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 RENEWAL OF NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



ANTI-FOURMIS

Product type 18

SPINOSAD

Case Number in R4BP: BC-GF054425-48

Evaluating Competent Authority: FR

Date: [day/month/year]

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**Note to the reader:**

This PAR (new template) for the renewal of the product authorisation ANTI-FOURMIS is based on the PAR of the first authorisation ANTI-FOURMIS granted by FR CA on 2016.

In part 2.1 of the consolidated PAR: the summary of product characteristics is pointed out and corresponds to the decision for the renewal.

In part 2.2 of this consolidated PAR: each section contains an update of the assessment applicable for the renewal of the product authorisation.

1. **History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | FR | BC-QQ010378-21 | 19/04/2016 | Initial assessmentANTI-FOURMIS |
| NA-RNL | FR | BC-GF054426-48 | Xx/xx/xx | Renewal application for ANTI-FOURMIS |

# CONCLUSION

***Intended Uses***

*ANTI-FOURMIS product based on 0.094% of spinosad, is type of product 18 for ant control. It is a gel-ready-to use bait (gel only or gel in bait boxes) used by general public for ant control. It is intended to be applied indoor on the ant paths (bait box and tube), or outdoor on the ant paths or near to the nest entrance (bait box).*

***Physico-chemical properties and analytical methods***

ANTI-FOURMIS is a ready-to-use PT 18. It is under the form of highly viscous gel. The product is stable 14 days at 54°C and four years at ambient temperature. Therefore a shelf life of 4 years can be granted. The product ANTI-FOURMIS is compatible with LDPE and HDPE packages. Since the active substance is sensitive to light (DT 50 lower than 1 day), it should be recommended on the label to store the product away from light.

The product does not have explosive and oxidising properties. The biocidal product is not flammable and has an auto-ignition temperature of 430°C. It is not corrosive to metals.

Analytical methods are available and validated for the determination of the active ingredient in the biocidal product. Methods for the determination of the residues are available in the CAR of the active substance.

***Efficacy***

For the renewal of the product ANTI-FOURMIS (0.094% w/w Spinosad), the efficacy evaluation is based on the efficacy studies submitted by the applicant for the first authrorisation.

Consequently, the product ANTI-FOUMIS (0.094 % w/w Spinosad), formulated as gel bait contained in bait box or in tube has shown a complete lethal efficacy against *Lasius niger* within 3 weeks.

The validated application rates are 1 bait box (4.9 g of product) per nest entry (1 up to 3 per nest) or 1 to 3 boxes per 10 m2 (0.49 to 1.47 g/m2), or 0.5 g/m2 when used in tube.

***Substances of concern***

None of the coformulants contained in the product ANTIFOURMIS are considered as substances of concern.

***Human Health***

An acceptable risk is identified for non-professional users.

The risk is considered acceptable for children and toddler if the product ANTI-FOURMIS contains a bittering agent and is placed out of reach of children and toddler.

The risk is also considered acceptable for companion animals, i.e. dogs and cats, if the product Anti-fourmis contains a bittering agent and is placed out of reach of pets. The risk mitigation measures should include the following statement on the label: “Do not apply in areas accessible to children, pets or other non-target animals in order to minimize the risk of poisoning.”

A dermal absorption of 70% is proposed according to the 2017 EFSA guidance.

***Dietary exposure***

The product ANTI-FOURMIS is intended to be applied by non-professional users, out of reach of food or feed and therefore does not leave residues in commodities for human or animal consumption.

In this purpose, the following precautionary statement should be indicated on the labels:

* Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.

***Environment***

For indoor application of ANTI-FOURMIS product in gel or in bait boxes, considering the active substance and its metabolites, risks are acceptables for the aquatic compartment (STP, surface water and sediment) and terrestrial compartment (soil and groundwater), taking into account the intended application rate and with respect to the use recommendations presented below.

For outdoor application, considering the active substance and its metabolites, taking into account the intended dose, risks to the environment following the use of ANTI-FOURMIS in bait boxes are acceptable for all the compartments and all the scenarios, only when rainwater which can wash-off the product is not directed to the STP, with respect to the use recommendations presented below.

Therefore, it can be concluded on acceptable environmental risks for the biocidal product ANTI-FOURMIS for indoor uses (bait boxes and gel) and outdoor uses (bait boxes only) with the following risk mitigation measure: “Apply only under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water”.

**GENERAL CONCLUSION :**

**FR CA considers that the product shall be renewed for**:

|  |  |  |
| --- | --- | --- |
| **Target organism** | **Application rates** | **Use conditions** |
| Black garden ant (*Lasius niger*)Nest (all stages) | 1 to 3 bait boxes (4.9 g of product) per 10 m² depending on the level of infestation | -Baits boxes applied on the ant paths or near the nest entries – Outdoor-Baits boxes applied on the ant paths - IndoorNon-professional users |
| Black garden ant (*Lasius niger*)Nest (all stages) | Application by tube: 0.5 g/m² (a drop of gel with a diameter of 5 mm corresponds to 0.1 g product). | Drops of the gel applied on the ant paths or near the nest entries - indoorNon-professional users |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| ANTI-FOURMISANTI-FOURMIS TUBEANTI-FOURMIS BOITE APPATBOITES ANTI-FOURMISANTI-FOURMIS BOITESTUBE ANTI-FOURMIS | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | COMPO France SAS |
| **Address** | Zone industrielle25220 Roche-lez-BeaupréFrance |
| **Authorisation number** |  |
| **Date of the authorisation** |  |
| **Expiry date of the authorisation** |  |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | FormiChem GmbH |
| **Address of manufacturer** | Anna-von-Philipp-Str. B3386633 Neuburg a.d. DonauGermany |
| **Location of manufacturing sites** | Anna-von-Philipp-Str. B3386633 Neuburg a.d. DonauGermany |

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

|  |  |
| --- | --- |
| **Active substance** | Spinosad |
| **Name of manufacturer** | Dow AgroSciences GmbH / CORTEVA agriscience France S.A.S  |
| **Address of manufacturer** | Immeuble Equinoxe 2, 1bis avenue du 8 Mai 1912, 78280- Guyancourt (France) |
| **Location of manufacturing sites** | 305 North Huron AvenueMichigan 48441Harbor BeachUSA |

### Product composition and formulation

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

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

Yes [ ]

No [x]

#### Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **ISO name** | Spinosad  |
| **IUPAC or EC name** | Spinosad as a mixture of 50-95% Spinosyn A and 5-50% Spinosyn D**Spinosad:**mixture of 50–95%(2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione and 50–5% (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione**Spinosyn A:**(2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione**Spinosyn D:**(2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione |
| **EC number** | Spinosad: 434-300-1 (ELINCS) |
| **CAS number** | Spinosad: 168316-95-8Spinosyn A: 131929-60-7Spinosyn D: 131929-63-0 |
| **Index number in Annex VI of CLP** | Not allocated |
| **Minimum purity / content** | 85% (w/w) spinosad\* |
| **Structural formula** |  |

#### Candidate(s) for substitution

The active substance spinosad contained in the biocidal product is a candidate for substitution in accordance with Article 10 of BPR because it is considered as P and T and therefore meets two of the criteria for being PBT.

#### Qualitative and quantitative information on the composition of the biocidal product[[2]](#footnote-3)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| --- | --- | --- | --- | --- | --- |
| Spinosad  | Spinosad as a 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-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dioneCAS: 131929-60-7**Spinosyn D:**(2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dioneCAS: 131929-63-0 | Active substance | 168316-95-8 | 434-300-1 |  0.094 (technical) |

#### Information on technical equivalence

The source of active substance was the same than the one evaluated for inclusion in the Union list of approved active substances. The minimum purity of the approved source is 85% w/w.

#### Information on the substance(s) of concern

None of the coformulants contained in the product ANTIFOURMIS are identified as substances of concern.

#### Assessment of endocrine disruption (ED) properties of the biocidal product

According to the assessment, none of the co-formulants contained in the product ANTIFOURMIS are identified as endocrine disruptors.

Please refer to Confidential Annex.

The ED assessment of the active substance is on-going at the renewal stage.

#### Type of formulation

|  |
| --- |
| RB, Bait (ready for use) |

### Hazard and precautionary statements[[3]](#footnote-4)

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

| **Classification** |
| --- |
| Hazard category | Aquatic chronic cat.3 |
| Hazard statement | H412: Harmful to aquatic life with long lasting effects. |
|  |
| **Labelling** |
| Signal words |  |
| Hazard statements | H412: Harmful to aquatic life with long lasting effects. |
| Precautionary statements | P273: Avoid release to the environment.P501: Dispose of unused product, its packaging and all other waste in accordance with local regulations |
|  |
| Note |  |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – indoor use: gel in tube

|  |  |
| --- | --- |
| **Product Type** | 18  |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Black garden ants (*Lasius niger*)Nest (all stages) |
| **Field of use** | Indoor |
| **Application method(s)** | The drops of gel are deposited on the ant paths in buildings. |
| **Application rate(s) and frequency** | Gel in tube: 0.5 g/m² (A bait droplet with a diameter of 5 mm released from the tube weights 0.1 g.)Period of time needed for the biocidal effect: 3 days after ingestion.Frequency of control: 1 time per week. Treatment duration: 3 weeks. |
| **Category(ies) of users** | Non-professionals  |
| **Pack sizes and packaging material** | The product is packaged in tubes of low density polyethylene (LDPE) of 30 g. |

#### Use-specific instructions for use

|  |
| --- |
| * Do not apply the product on absorbing surfaces.
 |

#### Use-specific risk mitigation measures

|  |
| --- |
| * - To protect pollinating insects, aquatic and terrestrial organisms, the product may only be used indoors
 |

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

|  |
| --- |
| - |

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

|  |
| --- |
|  |

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

|  |
| --- |
| - |

#### Use description

Table 2. Use # 2 –bait box – indoor and outdoor around buildings

|  |  |
| --- | --- |
| **Product Type** | 18  |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Black garden ants (*Lasius niger*)Nest (all stages) |
| **Field of use** | Indoor and Outdoor around buildings (e.g. terraces and patios) |
| **Application method(s)** | The bait boxes are deposited on the ant paths or near to the nest entrances. |
| **Application rate(s) and frequency** | Bait boxes of 4.9 g: Depending on the location and the infestation several bait boxes need to be placed along the ant´s paths and/or in the vicinity of the nest(s). Place 1 bait box per 10 m² (in case of heavy infestations up to 3 bait boxes per 10 m²) for at least 3 weeks. For outdoor applications use 1 bait box per ant nest entrance.Period of time needed for the biocidal effect: 3 days after ingestion.Check weekly if ants are still present and in case of heavy infestation (indoors and outdoors) replace the old bait box with a new one after 3-4 weeks.Treatment duration: 3 weeks. |
| **Category(ies) of users** | Non-professional |
| **Pack sizes and packaging material** | The product is packaged in bait boxes of high density polyethylene (HDPE) of 4.9 g. |

#### Use-specific instructions for use

|  |
| --- |
| * Do not force open the bait boxes and do not damage them, even when empty.
 |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Apply only under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.
 |

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

|  |
| --- |
| - |

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

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

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Comply with the instructions
* Respect the recommended application doses.
* Inform the authorisation holder if the treatment is ineffective.
* Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product.
 |

#### Risk mitigation measures

|  |
| --- |
| * Do not apply in areas accessible to children, pets or other non-target animals in order to minimize the risk of poisoning.
* Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
 |

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

|  |
| --- |
| IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.* If medical advice is needed, have product container or label at hand.
* This biocidal product contains Spinosad which is dangerous to bees.
 |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Remove all bait boxes after treatment
* Dispose of unused product, its packaging and all other waste (including bait boxes) in accordance with local regulations.
* Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
 |

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

|  |
| --- |
| * Keep out of the reach of children and pets.
* Shelf-life : 4 years
* Store away from light
 |

### Other information

|  |
| --- |
|  |

### Packaging of the biocidal product

The packaging claimed remain unchanged:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of packaging  | Size/volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, non-professional) | Compatibility of the product with the proposed packaging materials (Yes/No) |
| White screw-top bait box | The box has a diameter of 82 mm. Its height is 20.7 mm in the closed state. The bait box contains 4.9 g biocidal product. | HDPE | HDPE | non-professional | Yes |
| Tube | The tube contains 30 g biocidal product.  | LDPE | LDPE | non-professional | Yes |

Secondary packaging:

White box: 2 or 4 bait boxes are packed in a carton reinforced blister pack.

Tube: No secondary packaging. The tube is sold individually.

### Documentation

#### Data submitted in relation to product application

**Identity, physico-chemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal product anti- fourmis were provided by Compo GmbH & Co. KG. For the renewal, no new studies were submitted.

**Efficacy data**

The following efficacy studies were submitted:

- Arena and vivarium study according to CEB N°196[[4]](#footnote-5) method conducted with the product ANTI-FOURMIS, gel bait in bait box (0.094 w/w spinosad) on one ant species (*Lasius niger*).

Field test conducted with the product ANTI-FOURMIS, gel bait in bait box and tube (0.094 w/w spinosad) on one ant species (*Lasius niger*).

- Arena study according to CEB N°196 method conducted with the product ANTI-FOURMIS, gel bait in bait box (0.094 w/w spinosad), aged of 2.5 years, on one ant species (Lasius niger).

- Arena study according to CEB N°196 method conducted with the product ANTI-FOURMIS, gel bait in bait box (0.094 w/w spinosad), aged of 5 years, on one ant species (Lasius niger).

- Arena study according to CEB N°196 method conducted with the product ANTI-FOURMIS, gel bait in tube (0.094 w/w spinosad), aged of 4 years, on one ant species (Lasius niger).

- Arena study according to CEB N°196 method conducted with the product ANTI-FOURMIS, gel bait in tube (0.094 w/w spinosad), aged of 5 years, on one ant species (Lasius niger).

For the renewal of authorisation, no additional data was submitted

**Toxicology data**

The applicant submitted toxicological data on the formulation ANTI-FOURMIS.

**Residue data**

No specific residue data were submitted in the context of this dossier. The product ANTI-FOURMIS is intended to be applied by non-profesionnal users, out of reach of food or feed and therefore does not leave residues in commodities for human or animal consumption.

**Ecotoxicology data**

No new studies were conducted with ANTI-FOURMIS.

#### Access to documentation

COMPO France S.A.S. has access to data on the spinosad active substance generated from with a Letter of Access of Corteva agriscience / Dow AgroSciences GmbH.

Please refer to the LoA for the complete list of studies for which access has been granted.

## Assessment of the biocidal product

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

Table 1. Intended use #1 – Bait application – bait box, indoor and outdoor use

|  |  |
| --- | --- |
| **Product Type** | Product type 18: Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | Insecticide |
| **Target organism (including development stage)** | Black garden ant (*Lasius niger*)Adult, nest |
| **Field of use** | Indoor and outdoor |
| **Application method(s)** | White boxIndoor use:The bait boxes are deposited on the ant paths in buildings. Outdoor use:The bait boxes are deposited on the ant paths or near to the nest entrances. |
| **Application rate(s) and frequency** | White boxIndoor use: Application by bait boxes of 4.9 g: depending on the location and the infestation several bait boxes need to be placed along the ant´s paths. Place at least 1 bait box per 10 m² for at least 3 weeks. (In case of heavy infestations place up to 3 bait boxes per 10 m²).Period of time needed for the biocidal effect: 3 days after ingestion.Check weekly if ants are still present and in case of heavy infestation (indoors and outdoors) replace the old bait box with a new one after 3-4 weeks. Frequency of the treatment: once in a month. Outdoor use:Application by bait boxes of 4.9 g: depending on the location and the infestation several bait boxes need to be placed along the ant´s paths and/or in the vicinity of the nest(s). Place at least 1 bait box per 10 m² for at least 3 weeks. In case of heavy infestations up to 3 bait boxes per 10 m². For outdoor applications use 1 bait box per ant nest entrance. Period of time needed for the biocidal effect: 3 days after ingestion.Check weekly if ants are still present and in case of heavy infestation (indoors and outdoors) replace the old bait box with a new one after 3-4 weeks. Frequency of the treatment: once in a month.  |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | White screw-top bait box made of HDPE.The box has a diameter of 82 mm. Its height is 20.7 mm in the closed state. The bait box contains 4.9 g biocidal product.Secondary packaging: 2 or 4 bait boxes are packed in a carton reinforced blister pack. |

Table 2. Use #2 – Bait application – tube, indoor use

|  |  |
| --- | --- |
| **Product Type** | Product type 18: Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | Insecticide |
| **Target organism (including development stage)** | Black garden ant (*Lasius niger*)Adult, nest |
| **Field of use** | Indoor |
| **Application method(s)** | The drops of gel are deposited on the ant paths in buildings.  |
| **Application rate(s) and frequency** | Application by tube: 0.5 g/m² (a drop of gel with a diameter of 5 mm corresponds to 0.1 g product).Period of time needed for the biocidal effect: 3 days after ingestion.Frequency of control: 1 time per week. Treatment duration: 3 weeks.Frequency of the treatment: once in a month. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Tube made of LDPE containing 30 g biocidal product.No secondary packaging. |

### Physical, chemical and technical properties

**Product**

The tested product is Anti fourmis. Spinosad content in tested product is 0.08 % w/w of pure active substance (0.094 % w/w of technical spinosad). It is in the range of the FAO tolerance (15 %).

Note: some studies were performed with the product COM 111 06 I RB. This is the code for the biocidal product ANTI FOURMIS.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **GLP** | **Reference** | **eCA assessment** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual inspection | 0.08 % w/w pure spinosad Batch 05/035 | Appearance determined under GLP before and after accelerated storage: Highly viscous opaque formulation.Yellow brown to brown colour.After storage at 20 °C for 24 and 48 months: the surface of the formulation in the bait box is a little "skin-dried". | Y | Schieck, 2008a, 2008b | Acceptable. The formulation is a highly viscous formulation. |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa | *Olfactory inspection* | 0.08 % w/w pure spinosad Batch 05/035 | Appearance determined under GLP before and after accelerated storage: Aromatic odour | Y | Schieck, 2008a, 2008b | Acceptable. The formulation has an aromatic odour |
| pH of 1% dilution | CIPAC Method MT 75.3 | 0.08 % w/w pure spinosad Batch 05/035 | Results at 20 °C for a 1 % dilution of the product:pH = 4.53 (bait box)pH = 4.60 (tube) | Y | Schieck, 2008a, 2008b | Acceptable. The pH of a 1 % dilution of the product is 4.5 – 4.6 |
| Acidity / alkalinity |  |  | Not required as pH>4 |  |  | Acceptable.  |
| Relative density / bulk density | EEC Method A.3 | 0.08 % w/w pure spinosadBatch 05/035 | Density: 1.085 g/mL at 20.4 °C | Y | Schieck, 2008a, 2008b | Acceptable. |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 (storage)CIPAC MT 75.3 (pH)CIPAC MT 192 (viscosity)HPLC-DAD method (active substance content) | 0.08 % w/w pure spinosadBatch 05/035 | The storage was performed in the commercial tube package (i.e LDPE)The a.s. content was 0.084% before storage and 0.083% after the storage (-1.2 %).The appearance (highly viscous opaque formulation with yellow to brown colour and aromatic odour before and after storage), pH (4.60 before and 4.63 after storage) as well as viscosity (at 20°C 147000 mPa.s before storage and 115334 mPa.s after (0.03 rpm). No change was observed on the package. The storage was performed in the commercial bait box (i.e HDPE)The a.s. content was 0.083% before storage and 0.080% after the storage (-3.6 % of variation).The appearance (highly viscous opaque formulation with yellow brown colour and aromatic odour before and after storage, nevertheless, after storage the colour changed to brown), pH (4.53 before and 4.47 after storage) as well as viscosity (at 20°C 126084 mPa.s before storage and 106750 mPa.s after (0.03 rpm). No change was observed on the package | Y | Schieck, 2008a, 2008b | Analytical method used for the determination of active substance contents has been evaluated in the analytical part below. The formulation is stable during storage at 54°C during at least 14 days as percentage of variation of the active substance is lower than 5 % and no modification of the properties was observed.The commercial packages made of LDPE and HDPE are compatible with the formulation.  |
| Storage stability test – **long term storage at ambient temperature** | GIFAP Technical Monograph No. 17CIPAC MT 75.3 (pH)CIPAC MT 192 (viscosity)HPLC-DAD method (active substance content) | 0.08 % w/w pure spinosad Batch 05/035 | The storage was performed in the commercial tube package (i.e LDPE)The a.s. content was 0.087% before storage and 0.084% after the storage for 48 months (- 3.4 %).The appearance (highly viscous opaque formulation with yellow brown colour and aromatic odour before and after storage), pH (4.62 before and 4.32 after storage) as well as viscosity (at 20°C 2341 mPa.s before storage and 2500 mPa.s after (20 rpm). No change was observed on the package. The storage was performed in the commercial bait box (i.e HDPE)The a.s. content was 0.087% before storage and 0.084% after the storage for 48 months (-3.4%).The appearance (highly viscous opaque formulation with yellow brown colour and aromatic odour before and after storage, nevertheless, after storage the surface was a little “skin dried”), pH (4.48 before and 4.40 after storage) as well as viscosity (at 20°C 2341 mPa.s before storage and 2987 mPa.s after (20 rpm). No change was observed on the package | N | Schieck, 2010a, 2010b, 2012a and 2012b | Studies Schieck 2010 a and b provide acceptable results after two years of storage but not reported here as results after four years of storage are available.Analytical method used for the determination of active substance contents has been evaluated in the analytical part below. The formulation is stable during storage of at least 4 years at ambient temperature as percentage of variation of the active substance is lower than 5 % and no modification of the properties was observed. The commercial packages in LDPE and HDPE are compatible with the formulation. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Not applicable because the biocidal product is not liquid. | - | - | Not required |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | - | - | - | No study was submitted. The active substance is sensitive to light (DT 50 lower than 1 day), it should be recommended on the label to store the product away from light. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | - | - | - | Product is stable at high temperature (54°C). Please refer to the endpoint accelerated storage.  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | - | - | - | Compatibility with commercial packaging was demonstrated according to the shelf life study. Please refer to this endpoint for details.  |
| Wettability | - | - | Not applicable for this ready to use product. | - | - | Not applicable.  |
| Suspensibility, spontaneity and dispersion stability | - | - | Not applicable for this ready to use product. | - | - | Not applicable. |
| Wet sieve analysis and dry sieve test | - | - | Not applicable for this ready to use product. | - | - | Not applicable. |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not applicable for this ready to use product. | - | - | Not applicable. |
| Disintegration time | - | - | Not applicable (gel) | - | - | Not applicable. |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | Not applicable (gel) | - | - | Not applicable. |
| Persistent foaming | - | - | Not applicable for this ready to use product. | - | - | Not applicable. |
| Flowability/Pourability/Dustability | - | - | Not applicable for this ready to use product. | - | - | Not applicable. |
| Burning rate — smoke generators | - | - | Not applicable (gel) | - | - | Not applicable. |
| Burning completeness — smoke generators | - | - | Not applicable (gel) | - | - | Not applicable. |
| Composition of smoke — smoke generators | - | - | Not applicable (gel) | - | - | Not applicable. |
| Spraying pattern — aerosols | - | - | Not applicable (gel) | - | - | Not applicable. |
| Physical compatibility | - | - | Not applicable since the biocidal product will not be used with other products including other biocidal products. | - | - | Not applicable as the product is not intended to be mixed.  |
| Chemical compatibility | - | - | Not applicable since the biocidal product will not be used with other products including other biocidal products. | - | - | Not applicable as the product is not intended to be mixed. |
| Degree of dissolution and dilution stability | - | - | Not applicable for this ready to use product. | - | - | Not applicable. |
| Surface tension | - | - | Not applicable because the biocidal product is not liquid. Aspiration hazard can be excluded. | - | - | Not required. However the correct waiver should rather be “not required as the product is a viscous gel/liquid that is not intended to be diluted with water”.  |
| Viscosity | CIPAC Method MT 192(Digital-viscosimeter DV-II + Pro was used) | 0.08 % w/w pure spinosad Batch 05/035 | Before storage at 54 °C for two weeks:126084 mPa\*s at 20 °C (bait box)104667 mPa\*s at 40 °C (bait box)147000 mPa\*s at 20 °C (tube)121834 mPa\*s at 40 °C (tube)After storage at 54 °C for two weeks:106750 mPa\*s at 20 °C (bait box) 77208 mPa\*s at 40 °C (bait box) 115334 mPa\*s at 20 °C (tube) 88637 mPa\*s at 40 °C (tube) | Y | Schieck, 2008a, 2008b, | Acceptable. The formulation is a highly viscous formulation as previously indicated |

ANTI-FOURMIS is a ready-to-use PT 18. It is under the form of highly viscous gel.

The product is stable 14 days at 54°C and four years at ambient temperature. Therefore a shelf life of 4 years can be granted.

The product ANTI-FOURMIS is compatible with LDPE and HDPE packages.

For the renewal, no new physico chemical studies have been provided. All previous data have been considered adequate. However, since the active substance is sensitive to light (DT 50 lower than 1 day), it should be recommended on the label to store the product away from light. Indeed, the packaging is made of HDPE or LDPE but it may not be sufficiently barrier to light.

### Physical hazards and respective characteristics

Note: studies were performed with the product COM 111 06 I RB. This is the code for the biocidal product ANTI FOURMIS.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **eCa** |
| --- | --- | --- | --- | --- | --- |
| **Explosives** |  |  | The biocidal product does not contain components which are known to confer explosivity or to enhance explosibility properties. None of its ingredients is classified as explosive. Therefore the biocidal product is incapable of exothermic reaction and rapid decomposition with evolution of gases or release of heat and does not have explosive properties. Since the biocidal product does not present any risk for explosion, explosive properties of the formulation do not need to be tested. |  | Acceptable. The product is not explosive according to the composition. Active substance is not classified. Also none of the components contain chemical functions related to explosive properties.  |
| **Flammable gases** |  |  | The study does not need to be conducted because the biocidal product is not a gas. |  | Not applicable. |
| **Flammable aerosols** |  |  | The study does not need to be conducted because the biocidal product is not an aerosol. |  | Not applicable. |
| **Oxidising gases** |  |  | The study does not need to be conducted because the biocidal product is not a gas. |  | Not applicable. |
| **Gases under pressure** |  |  | The study does not need to be conducted because the biocidal product is not a gas. |  | Not applicable. |
| **Flammable liquids** | EEC A.9Closed cup, Rapid Tester, DIN EN ISO 3679 | Test item: COM 111 06 I RBBatch no.: 1904002Purity: not specified | Flash point : 135 °C at 1013 mbarNote: Before the test on flammability, further testing was conducted on the physical state of the formulated product (penetration test) and melting point were conducted. Since melting point was determined to be below 160°C, it was concluded that N.4 testing is not possible to be conducted.The outcome of penetration test was that the product is a paste.For more information please refer to the studies by Kruppa and Kirchhof below.The studies are submitted in IUCLID as a supporting study in section 4.6. | Grund, 2020a | Acceptable. The product is not flammable. |
| **Flammable solids** |  |  |  Not relevant as the product is a viscous liquid/gel. |  | Acceptable. The product is a viscous liquid/gel. Therefore flammability for liquids is more relevant. Please refer to the conclusion for flash point.  |
| **Self-reactive substances and mixtures** |  |  | Study scientifically not necessary to be conducted since none of the components present in the formulated product contain groups that are associated with explosive or self-reactive properties.A DSC test has also been provided and exothermic decomposition heat is largely below 300J/g. | Kirchhof, 2020 | Acceptable. Product is not self reactive according to DSC tests (exothermic effects with decomposition heat below 300 J/g) |
| **Pyrophoric liquids** |  |  | Study scientifically not necessary to be conducted since the product is stable in contact with air at room temperature for prolonged period of time (days). The classification procedure does not need to be applied. |  | Not applicable. |
| **Pyrophoric solids** |  |  | Not relevant as the product is a viscous liquid/gel. |  | Acceptable. |
| **Self-heating substances and mixtures** |  |  | Study scientifically not necessary to be conducted since none of the components present in the formulated product by the reaction with air and without energy supply is liable to self-heat. |  | Acceptable. According to the composition, there is clearly no risk of self heating. Additionally, the product is a viscous liquid/gel and its melting point is below 160°C. |
|  | ADR/RIDPenetration test | Test item: COM 111 06 I RBBatch no.: 2002007Purity: not specified | The test item is a pasty substance. | Kruppa, 2020 | Acceptable  |
|  | Internal methodDSC | Test item: COM 111 06 I RBBatch no.: 1904002Purity: not specified | The test item shows two glass temperatures each in the 1st and 2nd heating run between approx. -79 °C and 50 °C (softening of amorphous sample portions).In addition, the sample has a melting range in each of the heating runs with onset temperatures between approx. -29 °C and -28 °C with preceding cold crystallization. | Kirchhof, 2020 | Acceptable. The test item is expected to be completely molten below 160°C. Therefore self heating is not necessary. |
| **Substances and mixtures which in contact with water emit flammable gases** | Internal methodDSC | Test item: COM 111 06 I RBBatch no.: 1904002Purity: not specified | Study scientifically not necessary to be conducted since based on nature of the product it can be excluded, that during contact with water the flammable gases will occur or the substance will become spontaneously flammable.A DSC test has also been provided and exothermic decomposition heat is largely below 300J/g.  | Kirchhof, 2020 | Not relevant due to the composition and confirmed with DSC tests (exothermic effects with decomposition heat below 300 J/g) |
| **Oxidising liquids** |  |  | The biocidal product does not contain components which are known to enhance oxidising properties. None of its ingredients is classified as oxidising. Therefore the formulation may not react exothermically with a combustible material and does not have oxidising properties. Since oxidising properties of the biocidal product are unlikely, oxidising properties of the formulation do not need to be tested. |  | Not applicable. |
| **Oxidising solids** |  |  |  Not relevant as the product is a viscous liquid/gel. |  | Acceptable. please refer to conclusion for oxidising liquids.  |
| **Organic peroxides** |  |  | Study scientifically not necessary to be conducted since none of components present in the formulated product fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria. |  | Not applicable. |
| **Corrosive to metals** | UN test C1 | Test item: COM 111 06 I RBBatch no.: 2006007Purity: not specified | Steel and aluminium specimens were used for corrosive test and were completely dipped, half dipped or remained in the gas phase. The test item COM 111 06 I RB does not reach the annual corrosion rate of 6.25 mm/year (<0.02mm/y). No local corrosion effect was also noticed. Therefore, the test item COM 111 06 I RB is not classified as a metal-corrosive material in class 8 according to the Regulations on the Transport of Dangerous Goods. | Grund, 2020c | Acceptable. The product is not corrosive to metals. |
| **Auto-ignition temperatures of products (liquids and gases)** | EEC Method A.15 | Test item: COM 111 06 I RBBatch no.: 1911006Purity: not specified | Test item has an auto-ignition temperature of 430°C | Grund, 2020b | Acceptable. |
| **Relative self-ignition temperature for solids** |  |  | Study scientifically not feasible to be conducted since the biocidal product is not a solid. For more information on the physical state of the product please refer to the penetration test submitted in IUCLID in Section 4.6.( Kruppa, 2020)  |  | Acceptable. The product is a viscous liquid. Therefore auto ignition of liquids is more relevant.  |
| **Dust explosion hazard** |  |  | Study scientifically not necessary to be conducted since based on nature of the product the ignition or explosion of dust during exposition of the product to an ignition source when dispersed in water can be excluded.  |  | Not applicable. |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| Based on the evaluation of different physical hazards of the biocidal product it can concluded that the product does not have explosive and oxidising properties. The flash point of the product was determined to be 135 °C at 1013 mbar. The biocidal product has an auto-ignition temperature of 430°C. It is not classified as a metal-corrosive material. The product is evaluated as non-hazardous during appropriate use, storage and transport. |

### Methods for detection and identification

No new method was provided for the renewal .The following report was already found acceptable for the first authorisation and results are reported below.

Report Schieck, 2008 c study n° 48687 (GLP)

Principle: After dilution in mobile phase (methanol/acetonitrile/ammonium acetate buffer), the product is stirred until the formulation is smashed finely, then sonicated for approximately thirty minutes at room temperature. An aliquot of the extract is then filtered through a membrane filter and analyzed by HPLC-UV (250 nm).

Table 4: Analytical method for the determination of spinosad

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sample** | **Linearity** | **Specificity** | **Fortification range/ number of measurements** | **Recovery rate (%)** |
| **range** | **Mean** | **St dev.** |
| Batch: 05/035Spinosad 0.8 g/kg | Between 0.05 and 0.10 %N=12R: 0.999004 | Chromatograms were provided for blank, for formulation and for standard solution at two different concentrations (0.0005 and 0.005 %). No interference was observed | 0.05 % (n=4)0.07 % (n=4)0.10 % (n=4) | 102.13-103.07103.46-105.97103.29-105.59 | 102.58104.68104.76 | 0.451.341.28 |

Additionally, the precision was also determined by the analysis of six measurements of the same standard, RD was found equal to 2.94 %.

Limit of quantification in formulation is proposed by the applicant as equal to 0.01 %.

It is concluded that the provided method is validated and acceptable for the product ANTI FOURMIS according to the SANCO 3030/99 rev.4.

|  |
| --- |
| **Conclusion on the methods for detection and identificationof the product** |
| The method for the determination of the active ingredient in the biocidal product is acceptable and complies with the requirements of the BPR. |

|  |
| --- |
| **Conclusion on the methods for the determination of active substance residues**  |
| The analytical methods for the determination of residues of active substance in different matrices (soil, air, drinking and surface water, body fluids and tissues, in food and feedstuff) have been provided in the CAR of the active substance. No data gap have been identified. The applicant has acces to the methods with the letter of access. |

### Efficacy against target organisms

#### Function and field of use

The product ANTI-FOURMIS is presented as a ready-for-use gel, in a bait station or a tube. This product is an insecticidal bait preparation (product type 18) used to control ant infestations including nest population in and around buildings e.g. terraces and patios. The product is meant for use by non-professionals only.

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

According to the uses claimed by the applicant, ANTI-FOURMIS is intended to be used to control ants. The target organisms to be controlled are adults of black garden ants (*Lasius niger*). The products, organisms or objects to be protected are stored products and food.

Application rates recommended by the applicant are the following:

Bait box: The product is placed on the ground and is activated by twisting the box so that slits open allowing ants to feed on the bait formulation. Bait box contains 4.9 g of the formulation COM 111 06 I RB. The claimed application dose is one up to 3 bait boxes per 10 m² or one bait box per nest entry.

Tube: 5 droplets of 5 mm diameter per m² are deposited on ant paths or near to ant nests. Tube contains 30 g of the formulation COM 111 06 I RB. The bait droplets should preferably be placed on non-absorbing surfaces like flagstones, pieces of glass, tile or plastic, etc. which have to be located on places not accessible for children and pets. When applied outdoors with the tube the bait should be protected from water (like) rain.

A bait droplet with a diameter of 5 mm released from the tube weights 0.1 g. i.e. the maximal application rate is 5 droplets of 5 mm diameter per m² which results in 0.5 g/m². This rate equals to 5 g/10 m² which is almost identical with the application rate for the bait box (1 bait box with 4.9 g of product /10 m²).

#### Effects on target organisms, including unacceptable suffering

The applicant submitted following studies:

1. **Arena study and Vivarium study conducted with the product ANTI-FOURMIS, gel bait in bait box (0.094 % w/w spinosad) on one ant species *Lasius niger* (method CEB N°196).**

In the arena trial, the product was applied at the dose of 54.4 g / m2 (1 bait box containing 4.9 g / 900 cm²) on plates with 100+/-2 ants in each plate, with an alternative competition food. The mortality of the ants was recorded daily for 16 days. The test product was compared with an untreated control and different positive controls with a reference product (AFourmi F, 0.05 % w/w Fipronil). Three replicates were made for each test condition. The product ANTI-FOURMIS (0.094 % w/w Spinosad) showed a complete lethal efficacy against black garden ants, *Lasius niger*, within 5 days of treatment. The biocidal effect started 3 days after application. An equal efficacy compared to the marketed standard product has been shown.

In the vivarium trial, the product was applied at the dose of 54.4 g / m2 (1 bait box containing 4.9 g / 900 cm²) in a vivarium containing an acclimatized nest with all the development instars except the queen (approx. 1000 ants in each vivarium). The frequency of ants on surface and inside the nest was recorded weekly. After 5 weeks, the nest was opened and the number of remaining alive ants was counted. The test product was compared with an untreated control and different positive controls with a reference product (AFourmi F, 0.05% w/w Fipronil). Three replicates were made for each test condition. The product ANTI-FOURMIS (0.094 % w/w Spinosad) showed a complete lethal efficacy against ants. There were no ants in surface and inside the nest from the fourth week.

1. **Arena study conducted with the product ANTI-FOURMIS, aged of 2.5 years, gel bait in bait box (0.094 % w/w spinosad) on one ant species *Lasius niger* (method CEB N°196).**

The product was applied at the dose of 54.4 g / m2 (1 bait box containing 4.9 g / 900 cm²) on plates with 100+/-2 ants in each plate, with and without an alternative competition food. The mortality of the ants was recorded daily for 8 days. The test product was compared with an untreated control and with a reference product (AFourmi F, 0.05% w/w Fipronil). Four replicates were made for each test condition. The product ANTI-FOURMIS (0.094 % w/w Spinosad) aged of 2.5 years showed a complete lethal efficacy against black garden ants, *Lasius niger*, within 5 days of treatment. The biocidal effect started 2 days after application. An equal efficacy compared to a marketed standard product has been shown (100 % mortality within 5 days).

The complete mortality of the ants has proven that the product attracts the insects (because there is no difference between the results with and without competition food).

1. **Arena study conducted with the product ANTI-FOURMIS, aged of 5 years, gel bait in bait box (0.094 % w/w spinosad) on one ant species *Lasius niger* (method CEB N°196).**

The product was applied at the dose of 54.4 g / m2 (1 bait box containing 4.9 g / 900 cm²) on plates with 100+/-2 ants in each plate, with and without an alternative competition food. The mortality of the ants was recorded daily for 8 days. The test product was compared with an untreated control and with a reference product (AFourmi F, 0.05 % w/w Fipronil). Four replicates were made for each test condition. The product ANTI-FOURMIS (0.094 % w/w Spinosad) aged of 5 years showed a complete lethal efficacy against black garden ants, *Lasius niger*, within 6 days of treatment. The biocidal effect started 2-3 days after application. An equal efficacy compared to a marketed standard product has been shown (100 % mortality within 5 days).

The complete mortality of the ants has proven that the product attracts the insects (because there is no difference between the results with and without competition food).

1. **Arena study conducted with the product ANTI-FOURMIS, aged of 4 years, gel bait in tube (0.094 % w/w spinosad) on one ant species *Lasius niger* (method CEB N°196).**

The product was applied at the dose of 2.2 g / m2 (4 droplets of 3 mm i.e. 0.2 g / 900 cm²) on plates with 100+/-2 ants in each plate, with and without an alternative competition food. The mortality of the ants was recorded daily for 8 days. The test product was compared with an untreated control and with a reference product (AFourmi F, 0.05 % w/w Fipronil). Four replicates were made for each test condition. The product ANTI-FOURMIS (0.094 % w/w Spinosad) aged of 4 years showed a complete lethal efficacy against black garden ants, *Lasius niger*, within 6 days of treatment. The biocidal effect started 3 days after application. An equal efficacy compared to a marketed standard product has been shown (100 % mortality within 5 days).

The complete mortality of the ants has proven that the product attracts the insects (because there is no difference between the results with and without competition food).

1. **Arena study conducted with the product ANTI-FOURMIS, aged of 5 years, gel bait in tube (0.094 w/w spinosad) on one ant species *Lasius niger* (method CEB N°196).**

The product was applied at the dose of 2.2 g / m2 (4 droplets of 3 mm i.e. 0.2 g / 900 cm²) on plates with 100+/-2 ants in each plate, with and without an alternative competition food. The mortality of the ants was recorded daily for 8 days. The test product was compared with an untreated control and with a reference product (AFourmi F, 0.05 % w/w Fipronil). Four replicates were made for each test condition. The product ANTI-FOURMIS (Spinosad 0.094 % w/w) aged of 5 years showed a complete lethal efficacy against black garden ants, *Lasius niger*, within 6 days of treatment. The biocidal effect started 3 days after application. An equal efficacy compared to a marketed standard product has been shown (100% mortality within 5 days).

The complete mortality of the ants has proven that the product attracts the insects (because there is no difference between the results with and without competition food).

1. **Field test conducted with the product ANTI-FOURMIS, gel bait in tube and in bait box (0.094 w/w spinosad) on one ant species (*Lasius niger*).**

The product was applied at the dose of:

- 0.2 g to 0.5 g/m2 (4-5 droplets of 3-5 mm per m2) around the nest entry for the gel in tube

- 1 bait box (containing 4.9 g of product) per nest entry (i.e. 1 to 3 bait boxes per nest).

The ground surface activity was assessed before treatment, 1 and 3 days after and then every week after treatment. At the end of the trial, 3 weeks after treatment, the nests were opened and the remaining alive ants were counted. The test product was compared with an untreated control and with a reference product (AFourmi F, 0.05 % w/w Fipronil). Three replicates were made for each test condition. The reduction of the activity was total after 3 weeks and there was no remaining activity in the nest and no ants alive.

All efficacy studies are presented in annex 9.

Based on these efficacy data, the product ANTI-FOURMIS (coded COM 111 06 I RB) (0.094 % w/w Spinosad), formulated as gel bait in a bait box or in a tube, at a rate of 1 bait box (4.9 g of product) per nest entry (1 up to 3 per nest) or 1 to 3 boxes per 10 m2 (0.49 to 1.47 g/m2), or 0.5 g/m2 when used in tube showed a complete lethal efficacy against *Lasius niger* within 3 weeks.

In laboratory tests, the effect began 3 days after application.

Aged products of 2.5, 4 or 5 years have shown the same effectiveness as the fresh product.

No new data has been submitted for renewal of the application. Efficacity of the products is covered by the data submitted for the first authorisation.

#### Mode of action, including time delay

The effect begins around 3 days after ingestion of the product.

Spinosad acts by ingestion and also by contact, by movement of the insect onto a treated surface.

Spinosad is ingested by the insect. The worker ants are attracted by the special lure and carry in their crop parts of the bait into their nests, feeding the queen and the brood. The product shows that already after a few days ant´s activity declines visibly and after 3 weeks, the entire nest population is destroyed.

Spinosad activates the central nervous system of insects through interaction with the nicotinic acetylcholine receptors. Immediately after application, insect pests exhibit irreversible tremors, prostrate trembling and paralysis, leading to death.

In insects, the mode of action of spinosad is associated with excitation of the insect nervous system. Spinosad uniquely alters the function of nicotinic and GABA-gated ion channels, a manner consistent with the observed neuronal excitation. However, spinosad does not interact with known binding sites for other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, avermectins and cyclodienes. These data indicate that spinosad acts through a unique insecticidal mechanism.” (SPINOSAD, Technical Bulletin, Dow AgroSciences LLC).

#### Efficacy data

| **Test substance** | **Test organism(s)** | **Test system / concentrations applied / exposure time** | **Test results: effects, mode of action, resistance** | **Reference** | **RI** |
| --- | --- | --- | --- | --- | --- |
| ANTI-FOURMIS (COM 111 06 I RB), 0.094 % Spinosad,bait box | *Lasius niger* | Effectiveness of insecticide ant gel bait was tested against black garden ants.The methodology was based on the French official registration protocol C.E.B. n°196 (Novembre 1997) “Méthode d’étude de l’efficacité des préparations appâts insecticides sur les espèces communes de fourmis.”Climatic conditions: 25°C±1°C / 65%RH±4%RH/light 1500 lux 8/16 photoperiod- The “plates trial” was conducted with competition food (sugar wet cotton)Pre-test: in plastic arenas 30 cm ×30 cm × 15 cm with or without competition food. Only workers are exposed to the product. Three doses are tested and the best two were used for the next step.-Test: the semi-realistic trial was done in a vivarium (30 cm ×30 cm × 30 cm) containing an acclimatized nest with all the development instars except the queenDose tested : 1 box of 4.9 g for 900 cm², i.e. 54.4 g/m² | **Mean of replicates in the ARENA TRIAL**

|  |  |
| --- | --- |
|  | **Time of exposure to kill 100 % ants (in days)** |
| CELAFLOR 0.02 % fipronil | 5 |
| BLATTANEX 0.0875 % phoxime | 4 |
| AFOURMI F 0.05 % fipronil | 5 |
| COMPO station 0.1 g/kg bifenthrin | 5 |
| COMPO station 0.1 % CPE | 3 |
|  |  |
| COM 111 01 I RB 0.1 % | 5 |
| COM 111 06 I RB 0.094 % | 5 |
| COM 111 07 I RB 0.05 %  | 8 |
| COM 111 08 I RB 0.02 % | 16 |

**Mean of replicates in the VIVARIUM TRIAL (1)**

|  |  |
| --- | --- |
| **Frequency of ants in surface**  | **Days of exposure** |
| **No. of ants** | **+7 D** | **+14 D** | **+21 D** | **+28 D** | **+35 D** |
| Untreated | 81 | 67.7 | 71.2 | 75.5 | 74.4 |
| COM 111 01 I RB 0.1 % | 8.2 | 2.3 | 0 | 0 | 0 |
| COM 111 06 I RB 0.094 % | 24.1 | 8.6 | 0.2 | 0 | 0 |
| BLATTANEX 0.0875 % phoxim | 11.4 | 5.2 | 0.3 | 0 | 0 |
| COMPO station 0.1 g/kg bifenthrin | 33.2 | 12.5 | 0.9 | 0 | 0 |
| COMPO station 0.1 % CPE | 19.3 | 11.7 | 0.7 | 0 | 0 |
| AFOURMI F 0.05 % fipronil | 6 | 1 | 0.3 | 0 | 0 |
| CELAFLOR 0.02 % fipronil  | 5.5 | 0.4 | 0 | 0 | 0 |

**Mean of replicates in the VIVARIUM TRIAL (2)**

|  |  |
| --- | --- |
| **Inside frequency of ants** | **Days of exposure** |
| **No. of ants** | **+7 D** | **+14 D** | **+21 D** | **+28 D** | **+35 D** |
| Untreated | 52 | 46 | 49 | 56 | 51 |
| COM 111 01 I RB 0.1 % | 6.2 | 1.9 | 0 | 0 | 0 |
| COM 111 06 I RB 0.094 % | 18.7 | 9.6 | 3.1 | 0 | 0 |
| BLATTANEX 0.0875 % phoxim | 19.6 | 8.7 | 2.6 | 0 | 0 |
| COMPO station 0.1 g/kg bifenthrin | 30.2 | 9.5 | 1.1 | 0 | 0 |
| COMPO station 0.1 % CPE | 53.6 | 22.1 | 0.4 | 0 | 0 |
| AFOURMI F 0.05 % fipronil | 9 | 0.3 | 0 | 0 | 0 |
| CELAFLOR 0.02 % fipronil  | 14.1 | 8.5 | 0 | 0 | 0 |

 | B5.10(01) Serrano et al, 2004 | 2 |
| Anti-fourmis (COM 111 06 I RB), 0.094 % spinosad, bait box and gel tube | *Lasius niger* | Bioassays of the efficacy of different experimental products intended to control ants in garden and house environment were conducted.Nests were found in large meadows in 6 fields in the country or private gardens with no human intervention during the trial.Experimental design: 3 untreated nests and 3 nests treated with each experimental factor.Register of temperature during the trial is given in the report. | **% reductions of the frequency of ants in surface**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **+2 D** | **+7 D** | **+14 D** | **+21 D** |
| Untreated | -9.8 | 23.2 | -8.8 | -10.1 |
| COM 111 06 I RB bait box | 13.8 | 68.4 | 90.9 | 100 |
| COM 111 06 I RB gel tube | 9.9 | 48.6 | 89.6 | 100 |
| Standard AFOURMI F bait box | 28.3 | 59.2 | 93.1 | 100 |

**Final counts on ant nests (in number of insects)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | Tested dose | Final count of alive ants after 3 weeks |
| COM 111 06 I RB bait box | 0.094 % a.i. (spinosad) | Bait box | 1 up to 3/nest | 0 |
| COM 111 06 I RB gel tube | 0.094 % a.i. (spinosad) | Droplets | 4-5 droplets/m2 i.e. 0.2 to 0.5 g/m2 | 0 |
| AFOURMI F Standard bait box | 0.05 % a.i. (fipronil) | Bait box | 1 up to 3/nest | 0 |
| **Control** | - | - | - | > 1500 |

 | B5.10(02) Serrano et al, 2007 | 1 |
| ANTI-FOURMIS (COM 111 06 I RB), 0.094 % spinosad, bait box, 2.5 years aged bait | *Lasius niger* | Effectiveness of insecticide ant gel bait was tested against black garden ants.The methodology was based on the French official registration protocol C.E.B. n°196 (Novembre 1997) “Méthode d’étude de l’efficacité des préparations appâts insecticides sur les espèces communes de fourmis.”Climatic conditions: 25°C±1°C / 65%RH±4%RH/light 1500 lux 8/16 photoperiod- The “plates trial” was conducted with and without competition food (sugar wet cotton) in plastic arenas 30 cm ×30 cm × 15 cm. Only workers are exposed to the product.Dose tested : 1 box of 4.9 g for 900 cm², i.e. 54.4 g/m² | **Mean of replicates in the trial with competition food**

|  |  |
| --- | --- |
|  | **Days of exposure**% of mortality of ants |
|  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| **Untreated control** | 0 | 0 | 0.3 | 0.5 | 0.5 | 0.5 | 0.8 | 0.8 |
| **COM 111 06 I RB + 2.5 years** | 0 | 0.8 | 18 | 61 | 100 | 100 | 100 | 100 |
| **Standard product** | 0 | 22 | 79 | 92 | 100 | 100 | 100 | 100 |

**Mean of replicates in the trial without competition food**

|  |  |
| --- | --- |
|  | **Days of exposure**% of mortality of ants |
|  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| **Untreated control** | 0 | 0 | 0.3 | 0.5 | 0.5 | 0.5 | 0.8 | 0.8 |
| **COM 111 06 I RB + 2.5 years** | 0 | 0.3 | 21 | 67 | 100 | 100 | 100 | 100 |
| **Standard product** | 0 | 22 | 79 | 92 | 100 | 100 | 100 | 100 |

 | B5.10(03) Serrano et al, 2013(a) | 2 |
| ANTI-FOURMIS (COM 111 06 I RB), 0.094 % spinosad, bait box, 5 years aged bait | *Lasius niger* | Effectiveness of insecticide ant gel bait was tested against black garden ants.The methodology was based on the French official registration protocol C.E.B. n°196 (Novembre 1997) “Méthode d’étude de l’efficacité des préparations appâts insecticides sur les espèces communes de fourmis.”Climatic conditions: 25°C±1°C / 65%RH±4%RH/light 1500 lux 8/16 photoperiod- The “plates trial” was conducted with and without competition food (sugar wet cotton) in plastic arenas 30 cm ×30 cm × 15 cm. Only workers are exposed to the product.Dose tested : 1 box of 4.9 g for 900 cm², i.e. 54.4 g/m² | **Mean of replicates in the trial with competition food**

|  |  |
| --- | --- |
|  | **Days of exposure**% of mortality of ants |
|  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| **Untreated control** | 0 | 0 | 0.3 | 0.5 | 0.5 | 0.5 | 0.8 | 0.8 |
| **COM 111 06 I RB + 5 years** | 0 | 0 | 15 | 43 | 90 | 100 | 100 | 100 |
| **Standard product** | 0 | 22 | 79 | 92 | 100 | 100 | 100 | 100 |

**Mean of replicates in the trial without competition food**

|  |  |
| --- | --- |
|  | **Days of exposure**% of mortality of ants |
|  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| **Untreated control** | 0 | 0 | 0.3 | 0.5 | 0.5 | 0.5 | 0.8 | 0.8 |
| **COM 111 06 I RB + 5 years** | 0 | 0.5 | 16 | 54 | 93 | 100 | 100 | 100 |
| **Standard product** | 0 | 22 | 79 | 92 | 100 | 100 | 100 | 100 |

 | B5.10(04) Serrano et al, 2013(b) | 2 |
| ANTI-FOURMIS (COM 111 06 I RB), 0.094 % spinosad, gel tube, 4 years aged bait | *Lasius niger* | Effectiveness of insecticide ant gel bait was tested against black garden ants.The methodology was based on the French official registration protocol C.E.B. n°196 (Novembre 1997) “Méthode d’étude de l’efficacité des préparations appâts insecticides sur les espèces communes de fourmis.”Climatic conditions: 25°C±1°C / 65%RH±4%RH/light 1500 lux 8/16 photoperiod- The “plates trial” was conducted with and without competition food (sugar wet cotton) in plastic arenas 30 cm ×30 cm × 15 cm. Only workers are exposed to the product.Dose tested : of 2.2 g / m2 (4 droplets of 3 mm i.e. 0.2 g / 900 cm²) | **Mean of replicates in the trial with competition food**

|  |  |
| --- | --- |
|  | **Days of exposure**% of mortality of ants |
|  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| **Untreated control** | 0 | 0 | 0.3 | 0.5 | 0.5 | 0.5 | 0.8 | 0.8 |
| **COM 111 06 I RB + 4 years** | 0 | 0 | 24 | 76 | 91 | 100 | 100 | 100 |
| **Standard product** | 0 | 22 | 79 | 92 | 100 | 100 | 100 | 100 |

**Mean of replicates in the trial without competition food**

|  |  |
| --- | --- |
|  | **Days of exposure**% of mortality of ants |
|  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| **Untreated control** | 0 | 0 | 0.3 | 0.5 | 0.5 | 0.5 | 0.8 | 0.8 |
| **COM 111 06 I RB + 4 years** | 0 | 0 | 30 | 79 | 98 | 100 | 100 | 100 |
| **Standard product** | 0 | 22 | 79 | 92 | 100 | 100 | 100 | 100 |

 | B5.10(05) Serrano et al, 2013(c) | 2 |
| ANTI-FOURMIS (COM 111 06 I RB), 0.094 % spinosad, gel tube, 5 years aged bait | *Lasius niger* | Effectiveness of insecticide ant gel bait was tested against black garden ants.The methodology was based on the French official registration protocol C.E.B. n°196 (Novembre 1997) “Méthode d’étude de l’efficacité des préparations appâts insecticides sur les espèces communes de fourmis.”Climatic conditions: 25°C±1°C / 65%RH±4%RH/light 1500 lux 8/16 photoperiod- The “plates trial” was conducted with and without competition food (sugar wet cotton) in plastic arenas 30 cm ×30 cm × 15 cm. Only workers are exposed to the product.Dose tested : of 2.2 g / m2 (4 droplets of 3 mm i.e. 0.2 g / 900 cm²) | **Mean of replicates in the trial with competition food**

|  |  |
| --- | --- |
|  | **Days of exposure**% of mortality of ants |
|  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| **Untreated control** | 0 | 0 | 0.3 | 0.5 | 0.5 | 0.5 | 0.8 | 0.8 |
| **COM 111 06 I RB + 5 years** | 0 | 0 | 18 | 60 | 91 | 100 | 100 | 100 |
| **Standard product** | 0 | 22 | 79 | 92 | 100 | 100 | 100 | 100 |

**Mean of replicates in the trial without competition food**

|  |  |
| --- | --- |
|  | **Days of exposure**% of mortality of ants |
|  | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| **Untreated control** | 0 | 0 | 0.3 | 0.5 | 0.5 | 0.5 | 0.8 | 0.8 |
| **COM 111 06 I RB + 5 years** | 0 | 0 | 18 | 72 | 95 | 100 | 100 | 100 |
| **Standard product** | 0 | 22 | 79 | 92 | 100 | 100 | 100 | 100 |

 | B5.10(06) Serrano et al, 2013(d) | 2 |

The product ANTI-FOURMIS (0.094 % w/w Spinosad), as bait station (4.9 g of product), at a dose of 1 up to 3 bait stations for 10 m2 (0.49 à 1.47 g/m2) or one bait box per nest entry has shown a sufficient efficacy for the control of black garden ants (*Lasius niger*) within 3 weeks.

The product ANTI-FOURMIS (0.094 % w/w Spinosad), as gel bait in tube, at a dose of 0.5 g/m2 has shown a sufficient efficacy for the control of black garden ants (*Lasius niger*) within 3 weeks.

***Conditions of use linked to efficacy assessment***

* Respect the recommended application doses.
* The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.
* Do not apply the product on absorbing surfaces.
* Ensure the product is applied in water-sheltered areas
* The amount of bait per surface unit must be in accordance with the recommended efficacy dose.

In the frame of the renewal, efficacy of the product is covered by the data submitted for the first authorisation.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### Occurrence of resistance and resistance management

Due to the site-specific mode of action (nAChR activation) there is a risk of resistance formation.

The resistance to spinosad was first documented in both laboratory and field-selected strains several years after its introduction. Laboratory selection studies with *H. virescens* (Young et al., 2007[[5]](#footnote-6)) showed that high levels of resistance to spinosad could be developed through extensive selection of larvae for many generations. Likewise, a spinosad selected laboratory strain of *M. domestica* was also shown to exhibit resistance to spinosad (Shono & Scott., 2003[[6]](#footnote-7)). At the same time, studies with field strains of *Spodoptera exigua* (beet armyworm) from USA (Arizona) and Thailand demonstrated reduced susceptibility to spinosad compared to a USDA laboratory strain (Moulton et al ., 2000[[7]](#footnote-8)), although the more highly resistant strain from Thailand died off quickly in culture. In addition to the above mentioned studies, several other studies have demonstrated the development of spinosad resistance in the laboratory and the field in such diverse species as *Drosophila melanogaster* (fruit fly), *Liriomyza trifolii* (American serpentine leafminer), *Helicoverpa armigera* (cotton bollworm), and *Frankliniella occidentalis* (western flower thrips).(Sparks et al., 2011[[8]](#footnote-9))

Nevertheless, for the hymenoptera, order to which ants belong, only 3 % of insect species have developed resistance to spinosad, the population of *Cotesia plutella* were selected in laboratory conditions. The bibliographic researches don’t reveal any studies showing a resistance developed naturally by a population of ants.

Furthermore, for the biocidal use of spinosad as gel bait in a bait box or from a tube against antsthe probability of resistance is very low. Indeed, the individuals of this species are social insects from which only the queen can reproduce. The worker ants are attracted by the special lure and carry parts of the bait into their nests, feeding the queen and the brood with the bait material from their crop by regurgitation. Therefore, even if some worker ants would survive, the colony would disappear if the queen is dead, i.e. the resistance could then not be passed on to offspring. The application technique (bait box or tube gel with special lure) allows the ants to consume for an unlimited period of time and even less affected individuals would eat until the lethal dose is achieved. The probability that the most resistant individuals survive is thus very low.

From the first authorisation, no occurrence of resistance for ants has been reported in the literature. As the risk of developing resistance to spinosad cannot be excluded, the authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### Known limitations

Known

#### Evaluation of the label claims

According to the TNsG, for bait products, the label can only claim efficacy against species that have been tested under field conditions. So the claims must be “control of black garden ants (*Lasius niger*)”.

Tests on persistence of action and effectiveness after maximal storage period have been performed and show that the product is still effective after a 5 year storage period.

The bait droplets should preferably be placed on non-absorbing surfaces like flagstones, pieces of glass, tile or plastic, etc.

French competent authorities (FR CA) assessed that :

* the product ANTI-FOURMIS (0.094 % w/w Spinosad), as bait station (4.9 g of product), at a dose of 1 up to 3 bait stations for 10 m2 (0.49 à 1.47 g/m2) or one bait box per nest entry has shown a sufficient efficacy for the control of black garden ants (*Lasius niger*) within 3 weeks.
* The product ANTI-FOURMIS (0.094 % w/w Spinosad), as gel bait in tube, at a dose of 0.5 g/m2 has shown a sufficient efficacy for the control of black garden ants (*Lasius niger*) within 3 weeks.

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

### aRisk assessment for human health

#### Assessment of effects on Human Health

**Toxicology of the active substance**

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 4 “Toxicology and metabolism” must be taken into consideration.

The following corresponds to the summary of the effect assessment available in the assessment report of Spinosad.

Oral absorption of spinosad is rapid, and is assumed to be 50%. For the inhalation route 100% absorption is assumed. Dermal absorption of spinosad is low. For concentrated and diluted product dermal absorption values of respectively 0.1% and 2% are assumed. After oral administration spinosad is widely distributed in the body and rapidly excreted, predominantly in the faeces. It is noted that spinosad is extensively excreted in the bile. Metabolism is probably similar for both spinosyn A and D. The metabolites found in faeces were cysteine and glutathione conjugates. Other metabolites detected in faeces, urine and bile were: the glutathione conjugate of spinosyn A and D, and N-and/or O-demethylated spinosyn A and D with or without glutathione conjugation.

The acute oral, dermal and inhalation toxicity of spinosad is low (oral LD50 >2000 mg/kg bw, dermal LD50 >5000 mg/kg bw, inhalation LC50 >5.18 mg/L). Spinosad is not irritating to the skin and eyes and is not a skin sensitizer in a maximisation test.

The toxicological data base indicates that the critical toxicological endpoint for spinosad is the induction of vacuolation. This effect is observed in various tissues in mice, rats and dogs after oral administration in medium-term and long-term toxicity studies. There is no severe necrosis or organ dysfunction. As a consequence, classification with R48/22 is not necessary. The overall NOAEL for medium-term administration is 4.89 mg/kg bw/d, observed in a 90-day study in dogs. The overall NOAEL for long-term administration is 2.4 mg/kg bw/d, observed in a 2-year study in rats. The toxicity after repeated dermal administration is low, with an overall NOAEL of 1000 mg/kg bw/day. There is no evidence of a genotoxic potential of spinosad, and spinosad is unlikely to pose a carcinogenic risk. In a 2-generation reproductive toxicity study in rats, the NOAELs for parental, developmental and reproductive effects were set at 10 mg/kg bw/d. At the next higher dose level (100 mg/kg bw/day), parental effects noted were a decreased feed consumption and body weight, increased incidences of vaginal bleeding, dystocia and mortality during the lactation phase (females only), increased organ weights and histologic alterations (including vacuolation) in several organs. The developmental effects were decreases in gestation survival, litter size, pup weights and neonatal survival. Reproductive toxicity (dystocia, vaginal bleeding and decreased litter size) was observed in the presence of parental toxicity. The NOAEL for reproductive toxicity was 10 mg/kg bw/day. There is no evidence that spinosad induces developmental/teratogenic effects or neurotoxicity.

Overall NOAEL

The toxicological data base indicates that the critical toxicological endpoint for spinosad is the induction of vacuolation. This effect is observed in various tissues in mice, rats and dogs after oral administration in medium-term and long-term toxicity studies. The overall NOAEL for medium-term administration is 4.89 mg/kg bw/d, observed in a 90-day study in dogs. The overall NOAEL for long-term administration is 2.4 mg/kg bw/d, observed in a 2-year study in rats.

ADI (acceptable daily intake) and ARfD (acute reference dose).

*ADI (acceptable daily intake)*

No human epidemiological data, volunteer studies or case studies are available which allow the establishment of an acceptable daily intake (ADI) for spinosad. The ADI has therefore to be derived from the results of toxicity studies with experimental animals. The calculation of the ADI is based on the highest dose at which no adverse effect is observed in the most appropriate study in the most sensitive species. Spinosad was tested in several acute, medium-, and long-term toxicity studies in dogs, rats, and mice, providing the basis for the establishment of the ADI. Levels obtained in the neurotoxicity, reproduction, and teratogenicity studies were not critical for determining the overall NOAEL.

The lowest NOAEL (2.4 mg/kg bw/day) was obtained from an 24-month oral toxicity study in rats. This NOAEL is used as a starting point for the establishment of the ADI. Application of a safety factor for inter- and intraspecies differences of 100, results in an ADI of 0.024 mg/kg bw/day.

*ARfD (acute reference dose)*

Spinosad doesn’t induce effects in acute oral toxicity studies at doses of 2000 mg/kgbw/day or higher, does not induce acute effects in repeated dose studies, has no embryo, foetus or developmental or teratogenic effects without maternal toxicity and has no effects in the acute oral neurotoxicity study. Although acute exposure scenarios are possible, derivation of an ARfD is not necessary based on the toxicological properties of the substance. Therefore, it can be concluded that there is no concern with regard to the acute oral intake of spinosad by consumers.

Drinking water limit

According to Council Directive 97/57/EC, exposure to spinosad through the drinking water should account for not more than 10% of the ADI. If it is assumed that the average daily consumption of water amounts to 2 liter per person of 60 kilogram, a drinking water limit of ((60x0.024)/10)/2 mg/L, i.e. 0.072 mg/L can be established. According to Document 8064/VI/79 of the European Commission, the EU drinking water limit for pesticides of 0.1μg/L is applicable for spinosad.

AEL (acceptable exposure level)

SpY® (GF-739) (representative product of the spinosad CAR) will only be used by the professional farmer in animal housing. SpY® is not intended to be used by non-professionals. The use pattern indicates medium-term exposure of the professional user. Therefore a medium-term AEL is established. The AEL for medium-term exposure is based on the NOAEL of 4.89 mg/kg bw/day from oral the 90-day study in the dog, being the lowest relevant NAEL from medium-term oral toxicity studies. For establishment of an internal AEL according to the method used by the ECCO, a safety factor of 100 is used. For correction of incomplete oral absorption a factor of 0.5 is used. This results in an internal systemic medium-term AEL of 0.024 mg/kg bw/day.

Although a long-term AEL is not used in the risk assessment a long-term AEL is established. The lowest NOAEL (2.4 mg/kg bw/day) was obtained from an 24-month oral toxicity study in rats. A safety factor of 100 is used. For correction of incomplete oral absorption a factor of 0.5 is used. This results in an internal systemic long-term AEL of 0.012 mg/kg bw/day.

Although acute exposure scenarios are possible, derivation of an acute AEL is not necessary based on the toxicological properties of the substance. Therefore, it can be concluded that there is no concern with regard to acute exposure by primary exposure and indirect exposure.

*MOE (margin of exposure)*

SpY® (GF-739) will only be used by the professional farmer in animal housing. SpY® is not intended to be used by non-professionals. The use pattern indicates medium-term exposure of the professional user. Therefore the MOE will be based on the overall systemic NOAEL for short-term exposure. For reasons explained under the paragraph on the AEL, an oral study is used as starting point.

The MOE for medium-term exposure is based on the NOAEL of 4.89 mg/kg bw/day from oral the 90-day study in the dog, being the lowest relevant NOAEL from short-term oral toxicity studies. For correction of incomplete oral absorption a factor of 0.5 is used. Thus, a NOAELsystemic of 2.4 mg/kg bw/day will be used in the risk evaluation for the professional user.

For the risk assessment of spinosad for the professional user a MOE of ≥ 100 is considered acceptable, on the basis of the standard assessment factors of 100 (10 x 10) for the interspecies and intraspecies variability.

**Toxicology of the biocidal product**

The toxicology of the biocidal product was examined appropriately according to standard requirements.

The basis for the health assessment of the biocidal product is laid out in Annex 5 “Toxicology – biocidal product”.

**Percutaneous absorption**

According to the 2017 EFSA guidance on dermal absorption, the read across between the reference product of the CAR of Spinosad can not be done and the value of 2% is not aplicable.

A 70% default value is then proposed.

**Acute toxicity**

***Skin corrosion and irritation***

|  |
| --- |
| **Summary table of animal studies on skin corrosion /irritation** |
| **Method,Guideline,** **GLP status, Reliability** | **Species,Strain,Sex,No/group** | **Test substance, Vehicle, Dose levels, Duration of exposure** | **Results***Average score**(24, 48, 72h)/**observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological**findings* | **Remarks** *(e.g. major deviations)* | **Reference**  |
| *In vivo*,OECD TG 404, GLP,RL1 | rabbit, albino, male,3 | Anti-fourmis, no vehicle, 0.5 g, 4 h | Mean score (24, 48, 72 h) per animal:Erythema: 0, 0, 0 Edema: 0, 0, 0 | none | Julius, C. and Behlau, H. (2005c) |

 *[Please insert/delete rows according to the number of studies.]*

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Not irritating to skin |
| Justification for the value/conclusion | No indication of skin irritation was observed in an *in vivo* study according to OECD TG Guideline 404 with the b.p. Anti-fourmis. |
| Classification of the product according to CLP | Not classified |

***Eye irritation***

|  |
| --- |
| **Summary table of animal studies on serious eye damage and eye irritation** |
| **Method,Guideline,** **GLP status, Reliability** | **Species,Strain,Sex,No/group** | **Test substance,Dose levels, Duration of exposure** | **Results***Average score (24, 48, 72h)/**observations and time point of onset, reversibility* | **Remarks** *(e.g. major deviations)* | **Reference**  |
| *In vivo*,OECD TG 405, GLP,RL1 | Rabbit, albino, male, 3 | COM 111 06 I RB, no vehicle, 0.1 g, eyes rinsed after 24 h | Mean score (24, 48, 72 h) per animal:Cornea: 0, 0, 0Iris: 0, 0, 0Conjunctivae: 0, 0, 0Chemosis: 0, 0, 0 | none | Julius, C. and Behlau, H. (2005d) |

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | Not irritating to eyes |
| Justification for the value/conclusion | No indication of eye irritation was observed in an *in vivo* study according to OECD TG Guideline 405 with the b.p. Anti-fourmis. |
| Classification of the product according to CLP | Not classified |

***Respiratory tract irritation***

|  |
| --- |
| **Data waiving** |
| Information requirement | Based on the “Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: Information Requirements” (Version 1.2, May 2018), there are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation. Consequently respiratory irritation is not included in the testing strategies suggested. For mixtures, testing 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 (CLP regulation), and synergistic effects between any of the components are not expected. |
| Justification | For details on the assessment of the potential respiratory irritation properties please refer also to IUCLID Section point 8.7.The hazards of the active substances and the co-formulants are generally known and no synergistic effects are expected. Thus, toxicological properties and the classification of the biocidal product can be deduced from the respective properties of the active substances as well as the co-formulants.Based on the provisions of the CLP regulation for the classification of mixtures, the biocidal product does not need to be classified with respect to potential respiratory irritation. |

*[If not relevant, delete the table.]*

***Skin sensitization***

| **Summary table of animal studies on skin sensitisation** |
| --- |
| **Method,Guideline, GLP status, . Reliability** | **Species,Strain,Sex,No/group** | **Test substance, Vehicle,****Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)* | **Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)* | **Remarks***(e.g. major deviations)* | **Reference**  |
| In vivo,OECD TG 406, GLP,RL2 | Guinea pig, Dunkin-Hartley, male/female, 10 induced, 5 control animals, 6 pre-test | Anti-fourmis, water, 5% intradermal induction/25% topical induction/25% challenge, n.a./48 h/24 h | None of the test group animals showed signs of skin sensitisation. | None  | Julius, C. and Behlau, H. (2005e) |

[*Please insert/delete rows according to the number of studies.]*

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Not sensitizing to the skin |
| Justification for the value/conclusion | No indication of skin sensitisation was observed in an *in vivo* study according to OECD TG Guideline 406 with the b.p. Anti-fourmis. |
| Classification of the product according to CLP | Not classified |

***Respiratory sensitization (ADS)***

*[If no data is provided, please delete the table and indicate the justification for the adaptation/waiving of the data*

|  |
| --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | Not sensitizer for the respiratory tract |
| Justification for the value/conclusion | Based on available data on the composition of the product and according to the classification rules laid down in the CLP Regulation, no classification for the respiratory sensitisation is required for the product ANTI-FOURMIS.  |
| Classification of the product according to CLP  |  No classification |

|  |
| --- |
| **Data waiving** |
| Information requirement | - |
| Justification | Based on the “Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: Information Requirements” (Version 1.2, May 2018), there are currently no standard tests and no OECD test guidelines available for respiratory sensitisation.  |

*[If not relevant, delete the table.]*

***Acute toxicity***

*Acute toxicity by oral route*

*[If no data is provided, please delete the table and indicate the justification for the adaptation/waiving of the data requirement(s), including a reference to the IUCLID data point.]*

| **Summary table of animal studies on acute oral toxicity** |
| --- |
| **Method Guideline****GLP status, Reliability**  | **Species,Strain,Sex,No/group** | **Test substance****Dose levelsType of administration** *(gavage, in diet, other)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **ValueLD50** | **Remarks** *(e.g. major deviations)* | **Reference**  |
| *In Vivo*,OECD TG 423, GLP,RL1 | Rat, Sprague-Dawley, females, 3 per step | Anti-fourmis, physiological saline,2000 mg/kg bw,gavage | no mortality, no signs of toxicity | > 2000 mg/kg bw  | none | Julius, C. and Behlau, H. (2005a) |
|  |  |  |  |  |  |  |

*[Please insert/delete rows according to the number of studies.]*

|  |
| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | LD50 > 2000 mg/kg bw |
| Justification for the selected value | No mortality or any sign of toxicity was observed in an *in vivo* study according to OECD TG Guideline 423 with the b.p. Anti-fourmis at the limit dose 2000 mg/kg bw. |
| Classification of the product according to CLP  | Not classified |

*Acute toxicity by inhalation*

|  |
| --- |
| **Data waiving** |
| Information requirement | According to Chapter 3.1.5.2 “Acute toxicity by inhalation” of the “Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: Information Requirements” (Version 1.2, May 2018), testing on a product/mixture does not need to be conducted if valid data on each of the components in the mixture are available sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. |
| Justification | For details on the assessment of the acute inhalation toxicity please refer also to IUCLID Section point 8.5.2.The hazard of the active substances (a.s.) and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product(s) (b.p.) can be deduced from the respective properties of the a.s. as well as the co-formulants using the conventional method described in CLP Regulation. Considering only components classified for acute inhalation toxicity as well as respecting the cut-off limits as provided for in Table 1.1 “Generic cut-off values” of the CLP regulation, the biocidal product does not need to be classified and labelled with respect to acute inhalation toxicity. |

*[If not relevant, delete the table.]*

*Acute toxicity by dermal route*

|  |
| --- |
| **Summary table of animal studies on acute dermal toxicity** |
| **Method, Guideline,****GLP status,****Reliability** | **Species, strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LD50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| *In vivo*,OECD TG 402, GLP,RL1 | Rat, Sprague-Dawley, males and females, 5/sex | Anti-fourmis, moistened with water,2000 mg/kg bw,10% of body surface area | no mortality, no clinical signs of toxicity, no erythema and oedema | > 2000 mg/kg bw (males and females) | none | Julius, C. and Behlau, H. (2005b) |

*[Please insert/delete rows according to the number of studies.]*

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | LD50 > 2000 mg/kg bw |
| Justification for the selected value | No mortality or any sign of toxicity was observed in an *in vivo* study according to OECD TG Guideline 402 with the b.p. Anti-fourmis at the limit dose 2000 mg/kg bw. |
| Classification of the product according to CLP  | Not classified |

|  |
| --- |
| **Data waiving** |

***Information on dermal absorption***

|  |
| --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Substance | Spinosad |  |
| Value(s)\* | 70% |  |
| Justification for the selected value(s) | Default value (EFSA guidance, 2017). |  |

*\* please include the concentration range(s) the values are applicable for, if relevant*

|  |
| --- |
| **Data waiving** |
| Information requirement | According to Chapter 3.1.6 “Information on dermal absorption” of the “Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: Information Requirements” (Version 1.2, May 2018), information on dermal absorption are necessary when exposure occurs to the biocidal product. The assessment of this endpoint shall proceed using a tiered approach.It is not always mandatory to submit experimental data. Instead, as a first step default values can be used considering the OECD Guidance Document on Percutaneous absorption/ penetration (OECD, 2004a) and the EFSA Guidance Document on Dermal Absorption (EFSA, 2012).Dermal absorption studies with the biocidal product have not been conducted. |
| Justification | Spinosad:Data of the a.s. spinosad were evaluated by the Rapporteur Member State (RMS) Netherlands (Assessment Report (AR) PT18; RMS NL; 2010). According to the AR a dermal absorption value of 2% was used for exposure assessment purposes for a product with a concentration comparable to the biocidal product. But the read across can not be acceptable between the reference product and ANTIFOURMIS. A 70% defaut value is proposed according to the 2017 EFSA guidance(for gel/RB formulation, the value is 70% for dilution). |

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

According to the“Guidance on the BPR, volume III Human Health- Assessment & Evaluation (Parts B+C)” none of the co-formulants should be considered as substance of concern (SoC).

Please refer to Confidential Annex for further details.

***Available toxicological data relating to a mixture***

***Other***

#### Exposure assessment

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

In case of the bait box, there is no dermal exposure to the insecticidal formulation since it is safely contained in a tamper-proof HDPE casing. The box cannot be opened without a tool, so that small children cannot ingest the contents of the bait box.

In case of the tube, accidental dermal exposure to the bait material cannot be ruled out. The bait droplets should be applied only in places inaccessible by children and pets so that secondary exposure is unlikely. Furthermore, the biocidal product (b.p.) contains denatonium benzoate as a deterrent (bittering agent) against oral ingestion.

Nonetheless, incidental dermal and oral exposure will be addressed.

The vapour pressure of the most volatile component of spinosad, spinosyn A, is only 3×10–8 Pa so that exposure to spinosad vapours, especially under outdoor ventilation conditions, can be ruled out.

Ants are intended to carry parts of the bait material into their nests. In doing so, some of the carried bait material might contaminate the path between the location of the bait box and the nest. However, this amount is going to be light and hard to quantify.

There is no potential for considerable uptake of spinosad via the environment.

| **Summary table: relevant paths of human exposure** |
| --- |
| **Exposure path** | **Primary (direct) exposure**  | **Secondary (indirect) exposure**  |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| Dermal | n.a. | n.a. | yes | n.a. | n.a. | yes | no |
| Oral | n.a. | n.a. | n.a | n.a. | n.a. | yes | no |

***List of scenarios***

| **Summary table: scenarios** |
| --- |
| **Scenario number** | **Scenario**(e.g. mixing/ loading) | **Primary or secondary exposure** **Description of scenario** | **Exposed group**(e.g. professionals, non-professionals, bystanders) |
| [1] | Bait Box | Primary exposureUse of the bait box indoors and outdoors | non-professionals |
| [2] | Tube  | Primary exposureUse of tube application indoors and outdoors | non-professionals |
| [3] | Bait Box | Secondary exposureUse of the bait box indoors and outdoors | general public |
| [4] | Tube  | Secondary exposureUse of tube application indoors and outdoors | general public: toddler / child |
| [5] | Tube | Secondary exposureUse of tube application indoors and outdoors | Pets: dogs and cats |

***Industrial exposure***

Anti-fourmis will only be used by non-professionals. Therefore the assessment of industrial exposure is not relevant.

***Professional exposure***

Anti-fourmis will only be used by non-professionals. Therefore the assessment of professional exposure is not relevant.

***Non-professional exposure***

*Scenario [1] Primary exposure non-professional – Bait Box*

| **Description of Scenario [1]** |
| --- |
| Although the doses proposed for bait box are superior to the dose for gel in tube, the exposure following application with tube (Scenario 2) is considered as a worst-case. Indeed, product in bait will not be accessible if the box is not forced. In this context, the exposure to a bait box will not be assessed since the exposure to a tube is considered as a worst-case and will cover this scenario. Therefore, please refer to Scenario [2] for detailed information. |

*Scenario [2] Primary exposure non-professional – Tube*

| **Description of Scenario [2]** |
| --- |
| An adult (60 kg) may be dermally exposed during application of the gel. Inhalation exposure is negligible due to the low vapour pressure of the active substance (*spinosyn A* (99.9% w/w) 3.00E-08 Pa and *spinosyn D* (> 99% w/w) 2.00E-08 Pa at 25 °C2). A reverse scenario has been used to estimate the quantity of product that a non-professional user would have to touch to reach the AELmedium-term. |
|  | Parameters | Value |
| Tier 1 | Concentration [%, w/w] | Spinosad | 0.094 |
| Body weight [kg] | Adult | 601 |
| Dermal absorption [%] | Spinosad | 702 |
| Package size [kg] | 0.034 |
| AELmedium-term[mg/kg bw/day] | Spinosad | 0.0243 |

1 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure, Default human factor values for use in exposure assessments for biocidal products, 2017

2 European Food Safety Authorisation, Guidance on Dermal Absorption, EFSA Journal 2017;15(6):4873

3 Assessment Report Spinosad for PT18, 2010 (The Netherlands)

4 Product specification

**Calculations for Scenario [2]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Population** | **Body weight****(kg)** | **Quantity of AS to****reach the AEL****medium-term (mg) by****skin contact** | **Quantity of****product to reach****the AEL medium-term****(g) by skin****contact** | **Quantity of product to****reach the AEL medium-term****(in number of tubes****containing 30 g gel) by****skin contact** |
| Adult | 60 | Spinosad | Spinosad | Spinosad |
| 2.06 | 2.19 | 0.073 |

AS = active substance

Quantity of AS to reach the AELmedium-term (mg) by skin contact

$$= \frac{AELmedium-term \* body weight}{dermal absorption}$$

Quantity of product to reach the AELmedium-term (g) by skin contact

$$= \frac{Quantity of AS to reach the AELmedium-term (mg) by skin contact }{Concentration of AS in ANTI-FOURMIS}$$

Quantity of product to reach the AELmedium-term (in number of tubes containing 30 g gel) by skin contact

$$=\frac{Quantity of product to reach the AELmedium-term (g) by skin contact }{30 g}$$

According to the calculations, 0.073 tubes containing 30 g of gel should be applied on the skin of an adult to reach an exposure equal to the AELmedium-term for spinosad.

It represents 2.19g *i.e,* 21.9 drops.

***Exposure of the general public***

*Scenario [3] Secondary exposure general public – Bait Box*

| **Description of Scenario [3]** |
| --- |
| The product in bait will not be accessible if the box is not forced. In this context, secondary exposure to a bait box will not be assessed since the exposure to a tube is considered as a worst-case and will cover this scenario. Therefore, please refer to Scenario [4] for detailed information. |

*Scenario [4] Secondary exposure general public - Tube*

| **Description of Scenario [4]** |
| --- |
| Users are advised to place the bait droplets in places that are not accessible by playing children or crawling toddlers. The b.p. is formulated with a bittering agent that discourages oral ingestion by humans. However, as a worst case it is assumed that a toddler or a child may be exposed by touching drops of the gel. Subsequently, hand to-mouth transfer is the only realistic route for oral intake. A reverse scenario has been used to estimate the quantity of product that a toddler or a child would have to touch or to ingest (toddlers only) to reach the AELmedium-term. In addition the systemic dose after dermal and oral (toddlers only) exposure with regard to children and toddlers is estimated. |
|  | Parameters | Value |
| Tier 1 | Concentration [%, w/w] | Spinosad | 0.094 |
| Body weight [kg] | Toddler | 101 |
| Child | 15.61 |
| Dermal absorption [%] | Spinosad | 702 |
| Oral absorption [%] | Spinosad | 503 |
| Package size [kg] | 0.034 |
| In-use dose [g/m²] | 0.5 (maximum of 5 drops à 0.1 g/m²) |
| Surface area to be touched by children and toddler [m²] | 15 |
| AELmedium-term[mg/kg bw/day] | Spinosad | 0.0243 |
|  | Hand-to-mouth transfer value: 10% (taking into account that Anti-fourmis contains a bittering agent) [%] | Spinosad | 103 |

1 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure, Default human factor values for use in exposure assessments for biocidal products, 2017

2 European Food Safety Authorisation, Guidance on Dermal Absorption, EFSA Journal 2017;15(6):4873

3 Assessment Report Spinosad for PT18, 2010 (The Netherlands)

4 Product specification

5 Dermal exposure assumption (reasonable value considering that the product will be placed out of reach of children and infants)

**Calculations for Scenario [4]**

**Dermal exposure – Reverse scenario**

**Spinosad**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Population** | **Body weight****(kg)** | **Quantity of AS to****reach the AEL****medium-term (mg) by****skin contact** | **Quantity of****product to reach****the AEL medium-term****(g) by skin****contact** | **Quantity of product to****reach the AEL medium-term****(in number of tubes****containing 30 g gel) by****skin contact** | **Number of drops to****touch and****corresponding surface****area** |
| Child | 15.6 | 0.53 | 0.57 | 0.018 tubes | 6 drops on 1.1 m² surface area |
| Toddler | 10 | 0.34 | 0.36 | 0.01 tubes | 3.65 drops on 0.7 m² surface area |

Quantity of AS to reach the AELmedium-term (mg) by skin contact

$$= \frac{AELmedium-term \* body weight}{dermal absorption}$$

Quantity of product to reach the AELmedium-term (g) by skin contact

$$= \frac{Quantity of AS to reach the AELmedium-term (mg) by skin contact }{Concentration of AS in ANTI-FOURMIS}$$

Quantity of product to reach the AELmedium-term (in number of tubes containing 30 g gel) by skin contact

$$=\frac{Quantity of product to reach the AELmedium-term (g) by skin contact }{30 g}$$

Number of drops to touch:

$$1 drop = 0.1 g$$

Corresponding surface area

$$=\frac{Quantity of product to reach the AELmedium-term (g) by skin contact }{0.5 g/m2}$$

**Spinosad:**

A toddler would have to be dermally exposed to 1% of a tube containing 30 g of gel, and a child would have to be exposed to 2% of a tube containing 30 g of gel to reach the AELmedium-term. Since the in-use dose is 0.5 g/m² (maximum of 5 drops/m²), a child or a toddler would have to touch 6 drops on a surface area of 1.1 m² and 3.6 drops on a surface area of 0.7 m², respectively.

**Dermal exposure – Systemic exposure**

As a worst case scenario it is assumed, that a child (toddler) touches the contaminated area with both sides of their hands

**Spinosad**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population** | **Body weight (kg)** | **Surface area of the hands (m²)** | **Internal dermal exposure (mg/kg bw/day)** |
| Child | 15.6 | 0.03311 | 6.98E-04 |
| Toddler | 10 | 0.02601 | 8.55E-04 |

1 Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure, Default human factor values for use in exposure assessments for biocidal products, 2017

Internal dermal exposure

$$=\frac{(in-use dose \*hand surface area\* Concentration of{AS}/{}in ANTI-FOURMIS \* dermal absorption) }{body weight}$$

The dermal exposure of children and toddlers is 6.98E-04 and 8.55E-04 mg/kg bw/day for spinosad.

**Hand-to-mouth transfer – Reverse scenario**

Toddlers may be incidentally exposed orally to Anti-fourmis via hand-to-mouth behaviour. Even if the product contains a bittering agent, a reverse scenario calculation was included.

**Spinosad**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Population** | **Body weight****(kg)** | **Quantity of AS to****reach the AEL****medium-term (mg) by****ingestion** | **Quantity of****product to reach****the AEL medium-term****(g) by ingestion** | **Quantity of product to****reach the AEL medium-term****(in number of tubes****containing 30 g gel) by****ingestion** | **Number of drops to****touch and****corresponding surface****area** |
| Toddler | 10 | 0.48 | 0.6 | 0.02 tubes | 6 drops on 1.2 m² surface area |

Quantity of AS to reach the AELmedium-term (mg) by ingestion

$$= \frac{AELmedium-term \* body weight}{oral absorption}$$

Quantity of product to reach the AELmedium-term (g) by ingestion

$$= \frac{Quantity of AS to reach the AELmedium-term (mg) by ingestion }{Concentration of AS in ANTI-FOURMIS}$$

Quantity of product to reach the AELmedium-term (in number of tubes containing 30 g gel) by ingestion

$$=\frac{Quantity of product to reach the AELmedium-term (g) by ingestion }{30 g}$$

Number of drops to eat:

$$1 drop = 0.1 g$$

Corresponding surface area

$$=\frac{Quantity of product to reach the AELmedium-term (g) by ingestion}{0.5 g/m2}$$

**Spinosad:**

A toddler would have to eat less than one tube (2% of a tube containing 30 g of gel) to reach an exposure level equal to the AELmedium-term. Since the in-use dose is 0.5 g/m² (maximum of 5 drops/m²), a toddler would have to eat 6 drops on a surface area of 1.2 m² to reach the AELmedium-term.

**Hand-to-mouth transfer – Systemic exposure**

In addition, the exposure of a toddler ingesting Anti-fourmis via hand-to-mouth transfer has been calculated. Due to the bittering agent denatonium benzoate a value for dislodgeable fraction was set on 10%1. This value was adopted from the US EPA SOP for hand-to-mouth transfer, which is descibed in the HEEG Opinion 7 and similar for various product types (PT 2, 3, 4, 6, 18).

**Spinosad**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population** | **Body weight (kg)** | **Dislodgeable fraction (%)** | **Internal exposure (mg/kg bw/day)** |
| Toddler | 10 | 101 | 6.11E-05 |

Internal oral exposure

$$=\frac{(in-use dose \*hand surface area\* Concentration of AS in ANTI-FOURMIS \*0.1\* oral absorption) }{body weight}$$

The oral exposure of a toddler via hand-to-mouth transfer is estimated to be 6.11E-05mg/kg bw/day for spinosad.

**Combined exposure**

No combined exposure is assessed for the non-professional user and the children since only the dermal exposure is considered as relevant.

However, a combined systemic exposure has been calculated for a toddler who touches drops of Anti-fourmis and is orally exposed to Anti-fourmis via hand-to-mouth transfer.

**Spinosad**

|  |  |  |
| --- | --- | --- |
| **Population** | **Body weight****(kg)** | **Internal exposure (mg/kg bw/day)** |
| Toddler | 10 | 9.17E-04 |

***Dietary exposure***

The product ANTI-FOURMIS is intended to be applied by non-professional users, out of reach of food or feed and therefore does not leave residues in commodities for human or animal consumption.

In this purpose, the following precautionary statement should be indicated on the labels:

* Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.

*List of scenarios*

Not relevant

*Information of non-biocidal use of the active substance*

Residue definitions

Residue definitions from plant protection products regulation.

|  |
| --- |
| **Endpoints** |
| **Plant residue definition for monitoring** | Spinosad, sum of spinosyn A and spinosyn D(Regulation (EU) 2015/603) |
| **Plant residue definition for risk assessment** | Spinosad, sum of spinosyn A and spinosyn D(EFSA, 2012[[9]](#footnote-10))*For information only: Sum of spinosyn A, spinosyn D, spinosyn B, spinosyn K. (provisional) (EFSA, 2018)* |
| **Animal residue definition for monitoring** | Spinosad, sum of spinosyn A and spinosyn D(Regulation (EU) 2015/603) |
| **Animal residue definition for risk assessment** | Spinosad, sum of spinosyn A and spinosyn D, except poultry liver and eggs (spinosad, sum of spinosyn A, spinosyn D, *O-*demethylated spinosyn D and *N-*demethylated spinosyn D)(EFSA, 2012)*For information only – EFSA, 2018*[[10]](#footnote-11)*:* * *sum of spinosyn A, D, B, N-demethyl spinosyn D and MET A-Li-4(5b) in ruminants matrices*

*sum of spinosyn A, D, B and N-demethyl spinosyn D in poultry matrices* |
| **Conversion factor from enforcement to Risk Assessment** | Not applicable for plants Poultry, liver: 4 (tentative)Poultry, eggs: 1.5 (tentative)(EFSA, 2012) |

| **Summary table of other (non-biocidal) uses** |
| --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant protection products (Reg (EC) No 1107/2009) | Pesticide | MRLs value established for a variety of commodities (Reg EU 2015/603) – range of MRLs: 0.02 to 60 mg/kg |

1 e.g. plant protection products, veterinary use, food or feed additives

2 e.g. MRLs. Use footnotes for references.

Toxicological reference values derived in the plant protection products regulation

| Referencevalue | Source | Year | Value | Study relied upon | Safety factor |
| --- | --- | --- | --- | --- | --- |
| **Spinosad** |
| ADI | EC | 2006 | 0.024 mg/kg bw/d | 2-year rat | 100 |
| ARfD | EC | 2006 | Not necessary |
| EFSA(1) | 2018 | 0.01 mg/kg bw | Rabbit, developmental toxicity study | 100 |
| (1). In the framework of the renewal of the approval of spinosad, an ARfD of 0.1 mg/kg bw was proposed (EFSA, 2018).  |

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

Food or drinking water exposure of the active substance spinosad can be excluded when applied according to the recommended uses.

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

The biocidal product ANTI-FOURMIS is not intended to be used by professionals and/or industrials*.*

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

Food or drinking water exposure of the active substance spinosad can be excluded when applied according to the recommended uses.

***Summary of exposure assessment***

**Spinosad**

| **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 | 1/- | 0.073 tube |
| [2] | non-professionals | 1/- | 0.073 tube |
| [3] | general public: toddlerreverse scenario | 1/- | 0.01 tube(dermal exposure) |
|  |  | 1/- | 0.02 tubes(hand-to-mouth-transfer) |
|  | general public: toddlersystemic exposure | 1/- | 8.55E-04(mg/kg bw/day) |
|  | general public: childreverse scenario | 1/- | 0.01 tubes |
|  | general public: childsystemic exposure | 1/- | 6.98E-04(mg/kg bw/day) |
| [4] | general public: toddlerreverse scenario | 1/- | 0.01 tubes(dermal exposure) |
|  |  | 1/- | 0.02 tubes(hand-to-mouth-transfer) |
|  | general public: toddlersystemic exposure | 1/- | 8.55E-04 (mg/kg bw/day) |
|  | general public: childreverse scenario | 1/- | 0.01 tubes |
|  | general public: childsystemic exposure | 1/- | 6.98E-04 (mg/kg bw/day) |

#### **Risk characterisation for human health**

***Risk for industrial users***

Not relevant.

***Risk for professional users***

Not relevant.

***Risk for non-professional users***

Exposure to spinosad for non-professional users is exclusively dermal. Contributions via other routes (inhalation and oral) are considered negligible and not taken into account in the risk assessment.

Exposure was compared with the AELmedium-term set in the Assessment Report of the active substance. The AELmedium-term of 0.024 mg/kg bw/day was based on the 90-day dermal study in dogs with a NOAEL of 4.89 mg/kg bw/day and using an oral absorption factor of 0.5 (or 50%) and an assessment factor of 100 .

A reverse scenario was used to determine the number of tubes that an adult would have to put on his skin to reach an exposure level equal to the AELmedium-term.

According to the calculations 0.073 tubes tube containing 30 g of gel should be applied on the skin of an adult to reach an exposure equal to the AELmedium-term.

This value being considered as unrealistic (about 22 drops), the risk is then considered as acceptable for the non-professional users.

**Risk for indirect exposure**

**General Public**

**Dermal exposure**

A reverse scenario has been used to estimate the quantity of product that a child or a toddler would have to touch to reach the AELmedium-term.

Based on this reverse scenario, a toddler would have to be dermally exposed to 0.36g of product or to 1% of a tube containing 30 g of gel, and a child should be exposed to 0.56 g of product or 2% of a tube containing 30 g of gel to reach the AELmedium-term for spinosad.

Since the in-use dose is 0.5 g/m² (maximum of 5 drops/m²), a child or a toddler would have to touch 5.6 drops on a surface area of 1.1 m² and 3.6 drops on a surface area of 0.72 m² for spinosad, respectively.

These values are considered as unrealistic since the product should be applied out of reach of toddlers and children.

In addition, the internal dermal exposure for a child or a toddler touching drops of gel with their hands is well below the respective AEL and does not give rise for any concern.

**Spinosad**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population** | **Body weight (kg)** | **Internal dermal exposure****(mg/kg bw/day)** | **%AEL** |
| Child | 15.6 | 6.98E-04 | 3 |
| Toddler | 10 | 8.55E-04 | 3.5 |

The risk is considered acceptable for children or toddlers touching drops of Anti-fourmis.

**Hand-to-mouth transfer**

Toddlers may be incidentally exposed orally to Anti-fourmis via hand-to-mouth behaviour.

Based on the reverse scenario calculations, an toddlerwould have to eat less than one tube (2% of a tube containing 30 g of gel) to reach an exposure level equal to the AEL medium-term. Since the in-use dose is 0.5 g/m² (maximum of 5 drops/m²), a toddler would have to eat 6 drops on a surface area of 1.2 m² to reach the AEL medium-term.

This scenario could be considered as accidental since the presence of a bittering agent in the formulation will prevent the ingestion of drops of gel by toddlers and the product should be applied out of reach of children and toddlers.

In addition, the internal dermal exposure for a child or a toddler touching drops of gel with their hands is well below the respective AEL and does not give rise for any concern.

**Spinosad**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population** | **Body weight [kg]** | **Internal oral exposure [mg/ kg bw/day]** | **% AEL** |
| Toddler | 10 | 6.11E-05 | <1 |

Overall, the risk is considered as acceptable for toddlers orally exposed to Anti-fourmis via hand-to- mouth transfer, considering that the product Anti-fourmis contains a bittering agent and that the product is placed out of reach oftoddler (the product labelling should mention this condition).

**Risk for combined exposure**

The combined exposure for a toddler touching drops of gel placed on a surface area of 1 m² and eating drops of gel via hand-to-mouth transfer has been calculated and is well below the respective AEL and does not give rise for any concern.

**Spinosad**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population** | **Body weight [kg]** | **Internal oral exposure [mg/ kg bw/day]** | **% AEL** |
| Toddler | 10 | 9.17E-04 | <1 |

The risk is then considered as acceptable for toddlers touching drops of Anti-fourmis and eating Anti-fourmis via hand-to-mouth transfer, considering that the product Anti-fourmis contains a bittering agent and that the product is placed out of reach oftoddler (the product labelling should mention this condition).

**Conclusion on human health risk assessment**

An acceptable risk is identified for non-professional users.

The risk is considered as acceptable for children and toddlers if the product Anti-fourmis contains a bittering agent and is placed out of reach of children and toddlers.

***Risk for the general public***

**Maximum residue limits or equivalent**

See §Information of non-biocidal use of the active substance.

***Risk for consumers via residues in food***

Based on the proposed conditions and restrictions of use, the acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. The product should not be applied directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock as stated in the precautionary statement of the labels. Regarding consumer health protection, there are no objections against the intended uses.

### Risk assessment for animal health

Pets might be orally exposed to drops of the product which is applied indoors and outdoors via tube application. Therefore, exposure via ingestion is estimated for dogs and cats as representative animal species for companion animals.

**Secondary exposure**

*Scenario [5] Secondary exposure companion animals - Tube*

| **Description of Scenario [5]** |
| --- |
| Users are advised to place the bait droplets in places that are not accessible to pets. The b.p. is formulated with a bittering agent. However, several animal species (including dogs, cats, pigs, horses and deers) have been shown to be sensitive to bitterness, although to a lesser degree than humans (A trial to determine detection and bitterness recognition threshold of Bitrex hydrate and denatonium saccharide. Inveresk Research International report. No3189, September 1984). Thus, it is assumed that pets, i.e. dogs and cats may be orally exposed by licking and subsequent ingestion of the gel. A reverse scenario has been used to estimate the quantity of product that a dog or a cat would have to ingest to reach the AELmedium-term. In addition a margin of exposure approach was conducted for spinosad based on the NOAEL of a 90-day repeated dose toxicity study in the dog.  |
|  | Parameters | Value |
| Tier 1 | Concentration [%, w/w] | Spinosad | 0.094 |
| Body weight [kg] | Dog | 121 |
| Cat | 21 |
| Package size [kg] | 0.032 |
| in-use dose [g/m²] | 0.5 (maximum of 5 drops à 0.1 g/m²) |
| AELmedium-term[mg/kg bw/day] | Spinosad | 0.0243 |
| Tier 2 | NOAEL 90-day study in the dog | Dog | 4.89 mg/kg bw/day |

1 The Toxicologist’s pocket Handbook, Michael J. Derelanko (2008), Table 27

2 Product specification

3 Assessment Report Spinosad for PT18, 2010 (The Netherlands)

**Calculations for Scenario [5]**

**Oral exposure – Reverse scenario**

As a worst case approach a reversed scenario is performed based on the AELmedium-term.

**Spinosad**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Animal species** | **Body weight****(kg)** | **Quantity of AS to** **reach the AEL****medium-term (mg/day) by****ingestion** | **Quantity of****product to reach****the AEL medium-term****(g/day) by ingestion** | **Quantity of product to** **reach the AEL medium-term****(in number of tubes****containing 30 g gel) by****ingestion** | **Number of drops to****touch and****corresponding surface****area** |
| Dog | 12 | 0.288 | 0.36 | 0.012 tubes | 3.6 drops on 0.72 m² surface area |
| Cat | 2 | 0.048 | 0.06 | 0.002 tubes | 0.6 drops on 0.12 m² surface area |

Quantity of AS to reach the AELmedium-term (mg) by ingestion

$$=AELmedium-term \* body weight$$

Quantity of product to reach the AELmedium-term (g) by ingestion

$$= \frac{Quantity of AS to reach the AELmedium-term (mg) by ingestion }{Concentration of AS in ANTI-FOURMIS}$$

Quantity of product to reach the AELmedium-term (in number of tubes containing 30 g gel) by ingestion

$$=\frac{Quantity of product to reach the AELmedium-term (g) by ingestion }{30 g}$$

Number of drops to eat:

$$1 drop = 0.1 g$$

Corresponding surface area

$$=\frac{Quantity of product to reach the AELmedium-term (g) by ingestion }{0.5 g/m2}$$

**Spinosad:**

A dog would have to be orally exposed to 1.2% of a tube containing 30 g of gel, and a cat would have to be exposed to 0.2% of a tube containing 30 g of gel to reach the AELmedium-term. Since the in-use dose is 0.5 g/m² (maximum of 5 drops/m²), a dog or a cat would have to ingest 3.6 drops on a surface area of 0.72 m² and 0.6 drops on a surface area of 0.12 m², respectively.

Thus, since with regard to the active substance spinosad an unacceptable health risk for dogs and cats cannot be excluded a refinement is performed via application of the margin of exposure (MoE) approach.

**Oral exposure – Margin of exposure approach based on NOAEL of 90-day study in the dog**

According to the EFSA Guidance “Risk Assessment of Birds and Mammals” (2009) a margin of exposure (MoE; term used in the EFSA Guidance: toxicity-exposure-ratio; TER) of >10 is considered acceptable and no refinement is necessary. The MoE is calculated as follows:

$$MoE= \frac{NOAEL}{Exposure}$$

**Spinosad**

The NOAEL of an oral 90-day repeated dose toxicity study in the dog is 4.89 mg/kg bw/day.

Thus, the oral exposure that would lead to a MoE of 10 accounts for 0.489 mg/kg bw/day.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Animal species** | **Body weight****(kg)** | **Quantity of AS to****reach the MoE (mg/day) by****ingestion** | **Quantity of****product to reach****the MoE****(g) by ingestion** | **Quantity of product to reach the MoE****(in number of tubes****containing 30 g gel) by****ingestion** | **Number of drops to****touch and****corresponding surface****area** |
| Dog | 12 | 5.87 | 6.24 | 0.208 tubes | 62.4 drops on 12.5 m² surface area |
| Cat | 2 | 0.98 | 1.04 | 0.034 tubes | 10.4drops on 2.08 m² surface area |

Quantity of AS to reach the MoE (mg) by ingestion

= NOAEL/10 \* body weight

Quantity of product to reach the MoE (g) by ingestion

$$= \frac{Quantity of AS to reach the MoE (mg) by ingestion }{Concentration of AS in ANTI-FOURMIS}$$

Quantity of product to reach the MoE (in number of tubes containing 30 g gel) by ingestion

$$=\frac{Quantity of product to reach the MoE (g) by ingestion }{30 g}$$

Number of drops to eat:

$$1 drop = 0.1 g$$

Corresponding surface area

$$=\frac{Quantity of product to reach the MoE (g) by ingestion }{0.5g/m2 }$$

**Spinosad:**

A dog would have to be orally exposed to 20.8% of a tube containing 30 g of gel, and a cat would have to be exposed to 3.4% of a tube containing 30 g of gel to reach the MoE. Since the in-use dose is 0.5 g/m² (maximum of 5 drops/m²), a dog or a cat would have to ingest 62.4 drops on a surface area of 12.5 m² and 10.4 drops on a surface area of 2.08 m², respectively.

Overall, the risk is considered acceptable for dogs orally exposed to Anti-fourmis, considering that the product Anti-fourmis contains a bittering agent and that the product is placed out of reach of pets (the product labelling should mention this condition).

With regard to cats a higher risk is expected compared to dogs. However, considering the contained bittering agent and a statement on the label that the product should not be accessible to pets an unacceptable health risk is not assumed.

**Conclusion on animal health risk assessment**

The risk is considered acceptable for companion animals, i.e. dogs and cats, if the product Anti-fourmis contains a bittering agent and is placed out of reach of pets. The risk mitigation measures should include the following statement on the label: “Do not apply in areas accessible to children, pets or other non-target animals in order to minimize the risk of poisoning.”

### Risk assessment for the environment

###

The renewal assessment has been based on the conclusion for authorized uses from the initial assessment (2016). No new ecotoxicological information has been submitted at the renewal application for the product. The environmental risk is considered as acceptable for the biocidal product ANTI-FOURMIS for uses indoor (gel and bait boxes) and outdoor (bait boxes). Therefore, the conclusion remains unchanged.

A few minor changes have been made in order to update the assessment in line with EU discussions and agreement on biocide assessment and with new regulations:

* Reference to the Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0 October 2017 and updated reference from the TAB were used instead of TGD Part II and updated data from the MOTA.
* Details about the non-relevance of one co-formulant as SoC for risk assessment can be found in the confidential annex.
* A dedicated section on “Assessment of endocrine disruption (ED) properties of the biocidal product was added (see confidential annex).

Moreover, the new PAR template has been applied.

The summary of information about the active substance spinosad is carried out with the data from the CAR of spinosad supplied by the notifier DOW AGROSCIENCES B.V. (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Spinosad CAS 168316-95-8, Product Type 18 ([Insecticides](http://en.wikipedia.org/wiki/Insecticide), [acaricides](http://en.wikipedia.org/wiki/Acaricide) and products to control other [arthropods](http://en.wikipedia.org/wiki/Arthropods)), RMS The Netherlands, May 2010).

Spinosad is a mixture of two structurally similar molecules which are both active insecticidally and have been designated spinosyn A and spinosyn D. Equivalency of spinosyn A and spinosyn D has been evaluated based on environmental fate and ecotoxicology studies. It has been concluded that spinosyn A and spinosyn D exhibit equivalent behaviour and effects in the areas of environmental fate.

The applicant did not provide ecotoxicological data about the biocidal product ANTI-FOURMIS. The risk assessment is based on the data obtained from the active substance spinosad (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Spinosad CAS 168316-95-8, Product Type 18 ([Insecticides](http://en.wikipedia.org/wiki/Insecticide), [acaricides](http://en.wikipedia.org/wiki/Acaricide) and products to control other [arthropods](http://en.wikipedia.org/wiki/Arthropods)), RMS The Netherlands, May 2010).

There is no substance of concern in the biocidal product (detailed asssesment in the confidential annex). Therefore, FR CA considered that the effects of spinosad outweigh those of the non-active components of the product and that the effects assessment for the product ANTI-FOURMIS can be extrapolated from the effects assessment of the active substance spinosad.

#### Effects assessment on the environment

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

|  |
| --- |
| Classification for the environment of the Active Substance Spinosad according to the CAR (2010) |
| Value/conclusion | Aquatic acute 1 - Very toxic to aquatic life – H400 with M-factor = 10Aquatic chronic 1 - Very toxic to aquatic life with long-lasting effects – H410 with M-factor = 10  |

|  |
| --- |
| Classification for the environment of the Product ANTI-FOURMIS  |
| Value/conclusion | Aquatic chronic 3 - Harmful to aquatic life with long lasting effects - H412 |

***Further Ecotoxicological studies***

No new data is available

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

|  |
| --- |
| **Summary table of effects on specific, non-target organisms believed to be at risk** |
| **Method, Guideline, GLP status, Reliability** | Species/Inoculum | End point | Exposure | Results | Remarks | Reference |
| Design | Duration | EC50 |
| *FIFRA* | *Apis mellifera* | LD50 | oral | 48h | 0.057 µg/bee |  | CAR spinosad J47 |
|  |  | LD50 | contact |  | 0.0036 µg/bee |  | CAR spinosad J20 |

|  |
| --- |
| **Conclusion used in Risk Assessment – Effects on specific, non-target organisms** |
| Value/conclusion | Spinosad has potential effects on bees as non-target organisms  |
| Justification for the value/conclusion | LD50oral =0.057 µg/bee and LD50contact=0.0036 µg/bee |

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

No data available

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

No data available

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

No data available

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

Please refer to the exposure assessment below

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

No new data is available

***Leaching behaviour (ADS)***

No new data is available

***Testing for distribution and dissipation in soil (ADS)***

No new data is available

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

No new data is available

***Testing for distribution and dissipation in air (ADS)***

No new data is available

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

Not relevant

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

Not relevant

**Summary of the spinosad PNECs used for risk assessment**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Compartment** | **Item** | **Species** | **Endpoints** | **Safety factor** | **PNEC** |
| **(*Fresh*) Water** | **Spinosad** | *Chironomus riparius* | NOECemergence = 0.00062 mg/L | 10 | 0.062 μg/L |
| **Spinosyn B** | *Daphnia magna* | NOECreproduction = 0.00095 mg/L | 10 | 0.095 μg/L |
| **N-demethylated spinosyn D** | *Chironomus riparius* | NOECemergence = 0.00023 mg/L | 10 | 0.023 μg/L |
| **Sediment** | **Spinosad** | *Chironomus riparius* | NOECemergence = 0.06 mg/kg dw | 100 | 0.13 µg/kg ww |
| **Microorganisms (STP)** | **Spinosad** | Activated sludge | EC50 >100 mg/L | 10 | 10 mg/L |
| **Soil** | **Spinosad** | EPM | - | - | 7.53 µg/kg ww (twa) |
| **Spinosyn B** | EPM | - | - | 4.32 μg/kg ww (twa) |
| **N-demethylated spinosyn D** | EPM | - | - | 1.05 μg/kg ww(twa) |

The summary of information about the active substance spinosad is carried out with the data from the Competent Authority Report (CAR) of spinosad owned by the notifier DOW AGROSCIENCES B.V. (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, Spinosad CAS 168316-95-8, Product Type 18 ([Insecticides](http://en.wikipedia.org/wiki/Insecticide), [acaricides](http://en.wikipedia.org/wiki/Acaricide) and products to control other [arthropods](http://en.wikipedia.org/wiki/Arthropods)), RMS The Netherlands, May 2010). No new ecotoxicological information on the active substance spinosad has been submitted in the product dossier.

As stated in the CAR for spinosad, because of the uncertainties with respect to the experimental data, the PNECsoil is calculated from the PNECaquatic of 0.062 μg/L, applying equilibrium partitioning according to the Guidance on BPR Vol IV Parts B + C. Using the arithmetic mean Kpsoil of 137.6 L.kg-1, the Ksoil-water is 207 m3/m3 (Eq. 27), and then,

**PNECsoil = 7.53 μg.kg-1 ww soil (8.5 μg. kg-1 dw soil)**

This PNECsoil value can be considered as a time weighted average concentration. In fact as explained in the Vol IV Part B+C, if the PNECaquatic is based on study results that are expressed as time averaged concentrations; the PNECsoil is representative for time averaged exposure concentrations too. The same reasoning can applied for metabolites.

#### Exposure assessment

**Assessment of exposure to the environment**

The product ANTI-FOURMIS is an insecticidal bait preparation, which contains 0.094 % w/w of spinosad. It is sold in two different ready-to-use forms, bait box and gel tube, used by non-professionals only. It is applied in sheltered indoor and outdoor areas of private house and larger buildings for ants' nests destruction.

The intended uses lead to direct emissions to the terrestrial compartment and to indirect emissions *via* the sewage treatment plant (STP).

Indeed, for outdoor applications, the soil surrounding the treated building (private houses or larger buildings) can be directly exposed following wash-off of the treated areas by rainfall. This route of direct entry in the terrestrial compartment (soil and groundwater) has been assessed.

The intended uses can also lead to emissions in STP for indoor applications, when the treated zones are cleaned, or for outdoor applications in urban area, when the treated non-absorbing surface is washed off by rainfall. The risk for the aquatic compartment (STP, surface water and sediment) and for the terrestrial compartment indirectly exposed via contaminated STP sludge, have also been assessed.

In the following sections, emission values are derived by using the Emission Scenario Document (ESD) for PT18 (Insecticides for household and professional uses)[[11]](#footnote-12), equations from the Vol IV B+C and updated data from TAB.

The exposure assessment has been carried out for the active substance spinosad, but also for its two relevant metabolites in soil for the terrestrial compartment only.

In the frame of the renewal, the exposure assessment has been adapted to the new PAR template. No other change has been proposed.

General information

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: Indoor bait boxes application.Scenario 2: Indoor application of gel (Cracks and crevices barrier teatment scenario for private house and large building)\*.Scenario 3: Outdoor bait boxes application on terrace (private house).Scenario 4: Outdoor bait boxes application on bare soil (private house). |
| ESD(s) used | Emission scenario document for insecticides, acaricides and products to control arthropods for household and professional use (ESD for PT18, OECD, 17/07/2008) |
| Approach | Average consumption approaches |
| Distribution in the environment | Calculated based on ECHA Guidance on the BPR Vol IV Part B; April 2015 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: NoFormulation NoUse: YesService life: No |
| Remarks |  |

\* The cracks and crevices barrier treatment scenario was accepted at the time of the first authorization although no specific study on the efficiency of this product for a use in cracks and crevices was submitted as it was not claimed. Therefore, scenario 2 was recalculated using surface barrier treatment and a FCE of 0.25. The risk ratios for each environmental compartment were added in this assessment and can be found in the risk characterisation section below.

***Emission estimation***

**Release estimations from INDOOR applications**

**Scenario 1 - Gel in boxes**

According to the ESD for PT18, emissions to the environment during the indoor treatments are possible only when the box is eliminated to solid waste. Cleaning efficiency for gel in bait boxes is FCE = 0, no environmental emission is expected following indoor application of ANTI-FOURMIS bait boxes.

**Scenario 2 - Drops of gel**

Calculations for Scenario 2

According to the ESD for PT18, for gel applications, emissions can occur during 3 steps described below. The following assumptions are considered:

1. **Mixing and loading step:** the product is a ready-to-use gel product, therefore no mixing and loading is necessary and emission calculation for these steps is considered as not relevant (Eprep,applicator and Eprep,floor = 0 kg/d).
2. **Application step:** emissions to air, to the applicator, to floor and to treated surfaces are considered.
* *Emission to air, applicator and floor*

Due to formulation of the product as gel, the mode of application with a tube and the characteristics of the active substance (non-volatile), no emission to air, to the applicator and to the floor is expected (Eapplication,air, Eapplication,applicator andEapplication,floor = 0 kg/d).

* *Emission to treated surfaces:* the emission rate to the treated surfaces in the wet cleaned zone is calculated as follows (for one house or one large building):

**Eapplication,treated = Qprod,point \* Npoint \* FAI \*AREAtreated \* Fapplication,treated \* Nappl,building \* 10-3**

Where

Eapplication,treated: Emission to treated surfaces during application step (kg/day)

Qprod,point: Quantity of commercial product applied per square meter (specific value for ANTI-FOURMIS = 0.5 g/m2)

Npoint: Not relevant as the intended use is already expressed in g/m2. Set to 1.

FAI: Fraction of active substance in the commercial product (specific value for ANTI-FOURMIS = 0.00094)

AREAtreated: Surface treated with the product in the wet cleaned zone (default value for a standard house = 5.9 m² and larger building = 27.3 m²)

Fapplication,treated: Fraction emitted to treated surfaces during the application (default value ESD PT18 = 1)

Nappl,building: Number of applications per day per building (default value ESD PT18 = 1/day)

It is considered that ANTI-FOURMIS is used as a chemical barrier set up to cover insect access routes along floor/wall junctions and which covers a total surface of 20 m2 for a domestic house or 93 m2 for larger building. These values for barrier treatment are corrected for the wet cleaned zone. The wet cleaned zone for a private house of 131 m2 is 38.5 m2, is equal to the surface of the kitchen and bathroom (ConsExpo). This leads to a correction factor of 38.5 / 131 = 0.294, and then to the default values for barrier treatment of 5.9 m2 (20\*0.294) for a private house. The same correction factor is applied for larger building leading to the default values for barrier treatment of 27.3 m2 (93\*0.294). Then, emissions to treated surfaces in the wet cleaned zone during application step are:

**Eapplication,treated = 2.77E-06 kg/day for one private house**

**Eapplication,treated = 1.28E-05 kg/day for one larger building**

**3- Cleaning step:** the product is applied in sheltered areas where there is normally no cleaning. Nevertheless, it is not excluded that a fraction of the product applied could be eliminated through cleaning event.

For the product ANTI-FOURMIS, it is considered that the cleaning event results only in emission to wastewater. As defined in the ESD for PT18, it is considered that 100% of the surfaces are cleaned with water, then Fww = 1. The cleaning efficiency FCE is 3% for a gel formulation applied in sheltered areas. Emissions from treated surfaces to wastewater are calculated as follows:

**Etreated,ww = Eapplication,treated  \* Fww \* FCE**

where

Etreated,ww: Emission from treated surfaces to waste water during the cleaning step (kg/day)

Eapplication, treated: Emission to treated surfaces during the application step in private house or larger buildings (see above = 2.77E-06 kg/day or 1.28E-05 kg/day respectively)

Fww: Fraction emitted to wastewater during the cleaning step (default value ESD PT18 = 1)

FCE: Cleaning efficiency (default value ESD PT18 = 0.03)

**Etreated,ww = 8.32E-08 kg.d-1 for private houses**

**Etreated,ww = 3.85E-07 kg.d-1 for larger buildings**

**Releases to STP:**

Following the ESD PT18, it is assumed that 4000 houses and 300 larger buildings are connected to one STP. Simultaneity factors for indoor uses are introduced to reflect the possibility of simultaneous applications in different houses and large buildings of household insecticides. The estimated figures are from a French survey based on questionnaires to the general public.

According to the applicant, the product ANTI-FOURMIS is applied up to 1 time/month. Therefore, the default simultaneity factor for indoor use has been revised in order to take into account only three frequencies of use proposed in the French survey: one time per month, three to eleven time per year and one to two times per year. The simultaneity factor calculated for these frequencies of use was therefore 0.0139 instead of the default value of 0.055 for indoor applications.

Using the Etreated, ww calculated above and the following formula:

**Elocalstp = [(Etreated, ww private house \* Nhouse ) + (Etreated, ww larger building \* Nbuilding)] \* Fsimultaneity**

with

Elocal stp: Total emission to waste water (kg.d-1)

Etreated, ww: Emission to waste water for one private house and one larger building (see above: 8.32E-08 kg.d-1 and 3.85E-07 kg.d-1)

Nhouse: Number of private houses or larger buildings connected to the STP (default value ESD PT18 = 4000 or 300 respectively)

Fsimultaneity: Simultaneity factor for 1 application/month (specific value for ANTI-FOURMIS = 0.0139)

**Elocal stp = 6.21E-06kg.d-1**

| **Resulting local emission to relevant environmental compartments** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 6.21E-06 |  |

**Releases estimations from OUTDOOR applications**

Different scenarios have been performed covering all the intended uses. It has been considered that bait boxes can be used to treat infested zones on non-absorbing surfaces (“Terrace” scenario), but can also be placed directly on soil (“Bare soil” scenario). The bait boxes have only been assessed for private houses. This type of treatment has been considered as not relevant for large buildings according to the applicant.

In urban areas, the main receiving compartment is the STP directly exposed to the applied product transferred to the rainwater/sewage water system during the rain event. Risk assessments have also been proposed for the secondarily exposed aquatic (surface water and sediment) and terrestrial (soil and groundwater) compartments. For the “Bare soil” scenario, this direct route of entry is not relevant.

In rural areas, the only relevant receiving compartment is the soil surrounding the treated buildings.

**Scenario 3 and 4 - Gel in boxes - terrace scenario and bare soil**

Calculations for Scenario 3 (terrace) and 4 (bare soil)

The recommended dose of ANTI-FOURMIS is one bait station of 4.9 g of product for 10 m². But it is also indicated that one bait box has to be use to treat one infested area.

The applicant considered that bait boxes application around larger building is not relevant. Consequently, outdoor application of bait boxes is restricted to private house only.

According to the ESD for PT18, emissions can occur during the steps described below. The following assumptions are considered:

1. **Mixing and loading step:** the product is a ready-to-use box product, therefore no mixing and loading is necessary and emission is considered not relevant (Eprep,applicator and Eprep,floor = 0 kg/d).
2. **Application step:** emissions to air, to the applicator, to floor and to treated surfaces are considered.

*Emission to air, applicator and floor:*

Due the mode of application (bait boxes) and the characteristic of the active substance (non-volatile), no emission to air, applicator and floor is expected (Eapplication,air, Eapplication,applicator andEapplication,floor = 0 kg/d).

*Emission to treated surfaces:* Emissions from the treated surfaces are calculated considering, as realistic worst-case scenario, the placing of four bait stations (considering four infested areas) on a 30 m2 terrace of a private house (“Terrace” scenario) or one bait station on 1 m2 of bare soil for ants' nests treatment (“Bare soil” scenario).

The equation for local releases following application of ANTI-FOURMIS in bait boxes on a terrace or on bare soil is:

**Ebox, outdoor = Qprod \* FAI \* Nsites \* Fbox**

where:

Ebox, outdoor : Emission rate of active substance from outdoor application (g)

Qprod : Amount of product used per application site (specific value for ANTI-FOURMIS = 4.9 g)

FAI : Fraction of active substance in product (specific value for ANTI-FOURMIS = 0.00094)

Nsites : Number of application sites (default value ESD PT18 = 4 (‘Terrace’ scenario) or 1 (‘Bare soil’ scenario))

Fbox : Fraction released to the environment following wash-off by rainfall (default value ESD PT18 for bait box = 20%)

**Ebox, outdoor, terrace = 3.68E-03 g (‘Terrace’ scenario)**

**Ebox, outdoor, bare soil = 9.21E-04 g (‘Bare soil’ scenario)**

**Direct release to soil (rural areas, surfaces not connected to STP):**

Emissions to soil in rural areas are directly defined from the above values:

**Ebox, outdoor, terrace = 3.68E-03 g (‘Terrace’ scenario)**

**Ebox, outdoor, bare soil = 9.21E-04 g (‘Bare soil’ scenario)**

| **Resulting local emission to relevant environmental compartments (direct releases)** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [g/d]** | **Remarks** |
| Soil (Terrace) | 3.68E-03 | - |
| Soil (Bare soil) | 9.21E-04 | - |

**Indirect releases *via* the STP (urban areas):**

Simultaneity treatments in different houses have to be taken into account for releases to the STP. Then, following the ESD it is assumed that 2500 houses are connected to one STP for outdoor uses for outdoor uses. As for the indoor uses, the default value of the simultaneity factor for outdoor applications (0.03) has been revised in order to take into account only three frequencies of use proposed in the French survey: one time per month, three to eleven time per year and one to two times per year, considering the intended application frequency of 1 time/month. The simultaneity factor calculated for this frequency of use was therefore 0.0139 instead of 0.03.

The release to the STP is only relevant for the ‘Terrace’ scenario.

**Ebox, ww = Ebox, outdoor, terrace \* Nhouse \* Fsimultaneity\* 10E-03**

With

Ebox, ww: Total emission rate to wastewater from outdoor application (kg.d-1)

Ebox, outdoor, terrace: Emission rate of active substance from outdoor application for one house (see above 3.68E-03g (Terrace scenario))

Nhouse: Number of houses connected to STP (default value ESD PT18= 2500)

Fsimultaneity: Simultaneity factor for 1 application/month (specific value for ANTI-FOURMIS = 0.0139)

**Ebox, ww = 1.28E-04kg.d-1**

| **Resulting local emission to relevant environmental compartments (indirect releases)** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP (Terrace) | 1.28E-04 |  |

**Summary of environmental emissions from INDOOR and OUTDOOR uses**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **DIRECT releases to soil****Esoil (g spinosad)** | **INDIRECT releases *via* the STP****Eww** **(kg spinosad / d)** |
| **INDOOR uses** | Gel in bait boxes | Not relevant | Not relevant |
| Drops of gel (private houses + large buildings) | Not relevant | 6.21E-06 |
| **OUTDOOR uses** | Gel in bait boxes | ‘Bare soil’ | 9.21E-04 | Not relevant |
| ‘Terrace’ | 3.68E-03 | 1.28E-04 |

***Fate and distribution in exposed environmental compartments***

| **Identification of relevant receiving compartments based on the exposure pathway** |
| --- |
|  | Fresh-water | Fresh-water sediment | Sea-water | Sea-water sediment | STP | Air | Soil | Ground-water |
| Scenario 1 (indoor boxes) | No | No | Not relevant | Not relevant | No | No | No | No |
| Scenario 2 (indoor gel) | Yes | Yes | Not relevant | Not relevant | Yes | No | Yes | Yes |
| Scenario 3 (outdoor boxes terrace) | Yes | Yes | Not relevant | Not relevant | Yes | No | Yes | Yes |
| Scenario 4 (outdoor boxes soil) | No | No | Not relevant | Not relevant | No | No | Yes | Yes |

|  |
| --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** |
| Input  | Value  | Unit | Remarks |
| Molecular weight | Spinosyn A: 731.98Spinosyn D: 746.00 | g/mol | CAR Spinosad 2010 |
| Vapour pressure (at 25°C) | Spinosad: -**Spinosyn A: 3.0E-08**Spinosyn D: 2.0E-08 | Pa |
| Log Octanol/water partition coefficient | Spinosad: -Spinosyn A: 4.01 at 23 °C (pH 7)Spinosyn D: 4.53 at 23 °C (pH 7) | Log 10 |
| Organic carbon/water partition coefficient (Koc)  | Spinosyn AKF values (mean): 137.6KF was better correlated with the clay content than with organic matter content of the soil. Corresponding Kclay values (average): 584 Corresponding Koc values (average): **35024**It is assumed that spinosyn D has sorption characteristics equal to spinosyn A | L/kg |
| Henry’s Law Constant (at 25°C) | Spinosad not verifiedSpinosyn A: 1.89E-07**Spinosyn D: 2.32E-05** | Pa/m3/mol |
| Biodegradability | Not readily biodegradable  |  |
| DT50 for degradation in soil | Spinosad: **3.51**Relevant Metabolites:Spinosyn B: 2.11N-demethylated spinosyn D: 3.77 | d (at 12ºC) |

|  |
| --- |
| **Calculated fate and distribution in the STP** |
| Compartment | Percentage [%] | Remarks |
| Air | 1.40E-08 |  |
| Water | 100 |  |
| Sludge | 100 |  |
| Degraded in STP | 0 |  |

No valid data are available to estimate the fraction of emission directed to water (FSTP water) and sludge (FSTP sludge) by STP. The use of Koc value to estimate these fractions of emission is not suitable regarding the adsorption properties of spinosad related to the clay content and not to the organic matter of the soil. Consequently, concentrations values in the different indirect receiving compartments have been predicted assuming the worst case value of 100% for FSTP water and FSTP sludge. Nevertheless, the application of lower fractions (considering extrapolation from Kow values as proposed by NL, RMS for the active substance spinosad) does not change the conclusions of the risk assessment.

***Calculated PEC values***

|  |
| --- |
| **Summary table on calculated PEC values** |
| Scenario | **PECSTP** | **PECwater** | **PECsed** | **PECsoil (twa for indirect releases)** | **PECGW** |
| [mg/L] | [mg/L] | [mg/kgwwt] | [mg/kgwwt ] | [mg/L] |
| 1 (indoor boxes) | - | - | - | - | - |
| 2 (indoor gel) | 3.10E-06 | 3.10E-07 | 9.51E-06 | 2.17E-068.56E-07 (Spinosyn B)1.55E-06 (N-d Spinosyn D) | 2.99E-093.14E-09 (Spinosyn B) 5.70E-09 (N-d Spinosyn D) |
| 3 (outdoor boxes terrace) | INDIRECT RELEASE |
| 6.38E-05 | 6.37E-06 | 1.95E-04 | 4.45E-051.76E-05 (Spinosyn B)3.18E-05 (N-d Spinosyn D)  | 6.14E-086.45E-08 (Spinosyn B) 1.17E-07 (N-d Spinosyn D) |
| DIRECT RELEASE |
| - | - | - | 4.97E-043.31E-05 (Spinosyn B)5.99E-05 (N-d Spinosyn D) | 4.08E-067.19E-06 (Spinosyn B)7.30E-06 (N-d Spinosyn D) |
| 4 (outdoor boxes bare soil) | - | - | - | 1.08E-037.23E-05 (Spinosyn B)1.31E-04 (N-d Spinosyn D) | 8.90E-061.57E-05 (Spinosyn B)1.59E-05 (N-d Spinosyn D) |

**PEC calculations in detail**

In the following sections, environmental concentrations are derived by using the emission rates calculated above and the equations from the Vol IV B+C.

**Aquatic compartment (surface water, sediment, STP)**

Considering the intended uses of the product, only indirect releases to the aquatic compartment *via* the STP are foreseen.

Spinosad concentrations in the STP effluent and in surface water are calculated according to the Vol IV B+C equations considering the emissions to waste water (Eww) calculated above from indoor and outdoor applications of ANTI-FOURMIS and the different parameters presented. The PEClocalsed is calculated from the PEClocalwater by equilibrium partitioning according to the Vol IV B+C using the arithmetic mean Kpsusp of 137.6 L/kg (equal to Kpsoil), leading to a Ksusp-water of 35.3 m3.m-3 (Vol IV B+C) as defined in the CAR of spinosad.

Input and output values for calculation of concentrations in STP, surface water and sediment.

|  |  |  |  |
| --- | --- | --- | --- |
| ***Indirect releases to the aquatic compartment via the STP*** | **Values** | **Unit** | **Ref.** |
| **Indoor** | **Outdoor** |
| **Gel drops** | **Bait boxes** |
| **INPUTS** |
| Eww | Emission rate to wastewater | 6.21E-06 | 1.28E-04 | [kg.d-1] | - |
| Fstp water | Fraction emitted to water by STP | 100 | [%] | - |
| Kpsusp | Solids-water partitioning coefficient in suspended matter | 137.6 | [L.kg-1] | CAR (2010) |
| Ksusp-water | Suspended matter-water partitioning coefficient | 35.3 | [m3.m-3] | Vol IV B+C |
| **OUTPUTS** |
| PECSTP | Concentration in STP | 3.10E-06 | 6.38E-05 | [mg.L-1] | Vol IV B+C |
| PEClocalwater | Concentration in surface water | 3.10E-07 |  6.37E-06 | [mg.L-1] | Vol IV B+C |
| PEClocalsed | Concentration in sediment | 9.51E-06 |  1.95E-04 | [mg.kg-1wwt] | Vol IV B+C |

**Atmospheric compartment**

Spinosyn A and D have vapour pressure of 3E-08 and 2E-08 Pa, respectively, corresponding to Henry’s law constants of 1.89E-07 and 2.32E-05 Pa. m3·mol-1, respectively. The estimated photochemical oxidation half-lives are below 1 hour for spinosyn A and D. It is thus considered unlikely that significant volatilisation will occur after use of spinosad. Volatilisation from soil and plant surfaces was shown to be negligible.

**Terrestrial compartment (soil and groundwater)**

**INDIRECT releases**

The concentrations in agricultural soil, following the spreading of contaminated STP sludge, are calculated according to the Vol IV B+C equations considering the emission rates to wastewater (Eww) and the different parameters presented above. Degradation of spinosad in soil is based on DT50,field of 3.51 days; dissipation by leaching and volatilisation is also taken into account based on the Vol IV B+C equations.

Input and output values for the calculation of spinosad concentrations for the terrestrial compartment.

|  |  |  |  |
| --- | --- | --- | --- |
| ***Indirect releases to the terrestrial compartment via the STP (spinosad)*** | **Values** | **Unit** | **Reference** |
| **Indoor** | **Outdoor** |
| **Gel drops** | **Bait boxes** |
| **INPUTS** |
| Eww | Emission rate to wastewater | 6.21E-06 | 1.28E-04 | [kg.d-1] | - |
| Fstp sludge | Fraction emitted to water by STP | 100 | [%] | - |
| DT50 soil | Half life of spinosad in soil | 3.51 | [d] | CAR (2010) |
| ksoil | Rate constant for removal in soil based on biodegradation and dissipation | 0.2 | [d-1] | Vol IV B+C |
| Sludge rate | Rate of sewage sludge production | 710\* | [kg.d-1] | Vol IV B+C |
| Kpsoil | Solids-water partitioning coefficient in soil | 137.6 | [L.kg-1] | CAR (2010) |
| Ksoil water | Soil-water partitioning coefficient | 2.07E+02 | [m3.m-3] | Vol IV B+C |
| **OUTPUTS** |
| Csludge soil | Initial concentration in soil | 1.29E-05 | 2.64E-04 | [mg.kg-1wwt] | Vol IV B+C |
| PEC local soil | Concentration in soil after 10 years of application - Twa over 30 d | 2.17E-06 | 4.45E-05 | [mg.kg-1wwt] | Vol IV B+C |
| PEC local soil porewater | Concentration in porewater (based on PEC local soil after 10 years – Twa over 180 d) | 2.99E-09 | 6.14E-08 | [mg.L-1] | Vol IV B+C |

\*As the value of 710 is a worst case compared to updated value of 790, it has been kept for the renewal.

The relevant soil metabolites of spinosyn A and D are spinosyn B and N-demethylated spinosyn D respectively. The initial PECsoil for spinosyn B and N-demethylated spinosyn D was calculated based on the initial PECsoil of spinosad for maximum formation values of 67% and 68% respectively, and taking into account the molar mass ratio between metabolite and parent compound (717:732 for spinosyn B:spinosyn A and 732:746 for N-demethylated spinosyn D:spinosyn D). On the basis of the initial PECsoil for both metabolites, the time weighted average PECsoil over 30 days (TWA-PEC30soil) or over 180 days (for groundwater concentrations) was calculated assuming a first-order exponential decay with the DT50, field of 2.11 days and 3.77 days for spinosyn B and N-demethylated spinosyn D respectively. Resulting PECvalues for spinosyn B and N-demethylated spinosyn D are given in the table below.

Input and output values for the calculation of soil concentrations of spinosyn B and N-demethylated spinosyn D.

|  |  |  |  |
| --- | --- | --- | --- |
| ***Indirect releases to the terrestrial compartment via the STP (metabolites)*** | **Values** | **Unit** | **Reference** |
| **Indoor** | **Outdoor** |
| **Gel drops** | **Bait boxes** |
| **INPUTS** |
| Csludge soil | Initial concentration of spinosad in soil | 1.29E-05 | 2.64E-04 | [mg.kg-1wwt] | Vol IV B+C |
| DT50 soil | Spinosyn B | Half life of in soil | 2.11 | [d] | CAR (2010) |
| N-demethylated spinosyn D | 3.77 |
| ksoil | Spinosyn B | Rate constant for removal in soil based on biodegradation and dissipation | 0.33 | [d-1] | Vol IV B+C |
| N-demethylated spinosyn D | 0.18 |
| Kpsoil | Solids-water partitioning coefficient in soil | 51.4 | [L.kg-1] | CAR (2010) |
| Ksoil water | Soil-water partitioning coefficient | 77.3 | [m3.m-3] | Vol IV B+C |
| **OUTPUTS** |
| **Spinosyn B** |
| Csludgesoil  | Initial PEC soil | 8.44E-06 | 1.73E-04 | [mg.kg-1wwt] | Vol IV B+C |
| PECsoil  | Concentration in soil after 10 years of application – TWA over 30 days | 8.56E-07 | 1.76E-05 | [mg.kg-1wwt] | Vol IV B+C |
| PEC soil porewater  | Concentration in porewater (based on PEC local soil after 10 years – Twa over 180 d) | 3.14E-09 | 6.45E-08 | [mg.L-1] | Vol IV B+C |
| **N-demethylated spinosyn D** |
| Csludgesoil  | Initial PEC soil | 8.58E-06 | 1.76E-04 | [mg.kg-1wwt] | Vol IV B+C |
| PECsoil  | Concentration in soil after 10 years of application – TWA over 30 days | 1.55E-06 | 3.18E-05 | [mg.kg-1wwt] | Vol IV B+C |
| PEC soil porewater  | Concentration in porewater (based on PEC local soil after 10 years – Twa over 180 d) | 5.70E-09 | 1.17E-07 | [mg.L-1] | Vol IV B+C |

**DIRECT releases**

Outdoor applications of ANTI FOURMIS can lead to the contamination of the surrounding garden soil following weathering in rural environment. Then, direct exposure of the soil compartment was assessed.

The values were calculated considering a release of 20% of the applied product (sheltered areas as intended by the applicant).

* Soil areas

In accordance with scenarios where houses are treated by spray applications, a 0.5 m soil strip adjacent to the terrace is defined as the receiving compartment.

For the **‘Terrace’ scenario**, it is assumed that the 30 m2 terrace of a private house is quadratic and that one side of the terrace is adjacent to one side of the house (5.48 m). The surface of the two soil corners of 0.5 m side length is added. Hence, the soil area exposed around a terrace is:

AREAexposed = [3\*(5.48\*0.5)] + [2\*(0.5\*0.5)] = 8.72 m2 \* **(‘Terrace’ scenario)**

\*As the value of 8.72 m2 will not change the conclusion for this the evaluation, it has been kept for the renewal instead of the updated value of 8.5 m2 (TAB ENV 154, ver2.1 2019).

For the **‘Bare soil’ scenario**, the soil area considered for the treatment of ants’ nest with one bait box is a square of one meter wide, then:

AREAexposed = 1 m2 **(‘Bare soil’ scenario)**

Input and output values for the calculation of concentrations of spinosad following direct releases to terrestrial compartment.

|  |  |  |  |
| --- | --- | --- | --- |
| ***Direct emission of active substance to the soil compartment*** | **Bait boxes** | **Unit** | **Reference** |
| **INPUTS** |
| Esoil | Direct emission rate of spinosad to soil | 3.68E-03 Terrace9.21E-04 Bare soil | [g] | - |
| AREA exposed | Area of soil directly exposed to insecticide |  |  | - |
| Terrace scenario (private house only) | 8.72 | [m2] |  |
| Bare soil scenario | 1 | [m2] |  |
| Kpsoil | Solids-water partitioning coefficient in soil | 137.6 | [L.kg-1] | CAR (2010) |
| Ksoil water | Soil-water partitioning coefficient | 2.07E-02 | [m3.m-3] | Vol IV B+C |
| RHOsoil | Density of exposed soil | 1700 | [kg.m-3] | Vol IV B+C |
| DEPTHsoil | Depth of exposed soil | 0.5 | [m] | ESD PT18 |
| **OUTPUTS** |
| Csoil | Initial concentration in soil due to direct release |  |  | ESD PT18 Eq. 06 |
| Terrace scenario | 4.97E-04 | [mg.kg-1wwt] |  |
| Bare soil scenario | 1.08E-03 | [mg.kg-1wwt] |  |
| PECsoil porewater | Concentration in porewater (based on initial PEC soil) |  | [mg.L-1] | Vol IV B+C |
| Terrace scenario | 4.08E-06 | [mg.L-1] |  |
| Bare soil scenario | 8.90E-06 | [mg.L-1] |  |

The relevant soil metabolites of spinosyn A and D are spinosyn B and N-demethylated spinosyn D respectively. As for indirect release, the TWA-PECsoil for spinosyn B and N-demethylated spinosyn D was calculated based on the initial concentration of spinosad due to direct release in soil (Csoil, Table 15), for maximum transformation values of 67% and 68% respectively, and taking into account the molar mass ratio between metabolite and parent compound (717:732 for spinosyn B:spinosyn A and 732:746 for N-demethylated spinosyn D:spinosyn D). The first-order exponential decay with the DT50, field of 2.11 days and 3.77 days for spinosyn B and N-demethylated spinosyn D respectively have been considered. Resulting PECvalues for spinosyn B and N-demethylated spinosyn D following direct release to soil are given in the table below.

Soil concentrations of spinosyn B and N-demethylated spinosyn D due to direct releases to the soil compartment.

|  |  |  |  |
| --- | --- | --- | --- |
| ***Local emission of metabolites to terrestrial compartment during episode*** | **Bait boxes** | **Unit** | **Reference** |
| **INPUTS** |
| Csoil | Initial concentration of spinosad due to direct release in soil | 4.97E-04 Terrace1.08E-03 Bare soil  | [mg.kg-1wwt] | - |
| DT50 soil  | Spinosyn B | Half life of in soil | 2.11 | [d] | CAR (2010) |
| N-demethylated spinosyn D | 3.77 |
| Ksoil | Spinosyn B | Rate constant for removal in soil based on biodegradation and dissipation | 0.33 | [d-1] | Vol IV B+C |
| N-demethylated spinosyn D | 0.18 |
| Kpsoil | Solids-water partitioning coefficient in soil | 51.4 | [L.kg-1] | CAR (2010) |
| Ksoil water | Soil-water partitioning coefficient | 77.3 | [m3.m-3] | Vol IV B+C |
| **OUTPUTS** |
| **PECsoil spinosyn B (Concentration in soil – TWA over 30 days)** |
| Terrace scenario | 3.31E-05 | [mg.kg-1wwt] | **-** |
| Bare soil scenario | 7.23E-05 | [mg.kg-1wwt] | **-** |
| **PECsoil N-demethylated spinosyn D (Concentration in soil – TWA over 30 days)** |
| Terrace scenario | 5.99E-05 | [mg.kg-1wwt] | - |
| Bare soil scenario | 1.31E-04 | [mg.kg-1wwt] | - |
| **PECporewater spinosyn B (PEC in porewater based on the initial PEC soil)** |
| Terrace scenario | 7.19E-06 | [mg.L-1] | Vol IV B+C |
| Bare soil scenario | 1.57E-05 | [mg.L-1] | Vol IV B+C |
| **PECporewater N-demethylated spinosyn D (PEC in porewater based on the initial PEC soil)** |
| Terrace scenario | 7.30E-06 | [mg.L-1] | Vol IV B+C |
| Bare soil scenario | 1.59E-05 | [mg.L-1] | Vol IV B+C |

***Primary and secondary poisoning***

ANTI FOURMIS product is restricted to bait boxes for outdoor use. Thus, potential for primary and secondary poisoning should be considered negligible.

**Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)**

The ANTI FOURMIS product is intended for use outdoor as gel in bait boxes. Therefore, the potential for direct (primary poisoning) and indirect (secondary poisoning) exposure of non-target organisms should be considered.

Primary poisoning, i.e. the direct consumption of insecticide by birds or mammals and also honeybees is a topic only for outdoor uses. Considering the ESD for PT18, direct consumption of insecticide by birds or mammals may mainly occur when insecticides are applied as granular formulation. It is not believed that gels or any other sort of insecticides are in a form that could be sufficiently appetent to bird or mammals so they would be at risk.

For secondary poisoning, the low BCF values (98 L.kg-1 Spinosyn A and 229 L.kg-1 Spinosyn D suggest that spinosad has a low bioaccumulation potential. Therefore, no risk of secondary poisoning *via* ingestion of potentially contaminated fish and earthworm is expected.

**Effects on honeybees**

Spinosad was shown to be highly toxic to bees both by oral and contact exposure with LD50 of 0.057 µg per bee and 0.0036 µg per bee respectively. Considering the concentration of spinosad in ANTI FOURMIS (0.1% w/w) and its density (d=1.293), volumes of product necessary to reach LD50 oral  and the LD50 contact are respectively 0.055 µL and 0.003 µL per bee. Therefore, exposure of a honeybee at and above the LD50 is very likely.

The product is attractive to honeybees because of its sugar-based composition (50%). Regarding the toxicity of spinosad, the mortality of a honeybee which can consume the biocidal product can not be excluded. Exposure should be limited for indoor uses.

#### Risk characterisation

Scenario 2 (indoor gel application) ratios for barrier-surface treatment was added in this PAR renewal to cover the absence of a study on the efficiency of the product for cracks and crevices application as it was not claimed.

***Atmosphere***

Conclusion:Emissions and PECs in air are considered as negligible. It can be concluded that the use of the product ANTI-FOURMIS will not pose a significant risk to the atmospheric compartment.

***Sewage treatment plant (STP)***

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECSTP** |
| Scenario 1 (indoor boxes) | - |
| Scenario 2 (indoor gel) | 3.10E-07 |
| Cracks & crevices |
| Surface | 2.57E-06 |
| Scenario 3 (outdoor boxes terrace) | 6.38E-06 |
| Scenario 4 (outdoor boxes soil) | - |

***Aquatic compartment***

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Scenario 1 (indoor boxes) | - | - |
| Scenario 2 (indoor gel) | 5.00E-03 | 7.32E-02 |
| Cracks and crevices |
| Surface | 4.14E-02 | 6.07E-01 |
| Scenario 3 (outdoor boxes terrace) | 0.10 | **1.50** |
| Scenario 4 (outdoor boxes soil) | - | - |

Conclusion: Results show unacceptable risk for sediments from indirect emission (via STP) when product ANTI-FOURMIS is use as bait boxes outdoor.

***Terrestrial compartment***

|  |
| --- |
| **Calculated PEC/PNEC values** |
|  | **PEC/PNECsoil** |
| Scenario 1 (indoor boxes) | - |
| Scenario 2 (indoor gel) |  |
| Cracks and crevices | 2.88E-041.98E-04 (Spinosyn B)1.48E-03 (N-d Spinosyn D) |
| Surface\* | 2.38E-031.64E-03 (Spinosyn B)1.23E-02 (N-d Spinosyn D) |
| Scenario 3 (outdoor boxes terrace) | INDIRECT RELEASE |
| 5.91E-034.07E-03 (Spinosyn B)3.03E-02 (N-d Spinosyn D) |
| DIRECT RELEASE |
| 6.60E-027.67E-03 (Spinosyn B)5.70E-02 (N-d Spinosyn D) |
| Scenario 4 (outdoor boxes soil) | INDIRECT RELEASE |
| - |
| DIRECT RELEASE\*\* |
| 1.44E-011.67E-02 (Spinosyn B)0.12 (N-d Spinosyn D) |

*\* The cracks and crevices barrier treatment scenario was accepted at the time of the first authorization although no specific study on the efficiency of this product for a use in cracks and crevices was submitted as it was not claimed. Therefore, scenario 2 was recalculated using surface barrier treatment and a FCE of 0.25. Only the risk ratios for each environmental compartment were added in this assessment no PEC values were presented.*

\*\* If the correct surface of soil is considered according to the ESD (0.25 m2 instead of 1), this still leads to acceptable risks considering Pec values 4 x higher.

***Groundwater***

For all scenarios, the concentrations of spinosad and its metabolites spinosyn B and N-methylated spinosyn D are below the threshold value of 0.1 µg/L. The risks for groundwater of the biocidal product are acceptable for indoor use as gel drops and outdoor as bait boxes.

***Primary and secondary poisoning***

No risk for primary nor secondary poisoning is expected.

***Mixture toxicity***

There is no relevant mixture toxicity to take into account.

***Aggregated exposure (combined for relevant emmission sources)***

Taking into account the authorised uses by FR CA and the RMM (outdoor application restricted to bait boxes, cracks and crevices and places protected from rainfall), emissions sources from outdoor and indoor uses are not expected to cumulate in the STP compartment.



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

|  |
| --- |
| For indoor application of ANTI-FOURMIS product in gel or in bait boxes, considering the active substance and its metabolites, risks are acceptables for the aquatic compartment (STP, surface water and sediment) and terrestrial compartment (soil and groundwater), taking into account the intended application rate and with respect to the use recommendations presented below.For outdoor application, considering the active substance and its metabolites, taking into account the intended dose, risks to the environment following the use of ANTI-FOURMIS in bait boxes are acceptable for all the compartments and all the scenarios, only when rainwater which can wash-off the product is not directed to the STP, with respect to the use recommendations presented below.The following RMM should be applied: ‘*Apply only under a roof, on areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water*’.Therefore, it can be concluded on acceptable environmental risks for the biocidal product ANTI-FOURMIS for indoor uses (bait boxes and gel) and outdoor uses (bait boxes only). |

### Measures to protect man, animals and the environment

### Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

### Comparative assessment

#### Screening phase

**Description of the assessement of the existing chemical diversity in authorised biocidal products to minimise the occurrence of resistance.**

The French CA has granted authorisations for 123 biocidal products authorised under Product Type 18 (insecticide) of the BPD and BPR.

Each of these biocidal products contains at least one of the following active substances:

* Etofenprox
* Alpha-cyperméthrine
* *Bacillus thuringiensis var. Kurstaki*
* *Bacillus thuringiensis subsp. israelensis*, strain SA3A
* *Bacillus thuringiensis subsp. israelensis* Serotype H14, Strain AM65-52
* Deltamethrin
* Magnesium phosphide releasing phosphine
* Aluminium phosphide releasing phosphine
* Nitrogen
* Sulfuryl fluoride
* Indoxacarb (enantiomeric reaction mass S:R 75:25)
* Abamectin
* Fipronil
* Imidacloprid
* Extrait de margousier
* Dinotéfurane
* Cyanure d'hydrogène
* Pyriproxyfène
* 1 R-trans phenothrine
* Perméthrine
* Transfluthrine
* Diflubenzuron
* Carbon dioxide
* Metofluthrin
* Spinosad

Among these products, 29 products are used against black ants by non professional users indoor and outdoor. They contain one of the following active subtances

* Etofenprox
* Deltamethrine
* Imidacloprid
* Spinosad
* Fipronil
* 1-R transphenothrin
* Permethrin
* Alpha-cyperméthrine
* Lambda-cyhalothrine

Theses substances have different mode of action and different receptors on nerve and muscle. Therefore, there is a sufficient chemical diversity to minimise the occurence of resistance in the target harmful organism(s).

|  |  |
| --- | --- |
| **ACTIVE SUBSTANCES** | **MODE OF ACTION** |
| Etofenprox, Deltamethrin, permethrin, 1-R transphenothrin, Alpha-cyperméthrine, Lambda-cyhalothrine | PYRETHROIDS, PYRETHRINS | Keep sodium channels open, causing hyperexcitation and, in some cases, nerve block. |
| Imidacloprid | NEONICOTINOIDS | Bind to the acetylcholine site on nAChRs, causing a range of symptoms from hyper-excitation to lethargy and paralysis |
| Fipronil  | PHENYLPYRAZOLES (FIPROLES)  | Block the GABA-activated chloride channel, causing hyperexcitation and convulsions. GABA is the major inhibitory neurotransmitter in insects.  |
| Spinosad | SPINOSYNS | Allosterically activate nAChRs, causing hyperexcitation of the nervous system. Acetylcholine is the major excitatory neurotransmitter in the insect central nervous system.  |

 **Consideration on whether the active substance(s) meet(s) at least one of the exclusion criteria listed in Article 5(1) but that benefit from derogation in accordance with Article 5(2) of the BPR.**

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

**Conclusion of the screening phase: Stop comparative assessment / Tier IA / Tier IB / Tier II**

As there is a priori sufficient chemical diversity, Tier 1A approach shall be performed.

#### Tier IA

3 products have been identified as appropriate alternative of ANTI-FOURMIS. They all contain the same active substance. Consequently there is no a sufficient diversity to avoid resistance of target organism.

#### Tier II

The active substance Spinosad contained in the product ANTI-FOURMIS was authorized under the Directive 98/8/EC. Consequently, no public consultation was carried out by ECHA to identify non-chemical alternatives.

To conclude, no information about non-chemical alternatives are available to FR CA and it is not possible to determine if a non-chemical alternative with a better profile for the human health, animal health or the environment than ANTI-FOURMIS is available.

#### Overall conclusion

In the technical guidance note on comparative assessment of biocidal products, it is stated that :

* a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection ;
* as a general rule, at least three different and independent “active substance/mode of action” combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

Considering that only few products containing the same active substance have been identified as potential alternatives FR CA concludes that there is not an adequate chemical diversity in line with Article 23(3)(b) and the technical guidance note on comparative assessment.

Since spinosad does not meet the exclusion criteria as outlined in Article 5(1), no further assessment is needed at this point.

**The product ANTI-FOURMIS can be authorised for a period not exceeding 5 years in accordance with Article 23(6) of BPR.**

# Annexes

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title.Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Julius, C. and Behlau, H. | 2005a | Acute Oral Toxicity COM 111 06 I RB.BioChem GmbH, Karlsruhe, GermanyReport No:04 10 42 820 AGLP:YesPublished:No | Yes | COMPO GmbH & Co. KG |
| Julius, C. and Behlau, H. | 2005b | Acute Dermal Toxicity COM 111 06 I RB.BioChem GmbH, Karlsruhe, GermanyReport No:04 10 42 820 BGLP:YesPublished:No | Yes | COMPO GmbH & Co. KG |
| Julius, C. and Behlau, H. | 2005c | Acute Dermal Irritation / Corrosion COM 111 06 I RB.BioChem GmbH, Karlsruhe, GermanyReport No:04 10 42 820 CGLP:YesPublished:No | Yes | COMPO GmbH & Co. KG |
| Julius, C. and Behlau, H. | 2005d | Acute Eye Irritation / Corrosion COM 111 06 I RB.BioChem GmbH, Karlsruhe, GermanyReport No:04 10 42 820 DGLP:YesPublished:No | Yes | COMPO GmbH & Co. KG |
| Julius, C. and Behlau, H. | 2005e | Skin Sensitisation Study according to Magnusson & Kligman – COM 111 06 I RB.BioChem GmbH, Karlsruhe, GermanyReport No:04 10 42 820 EGLP:YesPublished:No | Yes | COMPO GmbH & Co. KG |
| COMPO GmbH & Co. KG (Ed.) | 2012 | Material Safety Data Sheet COM 111 06 I RB.Date: 2012-09-19 | Yes | COMPO GmbH & Co. KG |
| Schieck, S. | 2008a | COM 111 06 I RB (bait box). Accelerated storage test.Date: 2008-08-14 | Yes | COMPO GmbH & Co. KG |
| Schieck, S. | 2008b | Accelerated storage test (tube). COM 111 06 I RB.Date: 2008-08-14 | Yes | COMPO GmbH & Co. KG |
| Schieck, S. | 2010a | 2 years storage stability testing (bait box) COM 111 06 I RB.Date: 2010-10-25 | Yes | COMPO GmbH & Co. KG |
| Schieck, S. | 2010b | 2 years storage stability testing (tube) COM 111 06 I RB.Date: 2010-10-25 | Yes | COMPO GmbH & Co. KG |
| Schieck, S. | 2012a | 4 years storage stability testing (bait box) COM 111 06 I RB.Date: 2012-09-12 | Yes | COMPO GmbH & Co. KG |
| Schieck, S. | 2012b | 4 years storage stability testing (tube) COM 111 06 I RB.Date: 2012-09-12 | Yes | COMPO GmbH & Co. KG |
| Grund, D. | 2020a | Determination of the Flash Point (EEC A.9.) of the test item COM 111 06 I RBReport 20-09324Henkel AG & Co. KGaA, Düsseldorf, Germany | Yes | COMPO GmbH & Co. KG |
| Grund, D. | 2020b | Determination of the Auto Ignition Temperature (Liquids and Gases) (EEC A.15.) of the test item COM 111 06 I RBReport 20-09324/2-2Henkel AG & Co. KGaA, Düsseldorf, Germany | Yes | COMPO GmbH & Co. KG |
| Grund, D. | 2020c | Determination of the Corrosive properties of the test item COM 111 06 I RBReport 20-09324/3-3Henkel AG & Co. KGaA, Düsseldorf, Germany | Yes | COMPO GmbH & Co. KG |
| Kruppa, C. | 2020 | Investigation Report - Penetration testReport 20-06962Henkel AG& Co. KGaA, HSA-Corporate Analytics | Yes | COMPO GmbH & Co. KG |
| Kirchhof, D. | 2020 | Investigation report - Differential Scanning CalorimetryReport 20-04497Henkel AG& Co. KGaA, HSA-Corporate Analytics | Yes | COMPO GmbH & Co. KG |

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. Please delete as appropriate. [↑](#footnote-ref-3)
3. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-4)
4. CEB n° 196 method : ”efficacy trials method for bait insecticide products intended to control ants” [↑](#footnote-ref-5)
5. H.P. Young, W.D. Bailey, R.M. Roe, T. Iwasa, T.C. Sparks, G.D. Thompson, G.B. Watson, Mechanism of resistance ans cross-resistance in a laboratory, spinosad-selected strain of tobacco budworm ans resistance in laboratory-selected cotton bollworms, in: Proceedings of the 2001 Beltwide Cotton Production Conference, National Cotton Council, Memphis TN, 2001, pp.1167-1171. [↑](#footnote-ref-6)
6. T. Shono, J.G. Scott, Spinosad resistance in th house fly, Musca domestica, is due to a recessive factor on autosome I, Pestic. Biochem. Physiol. 75 (2003) 1-7. [↑](#footnote-ref-7)
7. J.K. Moulton, D.A Pepper, T.J. Dennehy, Beet armyworm (Spodoptera exigua) resistance to spinosad, Pest Manag. Sci. 56 (2000) 842-848. [↑](#footnote-ref-8)
8. T.C. Sparks, J.E. Dripps, G.B. Watson, D. Paroonagian, Resistance and cross-resistance to the spinosyns – A review and analysis, Pestic. Biochem. Physiol. 102 (2012) 1-10. [↑](#footnote-ref-9)
9. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for spinosad according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(3):2630, 89 pp. doi:10.2903/j.efsa.2012.2630 [↑](#footnote-ref-10)
10. EFSA (European Food Safety Authority), Arena M, Auteri D, Barmaz S, Brancato A, Brocca D, Bura L, Carrasco Cabrera L, Chiusolo A, Court Marques D, Crivellente F, De Lentdecker C, Egsmose M, Fait G, Ferreira L, Goumenou M, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Magrans JO, Medina P, Miron I, Molnar T, Nougadere A, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Serafimova R, Sharp R, Stanek A, Streissl F, Sturma J, Szentes C, Tarazona J, Terron A, Theobald A, Vagenende B and Villamar-Bouza L, 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance spinosad. EFSA Journal 2018;16(5):5252, 33 pp. https://doi.org/10.2903/j.efsa.2018.5252 [↑](#footnote-ref-11)
11. OECD Series on Emission Scenario Documents, Number 18, Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses, 17 July 2008 [↑](#footnote-ref-12)