Flammable aerosols				Not applicable Product is a liquid (aqueous solution) and will not be sprayed	
Oxidising gases				Not applicable Product is a liquid (aqueous solution)	
Gases under pressure				Not applicable Product is a liquid (aqueous solution)	
Flammable liquids				Expert statement: The formulation of the product “Ameisen-Köderdose” is a solution of 60.45 % non-flammable solids and 39.52 % water. Therefore it is not expected that the formulation is flammable, thus no test has been performed.	Lorenzen, V., 2019, Statement on non-submission of 4.6 flammable liquids

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
					for “Ameisen-Köderdose”
Flammable solids				Not applicable Product is a liquid (aqueous solution)	
Self-reactive substances and mixtures				Study does not need to be conducted because there are no chemical groups present in the mixture which are associated with explosive or self-reactive properties.	
Pyrophoric liquids			Ignition time on contact with air: Effect on filter paper:	The study does not need to be conducted because the substance is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure does not need to be applied.	Lorenzen, V., 2019, Statement on non-submission of 4.9 pyrophoric liquids for “Ameisen-Köderdose”
Pyrophoric solids				Not applicable.	
Self-heating substances and mixtures				The formulation of the product "Ameisen-Köderdose" is a solution of 60.48% solids and 39.52% water. None of the components is liable to undergo oxidative self-heating. Therefore the classification procedure does not need to be applied.	Lorenzen, V., 2019, Statement on non-submission of 4.11 self-heating substances and mixtures for “Ameisen-Köderdose”
Substances and mixtures which in contact with				Study does not need to be conducted because the experience in production or handling shows that	

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
water emit flammable gases				the substance does not react with water (product is an aqueous solution).	
Oxidising liquids				Expert statement: None of the individual constituents in the preparation are classified as oxidisers. Therefore it is concluded that Detia Spinosad ant bait formulation is unlikely to have oxidising properties.	Curl and Wright, 2012: Report no: TSGE_04-15-05_Spinosad_Oxp
Oxidising solids				Not applicable	
Organic peroxides				Study does not need to be conducted because the constituents of the biocidal product do not fall under the definition of organic peroxides.	
Corrosive to metals	UN Test in Part III of the UN-MTC, 37.4 (2015)		Ameisenköder Batch No.: 54050-1, Production date: 2019-02-21 0,072 % Spinosad	The product has no corrosive properties to metals. For uniform corrosion the highest observed weight losses over an exposure time of 7 days were: Steel: 0.05 wt % Aluminium: 0.01 wt % No intrusion depths cold be found microscopically. Type of materials: Steel (S235JR+CR) and Aluminium (7075-T6)	Seitz, S., 2019, Ameisenköder Determination of physico-chemical properties Corrosive Properties of Liquids (UN Test C.1) Study- No. CSL-19-03888.01
Auto-ignition temperature (liquids and gases)			Auto-ignition temperature:	Not applicable as the ant bait consists of a water bait solution absorbed on a cellulose pad which is tightly sealed in a metal tin.	IUCLID, Doc IIIB
Relative self-ignition				Not applicable	

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
temperature for solids					
Dust explosion hazard				Not applicable	

Table 9

Conclusion on the physical hazards and respective characteristics
First Authorization: No classification and labelling with regard to the physical hazards were proposed. Renewal 2019: No classification and labelling with regard to the physical hazards are proposed. The data and expert statements provided by the applicant are acceptable. New experimental data on corrosive properties to metals were provided: The product has no corrosive properties to metals. The biocidal product Ameisen-Köderdose contains 0.08% w/w spinosad and based on the components of the formulation it is not considered to be explosive, oxidizing or flammable. Based on experience in production and handling it can be concluded that the product is not pyrophoric or liable to self-heating and does not evolve flammable gases in contact with water. Ameisen-Köderdose should also not be considered for classification in the hazard classes of organic peroxide or self-reactives, as it does not meet the definition of an organic peroxide and there are no chemical groups present which are associated with explosive or self-reactive properties. All other physical hazard classes are not applicable. Ameisen-Köderdose is a liquid formulation absorbed on a cellulose pad which is tightly sealed in a metal tin. <u>Conclusions on classification and labelling:</u> The physical and chemical properties of the biocidal product do not fulfil the criteria for a classification according to Regulation (EC) No. 1272/2008 and therefore, no labelling is required for physical-chemical hazards.

3.4 Methods for detection and identification

Table 10

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Spinosad	HPLC-UV	One placebo sample is prepared and analysed in duplicate. Examination of the placebo chromatogram demonstrates that no interference occurred at the retention times as Spinosad.	0.05 – 0.104 mg/mL R= 1.00	Overall mean (n=9)	90.3 – 98.5	95.4	2.8	-	Rodriguez, 2012: Study No.: Mo4424
				n = 3 70% (0.056 mg/mL)	97.8 – 98.5	98.1	0.4		
				100% (0.080 mg/mL)	95.5 – 96.1	95.8	0.4		
				130% (0.104 mg/mL)	90.3 – 93.4	92.3	1.8		

Table 11

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	spinosyn A, spinosyn D, spinosyn B and N-demethyl spinosyn D	0.05 mg/kg	AR, list of endpoints, 05/2010
Drinking water	spinosyn A, spinosyn D	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
			AR for PT 18, list of endpoints, 05/2010
Surface water	spinosyn A, spinosyn D	0.62 µg/L	NOEC *Chironomous riparius* (spinosad), AR for PT 18, list of endpoints, 05/2010
Air	spinosyn A, spinosyn D	7.2 µg/m³	based on $AEL_{medium\ term}$: 0.024 mg/kg bw/d, AR for PT 18, list of endpoints, 05/2010
Animal and human body fluids and tissues	not residue relevant	-	not classified as toxic or very toxic for PT 18, AR, list of endpoints, 05/2010
Food of plant origin	not residue relevant	-	AR for PT 18, list of endpoints, 05/2010
Food of animal origin	sum of spinosyn A and spinosyn D, expressed as spinosad	milk 0.2 mg/kg meat 0.1 mg/kg eggs 0.2 mg/kg fat 0.1 mg/kg liver, kidney 0.02 mg/kg	AR for PT 18, list of endpoints, 05/2010 MRLs according to Regulation (EU) No 2015/603, annex II

Table 12

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
spinosyn A, spinosyn D	LC-MS/MS, ODS-AM column, APCI+, m/z 732.5→142 (spinosyn A),	no confirmation	spinosyn A: Y=2.75e5X (0.001 – 0.5 µg/L (high level will be diluted);	spinosyn A: 0.01 µg/L /6 0.1 µg/L /6 1 µg/L /6	 71 – 86 71 – 79 81 – 84 68 – 84	 78 75 83 77	 7 4 1 9	0.01 µg/L (per analyte)	CAR, doc IIIA, 4.2/03, Rutherford (2003)

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
	m/z 746.5→142 (spinosyn D)		R=0.9997) spinosyn D: Y=2.54e5X (0.001 – 0.5 µg/L (high level will be diluted); R=0.9998)	spinosyn D: 0.01 µg/L /6 0.1 µg/L /6 1 µg/L /6	69 – 77 77 – 82	72 79	4 3		
spinosyn A, spinosyn D	LC-MS, Prodigy ODS-3, APCI+; m/z 718.5, 732.5, 746.5	no confirmation	(0.03 – 6.25 µg/L)	spinosyn A: 0.1 µg/L /8 0.5 µg/L /8 1 µg/L /8 5 µg/L /8 spinosyn D: 0.1 µg/L /8 0.5 µg/L /8 1 µg/L /8 5 µg/L /8		 104 103 108 112 100 96 109 114	 4.1 2.6 2.6 3.4 6.1 6.3 2.1 3.0	0.01 µg/L (per analyte)	CAR, doc IIIA, 4.2, Boothroyd (1999)

Table 13

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
spinosyn A, spinosyn B, spinosyn D, N-demethyl-spinosyn D	LC-MS/MS, ODS-AM column, APCI+, m/z 732.6→142 (spinosyn A), m/z 746.5→142 (spinosyn D), m/z 718.6→128 (spinosyn B), m/z 732.6→128 (N-demethyl spinosyn D)	no confirmation	spinosyn A: Y=8.16e6X-203 (0.001 – 0.5 mg/kg (high level will be diluted); R=0.9999) spinosyn D: Y=7.41e6X-187 (0.001 – 0.5 mg/kg (high level will be diluted); R=0.9999) spinosyn B: Y=1.07e7X-148 (0.001 – 0.5 mg/kg (high level will be diluted); R=0.9999) N-demethyl-spinosyn D: Y=8.33e6X-115 (0.001 – 0.5 mg/kg (high level will be	spinosyn A: 0.005 mg/kg /14 0.05 mg/kg /14 0.25 mg/kg /14 1 mg/kg /14 spinosyn D: 0.005 mg/kg /14 0.05 mg/kg /14 0.25 mg/kg /14 1 mg/kg /14 spinosyn B: 0.005 mg/kg /14 0.05 mg/kg /14 0.25 mg/kg /14 1 mg/kg /14 N-demethyl-spinosyn D: 0.005 mg/kg /14 0.05 mg/kg /14 0.25 mg/kg /14 1 mg/kg /14	 81 – 111 76 – 93 86 – 98 79 – 100 86 – 107 74 – 96 84 – 101 78 – 96 80 – 101 76 – 93 83 – 97 80 – 98 77 – 101 78 – 92 83 – 95 77 – 95	 96 88 92 91 94 88 92 90 88 86 90 89 88 86 90 89	 7.9 5.6 3.6 6.5 6.6 6.5 5.3 6.3 7.4 5.4 4.4 6.6 9.3 5.2 4.3 6.4	0.005 mg/kg (per analyte)	CAR; doc IIIA; 4.2/01; Hastings (2003)

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
			diluted); R=0.9999)						
spinosyn A, spinosyn B, spinosyn D, N-demethyl-spinosyn D	HPLC-UV, ODS-AQ column, 250 nm	only for confirmation	(0.01 – 0.15 mg/kg (high level will be diluted)	spinosyn A: 0.01 mg/kg /14 0.025 mg/kg /3 0.05 mg/kg /3 0.075 mg/kg /3 0.1 mg/kg /3 1 mg/kg /8 spinosyn D: 0.01 mg/kg /14 0.025 mg/kg /3 0.05 mg/kg /3 0.075 mg/kg /3 0.1 mg/kg /3 1 mg/kg /8 spinosyn B: 0.01 mg/kg /14 0.025 mg/kg /3 0.05 mg/kg /3 0.075 mg/kg /3 0.1 mg/kg /3 1 mg/kg /8 N-demethyl-spinosyn D: 0.01 mg/kg /14 0.025 mg/kg /3 0.05 mg/kg /3 0.075 mg/kg /3 0.1 mg/kg /3 1 mg/kg /8		 81 81 76 82 83 85 83 84 77 82 83 84 76 82 72 80 82 81 73 76 69 78 79 80	 7 9 6 8 5 2 11 8 8 9 5 2 6 6 6 3 3 2 5 8 7 6 5 3	0.01 mg/kg (per analyte)	CAR; doc IIIA, 4.2; West (1995)

Table 14:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
spinosyn A spinosyn D (in air 35 °C/ 80 % r.h.)	LC-MS/MS; Prodigy ODS, APCI+, m/z 732.6→142 (spinosyn A), m/z 746.6→142 (spinosyn D)	no confirmation	spinosyn A: Y=348000X+890 (0.14 – 14 µg/m³, highest level will be diluted 1:10); R=1.000) spinosyn D: Y=756000X+78.9 (0.14 – 14 µg/m³, highest level will be diluted 1:10); R=1.0000)	spinosyn A: 0.63 µg/m³ /5 6.3 µg/ m³/5 63 µg/ m³ /5 spinosyn D: 0.1 µg/m³ /5 1 µg/ m³/5 10 µg/ m³ /5	 92 – 94 76 – 85 92 – 101 92 – 95 75 – 87 89 – 93	 93 81 94 93 81 94	 1.1 4 4.1 1.1 5.5 1.6	0.73 µg/m³ (spinosad)	Doc IIIA, 4.2/02, Atkinson (2002)

Table 15

Analytical methods for surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
spinosyn A, spinosyn D	LC-MS/MS, ODS-AM column, APCI+, m/z 732.5→142 (spinosyn A),	no confirmation	spinosyn A: Y=2.75e5X (0.001 – 0.5 µg/L (high level will be diluted);	spinosyn A: 0.01 µg/L /6 0.1 µg/L /6 1 µg/L /6 spinosyn D: 0.01 µg/L /6	 77 – 96 75 – 93 84 – 91 74 – 95	 87 86 88 84	 9 8 3 9	0.01µg/L (per analyte)	CAR, doc IIIA, 4.2/03, Rutherford (2003)

Analytical methods for surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
	m/z 746.5→142 (spinosyn D)		R=0.9997) spinosyn D: Y=2.54e5X (0.001 – 0.5 µg/L (high level will be diluted); R=0.9998)	0.1 µg/L /6 1 µg/L /6	81 – 90 82 – 86	86 84	4 2		
spinosyn A, spinosyn D	LC-MS, Prodigy ODS-3, APCI+; m/z 718.5, 732.5, 746.5	no confirmation	(0.03 – 6.25 µg/L)	spinosyn A: 0.1 µg/L /8 0.5 µg/L /8 1 µg/L /8 5 µg/L /8 spinosyn D: 0.1 µg/L /8 0.5 µg/L /8 1 µg/L /8 5 µg/L /8		 99 101 95 101 101 97 94 105	 4.1 3.4 4.3 9.8 5.4 4.2 7.1 9.8	0.01 µg/L (per analyte)	CAR, doc IIIA, 4.2, Boothroyd (1999)

Table 16

Analytical methods for monitoring of active substances and residues in food and feeding stuff of animal origin									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
spinosyn A, spinosyn D	HPLC-UV, ODS-AQ	no confirmation	0.1 – 1.5 µg/mL	spinosyn A: eggs: 0.01 mg/kg /8		 84	 6	0.01 mg/kg (per analyte)	CAR; doc IIIB, 4.2/07; Turner & West (1996)

	column, 250 nm			0.025 mg/kg /3 0.05 mg/kg /3 0.1 mg/kg /3 1 mg/kg /3 meat: 0.01 mg/kg /8 1 mg/kg /3 liver: 0.01 mg/kg /8 1 mg/kg /3 fat: 0.01 mg/kg /8 1 mg/kg /3 meat with skin and fat: 0.01 mg/kg /8 1 mg/kg /3 spinosyn D: eggs: 0.01 mg/kg /8 0.025 mg/kg /3 0.05 mg/kg /3 0.1 mg/kg /3 1 mg/kg /3 meat: 0.01 mg/kg /8 1 mg/kg /3 liver: 0.01 mg/kg /8 1 mg/kg /3 fat: 0.01 mg/kg /8 1 mg/kg /3 meat with skin and fat: 0.01 mg/kg /8 1 mg/kg /3		82 96 91 95 95 92 98 86 116 110 88 80 86 79 93 87 92 88 89 85 83 113 109 77 77	11 5 7 1 4 8 7 1 5 1 5 5 6 11 6 6 1 5 7 8 2 5 1 5 6		

spinosyn A, spinosyn D	HPLC-UV, ODS-AQ column	no confirmation	spinosyn A: Y=3.6194e4X (0.01 – 0.15 mg/kg; R=0.9999) spinosyn D: Y=3.1051e4X (0.01 – 0.15 mg/kg; R=0.9999) 0.01 – 0.15 mg/kg	spinosyn A: eggs: 0.01 mg/kg /2 0.05 mg/kg /2 meat: 0.01 mg/kg /2 0.05 mg/kg /2 liver: 0.01 mg/kg /2 0.05 mg/kg /2 fat: 0.01 mg/kg /2 0.05 mg/kg /2 spinosyn D: eggs: 0.01 mg/kg /2 0.05 mg/kg /2 meat: 0.01 mg/kg /2 0.05 mg/kg /2 liver: 0.01 mg/kg /2 0.05 mg/kg /2 fat: 0.01 mg/kg /2 0.05 mg/kg /2		101 103 97 77 85 92 88 86 95 98 96 75 81 87 81 85		0.01 mg/kg (per analyte)	CAR; doc IIIB, 4.2/08, Turner & Yackovich (1996)
spinosyn A, spinosyn D	HPLC-UV, ODS-AQ column, 250 nm	no confirmation	spinosyn A: Y=3.69987X-0.01792 (0.01 – 0.15 µg/mL; R=0.99996)	spinosyn A: milk: 0.01 mg/kg /8 0.025 mg/kg /3 0.05 mg/kg /3 0.1 mg/kg /3 1 mg/kg /3 cream: 0.01 mg/kg /8 10 mg/kg /3	 99-116 97-104 95-106 100-108 103-105 96-113 100-114	 108 101 99 104 104 102 106	 6 4 6 4 1 6 7	0.01 mg/kg (per analyte)	CAR, doc IIA, chapter 1.4.3, West & Turner (1995)

				meat: 0.01 mg/kg /8 10 mg/kg /3 liver: 0.01 mg/kg /8 10 mg/kg /3 kidney: 0.01 mg/kg /8 10 mg/kg /3 fat: 0.01 mg/kg /8 10 mg/kg /3 spinosyn D: milk: 0.01 mg/kg /8 0.025 mg/kg /3 0.05 mg/kg /3 0.1 mg/kg /3 1 mg/kg /3 cream: 0.01 mg/kg /8 10 mg/kg /3 meat: 0.01 mg/kg /8 10 mg/kg /3 liver: 0.01 mg/kg /8 10 mg/kg /3 kidney: 0.01 mg/kg /8 10 mg/kg /3 kidney: 0.01 mg/kg /8 10 mg/kg /3	 89-107 81-86 97-120 97–99 76–97 83–93 81–108 83–93 90–114 91–101 93–103 98–105 102 87–102 103–115 83–110 94–98 99–116 97–104 76–99 80–88 84–107 89–92	 83 86 109 98 82 88 101 90 104 97 97 101 102 95 108 90 96 113 109 85 83 97 90	 3 1 7 1 10 7 9 3 7 6 6 4 0 7 6 11 2 5 1 11 5 8 2		
spinosyn A, spinosyn D	HPLC-UV, ODS-AQ column, 250 nm	no confirmation	spinosyn A: Y=78.0X-0.109 (0.01 – 0.15	spinosyn A: milk: 0.01 mg/kg /2 0.05 mg/kg /2	 107, 120 105, 119	 114 112		0.01 mg/kg (per analyte)	CAR; doc IIA, chapter 1.4.3; West & Kendall (1996)

			µg/mL; R=0.9997)	spinosyn D: milk: 0.01 mg/kg /2 0.05 mg/kg /2	 117, 102 108, 119	 110 114			

Table 17

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.1. Analytical method including validation parameters for determining the concentration of the active substance(s), residues, relevant impurities and substances of concern in the biocidal product 2. 5.2.4 Animal and body fluids and tissues 3. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant origin or feeding stuffs and other products where relevant
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 18

Conclusion on the methods for detection and identification
The method(s) provided regarding the active substance(s), residues and substances of concern was/were acceptable. The methods provided regarding residues in soil, in air, in drinking and surface water and in food and feeding stuff of animal origin were acceptable. Method(s) regarding residues and substances of concern were not necessary.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

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

The biocidal product “Ameisen-Köderdose” is a bait product containing 0.08% Spinosad w/w as active substance. It is a ready-to-use bait station (completely closed aluminium box with pre-punched points where the box can be opened on the sides) prefilled with a cellulose pad soaked with 5 g bait solution.
The biocidal product “Ameisen-Köderdose” is intended to be used to knock down and subsequently kill adult and larval individuals of the black garden ant (*Lasius niger)*.

The product “Ameisen-Köderdose” should be applied directly on the runway of the ants for 6 to 8 weeks. The application dose for weak infestation is 1 can per 12 m² (nest / infestation site) and for high infestation 2 cans per 12 m² (nest / infestation site). It is intended for indoor and outdoor use in residential houses and adjacent areas like balconies and terraces by professional, trained professional and non-professional users.

The submitted studies are suitable to support the claim “knocks down and kills individuals of the black garden ant (*Lasius niger)”.* Also the claim “nest kill” is supported. As the product does contain a preservative a shelf life of two years is supported.

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

The biocidal product “Ameisen-Köderdose” is intended to be used to control adults and larvae of the black garden ant (*Lasius niger)* in residential houses and adjacent areas like balconies and terraces.
The intended uses include indoor and outdoor application using a ready-to-use bait station. Bait stations should be applied directly on the runway of the ants.

3.5.3 Effects on target organisms, including unacceptable suffering

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

Workers of the ant population will feed on the bait and will pass it on to other workers, larvae and the queen within the nest.

3.5.4 Mode of action, including time delay

Spinosad acts on ants by contact and ingestion and which causes convulsions, paralysis and ultimately death. It alters the function of nicotinic and GABA-gated ion channels, causing overstimulation of neurons, involuntary muscular contractions and, finally, paralysis and insect death.
However, when ants are the target organisms, a sufficiently long latency period between bait ingestion and the beginning of poisoning symptoms is necessary in order to ensure recruitment (development of a pheromone trail) and transfer of the bait to the offspring and queen in the nest.

3.5.5 Efficacy data

For the initial approval the applicant submitted simulated-use (Heller 2007, 2012) and field tests (Heller 2012) with the target organism *Lasius niger* (detailed study summary see table 26).

However, the German CA evaluates the simulated-use study by Heller (2007) only as supportive material. As in accordance with the TNsG (2012, chapter 4.2.2.3) in simulated-use tests ants must have a free choice between an alternative food source and the bait product. However, the “acceptance and toxicity” trial was a no-choice test. And the results from the “food choice” trial do not meet the requirements of at least 90% population reduction (TNsG 2012) in all 3 colonies. This might be due to the observation period of only 14 days, furthermore the application of a second bait box might be necessary (as described by Lüpkes 2017b).
The second study by Heller (2012) is also evaluated as supportive material. As the simulated-use and field test were not conducted in accordance with the requirements in the (TNsG 2012, chapter 4.2.2.3 and 4.2.2.4).

During the renewal additional laboratory, simulated-use and field tests with *Lasius niger* (Lüpkes 2017a, b, c) were submitted (detailed study summary see Table 19). All tests were conducted with a bait station called “Profissimo Ameisenköder”, which is a synonym for the product “Ameisen-Köderdose” (identical formulation).

In the laboratory tests (Lüpkes 2017a) with *Lasius niger* one bait station was applied in a test arena. After 21 days 90% mortality was observed and total mortality was reached after 28 days. Mortality in the controls was 15% after 28 days. Therefore, the laboratory tests demonstrated a mortality of more than 95% as requested for bait products (TNsG 2012, chapter 4.3.1) and sufficiently prove the palatability of the product.

In the simulated-use study by Lüpkes (2017b) one bait station was applied during the first 4 weeks in the arena with a *Lasius niger* colony (approx. 1000 workers, brood, queen), than a second bait station was introduced up to the end of the test period of 10 weeks. After 4 weeks one of the 4 colonies was killed (no brood, dead queen), whereas in the 4 remaining nests approx. 100 to 450 living ants were observed. 8 weeks after the treatment a second colony was killed. In the 3 other replicates approx. 25 to 100 living individuals were determined, which corresponds to a population reduction of 90% to 97.5%. At the end of the test period after 10 weeks colony kill was reached in all replicates. For the untreated controls no colony kill was observed and the number of living ants was similar to the beginning.
In the TNsG (2012) "≥ 90% reduction of the population within a few weeks" is required. This requirement was meet after 8 weeks. The German CA considers this as an acceptable amount of time, especially as the nests in the simulated-use test were quite large (approx. 1000 workers, brood, queen).
In the field tests by Lüpkes (2017c) nest kill, indicated by no ant activity, dead workers, no brood and no living queen, were observed in all three colonies two weeks after the treatment with one bait station per nest (next to one entrance). During the test period activity in the control colonies was reduced due to seasonal changes in ant activity. In accordance to the TNsG (2012) these results fulfil the requirements for the claim nest kill. The German CA is of the opinion that the results in the simulated-use studies are outweighed by these robust field studies (TNsG 2012, chapter 4.2.3).

To sum up the results of the submitted studies, it can be concluded that the product "Ameisen-Köderdose" is effective against the black garden ant (*Lasius niger*) and a claim "nest kill" is supported. As the product contains a preservative a shelf life of two years is supported.

Table 19

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>PT 18</td><td>in- and outdoor (in residential houses and adjacent areas like balconies and terraces)</td><td>Detia ant bait
0.05% and
0.08%
Spinosad w/w
a.i.</td><td>Lasius niger
Common
black
garden ant,
colonies,
all develop-
ment stages</td><td>Simulated
-use study</td><td>-Arena: nest box
(20 x 20 x 8.5
cm plastic
container)
connected to an
outlet and
feeding box (20
x 20 x 8.5 cm)
-Food: sugar/
honey/ insects
<u>Acceptance and
toxicity testing:</u>
- glucose
solution in outlet
box until
foraging was
initiated, than
glucose was
exchanged for a
bait solution</td><td><u>Acceptance and toxicity testing:</u>
<table><tr><th rowspan="3">Time (h) after ingestion of bait</th><th colspan="4">Number of ants with symptoms</th></tr><tr><th colspan="2">0.08% Spinosad</th><th colspan="2">0.05% Spinosad</th></tr><tr><th>Rep. 1 (nA= 10)</th><th>Rep. 2 (nA= 13)</th><th>Rep. 1 (nA= 14)</th><th>Rep. 2 (nA= 13)</th></tr><tr><td>1</td><td>1 fs</td><td>0</td><td>0</td><td>0</td></tr><tr><td>2</td><td>1 is, 1 fs</td><td>1 ms, 2 fs</td><td>2 is</td><td>0</td></tr><tr><td>4</td><td>3 fs</td><td>3 is, 6 fs</td><td>1 is, 4 fs</td><td>1 is</td></tr><tr><td>6</td><td>5 fs</td><td>10 fs</td><td>7 fs</td><td>1 is, 1 ms, 1 fs</td></tr><tr><td>8</td><td>1 ms, 5 fs</td><td>11 fs</td><td>7 fs</td><td>1 is, 5</td></tr><tr><td>10</td><td>2 is, 6 fs</td><td>13 fs</td><td>1 is, 10 fs</td><td>6 fs</td></tr><tr><td>12</td><td>1 is, 9 fs</td><td></td><td>12 fs</td><td>6 fs</td></tr><tr><td>24</td><td>10 fs</td><td></td><td>14 fs</td><td>11 fs</td></tr><tr><td>30</td><td></td><td></td><td></td><td>1 ms, 12 fs</td></tr><tr><td>48</td><td></td><td></td><td></td><td>13 fs</td></tr></table>
Abbreviations:
Rep. 1 or 2 = repetition 1 and 2
nA = number of ants in the test
is = initial symptoms (slight anomalies in movement, slowed walking)
ms = moderate symptoms (increased inability to walk)
fs = final symptoms (paralysis, death)
no mortality in the control groups

<u>Food choice experiment:</u></td><td>Heller
(2007)</td></tr>
</table>

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
					- acceptance assessment: direct observation - toxicity: transfer of feeding ants into a small box (9x 9 x 5 cm) - 10 ants per treatment <u>Food choice experiment:</u> -liquid bait and alternative food (glucose solution) in outlet box -Starvation: 3 days		

Time after begin of baiting (minutes)	Number of ants at the bait			Number of ants at the alternative food source		
	Colony 1	Colony 2	Colony 3	Colony 1	Colony 2	Colony 3
5		4	3 1	3	3	25
10	2	9	approx. 50	0	5	35
15	4	15	approx. 50	4	12	33
20	2	7	35	2	3	11
25	3	6	8	2	1	4
30	0	3	2	3	3	5
35	3	0	0	2	0	1
40	2			1		
45	0			0		

Time after baiting (days)	Number of dead ants and ants with severe symptoms		
	Colony 1	Colony 2	Colony 3
1	n.e.	n.e.	211
2	102	374	289
3	26		86
4	32	104	6
5	45	425	
6	11	49	
7	7	26	
10	9	9	
14	0	0	
Total no. of ants with symptoms	232	987	592
Recovered ants	6	151	0
Total no. of dead ants	226	836	592
Total no. of live ants	approx. 1000	349	0
Original colony size	approx. 1200	1185	592
Mortality rate	**15 - 20%**	**71%**	**100%**

Abbreviation: n.e. = not evaluated

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>- mortality assessment</td><td></td><td></td></tr>
<tr><td>PT 18</td><td>in- and outdoor (in residential houses and adjacent areas like balconies and terraces)</td><td>Detia ant bait can
0.08% Spinosad w/w a.i.;

artificial aged product (14 days at 54°C)</td><td>Lasius niger
Common black garden ant,
colonies,
all develop-ment stages</td><td>Simulated -use study, Field trial</td><td><u>Acceptance and toxicity testing:</u>
- glucose solution in outlet box until foraging was initiated, than glucose was exchanged for a bait solution
- acceptance assessment: direct observation
- 10 ants per treatment

<u>Toxicity by food exchange (trophallaxis test):</u>
-arena: 20 x 20 cm container
-150 worker housed in a tube</td><td><u>Acceptance and toxicity testing:</u>
<table><tr><th rowspan="2">Time (hrs.) after intake of bait</th><th colspan="4">Number of ants with symptoms</th></tr><tr><th>Fresh bait 1 (nA = 16)</th><th>Fresh bait 2 (nA = 11)</th><th>Stored bait (nA = 20)</th><th>Control (nA = 14)</th></tr><tr><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td></tr><tr><td>2</td><td>1 iS, 2 fS</td><td>1 iS, 1 fS</td><td>1 iS</td><td>0</td></tr><tr><td>3</td><td>1 iS, 6 fS</td><td>1 iS, 2 fS</td><td>1 iS, 2 fS</td><td>0</td></tr><tr><td>4</td><td>2 iS, 10 fS</td><td>1 iS, 7 fS</td><td>1 iS, 5 fS</td><td>0</td></tr><tr><td>5</td><td>14 fS</td><td>10 fS</td><td>4 iS, 12 fS</td><td>0</td></tr><tr><td>6</td><td>14 fS</td><td>10 fS</td><td>4 iS, 14 fS</td><td>0</td></tr><tr><td>7</td><td>14 fS, 2 iS</td><td>10 fS</td><td>3 iS, 17 fS</td><td>0</td></tr><tr><td>8</td><td>16 fS</td><td>11 fS</td><td>20 fS</td><td>0</td></tr></table>Abbreviations:
nA = number of ants
iS = initial symptoms (slight movement or behaviour disturbance)
fS = final symptoms (supine position, paralysis, dead)

<u>Toxicity by food exchange (trophallaxis test):</u>
<table><tr><th rowspan="2">Days after bait intake</th><th colspan="4">Number of dead ants</th></tr><tr><th>Fresh bait 1</th><th>Fresh bait 2</th><th>Stored bait</th><th>Control</th></tr><tr><td>2</td><td>6</td><td>2</td><td>4</td><td>0</td></tr><tr><td>4</td><td>7</td><td>13</td><td>6</td><td>0</td></tr><tr><td>7</td><td>2</td><td>6</td><td>5</td><td>0</td></tr><tr><td>10</td><td>8</td><td>2</td><td>8</td><td>0</td></tr><tr><td>14</td><td>2</td><td>0</td><td>3</td><td>0</td></tr><tr><td>17</td><td>0</td><td>0</td><td>0</td><td>0</td></tr><tr><td>Total</td><td>25</td><td>23</td><td>26</td><td>0</td></tr><tr><td>Mortality %</td><td>16.7</td><td>15.3</td><td>17.3</td><td>0</td></tr></table></td><td>Heller (2012)</td></tr>
</table>

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>-Starvation: 3 days
-5 worker had access to bait and were transferred to their colony after eating
-Alternative food: sugar

<u>Food choice experiment:</u>
-Arena: nest box (20 x 20 x 8.5 cm plastic container) connected to an outlet and feeding box (20 x 20 x 8.5 cm)
-bait (1 cm² pad segment) and alternative food (glucose solution) in outlet box</td><td><u>Food choice experiment:</u>
<table><tr><th rowspan="2">Time (min.) after onset of baiting</th><th colspan="2">Number of ants on</th><th rowspan="2">Days after baiting</th><th colspan="2">Number of markedly damaged and dead ants (workers)</th></tr><tr><th>Bait</th><th>Control food</th><th>damaged</th><th>dead</th></tr><tr><td>1</td><td>2</td><td>3</td><td>3</td><td>47</td><td>130</td></tr><tr><td>5</td><td>7</td><td>9</td><td>5</td><td>30</td><td>56</td></tr><tr><td>10</td><td>18</td><td>28</td><td>7</td><td>8</td><td>25</td></tr><tr><td>15</td><td>25</td><td>23</td><td>11</td><td>30</td><td>24</td></tr><tr><td>20</td><td>19</td><td>22</td><td>14</td><td>0</td><td>33</td></tr><tr><td>25</td><td>7</td><td>16</td><td>18</td><td>0</td><td>0</td></tr><tr><td>30</td><td>4</td><td>6</td><td></td><td></td><td>Total = 268</td></tr><tr><td>35</td><td>5</td><td>6</td><td></td><td></td><td></td></tr></table>
<u>Field trial:</u>
<table><tr><th rowspan="2">Time (min.) after onset of baiting</th><th colspan="5">Number of ants at baits</th></tr><tr><th>Colony 1</th><th>Colony 2</th><th>Colony 3</th><th>Colony 4</th><th>Colony 5</th></tr><tr><td></td><td></td><td>18</td><td>> 50</td><td>8</td><td>16</td></tr><tr><td>30</td><td>> 100</td><td>> 100</td><td>> 100</td><td>15</td><td>>50</td></tr><tr><td>45</td><td>> 100</td><td>> 100</td><td>> 100</td><td>21</td><td>31</td></tr><tr><td>60</td><td>> 50</td><td>> 100</td><td>> 100</td><td>24</td><td>13</td></tr><tr><td>90</td><td>22</td><td>13</td><td>> 100</td><td>14</td><td>9</td></tr><tr><td>120</td><td>5</td><td>8</td><td>> 50</td><td>2</td><td>1</td></tr></table>
colony1: nest kill after 21 days (repeated baiting after 13 days)
colony2: no ant activity after 28 days (nest not observed; repeated baiting after 8 days)</td><td></td></tr>
</table>

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>-Starvation: 3 days
- mortality assessment

<u>Field trial:</u>
-Treatment of wild ant nests
-Dosage:1 bait station per nest (next to the nest entrance)
-3 replicates (3 controls)
-Assessment intervals: 1, 2, 3, 4 weeks after application
-Effects investigated: activity of ants</td><td>colony3: no ant activity after 2 days
colony4: no effects (baiting was not repeated)
colony5: no effects (baiting was not repeated)
colony 4 and 5:low bait acceptance due to plants with aphids in the vicinity of the ant colonies</td><td></td></tr>
<tr><td>PT 18</td><td>in- and outdoor (in residential houses and adjacent areas like</td><td>„Profissimo Ameisenköder ”</td><td>Lasius niger
Common black garden ant,</td><td>Laboratory study</td><td>-Application as bait station (ready to use product)
-Arena: plastic container (18.3 x</td><td>
<table>
<tr><td>replicate</td><td colspan="7">%mortality out of 20 after days (d)</td></tr>
<tr><td></td><td>1 d</td><td>3 d</td><td>7 d</td><td>9 d</td><td>14 d</td><td>21 d</td><td>28 d</td></tr>
<tr><td>1</td><td>5</td><td>30</td><td>90</td><td>90</td><td>90</td><td>100</td><td>100</td></tr>
<tr><td>2</td><td>0</td><td>10</td><td>55</td><td>75</td><td>75</td><td>80</td><td>100</td></tr>
<tr><td>3</td><td>15</td><td>20</td><td>70</td><td>85</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>4</td><td>0</td><td>0</td><td>10</td><td>40</td><td>40</td><td>50</td><td>100</td></tr>
</table>
</td><td>Lüpkes (2017a), report no.: BIO122-17</td></tr>
</table>

<table>
<tr><th colspan="7">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td>balconies and terraces)</td><td>0.08% Spinosad w/w a.i. (synonym for the product “Ameisen-Köderdose”)</td><td>workers</td><td></td><td>13.7 x 6.1 cm, filled with soil and cardboard cubs a shelter)
-Temperature: 24 – 25°C
-Rel. humidity: 52 – 60%
-Dosage:1 bait station
-Acclimatisation: 1 d before treatment
-Starvation: no
-Alternative food: sugar
-7 replicates (5 controls)
-20 workers per replicate
-Assessment intervals: 1, 3, 7, 9, 14, 21, 28 days after application</td><td>
<table>
<tr><td>5</td><td>10</td><td>10</td><td>40</td><td>85</td><td>95</td><td>100</td><td>100</td></tr>
<tr><td>6</td><td>10</td><td>85</td><td>100</td><td>100</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>7</td><td>10</td><td>90</td><td>100</td><td>100</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>Ø</td><td>7</td><td>35</td><td>66</td><td>82</td><td>86</td><td>90</td><td>100</td></tr>
<tr><td>control1</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>10</td><td>20</td></tr>
<tr><td>control2</td><td>0</td><td>0</td><td>0</td><td>0</td><td>5</td><td>5</td><td>5</td></tr>
<tr><td>control3</td><td>0</td><td>0</td><td>0</td><td>0</td><td>5</td><td>10</td><td>15</td></tr>
<tr><td>control4</td><td>0</td><td>0</td><td>5</td><td>10</td><td>10</td><td>15</td><td>15</td></tr>
<tr><td>control5</td><td>0</td><td>0</td><td>0</td><td>5</td><td>10</td><td>10</td><td>20</td></tr>
<tr><td>controlØ</td><td>0</td><td>0</td><td>1</td><td>3</td><td>6</td><td>10</td><td>15</td></tr>
</table>
</td><td></td></tr>
</table>

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>-Effects investigated: % mortality</td><td></td><td></td></tr>
<tr><td>PT 18</td><td>in- and outdoor (in residential houses and adjacent areas like balconies and terraces)</td><td>„Profissimo Ameisenköder“

0.08% Spinosad w/w a.i. (synonym for the product “Ameiesn-Köderdosee”)</td><td>Lasius niger
Common black garden ant, colonies,
all develop-ment stages; approx. 1000 worker</td><td>Simulated -use study</td><td>- Application as bait station (ready to use product)
-Arena: waxed card-board box (60 x 40 x 15 cm) with one colony per replicate
-Temperature: 24 – 26°C
-Rel. humidity: 54 – 62%
-Dosage:1 bait station per arena (in the first 4 weeks), 2 stations (after 4 weeks)
-Acclimatisation: 7 d before treatment
-Starvation: 4 d (only water)</td><td>8 weeks after treatment:
<table><tr><th>replicate/ nest</th><th>number of dead ants visible in the arena (ca.)</th><th>number of living ants visible in the arena and nest (ca.)</th><th>brood</th><th>living queen</th><th>colony kill</th></tr><tr><td>1</td><td>450</td><td>50</td><td>no</td><td>yes</td><td>no</td></tr><tr><td>2</td><td>150</td><td>25</td><td>no</td><td>yes</td><td>no</td></tr><tr><td>3</td><td>250</td><td>100</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td>4</td><td>200</td><td>0</td><td>no</td><td>no</td><td>yes</td></tr><tr><td>5</td><td>500</td><td>0</td><td>no</td><td>no</td><td>yes</td></tr><tr><td>control 1</td><td>4</td><td>1000</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td>control 2</td><td>15</td><td>1000</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td>control 3</td><td>20</td><td>950</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td>control 4</td><td>10</td><td>1000</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td>control 5</td><td>13</td><td>1000</td><td>yes</td><td>yes</td><td>no</td></tr></table>
10 weeks after the treatment:
All treated colonies were killed (no brood, no living queens, no living workers).
In the untreated controls 950 to 1000 living workers, brood and queens were observed.</td><td>Lüpkes (2017b), report no.: BIO128-17</td></tr>
</table>

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function</th><th>Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>-Alternative food: sugar
-5 replicates (5 controls)
-Assessment intervals: biweekly after application up to 10 weeks
-Effects investigated: activity, determination of nest kill and killed queen</td><td></td><td></td></tr>
<tr><td>PT 18</td><td>in- and outdoor (in residential houses and adjacent areas like balconies and terraces)</td><td>„Profissimo Ameisenköder“
0.08% Spinosad w/w a.i. (synonym for the product “Ameiesn-Köderdosee”)</td><td>Lasius niger
Common black garden ant, colonies,
all develop-ment stages</td><td>Field trial</td><td>-Treatment of wild ant nests (Germany)
-Dosage:1 bait station per nest (next to the nest entrance)
-3 replicates (3 controls)</td><td>
<table>
<tr><th rowspan="2">replicate/ nest</th><th colspan="4">activity of ants (number of ants)</th></tr>
<tr><th>1 minute before treatment</th><th>1 week after treatment</th><th>2 weeks after treatment</th><th>3 weeks after treatment</th></tr>
<tr><td>1</td><td>approx. 200*</td><td>0</td><td>0**</td><td>0**</td></tr>
<tr><td>2</td><td>approx. 50*</td><td>approx. 10</td><td>0**</td><td>0**</td></tr>
<tr><td>3</td><td>approx. 100*</td><td>approx. 10</td><td>0**</td><td>0**</td></tr>
<tr><td>control 1</td><td>200*</td><td>250*</td><td>200*</td><td>50</td></tr>
<tr><td>control 2</td><td>400*</td><td>200</td><td>100*</td><td>50</td></tr>
<tr><td>control 3</td><td>50*</td><td>10</td><td>20</td><td>20</td></tr>
</table>
*with brood
</td><td>Lüpkes, (2017c), report no.: BIO125-17</td></tr>
</table>

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**
					-Assessment intervals: 1, 2, 3 weeks after application -Effects investigated: activity of ants, number of individuals after short liftnig of nest coverage, determination of nest kill by excavation of nests	** excavation: no activity, dead workers, no brood, no living queen	

3.5.6 Occurrence of resistance and resistance management

While Spinosad is a fairly new addition to the repertory of insecticides, its worldwide use over that last years has induced resistance development in some insect species, among them moths and flies. Even though no resistance development has been reported for ants as yet, a low risk could not be excluded.
Resistance management advice for non-professional use on the label:

- In the case of reduced efficacy or suspected development of resistance, the use of the product has to be discontinued immediately and a professional pest control operator needs to be contacted.
- To reduce the risk of resistance development different products containing various active substances (with different mode of actions) should be used alternately.
- products should always be used in accordance with label recommendations

As the product will affect other organisms in the treated area, and since resistance to Spinosad is known in other insects the product should be used with care.

3.5.7 Known limitations

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

3.5.8 Evaluation of the label claims

The submitted studies are suitable to support the claim “knocks down and kills individuals of the black garden ant (*Lasius niger)”.* Also the claim “nest kill” is supported. As the product does contain a preservative a shelf life of two years is supported.

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

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

3.5.10 Data waiving and conclusion

Table 20

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 21

Conclusion on the efficacy
The submitted studies are suitable to support the claim “knocks down and kills individuals of the black garden ant (*Lasius niger)”.* Also the claim “nest kill” is supported. Shelf life: 2 years

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 22

spinosad	Value	Study	Safety factor
AEL long-term	0.012 mg/kg bw/d[1,3]	24-month rat; Bond et al.(1995; 1996)	100
AEL medium-term	0.024 mg/kg bw/d[1,3]	90-day dog; Harada (1994)	100
AEL acute	Not necessary[1,2]		

Table 23

spinosad	Value	Reference
Inhalative absorption	Not established (calculated with 100 %)[1]	100%, default
Oral absorption	Rapid, about 60 % for spinosyn A and 45 % for spinosyn D within 24h, based on urinary and biliary excretion[1]	Domaradzki et al.(1995) Mendrala et al. (1995a, 1995b)
Dermal absorption	0.1 % for the concentrated product[1,4]	Van de Sandt (2002)
	2 % for a concentration comparable to the spray liquid[1,4]	Bogaards (2002)
	75/25 % (depending on concentration in the product)	Default

[1] Based on Assessment Report
[2] No acute effects; in case of acute exposure use the $AEL_{medium\text{-}term}$
[3] 50 % correction for oral absorption
[4]
The dermal absorption values were derived according to "Triple Pack" approach based on the studies by van de Sandt (2002) und Bogaards (2002) but are not conform with the current regulation (OECD 2011, EFSA 2012). This mainly refers to:

- The "Triple Pack" approach should be used only when the three studies are conducted under the same experimental conditions, including identical concentration of test substance, which was not the case.
- The *in vitro* study is of limited acceptability due to recovery < 90 % in some groups.
- The dermal absorption was not completed within the *in vitro* and *in vivo* studies; therefore it ought to be determined by adding the absorbed dose and the chemical remaining in the application site and the surrounding skin following washing.
- The dermal absorption values were not corrected for variability.
- There is no unacceptable human health risk associated even when the default values from the EFSA guidance were used.

Because of concern that the values of dermal absorption derived in Annex I might be underestimated and since the studies were performed with active substance they must not be used for product authorisation. Default values or additional study requirements should be considered instead.

3.6.2 Assessment of effects of the product on human health

Neither for the biocidal product nor for its components new data are available. The SDS submitted by the applicant does not contain additional relevant information, which may change the assessment. Also from other sources (e.g. ECHA registration reports) no new relevant information is available. New guidance on human health effect assessment is also not available. Accordingly, the conclusion from the former assessment regarding effects of the biocidal product on human health remains valid.

3.6.2.1 Skin corrosion and irritation

Table 24

Data waiving was acceptable for the following information requirements	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 25

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin.
Justification for the value/conclusion	According to Regulation (EC) No 1272/2008 Annex VI the active substance is not skin irritating. The biocidal product does not contain skin-irritating or corrosive substances in relevant concentrations. According to the CLP criteria, the biocidal product does not need to be classified with respect to local effects on the skin.
Classification of the product according to CLP	Classification for skin corrosion or irritation is not required.

3.6.2.2 Eye irritation

Table 26

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 27

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to eyes.
Justification for the value/conclusion	According to Regulation (EC) No 1272/2008 Annex VI the active substance is not eye irritating. The biocidal product does not contain eye-irritating or corrosive substances in relevant concentrations. According to the CLP criteria, the biocidal product does not need to be classified with respect to local effects on eyes.
Classification of the product according to CLP	Classification for eye damage or irritation is not required.

3.6.2.3 Respiratory tract irritation

Table 28

Data waiving	
Information requirement	Annex III of BPR (Regulation (EU) 528/2012), 8.7.1, "other endpoints"
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal product does not contain components classified for respiratory irritation in relevant concentrations.

Table 29

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.

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

3.6.2.4 Skin sensitization

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin-sensitising properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 31

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	Based on the known intrinsic properties of individual components and their concentration in the formulation the biocidal product is considered as not skin-sensitising.
Classification of the product according to CLP	Classification for skin sensitisation is not required.

3.6.2.5 Respiratory sensitization (ADS)

Table 32

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation

Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or the components are not available.

Table 33

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Respiratory sensitisation is not expected.
Justification for the value/conclusion	Data on respiratory sensitisation for the biocidal product or their components are not available.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected. The composition of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 35

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acute toxicity via the oral route.
Justification for the selected value	The oral LD_{50} of all components are > 2000 mg/kg bw. Hence, the oral LD_{50} of the biocidal product is estimated as > 2000 mg/kg bw.
Classification of the product according to CLP	Classification for acute oral toxicity is not required.

3.6.2.6.2 Acute toxicity by inhalation

Table 36

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected. The composition of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 37

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acute toxicity via the inhalation route.
Justification for the selected value	The inhalations LC_{50} of all components are assumed to be above the limits for classification. Hence, the inhalation LC_{50} of the biocidal product will be also above these limits.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

3.6.2.6.3 Acute toxicity by dermal route

Table 38

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2017), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected. The composition of the biocidal product is known. Data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal product is not required.

Table 39

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acute toxicity via the dermal route.

Value used in the Risk Assessment – Acute dermal toxicity	
Justification for the selected value	The dermal LD_{50} of all components are assumed to be > 2000 mg/kg bw. Hence, the dermal LD_{50} of the biocidal product is estimated as > 2000 mg/kg bw.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.6.2.7 Information on dermal absorption

The proposed dermal absorption value of 2 % was used in the former assessment. This value is based on the triple pack approach with a rat *in vivo* study (Bogaards, 2002, Dermal absorption study in rats with [^{14}C]-Spinosyn A, formulated as a suspension concentrate and as a spray dilution) and a rat and human skin *in vitro* study (van de Sandt, 2002, In vitro percutaneous absorption study with [^{14}C]-Spinosyn A through rat and human skin membranes). These studies do not fulfil the criteria of the EFSA Guidance on Dermal Absorption (2012 and 2017) with respect to the required identical treatment conditions between *in vitro* and *in vivo* studies.

Referring to the *in vitro* study the absorbable fraction in the skin was not considered. Since no tape stripping was performed in this study the whole amount in the skin has to be considered as absorbable. The variability of the measured values and the recovery was also not taken into consideration.

The similarity of the test substances and the biocidal product was also not evaluated in accordance to the current EFSA Guidance on Dermal Absorption. It should be noted that the test substance in the studies was a suspension concentrate with 480 g/L active substance and the corresponding dilutions.

Based on these deficiencies we expect that these studies are not appropriate to derive a reliable dermal absorption value for the biocidal product. Consequently, for the renewal of the active substance evaluation, we consider it necessary to re-assess the dermal absorption studies, to use the default value for water-based dilutions according to EFSA Guidance on Dermal Absorption (2017) or to evaluate new data on dermal absorption if available.

The approval of the active substance spinosad will expire in 2022, thus re-evaluation will start soon. Therefore, the value of 2 % dermal absorption for spinosad dilutions is used for the interim period until active substance re-evaluation and subsequent adoption for extension of biocidal product authorisations. There is no unacceptable human health risk associated even when the default values from the EFSA guidance were used.

3.6.2.8 Available toxicological data relating to nonactive substance(s) (i.e. substance(s) of concern)

Not relevant. There are no substances of concern in the biocidal product. Refer also to the Confidential Annex Information on the substance(s) of concern in the product.

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

Not available

3.6.2.11 Summary of effects assessment

Table 40

Endpoint	Brief description
Skin corrosion and irritation	Based on the properties of single components not classified for skin irritation or corrosion.
Eye irritation	Based on the properties of single components not classified for eye irritation or damage.
Respiratory tract irritation	Based on the properties of single components not classified for respiratory tract irritation.
Skin sensitisation	Based on the properties of single components not classified for skin sensitisation.
Respiratory sensitization (ADS)	Based on the properties of single components not classified for respiratory sensitisation.
Acute toxicity by oral route	Based on the properties of single components not classified for acute oral toxicity. Oral LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw.
Acute toxicity by inhalation	Based on the properties of single components not classified for acute inhalation toxicity. Inhalation LC_{50} calculated from information on the ingredients: > 5.0 mg/L (dust, mist)
Acute toxicity by dermal route	Based on the properties of single components not classified for acute dermal toxicity. Dermal LD_{50} calculated from information on the ingredients: > 2000 mg/kg bw
Information on dermal absorption	2 %
Available toxicological data relating to non-active substance(s)	Not relevant.
Available toxicological data relating to a mixture	Not relevant.
Other relevant information	Not available.

3.6.3 Exposure assessment

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

Table 41

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

List of scenarios

Table 42

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	Ready-to-use bait station	Primary exposure of workers resulting from opening and placing ready-to-use bait stations. Secondary exposure of a professional bystander is not expected.	Professional
2	Ready-to-use bait station	Secondary exposure of toddlers getting into contact with the impregnated pad in a bait station, representing also a worst case scenario for older children and adults and for primary exposure of non-professional users	General public. Non-professional users

3.6.3.1.1 Professional exposure

- **Scenario 1 Ready-to-use bait station**

Table 43

Description of Scenario 1 for professional use
„Ameisen-Köderdose" is a pre-filled insecticide bait for the control of ants which is supplied in a bait station marketed in size of 5 g. The b.p. is formulated in a bait matrix as a cellulose pad impregnated with an aqueous solution of the b.p. „Ameisen-Köderdose" is a ready-to-use product; no refilling occurs. The bait stations themselves are cylindrical metal tins. The cover and the bottom part of the metal tins are sealed with a rubber sealant. Prior to use, a screwdriver is used to open the metal tin on two small areas on the side of the can. The ready-to-use bait stations are distributed indoors / outdoors in proximity to insect nests or directly onto insect trails. After successful eradication of the target organisms the bait stations are collected and disposed. *Dermal exposure* The design of the bait station prevents users from coming into direct contact with the cellulose pad containing the b.p.. Exposure to skin is only expected to occur infrequently during opening of the bait stations. As a rare event, it is expected that the contact of the b.p. to the hands might not occur more than once per day, even if a higher number of applied bait is taken into account. In the *Biocides Human Health Exposure Methodology Document Version 1 (October 2015)* no suitable model is mentioned to assess the described exposure situation. The b.p. is assumed to be distributed evenly within a bait station. As a reasonable worst case scenario, the potential exposure to the hands is assessed taking into account the amount of b.p. in each bait station, the fraction of b.p. that is accessible to the hands and the transfer efficiency of the b.p., e.g. that fraction of the accessible b.p. which might be transferred to the hands. Since the biocidal product is a ready-to-use product, no mixing and loading phase is assumed. For removal and disposal of the bait stations, it appears reasonable to assume that a small contamination of the bait stations could occur by insects taking the substance out of the bait stations. However, exposure resulting from removing and disposing of lightly contaminated bait stations is assumed to be substantially lower than the exposure resulting from opening them. Thus, exposure from removal and disposal is covered by the worst case assumption made for assessing application of the bait stations. *Exposure by inhalation* Due to the non-volatile nature and the packaging of the b.p. inhalation exposure to aerosols or vapour is not expected for all phases of the application.

Description of Scenario 1 for professional use		
According to the CAR of spinosad, experimental data indicate that the vapour pressure for both isomers (spinosyn A and spinosyn D) is less than 10^{-5} Pa at 20°C. Therefore, exposure via inhalation of vapour is not considered to occur.		
	Parameters	Value
Tier 1	Concentration of the a.s. spinosad in the b.p.	0.08% (w/w)
	Total amount of a.s. on cellulose pad	4 mg
	Surface of cellulose pad in bait box	40cm^2
	Hand surface in contact to cellulose pad (section of fingertips)	10cm^2
	Transfer coefficient	20 %

Calculations for Scenario 1

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised inTable 44.

According to the calculation performed in TIER 1, additional protective equipment is not necessary; a risk for professional users is unlikely.

For details of the calculation of dermal and inhalation exposure, please refer to Annex “Output tables from exposure assessment tools“ of this PAR. For risk characterisation, see the relating section “Risk for professional users”

- **Summary of professional exposure**

The described exposure assessment is valid for professional users (e.g. housekeepers) or specialised professional users (e.g. pest control operators).

No secondary exposure of professionals is expected in view of the anticipated use patterns.

Table 44 Summary of external exposure assessment

Scenario 1: Professional user getting in contact with the a.s. on cellulose pad in the bait box

Ingredient biocidal product	TIER 1		TIER 2	
	potential inhalation [mg/m³]	potential dermal [mg/day]	actual inhalation [mg/m³]	actual dermal [mg/day]
a.s.: spinosad	not expected	0.2	not expected	0.02

- **Combined scenarios**

Not applicable.

3.6.3.1.2 Non-professional exposure

Although new guidance documents on human exposure are available (Biocides Human Health Exposure Methodology, 2015; up to date recommendations of the Ad hoc Working Group on Human Exposure) this will not change the former assessment for non-professional users significantly. Hence, the former exposure assessment remains valid. Exposure assessment was directly adapted from the former PAR.

It is expected that the non-professional user may get in contact with the impregnated pad when preparing (opening the holes) and placing the metal tin. This scenario is very similar to the secondary exposure scenario for infants. It is assumed that this secondary exposure scenario represent also 'worst case' conditions for the primary exposure of an adult. Therefore, only the secondary exposure scenario was assessed.
Exposure of non-professional users may occur over several months when ants are active. Since one box is efficient for 6 to 8 weeks exposure is considered as medium-term exposure.

3.6.3.1.3 Secondary exposure of the general public

Although new guidance documents on human exposure are available (Biocides Human Health Exposure Methodology, 2015; up to date recommendations of the Ad hoc Working Group on Human Exposure) this will not change the former assessment for the general public significantly. Hence, the former exposure assessment remains valid. Exposure assessment was directly adapted from the former PAR.

- **Scenario [2]**

Table 45

Description of Scenario [2] for general public and non-professional use
A cylindrical metal tin containing a cellulose pad impregnated with the biocidal product is used for application. The diameter of the box is 78.8 mm on the upper side and 82.5 mm on the bottom side. The height is 20.5 mm. The ants get into contact with biocide after entering the bait via two small holes, which were opened by the user. It is assumed that an infant or a user can grasp into the tin through these holes with their finger tips and get in dermal contact with the impregnated cellulose pad. According to the applicant, the total amount of spinosad in one tin is about 4 mg. The applicant did not provide information on the size of the cellulose pad in the box. It is assumed that the pad has a diameter of 50 mm resulting in a total surface of 40 cm^2 on both sides. The height of the pad is not taken into

consideration. Thus, the pad is impregnated with 0.1 mg/cm^2. It is assumed that an infant gets in contact with about 10 cm^2 of its hand (representing the finger tips), when grasping into the tin through the hole. Taking into account a transfer coefficient of 20 % for dried fluids on cellulose the external exposure is about 0.2 mg spinosad.

For Annex I inclusion a dermal absorption study with an aqueous spray dilution was submitted. The dermal absorption value from this study (2 %) is still considered applicable for the biocidal product. The composition of the biocidal product and the tested dilution differs significantly. However, the main components of these mixtures are water (for the test dilution) and water, sugar and cellulose pad (for the biocidal product). These components are not expected to influence dermal absorption significantly. The concentrations of other components, which may have an effect due to their irritating properties, are strongly diluted far below any concentration limit for classification. Thus, significant effects on dermal absorption are not expected. The concentration of the active substance in the biocidal product is significantly higher than in the tested dilution particularly since the biocidal product dried after impregnation of the cellulose pad. Based on the dermal absorption studies submitted for active substance evaluation of spinosad it can be assumed that dermal absorption values for this active substance decrease with higher concentrations. Thus, the value of 2 % represents 'worst case' conditions for the active substance spinosad in this biocidal product.

Taking into account a dermal absorption of 2 % and a body weight of 10 kg for toddler a systemic dermal exposure of 0.0004 mg/kg bw can be calculated.

For oral exposure it is assumed that 50 % of the external dermal dose (0.2 mg) is ingested orally. This factor is adopted from the HEAhoc recommendation No. 5 (Non-professional use of antifouling paints: exposure assessment for a toddler, 2015) Although this factor is proposed for dried paints it is considered also applicable for other dried residues transferred to hands. Taking into account an oral absorption of 50 % and a body weight of 10 kg the systemic oral exposure is 0.005 mg/kg. As a worst case reduction of the dermal load by oral uptake is not taken into account.

Due to the low vapour pressure of less than 3.0 x 10^{-8} (25 °C, spinosad A) a significant influence of inhalation exposure on the total systemic exposure is not expected.

The estimated total systemic exposure is 0.0054 mg/kg bw.

Exposure of infants is expected to be an incidental event occurring only occasionally and which would be considered as acute exposure. However, since an AEL_{acute} has not been derived, exposure is compared to the $AEL_{medium\text{-}term}$.

	Parameters	Value
Tier 1	Oral absorption (CAR, 2010)	50 %
	Dermal absorption (CAR, 2010; justification above)	2 %
	Body weight toddler (HEAdhoc recommendation No. 14, 2017)	10 kg
	Spinosad content in one bait tin (applicant)	4 mg
	Surface of cellulose pad in the bait tin (applicant)	40 cm^2

	Skin surface (fingertips) in contact to pad in the tin (expert judgement)	10 cm^2
	Transfer coefficient pad to skin (Biocides Human Health Exposure Methodology, 2015)	20 %
	Transfer coefficient hand-to-mouth (HEAhoc recommendation No. 5, 2015)	50 %

Calculations for Scenario [2]

Dermal systemic exposure = Spinosad content in one bait tin / surface of cellulose pad in the bait tin x skin surface (fingertips) x transfer coefficient x dermal absorption / body weight

= 4 mg / 40 cm^2 x 10 cm^2 x 20 % x 2 % /10 kg

= 0.0004 mg/kg bw/d

Oral systemic exposure = Spinosad content in one bait tin / Surface of cellulose pad in the bait tin x Skin surface (fingertips) x transfer coefficient x transfer-hand-to-mouth x oral absorption / body weight

= 4 mg / 40 cm^2 x 10 cm^2 x 20 % x 50 % x 50 % /10 kg

= 0.005 mg/kg bw/d

Total systemic exposure = 0.0054 mg/kg bw

Table 46

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	1	-	0.0004	0.005	0.0054

- **Combined scenarios**

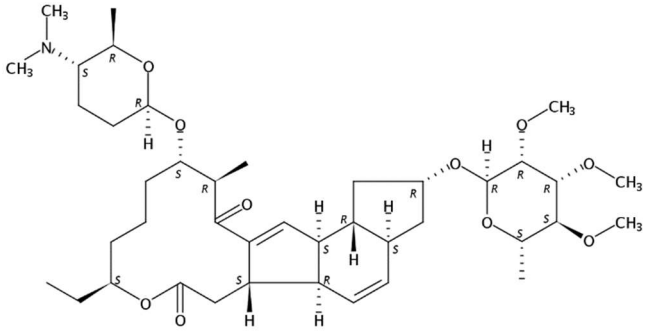
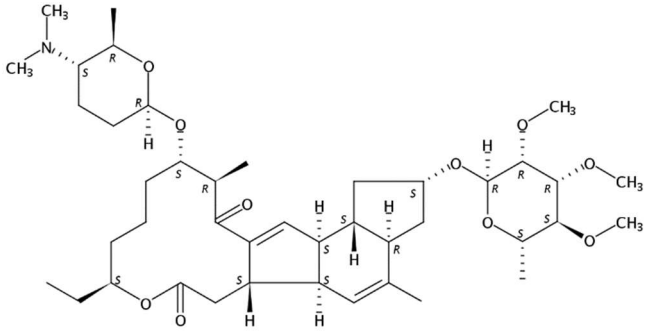
Not relevant.

3.6.3.2 Dietary exposure

The intended use descriptions of the spinosad-containing biocidal product for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The biocidal product is to be used for control of ant pests by bait application to localised areas so that the biocidal product does not come into contact with food and feedstuff. However, to ensure that there will be no contact with food and feedstuff a risk mitigation measure should be added on the label.

3.6.3.2.1 General information on active substance(s)

Table 47

Active substance (Common Name)	spinosad (ISO, ANSI) is a mixture of spinosyn A and spinosyn D. Spinosad typically contains spinosyn A and spinosyn D in a ratio of 85:15 (w/w) and a range between 95:5 (w/w) and 50:50 w/w.
CAS number	**spinosad** 168316-95-8 **spinosyn A** 131929-60-7 **spinosyn D** 131929-63-0
Chemical structure	**spinosyn A**  **spinosyn D** 
Molecular formular	**spinosyn A**: $C_{41}H_{65}NO_{10}$ **spinosyn D**: $C_{42}H_{67}NO_{10}$
Molar mass	**spinosyn A**: 731.98 g/mol **spinosyn D**: 746.00 g/mol
Log Po/w	**spinosad** not verified **spinosyn A** (97% w/w) Log K_{ow} = 3.91 at 23 °C (water) Log K_{ow} = 2.78 at 23 °C (pH 5) Log K_{ow} = 4.01 at 23 °C (pH 7) Log K_{ow} = 5.16 at 23 °C (pH 9) **spinosyn D** (98% w/w) Log K_{ow} = 4.38 at 23 °C (water) Log K_{ow} = 3.23 at 23 °C (pH 5) Log K_{ow} = 4.53 at 23 °C (pH 7) Log K_{ow} = 5.21 at 23 °C (pH 9)

Active substance approval	PT: 18; RMS: NL
Restrictions	-
Current regulations on MRLs	-

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

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Summary of exposure assessment

Table 48

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	Non-professionals, bystanders	1	0.0054 mg/kg bw/d
Use of ready-to-use bait station	Professional user	1 (no PPE)	Acceptable[5]

[5] For external exposure values please refer to Table 44 Summary of external exposure assessment

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report as in Table 22 and Table 23 of Section 3.6.1 Assessment of effects of the active substance on human health.

3.6.4.2 Maximum residue limits or equivalent

No MRLs are required.

3.6.4.3 Risk for industrial users

No industrial applications are intended.

3.6.4.4 Risk for professional users

Based on the risk assessment of spinosad via the dermal route, a risk for professional users resulting from the intended use with the biocidal product ‘Ameisen-Köderdose’ is unlikely. Regarding occupational safety, there are no objections against the intended use taking into account the provisions described in chapter 2 of this PAR.

Spinosad:

According to chapter 3.6.3.1.1 Professional exposure of this PAR inhalation exposure of professional users to spinosad is not expected. Thus the quantitative risk characterisation for professional users which is presented in this PAR takes into account dermal exposure to spinosad resulting from use of the biocidal product ‘Ameisen-Köderdose’. The internal reference value 0.012 mg/kg bw/d ($AEL_{long\text{-}term}$) is used and converted to an external reference value in order to allow for a comparison with external exposure concentrations of spinosad.

Table 49 gives an overview of the risk characterisation results referring to spinosad for the biocidal product ‘Ameisen-Köderdose’. It is noted that the risk index (RI) is rounded up or down to two decimal places in this table. For detailed calculations and risk indices see Annex 4.3.1

Table 49 Overview of the risk characterisation results referring to spinosad for use of the biocidal product 'Ameisen-Köderdose'.

Intended Use	TIER 1		TIER 2	
	Concern	RI_I	Concern	RI
professional user getting in contact with the a.s. in the bait box	**no**	0.01	n.a.	n.a.

3.6.4.5 Risk for non-professional users

Since the former exposure assessment remains valid and also human health assessments for the active substance and for one of the potential substances of concern do not change (including reference values) a revision of the risk characterisation is not required. For the other potential substance of concern a local risk assessment is not required. The risk characterisation from the former assessment remains valid.
Note that the risk assessment for non-professional user is covered by the secondary exposure assessment for the general public if the biocidal product is used as intended. Hence, refer to the risk assessment for the general public for more details.
Based on the secondary exposure assessment primary exposure of the non-professional user is below the AEL.

- **Local effects**

Local effects are not expected.

Conclusion

Exposure of the non-professional user to the biocidal product containing 0.08 % (w/w) spinosad as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

3.6.4.6 Risk for the general public

Since the former exposure assessment remains valid and also human health assessments for the active substance and for one potential substance of concern do not change (including reference values) a revision of the risk characterisation is not required. For the other potential substance of concern a local risk assessment is not required. The risk characterisation form the former assessment remains valid

Systemic effects

Table 50: 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)
2	1	2.4	0.024	0.0054	22.5	yes

Local effects

Local effects are not expected.

Conclusion

Exposure of the general public to the biocidal product containing 0.08 % (w/w) spinosad as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

3.6.4.7 Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

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

A risk characterisation from combined exposure is not applicable.

3.6.4.9 Summary of risk characterisation

3.6.4.9.1 Summary of risk characterisation for industrial user

Not applicable

3.6.4.9.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product Ameisen-Köderdose is unlikely for the intended use getting in contact with the bait box. No risk mitigation measures have to be taken into account in order to ensure safe use of the biocidal product Ameisen-Köderdose.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.9.3 Summary of risk characterisation for non-professional user

Table 51

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
1 (based on exposure assessment of the general public)	0.024	0.0054	22.5	yes

3.6.4.9.4 Summary of risk characterisation for indirect exposure

Table 52

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
1	0.024	0.0054	22.5	yes

3.6.4.10 Endocrine disrupting properties

No co-formulant of the biocidal product was identified as an ED in accordance with Article 57(f) and Article 59 (1) REACH or in any EU decision.
There are no data indicating that any co-formulant of the biocidal product may have endocrine disrupting properties based on the existing knowledge and the available scientific information. Therefore, the co-formulants are not considered to have endocrine disrupting properties.

3.7 Risk assessment for animal health

A risk assessment for animals (pets, domestic animals) was not performed at the first evaluation. There is no information on a specific sensitivity of pets and domestic animals. As a worst case it is assumed that the secondary exposure and risk assessment for the general public is also applicable for these animals. Hence, specific measures to protect pets and domestic animals are not required.

3.8 Risk assessment for the environment

3.8.1 General information

The biocidal product (b.p.) 'Ameisen-Köderdose' is used as insecticide (PT18) to control ants (*formicidae*) in and around buildings. The product is for indoor and outdoor use by non-professional, professional and trained professional users. The ready-to-use bait box contains 5 g of a liquid bait solution soaked on a pad, the bait solution itself contains 0.08 % of the active substance spinosad.

Besides the active substance spinosad itself, no further substances within the biocidal product trigger a classification for the environment. It can therefore be concluded that no substances of concern (SoC) have to be considered within the risk assessment in line with the relevant guidance Vol. IV Part B 1.0 (04/2015).

No further studies for the active substance or the product were submitted. Consequently, the environmental risk assessment for this product is based on the agreed assessment report for the active substance spinosad PT18 by NL from 2010.

3.8.2 Effects assessment

The environmental effects assessment is based on the final Assessment Report of the active substance spinosad of May 2010 (Rapporteur NL). Detailed data on the environmental effect assessment and the PNEC derivation of the active substance and its transformation products can be found in the final Assessment Report (May 2010) for spinosad (PT18).

It should be noted that the PNEC values that were originally stated in the CAR contain minor errors for soil and sediment: For calculating the equilibrium partitioning method for soil, the arithmetic mean instead of the geometric mean Kp_{soil} should be used, and for sediment, the conversion factor for wet weight has to be corrected. No updated CAR is available currently, but member states have agreed to already apply the corrected PNEC values for soil and sediment. A summary is included in the chapters below.

3.8.2.1 Aquatic compartment (including sediment and STP)

In the Assessment report for spinosad, a $PNEC_{water}$ of 0.062 µg a.s./L has been derived. For the metabolites the $PNEC_{water}$ values are 0.095 µg/L for spinosyn B and 0.023 µg/L for N-demethylated spinosyn D.

Sediment: The $PNEC_{sed}$ for spinosad was derived from a study with *Chironomus riparius* (NOEC = 60 µg/kg dw) and an AF of 100, resulting in a $PNEC_{sed}$ of 0.6 µg/kg dw. Applying a conversion factor of 4.3 results in a $PNEC_{sediment}$ of 0.13 µg/kg wet weight. It should be noted that the CAR from 2010 contains a different value (0.23 µg/kg wet weight), based on an error in the conversion to wet weight, and the error was identified in 2014 during the evaluation of a different product. No transformation product was considered relevant for the sediment phase.

STP: In a study according to OECD 209 spinosad had no effects at the tested concentrations. Based on this study and an AF of 10, $PNEC_{STP\ microorganisms}$ results in >10 mg/L.

3.8.2.2 Terrestrial compartment (including groundwater)

Based on equilibrium partitioning, the $PNEC_{soil,EP}$ for spinosad is 7.53 µg/kg ww soil. The $PNEC_{soil,EP}$ for major metabolites spinosyn B and N-demethylated spinosyn D are 4.32 and 1.05 µg/kg ww, respectively. It should be noted that the values in the assessment report from 2010 are slightly lower, due to contradicting use of arithmetic and geometric mean values for Kp_{soil} (despite the conclusion regarding calculation method for mean Kp_{soil} in the fate section, a different mean was applied for the effect assessment for $PNEC_{soil,EP}$ in the assessment report from 2010).

Toxicity to bees: Spinosad is highly toxic to bees both by oral und contact exposure. Based on a 48 hour study with honeybees, an LD_{50} for oral toxicity in the range 0.049 to 0.057 µg a.s./bee and for contact toxicity LD_{50} between 0.0036 to 0.05 µg a.s./bee have been determined.

3.8.2.3 Atmosphere

Exposure of the air compartment is not to be expected, due to the low volatility of the active substance and the intended use of the b.p. Ameisen-Köderdose.

3.8.2.4 Non-compartment specific effects

Primary poisoning: An assessment of primary poisoning is not required according to the recommendations given in the Emission Scenario Document for PT 18 No. 18 (2008).

Secondary poisoning: Since the log K_{OW} for spinosyn A and spinosyn D exceed 3, an assessment of the risk to the food chain due to secondary poisoning is considered to be necessary according to Guidance on BPR Vol. IV Part B+C (2017). Furthermore, the ESD PT18, No.18 provides a further approach for assessment of secondary poisoning; via intake of contaminated feed and the risk of secondary poisoning should be considered at the local scale. For mammals a $PNEC_{oral}$, mammal of 3.33 mg/kg feed and for birds a $PNEC_{oral}$, bird of 18.3 mg/kg feed is given in the Assessment Report for spinosad (2010).

3.8.2.5 Summary of effects assessment

Predicted no effect concentration values (PNEC) are based on the Assessment Report for spinosad in PT18 (2010), including corrections with regard to mean Kp_{soil} (for $PNEC_{soil}$) and conversion to wet weight (for $PNEC_{sediment}$).

Table 53

Summary table on calculated PNEC values			
Compartment	**Spinosad**	**Spinosyn B**	**N-demethylated spinosyn D**
Water [µg/L]	0.062	0.095	0.023
Sediment [µg/kg wwt]	0.13	–	–
STP [mg/L]	> 10	–	–
Soil [mg/kg wwt]	7.53×10^{-3}	4.32×10^{-3}	1.05×10^{-3}

3.8.2.6 Bioconcentration

Partitioning in octanol/water system of spinosyn A and D at pH 7 has been determined with log K_{ow} = 4.01 and 4.53, respectively, indicating that spinosad is likely to bioaccumulate in aquatic or terrestrial species. However, valid BCF studies on fish showed depuration time in fish < 5 days and low BCF_{fish} values of 84 and 114 L/kg for spinosyn A and 100 and 115 for spinosyn D (mean BCF = 103 L/kg for Spinosad). Those measured BCF_{fish} are used for risk assessment indicating the low potential of spinosad to bioaccumulate in fish.

3.8.3 Exposure assessment

3.8.3.1 General information

The 'Ameisen-Köderdose' is used under PT 18 Insecticides, acaricides and products to control other anthropods for household an professional uses, July, 17, 2008 (ENV/JM/Mono(2008)14).
The product is a ready-to-use bait box, which can be used indoor and outdoor.

Table 54

Assessed PT	PT 18
Assessed scenarios	Outdoor spot application (bait boxes) Scenario 1: Spot application on terraces for non-professional use Scenario 2: Spot application around buildings on unpaved surfaces for professional use Scenario 3: Spot application around buildings on paved surfaces for professional use

ESD(s) used	Emission Scenario Document for Product Type 18: Insecticides, acaricides and products to control other anthropods for household an professional uses, July, 17, 2008 (ENV/JM/Mono(2008)14)
Approach	Scenario 1: Average consumption Scenario 2: Average consumption Scenario 3: Average consumption
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation Vol. IV Environment – Assessment and Evaluation (Parts B + C), Version 2.0 (October 2017)
Groundwater simulation	No higher tier model was performed
Confidential Annexes	
Life cycle steps assessed	Scenario 1/2/3: Production: No Formulation No Use: Yes Service life: No
Remarks	

3.8.3.2 Fate and distribution in exposed environmental compartments

The environmental exposure to Spinosad was assessed for the use of the active substance integrated in a liquid formulation of a watery bait solution absorbed on a cellulose pad which is tightly sealed in a metal tin ('Ameisen-Köderdose') for use as bait against ants (product type 18). Target organisms are ants, e.g. Black Ants (*Lasius niger*).

The local environmental concentrations of Spinosad were estimated based on the respective Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD ESD PT18 No. 18, 2008), the Guidance BPR Vol. IV B+C ENV (2017), the assessment report of Spinosad (Assessment Report Spinosad PT 18, May 2010) and the CAR Spinosad, RMS The Netherlands (May 2010).

For the environmental exposure estimation the following endpoints are considered:

Spinosad is a naturally derived bacterial fermentation product which contains a mixture of two structurally similar molecules, Spinosyn A and Spinosyn D at a ratio of 85:15 (w/w). Both molecules are active insecticides.

Spinosad is not considered to be volatile (vapour pressure 1.195×10^{-8} Pa and 7.966×10^{-9} Pa at 285 K for Spinosyn A and Spinosyn D, respectively). A half-life of 1.25 hours is estimated for Spinosad due to phototransformation in air (OH radical concentration of 5×10^{5} radicals$\times$cm^{-3} over 24 hours) assuming no accumulation potential of the a.s. in the atmosphere.

Spinosyn A is moderately soluble in water (209 mg/L at neutral conditions and 285 K) while Spinosyn D is slightly soluble in water (0.295 mg/L at neutral conditions and 285 K). Both components are hydrolytically stable in the pH range of natural water, and susceptible to photolysis in water.

Elimination in sewage treatment plant: as Spinosyn is not biodegradable the degradation rate constant in sewage treatment plant is k_{STP} = 0 h^{-1} (Guidance BPR Vol. IV B+C ENV, 2017, chapter 2.3.6.4, table 4). The distribution and degradation of the a.s. in the STP is simulated using the model SimpleTreat (version 4.0). The fraction of emissions directed to water (F_{water}) amounts to 17.8 % and the fraction of emissions directed to sludge (F_{sludge}) amounts to 82.1 %.
The degradation rate constant in soil k_{bio_soil} is equal to 1.47×10^{-2} d^{-1} and 1.01×10^{-2} d^{-1} for Spinosyn A and Spinosyn D, respectively. According to the assessment report for Spinosad the main metabolite of Spinosyn A is Spinosyn B and the main metabolite of spinosyn D is N-demethylated spinosyn D, both metabolites were detected in all available soil degradation studies.
Based on the given organic carbon-water partitioning coefficient K_{oc} of 35024 L/kg (for both parent components), the soil-water partitioning coefficient $K_{soil\text{-}water}$ of 1,050 $m^3 x m^{-3}$ is calculated and the partition coefficient suspended matter-water $K_{susp\text{-}water}$ equals to 875.8 $m^3 x m^{-3}$. The high K_{oc} value for the a.s. as well as the K_{oc} of 20328 L/kg for both metabolites indicate that the mobility of the a.s. and its metabolites is expected to be low. As it was discussed in Doc IIA, chapter 4.1.2.1, of the final draft CAR for spinosad (eCA NL) instead of the K_{oc}-values the K_{ads}-values (arithmetic mean 137.6 L/kg for the parent components) should be used to calculate $K_{soil\text{-}water}$. Then, a soil-water partitioning coefficient $K_{soil\text{-}water}$ of 206.6 $m^3 x m^{-3}$ is calculated for Spinosyn A and D. Based on the K_{ads} of 51.4 L/kg (for the metabolites) the value $K_{soil\text{-}water}$ of 77.3 $m^3 x m^{-3}$ should be used for the metabolites.
The formulation of the biocidal product ‘Ameisen-Köderdose’ is considered not to alter any of the physicochemical properties of the active substance Spinosad.

‘Ameisen-Köderdose’ is marketed as two-pieces blisters with entirely closed ready-to-use aluminium boxes (each 5 g) for professionals and consumers containing the active substance Spinosad at a concentration of 0.8 mg/g (0.08% w/w). The product ‘Ameisen-Köderdose’ containing Spinosad is used for the control of ants in buildings and in close proximity to gardens and buildings, e.g. on terraces and around a building. According to the OECD ESD PT18 No. 18 (2008), chapter 2.4.9, insecticides in sealed bait boxes (bait stations) are usually ready-to-use products (i.e. neither mixing nor loading steps) and for these products emissions to the environment during handling are negligible. Furthermore, it is assumed that no release will occur during the service life stage for solid baits and gels deployed in bait stations and used for indoor treatments (ref. to Table 3.3-8 in OECD ESD PT 18 No. 18). The only possible emission route is when the box is eliminated to waste (indoor and outdoor use) and through flooding and insect dispersion during outdoor uses. The latter emission scenarios are included in the presented environmental exposure assessment and risk assessment.

Table 55: Identification of relevant receiving compartments based on the exposure pathway

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Soil**	**Ground-water**	**Air**	**Secondary poisoning**
Scenario 1	-	-	-	-	-	++	++	-	+
Scenario 2	-	-	-	-	-	++	++	-	+
Scenario 3	+	+	-	-	++	+	+	-	+

++ direct exposure

+ indirect exposure (from STP discharge: surface water, sludge application: soil, groundwater))

Table 56: Input parameters (only set values) for calculating the fate and distribution in the environment

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight			
Spinosyn A	731.98	g/mol	LOEP
Spinosyn D	746.00	g/mol	LOEP
Melting point			
Spinosyn A (98.3% w/w)	84.0 to 99.5	°C	LOEP
Spinosyn D (98.00 w/w)	161.5 to 170.0	°C	LOEP
Boiling point	Decomposition before boiling	°C	LOEP
Vapour pressure (at 25°C)			
Spinosyn A	3.0×10^{-8}	Pa	LOEP
Spinosyn D	2.0×10^{-8}	Pa	LOEP
Water solubility (at 20°C)			
Spinosyn A (pH 7)	235	mg/L	LOEP
Spinosyn D (pH 7)	0.331	mg/L	LOEP
Log Octanol/water partition coefficient			
Spinosyn A (pH 7)	4.01	Log 10	LOEP
Spinosyn D (pH 7)	4.53	Log 10	LOEP
Organic carbon/water partition coefficient (Koc)			
Spinosyn A / D	35024	L/kg	LOEP
Soil-water partitioning coefficient (Ksoil-water)			
Spinosyn A / D	206.6	m^3/m^3	CAR
Biodegradability	*Not biodegradable*		
DT_{50} for degradation in soil			
Spinosyn A	47 d	d (at 12ºC)	LOEP
Spinosyn D	69 d	d (at 12 °C)	LOEP

Table 57: Summary table on relevant metabolites

Summary table on relevant metabolites		
Metabolite/transformation- or reaction product	**Compartment**	**% Active Substance**
Spinosyn B	terrestrial compartment	max. 67%
N-demethylated spinosyn D	terrestrial compartment	max. 68%

3.8.3.3 Aquatic compartment (including sediment and STP)

Emission estimation

According to the use of 'Ameisen-Köderdose' on unpaved surfaces (outdoor on terraces in close proximity to gardens or around buildings) the aquatic compartment is not the receiving compartment for emission of Spinosad from the bait boxes. In case of the use of 'Ameisen-Köderdose' on paved surfaces around buildings emissions to the STP and the subsequent receiving compartments are possible. The only relevant pathway to the aquatic compartment is via STP.

- **Scenario 1 and 2: Spot application on terraces for non-professional use and Spot application around buildings on unpaved surfaces for professional use**

Both use scenarios are not relevant for emission to aquatic compartment as emission to STP or surface water and sediment is not expected.

- **Scenario 3: Spot application around buildings on paved surfaces for professional use**

The spot application of the b.p. 'Ameisen-Köderdose' on paved surfaces around larger buildings is considered as relevant emission path for the aquatic compartment. The amount of b.p. that is used during treatment, is indicated with 1 or 2 boxes per 12 m² (each box includes 5 g b.p.) depending on the level of ant pressure. Regarding the decision at WG ENV V 2018 it is agreed that the perimeter around larger buildings is equal to 100 m. An extrapolation according to the amount of max. 2 bait boxes per 12 m² results in 9 bait boxes on 100 m around larger buildings, considering a distance of 0.5 m from the wall of the building. It is indicated in the OECD ESD PT 18 No.18 that about 80% of the product is consumed by target insects whereas 20% remain in the bait station and can be emitted ($F_{spot,bait}$) by flooding after a rain event. The input parameters for calculating $E_{spot_{local}}$ are summarised in Table 58.

Table 58 Overview of input parameters of Spinosad following application of 'Ameisen-Köderdose' (outdoor, around larger buildings on paved surfaces)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 3: **Spot application around buildings on paved surfaces for professional use**			
Amount of product used at each refilling in the control operation for each bait box (Q_{prod})	5	g	S
Fraction of a.s. in product (F_{AI})	0.0008	-	S
Number of application sites (N_{sites})	9	-	S
Fraction of a.s. emitted to soil during outdoor bait application ($F_{spot,bait}$)	0.2	-	D

Calculations for Scenario 3: Spot application around buildings on paved surfaces for professional use

$$E_{spot\_local} = Q_{prod} \times F_{AI} \times N_{sites} \times F_{spot\_bait}$$

The application of the b.p. around larger buildings on paved surfaces results in a release of **7.2 mg** Spinosad to the sewer system.

The local emission of both similar molecules, Spinosyn A and Spinosyn D at a ratio of 85:15 (w/w) are summarised in

Table **59**.

Table 59 Resulting local emission to relevant environmental compartment: STP

Resulting local emission to relevant environmental compartment: STP		
	Local emission ($Elocal_{compartment}$) mg/d	Remarks
Spinosad	7.2	$Espot_{local}$
Spinosyn A	6.12	
Spinosyn D	1.08	

As already mentioned here above (ref. to chapter 4.9.3.2), the distribution and degradation of the a.s. in the STP was simulated using the model SimpleTreat (version 4.0):

Table 60 Calculated fate and distribution in the STP

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	Scenario 3	
Air	0.0	Model used Simple Treat 4.0
Water	17.8	
Sludge	82.1	
Degraded in STP	0.0	

Calculating the local release to STP a simultaneity factor F_{sim} of 0.81% is applied considering a frequency of use of b.p. up to eleven times per year. A number of 300 larger buildings connected to the STP are considered, as it is described in ENV 140 TAB version 2.0 (2018).
According to the intended use of 'Ameisen-Köderdose' in scenario 3, indirect emission to surface water and sediment via output of the effluent from STP occurs. The predicted environmental concentrations for STP, surface water and sediment are estimated as follows:

PEC_{STP} (=$Clocal_{inf}$) and $Clocal_{eff}$ according to equation 35, 36 and 42, chapter 2.3.6.7, Guidance BPR Vol. IV B+C ENV (2017)

$PEClocal_{surfacewater}$ according to equation 51, chapter 2.3.7.3.1, Guidance BPR Vol. IV B+C ENV (2017)

$PEClocal_{sediment}$ according to equation 53, chapter 2.3.7.3.2, Guidance BPR Vol. IV B+C ENV (2017)

The results are summarised in Table 61.

Table 61 Summary of STP influent ($Clocal_{inf}$) and effluent ($Clocal_{eff}$), PEC_{STP}, $PEClocal_{surface\ water}$ and $PEClocal_{sediment}$

	$Clocal_{inf}$ [mg/L]	**$Clocal_{eff}$** [mg/L]	**PEC_{STP}** [mg/L]	**$PEClocal_{surface\ water}$** [mg/L]	**$PEClocal_{sediment}$** [mg/kg]
Spinosyn A	7.48×10^{-6}	1.33×10^{-6}	7.48×10^{-6}	1.27×10^{-7}	9.68×10^{-5}
Spinosyn D	1.32×10^{-6}	2.35×10^{-7}	1.32×10^{-6}	2.23×10^{-8}	1.70×10^{-5}

3.8.3.4 Terrestrial compartment (including groundwater)

- **Emission estimation**

Scenario 1: Spot application on terraces for non-professional use

For the estimation of direct emissions to soil the emission scenario "spot application" from OECD ESD PT18 No. 18, chapter 4.4.5 is used. The direct amount of b.p., that is used during treatment, is indicated with 1 or 2 boxes per 12 m² (1 or 2 boxes (each 5 g b.p.) placed on a terrace per house) depending on the level of ant pressure. According to the TAB 2.0 (August 2018) ENV 154 flooding rain event refers to a terrace of about 30 m² and a receiving adjacent soil area of 8.5 m² (taking into account three sides of the terrace) of one house. Regarding a high infestation 5 boxes were considered. It is indicated in the OECD ESD PT 18 No.18 that about 80% of the product is consumed by the insects whereas 20%

remain in the bait station and can be emitted into soil ($F_{spot,bait}$) by flooding after a rain event. The input parameters for calculating the direct emission to soil (E_{spot_soil}) are summarised in **Table 60**.

Table 62: Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Spot application on terraces for non-professional use			
Amount of product used at each refilling in the control operation for each bait box (Q_{prod})	5	g	S
Fraction of a.s. in product (F_{AI})	0.0008	-	S
Number of application sites (N_{sites})	5	-	S
Fraction of a.s. emitted to soil during outdoor bait application ($F_{spot,bait}$)	0.2	-	D
Area directly exposed to insecticide ($AREA_{exposed}$)	8.5	m²	D (TAB 2.0, 2018)
Depth of exposed soil ($DEPTH_{soil}$)	0.5	m	D
Density of exposed soil (RHO_{soil})	1700	kg/m³	D

Calculations for Scenario 1

$$E_{spot\_soil} = Q_{prod} \times F_{AI} \times N_{sites} \times F_{spot\_bait}$$

Table 63: Resulting local emission to relevant environmental compartments: Soil

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ($Elocal_{compartment}$) mg/d	Remarks
Soil	4	E_{spot_soil}

The application of the b.p. on a terrace results in a release of **4 mg** to the surrounding soil.

Using the above indicated input parameters the following predicted concentrations of Spinosad in soil (ref. to ESD PT18 No. 18, eq. 60, chapter 4.4.5) and groundwater (ref. to Guidance BPR Vol. IV B+C ENV (2017), eq. 71, chapter 2.3.7.6) were calculated following the application of b.p. 'Ameisen-Köderdose' outdoor on terraces:

Table 64: Summary of $PEClocal_{soil}$ and $PEClocal_{groundwater}$

Calculated PEC values		
	PEC_{soil}	**PEC_{GW}**
	[mg/kg]	[µg/L]
Scenario 1: Spot application on terraces for non-professional use		
Spinosyn A	4.70×10^{-4}	3.87×10^{-3}

Spinosyn D	8.30×10^{-5}	6.83×10^{-4}

The estimated PEC for groundwater in Scenario 1 is below the groundwater trigger value of 0.1 µg/L.

Scenario 2: Spot application around buildings on unpaved surfaces for professional use

For the estimation of local emission to soil due to direct release after a campaign around buildings the emission scenario "spot application" from OECD ESD PT18 No. 18, chapter 4.4.5 is used. The direct amount of b.p. is about 5 g b.p. and the same number of bait boxes as assumed in scenario 3 are placed around a larger building. Nevertheless, in this case the estimation is based on one bait box and is further related to an area of 0.25 m² as it is described in the ESD PT 18 No. 18 (2008). It is indicated in the OECD ESD PT 18 No.18 that about 80% of the product is consumed by the insects whereas 20% remain in the bait station and can be emitted into soil ($F_{spot,bait}$). The input parameters for calculating the direct emission to soil (E_{spot_soil}) are summarised in **Table 65**.

Table 65: Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: **Spot application around buildings on unpaved surfaces for professional use**			
Amount of product used at each refilling in the control operation for each bait box (Q_{prod})	5	g	
Fraction of a.s. in product (F_{AI})	0.0008	-	
Number of application sites (N_{sites})	1	-	
Fraction of a.s. emitted to soil during outdoor bait application ($F_{spot,bait}$)	0.2	-	
Area directly exposed to insecticide ($AREA_{exposed}$)	0.25	m²	
Depth of exposed soil ($DEPTH_{soil}$)	0.5	m	
Density of exposed soil (RHO_{soil})	1700	kg/m³	

Calculations for Scenario 2

$$E_{spot\_soil} = Q_{prod} \times F_{AI} \times N_{sites} \times F_{spot\_bait}$$

Table 66: Resulting local emission to relevant environmental compartments: Soil

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ($Elocal_{compartment}$) mg/d	Remarks
soil	0.8	E_{spot_soil}

The application of the b.p. around a larger building results in a release of **0.8 mg** Spinosad to local soil compartment.

Using the above indicated input parameters the following predicted concentrations of Spinosad in soil (ref. to ESD PT18 No. 18, eq. 60, chapter 4.4.5) and groundwater (ref. to Guidance BPR Vol. IV B+C ENV (2017), eq. 71, chapter 2.3.7.6) were calculated following the application of b.p. 'Ameisen-Köderdose' around larger buildings on unpaved soil:

Table 67: Summary of PEClocal$_{soil}$ and PEClocal$_{groundwater}$

Calculated PEC values		
	PEC_{soil}	**PEC_{GW}**
	[mg/kg]	[µg/L]
Scenario 2: Spot application around buildings on unpaved surfaces for professional use		
Spinosyn A	3.20×10^{-3}	2.63×10^{-2}
Spinosyn D	5.65×10^{-4}	4.65×10^{-3}

The estimated PEC for groundwater in Scenario 2 is below the groundwater trigger value of 0.1 µg/L.

Scenario 3: Spot application around buildings on paved surfaces for professional use

It is assumed, that the spot application of the b.p. 'Ameisen-Köderdose' on paved surface around larger buildings leads to indirect emission to the terrestrial compartment via sewage sludge application on agricultural land. The release estimation for STP is already presented in chapter 4.9.3.3. Aquatic compartment (including sediment and STP). The concentration in dry sewage sludge is equal to 1.55×10^{-2} mg/kg and 2.75×10^{-3} mg/kg, for Spinosyn A and Spinoisyn D respectively.
The PEC_{soil} is estimated according to equation 69, chapter 2.3.7.5.1, Guidance BPR Vol. IV B +C ENV (2017) and the $PEC_{groundwater}$ is calculated according to equation 71, chapter 2.3.7.6, Guidance BPR Vol. IV Part B + C ENV (2017):

Table 68: Summary of PEClocal$_{soil}$ and PEClocal$_{groundwater}$

Calculated PEC values		
	PEC_{soil}	**PEC_{GW}**
	[mg/kg]	[µg/L]
Scenario 3: Spot application around buildings on paved surfaces for professional use		
Spinosyn A	1.86×10^{-5}	6.62×10^{-5}
Spinosyn D	3.58×10^{-6}	1.57×10^{-5}

The estimated PEC for groundwater in Scenario 3 is below the groundwater trigger value of 0.1 µg/L.

3.8.3.5 Atmosphere

In view of the limited volatility of Spinosad and the anticipate use patterns, emission to the air are regarded to be not significant in relation to the intended use pattern.

3.8.3.6 Non-compartment specific effects

- **Primary poisoning**

Primary poisoning of birds and mammals is not considered relevant for the case of insecticide treatment with 'Ameisen-Köderdose' as the OECD ESD PT 18 No. 18 indicates that there is no risk of direct uptake from bait stations.

- **Secondary poisoning**

Predatory birds and mammals are especially susceptible for indirect poisoning effects caused by the intake of already accumulated substances with their prey. In case of a.s. release to sewer system (scenario 3 - spot application on paved soil around large buildings) two different accumulation pathways have to be distinguished:

(A) The bioaccumulation of spinosad via the aquatic food chain in fish and consequently in fish-eating birds or mammals: The concentration of spinosad in food (fish) of fish eating predators ($PEC_{oral,\ predator}$) is calculated according to eq. 95 in chapter 3.8.3.4 of Guidance for BPR Vol. IV Part B+C (2017) from the regional PEC in surface water, the estimated bioconcentration factor BCF (103 L/kg) for fish and the biomagnification factor (BMF = 1), ref. to table 23 of Guidance for BPR Vol. IV Part B+C (2017). The PEC in surface water (1.49×10^{-4} µg/L) was taken from the scenario 3.

PEC_{oral} for fish eating predators = 7.69×10^{-6} mg·kg^{-1}.

(B) The bioaccumulation of spinosad via the terrestrial food chain in earthworms and consequently in worm eating birds or mammals: The $PEC_{oral,predator}$ is a function of PEC_{soil}, $PEC_{porewater}$ as well as bioconcentration for earthworms (cf. Guidance for BPR Vol. IV Part B+C (2017), chapter 3.8.3.7). The predicted environmental concentration of a.s. and its residues in food via this pathway are estimated for the scenario 3 (spot application on paved soil around large buildings):

$PEC_{oral,\ predator}$ = 5.67×10^{-6} mg·kg^{-1}

The OECD ESD PT18 No. 18 (2008) provides a further approach for assessment of secondary poisoning; it states that the most important route of exposition is the intake of contaminated feed and the risk of secondary poisoning should be considered at the local scale. Non-target animals (birds and mammals) have potentially a risk of secondary poisoning in the following ways: (1) by consumption of

worms from contaminated soil, (2) by consumption of contaminated vegetation and (3) through eating treated insects that have ingested the poison.

The estimated theoretical exposure (ETE) will be calculated for indicator species among mammals and birds, and ETE corresponds to the PEC_{oral} per day. The ETE is used for the risk assessment. In consideration of the intended use of the product 'Ameisen-Köderdose' as well as the realistic emission path of the a.s. into the environment (here: soil compartment) the assessment of secondary poisoning via consumption of contaminated worms or insects is carried out (i.e. calculation of ETE for (1) and (3)). The procedure for ETE calculation is described in chapter 5.2.3.4 of OECD ESD PT18 No. 18. The relevant input parameters are presented in Table 69, the application rate of a.s. T_{appl} as well as the concentration of a.s. in fresh diet $c_{earthworm}$ are applied considering the worst case values from scenario 2 (application around large buildings on unpaved soils) The values taken from the pick lists of the ESD (Table 5.2-5, 5.2-7) are not repeated here.

Table 69: Parameters used for estimation of daily uptake of a compound

Determinants of the emission scenario according to chapter 5.2.3.4, OECD ESD PT18 No. 18 (2008)	Symbol	Value	S/D/O/P
Application rate of a.s.	T_{appl}	3.2×10^{-6} kg·m^{-2}	S
Concentration of a.s. in fresh diet	$c_{earthworm}$	3.823×10^{-3} mg·kg^{-1}	S
Avoidance factor	*AV*	1	S/D
Fraction of diet obtained in treated area	*PT*	1	S/D
Fraction of food type in diet	*PD*	1	S/D

The values of the expected daily uptake ETE for assessment of secondary poisoning via consumption of contaminated worms and insects (acute and short term) for selected indicator species are shown in **Table 70**.

Table 70: Expected daily uptake (ETE) of Spinosad for selected indicator species following single spot application of 'Ameisen-Köderdose' on unpaved soil

Species		ETEworm [mg (kg^{x}d)$^{-1}$]	ETEinsect [mg·(kg^{x}d)$^{-1}$]	
			Acute	Short term
Pipistrelle	*Pipistrellus pipistrellus*	-	**3.06×10^{-5}**	**1.12×10^{-5}**
Shrew	*Sorex araneus*	2.41×10^{-3}	2.82×10^{-5}	1.03×10^{-5}
Mole	*Talpa europaea*	**2.75×10^{-3}**	-	-
Hedgehog	*Erinaceus europaeus*	1.30×10^{-3}	7.01×10^{-6}	2.55×10^{-6}
Badger	*Meles meles*	6.76×10^{-4}	3.65×10^{-6}	1.33×10^{-6}

Species		ETEworm [mg (kg^{x}d)$^{-1}$]	ETEinsect [mg·(kg^{x}d)$^{-1}$]	
			Acute	Short term
Tree sparrow	*Passer domesticus*	-	**1.36×10^{-4}**	**7.59×10^{-5}**
Blackbird	*Turdus merula*	2.95×10^{-3}	3.45×10^{-5}	1.26×10^{-5}
Black-billed Magpie	*Pica pica*	**3.41×10^{-3}**	1.84×10^{-5}	6.70×10^{-6}

The maximum values of expected daily uptake of Spinosad via contaminated worms are calculated for moles (mammals) and black-billed magpie (birds). The maximum values of expected daily uptake of Spinosad via contaminated insects are calculated for pipistrelle (mammals) and tree sparrow (birds) for acute and for short-term (poisoning) situations (cf. Table 70). Bold values (ETE_{worm} and ETE_{insect}) are used as PEC_{oral} for the first tier risk characterisation of secondary poisoning for birds and mammals, respectively.

3.8.3.7 Calculated PEC values

Table 71: Summary table on calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	**[mg/l]**	**[mg/kg$_{wwt}$]**	**[mg/l]**	**[mg/kg$_{wwt}$]**	**[mg/kg]**	**[µg/l]**	**[mg/m^3]**
Scenario 1								
Spinosyn A	-	-	-	-	-	4.70×10^{-4}	3.87×10^{-3}	-
Spinosyn D	-	-	-	-	-	8.30×10^{-5}	6.83×10^{-4}	-
Scenario 2								
Spinosyn A	-	-	-	-	-	3.20×10^{-3}	2.63×10^{-2}	-
Spinosyn D	-	-	-	-	-	5.65×10^{-4}	4.65×10^{-3}	-
Scenario 3								
Spinosyn A	7.48×10^{-6}	1.27×10^{-7}	9.68×10^{-5}	-	-	1.86×10^{-5}	6.62×10^{-5}	-
Spinosyn D	1.32×10^{-6}	2.23×10^{-8}	1.70×10^{-5}	-	-	3.58×10^{-6}	1.57×10^{-5}	-

- **Calculated PEC values for Metabolites**

The main metabolite of Spinosyn A was Spinosyn B, which was detected at maximum percentages ranging up to 67% and the main metabolite of Spinosyn D was N-demethylated Spinosyn D, which was also detected at maximum percentages ranging up to 68%.
In case of direct a.s. release to terrestrial compartment (scenario 1 and 2) predicted environmental soil metabolite concentrations can be calculated by multiplying the PEC_{soil} of the parent by a correction factor for the molecular weight and considering the highest percentage of metabolite occurrence (from soil degradation studies).

From those PEC_{soil} of the metabolites, the PEC_{gw} for the expected groundwater concentrations were calculated according to the Guidance for BPR Vol. IV Part B+C (2017), (eq. 70) using $K_{soil\text{-}water}$ coefficients calculated for each metabolite.

The quantitative exposure assessment of relevant metabolites in the terrestrial compartment for indirect a.s. release to terrestrial compartment (i.e. via sewage sludge application) is performed according to ENV 10 TAB 2.0 (2018).

Table 72: Input parameters (only set values) for calculating the fate and distribution in the environment

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight			
Spinosyn B	717.95	g/mol	
N-demethylated spinosyn D	731.98	g/mol	
Vapour pressure (at 25°C)			
Spinosyn B	4.48x10-17	Pa	EPI-Suite
N-demethylated spinosyn D	2.65x10-17	Pa	EPI-Suite
Water solubility (at 25°C)			
Spinosyn B	0.6237	mg/L	EPI-Suite
N-demethylated spinosyn D	0.1714	mg/L	EPI-Suite
Organic carbon/water partition coefficient (Kfoc)			
Spinosyn B, N-demethylated spinosyn D	20328	L/kg	LOEP
Soil-water partitioning coefficient (Ksoil-water)			
Spinosyn B, N-demethylated spinosyn D	77.3	m^3/m^3	CAR
DT_{50} for degradation in soil (at 12ºC)			
Spinosyn B	316	d	LOEP
N-demethylated spinosyn D	962	d	LOEP

Table 73: Summary table on calculated PEC values for Spinosyn B

	PEC_{soil}	PEC_{GW}
	[mg/kg]	[µg/L]
Scenario 1	3.08×10^{-4}	6.78×10^{-3}
Scenario 2	**2.10×10^{-3}**	**4.62×10^{-2}**
Scenario 3	2.81×10^{-5}	5.34×10^{-4}

Table 74: Summary table on calculated PEC values for N-demethylated Spinosyn D

	PEC_{soil}	PEC_{GW}
	[mg/kg]	[µg/L]
Scenario 1	5.54×10^{-5}	1.22×10^{-3}
Scenario 2	**3.77×10^{-4}**	**8.29×10^{-3}**
Scenario3	1.04×10^{-5}	2.16×10^{-4}

The estimated PEC values for groundwater for both metabolites are below the ground water trigger value of 0.1 µg/L in all calculated scenarios. The highest value for groundwater was achieved in scenario 2 with an amount of **4.62×10^{-2} µg/L** for Spinosyn B and **8.29×10^{-3} µg/L** for N-demethylated Spinosyn D.

3.8.3.8 Aggregated exposure (combined for relevant emission sources)

At the time of preparation of the environmental assessment for this PAR, no EU agreed guidance was available on how to perform a full aggregated exposure assessment. Therefore, no detailed assessment has been made at this stage. This area may need to be re-assessed in the future once agreed guidance has been made available.

3.8.4 Risk characterisation

The risk characterisation is performed for the biocidal product ‘Ameisen-Köderdose’ for use in buildings and in close proximity to gardens and buildings (e.g. on terraces and balconies) on paved and unpaved soil. The product is applied as ready-to-use bait boxes containing 5 g of a solution with the active substance spinosad at a concentration of 0.08 % w/w. No substance of concern with regard to the environment was identified. Therefore, the risk characterisation is based on the active substance under consideration of the intended use. Spinosad represents a mixture of spinosyn A and D (in a ratio of 85:15 w/w). Predicted environmental concentrations have been calculated for spinosyn A and D

separately, however the sum of spinosyn A and D was considered for the risk assessment as Predicted No-Effect Concentrations are only available for spinosad.
No significant emissions to the environment have been considered for indoor use. For outdoor use, the following scenarios for outdoor spot application (bait boxes) have been calculated:

Scenario 1: Spot application on terraces for non-professional use

Scenario 2: Spot application around buildings on unpaved surfaces for professional use

Scenario 3: Spot application around buildings on paved surfaces for professional use

With regard to outdoor use, the risk assessment for the environment covers the use of up to two bait boxes per 12 m² with a maximum use frequency of 11 of such applications per year. It should be considered for product authorisation, especially with regard to non-professional users, to include this as upper limits for bait boxes per treatment site and for treatments per year on the label: Apply up to 2 bait boxes per 12 m² and do not exceed 11 of such treatments per year.

3.8.4.1 Aquatic compartment (including sediment and STP)

Emissions to the aquatic compartment (via STP) are considered relevant for spot application around buildings on paved surfaces for professional use (Scenario 3), whereas indoor (no emission) and outdoor use on terraces by non-professional users (scenario 1) and by professional users on unpaved soil (scenario 2) are not assumed to be relevant for emissions to the aquatic compartment, as explained above. The risk quotient (as PEC/PNEC ratio) is calculated for the active substance spinosad, consisting of spinosyn A and D, and no further transformation products are considered relevant for the aquatic compartment.

- **Surface water**

The intended uses of the biocidal product ‘Ameisen-Köderdose’ will not pose an unacceptable risk to surface water (see summary table).

Table 75

Summary table on calculated PEC/PNEC values			
	PEC_{water} [mg/L]	**$PNEC_{water}$ [mg/L]**	**$PEC/PNEC_{water}$**
Scenario 3: Spot application around buildings on paved surfaces for professional use			
Spinosyn A	1.27×10^{-7}	–	–
Spinosyn D	2.23×10^{-8}	–	–
Spinosad	1.49×10^{-7}	6.20×10^{-5}	2.41×10^{-3}

- **Sediment**

The intended uses of the biocidal product ‘Ameisen-Köderdose’ will not pose an unacceptable risk to sediment (see summary table).

Table 76

Summary table on calculated PEC/PNEC values			
	PEC_{sed} [mg/kg ww]	**$PNEC_{sed}$ [mg/kg ww]**	**$PEC/PNEC_{sed}$**
Scenario 3: Spot application around buildings on paved surfaces for professional use			
Spinosyn A	9.68×10^{-5}	–	–
Spinosyn D	1.70×10^{-5}	–	–
Spinosad	1.14×10^{-4}	1.30×10^{-4}	8.75×10^{-1}

- **STP**

The intended uses of the biocidal product 'Ameisen-Köderdose' will not pose an unacceptable risk to sewage treatment plant (see summary table).

Table 77

Summary table on calculated PEC/PNEC values			
	PEC_{STP} [mg/L]	**$PNEC_{STP}$ [mg/L]**	**$PEC/PNEC_{STP}$**
Scenario 3: Spot application around buildings on paved surfaces for professional use			
Spinosyn A	7.48×10^{-6}	–	–
Spinosyn D	1.32×10^{-6}	–	–
Spinosad	8.80×10^{-6}	$> 1.00 \times 10^{-2}$	$< 8.80 \times 10^{-4}$

Conclusion

Only for scenario 3 (spot application around buildings on paved surfaces for professional use) emission to surface water are considered relevant and all risk ratios (expressed as PEC/PNEC) for surface water, sediment and STP are below 1. Therefore the intended uses of the biocidal product 'Ameisen-Köderdose' will not pose an unacceptable risk to the aquatic compartment, including surface water, sediment and STP.

3.8.4.2 Terrestrial compartment (Soil/Groundwater)

According to OECD ESD No. 18 for PT18 direct emissions to soil from bait boxes may occur by flooding due to a rain event. Furthermore, indirect exposure has to be assessed for the use on paved surfaces.

- **Soil**

The intended uses of the biocidal product 'Ameisen-Köderdose' will not pose an unacceptable risk to soil (see summary table).

Table 78

Summary table on calculated PEC/PNEC values			
	PEC_{soil} [mg/kg ww]	**$PNEC_{soil}$ [mg/kg ww]**	**$PEC/PNEC_{soil}$**
Scenario 1: Spot application on terraces for non-professional use			
Spinosyn A	4.70×10^{-4}	–	–
Spinosyn D	8.30×10^{-5}	–	–
Spinosad	5.53×10^{-4}	7.53×10^{-3}	7.34×10^{-2}
Spinosyn B	3.08×10^{-4}	4.32×10^{-3}	7.14×10^{-2}
N-demethylated spinosyn D	5.54×10^{-5}	1.05×10^{-3}	5.27×10^{-2}
Scenario 2: Spot application around buildings on unpaved surfaces for professional use			
Spinosyn A	3.20×10^{-3}	–	–
Spinosyn D	5.65×10^{-4}	–	–
Spinosad	3.77×10^{-3}	7.53×10^{-3}	5.00×10^{-1}
Spinosyn B	2.10×10^{-3}	4.32×10^{-3}	4.86×10^{-1}
N-demethylated spinosyn D	3.77×10^{-4}	1.05×10^{-3}	3.59×10^{-1}
Scenario 3: Spot application around buildings on paved surfaces for professional use			
Spinosyn A	1.86×10^{-5}	–	–
Spinosyn D	3.58×10^{-6}	–	–
Spinosad	2.21×10^{-5}	7.53×10^{-3}	2.94×10^{-3}
Spinosyn B	2.81×10^{-5}	4.32×10^{-3}	6.50×10^{-3}
N-demethylated spinosyn D	1.04×10^{-5}	1.05×10^{-3}	9.89×10^{-3}

- **Groundwater**

The maximum permissible concentration as laid down for drinking water and groundwater in Directives 98/83/EC and 2006/118/EC, a general limit of 0.1 µg/L for pesticides and their relevant metabolites, degradation and reaction products, is compared to $PEC_{groundwater}$ for Spinosad and relevant transformation products.

Table 79

Summary table on calculated PEC values	
	$PEC_{groundwater}$ [µg/L]
Scenario 1: Spot application on terraces for non-professional use	
Spinosyn A	3.87×10^{-3}
Spinosyn D	6.83×10^{-4}
Spinosad	4.55×10^{-3}
Spinosyn B	6.78×10^{-3}
N-demethylated spinosyn D	1.22×10^{-3}
Scenario 2: Spot application around buildings on unpaved surfaces for professional use	
Spinosyn A	2.63×10^{-2}
Spinosyn D	4.65×10^{-3}
Spinosad	3.10×10^{-2}
Spinosyn B	4.62×10^{-2}

Summary table on calculated PEC values	
	$PEC_{groundwater}$ [µg/L]
N-demethylated spinosyn D	8.29×10^{-3}
Scenario 3: Spot application around buildings on paved surfaces for professional use	
Spinosyn A	6.62×10^{-5}
Spinosyn D	1.57×10^{-5}
Spinosad	8.19×10^{-5}
Spinosyn B	5.34×10^{-4}
N-demethylated spinosyn D	2.16×10^{-4}

Conclusion

All PEC/PNEC values for soil are below 1, not indicating an unacceptable risk for the soil compartment. All PEC values for groundwater are below 0.1 µg/L and therefore none of the evaluated uses is expected to exceed the relevant limits for groundwater and drinking water.

3.8.4.3 Atmosphere

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

3.8.4.4 Non-compartment specific

- **Primary poisoning**

Based on the intended use of the biocidal product 'Ameisen-Köderdose', primary poisoning of birds and mammals is not considered relevant.

Risk Assessment for bees

A risk assessment for bees was not conducted for the biocidal product 'Ameisen-Köderdose'. Due to the intended application method in ready-to-use bait boxes, significant exposure of bees is considered to be negligible. Furthermore, development of guidance for risk assessment for bees is still ongoing and no aligned approach was available while revising the risk assessment for this product.

- **Secondary poisoning**

The use evaluated in scenario 3 (spot application on paved soil around large buildings) could result in release of the a.s. spinosad to sewer system and subsequently to surface water. The risk for secondary poisoning has therefore been assessed in accordance to BPR Guidance Vol. IV Part B+C (2017) for (A) the bioaccumulation in the aquatic food chain (from fish to fish-eating predators) and (B) in the terrestrial food chain (from earthworms to earthworm-eating birds and mammals). According to OECD ESD PT18 No. 18 (2008), secondary poisoning should also be assessed on local level: Non-target animals (birds

and mammals) have potentially a risk for 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 accumulated the poison. Therefore, a risk characterisation for secondary poisoning of birds and mammals is necessary and performed for scenarios A, B, 1 and 3. The worst case for each category is presented in the table.

Table 80

Summary table on secondary poisoning			
Scenario	**$PEC_{oral\ predator}$ [mg/kg]**	**$PNEC_{oral\ predator}$ [mg/kg feed]**	**PEC/PNEC**
A: Mammals feeding on fish	7.69×10^{-6}	3.33	2.31×10^{-6}
A: Birds feeding on fish	7.69×10^{-6}	18.3	4.20×10^{-7}
B: Mammals feeding on worms	5.67×10^{-6}	3.33	1.70×10^{-6}
B: Birds feeding on worms	5.67×10^{-6}	18.3	3.10×10^{-7}
1: Mammals feeding on worms (Mole)	2.75×10^{-3}	3.33	8.26×10^{-4}
1: Birds feeding on worms (Black-billed Magpie)	3.41×10^{-3}	18.3	1.86×10^{-4}
3: Mammals feeding on insects (Pipistrelle, acute)	3.06×10^{-5}	3.33	9.19×10^{-6}
3: Mammals feeding on insects (Pipistrelle, short term)	1.12×10^{-5}	3.33	3.36×10^{-6}
3: Birds feeding on insects (Tree sparrow, acute)	1.36×10^{-4}	18.3	7.43×10^{-6}
3: Birds feeding on insects (Tree sparrow, short term)	7.59×10^{-5}	18.3	4.15×10^{-6}

Conclusion

The PEC/PNEC values calculated for secondary poisoning are below 1, indicating no unacceptable risk.

3.8.4.5 PBT assessment

The average DT50,water of spinosad as determined in freshwater water/sediment systems is 21 days at 20 °C (range 16-27 days). The average DT50,system is 149 days at 20 °C. The dissipation of spinosad from the water phase is mainly determined by sorption to sediment, and the DT50,system can thus be regarded as valid for sediment. Spinosad does not fulfil the B criterion, the average BCF for fish is 103 L/kg ww. The lowest chronic NOEC of spinosad for marine or freshwater organisms is 0.0012 mg/L (*Daphnia magna*). Spinosad should thus be considered as Persistent and Toxic, but not as bioaccumulative and is therefore not classified as PBT.

3.8.4.6 Endocrine disrupting properties

Active substance: According to the CAR for spinosad, there are no indications of endocrine disrupting (ED) properties on non-target organisms in the environment for this active substance. However, a comprehensive assessment of the criteria for endocrine disruption in non-target organisms for the active substance according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance for the identification of endocrine disruptors will need to be performed at the renewal stage.

Non-active substances in the product: Based on the data provided by the applicant and the full composition as given in Confidential Annex there are no indications that a non-active substance in the product may have endocrine disrupting properties. Nonetheless, the eCA has considered in its evaluation further information: None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation, the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards. Furthermore, no indications on potential endocrine disrupting effects on environmental non-target organisms have been found in scientific literature.

Conclusion

The biocidal product ‘Ameisen-Köderdose’ is not considered as having endocrine disrupting properties according to current guidance.

3.8.4.7 Summary of risk characterisation

The intended use of the biocidal product ‘Ameisen-Köderdose’ by non-professional, professional and trained professional users in and around buildings will not pose an unacceptable risk for the environment: All risk ratios for the active substance and relevant metabolites are well below 1 and also concentrations in groundwater are below the trigger for pesticides.

Table 81

Summary table on calculated PEC/PNEC values				
	PEC/ $PNEC_{STP}$	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**	**PEC/ $PNEC_{soil}$**
Spinosad (Spinosyn A + D, active substance)				
Scenario 1: Spot application on terraces for non-professional use	–	–	–	0.073
Scenario 2: Spot application around buildings on unpaved surfaces for professional use	–	–	–	0.50
Scenario 3: Spot application around buildings on paved surfaces for professional use	< 0.00088	0.0024	0.88	0.0029

Summary table on calculated PEC/PNEC values				
	PEC/ $PNEC_{STP}$	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**	**PEC/ $PNEC_{soil}$**
Spinosyn B (transformation product)				
Scenario 1: Spot application on terraces for non-professional use	–	–	–	0.071
Scenario 2: Spot application around buildings on unpaved surfaces for professional use	–	–	–	0.49
Scenario 3: Spot application around buildings on paved surfaces for professional use	–	–	–	0.0065
N-demethylated spinosyn D (transformation product)				
Scenario 1: Spot application on terraces for non-professional use	–	–	–	0.053
Scenario 2: Spot application around buildings on unpaved surfaces for professional use	–	–	–	0.36
Scenario 3: Spot application around buildings on paved surfaces for professional use	–	–	–	0.0099

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

3.10.1 Background

The biocidal product “Ameisen-Köderdose” contains the active substance Spinosad, which meets the criteria for substitution under Article 10 of the Biocides Regulation (EU) No 528/2012. Spinosad is considered to be persistent (P) and toxic (T) but not bioaccumulative (B) and therefore meets two of the criteria for being PBT. Therefore, in line with Article 23 (1) of the Biocides Regulation the German CA has to conduct a comparative assessment for the product ”Ameisen-Köderdose” according to the “Technical Guidance Note on comparative assessment of biocidal products” as agreed upon by the member states on the 55th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 (document: CA-May15-Doc.4.3.a - Final - TNG on comparative assessment.doc).
In accordance with the Technical Guidance Note on comparative assessment of biocidal products (CA-May-15-Doc-4.3a-final) the biocidal product Ameisen-Köderdose was only compared to the alternative biocidal products authorised in Germany as the R4BP3 is not yet populated with searchable SPCs and no search tool has been provided by ECHA yet.

3.10.2 Application administrative details

Procedure: NA-RNL
Purpose: Renewal
Case Number in R4BP: BC-PH036377-32
Evaluating Competent Authority: Germany
Applicant: Detia Freyberg GmbH
(Prospective) Authorisation holder: Detia Freyberg GmbH

3.10.3 Administrative information of the BP

Trade name: Ameisen-Köderdose, Bayer Ameisen-Köderdose, Ameisen-Köder, Ameisen Köderdose Natria, Profissimo Ameisen-Köder, Detia Ameisen-Köder, recozit Ameisenköderdose, AMEISEN-FREI KÖDERDOSE
Product type: 18 (Insecticides, Acaricides and products against other arthropods)
Active substance: Spinosad (CAS-No.: 168316-95-8)

3.10.4 Intended use(s) for the relevant BP in the application

The biocidal product “Ameisen-Köderdose” is an insecticide (PT18) which contains the active substance spinosad. The product is to be used indoors and around buildings by non-professionals and professionals to control ants.

Table 82 lists the intended uses of the biocidal product, which determines the focus of the comparative assessment.

Table 82: Intended use(s) of the biocidal product

Product type(s)	Insecticide (PT 18)
Where relevant, an exact description of the authorised use	Insecticide, Ingestion
Target organism (including, where relevant) development stage)	Black garden ant (Formicinae, Lasius niger, Larvae, Imagines
Field(s) of use	In and around buildings
Application method(s)	Bait application
Category(ies) of users	professional, trained professional, non-professional

The Ameisen-Köderdose is placed on the market as a ready-to-use product and applied in bait boxes.
It is effective against ants (Lasius niger).
The active substance Spinosad is a contact and stomach poison, which has an effect on the insect nervous system.

3.10.5 Mapping of existing alternatives to the relevant BP in Germany

Identified eligible alternative BPs[6]

According to the information available, there are about 59 biocidal products which were authorised for product type 18 (insecticides) in Germany (as of 03.05.2018). These products are based on 12 active substances. Six of these active substances are used in products for the control of ants: Spinosad, Imidacloprid, Indoxacarb, Deltamethrin, Fipronil and trans-Phenothrin.

Products containing Indoxacarb are only authorised for use by professionals. Products containing Deltamethrin are only authorised to be used by spraying or pouring.

Accordingly, the only remaining alternative products for the control of ants by non-professionals and professionals in Germany are products containing Imidacloprid, Fipronil and trans-Phenothrin as active substances.

Table 83 lists the mode of action of the remaining active substances and the risk of resistance development.

Table 83: Mode of action and risk of resistance development for PT18 (Insecticides, acaricides and products against other arthropods)

Active Substance	Mode of action	Resistance reported
Trans-Phenothrin	d-Phenothrin, is a synthetic pyrethroid insecticide. It acts by being absorbed by invertebrate neuronal membranes and binding to the sodium channels. The prolonged opening of sodium channels produces a protracted sodium influx which leads to repetitive firing of sensory nerve endings which may progress to hyperexcitation of the entire nervous system. At high pyrethroid concentrations conduction block can occur and the insects will die.	Yes
Imidacloprid	Imidacloprid is a neonicotinoid insecticide which acts on organisms by contact and ingestion.	Yes

6 In accordance with the Technical Guidance Note on comparative assessment of biocidal products (CA-May-15-Doc-4.3a-final) the biocidal product Ameisen-Köderdose was only compared to the alternative biocidal products authorised in Germany as the R4BP3 is not yet populated with searchable SPCs and no search tool has been provided by ECHA yet.

	It has residual activity. Like other neonicotinoids and nicotine, it acts on the insects central nervous system as an agonist of the postsynaptic nicotinic acetyl-choline receptors (nAChRs).	
Fipronil	The mode of action of Fipronil is a contact/ingested insecticide acting on the nervous system, blocking the GABA regulated chloride channel. It leads to reduce cockroach infestations through the death of insects consuming the bait.	Yes
Spinosad	Spinosad is a contact and stomach poison, which has an effect on the insect nervous system. The spinosyns and spinosoids have a novel mode of action, primarily targeting binding sites on nicotinic acetylcholine receptors (nAChRs) of the insect nervous system. Spinosoid binding leads to disruption of acetylcholine neurotransmission. Spinosad also has secondary effects as a ɣ-amino-butyric acid (GABA) neurotransmitter agonist. Spinosad kills insects via hyperexcitation of the insect nervous system.	Yes

Identified eligible non-chemical alternatives

Not relevant in the screening phase

3.10.6 Screening phase

Description of the assessment of the adequate chemical diversity in authorised BPs to minimise the occurrence of resistance and conclusion.

Chemical diversity

In accordance with Article 23 (3) (b) of the BPR, the German CA has checked whether the chemical diversity of the available active substances within the identified alternative biocidal products can be considered adequate to minimise the occurrence of resistance in the target harmful organisms (i.e. ants). Ready-to-use products containing trans-phenothrin, Fipronil and Imidacloprid were authorised in Germany for non-professional users and could be considered to be alternatives for the non-professional use of “Ameisen-Köderdose”. In addition, for Fipronil and Imidacloprid products have been authorised for professional users and could be considered to be alternatives for the non-professional use of “Ameisen-Köderdose”.

For all alternative active substances mentioned above resistance has been reported for cockroaches. Furthermore, it is considered possible that resistance can occur in ants.

As such the German CA considers the chemical diversity as not adequate to minimise the occurrence of resistance.

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.

Based on the Assessment Report for active substance approval, spinosad shall be considered a candidate for substitution using the criteria in Article 10 (1). Spinosad is not considered as meeting the exclusion criteria according to Article 5 (1). Spinosad is considered to be persistent (P) and toxic (T) but not bioaccumulative (B) and therefore meets two of the criteria for being PBT.

Conclusion of the screening phase:

Stop comparative assessment. The German CA concludes that there is not an adequate chemical diversity.

The comparative assessment is finalised at this stage. The product “Ameisen-Köderdose” is authorised for a period not exceeding 5 years in accordance with Article 23 (6).

4 Annexes

4.1 List of studies for the biocidal product

Table 84

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	Title 1, No. 3.3	Relative density A.3. (OECD 109) Study No.: PS20190017-1	Winkler, S.	2019	Detia Freyberg GmbH
2	Title 1, No. 3.8	Surface tension A.5. (OECD 115) Study No.: PS10290017-2	Winkler, S.	2019	Detia Freyberg GmbH
3	Title 1, No. 3.9	Viscosity of liquids (OECD 114) Study No.: PS20190017-3	Winkler, S.	2019	Detia Freyberg GmbH
4	Title 1 No. 4.1	Expert Statement on the explosive Properties of Detia Spinosad Ant Bait Formulation	Curl and Wright	2012	Detia Freyberg GmbH
5	Title 1 No. 4.6	Statement on non-submission of 4.6 flammable liquids for “Ameisen-Köderdose”	Lorenzen, V.	2019	Detia Freyberg GmbH
6	Title 1 No. 4.9	Statement on non-submission of 4.9 pyrophoric liquids for “Ameisen-Köderdose”	Lorenzen, V.	2019	Detia Freyberg GmbH
7	Title 1, No. 4.11	Statement on non-submission of 4.11 self-heating substances and mixtures for “Ameisen-Köderdose”	Lorenzen, V.	2019	Detia Freyberg GmbH
8	Title 1 No. 4.13	Expert Statement on the oxidizing Properties of Detia Spinosad Ant Bait Formulation	Curl and Wright	2012	Detia Freyberg GmbH
9	Title 1, No. 4.16	Ameisenköder Determination of physico-chemical properties Corrosive Properties of Liquids (UN Test C.1) Study- No. CSL-19-03888.01	Seitz, S.	2019	Detia Freyberg GmbH

4.2 List of studies for the active substance(s)

4.2.1 Spinosad

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

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[7]) of the active substance spinosad for use in 18 (Insecticides, acaricides and products against other arthropods) (product-type 18). Please, refer to the corresponding Assessment Report for a reference list.

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

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Safety for professional users

The following table gives an overview of the exposure assessment and the used calculation:

Table 85: Exposure assessment for the biocidal product `Ameisen-Köderdose´ - Professional user getting in contact with the a.s. on cellulose pad in the bait box

INHALATION EXPOSURE	TIER 1		INHALATION EXPOSURE	TIER 2	
Mixing & Loading	not applicable		**Mixing & Loading**	not applicable	
Application	not expected		**Application**	not expected	
Post-Application	not expected		**Post-Application**	not expected	
All phases			**All phases**		
Total potential inhalation exposure a.s.	not expected		Total actual inhalation exposure a.s.	not expected	
DERMAL EXPOSURE	**TIER 1**		**DERMAL EXPOSURE**	**TIER 2**	
Mixing & Loading	not applicable		**Mixing & Loading**	not applicable	
Application + Post-Application			**Application + Post-Application**		
impregnation of cellulose pad	0.1	mg/cm^2	Potential dermal exposure a.s.	0.2	mg a.s.
Potential dermal exposure a.s.	0.2	mg a.s.	RMM: protective gloves	10%	
			Actual dermal exposure a.s.	0.02	mg a.s.
All phases			**All phases**		
Total potential dermal exposure all phases a.s.	0.2	mg a.s.	Total actual dermal exposure all phases a.s.	0.02	mg a.s.

Calculation details:

Total amount of a.s. on cellulose pad: 4 mg
Surface of cellulose pad in bait box: 40cm^2
Hand surface in contact to cellulose pad (section of fingertips): 10cm^2

Transfer coefficient: 20 %

Calculation: 4 mg : 40cm^2 = 0.1mg/cm^2 ; 0.1 mg/cm^2 x 10 cm^2 x 20% = 0.2 mg a.s.

Details of risk characterisation -spinosad

Reference values

As mentioned in chapter 3.6.3.1.1 of this PAR inhalation exposure to spinosad is not expected. Therefore no risk characterisation for the inhalation route is carried out.

For the purpose of risk characterisation resulting from dermal exposure of professional users to spinosad from the biocidal product 'Ameisen-Köderdose', dermal exposure to spinosad is assessed. For this, the internal reference value $AEL_{long\text{-}term}$ (0.012 mg/kg bw/d) of spinosad is used. Since this systemic reference value is to be compared with external dermal exposure concentrations of spinosad, the corresponding $AEL_{long\text{-}term}$ is converted to an external dermal reference value (RV_{derm}) according to the equation:

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

By this means, RV_{derm} equivalent to 0.6 mg/kg bw/d is calculated for spinosad.

Dermal absorption rate

A value equivalent to 2 % is used as dermal absorption rate for spinosad. This value is taken from the assessment report (RMS NL (2010)).

Calculation of risk quotient RQ_{inhal}, risk quotient RQ_{derm} and the substance specific RI

As mentioned in chapter 3.6.3.1.1 Professional exposure of this PAR inhalation exposure to spinosad is not expected. Therefore no risk quotient for the inhalation route (RQ_{inhal}) is determined.

The risk quotient for the dermal route (RQ_{derm}) referring to the active substance spinosad resulting from use of the biocidal product 'Ameisen-Köderdose' is determined according to the equation:

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

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

The summation of both RQs within a scenario gives the corresponding substance specific risk index (RI). Table 86 gives a detailed overview of the risk assessment results referring to the active substance spinosad for the biocidal product 'Ameisen-Köderdose'. It is noted that for clarity reasons exposure values, risk quotients and risk indices are rounded to three decimal places in Table 86. However, the underlying calculations are based on unrounded exposure values.

Table 86 Overview of detailed risk assessment results referring to the active substance spinosad for the biocidal product 'Ameisen-Köderdose'

Scenario		dermal external				RI_{total}
		potential exposure		RV_{derm}	RQ_{derm}	
		mg/person	mg/kg			
Professional user getting in contact with the bait box	Tier 1	0.20	$3.33x10^{-3}$	0.60	0.01	0.01

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI_{total}: total risk index; if < 1 no concern

Conclusion and risk assessment – spinosad

A risk for professional users referring to the active substance spinosad resulting from the use of the biocidal product Ameisen-Köderdose is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 86, the scenario 'professional user getting in contact with the bait box' yields a RI of less than 1 already in TIER 1 with an index of 0.01.

In summary, a risk for professional users referring to the active substance spinosad resulting from the scenario 'professional user getting in contact with the bait box' is unlikely since the respective risk characterisation consistently yields total risk indices of less than 1 after TIER 1 consideration.