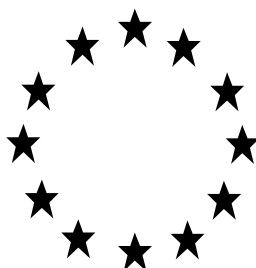


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

## **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 to control other arthropods)
Active ingredient(s):	Spinosad
Case No. in R4BP	BC-GK058069-32
Asset No. in R4BP	DE-0006715-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/18.00004 710-05-18-00004-01-02
Date	26.05.2020

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# 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)
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	Administrative 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	Administrative 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
NA-AAT	DE	BC-CK057996-22	19.03.2020	Amendment by CA (correction of mistake concerning packaging)
NA-MIC	DE	BC-GK058069-32	26.05.2020	Minor change (Amendment of storage stability from 24 months to 36 months)

# **Current consolidated Summary of the product assessment**

## **Summary of product characteristics**

**Ameisen-Köderdose**

**Product type 18**

**Authorisation number DE-0006715-18**

**R4BP asset number DE-0006715-0000**

# 1 Administrative information

## 1.1 Trade name(s) of the product

Trade name(s)
<b>Ameisen-Köderdose</b> Profissimo Ameisen-Köder  Detia Ameisen-Köder Ameisen-Köder Bayer Ameisen-Köderdose recozit Ameisenköderdose Ameisen Köderdose Natria AMEISEN-FREI KÖDERDOSE

## 1.2 Authorisation holder

<b>Name and address of the authorisation holder</b>	<b>Name</b>	Detia Freyberg GmbH
	<b>Address</b>	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany
<b>Authorisation number</b>	DE-0006715-18	
<b>R4BP asset number</b>	DE-0006715-0000	
<b>Date of the authorisation</b>	03.07.2014	
<b>Expiry date of the authorisation</b>	05.03.2025	

## 1.3 Manufacturer(s) of the product

<b>Name of manufacturer</b>	Detia Freyberg GmbH
<b>Address of manufacturer</b>	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany
<b>Location of manufacturing site</b>	Dr.-Werner-Freyberg-Str. 11 69514 Laudenbach Germany

## 1.4 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 Product composition and formulation

### 2.1 Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Spinosad technical	Mixture of 50-95 % spinosyn A and 5-50 % spinosyn D  <b>Spinosyn A:</b> (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-tetradecoxy-.beta.-D-erythropranosyloxy)-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  <b>Spinosyn D:</b> 2-((6-Deoxy-2,3,4-tri-O-methyl-.alpha.-L-mannopyranosyl)oxy)-13-((5-	active substance	168316-95-8	434-300-1	0.08 <sup>1</sup>

<sup>1</sup> technical grade spinosad, considering the purity of technical grade spinosad (94%) the exact content of pure spinosad in the formulation is 0.0752%

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
	(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				

## 2.2 Type of formulation

Bait solution (absorbed on a cellulose pad)

## 3 Hazard and precautionary statements

Hazard statements	H412 Harmful to aquatic life with long lasting effects
Precautionary statements	P273 Avoid release to the environment. P501 Dispose of contents/container according to national legislation.

## 4 Authorised use(s)

### 4.1 Authorised use 1 – Use of bait stations against ants – professional user, trained professional user

Product Type	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 ( <i>Lasius niger</i> ), 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.
<b>Application rate(s) and frequency</b>	Low infestation: 1 bait station per 12m <sup>2</sup>  High infestation: 2 bait station per 12m <sup>2</sup>
<b>Category(ies) of users</b>	Trained professional users, professional users
<b>Pack sizes and packaging material</b>	1-2 bait stations, ready-to-use with pre-filled liquid bait on cellulose pad, single or in cardboard packaging

#### **4.1.1 Use-specific instructions for use**

See chapter 2.5

#### **4.1.2 Use-specific risk mitigation measures**

See chapter 2.5

#### **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

#### **4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging**

See chapter 2.5

#### **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



## 4.2 **Authorised use 2 – Use of bait stations against ants – non-professional user**

<b>Product Type</b>	18
<b>Where relevant, an exact description of the use</b>	Insecticides, acaricides and products to control other arthropods
<b>Target organism(s) (including development stage)</b>	black garden ant ( <i>Lasius niger</i> ), Larvae, Adults
<b>Field(s) of use</b>	In and around buildings
<b>Application method(s)</b>	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.
<b>Application rate(s) and frequency</b>	Low infestation: 1 bait station per 12m <sup>2</sup>  High infestation: 2 bait station per 12m <sup>2</sup>
<b>Category(ies) of users</b>	Non-professional users
<b>Pack sizes and packaging material</b>	1-2 bait stations, ready-to-use with pre-filled liquid bait on cellulose pad, single or in cardboard packaging

### 4.2.1 **Use-specific instructions for use**

See chapter 2.5

### 4.2.2 **Use-specific risk mitigation measures**

See chapter 2.5

### 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

#### **4.2.4      Where specific to the use, the instructions for safe disposal of the product and its packaging**

See chapter 2.5

#### **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

## **5            General directions for use**

### **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 m<sup>2</sup> 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.

### **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.

### **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.

## **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.

## **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: 36 months.

# **6             Other information**

### Resistance management:

- 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.

# **Changes after renewal**

## **7 Change / amendment 1 - NA-AAT - BC-CK057996-22**

Case No.	BC-CK057996-22
Internal registration/file no:	5.0-710 05/18.00004 710-05-18-00004-00-00
Case type(s)	Amendment of national authorisation (NA-AAT)
CMS	-
Entry into force of change / amendment	19.03.2020

### **7.1 Amendment necessary**

The SPC contained a mistake in the description of the packaging. This was amended.

### **7.2 Assessment of new data**

No new data was necessary.

### **7.3 List of new data**

No new data was submitted.

### **7.4 Conclusion**

The conclusion with regard to the fulfilment of the conditions of Article 19 is still valid.

## 8 Change / amendment 2 - NA-MIC - BC-GK058069-32

Case No.	BC-GK058069-32
Internal registration/file no:	5.0-710 05/18.00004 710-05-18-00004-00-00
Case type(s)	Minor change (NA-MIC)
CMS	-
Entry into force of change / amendment	26.05.2020

### 8.1 Changes sought

The applicant applied for the extension of the storage stability from 24 to 36 months.

### 8.2 Assessment of new data

The applicant therefore submitted an efficacy study with a 3 years aged product and the final report of the storage stability study (Brux. 2017: Study No.: Mo4363) after 60 months storage at 20°C.

#### Efficacy

In the simulated use choice study (Kalla, K. 2019; details in the table below) a 3 years aged bait station called “Ameisen-Köder” (0.08% Spinosad w/w a.i.), which is a synonym for the product “Ameisen-Köderdose” (identical formulation) was tested against *Lasius niger* colonies (approx. 1000 workers, brood, queen). Therefore, one bait station was applied during the first 4 weeks in the arena and a second bait station was introduced up to the end of the test period of 10 weeks.

After an exposure of 6 weeks 2 out of 5 colonies were killed (no brood, dead queen and workers), whereas in the 3 remaining nests approx. 100 to 700 living workers were observed. 8 weeks after the treatment 3 colonies were killed. In the 2 other replicates approx. 7 to 11 living individuals were determined, which corresponds to a population reduction of > 90%. 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 met after 8 weeks.

Therefore, the efficacy of the 3 years aged product is proven and a shelf life of 3 years can be claimed.

#### Changes after renewal

# Experimental data on the efficacy of the biocidal product against target organism(s)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference																																																																																																																											
PT 18	in- and outdoor (in residential houses and adjacent areas like balconies and terraces)	„Ameisen-Köder“  0.08% Spinosad w/w a.i. (synonym for the product “Ameiesen-Köderdosee”)  3 years aged	<i>Lasius niger</i>  Common black garden ant,  colonies,  all develop- ment stages; approx. 1000 workers	Simulated- use study	- 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 – 25°C -Rel. humidity: 57 – 67% -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) -Alternative food: sugar -5 replicates (5 controls) -Assessment intervals: biweekly	8 weeks after treatment <div><div>1 study</div><div><u>Insecticidal effect of a 3 years aged ant bait station against nests of Black Ants, <i>Lasius niger</i> in Laboratory Simulated-use Tests.</u></div><div>8 weeks after treatment</div><div><div>Study: BIO2019-006 Methodology: BioG B 413-02 (modified)</div><div>temperature: 25 °C rel. humidity: 65 %</div></div><table><thead><tr><th>Test</th><th>replicate/ nest</th><th>number of bait stations per nest</th><th>number of dead ants visible in test arena (ca.)</th><th>number of living ants in test arena including nest (ca.)</th><th>activity (number of ants seen in test arena at evaluation)</th><th>brood</th><th>living queen</th><th>colony kill</th></tr></thead><tbody><tr><td rowspan="7">Ameisen - Köder (3 years old) Product type: Bait station Active: 0.8 g / kg Spinosad Batch: 51178.14 Production date: 09.2016 Expiry date: 09.2018</td><td>1</td><td>2</td><td>700</td><td>0</td><td>0</td><td>no</td><td>no</td><td>yes</td></tr><tr><td>2</td><td>2</td><td>200</td><td>0</td><td>0</td><td>no</td><td>no</td><td>yes</td></tr><tr><td>3</td><td>2</td><td>150</td><td>7</td><td>0</td><td>no</td><td>no</td><td>no</td></tr><tr><td>4</td><td>2</td><td>800</td><td>0</td><td>0</td><td>no</td><td>no</td><td>yes</td></tr><tr><td>5</td><td>2</td><td>600</td><td>11</td><td>0</td><td>no</td><td>no</td><td>no</td></tr><tr><td colspan="2">Ø</td><td>490</td><td>4</td><td>0</td><td>no</td><td>no</td><td>2 times no 3 times yes</td></tr><tr><td colspan="2">range</td><td>150 - 800</td><td>0 - 11</td><td>no range</td><td>no</td><td>no</td><td>yes - no</td></tr><tr><td rowspan="7">Control (without bait station)</td><td>1</td><td>-</td><td>50</td><td>1000</td><td>21</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td>2</td><td>-</td><td>10</td><td>700</td><td>13</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td>3</td><td>-</td><td>12</td><td>1000</td><td>10</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td>4</td><td>-</td><td>30</td><td>800</td><td>5</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td>5</td><td>-</td><td>50</td><td>1000</td><td>19</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td colspan="2">Ø</td><td>30</td><td>900</td><td>14</td><td>yes</td><td>yes</td><td>no</td></tr><tr><td colspan="2">range</td><td>10 - 50</td><td>700 - 1000</td><td>5 - 21</td><td>no range</td><td>no range</td><td>no range</td></tr></tbody></table><div>Note: All means were rounded to integers</div></div> <div>10 weeks after treatment:</div>	Test	replicate/ nest	number of bait stations per nest	number of dead ants visible in test arena (ca.)	number of living ants in test arena including nest (ca.)	activity (number of ants seen in test arena at evaluation)	brood	living queen	colony kill	Ameisen - Köder (3 years old) Product type: Bait station Active: 0.8 g / kg Spinosad Batch: 51178.14 Production date: 09.2016 Expiry date: 09.2018	1	2	700	0	0	no	no	yes	2	2	200	0	0	no	no	yes	3	2	150	7	0	no	no	no	4	2	800	0	0	no	no	yes	5	2	600	11	0	no	no	no	Ø		490	4	0	no	no	2 times no 3 times yes	range		150 - 800	0 - 11	no range	no	no	yes - no	Control (without bait station)	1	-	50	1000	21	yes	yes	no	2	-	10	700	13	yes	yes	no	3	-	12	1000	10	yes	yes	no	4	-	30	800	5	yes	yes	no	5	-	50	1000	19	yes	yes	no	Ø		30	900	14	yes	yes	no	range		10 - 50	700 - 1000	5 - 21	no range	no range	no range	Kalla, K. (2019), report no.: BIO123a- 19
Test	replicate/ nest	number of bait stations per nest	number of dead ants visible in test arena (ca.)	number of living ants in test arena including nest (ca.)	activity (number of ants seen in test arena at evaluation)	brood	living queen	colony kill																																																																																																																										
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Changes after renewal

Change / amendment 2 - NA-MIC - BC-GK058069-32

## Experimental data on the efficacy of the biocidal product against target organism(s)

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Changes after renewal

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### **Storage stability**

The applicant submitted the final report of the storage stability study (Brux, 2017: Study No.: Mo4363) after 60 months storage at 20°C. The results after 24 months were included in the PAR.

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 study provided proves that the active substance decreased only slightly over 60 months (-6.5%).

Additionally to the active substance content, the study provided validated data on the following endpoints: Stability of the packaging material, Weight loss, Appearance, colour and odour (visual) and pH.

The results of the storage stability study are summarized in the following table.



	start	12 months	24 months	36 months	48 months	60 months
Stability of the packaging material (visual)	Sample in sound condition, sealed and without leakages	Sample in sound condition, sealed and without leakages	Sample in sound condition, sealed and without leakages	Sample in sound condition, sealed and without leakages	Sample in sound condition, sealed and without leakages	Sample in sound condition, sealed and without leakages
	Dimensional stability [mm]: Height = 19.8 width (lid) = 70 width (bottom) = 75.7	Dimensional stability [mm]: Height = 20.03 width (lid) = 70.03 width (bottom) = 75.60	Dimensional stability [mm]: Height = 19.9 width (lid) = 70 width (bottom) = 75.7	Dimensional stability [mm]: Height = 19.0 width (lid) = 70.2 width (bottom) = 75.8	Dimensional stability [mm]: Height = 20.5 width (lid) = 70.2 width (bottom) = 74.75	Dimensional stability [mm]: Height = 20.7 width (lid) = 70.1 width (bottom) = 75.7
Weight loss		A change in weight of $\leq 0.08\%$ was found after storage.	A change in weight of $\leq 0.12\%$ was found after storage.	A change in weight of $\leq 0.12\%$ was found after storage.	A change in weight of $\leq 0.19\%$ was found after storage.	A change in weight of $\leq 0.21\%$ was found after storage.
Appearance, colour and odour (visual)	Tin with white pad inside, Slightly perfumed synthetic odor	Tin with white pad inside, Slightly perfumed synthetic odor	Tin with white pad inside, Slightly perfumed synthetic odor	Tin with white pad inside, Slightly perfumed synthetic odor	Tin with white pad inside, Slightly perfumed synthetic odor	Tin with white pad inside, Slightly perfumed synthetic odor
Content of active ingredient (HPLC-UV)	3.85 Spinosad [mg per tin]	3.84 Spinosad [mg per tin] (-0.3%)	3.58 Spinosad [mg per tin] (-6.5%)	3.76 Spinosad [mg per tin] (-7.1%)	3.74 Spinosad [mg per tin] (-2.9%)	3.60 Spinosad [mg per tin] (-6.5%)
pH value; 1% aqueous solution	5.8	5.5	5.6	5.4	5.5	5.8

Changes after renewal

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### 8.3 *List of new data*

Section No.	Author	Year	Title	Owner of data
3.4.1	Brux A.	2017	Determination of Physico-Chemical Properties and Storage Stability Test for Detia Ant Bait Tins with Spinosad: Final	Detia Freyberg GmbH
6.6	Kalla, K.	2019	“Efficacy of an ant product against Black ants, <i>Lasius niger</i> ”, report no.: BIO123a-19	Detia Freyberg GmbH

### 8.4 *Conclusion*

The submitted efficacy study is sufficient to prove the efficacy of the 3 years aged product and a shelf life of 3 years can be claimed.

Based on the submitted storage stability data it is acceptable to extend the shelf-life from 24 months to 36 months.

Therefore, the shelf-life of the product is extended to 36 months.