# Product Assessment Report

# Elector

12 April 2013

| | |
|---|---|
| Internal registration/file no: | 20110974 THB |
| Authorisation/Registration no: | 13380 |
| Granting date/entry into force of authorisation/ registration: | 8 March 2013 |
| Expiry date of authorisation/ registration: | 1 November 2022 |
| Active ingredient: | spinosad |
| Product type: | PT18 |

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Biocidal product assessment report related to product authorisation under Directive 98/8/EC

# Contents

# 1 General information about the product application

## 1.1 Applicant

| | |
|---|---|
| **Company Name:** | Eli Lilly Benelux NV/SA |
| **Address:** | Markiesstraat 1 |
| **City:** | Brussels |
| **Postal Code:** | 1000 |
| **Country:** | Belgium |
| **Telephone:** | +32 473 983 502 |
| **Fax:** | +32 14 611 721 |
| **E-mail address:** | Soenen_bert@elanco.com |

### 1.1.1 Person authorised for communication on behalf of the applicant

| | |
|---|---|
| **Name:** | Bert Soenen |
| **Function:** | Regulatory Manager |
| **Address:** | Antwerpsesteenweg 51 bus 1 |
| **City:** | Vosselaar |
| **Postal Code:** | 2350 |
| **Country:** | Belgium |
| **Telephone:** | +32 473 983 502 |
| **Fax:** | +32 14 611 721 |
| **E-mail address:** | soenen_bert@elanco.com |

## 1.2 Current authorisation holder

| | |
|---|---|
| **Company Name:** | Eli Lilly Benelux NV/SA |
| **Address:** | Markiesstraat 1 |
| **City:** | Brussels |
| **Postal Code:** | 1000 |
| **Country:** | Belgium |
| **Telephone:** | +32 473 983 502 |
| **Fax:** | +32 14 611 721 |
| **E-mail address:** | soenen_bert@elanco.com |
| **Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):** | Not applicable |

## 1.3 Proposed authorisation holder

| | |
|---|---|
| **Company Name:** | Eli Lilly Benelux NV/SA |
| **Address:** | Markiesstraat 1 |
| **City:** | Brussels |
| **Postal Code:** | 1000 |
| **Country:** | Belgium |
| **Telephone:** | +32 473 983 502 |
| **Fax:** | +32 14 611 721 |
| **E-mail address:** | soenen_bert@elanco.com |
| **Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):** | Not applicable |

## 1.4 Information about the product application

| | |
|---|---|
| **Application received:** | 7th of November 2011 |
| **Application reported complete:** | 3rd of October 2012 |
| **Type of application:** | Reregistration |
| **Further information:** | Applicant has indicated to submit an application for mutual recognition in AT, BE, CH, CZ, DE, DK, ES, FI, FR, HU, IE, IT, PL, PT, SE, SK and UK. |

## 1.5 Information about the biocidal product

### 1.5.1 General information

| | |
|---|---|
| **Trade name:** | Elector |
| **Manufacturer's development code number(s), if appropriate:** | Not allocated |
| **Product type:** | 18 |
| **Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):** | Spinosad 480 g/L |
| **Formulation type:** | SC |
| **Ready to use product (yes/no):** | No |
| **Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC** | No |

| | |
|---|---|
| **(yes/no);<br>If yes: authorisation/registration no. and product name:<br>or<br>Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):** | |

### 1.5.2 Information on the intended uses

| | |
|---|---|
| **Overall use pattern (manner and area of use):** | Control of flies, beetles (lesser mealworm) and red poultry mites in animal production facilities including intensive poultry/pig/cattle housing.<br>For non-professional use the product is used mainly for treatment against poultry red mites in hobby aviaries for domestic birds or small-scale chicken houses owned by non-professionals. |
| **Target organisms:** | *Dermanyssus gallinae* (poultry red mite)<br>*Musca domestica* (house fly)<br>*Stomoxys calcitrans* (stable fly)<br>*Alphitobius diaperinus* (darkling beetle / lesser mealworm ) |
| **Category of users:** | Both professional and non-professional use. |
| **Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:** | General use:<br>The product is an SC formulation containing 44.2% (w/w) a.s. which is diluted before use.<br><br>Dose:<br>poultry red mite:<br>30 ml product in 3.5-7 litres water (equivalent to 0.2-0.4% spinosad) to spray 250 $m^2$, sprayed onto cages and cracks.<br><br>house fly / stable fly<br>30 ml product in 18-36 litres water (equivalent to 0.04-0.08% spinosad) to spray 500 $m^2$, sprayed onto flies and the resting areas of the flies<br><br>darkling beetle/mealworm<br>30 ml product in 9-18 litres water (equivalent to 0.08-0.16% spinosad) to spray 250 $m^2$, sprayed onto cracks and around feeders<br><br>Application:<br>The diluted product is applied as coarse, low-pressure spray or a low volume high pressure spray. |
| **Potential for release into the** | Yes |

| | |
|---|---|
| **environment (yes/no):** | |
| **Potential for contamination of food/feedingstuff (yes/no)** | Yes |
| **Proposed Label:** | Translation of the Dutch labels, see below table |
| **Use Restrictions:** | Do not apply as fog, do not apply directly onto livestock |

**<u>Labels</u>**
As additional information on the intended use the translated Dutch legal instructions for use are presented below:

**Professional use:**

A.
<u>LEGAL INSTRUCTIONS FOR USE</u>

This product can only be used for the control of house flies, stable flies, lesser mealworm and poultry red mite in animal production facilities including intensive poultry/pig/cattle housing.

To protect soil and water living organisms, residues (such as dirt and waste water containing the product) need to be removed to the manure deposit.

The dose and control frequency as stated in the directions for use (B) should be sustained.

This product is intended for professional  use.

B.
<u>DIRECTIONS FOR USE</u>

**General use:** Elector can be used after dilution of the product in water by spraying surfaces. The diluted product can be used as a surface treatment or by application to cracks and around feeders.

**House  and stable flies:** treat the resting areas of the flies, spray carefully the side-walls, locations at the extremities of the building, the upper parts of door styles and beams, but avoid run-off. Apply in the early morning when the flies are resting. Avoid spraying food, feed and drinking water.

**Lesser mealworm or darkling beetle**: treat the floor, in particular areas around and under feeders and under drinking facilities, walls and beams, but avoid run-off. Also treat cracks in insulation material and places where beetles or their larvae are spotted or expected to be present. Avoid spraying food, feed and drinking water.

**Poultry red mite:** Treat the hiding locations of the mites, such as cages, cracks and crevises, but avoid run-off. Do not apply directly onto livestock and avoid spraying food, feed and drinking water.

**<u>Dosage</u>:**

Mix the indicated volume of Elector in the table in the indicated volume of water. The volume is sufficient to treat the indicated surface.

| | Darkling beetle/mealworm | Stable fly | House fly | Poultry red mite |
|---|---|---|---|---|
| **Elector** | 30 ml | 30 ml | 30 ml | 30 ml |
| **Water*** | 9 – 18 lt | 18 – 36 lt | 18 – 36 lt | 3.5 – 7 lt |
| **Area** | 250 $m^2$ | 500 $m^2$ | 500$m^2$ | ** |

*The amount of water to be used depends on the infection pressure. Use less water at high infection levels to get higher concentrations of the product.
** not relevant when cages, cracks or fisures are treated, avoid run-off.

**Resistence management**
To avoid development of resistance do not use the product more that 5 times per year and do not use a dosages lower than advised. If sequential treatments are required it is recommended to use a product with a different active ingredient and if necessary a different control method.

**Restrictions:**
- Do not apply directly onto livestock. Animals are allowed to stay in the stable during application
- avoid run-off.
- avoid contamination of food, feed and drinking water
- do not apply as fog
- do not mix with other products in the spraying equipment

**Non-professional use:**

A.
LEGAL INSTRUCTIONS FOR USE

This product can only be used for the control of house flies, stable flies, lesser mealworm and poultry red mite in animal production facilities including intensive poultry/pig/cattle housing.

The dose and control frequency as stated in the directions for use (B) should be sustained.

This product is intended for non-professional use.

B.
DIRECTIONS FOR USE

**General use:** Elector can be used after dilution of the product in water by spraying surfaces. The diluted product can be used as a surface treatment or by application to cracks and around feeders.

**House and stable flies:** treat the resting areas of the flies, spray carefully the side-walls, locations at the extremities of the building, the upper parts of door styles and beams, but avoid run-off. Apply in the early morning when the flies are resting. Avoid spraying food, feed and drinking water.

**Lesser mealworm or darkling beetle**: treat the floor, in particular areas around and under feeders and under drinking facilities, walls and beams, but avoid run-off. Also treat cracks in insulation material and places where beetles or their larvae are spotted or expected to be present. Avoid spraying food, feed and drinking water.

**Poultry red mite:** Treat the hiding locations of the mites, such as cages, cracks and crevises, but avoid run-off. Do not apply directly onto livestock and avoid spraying food, feed and drinking water.

**Dosage:**
Mix the indicated volume of Elector in the table in the indicated volume of water. The volume is sufficient to treat the indicated surface.

| | Darkling beetle/mealworm | Stable fly | House fly | Poultry red mite |
|---|---|---|---|---|
| **Elector** | 30 ml | 30 ml | 30 ml | 30 ml |
| **Water*** | 9 – 18 lt | 18 – 36 lt | 18 – 36 lt | 3.5 – 7 lt |
| **Area** | 250 $m^2$ | 500 $m^2$ | 500$m^2$ | ** |

*The amount of water to be used depends on the infection pressure. Use less water at high infection levels to get higher concentrations of the product.
** not relevant when cages, cracks or fisures are treated, avoid run-off.

**Resistence management**
To avoid development of resistance do not use the product more that 5 times per year and do not use a dosages lower than advised. If sequential treatments are required it is recommended to use a product with a different active ingredient and if necessary a different control method.

**Restrictions:**
- Do not apply directly onto livestock. Animals are allowed to stay in the stable during application
- avoid run-off.
- avoid contamination of food, feed and drinking water
- do not apply as fog
- do not mix with other products in the spraying equipment

### 1.5.3 Information on active substance(s)

| | |
|---|---|
| **Active substance chemical name:** | Spinosad is a mixture of 50-95% spinosyn A and 5-50% spinosyn D |

| | | |
|---|---|---|
| | **Spinosyn A**: (2*R*,3a*S*,5a*R*,5b*S*, 9*S*,13*S*,14*R*,16a*S*, 16b*R*)-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,6,7,9,10, 11,12,13,14,15,16a, 16b-hexadecahydro-14-methyl-1H-8-oxacyclododeca[b]as-indacene-7,15-dione<br>[IUPAC name] | **Spinosyn D:** (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-[(6-deoxy-2,3,4- tri-O-methyl-α-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14- dimethyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione<br>[IUPAC name] |
| **CAS No:** | 131929-60-7 | 131929-63-0 |
| | Spinosad: 168316-95-8 | |
| **EC No:** | None | None |
| | Spinosad: 434-300-1 (mixture of spinosyn A and D) | |
| **Purity (minimum, g/kg or g/l):** | Minimum 85%, with 50-95% spinosyn A and 5-50% spinosyn D | |
| **Inclusion directive:** | 2010/72/EU (Annex I of 98/8/EG for PT18) | |
| **Date of inclusion:** | 1 November 2012 | |
| **Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):** | Yes | |
| **CONFIDENTIAL: this information should not be disclosed to third parties** | | |
| **Manufacturer of active substance(s) used in the biocidal product:** | | |
| **Company Name:** | DOW AgroSciences | |
| **Address:** | 305 North Huron Avenue | |
| **City:** | Michigan | |
| **Postal Code:** | MI 48441 | |
| **Country:** | USA | |
| **Telephone:** | + 1 517-479-5233 | |
| **Fax:** | + 1 517-479-9410 | |
| **E-mail address:** | Not available | |

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

No substances of concern are present in the active substance/formulation.

## 1.6 Documentation

### 1.6.1 Data submitted in relation to product application

New studies concerning the product Elector have been submitted with respect to physical-chemical properties of the product, analytical methods, toxicity and efficacy. The studies are listed in Annex 2.

### 1.6.2 Access to documentation

A letter of access was provided by Dow Agro Sciences for the data submitted in support of the crop protection product TRACER and the spinosad active substance data submitted in support of the biocide SPY. These data comprise the data underlying Annex I inclusion (spinosad CAR).

# 2 Summary of the product assessment

## 2.1 Identity related issues

| | | | | |
|---|---|---|---|---|
| Trade name | Elector | | | |
| Active ingredient | Purity (%w/w) | CAS No. | EC No. | Content (g/L) |
| Spinosad | > 85.0% w/w | 168316-95-8 | 434-300-1 | 480 (pure active) (44.2 %) |

Remark: Spinosad is a mixture of 50-95% spinosyn A and 5-50% spinosyn D

No substance of concern is present in Elector.

## 2.2 Classification, labelling and packaging

### 2.2.1 Harmonised classification and labelling of the biocidal product

#### 2.2.1.1 Proposal for the classification and labelling of the formulation concerning physical chemical properties

Proposed classification based on Directive 1999/45/EC:
Classification and labeling of the formulation concerning physical chemical properties is not required.

Proposed classification based on Regulation EC 1272/2008

Classification and labeling of the formulation concerning physical chemical properties is not required.

Supported shelf life of the formulation: three years in HDPE or PET

#### 2.2.1.2 Proposal for the classification and labelling of the formulation concerning human toxicology properties

Proposed classification based on Directive 1999/45/EC:

Professional use

| Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances): | | | |
|---|---|---|---|
| - | | | |
| Symbol: | - | Indication of danger: | - |
| R phrases | - | - | |
| S phrases | S36/37 | Wear suitable protective clothing and gloves | |
| | S42 | During fumigation/spraying wear suitable respiratory equipment (appropriate wording to | |

| | | | |
|---|---|---|---|
| | | be specified by the manufacturer) | |
| Special provisions: | - | - | |
| DPD-phrases | | | |
| Child-resistant fastening obligatory? | | | Not applicable |
| Tactile warning of danger obligatory? | | | Not applicable |

| Explanation: | |
|---|---|
| Hazard symbol: | - |
| Risk phrases: | - |
| Safety phrases: | S2 and S13 are not indicated, as no risk phrases are assigned. S36/37 and S42 are assigned based on the risk assessment for professional users. |
| Other: | - |

Non-professional use

| Substances, present in the formulation, which should be mentioned on the label by their chemical name (other very toxic, toxic, corrosive or harmful substances): | | | |
|---|---|---|---|
| - | | | |
| Symbol: | - | Indication of danger: | - |
| R phrases | - | - | |
| S phrases | - | - | |
| Special provisions: | - | - | |
| DPD-phrases | | | |
| Child-resistant fastening obligatory? | | | No |
| Tactile warning of danger obligatory? | | | No |

| Explanation: | |
|---|---|
| Hazard symbol: | - |
| Risk phrases: | - |
| Safety phrases: | S2 and S13 are not indicated, as no risk phrases are assigned. |
| Other: | - |

Proposed classification based on Regulation EC 1272/2008

Professional use

| **Signal word:** | - | | |
|---|---|---|---|
| **Pictogram:** | - | | |
| | **Hazard class-and-Category** | **Code** | **Hazard statement** |
| **Hazard statements:** | - | - | - |
| **Precautionary statements:** | | P280c | Wear protective gloves/protective clothing |
| | | P284 | Wear respiratory protection |

| Explanation: | |
|---|---|
| Pictogram: | - |
| H-statements: | - |
| P-statements: | P280c and P284 are assigned based on the risk assessment for professional users |

Non-professional use

| | | | |
|---|---|---|---|
| **Signal word:** | - | | |
| **Pictogram:** | - | | |
| | **Hazard class-and-Category** | **Code** | **Hazard statement** |
| **Hazard statements:** | - | - | - |
| **Precautionary statements:** | - | - | - |

| | |
|---|---|
| Explanation: | |
| Pictogram: | - |
| H-statements: | - |
| P-statements: | - |

**2.2.1.3 Proposal for the classification and labelling of the formulation concerning environmental properties**

Proposed classification based on Directive 1999/45/EC:

Professional use
Based on the profile of the substance, the provided toxicology of the preparation and the characteristics of the co-formulants, the following labeling of the preparation is proposed:

| | | | |
|---|---|---|---|
| Symbol: | N | Indication of danger: | Dangerous for the environment |
| R phrases | R50/53 | Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. | |
| S phrases | S60 | This material and its container must be disposed of as hazardous waste. | |
| | S61 | Avoid release to the environment. Refer to special instructions/safety data sheets. | |
| Special provisions (DPD-phrases) : | - | - | |

| | |
|---|---|
| Explanation: | |
| Hazard symbol: | Classification based on toxicity of the active substance and the triggers laid down in the Dangerous Preparation Directive 1999/45/EC and Directive 2008/6/EC |
| Risk phrases: | Classification based on toxicity of the active substance and the triggers laid down in the Dangerous Preparation Directive 1999/45/EC and Directive 2008/6/EC |
| Safety phrases: | S60 and S61 are assigned to biocidal products for professional use with N, R50/53 |
| Other: | - |

Non-professional use

Based on the profile of the substance, the provided toxicology of the preparation and the characteristics of the co-formulants, the following labeling of the preparation is proposed:

| | | | |
|---|---|---|---|
| Symbol: | N | Indication of danger: | Dangerous for the environment |

| | | |
|---|---|---|
| R phrases | R50/53 | Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. |
| S phrases<br>Special provisions (DPD-phrases) : | S29<br>- | Do not empty into drains.<br>- |

| Explanation: | |
|---|---|
| Hazard symbol: | Classification based on toxicity of the active substance and the triggers laid down in the Dangerous Preparation Directive 1999/45/EC and Directive 2008/6/EC |
| Risk phrases: | Classification based on toxicity of the active substance and the triggers laid down in the Dangerous Preparation Directive 1999/45/EC and Directive 2008/6/EC |
| Safety phrases: | S29 is assigned to biocidal products for non-professional use with N, R50/53 |

Proposed classification based on Regulation EC 1272/2008

Professional and non-professional use

| **Signal word:** | Warning | | |
|---|---|---|---|
| **Pictogram:** | GHS09 | | |
| | **Hazard class-and-Category** | **Code** | **Hazard statement** |
| **Hazard statements:** | Aquatic acute 1<br>Aquatic chronic 1 | H400<br>H410 | Very toxic to aquatic life<br>Very toxic to aquatic life with long lasting effects |
| **Precautionary statements:** | | P273<br>P391<br>P501 | Avoid release to the environment.<br>Collect spillage.<br>Dispose of contents/container ... (in accordance with local/regional/ national/international regulation (to be specified)). |

### 2.2.2 Packaging of the biocidal product

**Professional and non-professional use**

| | |
|---|---|
| **Material:** | HDPE |
| **Capacity:** | 237 mL and 1000 mL |
| **Type of closure and size of opening:** | Screw cap closure, opening: 15.6 mm (237 mL), 56.8 mm (1000 mL) |
| **Other information** | - |

## 2.3 Physico/chemical properties and analytical methods

The applicant has access to the Annex I dossier. The physico/chemical properties for the active substance spinosad are detailed in the Annex I dossier, Doc IIIA, Section 3.

The methods for the active substance spinosad, the impurities and the spinosyn ratios of the active substance in the technical active substance are detailed in the Annex I dossier, Doc IIIA, Section 4.1.

### 2.3.1 Physico-chemical properties

**Physico-chemical properties of the biocidal product**:

| | Method | Purity/Specification | Results | Reference |
|---|---|---|---|---|
| Physical state and nature | GLP<br>Visual inspection | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Liquid, mobile suspension | McGrath, 1997a |
| Colour | GLP<br>Visual inspection | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Beige | McGrath, 1997a |
| Odour | Not investigated | | | |
| Explosive properties | GLP<br>EC method A.14 | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | The biocidal product does not present explosive properties. | McGrath, 1997b |
| Oxidizing properties | | | Statement:<br>The biocidal product does not present oxidising properties. | |
| Flash point | GLP<br>EC method A.9<br>(closed cup) | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Non-flammable; no flash point observed before test material boiled at approximately 100 °C. | McGrath, 1997b |
| Autoflammability | GLP<br>EC method A.15 | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | None below 400 °C.<br>An evolution of flammable gases can be excluded when the biocidal product comes in contact with water. | McGrath, 1997b |
| Other indications of flammability | - | - | - | - |
| Acidity / Alkalinity | GLP<br>CIPAC Method MT 75.1 | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | pH value of the neat formulation: 7.52<br>The determination of the acidity or alkalinity, respectively, does not need to be performed because the pH-value of the formulation is between 4 and 10. | McGrath, 1997a |
| | GLP<br>CIPAC Method MT 75.2 | | pH value of a 1% dilution of the formulation:<br>Before storage at 54 °C for 14 days: | |

| | Method | Purity/Specification | Results | Reference |
|---|---|---|---|---|
| | | | pH = 7.39<br>After storage at 54 °C for 14 days: pH = 7.38 | |
| Relative density / bulk density | GLP Internal method EU-AM-91-33 using a Paar densitometer | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Results at 20 °C:<br>Before storage at 54 °C for 14 days: 1.097<br>After storage at 54 °C for 14 days: 1.096 | McGrath, 1997a |
| Storage stability – stability and shelf life | | | | |
| Accelerated storage stability | GLP<br>CIPAC Method MT 46.1 | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | The formulation is stable at 54 °C for 14 days. No significant changes of physico-chemical properties were observed.<br>Spinosad content (Spinosyn A + D) before storage: 476 g/L<br>Spinosad content (Spinosyn A + D) after storage at 54 °C for 14 days: 480 g/L.<br>The appearance, pH, density, suspensibilty, wet sieve, viscosity as well as particle size were measured before and after storage. Results for these tests were considered acceptable. | McGrath, 1997a |
| Low temperature stability | GLP<br>CIPAC MT 39.2 | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | The formulation is stable at 0 °C for 2 days. No significant changes were observed. | McGrath, 1997a |
| Long-term storage stability, shelf life | GLP<br>Storage of the biocidal product for two years at ambient temperature.<br>OPPTS 830.6317 OPPTS | NAF-85, 43 % spinosad, commercial lot 01229701 (TSN101374) | The formulation is stable at ambient temperature for 24 months in commercial packaging (HDPE and PET bottles). No significant changes of physico-chemical properties | Krause, 1999 |

| | Method | Purity/Specification | Results | Reference |
|---|---|---|---|---|
| | 830.6320 GIFAP Monograph No. 17 | | (density, pH, particle size, foaming, wet sieve, viscosity, pourabiliy) and packaging material occurred during the test.<br>The spinosad content showed 99% or better retention after storage of the formulation in PET bottles. After the same storage of the formulation in HDPE bottles spinosad retention was 95% or better. | |
| | Re-assay of retained samples of the biocidal product stored for three to four years in an ambient warehouse. | GF-976, 480 g spinosad/L nominal content | No loss of activity was measured after four years storage of the formulation in HDPE containers in an ambient warehouse. The spinosad content is not changing with time. No other phys. chem. properties were evaluated. | Boucher, 2006 |
| Effects of temperature | See above, no effects observed in storage stability studies | | | |
| Effects of light | Not investigated | | | |
| Reactivity towards container material | See above, no reactivity observed in storage stability studies | | | |
| | GLP<br>Three year storage at ambient temperature.<br>CIPAC MT 75.3, MT 47.2, MT 59.3, MT 161, MT 160, MT 148, visual inspection and HPLC-UV | GF-976, TSN014788-0074, Lot no. UF29164911, purity: 43.5% wt/wt spinosad | The formulation is stable at ambient temperature for three years in commercial packaging (HDPE and PET bottles). Spinosad contents after 3 years of storage were 100-104%. The properties pH, persistent foaming, wet sieve, suspensibility, spontaneity of dispersion, pourability and appearance were evaluated. It was concluded that these did not | Stock, 2012 |

| | Method | Purity/Specification | Results | Reference |
|---|---|---|---|---|
| | | | significantly deviate from the time zero analyses. | |
| Effects of temperature | Not investigated | | | |
| Effects of light | Not investigated | | | |
| Reactivity towards container material | No reactivity towards PET and HDPE. | | | |
| Technical characteristics in dependence of the formulation type | | | | |
| Suspensibility | GLP<br>CIPAC MT 161 | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Results for spinosad factor A:<br>Before storage at 54 ℃ for 14 days: 98.7%<br>After storage at 54 ℃ for 14 days: 98.5%<br>Results for spinosad factor D:<br>Before storage at 54 ℃ for 14 days: 98.5%<br>After storage at 54 ℃ for 14 days: 98.3% | McGrath, 1997a |
| Wet sieve | GLP<br>CIPAC MT 59.3 | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Before storage at 54 ℃ for 14 days: 0.0295% retained on 75 µm sieve<br>After storage at 54 ℃ for 14 days: 0.0279% retained on 75 µm sieve | McGrath, 1997a |
| Persistent foam | GLP<br>CIPAC MT 47.2 | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Volume of foam:<br>Initial:10 mL<br>10 sec: 0 mL<br>1 min: 0 mL<br>3 min: 0 mL<br>12 min: 0 mL | McGrath, 1997a |
| Pourability / Rinsability | GLP<br>CIPAC MT 148 | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Residue:2.25%<br>Rinsed residue:0.11% | McGrath, 1997a |
| Spontaneity | GLP<br>CIPAC MT 160 | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Spinosyn A:98.7<br>Spinosyn D:99.0 | McGrath, 1997a |
| Dilution stability | GLP<br>Internal method PA-AM-96-4 (chemical assay) | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Chemical loss at maximum application rate:<br>SpinosynA:none<br>SpinosynD:none<br>Chemical loss at minimum application rate:<br>Spinosyn A: | McGrath, 1997a |

| | Method | Purity/Specification | Results | Reference |
|---|---|---|---|---|
| | | | 1.32%<br>Spinosyn D:none | |
| Compability with other products | Not applicable because the biocidal product will not be used with other products including other biocidal products. | | | |
| Surface tension | GLP<br>EC method A.5 (ring method) | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Results at 20 ℃:<br>30.5 mN/m (2% v/v suspension)<br>43.0 mN/m (0.05% v/v suspension) | McGrath, 1997b |
| Viscosity | GLP<br>Internal method EU-AM-93-02 using a Haake VT181 viscometer | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Results at 20 ℃ and a shear rate of 106 $s^{-1}$:<br>Before and after storage at 54 ℃ for 14 days: 134.6 mPa*s | McGrath, 1997a |
| Particle size distribution | GLP<br>Internal method EU-AM-93-3 using a Malvern Mastersizer | NAF-85, 480 g spinosad/L nominal content, batch reference 01079701 | Particle size results for D(v, 0.5):<br>Before storage at 54 ℃ for 14 days: 4.06<br>After storage at 54 ℃ for 14 days: 4.05<br>Particle size results for D(v, 0.9):<br>Before storage at 54 ℃ for 14 days: 12.58<br>After storage at 54 ℃ for 14 days: 12.50 | McGrath, 1997a |

### 2.3.2 Analytical methods

| | Principle of method |
|---|---|
| Technical active substance as manufactured: | Two valid HPLC-UV methods. |
| Impurities in technical active substance: | Valid methods are available for analysis of the significant (> 1 g/kg) impurities in the technical material. |
| active substance in the formulation: | CIPAC method 636/SC/(M)<br>An aliquot of the biocidal product is dissolved in methanol/water and afterwards the spinosad content is determined by HPLC-UV (250 nm). Quantification is by external standardisation |

## 2.4 Risk assessment for Physico-chemical properties

No new data/information on physico-chemical properties has been submitted for the product or for the active substances that provides additional data for the risk assessment.

# 2.5 Effectiveness against target organisms

### 2.5.1 Function
Elector is an insecticide (PT18) based on spinosad (480 g/L, 44.2% w/w). The product is intended for professional and non-professional use.

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

The proposed field of use of Elector is the control of:
- *Musca domestica* (house fly)
- *Stomoxys calcitrans* (stable flies)
- *Alphitobius diaperinus (*darkling beetle / lesser mealworm)
- *Dermanyssus gallinae* (poultry red mite)

Elector is applied in animal production facilities including intensive poultry, pig or cattle housing.

Elector may also be used by non-professionals, mainly for treatment against bird mites in hobby aviaries for domestic birds or small-scale chicken houses owned by non-professionals.

These uses are included in PT18.

### 2.5.3 Effects on target organisms
Elector differs from the product described in the CAR of Spinosad, since the product of the CAR is a granular solid, whereas Elector is a suspension concentrate formulation (SC formulation), therefore new studies are provided (see annex 2). Not all studies presented here are performed with Elector but with similar suspension concentrate formulations. These studies were accepted for the following reasons. A statement on the composition of the tested items in the efficacy studies was provided by the applicant. The active substance concentration tested in all studies was in agreement with the recommended concentrations given on the label. Since the product is not a ready to use product the effect of the co-formulants is little: in in-use situation the concentration of the co-formulants is 0.13% to 0.013%. Therefore, the effect of the co-formulants will be expected not to make a significant difference in the results of the tests.

The results of the efficacy studies are summarised in the text below and in tables 1 to 8. They are summarized and discussed per label claim. Full details of the studies can be found in Annex 9.

The species to be controlled are:
- *Stomoxys calcitrans* (stable flies)
- *Musca domestica* (house fly)
- *Alphitobius diaperinus* (darkling beetle / lesser mealworm)
- *Dermanyssus gallinae* (poultry red mite)

**Stable fly (*Stomoxys calcitrans*)**
The efficacy of spinosad for the control of *Stomoxys calcitrans* is demonstrated in 5 studies that are summarized below. More details on the studies can be found in Annex 9.

A laboratory test was conducted with stable flies of the species *Stomoxys calcitrans*. The flies were released in a fly container construction which was attached to one-foot squares of painted, non-pressure treated wood. Ten mixed sex adults of stable flies were placed in each fly container on day 0, day 7, day 14 and day 21. The number of dead, moribund, and live flies was recorded after 72 hours exposure. Each test was done in four replicates at 22-24 °C. Spinosad 25 g/L SC was tested at a dose rate of 805.9 ppm spinosad (claim Elector 400-800 ppm) and compared to a reference product (Atroban 11% EC, permethrin 11%) and untreated control. Results of the test are shown in table 1.

**Table 1:** Percent efficacy of Spinosad 25 g/L SC and Atroban 11% and the mean number of living flies in control treatment, 72 hours after fly release on painted, non-pressure treated wood.

| **Treatment*** | **Day 3** | **Day 10** | **Day 17** | **Day 24** |
|---|---|---|---|---|
| Control | 8.3 | 7.9 | 7.6 | 8.5 |
| Spinosad 805.9 ppm | 97.0% | 98.4% | 78.7% | 30.1% |
| Atroban 11% EC | 100% | 100% | 73.0% | 69.1% |

*: flies were released onto the wood on day 3, 10, 17 and 24 after treatment of the wood.

A second laboratory test was conducted with stable flies of the species *Stomoxys calcitrans*. The flies were released in a fly container construction which was attached to one-foot squares of non-painted concrete blocks. Ten mixed sex adults of stable flies were placed in each fly container on day 0, day 7, day 14 and day 21. The number of dead, moribund, and live flies was recorded after 72 hours exposure. Each test was done in four replicates at 19-30℃. Spinosad 25 g/L SC was teste d at a dose rate of 805.9 ppm spinosad (claim Elector 400-800 ppm) and compared to a reference product (Atroban 11% EC, permethrin) and untreated control. Results of the test are shown in table 2.

**Table 2:** Percent efficacy of Spinosad 25 g/L SC and Atroban 11% and the mean number of living flies in control treatment, 72 hours after fly release on non-painted concrete blocks.

| **Treatment*** | **Day 3** | **Day 10** | **Day 18** | **Day 25** | **Day 31** |
|---|---|---|---|---|---|
| Control | 8.6 | 8.6 | 9.3 | 7.8 | 7.7 |
| Spinosad 805.9 ppm | 99.3% | 99.3% | 100% | 98.4% | 93.5% |
| Atroban 11.0% EC | 100% | 97.8% | 83.3% | 87.9% | 83.7% |

*: flies were released onto the concrete on day 3, 10, 18, 25 and 31 after treatment of the concrete.

A third laboratory test was conducted with stable flies of the species *Stomoxys calcitrans*. The flies were released in a fly container construction which was attached to one-foot squares of painted concrete blocks. Ten mixed sex adults of stable flies were placed in each fly container on day 0, day 7 and day 14. The number of dead, moribund, and live flies was recorded after 72 hours exposure. Each test was done in four replicates at 21-25°C. Spinosad 25 g/L SC was tested at a dose rate of 805.9 ppm spinosad (claim Elector 400-800 ppm) and compared to a reference product (Atroban 11% EC, permethrin) and untreated control. Results of the test are shown in table 3.

**Table 3:** Percent efficacy of Spinosad 25 g/L SC and Atroban 11% and the mean number of living flies in control treatment, 72 hours after fly release on painted concrete blocks.

| **Treatment*** | **Day 3** | **Day 10** | **Day 17** |
|---|---|---|---|
| Control | 9.1 | 7.5 | 8.0 |
| Spinosad 805.9 ppm | 65.9% | 64.0% | 61.3% |
| Atroban 11.0% EC | 91.2% | 64.0% | 53.8% |

*: flies were released onto the concrete on day 3, 10 and 17 after treatment of the concrete.

A fourth laboratory test was carried out with stable flies of the species *Stomoxys calcitrans*. The flies were released in a fly box construction with the bottom site left open for the addition of the sprayed plywood cutouts. After the sprayed cutouts dried, three cutouts were placed vertically to three sides of each fly box. Thirty adults of stable flies were placed in each fly box on day 0, day 6 and day 13. The number of dead, moribund, and live flies was recorded after 1, 2, 7, 8, 14 and 15 days exposure. Each test was done in four replicates at 23℃. Spinosad 25 g/L SC was tested a t a dose rate of 800 ppm spinosad (claim Elector 400-800 ppm) and compared to two reference products (Rabon 50WP; tetrachlorvinphos and Atroban 42.5% EC; permethrin) and untreated control. Results of the test are shown in table 4.

**Table 4:** Percent efficacy of Spinosad 25 g/L SC, Rabon 50 WP and Atroban 42.5% and the mean number of dead flies in control treatment, 48 hours after fly release on sprayed plywood cutouts

| **Treatment*** | **Day 2** | **Day 8** | **Day 15** |
|---|---|---|---|
| Control | 3.5 | 3.5 | 4.0 |
| Spinosad 800 ppm | 75.0% | 47.5% | 49.2% |
| Rabon 50 WP | 85.0% | 92.5% | 93.3% |
| Atroban 42.50% EC | 88.3% | 94.2% | 92.5% |

*: flies were released onto the wood on day 2, 8 and 15 after treatment of the wood.

One semi field test was carried out. The trial was conducted with stable flies of the species *Stomoxys calcitrans*. Four separate and isolated rooms with screened entryways were used for this study. Each room was approximately 3 by 5 by 2.6 meters. Three walls and the ceiling were painted with high gloss paint. One wall was not painted. All four walls and the ceilings were sprayed, floors were not sprayed. Three rooms were sprayed with spinosad 25 g/L SC and one room was sprayed with tapped water (negative control). One hundred flies were released per room twice (zero and seven days after treatment). The number of dead or live flies was recorded 24 hours after fly release. Spinosad 25 g/L SC was tested at a dose rate of 400 and 800 ppm spinosad (claim Elector 400-800 ppm) and compared to an untreated control. Results of the test are shown in table 5.

**Table 5:** Percent efficacy after 24-hour fly exposure in rooms treated with 400 or 800 ppm spinosad and the mean number of dead flies in negative control

| **Treatment** | **Day 1** | **Day 8** |
|---|---|---|
| Control | 5.5 | 6.5 |
| Spinosad 400 ppm | 92.4% | 91.5% |
| Spinosad 800 ppm | 94.1% | 87.0% |

**Summary stable fly**
The laboratory tests with 800ppm spinosad show 65 to 99% mortality after 3 days and significant reduction in flies for a longer period (up to 1 month). Normally ≥90% mortality in 24 hours is required in laboratory tests (TNsG on product evaluation). It is to be expected that ≥90% mortality in 24 hours was reached in these tests. The semi field test with 400 and 800ppm spinosad shows ≥90% mortality in 24 hours. Normally a reduction in the amount of flies according to the claim (or compared to the control situation) is required in a field test (TNsG on product evaluation).
These tests show sufficient efficacy of a SC formulation with 400 to 800 ppm spinosad against stable flies.

**House fly (*Musca domestica*)**

Two field trials were conducted to evaluate the efficacy of spinosad against house flies, when applied as a poultry premise spray when no animals or eggs were present. These studies are summarized below. More details on the studies can be found in Annex 9.

In each test four buildings (caged layer houses) were treated either with water (negative control), spinosad at a dose rate of 800 ppm, spinosad at a dose rate of 800 ppm plus 5% commercial white sugar or Tempo (20% cyfluthrin, positive control). House fly (*Musca domestica*) infestations were assessed using a variety of sampling methods: fly speck card count (7.6x12.7 cm plain white fiber file cards), sticky fly ribbons (hand carried traps) and observational fly population inspection. All observations were conducted daily for the first seven days and then every seventh day for a 28-day period.

In the first test the two buildings that received 800 ppm Spinosad had rapid reductions in sticky fly ribbon and fly speck card. The sticky fly ribbon counts for the negative control building essentially remained the same during the trial. In this test the three buildings that received 800 ppm Spinosad, 800 ppm Spinosad + Sugar and Tempo, respectively, also all had rapid reductions in adult house fly counts on pillars and walls, as compared to the negative control building.

In the second test the house fly numbers were effectively controlled by the 800 ppm spinosad treatmentwith 5% sugar.

The two treatments (spinosad 800 ppm and positive control Tempo) kept adult fly numbers from increasing, compared to an increase in fly numbers in the negative control treatment.

**Summary house fly**
Two field tests show a reduction in the amount of flies compared to the control situation when a SC formulation with 800 ppm spinosad is used according to the intended use. Normally a reduction in the amount of flies according to the claim (or compared to the control situation) is required in a field test (TNsG on product evaluation).
These tests show sufficient efficacy of a SC formulation with 800 ppm spinosad against house flies.

**Lesser mealworm (*Alphitobis diaperinus*)**
The efficacy of spinosad or the control of *Alphitobis diaperinus* is demonstrated in 5 studies that are summarized below. More details on the studies can be found in Annex 9.

The objective of the first study was to evaluate the efficacy of the test substance spinosad administered as a premise and litter spray in broiler chicken premises, for the control of *Alphitobius diaperinus* (lesser mealworm or darkling beetle). The type of confined poultry premises used in this study was a multi-pen poultry research house. Each pen was treated with water (negative control), spinosad at a dose rate of 400, 600, 800 and 1600 ppm (claim Elector 800-1600 ppm) or Tempo (20% cyfluthrin, positive control). The infection with the beetles was done artificially and the infestation period was 30 days. Four tube traps per pen were set in each pen. Beetles crawled into these tubes during the seven day interval between counting and removal.
Spinosad was effective at reducing darkling beetle infestations at levels at and above 400 ppm, applied at either 1 or 2 gal/1000 $ft^2$ (3.8 or 7.6 L/90 $m^2$) up to 49 days of the last phase when compared to the negative control (84-99% efficacy). The wrong (double) dose of the positive control was used. For this reason no comparison with this treatment could be made.

The second study utilized an artificial infestation model where infested litter, containing both adult and larval forms of the lesser mealworm, was manually placed in each of 975.8 $m^2$ pens of a multi-pen research facility of commercial broiler-type construction. The treatments consisted of spinosad applied at 400, 800, or 1600 ppm, tap water (negative control) and Tempo SC Ultra (positive control, 11% beta-cyfluthrin). All were applied at a volume of two gallons per 1,000 $ft^2$ (7.6 L / 90 $m^2$). Treatments were applied using commercially available spraying equipment. Four tube traps were placed in each pen and were collected and counted at seven-day intervals on day 7, 14, 21, 28, 35, 42 and 49. The live and dead beetles (adult and larvae) were individually counted. Results of the test are shown in table 6.

**Table 6:** Percent Improvement* live and dead, adult and larval *A. diaperinus* counts versus negative control counts (% control) by test and reference substance

| **Treatment** | **Conc. (ppm)** | **Day 0** | **Day +7** | **Day +14** | **Day +21** | **Day +28** | **Day +35** | **Day +42** | **Day +49** |
|---|---|---|---|---|---|---|---|---|---|
| Spinosad | 400 | 88.2 | 0** | 32.5 | 80.3 | 81.2 | 80.7 | 42.4 | 58.2 |
| Spinosad | 800 | 94.1 | 0 | 76.6 | 96.8 | 97.7 | 87.7 | 59.7 | 74.7 |
| Spinosad | 1600 | 88.2 | 0 | 78.2 | 98.3 | 99.4 | 93.6 | 84.2 | 87.3 |
| Tempo SC Ultra | 8 ml / 2 gal | 100 | 0 | 62.5 | 90.8 | 95.4 | 83.6 | 56.5 | 65.8 |

* Percent Improvement= ((mean of negative control - mean of treatment) / mean negative control) x 100%

** If the mean of the negative control was equal or less than the mean of the treatment, then the percent improvement was taken to be 0.

These data show that 800 and 1600 ppm spinosad (claim Elector 800-1600 ppm) are effective for the control of infestations of the lesser mealworm in commercial poultry facilities. The 400 ppm spinosad treatment was shown to be moderately effective.

The third study utilized an artificial infestation model where infested litter, containing both adult and larval forms of the lesser mealworm, was manually placed in each of 10 x 23.2 $m^2$ pens of a multi-pen research facility of commercial broiler-type construction. Each pen was populated with 265 birds (males and females) one day after treatments had been topically applied to the infested litter. The treatments consisted of spinosad applied at 400, 800, or 1600 ppm, tap water (negative control) and Tempo SC Ultra (positive control, 11% beta-cyfluthrin). All were applied at a volume of two gallons per 1,000 $ft^2$ (7.6 L / 90 $m^2$). Treatments were applied using commercially available spraying equipment. Four tube traps were placed in each pen and were collected and counted at seven-day intervals on day 7, 14, 21, 28, 35, 42 and 49.

**Table 7:** Percent improvement* live and dead, adult and larval *A. diaperinus* counts versus negative control counts (% control) by test and reference substance

| **Treatment** | **Conc. (ppm)** | **Day 0** | **Day +7** | **Day +14** | **Day +21** | **Day +28** | **Day +35** | **Day +42** | **Day +49** |
|---|---|---|---|---|---|---|---|---|---|
| Spinosad | 400 | 5.4 | 75.3 | 64.6 | 28.3 | 62.7 | 61.4 | 44.8 | 26.0 |
| Spinosad | 800 | 10.4 | 66.9 | 71.2 | 54.8 | 25.2 | 51.8 | 37.1 | 34.5 |
| Spinosad | 1600 | 20.3 | 74.6 | 89.0 | 70.1 | 66.3 | 65.5 | 57.6 | 49.8 |
| Tempo SC Ultra | 8 ml / 2 gal | 33.8 | 85.7 | 82.0 | 41.5 | 82.2 | 61.8 | 62.2 | 40.7 |

* Percent improvement= ((mean of negative control - mean of treatment) / mean negative control) x 100%

The live and dead beetles (adult and larvae) were individually counted. Results of the test are shown in table 7. A variable efficacy of spinosad 400 and 800 ppm was found. When spinosad was applied at 1600 ppm, efficacy was comparable to the reference treatment.

The fourth study utilized an artificial infestation model where infested litter, containing both adult and larval forms of the lesser mealworm, was manually placed in each of ten 181.36 $ft^2$ pens of a multi-pen research facility of commercial broiler-type construction. Each pen was populated with 220 birds (males and females) one day after treatments had been topically applied to the infested litter. The study was initiated when lesser mealworm counts ranged from 26 to 100 adult and larval forms per trap. The treatments consisted of spinosad applied at 400, 800 or 1600 ppm, tap water (negative control) and Tempo (positive control, 11% beta-cyfluthrin). All were applied at a volume of two gallons per 1,000 $ft^2$ (7.6 L / 90 $m^2$). Treatments were applied using commercially available spraying equipment

**Table 8:** Percent improvement* live and dead, adult and larval *A. diaperinus* counts versus negative control counts (% control) by test and reference substance

| Treatment | Conc. (ppm) | Day 0 | Day +7 | Day +14 | Day +21 | Day +28 | Day +35 | Day +42 | Day +49 |
|---|---|---|---|---|---|---|---|---|---|
| Spinosad | 400 | 47.2 | 50.8 | 10.5 | 44.8 | 60.0 | 82.7 | 82.0 | 88.7 |
| Spinosad | 800 | 48.0 | 0** | 0 | 42.4 | 59.0 | 91.4 | 94.7 | 81.7 |
| Spinosad | 1600 | 37.6 | 49.2 | 44.8 | 32.6 | 19.0 | 76.9 | 75.2 | 84.5 |
| Tempo® | 8 ml / 2 gal | 33.2 | 22.5 | 0 | 44.8 | 38.0 | 39.4 | 79.0 | 61.3 |

* Percent improvement= ((mean of negative control - mean of treatment) / mean negative control) x 100%

** If the mean of the negative control was equal or less than the mean of the treatment, then the percent improvement was taken to be 0.

Four tube traps were placed in each pen and were collected and counted at seven-day intervals on day 7, 14, 21, 28, 35, 42 and 49. The live and dead beetles (adult and larvae) were individually counted. Results of the test are shown in table 8.
These data show that 400, 800 and 1600 ppm spinosad are effective for the control of infestations of the lesser mealworm in commercial poultry facilities.

The fifth study was performed to evaluate the efficacy of spinosad in controlling *Alphitobius diaperinus* (darkling beetle or lesser meal worm) in broiler sheds when sprayed onto the floor and walls of chicken sheds prior to chickens entering the shed. The following dose rates were tested: 0, 125, 250 and 500 ml/$m^2$ of a 250 ppm spinosad solution. The spinosad treatments were compared to a standard product (Tugon WP, 100g/kg cyfluthrin, positive control) and tap water (negative control). The study was run in a commercial broiler farm in Queensland, Australia. There were approximately 270,000 birds across seven sheds during the trial.
Chickens were placed one day after spray treatment of the shed walls and floor. The study was run over three batches of birds and spraying was repeated at the beginning of each batch of birds. The sheds had compacted earth floors and the *A. diaperinus* populations were considered to be high to very high.
Only the highest application rate of spinosad (500 ml/$m^2$ at 250 ppm) (claim Elector 800-1600 ppm in 36-72 ml/$m^2$, which is similar) gave a consistently and significant suppression of *A. diaperinus*. All other dose rates of spinosad and the positive control gave unsatisfactory results.

**Summary *Alphitobius diaperinus* (darkling beetle or lesser meal worm)**
Five field tests show that 800 and 1600 ppm spinosad (claim Elector 800-1600 ppm) are effective for the control of infestations of the *A. diaperinus* in commercial poultry facilities, multi-pen research facilities and broiler sheds. Although normally also laboratory test showing >90% mortality would be required, the field tests show such good results (up to 99% reduction) that the absence of laboratory tests is acceptable.

**Poultry red mite *(Dermanyssus gallinae)***
One in vitro study and two field studies were provided to support the claim for control of poultry red mite by Elector, these are summarized below. More details on the studies can be found in Annex 9.

A laboratory study was conducted to determine the efficacy of Elector (480 g/L spinosad) against poultry red mites. Poultry red mites collected from a commercial layer facility were exposed to the test product in air tight glass vials coated with spinosad on the walls and lid. Seven dose levels, including the negative control (water) were tested: 0, 250, 500, 750, 1000, 1250 and 1500 mg spinosad/Lwater (or ppm spinosad). These tested doses are lower than the intended use of Elector (30 ml Elector / 3,5 – 7 L water = 2000 – 4000 ppm spinosad). Dead and moribund mites were counted after 2, 4, 24 and 48 hours. The highest efficacy after 24 hours was achieved at a dose level of 1000 mg spinosad/L (92%). The additional positive effect after 48h of exposure was small (up to 100%). Effects on a dose level of 1250  mg spinosad/L were similar to the dose level of 1000 mg spinosad/L, whereas effects on the highest dose of 1500 mg spinosad/L were less pronounced.

A field study was done in a commercial layer house where poultry was raised. The birds were artificially infested with red mite four weeks before the test. The study involved four replicates of three treatments. Each treatment group consisted of six cages (in two columns of three) and each cage contained four Lohmann hens at the start of the study. Elector (480 g/L spinosad) was sprayed on the cages at a dose rate of 4.3 ml Elector/L and 8.6 ml Electorl/L to the point of run off. This complies with the intended use of Elector (30 ml Elector / 3.5 – 7 L water = 2000-4000 ppm). The study demonstrated that, compared to the untreated control, a significant reduction of red mites can be achieved for a period of up to 28 days post spraying.

A second field study was done in a commercial facility with two poultry layer houses. A different facility served as an untreated control. Two houses were treated with Elector (480 g/L spinosad) one time and one house was not treated. The poultry house (stable) was sampled for red mites from 10 locations throughout each house (treated and untreated). The 10 locations were sampled from the caged area of the house. The collecting sites were sampled prior to treatment (day 0) up to day 93. Elector was applied one time using commercial application equipment. The commercial Elector formulation was diluted in water according to the following scheme: 30 or 60 ml Elector in 7 L water (2000-4000 ppm) which is according to the intended use. The field study showed that Elector provided effective control of red mites infesting poultry houses for up to 35 days (93.4% reduction) for the 30 ml dose and up to 77 days (94% reduction) at the 60 ml dose. Red mite populations in the untreated control group remained constant throughout the study. Visual observations by the producer showed a re-treatment would be required on day 56 (10,310 red mites sampled) for the 30 ml dose and day 93 (11,510 red mites sampled) in the 60 ml dose.
The provided efficacy tests demonstrate efficacy of Elector against poultry red mite (*Dermanyssus gallinae*).

**Summary poultry red mite**
One laboratory and two field studies show that Elector, when used according to the intended use (2000 and 4000 ppm spinosad) is sufficiently effective in controlling infestations of poultry red mite. Although no specific requirements are set for poultry red mite a 90% reduction in both laboratory and field trials is expected to be sufficient effective.

**Conclusion**
Based on the data submitted it can be concluded that Elector is effective in controlling *Stomoxys calcitrans* (stable flies), *Musca domestica* (house fly), *Alphitobius diaperinus* (darkling beetle / lesser mealworm) and *Dermanyssus gallinae* (poultry red mite) in animal production facilities including intensive poultry, pig or cattle housing, when used according to the label instructions and at the advised use dosage according table 9.

#### 2.5.3.1 Dose
Elector has to be diluted with water before use as indicated in table. In this table a dilution range is indicated for a given treated area.

**Table 2.5.3.1:** Use dose of Elector

| | Poultry red mite | House fly / stable fly | Darkling beetle/mealworm |
|---|---|---|---|
| | | | |

| Elector | 30 ml | 30 ml | 30 ml |
|---|---|---|---|
| **Water** | 3.5 – 7 L | 18 – 36 L | 9 – 18 L |
| **Treated surface** | 250 $m^2$ (Cracks, crevices and cages) | 500 $m^2$ | 250 $m^2$ |
| **Use concentration (% spinosad)** | 0.2- 0.4% | 0.04- 0.08% | 0.08- 0.16% |

#### 2.5.3.2 Mode of action
Spinosad causes excitation of the insect nervous system, leading to involuntary muscle contractions, prostration with tremors and finally paralysis. These effects are consistent with the activation of nicotinic acetylcholine receptors. Spinosad also effects on GABA receptor function that may contribute further to its insecticidal activity.

#### 2.5.3.3 Limitations
The product may not be applied as fog. No application directly onto livestock.

#### 2.5.3.4 Resistance
The unique mode of action of spinosad reduces the risk of cross-resistance due to altered target sites for existing insect control products. To date no evidence of resistance to spinosad in the target species has been observed. However, it is assumed that species have the ability to develop resistance to any new insecticide active substance.
In the case of treating animal houses for the control of flies and mites use patterns vary but can, in high infestation situations, involve the repeated application of insecticides on an almost weekly basis. With generation cycles of only 10-15 days under ideal conditions, the potential for rapid population build up and the need for frequent treatment is high. The combination of a high risk organism (*M. domestica*) and unrestricted use pattern could lead to resistance at some point and modelling shows that if the current resistance allele frequency is high then this could be a matter of a few years. In view of the fact that in particular *M. domestica* has shown the ability to develop resistance at some point to all classes of insecticides, it is assumed that this could also potentially occur with spinosad.

#### 2.5.3.5 Resistance management strategy
A resistance management strategy for Elector is proposed. The product must not be used continually against flies in intensive or controlled environment animal houses because it is likely to cause control failure due to insecticide resistance. The label for Elector states that it should not be used more than five times per year and should only be used in rotation with at least one other product with a different mode of action. This is in agreement with resistance management guidelines of IRAC.

#### 2.5.3.6 Humaneness
As no vertebrates are controlled, this point is not relevant.

### 2.5.4 Evaluation of the label claim
The label claim provided by the applicant is accepted. For the convenience of the competent authorities authorising this product through mutual recognition the Dutch label claim, translated in English, is added to the PAR at the end of section 1.5.2.

## 2.6 Exposure assessment

### 2.6.1 Description of the intended use(s)

Elector is a biocidal product containing the active substance spinosad (480g/L, 44.2% w/w) as an insecticide for the control of pest species in agricultural and domestic animal premises. Elector can be used after dilution of the product in water by spraying surfaces. The diluted product can be used as a surface treatment or by application to cracks and around feeders. The product is efficacious against poultry red mites, house flies, stable flies and darkling beetles/mealworms in animal production facilities including intensive poultry/pig/cattle housing (poultry houses and some livestock animal housings). For non-professional use the product is used mainly for treatment against poultry red mites in hobby aviaries for domestic birds or small-scale chicken houses owned by non-professionals.The general use dosages are 30 ml in 3.5-18 litres of water per 250-500 $m^2$.

The product is intended for both professional and non-professional use.

Elector is PT18 product (Directive 98/8/EU).

### 2.6.2 Assessment of exposure to humans and the environment

<u>Intended use</u>

Elector is a biocidal product containing the active substance spinosad as an insecticide for the control of pest species in agricultural animal premises. The product is efficacious against poultry red mites, house flies, stable flies and darkling beetles/mealworms in animal production facilities including intensive poultry/pig/cattle housing (poultry houses and some livestock animal housings). The product is intended for professional and non-professional use.

Therefore, Elector falls in the category of product type 18 of Directive 98/8/EU. Biocidal products of product type 18 of the BPD are biocidal (i.e., non agricultural) insecticides, acaricides and products to control other arthropods. They can be used in many different applications and may be applied in- or outdoors (OECD, 2008[1]).

<u>Objects to be treated, dose and frequency</u>

A professional or non-professional user sprays Elector on the surface to be treated depending on the type of target insect and level of infestation (normal or severe infestation). The use of the product is summarised in the table below:

**Table 2.6.2-1: Application rates, areas to be treated, frequency**

| Target | Highest application rate g product/$m^2$ (g a.i./$m^2$)[a] | Minimum interval between applications (weeks) | Maximum no. of treatments per year | Areas sprayed |
|---|---|---|---|---|
| **1) Poultry houses** | | | | |
| a) Flies | 0.07[b] (0.029) | 1 (stable flies) 3 | 5 | Walls and ceilings (not floors) |

[1] OECD (2008): Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses. OECD series on Emission scenario documents, number 18; ENV/JM/MONO(2008)14; 17-Jul-2008

| | | | | |
|---|---|---|---|---|
| | | (house flies) | | |
| b) Darkling beetles/mealworms | 0.13 [b] (0.058) | 7 | 5 | Floor areas only |
| c) Red mites | 0.13 (0.058) | 12 | 5 | Floor areas only |
| **2) Livestock** | | | | |
| a) Flies | 0.07 [b] (0.029) | 1 (stable flies) 3 (house flies) | 5 | Walls and ceilings (not floors) |

Notes:
[a] assuming a product density of 1086 g/L
[b] in case of a severe infestation, double the concentration of Elector can be used

In poultry houses, for treatments against flies Elector is used to treat areas where flies rest, paying attention to side walls, the ends of buildings, upper sides of posts and crossbeams. In poultry houses, for treatments against darkling beetles/mealworms, Elector is used to treat floor areas especially to litter around and under feeders and water lines and to walls and support beams. In poultry houses, for treatments against red mites, Elector is used to treat areas where red mites rest e.g. cages, cracks and crevices and where pests have been seen or can find harborage. In livestock animal housings, for treatments against flies, Elector is used to treat vertical and overhead surfaces where flies may congregate.
The maximum recommended number of treatments per year is five for all uses. As indicated in the table above, for instances of severe infestation the treatment rate of Elector can be doubled, however this is unlikely to occur more than once per year.

Concentration of active substance
The product is a SC formulation containing 480 grams/liter spinosad (44.2% w/w a.s.) which is diluted before at several specified rates depending on the pest to be controlled:

- Darkling beetles: 30 mL concentrate per 9 to 18L of water to 250 $m^2$ surface
- House and stable flies: 30 mL per 18 to 36 L of water to 500 $m^2$ surface
- Red mites: 30 mL of the product are diluted in 3.5 to 7 L water to 250 $m^2$ surface of cracks, crevices and cages (highest application rate equivalent to a concentration of 0.4% spinosad in the spray solution)

Elector is a SC formulation containing 480 g/L of the active substance spinosad. It is intended to be used as insecticide for the control of pest species in agricultural animal premises. The product is diluted in water at specified rates and subsequently applied to the specific areas to be treated as a course, low pressure spray or a low volume high pressure spray by professionals.
Emission of the active substance after application in animal housing occurs mainly via manure and waste water (STP), the latter only in some types of poultry houses.
Emissions to the environment can occur indirectly via the application of liquid waste/manure containing spinosad as fertilizer to soil. Following the contamination of soil, groundwater and surface waters can be contaminated by leaching and/or run-off. Due to the characteristics of the active substance (not volatile), no emissions to air are to be expected.
Across Europe a discharge of waste water containing manure/slurry to the public (municipal) sewer is prohibited. Hence, public sewage treatment plants are not exposed following the use of spinosad as insecticide. Liquid waste containing manure as well as water from wet cleaning operations is collected together in a slurry or waste water collection tank and may subsequently be applied as fertilizer on agricultural fields.

The product was not a reference product in the EU-review program for inclusion of the active substance in Annex I of Directive 98/8/EC. The applicant has submitted an exposure and risk assessment for Elector. The RMS NL has updated this exposure and risk assessment for the environmental aspect. For authorisation purposes the risk assessment of Elector performed by the applicant is included in this Product Authorisation Report. See for more detail section 2.8.

## 2.7 Risk assessment for human health

Elector is a suspension concentrate containing spinosad (480 g/L) as an active substance. Intended uses of Elector are the control of house flies, stable flies, tempex beetles and blood louse in and around accommodations for livestock, pigs and poultry. The formulation needs to be diluted with water prior to application; the resulting dosages and the area to be treated are provided below:

| | **Tempex beetle** | **Stable fly** | **House fly** | **Blood louse** |
|---|---|---|---|---|
| **Elector** | 30 ml | 30 ml | 30 ml | 30 ml |
| **Water*** | 9 – 18 liter | 18 – 36 lt | 18 – 36 lt | 3.5 – 7 lt |
| **Area to be treated** | 250 $m^2$ | 500 $m^2$ | 500 $m^2$ | n.a.** |

* The exact amount of water to be used is dependent on the contamination: by higher contamination less water should be used to achieve a higher concentration of the formulation

** Not applicable – to be used in cages, cracks and crevices

Elector was not a reference product of the CAR for spinosad.

The GLP-compliant studies on acute oral, acute dermal and acute inhalation toxicity with Elector have been submitted by the applicant (see 2.7.1.3 for results). These studies have been evaluated in the CAR of spinosad, and acute oral and acute dermal toxicity studies and skin and eye irritation studies were found acceptable for the risk assessment purposes. The acute inhalation toxicity study and skin sensitization study were concluded to be not acceptable. The classification and labelling of the product for these two endpoints is therefore derived by the RMS based on the calculation rules in accordance with Directive 1999/45/EC and Directive 1272/2008/EC.

### 2.7.1 Hazard potential

#### 2.7.1.1 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.

#### 2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product contains ca. 0.04% of 1,2-benzisothioazolin-3-one. 1,2-Benzothiazolin-3-one is currently under evaluation for Annex I inclusion under BPD. 1,2-Benzothiazolin-3-one is included in Annex VI Table 3.1 of Regulations (EC) No 1272/2008, with a specific concentration limit of C ≥ 0.05% for R43/H317. At a concentration of 0.04% it does not contribute to the classification of Elector for human health effects. Therefore it is not regarded as a substance of concern.

#### 2.7.1.3 Toxicology of the biocidal product

GLP-compliant studies with Elector have been submitted by the applicant to address acute oral, acute dermal and acute inhalation toxicity, skin and eye irritation and skin sensitization properties of the product. The submitted studies have already been evaluated in the CAR of spinosad. Based on these studies, Elector does not need to be classified for acute oral and acute dermal toxicity, skin irritation and eye irritation. The studies on acute inhalation toxicity and skin sensitization were found to be unacceptable in the CAR of spinosad. Based on the calculation rules according to Directive 1999/45/EC and Directive 1272/2008/EC, classification for acute inhalation toxicity and skin sensitization is not warranted for spinosad.

No data on dermal absorption have been submitted, but the applicant has proposed to use the value of 0.1% for undiluted product and 2% for the in-use dilution of Elector. The same values for dermal absorption have been proposed in the CAR of spinosad. As in the CAR a more diluted product (1% active substance) has been assessed, and the percentage dermal absorption usually decreases with increasing concentration, these values are considered to be acceptable for the risk assessment of Elector.

### 2.7.2 Exposure

The biocidal product Elector contains the active substance spinosad (pure: 480 g/kg). Elector is a suspension concentrate used in the control of house flies, stable flies, beetles and blood louse in and around accommodations for livestock, pigs and poultry. The formulation is diluted with water prior to use at a maximum dosage of 30 ml Elector in 3.5 L of water (generating a 4.1 g/L spinosad solution). The product is intended for both professional and non-professional use.

The potential for exposure to spinosad is summarized in the table below.

| Exposure path | Industrial use | Professional use | General public | Via the environment |
|---|---|---|---|---|
| Inhalation | Not relevant | Potentially significant | Not relevant | Negligible |
| Dermal | Not relevant | Potentially significant | Potentially significant | Negligible |
| Oral | Not relevant | Negligible | Potentially significant | Negligible |

**Inhalation exposure**
Spinosad is not volatile (vapour pressure of ca. $10^{-8}$ Pa at 20 ºC). The product is applied by coarse spraying, therefore inhalation exposure of professional and amateur users is possible. Secondary exposure of bystanders is however considered to be unlikely due to the low volatility of the active substance.

**Dermal exposure**
Dermal exposure to spinosad of professional and amateur users may occur during the mixing and loading and the application of Elector by spraying. Furthermore, secondary exposure of general public is possible following the contact with treated surfaces.

**Oral exposure**
Oral exposure of professional and amateur users during the application is considered to be negligible. However, secondary exposure of children is possible after touching the treated surfaces due to hand-mouth contact.

Livestock may be present in the treated facilities during the product application and thus may be directly exposed to spinosad residues. Furthermore, animals may be exposed to Elector by licking the treated surfaces and eating the dead flies and beetles. Therefore humans may be indirectly exposed to spinosad by consumption of food of animal origin containing spinosad residues.

#### 2.7.2.1 Exposure of professional users

In Annex 6„Safety for professional operators“, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.

The estimation of professional exposure to Elector was performed by the RMS The Netherlands according to the User Guidance for the Technical Notes for Guidance on human exposure to biocidal products. The exposure was calculated by using Spraying model 1, which describes mixing and loading and the application of the preparation at 1 to 3 bar pressure in compression sprayers as a coarse or medium spray, indoors and outdoors, overheads and downwards.

The application duration for professional users is considered to be 400 minutes suggested in the Technical Notes for Guidance (part 2, page 59) for the average duration of disinfection of poultry units with the average area of 4000 $m^2$. The applicant has indicated that Elector will be used no more than 5 times per year. Operator body weight is assumed to be 60 kg. The dermal penetration of spinosad is considered to be 2% for the in-use dilution.

The estimated combined internal inhalation and dermal exposure for the highest in-use concentration of Elector (30 mL Elector per 3.5 L water, generating 4.1 g/L spinosad solution) is 0.208 mg spinosad/kg bw day without PPE.

#### 2.7.2.2 Exposure of non-professional users and the general public

In Annex 7 “Safety for non-professional operators and the general public”, the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.

The estimation of professional exposure to Elector was performed by the RMS The Netherlands according to the User Guidance for the Technical Notes for Guidance on human exposure to biocidal products. The exposure was calculated by using Spraying model 1, which describes mixing and loading and the application of the preparation at 1 to 3 bar pressure in compression sprayers as a coarse or medium spray, indoors and outdoors, overheads and downwards.

The application duration for non-professional users is considered to be 40 minutes suggested in the Technical Notes for Guidance (part 2, page 59) for the disinfection of pig unirs with the average area of 390 $m^2$. Operator body weight is assumed to be 60 kg. The dermal penetration of spinosad is considered to be 2% for the in-use dilution.

The estimated combined inhalation and dermal exposure for the highest in-use concentration of Elector (30 mL Elector per 3.5 L water, generating 4.1 g/L spinosad solution) is 0.021 mg spinosad/kg bw day without PPE.

Secondary exposure of the general public may arise during the re-entry of treated accommodations. As spinosad is not volatile, inhalation exposure is considered to be negligible. Dermal exposure may however occur upon touching of treated surfaces. Oral exposure is considered to be possible in case of young children due to hand to mouth transfer. As a worst-case, exposure of an infant weighing 10 kg by touching the treated surface is considered. As a maximal dosage, the application of 30 mL Elector per 250 $m^2$ is considered, resulting in the dosage of $5.76 \times 10^{-3}$ mg spinosad/$cm^2$. The exposure assessment was performed according to the method proposed in the User Guidance (part 1, page 53) for the risk assessment of wood preservatives. The hand surface area of 200 $cm^2$ is considered and as a worst case, 20% of the hand is considered to be contaminated in accordance with the User Guidance. As a worst-case, it is assumed that all substance from the hands of a child will be ingested due to hand-to-mouth transfer.

The estimated internal oral exposure of an infant is 0.011 mg/kg bw/day.

#### 2.7.2.3 Exposure to residues in food

In Annex 8 "Residue behaviour", the results of the residue assessment are laid out.

A screening level risk assessment for biocide residues in livestock was conducted according to the proposal by the Dietary Risk Assessment Working Group (DRAWG) by the following formula:

External Exposure Animal = Application rate × Treated area ÷ number of animals per treated area ÷ BW of single animal

If the calculated exposure values fall below the proposed trigger value of 0.004 mg/kg bw/day, no additional risk assessment is necessary. If the trigger value is exceeded, a higher tier risk assessment needs to be performed.

The applicant has provided the calculations of the estimated external exposure of the livestock using the defaults from the OECD Emission Scenario Document No. 14 (ENV/JM/MONO(2006)4). Indicative body weights for the various types of livestock were obtained from public literature. The calculated external exposure values are presented in the table below:

| | **Turkey** | **Broiler** | **Laying hen** | **Veal calves** | **Dairy cattle** | **Fattening pigs** |
|---|---|---|---|---|---|---|
| % a.s. in b.p. (w/w) | 48.0% | 48.0% | 48.0% | 48.0% | 48.0% | 48.0% |
| Application volume (mL/m²) | 0.12 | 0.12 | 0.12 | 0.06 | 0.06 | 0.06 |
| Application rate (mg a.s./m²) | 57.6 | 57.6 | 57.6 | 28.8 | 28.8 | 28.8 |
| Treated area (m²) | 3300 | 1110 | 1270 | 160 | 1170 | 600 |
| No. of animals | 10,000 | 20,000 | 20,000 | 80 | 100 | 400 |
| BW per animal (kg) | 12.0 | 1.6 | 2.0 | 100.0 | 500.0 | 100.0 |
| **Screening exposure (mg/kg bw)** | **1.58** | **2.00** | **1.82** | **0.58** | **0.67** | **0.43** |

The calculated values are well above the trigger value of 0.004 mg/kg bw/day, therefore further risk assessment needs to be performed.

Although no residue studies with Elector are available, the applicant has submitted two residue studies with a more diluted spinosad-cotaining product (in-use dilution concentrations of 0.04-0.08% spinosad) used in the treatment of cows and hens. The tested application involved direct application of the product onto the animals, resulting in external exposures comparable to the estimated external exposures of animals for Elector (0.44 mg/kg bw for cows and 1.9 mg/kg bw for hens). The application involved repeated application (5 times) with either 7, 14 or 21 days interval between the applications by either spraying (cows and hens) or pouring on (cows only). For cows, milk samples were collected at both milkings 4 days per week. Tissue samples were collected 2, 7 and 14 days after the last treatment. For hens, eggs were sampled on days 0, 7, 14, 21, 28, 35, 42, 49, 56 during the treatment and on days 0, 1, 3, 5, 7, 10, 14, 21, 28 and 42 after the treatment had stopped. Tissue samples were collected on days 0, 1, 3, 5, 7, 10, 14, 21, 28 and 42 after the end of the treatment.

The maximal average concentrations of spinosad in the tissues of cows were 0.033 ppm for the spray application and 0.14 ppm for the pour-on application in muscle tissues, 0.11 and 0.46 ppm in the kidney, 0.19 and 0.73 ppm in the liver, 0.35 and 1.3 ppm in subcutaneous fat and 0.39 and 1.3 ppm in renal fat. The maximum average value found in milk was 0.092 ppm for the spray application and 0.647 ppm for the pour-on application. These maxima were seen 1 day after the spray treatment and 2 days after the pour-on treatment.

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The maximal average concentration of spinosad in eggs was 0.0424 ppm after the application. The maximal residues found in muscles was 0.0141 ppm, in liver 0.0871 ppm, in fat 0.353 ppm and in skin 0.243 ppm.

For spinosad, up till now MRLs for ruminant commodities (cattle, sheep, goat) and poultry commodities (chicken, turkey, geese, ducks) have only been established for pesticides (91/414/EC). The European commission has recently made an inventory of existing national MRLs in EU MS for substances used for PPP. This resulted in temporary MRLs (MRLs), which are listed in Annex III of Regulation (EC) 556/2012:

| Commodity | MRL [mg/kg] |
|---|---|
| **Cattle** | |
| meat | 0.3 |
| kidney | 1.0 |
| liver | 2.0 |
| fat | 3.0 |
| edible offal | 0.5 |
| milk | 0.5 |
| **Chicken** | |
| meat | 0.2 |
| kidney | 0.2 |
| liver | 0.2 |
| fat | 1.0 |
| edible offal | 0.2 |
| eggs | 0.2 |

These MRLs were used as input for consumer risk assessment for chronic dietary intake using the EFSA Pesticide Residue Intake (PRIMo) Model rev. 2[2], in which all national EU diets are incorporated.

### 2.7.3 Risk Characterisation

With proper use in accordance with regulations harmful effects on the health of users and third parties are not expected. The estimated exposures for the intended use are compared to the respective systemic AEL and the MRLs of spinosad.

The following reference values have been set in the CAR of spinosad:

ADI (if residues in food or feed): 0.024 mg/kg bw/day
$AEL_{acute}$; not derived
$AEL_{medium\text{-}term}$: 0.024 mg/kg bw/day
$AEL_{long\text{-}term}$: 0.012 mg/kg bw/day
Drinking water limit: 0.1 µg/L.

[2] http://www.efsa.europa.eu/de/mrls/docs/calculationacutechronic_2.xls accessed 30 May 2011

The applicant has indicated that Elector will be used maximal 5 times per year. Therefore it is considered to be appropriate to compare the estimated exposure levels of professional and amateur users with the $AEL_{medium\text{-}term}$.

#### 2.7.3.1 Risk for Professional Users

The following total systemic exposures to spinosad have been estimated for professional users for the product application by coarse spraying:

| Route | Estimated internal exposure (mg/kg bw/day) | Systemic AEL (mg/kg bw/day) | % AEL |
|---|---|---|---|
| **Professional operators, application by spraying** | | | |
| *Without PPE* | | | |
| Dermal | 0.149 | 0.024 | 620.8 |
| Respiratory | 0.059 | 0.024 | 245.8 |
| Total | 0.208 | 0.024 | 866.7 |
| *With PPE (gloves and respiratory protective equipment, 90% reduction)* | | | |
| Dermal | 0.015 | 0.024 | 62.1 |
| Respiratory | 0.006 | 0.024 | 24.6 |
| Total | 0.021 | 0.024 | 87.5 |

Based on the risk assessment, it can be concluded that no adverse effects are expected for the protected professional users wearing PPE (gloves, coverall and respiratory protective equipment) after dermal and respiratory exposure to spinosad as a result of the application of Elector.

#### 2.7.3.2 Risk for non-professional users and the general public

The following total systemic exposures to spinosad have been estimated for amateur users applying Elector by coarse spraying:

| Route | Estimated internal exposure (mg/kg bw/day) | Systemic AEL (mg/kg bw/day) | % AEL |
|---|---|---|---|
| **Professional operators, application by spraying** | | | |
| *Without PPE* | | | |
| Dermal | 0. 015 | 0.024 | 62.1 |
| Respiratory | 0.006 | 0.024 | 24.6 |
| Total | 0.021 | 0.024 | 87.5 |

Based on the risk assessment, it can be concluded that no adverse effects are expected for unprotected amateur users after dermal and inhalation exposure to spinosad as a result of the application of Elector.

Total indirect exposure to spinosad following the dermal contact with treated surfaces was calculated for an infant of 10 kg. As a worst-case, it was assumed that the complete amount of spinosad on hands will be ingested due to hand to mouth transfer. The calculated internal exposure to spinosad is 0.011 mg/kg bw/day. This corresponds to 47.75% of the $AEL_{medium\text{-}term}$.

In reality, it is expected that bystanders, including children, will probably not enter the treated areas. The contact with treated surfaces is therefore expected to have an incidental, rather than a regular character. Therefore based on the risk assessment no concern exists for the adverse effects of spinosad for general public following contact with treated surfaces.

#### 2.7.3.3 Risk for consumers via residues

Based on the two residue studies with a spinosad-containing product provided by the applicant the maximal average residues of spinosad in the meat of treated cattle (cow) and poultry (hens), as well as milk and eggs, have been determined.

When these values are compared with the MRLs for spinosad as laid out in Annex III of Regulation (EC) 556/2012, it can be concluded that in case of a spraying application, they are well below the MRLs. In case of a pour on application, the MRL in milk is exceeded. However, this pour-on application is not intended for the proposed biocidal use of Elector and is thus not considered critical for risk assessment.

The tMRLs were used as input for consumer risk assessment for chronic dietary intake using the EFSA Pesticide Residue Intake (PRIMo) Model rev. 2., in which all national EU diets are incorporated.

When using the MRLs of spinosad from Regulation (EC) 396/2005, the conversion factor for liver and egg for poultry products and the PRIMo Model, for the Total Mean Daily Intake (TMDI) calculation the ADI is used for 182.8%, maximally, for the NL children (1-6 years). Assuming that the STMR (Supervised Trial Median Residue) values are 50% of the MRL maximally, the refined Estimated Daily Intake (EDI) calculation shows that 91.4% of the ADI is used maximally for the NL children (1-6 years). All other national diets use less of the ADI.

If only the use as a biocide is taken into account, the TMDI calculation is 86.9% of the ADI, maximally, for FR toddlers. In all other national diets the MRLs for animal products alone use less of the ADI.

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the general public to spinosad as a result of the application of Elector.

## 2.8 Risk assessment for the environment

The exposure and risk characterisation for the environment is based on the summary dossier for the product Elector from the applicant and the final Assessment Report of the active substance spinosad of May 2010 (Rapporteur NL).
No studies were submitted with the product authorisation application for the active substance or for the product that were not already evaluated during the Annex I active review stage or studies. Detailed data on the fate and distribution of spinosad in the environment and the effect of the active substance on environmental organisms can be consulted in Doc IIA of the final Assessment Report (May 2010) for spinosad (PT18).
The PNEC derivation is also described in detail in the Assessment Report for spinosad (Product Type 18), section 4.2.7 and a summary is included in the table below.

The PNECsoil in the CAR was calculated from the PNECaquatic of 0.062 µg a.s./L, applying equilibrium partitioning according to the TGD. Using the geometric mean $Kp_{soil}$ of 41.3 L/kg, the $Ksusp_{soil\text{-}water}$ is 62.2 $m^3/m^3$ (Eq. 24), and the PNECsoil,EP is 2.27 µg a.s./kg ww soil or 2.57 µg a.s./kg dw soil.

However, equilibrium partitioning may not be appropriate because the adsorption of spinosad is not related to organic carbon.
The data on non-target arthropods included in the CAR are foliage or soil dwelling insects, that are relevant to agricultural crops. The proposed applications involve indoor uses in stables, at which stage exposure of non-target arthropods is not relevant. The majority of the tested non-target arthropods species will also not be exposed to residues of spinosad that may be present in manure, since the manure will be incorporated into the soil, either by injection or by mixing.

**Table 2.8-1 Overview of predicted no effect concentrations (PNECs) for Spinosad**

| Compartment | Predicted No Effect Concentrations | |
|---|---|---|
| Water | PNECaquatic | 0.062 µg/L |
| | PNECsediment | 0.23 µg/kg ww (0.6 µg/kg dw) |
| Terrestrial | PNECsoil | 2.27µg/kg ww soil or 2.57 µg/kg dw soil |
| Air | Not determined | |
| Waste water treatment | PNECSTP | > 10 mg/L |
| Groundwater | | * 0.1 µg/L |
| Primary poisoning birds | Acute LD50 > 2000 mg/kg bw.d<br>long-term PNECbirds | 18.3 mg/kg feed or 2.2 mg/kg bw.d |
| Secondary poisoning birds | PNECoral, bird | 18.3 mg/kg feed or 2.2 mg/kg bw.d |
| Primary poisoning mammals | Acute LD50 > 2000 mg/kg bw.d<br>long-term PNECmammals | 3.33 mg/kg feed or 0.33 mg/kg bw.d |
| Secondary poisoning mammals | PNECoral, mammals | 3.33 mg/kg feed or 0.33 mg/kg bw.d |

* Limit value for pesticides derived from drinking water directive

**Table 2.8-2 Overview of predicted no effect concentrations (PNECs) for metabolites of Spinosad**

| Compartment | Metabolite | Predicted No Effect Concentrations | |
|---|---|---|---|
| Water | spinosyn B | $PNEC_{aquatic}$ | 0.095 µg/L |
| | N-demethylated spinosyn D | $PNEC_{aquatic}$ | 0.023 µg/L |
| | β-13,14-dihydropseudo-aglycone of spinosyn A | $PNEC_{aquatic}$ | 56.7 µg/L |
| | β-13,14-dihydropseudo-aglycone of spinosyn D | $PNEC_{aquatic}$ | 6.3 µg/L |
| | | $PNEC_{sediment}$ | Not determined |
| Terrestrial | spinosyn B | $PNEC_{soil,EP}$ | 1.43 µg/kg ww soil |
| | N-demethylated spinosyn D | $PNEC_{soil,EP}$ | 0.35 µg/kg ww soil |
| Air | | | Not determined |

| Compartment | Metabolite | Predicted No Effect Concentrations | |
|---|---|---|---|
| | | | |
| Waste water treatment | | $PNEC_{STP}$ | Not determined |
| Groundwater | | | * 0.1 µg/L |
| Primary poisoning birds | | | Not determined |
| Secondary poisoning birds | | | Not determined |
| Primary poisoning mammals | | | Not determined |
| Secondary poisoning mammals | | | Not determined |

* Limit value for pesticides derived from drinking water directive

### 2.8.1 Emissions to the environment

The environmental risk assessment for the b.p. Elector is based on the emission scenario document for products used as insecticides in animal housing and manure storage systems (PT 18; OECD, 2006[3]) as well as on the Technical Guidance Document on Risk Assessment (EC, 2003 in the following cited as TGD, 2003[4]).
In the following, the main destination of the insecticide after application according to user's instructions is identified since the focus is placed on methods to estimate the emission rate of insecticides to the primary receiving environmental compartments.
The ESD for PT 18 on general insecticides (OECD, 2006) covers the following life-cycle steps as being potentially relevant for environmental emissions: mixing/loading, application (indoor), and releases from treated surfaces by cleaning.
Due to this kind of formulation, the following release pathways can be excluded or can be identified to be relevant for environmental exposure:

**Mixing/loading**
The product is marketed as a suspension concentrate, therefore, mixing and loading is required as described in the label. The vapour pressure of the most volatile component of spinosad, spinosyn A, is only $3\times10^{-8}$ Pa so that exposure to spinosad vapours can be ruled out.
Other ways of release of the active substance are not foreseen in the PT18 ESD for stables and manure. Furthermore, the mixing/loading step is reserved to professionals.

**Application**
The ESD for PT18 in stables (OECD, 2006) assumes that emission of the active substance after application in animal housing occurs mainly via manure and waste water (STP), the latter only in some types of poultry houses or by non-professionals. The fractions of the active substance that are emitted to those streams are determined by the type of pest, the type of product, the mode of application of the product and the type of housing.
In line with the emission scenario described in the ESD, following use of the formulated product in animal houses and subsequent land application of manure (arable land and grassland), exposure of the active substance to ground water and surface water could

[3] OECD (2006): Emission Scenario Document for Insecticides for Stables and Manure Storage Systems. OECD series on Emission scenario documents, number 14; ENV/JM/MONO(2006)4; 25-Jan-2006.
[4] European Commission (2003): Technical Guidance Document on Risk Assessment. European Commission Joint Research Centre, EUR 20418.

potentially occur as a result of leaching and/or run-off from areas treated with manure. The emissions to air are negligible (see comments in the mixing/loading step).
Secondary poisoning can occur since the log Kow was determined to be above 4 at pH 7 or higher indicating that bioaccumulation can occur. Furthermore, the highest experimentally determined BCF was 115 L/kg.

**Cleaning step**
In the case of some housing types for poultry the ESD requires to assess emission to waste water, following passage of a (municipal) sewage treatment plant.
However, a discharge of waste water containing manure/slurry to the public (municipal) sewer will generally not be the case for professional use and will depend on national legislation.
The liquid waste from stable cleaning containing manure then may be either removed to a slurry or waste water collection tank and commonly be applied to land or treated in an adapted communal or on-farm waste water treatment plant. In contrast, non-professionals may discharge waste water containing manure/slurry to the public (municipal) sewer.
For the case that the liquid wastes are discharged to the sewer, the calculation has to be made for the standard STP (TGD, 2003) and the discharge from STP to a surface water body. Furthermore, emission to the agricultural soil is expected since the sludge from the STP is used as fertiliser.

## 2.8.2 Fate and distribution in the environment

For the general assessment of the environmental fate and behaviour of the active substance please refer to the “Assessment Report on spinosad” (RMS NL, 2010).
Spinosad is a mixture of two structurally similar molecules which have both insecticidal properties and are designated as spinosyn A and spinosyn D. Spinosad typically contains spinosyn A and D in a ratio of approximately 85% A : 15% D.

### 2.8.2.1 Degradation of spinosad in the aquatic compartment

Spinosyn A and D have shown to be hydrolytically stable. Aqueous photolysis studies with spinosyn A and D show that both compounds are susceptible to photolysis (both with $DT_{50}$ < 1d). In a ready biodegradation test, negligible degradation of spinosad was observed, classifying spinosad as not readily biodegradable.
The aquatic dissipation of spinosyn A and D was further investigated in water/sediment systems under aerobic (20℃) and anaerobic conditions (25℃) as well as in a microcosm study (20 - 21℃). The studies revealed the dissipation of both compounds to be dominated by sorption to sediment. The decrease of water concentrations was fast (average dissipation $DT_{50}$ values for the water phase and both isomers in the aerobic water/sediment study: 20 d; anaerobic study: < 7 days; microcosm study: 18-27 hours). Once distributed to the sediment, the dissipation was low, leading to $DT_{50}$ values for the whole system of 145 days (aerobic conditions, both isomers, 20℃) and 239 and 443 days (anaerobic conditions, both isomers, 25℃). Under aerobic conditions, no degradation products were detected in the water phase or in sediment at a level > 10%.

### 2.8.2.2 Degradation of spinosad in soils

Soil photolysis was tested under sunlight, in air-dried and moisturised soil. In air-dried soil, spinosyn A was photolysed with a DT50 of 74 days; in moisturised soil with a DT50 of 13 days. Photolysis of spinosyn D was only tested with air-dried soil; the DT50 was 42 days.
In a laboratory aerobic biodegradation study, maintained in the dark, both spinosyn A and D are rapidly N-demethylated. The geometric mean DT50 for spinosyn A and D was 25 and 37 days, respectively, at 20°C and 47 and 69 days, respectively, when expressed to the average EU outdoor temperature of 12 ºC. The mineralisation for both compounds after 80 to 91 days was less than 10%, whereas unextractables accounted for 8.1% to 39% for the

same time period. Spinosyn B was the major degradation product of spinosyn A, amounting to 67% AR at maximum. The main degradation product of spinosyn D was N-demethylated spinosyn D, representing 68% AR at maximum. No other metabolites were detected at levels of > 10% of AR. Whereas spinosyn B was slightly more persistent in soils (average DT50 = 157 and 194 days at 20℃), N-demeth ylated spinosyn D had a markedly higher DT50 value (531 days, 20℃).
In the field study much more favourable DT50 values were determined. An outdoor field study, using locations in the UK, Italy, Northern and Southern France was carried out. Only the data for the UK soil are considered reliable (DT50: 2.37, 3.51, 2.11 and 3.77 days for spinosyn A, D, B and N-demethylated spinosyn D, respectively).
A $DT_{50, field}$ of 3.51 day was selected based on the UK study, which indicated $DT_{50, field}$ values of 2.37 and 3.51 days for spinosyn A and spinosyn D, respectively. For metabolites, the $DT_{50, field}$ was 2.11 and 3.77 days for spinosyn B and N-demethylated spinosyn D, respectively.

The adsorption and desorption behaviour of spinosyn A and B was investigated in batch equilibrium tests with 4 and 5 soils according to EPA Pesticide Assessment Guideline 163-1, 1982. The arithmetic mean Kpsoil of spinosyn A is 137.6 L/kg. In line with the conclusions reached during the pesticide assessment in the framework of Directive 91/414/EC, this value is assumed to be valid for spinosyn D as well. The arithmetic mean Kpsoil of spinosyn B is 51.4 L/kg, which is assumed to be valid also for N-demethylated spinosyn D. The Kpsoil is used for the calculation of the PECsed, PECporewater and PNECsoil which are all based on equilibrium partitioning.

#### 2.8.2.3 Degradation of spinosad in the air

Spinosyn A and D have a low vapour pressure (spinosyn A: $3.0 \times 10^{-8}$ Pa at 25℃ and spinosyn D: $2.0 \times 10^{-8}$ Pa at 25℃).
The Henry's law constant was calculated as $1.89 \times 10^{-7}$ Pa x $m^3$ x $mol^{-1}$ (25℃) for spinosyn A and $2.32 \times 10^{-5}$ Pa x $m^3$ x $mol^{-1}$ (25℃) for spinosyn D. According to the correlatio n established by Lyman et al. (1990)[5] substances with Henry constants of ca. $10^{-6}$ atm x $m^3$ x $mol^{-1}$ or smaller can be classified as being non volatile from aqueous surfaces.
The Henry's law constant is used for the determination of $PEC_{GW}$.
A calculation of the chemical lifetime of spinosad in the troposphere due to indirect photodegradation resulted in half-lives of 20 min for spinosyn A and 19 min for spinosyn D. An experiment on the volatilisation of spinosad from plant and soil surfaces yielded < 2% exhalation of spinosyn A or D within 24 h. Therefore, spinosad is not volatile and even when entering the atmosphere, the compound is rapidly degraded by photochemical processes and neither accumulation in the air nor transport over longer distances is to be expected.

### 2.8.3 PEC calculations

As developed above, emissions of spinosad to the environment may occur when contaminated manure is applied onto the soil or via waste water (STP).

#### 2.8.3.1 PEC calculations via manure application

The predicted environmental concentration (PEC) of the active substance in soil has been determined using the Tier I procedure provided in the ESD for PT18 (OECD, 2006). Some of the PEC calculations are also based on Chapter 3 of the TGD for Risk Assessment (European Commission, 2003).

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[5] Lyman at al., 1990: Handbook of chemical property estimation methods. American Chemical Society, Washington, DC.

Predicted Environmental Concentrations for soil are calculated since this is the primary target of emissions by application of manure. Furthermore, the soil pore water concentration as an indicator for potential concentrations in groundwater is assessed. Predicted Environmental Concentrations for spinosad are calculated for surface water (PECsw) and sediment (PECsed) due to run-off from the field. For the initial identified risk for sediment organisms a higher tier assessment is made with the FOCUS surface water model SWASH (MACRO, PRZM, TOXSWA). Further, the exposure of organisms higher in the food chain i.e. secondary poisoning is estimated since spinosad fulfils the indication for possessing a bioaccumulation potential.
Primary poisoning of non-target organisms is not a topic since spinosad is used as an indoor spray application. Due to the very low volatility of spinosad an estimation of atmospheric concentrations after use is not necessary.
A determination of regional concentrations for the proposed use pattern of Elector has not been made since the product's use is not considered to be of sufficiently large scale to warrant such prediction.

#### 2.8.3.2 PECsoil

Following use of Elector (treatment rates indicated in the table above) to suitable surfaces in animal houses, the active substance is potentially collected along with the manure and stored as per normal farming practices. Subsequent land application of the manure after storage releases the active substance to soil. The amount of manure that is permitted to be applied to land is controlled by the nitrogen and/or phosphate content of the manure. However, at the product authorisation level the N-standards are taken into consideration, since the majority of EU countries have legislations setting standards for the maximum amount of nitrogen. In an additional ESD paper for PT3 biocides (EC, 2010[6]) the N-standards are also recommended for assessment purposes.
The resulting concentration of the active substance in arable or grassland soil is given by the equations below (see equations 25 and 24, respectively from the ESD):

$$\mathrm{PIECars\text{-}N} = \frac{100 \times \mathrm{Qai\text{-}arab} \times Q_{\mathrm{N,\,arable\_land}}}{\mathrm{Qnitrog\text{-}arab} \times \mathrm{Nlapp\text{-}arable} \times \mathrm{DEPTH}_{\mathrm{arable\_land}} \times \mathrm{RHOsoil}_{\mathrm{wet}}}$$

$$\mathrm{PIECgrs\text{-}N} = \frac{100 \times \mathrm{Qai\text{-}grass} \times Q_{\mathrm{N,\,grassland}}}{\mathrm{Qnitrog\text{-}grass} \times \mathrm{Nlapp\text{-}grass} \times \mathrm{DEPTH}_{\mathrm{grassland}} \times \mathrm{RHOsoil}_{\mathrm{wet}}}$$

*Where, for arable land (using equations 10, 14, 17):*

$$\mathrm{Qai\text{-}arab} = \left( \mathrm{F} \times \left( 10^{-5} \times \mathrm{Qprod\text{-}uins} \times \mathrm{Fbioc\%} \times \frac{\mathrm{AREA}}{\mathrm{AREAui}} \right) \right) \times \mathrm{Napp\text{-}manure}_{\mathrm{ar}}$$

*and (using equation 20):*

$$\mathrm{Qnitrog\text{-}arab} = \mathrm{N} \times \mathrm{Qnitrog} \times \mathrm{Tar\text{-}int}$$

Equivalent equations are applicable to the grassland calculations.
In conclusion, the amount of manure that may be applied to arable soil or grassland is determined by the storage time of the manure and the legal standard on nitrogen. In this document, the estimations of PIECsoil for arable and grassland scenarios are based on the

[6] EC (2010): Technical Notes for Guidance. Supplement to the Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products. ENV.D.4 - Biotechnology, Pesticides and Health.

nitrogen immission standards of 170 kg $N.ha^{-1}.yr^{-1}$ (OECD 2006, table 5.9, values for The Netherlands).
For an overview of the default-values taken for the areas to be treated, please confer Table 2.8.3.2-1 The values are given in the ESD for PT18 in stables and manure (OECD, 2006):

**Table 2.8.3.2-1: Defaults for the surface area of walls and ceilings (flies) as well as floor surface with walls and ceilings (darkling beetles and red mites):**

| Category | i1 | i2 | i3 | i4 | i5 | i6 | i7/8/9/10 | i11 |
|---|---|---|---|---|---|---|---|---|
| Surface for flies (wall and roof) | 1670 | 1000 | 330 | 910 | 1160 | 970 | 1100 | 2030 |
| | **i12** | **i13** | **i14** | **i15** | **i16** | **i17** | **i18** | |
| | 1600 | 1822 | 600 | 750 | 4650 | 2820 | 3500 | |
| Surface for darkling beetles and red mites (floor surface) | **i1** | **i2** | **i3** | **i4** | **i5** | **i6** | **i7/8/9/10** | **i11** |
| | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | 750 | 1430 |
| | **i12** | **i13** | **i14** | **i15** | **i16** | **i17** | **i18** | |
| | 1110 | 1270 | 390 | 500 | 3330 | 2000 | 2500 | |

n.a. = not applicable (only poultry houses are affected by these pests)

Using the formulas given above and the default values given in the ESD (see Table 2.8.3.2-2 below) the concentration of the active substance in soil following a single land application of manure is calculated.

**Table 2.8.3.2-2: Input parameters for emission calculations to soil following treatment in stables against darking beetles/mealworms/red mites/flies**

| Parameters | Nomenclature | Value | Unit | Origin (ESD) |
|---|---|---|---|---|
| Input | | | | |
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | * | | S<br>(Appendix1: Table 7) |
| Content of active ingredient in formulation (product) | Fbioc | 480 | [g.kg] | S |
| Amount of (undiluted) product prescribed to be used per m² | Vprod | 0.00006 for flies<br>0.00012 for beetles/red mites | [kg/m²] | S |
| Dilution factor (for preparation of the working solution from the formulation (product)) | Fdil A) | 1 | [ - ] | S |
| Application days per year | days | 6 | day | S |
| Half-life for biodegradation in bulk soil | DT50bio_soil | 3.51 | day | S |
| Defaults | | | | |
| Fraction of active ingredient released | (Fstp = Fww)<br>Fstp_i1,i2,i3,i4 | 0 | [ - ] | P (Table 10) |
| | Fslurry/manure_ i1,i2,i3,i4 E) | 0.5 | [ - ] | P (Table 10) |
| | Fair F) | 0 | [ - ] | S (only when applied by fogging or aerosolisation) |
| Area of the housing for application | AREA | * | [m²] | P (Table 8) |
| Number of disinfectant applications in one year | Napp-bioc | 6 | [ - ] | P (Appendix 1: Table 9) |
| Biocide application interval | Tbioc-int B) | 60.83333333 | [ d ] | P (Table 9) |

| Parameters | Nomenclature | Value | Unit | Origin (ESD) |
|---|---|---|---|---|
| Number of manure applications for grassland | Nlapp-grass | 4 | [ - ] | D |
| Number of manure applications for arable land | Nlapp-arab | 1 | [ - ] | D |
| Manure application time interval for grassland | Tgr-int | 53 | [ d ] | D<br>(Appendix 1: Table 12) |
| Manure application time interval for arable land | Tar-int | 212 | [ d ] | D<br>(Appendix 1: Table 12) |
| Number of animals in housing for category/subcategory i1 =1 | Nanimali1 | * | [ - ] | P<br>(Appendix 1: Table 8)<br>(Appendix 1: Table 11) |
| Amount of nitrogen per animal for category/subcategory i1 =1 | Qnitrogi1 | * | [kg.d-1] | P<br>(Appendix 1: Table 11)<br>(Appendix 1: Table 13) |
| If nitrogen immission standards are applied: C) | | | | |
| Nitrogen immission standard for one year on grassland | QN,grassland | 170 | [kg.ha-1] | D<br>(Appendix 1: Table 13) |
| Nitrogen immission standard for one year on arable land | QN,arable_land | 170 | [kg.ha-1] | D<br>(Appendix 1: Table 13) |
| Conversion factor arable to grass land in case of nitrogen imission standards | ConvN | 2 | - | D |
| Standard concentration in air at 100 m from source for a source strength of 1 kg.d-1 | Cstd_air D) | 2.78E-04 | $mg/m^3$ | D |
| Mixing depth with soil, grassland | DEPTHgrassland C) | 0.1 | [ m ] | D |
| Mixing depth with soil, arable land | DEPTHarable_land C) | 0.2 | [ m ] | D |
| Density of wet bulk soil | RHOsoilwet C,D) | 1700 | [kg.m-3] | D |

D:default, S: set

I2=1: disinfectant

I3=1: spraying

I4 = 1,3,4: manure, slurry, air

* Variable input parameter depending on type of animal category

A) For example: If the formulation is diluted 1/10 (= 1:10), the dilution factor is 10-1. If the formulation (product) is also used as working solution, the dilution factor is 1.

B) At least one of the immission standards should be applied.

C) According to ESD for PT 18 No. 14. Default value of 0.05 m for grassland adjusted to 0.1 cm, which is common in The Netherlands as manure has to be injected.

D) According to Technical Guidance Document on Risk Assessment (TGD) in support of … Directive 98/8/EC, Part II (EC 2003a).

E) Degradation of the active substance in slurry/manure is not considered in the first tier. A methodology to include biodegradation in manure and slurry as second-tier approach in the emission estimation is provided in the ESD for PT 18 No. 14.

F) ESD for PT 18 No. 14: "The main emission to air occurs when the diluted formulation or spraying powder is sprayed, or fogging or aerosol treatment is applied. Most insecticide will settle soon within the housing with the droplets or powder. It is assumed for the model that the emission factor to air is zero, with the exception of fogging and aerosols for this application in which case an emission the air will be relevant."

The exposure scenario is defined for both types of agricultural soil, arable land and grassland. Calculations are performed for all animal housings where different animal categories and subcategories are kept after Elector is used against a) flies, b) darkling beetles/mealworms and c) red mites. The results are summarised in the following tables:

**Table 2.8.3.2-3: Summary of the PEC in soil (without degradation) following manure application to land for all animal categories and subcategories after treatments against a) flies:**

| Index | Category | Sub-category | Iniatial soil concentration (mg/kg wwt) | |
|---|---|---|---|---|
| | | | Grassland | Arable land |
| 1 | Cattle | Dairy cows | 0.0012 | 0.0006 |
| 2 | - | Beef cattle | 0.0007 | 0.0003 |
| 3 | - | Veal calves | **0.0041** | **0.0020** |
| 4 | Pigs | Sows, in individual pens | 0.0023 | 0.0011 |
| 5 | - | Sows in groups | 0.0029 | 0.0015 |
| 6 | - | Fattening pigs | 0.0019 | 0.0009 |
| 7 | Poultry | Laying hens in battery cages without treatment | 0.0006 | 0.0003 |
| 8 | - | Laing hens in battery cages with aeration (belt drying) | 0.0007 | 0.0003 |
| 9 | - | Laying hens in batters cages with forced drying (deep pit, high rise) | 0.0011 | 0.0005 |
| 10 | - | Laying hens in compact battery cages | 0.0007 | 0.0003 |
| 11 | - | Laying hens in free range with litter floor (partly litter floor, partly slatted) | 0.0017 | 0.0008 |
| 12 | - | Broilers in free range with litter floor | 0.0007 | 0.0004 |
| 13 | - | Laying hens in free range with grating floor (aviary system) | 0.0013 | 0.0006 |
| 14 | - | Parent broilers in free range with grating floor | 0.0007 | 0.0003 |
| 15 | - | Parent broilers in rearing with grating floor | 0.0014 | 0.0007 |
| 16 | - | Turkeys in free range with litter floor | 0.0014 | 0.0007 |
| 17 | - | Ducks in free range with litter floor | 0.0015 | 0.0007 |
| 18 | - | Geese in free range with litter floor | 0.0010 | 0.0005 |

All calculations are based on the fraction of the active substance released to the slurry waste stream unless otherwise specified.

1 Manure waste stream.

**Table 2.8.3.2-4: Summary of the PEC in soil (without degradation) following manure application to land for all animal categories and subcategories after treatments against b) darkling beetles/mealworms and c) red mites:**

| Index | Category | Sub-category | Iniatial soil concentration (mg/kg wwt) | |
|---|---|---|---|---|
| | | | Grassland | Arable land |
| 1 | Cattle | Dairy cows | 0.0016 | 0.0008 |
| 2 | - | Beef cattle | 0.0005 | 0.0002 |
| 3 | - | Veal calves | **0.0040** | **0.0020** |
| 4 | Pigs | Sows, in individual pens | 0.0028 | 0.0014 |
| 5 | - | Sows in groups | 0.0036 | 0.0018 |
| 6 | - | Fattening pigs | 0.0023 | 0.0012 |
| 7 | Poultry | Laying hens in battery cages without treatment | 0.0008 | 0.0004 |
| 8 | - | Laing hens in battery cages with aeration (belt drying) | 0.0009 | 0.0005 |
| 9 | - | Laying hens in batters cages with forced drying (deep pit, high rise) | 0.0015 | 0.0007 |
| 10 | - | Laying hens in compact battery cages | 0.0009 | 0.0005 |
| 11 | - | Laying hens in free range with litter floor (partly litter floor, partly slatted) | 0.0024 | 0.0012 |
| 12 | - | Broilers in free range with litter floor | 0.0010 | 0.0005 |
| 13 | - | Laying hens in free range with grating floor (aviary system) | 0.0018 | 0.0009 |
| 14 | - | Parent broilers in free range with grating floor | 0.0009 | 0.0004 |
| 15 | - | Parent broilers in rearing with grating floor | 0.0019 | 0.0010 |
| 16 | - | Turkeys in free range with litter floor | 0.0020 | 0.0010 |
| 17 | - | Ducks in free range with litter floor | 0.0021 | 0.0010 |
| 18 | - | Geese in free range with litter floor | 0.0015 | 0.0007 |

All calculations are based on the fraction of the active substance released to the slurry waste stream unless otherwise specified.

1 Manure waste stream

In the calculations presented the total number of applications is increased from 5 to 6, taking into account the possibility that one of the applications could be made at double the treatment rate.

The worst-case soil PIECs calculated above take into account the nitrogen limitations adhered to in the Netherlands for the arable and grassland situations. Following each land application of manure the active substance is assumed to be evenly distributed in the upper soil layer (20 cm for arable land due to ploughing and 10 cm for grassland).

The worst-case concentrations of the active substance in soil following a single land application of manure are **0.0041 (4.1 µg/kg wwt) and 0.0020 mg/kg wwt (2 µg/kg wwt) for grassland and arable land, respectively**. These values represent the concentration in soil to which organisms are exposed to immediately after the first application.

No information is available on the potential degradation of the active substance in manure and therefore no degradation is assumed for worst-case reasons.

Potential accumulation following repeated applications of manure to land is now considered. Once in soil, residues of the active substance spinosad could accumulate following one or more applications of manure to land each year. Under aerobic conditions the average degradation rates of the active substance i.e. $DT_{50}$ values are clearly under 70 days at 12℃ (for both spinosyn A and spinosyn D). Land applications of manure are only conducted once per year for arable land and therefore low accumulation of the active substance in soil is expected under these circumstances. However, a maximum of four manure applications can be made to grassland which are assumed to be made between 1st February and 1st September and equally spaced every 53 days in accordance with the ESD.

For the risk assessment i.e. PEC/PNEC comparison, the PECsoil which is relevant for the terrestrial ecosystem is the one which considers the accumulation of substance over the years after the last application. As a realistic worst-case assumption for exposure, it is assumed that manure application takes place for 10 consecutive years.

For a more realistic appreciation, the average $Clocal_{soil}$ over the first 30 days period after the last application of manure in the 10th year is determined, considering degradation. For the ecosystem a period of 30 days is taken as a relevant time period with respect to chronic exposure of soil organisms.

**Derivation of the initial soil concentration after 10 years of manure application**

At the end of each year, a fraction of the initial concentration remains in the top-soil layer (Facc). This fraction differs in dependence on the application interval, i.e. it is lower for arable land (with an application interval of 365 days) than for grassland (with an application interval of 53 days during 1st of February and 1st of September).

The initial concentration after 10 applications of manure is given by the equation below (incorporating equations 62 and 63 from TGD). $Csludge_{soil\ 10}$ has been replaced by $Cmanure_{soil\ 10}$. Deposition via air can be excluded.

$$Cmanure_{soil\ 10}(0) = Cmanure_{soil\ 1}(0) \times \left[1 + \sum_{n=1}^{9} Facc^{n}\right]$$

Where, the $Facc^n$ can be calculated as follows (using equation 61 from TGD):

$$Facc = e^{-365\ k} \text{ for arable land}$$

$$Facc = e^{-53\ k} \text{ for grassland}$$

With “k” as the first order rate constant for removal from top soil. Only biodegradation in soil is taken into account. A $DT_{50,\ field}$ of 3.51 day was selected based on a UK study, which indicated $DT_{50,\ field}$ values of 2.37 and 3.51 days for spinosyn A and spinosyn D, respectively. For metabolites, the $DT_{50,\ field}$ was 2.11 and 3.77 days for spinosyn B and N-demethylated spinosyn D, respectively.

The following equation can be used to convert $DT_{50}$ to a rate constant for biodegradation in soil (equation 29 from TGD):

$$k = \ln 2 / DT_{50}$$

Since the four-fold annual application of manure to grassland is already taken into account for the calculation of PIECgrs-N, which is equal to $Cmanure_{soil\ 1}(0)$, the calculated value for $C_{soil\ 10}$ (0) does contain the 40-fold manure application to grassland as assumed in the ESD for PT18. However, it should be stated that this methodological approach is overestimating the realistic spinosad concentrations after 10 years of consecutive applications in grassland-soil since it is based on simplified assumptions: as a starting point for the calculation of the concentration in soil after 10 years ($=Csoil_{10}(0)$) the value for PIECgrs-N is used, which does not reflect the degradation in soil for the 53 days in between the four manure applications. Moreover the assessment performed for the nine years of manure application to follow is done under the premise that only 53 days are in between the consecutive applications which applies only for the time period between 1st of February and 1st of September. Therefore, the value calculated for $Csoil_{10}(0)$ does clearly comprise a number of worst-case assumptions and thus overestimates the realistic concentration.

Using the formulae given above, the theoretical maximum concentration in soil after consecutive manure/slurry applications over a 10 years period is estimated.
The resulting initial concentration in soil after 10 years of applications of manure/slurry amounts to **0.84 µg/kg wwt and 1.64 µg/kg wwt** for grassland and arable land, respectively.
The concentration in soil is not constant in time. The concentration will be higher just after manure/slurry application and lower with time due to removal processes. Therefore, the concentration needs to be averaged over a certain time period. According to Chapter 3 of the TGD for Risk Assessment (2003) an averaging time of 30 days should be considered for the ecosystem after application of manure/slurry.

**Calculation of PEClocal$_{soil}$**

PEClocal$_{soil}$ is derived from the average concentration in soil over 30 days after 10 years of application (Clocal$_{soil}$) using the equation below (equation 55 from TGD). For the calculation, aerial deposition flux is not considered ($D_{air}$ = 0) and an averaging time (T) of 30 days is taken for the ecosystem as relevant time period with respect to chronic exposure of soil organisms (TGD 2003, Table 11).

$$\mathrm{Clocal_{soil}} = \frac{\mathrm{D_{air}}}{\mathrm{k}} + \frac{1}{kT}\left[C_{soil}(0) - \frac{D_{air}}{k}\right] \times \left[1 - e^{-kT}\right]$$

Using the equation given above, the average concentration in soil over 30 days is estimated.
The resulting average concentration in soil over 30 days (Clocal$_{soil}$ = PEClocal$_{soil}$) amounts to **0.14 µg/kg wwt (grassland) and 0.28 µg/kg wwt (arable land),** respectively, for the assessment of spinosad used as insecticide in stables or poultry houses. Both concentrations are used for the calculation of the concentration of spinosad in soil pore water.

**PEClocal $_{soil}$ of major soil metabolites**

According to laboratory studies, degradation of the active substance in soil leads to the formation of two significant soil metabolites under aerobic conditions, spinosyn B (molecular weight 717.9 g/mol) and N-demethylated spinosyn D (molecular weight 753.0 g/mol). In studies conducted at relevant dose rates, the metabolite spinosyn B was observed at a maximum level of 39 to 67% of initial levels after 28 to 182 days and the metabolite N-demethylated spinosyn D was observed at a maximum level of 28 to 68% of initial levels after 28 to 237 days. Therefore the maximum potential concentrations of the metabolites in soil (wet weight) can be calculated as below:

For grassland

$$\text{Concentration of spinosyn B in soil} = 0.14 \times \frac{67}{100} \times \frac{717.9}{731.98} = 0.09\,\mu\text{g/kg wwt}$$

$$\text{Concentration of N-demethylated spinosyn D in soil} = 0.14 \times \frac{68}{100} \times \frac{753.0}{746.0} = 0.10\,\mu\text{g/kg wwt}$$

For arable land

$$\text{Concentration of spinosyn B in soil} = 0.28 \times \frac{67}{100} \times \frac{717.9}{731.98} = 0.18\,\mu\text{g/kg wwt}$$

$$\text{Concentration of N} - \text{demethylated } sp\text{inosyn D in soil} = 0.28 \times \frac{68}{100} \times \frac{753.0}{746.00} = 0.19\,\mu\text{g/kg wwt}$$

The maximum concentration of the metabolites spinosyn B and N-demethylated spinosyn D are **0.09 and 0.10 µg/kg (wet weight) for grassland and 0.18 and 0.19 µg/kg (wet weight) for arable land**, respectively.
In laboratory soil degradation studies, the metabolites spinosyn B and N-demethylated spinosyn D are shown to be degraded in soil with average DT50 values of 194 and 531 days at 25℃, respectively. However, there is also available field data for the degradation of the metabolites spinosyn B and N-demethylated spinosyn D in soil and this information shows that under more representative conditions the metabolites degrade with an average DT50 value of 2.11 and 3.77 days, respectively. Therefore it is not expected that significant residues of the metabolites will accumulate.

#### 2.8.3.3 PEC in groundwater

A simple Tier I assessment of the predicted concentration in groundwater (PECgw) has been carried out by calculating the porewater concentration of the active substance in soil according to the TGD (Technical Guidance Document), as suggested by the ESD. The Tier 1 assessment is based on the assumption that the concentration in groundwater will not exceed the maximum soil porewater concentration.
Elector is used inside animal housings and therefore direct application to soil is not relevant. Potential exposure to soil is anticipated via application of stored manure to land, subsequent leaching from affected areas to groundwater. It should be noted that this represents a very simplified approach, neglecting transformation processes and dilution in deeper soil layers.
Once present in soil, the porewater concentration of the active substance is calculated using the equation below (eq 67 from TGD):

$$\text{PEClocal}_{\text{soil, porew}} = \frac{\text{PEClocal}_{\text{soil}} \times \text{RHOsoil}}{\text{K}_{\text{soil-water}} \times 1000}$$

Where $K_{soil\text{-}water}$ is given by (incorporating eqs 22, 23, 24 from TGD):

$$K_{soil-water} = \left( Fair_{soil} \times \frac{HENRY}{R \times TEMP} \right) + Fwater_{SOIL} + \left( Fsolid_{SOIL} \times \frac{Kp_{soil}}{1000} \times RHOsolid \right)$$

Using this exposure scenario and the formulae given above, the theoretical maximum concentration in groundwater is estimated in the table below:

**Table 2.8.3.3-1: Determination of the PEC in groundwater ($PEC_{GW}$)**

| Parameter | | Description | | Value | |
|---|---|---|---|---|---|
| | | | | grassland | arable land |
| $PEClocal_{soil}$ | = | Predicted environmental concentration in soil (mg/kg wwt), *Values for grassland and arable land* | = | 0.00014 | 0.00028 |
| $RHOsoil_{wet}$ | = | Bulk density of wet soil (kg wet wt/m$^3$). | = | 1700 (default) [1] | |
| $Fair_{soil}$ | = | Fraction of air in soil compartment (m$^3$/m$^3$) | = | 0.2 (default) [1] | |
| HENRY | = | Henry's law constant (Pa m$^3$/mol) | = | 1.89 x 10$^{-7}$ Pa | |
| R | = | Gas constant (Pa m$^3$/mol/k) | = | 8.314 (default) [1] | |
| TEMP | = | Temperature of the air-water interface | = | 285 (default) [1] | |
| $Fwater_{soil}$ | = | Fraction of water in soil compartment (m$^3$/m$^3$). | = | 0.2 (default) [1] | |
| $Fsolid_{soil}$ | = | Fraction of solids in soil compartment (m$^3$/m$^3$). | = | 0.6 (default) [1] | |
| Kpsoil | = | Partition coefficient organic carbon-water (L/kg), | = | 137.6 | |
| RHOsolid | = | Density of the solid phase (kg/m$^3$) | = | 2500 (default) [1] | |
| $K_{soil\text{-}water}$ | = | Soil-water partitioning coefficient (mL/g), *calculated using the equation given.* | | 206.6 | |
| **$PEClocal_{soil,\ porew}$** | = | Resulting soil porewater concentration, (µg/L). | = | **0.0012 µg/L** | **0.0023 µg/L** |
| [1] Default value from general TGD on Risk Assessment. | | | | | |

Using this simple exposure scenario the maximum potential concentration of the active substance in groundwater (assumed to be, as a worst-case, the maximum porewater concentration) is **0.0012 or 0.0023 µg/L** for grassland and arable land situations, respectively. As mentioned above, this estimation represents the pore water concentration in soil resulting from the worst-case maximum soil concentration. It does not take into account transformation or dilution in deeper soil layers.
The potential concentrations in groundwater of any soil metabolites will be at correspondingly lower levels.
According to Council Directive 98/83/EC relating to the quality of water intended for human consumption, the maximum admissible concentration for pesticides in drinking water is 0.1 µg/L for substances considered separately. Therefore, overall Elector can be used safely throughout the EU without an unacceptable risk to groundwater.

#### 2.8.3.4 PEC in surface water

Use of Elector is not carried out near surface water bodies. However, in line with the emission scenario outlined in the ESD, following use of the formulated product in animal houses and subsequent land application of manure, exposure of the active substance to surface water could potentially occur as a result of run-off from areas treated with manure. The predicted environmental concentration (PEC) of the active substance in surface water has been determined using a Tier I procedure provided in the ESD calculated from the pore water concentration according to the method of Montforts (1999)[7] and assuming a dilution of a factor of 10 on entry of run-off water into receiving water.

[7] Montforts, M.H.M.M. (1999): Environmental risk assessment for veterinary medicinal products. Part 1. Other than GMO-containing and immunological products. First update National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands, Report no. 601300 001.

The potential concentration of the active substance in surface water is given in the equation below:

$$PECsurface\ water = \frac{PEClocal_{soil,\ porew}}{DILUTIONrun - off}$$

Using this exposure scenario and the equation above, the potential concentration of the active substance in surface water is determined for arable land and grassland in the table below:

**Table 2.8.3.4-1:Determination of the PEC in surface water ($PEC_{SW}$) resulting from run-off from grassland and arable land**

| Parameter | | Description | | Value | |
|---|---|---|---|---|---|
| | | | | Grassland | Arable - land |
| $PEClocal_{soil,\ porewater}$ | = | Soil porewater concentration, (µg/L) from grassland and arable land<br>*Value taken from table 2.8.3.3-1* | | 0.0012 | 0.0023 |
| $DILUTION_{run\text{-}off}$ | = | Dilution factor (no units),<br>Default value x 10 taken from Table 6.1 in the ESD. | = | 10 | |
| **$PEC_{SW}$** | = | Resulting concentration in surface water (µg/L) from grassland and arable land | = | **0.00012 µg/L** | **0.00023 µg/L** |

The worst-case concentration of the active substance in surface water is estimated to be **0.00023 µg/L**, resulting from run-off following land applications of stored manure to arable land (i.e. covered soil).
In laboratory studies no significant degradation products (i.e. >10%) were observed in the water or sediment layers during the degradation of the active substance in aquatic systems, therefore predicted environmental concentrations of any metabolites in water have not been calculated.

#### 2.8.3.5 PEC in sediment

To determine the potential concentration of the active substance in sediment, the procedure outlined in the general TGD on Risk Assessment can be used, as suggested by the ESD. The potential concentration of the active substance in sediment is determined by calculating the concentration in freshly deposited sediment i.e. suspended matter, using the following equation (equation 50 from the TGD):

$$\mathrm{PEClocal_{sed}} = \frac{\mathrm{K_{susp-water}}}{\mathrm{RHOsusp}} \times \mathrm{PEClocal_{surface\ water}} \times 1000$$

where $K_{susp\text{-}water}$ is (using equations 23 and 24 from TGD):

$$K_{susp-water} = Fwater_{susp} + \left( Fsolid_{susp} \times \frac{Kp_{susp}}{1000} \times RHOsolid \right)$$

The potential concentration of the active substance in sediment is summarised in the table below:

**Table 2.8.3.5-1: Determination of the PEC in sediment ($PEC_{sed}$)**

| Parameter | | Description | | Value | |
|---|---|---|---|---|---|
| | | | | Grassland | arable land |
| $Fwater_{susp}$ | = | Volume fraction of water in suspended matter ($m^3/m^3$). | = | 0.9 (default) [1] | |
| $Fsolid_{susp}$ | = | Volume fraction of solids in suspended matter ($m^3/m^3$). | = | 0.1 (default) [1] | |
| $Kp_{susp}$ | = | Partition coefficient organic carbon-water (L/kg) | = | 137.6 | |
| RHOsolid | = | Bulk density of the solid phase ($kg/m^3$) | = | 2500 (default) [1] | |
| $K_{susp\text{-}water}$ | = | Suspended matter-water partitioning coefficient ($m^3/m^3$), *calculated using the equation given (TGD 23, 24).* | | 35.3 | |
| RHOsusp | = | Bulk density of (wet) suspended matter ($kg/m^3$) | = | 1150 (default) [1] | |
| $PEClocal_{surface\ water}$ | = | Predicted environmental concentration in surface water (µg/L), from arable land (from grassland)<br>*Value taken from table 2.8.3.4-1* | = | 0.00012 µg/L | 0.00023 µg/L |
| **$PEClocal_{sed}$** | = | Resulting predicted environmental concentration in freshly deposited sediment (µg/kg wwt), from arable land or grassland<br>*Using the equation above (TGD 50)* | = | **0.0037 µg/kg wwt** | **0.0071 µg/kg wwt** |
| [1] Default value from general TGD on Risk Assessment. | | | | | |

Using this simple exposure scenario the maximum potential concentration of the active substance in sediment is **0.0037 and 0.0071 µg/kg wwt for grassland and arable land.**

**<u>Higher tier assessment of PECsed</u>**

As the calculation of PECsed with TGD-equation 50 shows an exceedance of the PNEC value for sediment dwellers, a higher tier assessment is conducted.
The assessment of risk to sediment dwelling organisms is refined using the FOCUS modelling approach for surface water (SWASH) to generate Step 3 PECs. FOCUS SWASH is a surface water modelling tool that estimates concentrations (PECs) in sediment due to agricultural use of substances applied to crops.
The basis for this assessment is the maximum PEClocal in soil as calculated in section 2.8.3.2 of 0.28 µg as/kg wwt soil as this is the worst case value.
A FOCUS calculation was already submitted for spinosad in Sweden in the context of the national registration in March of 2011 (Shannon and Andrew, 2011). This study can be used to assess spinosad concentrations in sediment due to soil run-off.
In the calculation by Shannon and Andrew (2011) it is assumed that the 'crop' was grass. The critical model inputs are based on the final CA-report for spinosad. Loss of spinosad is assumed to be via exposure pathways such as run-off or drainage to surface water bodies, as consequence of amending grassland soil with slurry or manure potentially contaminated with spinosad from animal housings.
In SWASH, ten realistic worst-case scenarios with respect to surface water exposure are calculated, which are representative of the range of grassland soil types in the EU overall. Three water body types are assessed (ditch, stream and pond) and potential concentrations of Spinosad from drainage and runoff are estimated by specific simulation models that are linked by the SWASH shell. These models are MACRO, PRZM and TOXSWA.
In order to derive an input for the FOCUS surface water model, this PEC is converted into its equivalent agricultural application rate in weight of spinosad per hectare (hectare = 10,000 $m^2$) of soil using standard FOCUS soil methods. This value is calculated in a worst

case manner without taking into account any degradation or crop interception. The maximum number of applications per year is set to 4 for grassland.
For a soil concentration of 9 µg/kg wwt soil, the model calculation yielded a sediment concentration due to run-off of 0.0120 µg /kg wwt sediment.
Assuming that the FOCUS model has a linear dependency based on soil concentration, the resulting concentration for spinosad in sediment can be extrapolated.
The $PEClocal_{soil}$ and the soil concentration used in the FOCUS calculation differ by a factor of 0.031. Therefore, for a $PEClocal_{soil}$ of 0.28 µg/kg wwt soil a sediment concentration of **0.0004 µg /kg wwt sediment** is derived.

#### 2.8.3.6 PEC for atmosphere

Elector is used as a low pressure spray in animal houses. Furthermore, based on the vapour pressure (< $10^{-7}$ Pa at ambient temperature) and the Henrys Law Constant (1.89 x $10^{-7}$ and 2.32 x $10^{-5}$ Pa×m³/mol at 25℃ for spinosyn A and spinosyn D, r espectively), volatilisation is negligible.
A further study on volatilisation from plant and soil surfaces yielded < 2% exhalation of spinosyn A or D within 24 h.
The calculated half-live of spinosad in the troposphere due to indirect photodegradation resulted in half-lives of 20 min for spinosyn A and 19 min for spinosyn D.
Therefore, spinosad is not volatile and even when entering the atmosphere, the compound is rapidly degraded by photochemical processes and neither accumulation in the air nor transport over longer distances is to be expected.
In the ESD for PT18 in stables and manure storage systems it is assumed there is no emission to the atmosphere for this group of biocides with this intended use i.a. for spinosad.

#### 2.8.3.7 PEC in biota

**Primary poisoning**
Primary poisoning is the direct consumption of insecticide by birds or mammals. Primary poisoning of non-target organisms is not a topic since spinosad is used as an indoor spray application.

**Secondary poisoning**
After the utilisation of Elector, birds and mammals may be poisoned secondarily by the consumption of earthworms from contaminated soil or contaminated fish. The partition coefficient log $K_{ow}$ at 23 ℃ is 2.78-4.01-5.16 at pH 5, 7, 9 for spino syn A and 3.23-4.53-5.21 for spinosyn D (3.91 and 4.38 in unbuffered water for spinosyn A and spinosyn D, respectively). Log $K_{ow}$ values above 3 at pH 7 or higher indicate that bioaccumulation can occur. Furthermore, the highest experimentally determined BCF was 115 L/kg, which is above the trigger value for bioaccumulation potential.

**<u>Secondary poisoning via the consumption of contaminated worms</u>**
For the assessment of secondary poisoning via the consumption of contaminated worms, the PEC corresponds to $C_{earthworm}$ and can be calculated according to the EU TGD part II chapter 3.8.3.7, equation 82c from TGD:

$$C_{earthworm} = \frac{BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut} \text{ x } CONV_{soil}}{1 + F_{gut} \text{ x } CONV_{soil}}$$

Where, $BCF_{earthworm}$ is (according to equation 82d from TGD):

$$BCF_{earthworm} = (0.84 + 0.012\ K_{ow})/RHO_{earthworm}$$

And, $CONV_{soil}$ can be derived as follows (equation 82b from TGD, all parameters are default values):

$$CONV_{soil} = RHO_{soil} /(F_{solid} \text{ x } RHO_{solid})$$

For the assessment of PECbiota, the Csoil value is reduced to 50% according to the TGD (EC, 2003). In the TGD, a scenario where 50% of the diet comes from a local area and 50% of the diet comes from a regional area is considered. The PECregional, as previously mentioned, was not predicted since Elector is not used at a sufficiently large scale to warrant such prediction.
Using the equations given above, the Predicted Environmental Concentration in earthworms is estimated in the table below:

**Table 2.8.3.7-1: Determination of the predicted environmental concentration in earthworms**

| Parameter | | Description | | Value | |
|---|---|---|---|---|---|
| | | | | **grassland** | **arable land** |
| $C_{soil}$ | = | 50% of the local concentration in soil [mg x $kg^{-1}$ wwt] ~ $PEClocal_{soil}$ / 2<br>*Value taken from section 2.8.3.2 and adapted to the diet assumptions (expressed as wwt)* | = | $7.0 \times 10^{-5}$ | $1.4 \times 10^{-4}$ |
| $K_{ow}$ | = | Octanol/water partition coefficient [-] for the active substance (see note below) | = | 23988 | |
| $RHO_{earthworm}$ | = | Density of earthworm [$kg_{wwt}$ x $L^{-1}$] | = | 1 (Default)[1] | |
| $BCF_{earthworm}$ | = | Bioconcentration factor for earthworm on wet weight basis [L × $kg_{wet\ earthworm}^{-1}$]<br>*TGD, Equation 82d* | = | 289 | |
| $F_{gut}$ | = | Fraction of gut loading in worm [$kg_{dwt}$ x $kg_{wwt}^{-1}$] | = | 0.1 (Default)[1] | |
| $CONV_{soil}$ | = | Conversion factor for soil concentration wet-dry weight soil [$kg_{wwt}$ x $kg_{dwt}^{-1}$] | = | 1.133333 (Default)[1] | |
| $C_{,porewater}$ | = | Predicted Environmental Concentration in pore water [mg x $L^{-1}$] ~ $PEClocal_{soil,porewater}$<br>*Value taken from table 2.8.3.3-1* | = | $1.2 \times 10^{-6}$ | $2.3 \times 10^{-6}$ |
| ***Cearthworm*** | = | Predicted Environmental Concentration in earthworms [mg × $kg_{wet\ earthworm}^{-1}$]<br>*TGD, Equation 82c* | = | **$6.0 \times 10^{-4}$ = 0.60 µg/kg** | **$3.3 \times 10^{-4}$ =0.33 µg/kg** |

[1] Default value from general TGD on Risk Assessment.
Note: Maximal value obtained in unbuffered water (log Kow = 4.38 for spinosad D).

**<u>Secondary poisoning via the consumption of contaminated fish</u>**

For the assessment of secondary poisoning via the consumption of contaminated fish, the $PEC_{oral,predator}$ can be calculated according to the EU TGD part II chapter 3.8.3.4, equation 76 from TGD:

$$PEC_{oral,predator} = PEC_{water} \times BCF_{fish} \times BMF$$

Furthermore, the same scenario is used as for the terrestrial food chain (see above): i.e. 50% of the diet comes from PEClocal and 50% from PECregional.

**Table 2.8.3.7-2: Determination of the predicted environmental concentration in fish**

| Parameter | | Description | | Value | |
|---|---|---|---|---|---|
| | | | | **grassland** | **arable land** |
| $PEC_{surface\ water}$ | = | 50% of the Predicted Environmental Conc. in water [µg × $L^{-1}$]<br>*Value taken from table 2.8.3.4-1 and adapted to the diet assumptions* | = | 0.00006 | 0.00012 |
| BCF | = | Bioconcentration factor for fish on wet weight basis [L × $kg_{wet\ fish}^{-1}$]<br>*Experimental value* | = | 115 | |
| BMF | = | Biomagnification factor in fish [-] | = | 1 (Default)[1] | |
| **$PEC_{oral,\ predator}$** | = | Concentration in the food of the predator [µg × $kg_{wet\ fish}^{-1}$] | = | **0.007** | **0.013** |
| [1] Default value from general TGD on Risk Assessment.<br>Note: Maximal value obtained in the bioconcentration study | | | | | |

The concentrations of spinosad to which predators (mammals and/or birds) can be exposed via the aquatic or terrestrial food chain, are calculated as the $PEC_{oral,predator}$, which is the estimated concentration of spinosad that can be found in fish or earthworm. The worst-case concentrations obtained in the tables above are **0.60 µg/kg for earthworm-eating predators and 0.013 µg/kg for fish-eating predators.**

### 2.8.3.8 Non compartment specific exposure relevant to the food chain

The very low predicted concentrations of spinosad in environmental compartments as well as in organisms being food for non-target birds and mammals suggest that a secondary exposure route to man via the food chain is unlikely for this use pattern. There is no need to assess this exposure route further.

### 2.8.3.9 PEC calculations via STP route

After mandatory emptying the housing cleaning has to be carried out. The liquid waste is collected in tanks and may be discharged to the sewer (connected to an STP). Discharge of poultry houses cleaning water to the municipal STP might be possible, although this is no common procedure for professionals and regulated by national legislation.
In contrast, non-professionals may discharge waste water containing manure/slurry to the public (municipal) sewer.
If liquid wastes are discharged to the sewer, the calculation is made for the standard STP.
The model presented in the ESD comprises a calculation of the amount emitted to waste water, either being treated in an on-farm (private) waste water treatment plant (WWTP) or a municipal sewage treatment plant (STP).
The worst-case emission rate calculated is transformed to an environmental concentration ($Clocal_{effluent}$) which represents the PEC in the STP which the microorganisms are exposed to. Following this compartment the spinosad concentration in the effluent will be diluted in the surface water.
The soil compartment can also be contaminated through the fertilisation of agricultural soil by means of the application of sewage sludge coming from the STP. Therefore, the $Clocal_{soil}$ has to be calculated.
The PEC calculations were based on Chapter 3 of the TGD for Risk Assessment (European Commission, 2003).

Following the use of Elector in poultry houses, the active substance is emitted to the waste water. The resulting concentration is given by the equation below (see equation 34 from the ESD):

$$Qai\text{-}stp = F \times Qai\text{-}prescr$$

Where, Qai-prescr is (equation 11 from ESD):

$$Qai\text{-}prescr = 10^{-3} * Vprod\text{-}uins * Fbioc * AREA / AREAui$$

According to the ESD, only the animal species kept in poultry houses within certain types of housing are considered (relevant subcategories: 8, 11, 12, 16, 17, 18) for professional use and the assumption has been made that a discontinuous process is involved with one occurrence every month. This means a peak release from one application at the time reaching the WWTP. According to the ESD, table 5.4, the fraction of the insecticide, i.e. the active ingredient, reaching the waste water is 0.2 for all categories-subcategories if applied as a spray.

**Table 2.8.3.9-1: Summary of $Elocal_{water}$ for all relevant categories**

| Index i1 | Category | Sub-category | Emission rate to STP (g/d) according to application | |
|---|---|---|---|---|
| | | | **Flies** | **Darkling beetles/ mealworms/red mites** |
| 8 | Poultry | Laying hens in battery cages with aeration (belt drying) | 6.34 | 8.64 |
| 11 | - | Laying hens in free range with litter floor (partly litter floor, partly slatted) | 11.69 | 16.47 |
| 12 | - | Broilers in free range with litter floor | 9.22 | 12.79 |
| 16 | - | Turkeys in free range with litter floor | 26.78 | 38.36 |
| 17 | - | Ducks in free range with litter floor | 16.24 | 23.04 |
| 18 | | Geese in free range with litter floor | 20.16 | 28.80 |

In summary, following the use of Elector to treat poultry houses and after stable cleaning, considering that a discontinuous process is involved with one occurrence every month, **the worst-case emission rate in waste water is 38.36 g/d.** An example calculation is presented in the table below to aid clarification.

**Table 2.8.3.9-2: Example calculation: determination of emission rate to STP for category i16 against red mites (turkeys in free range with litter floor)**

| Parameter | | Description | | Value |
|---|---|---|---|---|
| Vprod-uins | = | Amount of product prescribed to be used for area specified for application [L]<br>*Value based on formulation label (30 mL product per 250 $m^2$ or 0.12 mL/$m^2$)* | = | 0.00012 |
| Fbioc | = | Content of active ingredient in formulation [g/L] | = | 480 |
| AREA | = | Area of the housing for application ($m^2$).<br>*Default value taken from Table 5.2 of the ESD.* | | 3330 |
| AREAui | = | Area to be treated with amount prescribed for application [$m^2$]<br>*Value taken from formulation label (in this case per unit area).* | = | 1 |
| Qai-prescr | = | Amount of active ingredient used per square meter of area for one application [kg/$m^2$]<br>*Determined using the equation above.* | = | 0.192 |
| F | = | Fraction of active ingredient released [-]<br>*Default value taken from Table 5.2 of the ESD.* | = | 0.2 |
| **Qai-stp** | = | Amount of active ingredient reaching the standard STP [kg/d]<br>*Determined using the equation above.* | = | **0.0383<br>= 38.36 g/d** |

The local emission to a standard STP or an on-site waste water treatment plant, the so-called Qai-STP from Table 2.8.3.9-2, is the highest amount of spinosad emitted to waste water (=$Elocal_{water}$ in the TGD). This spinosad load is subsequently treated in the mentioned WWTP or STP.
No information is available on the potential degradation of the active substance in waste water and therefore no degradation is assumed for worst-case reasons.

The highest amount of spinosad emitted to waste water, which is subsequently treated in a WWTP or STP, was estimated ($Elocal_{water}$ = 38.36 g/d). The parameter $Elocal_{water}$ is the time-related emission rate resulting from one application event. Considering information about the receiving environmental compartment (e.g. size of STP) the emission rate can be transformed to an environmental concentration (Clocal).
The worst-case concentration the microorganisms are exposed to in the sewage treatment plant can be calculated with the equation below (see equation 33 of TGD):

$$Clocal_{eff} = Clocal_{inf} \times Fstp_{water}$$

Where, $Clocal_{inf}$ is the influent concentration in untreated waste water and is calculated with the equation 32 of the TGD:

$$Clocal_{inf} = \frac{\mathrm{Elocal_{water}} \ \mathrm{x}\, 10^6}{\mathrm{EFFLUENT_{stp}}}$$

Where, the fraction of emission directed to water by STP ($Fstp_{water}$) is estimated with the Simple Treat Model (appendix II of TGD, taking into account that spinosad is not biodegradable, a Henry law constant of 1.89 x $10^{-7}$ Pa x $m^3$ x $mol^{-1}$ from the less volatile spinosyn compound and a log Kow of 4.38).
The parameter $Clocal_{eff}$ can also be regarded as the $PEC_{STP}$ of spinosad (*cf.* TGD for Risk Assessment, Equation 38).
Using the formulae given above and the default values for the parameters given in the TGD, the resulting worst case concentration of the active substance in the effluent of the STP after treatment is calculated in the table below for category i16 – treatment against red mites (turkeys in free range with litter floor) :

**Table 2.8.3.9-3 Determination of the predicted environmental concentration in the effluent ($PEC_{STP}$)**

| Parameter | | Description | | Value |
|---|---|---|---|---|
| $Elocal_{water}$ | = | Local emission rate to waste water [kg × day$^{-1}$] *Taken from table 2.8.3.9-2* | = | 0.0383 |
| $EFFLUENT_{stp}$ | = | Sewage treatment plant effluent discharge rate [L × day$^{-1}$] *data of TGD: "waste water flow of 200 L per capita per day for a population of 10,000 inhabitants"* | = | 2,000,000 (Default)[1] |
| $Clocal_{inf}$ | = | Influent conc. in untreated waste water [mg × L$^{-1}$] *TGD, equation 32* | = | 0.0192 |
| $Fstp_{water}$ | = | Fraction of emission directed to water by STP [-] *Appendix II of TGD, no biodegradability* | = | 0.64 |
| $Clocal_{eff}$ | = | Total concentration of a.s. in the STP effluent [mg × L$^{-1}$] *TGD, equation 33* | = | 0.0123 |
| **$PEC_{STP}$** | = | PEC for microorganisms in the STP [mg × L$^{-1}$] *TGD, equation 38* | = | **0.0123 = 12.3 µg/L** |
| [1]Default value from general TGD on Risk Assessment. | | | | |

### 2.8.3.10 $PEC_{surface\ water}$ and $PEC_{sediment}$ (via $sludge_{STP}$ application)

**$PEC_{surface\ water}$ via STP**

The effluent of the sewage treatment plant is diluted into the surface water. For the following calculations, complete mixing of the effluent in surface water is assumed and volatilisation, degradation and sedimentation are ignored (for the calculation of the initial concentration) because of the short distance between the point of effluent discharge and the exposure location.

Using the following equation (equation 45 of TGD), the local concentration in surface water is calculated in the table below:

$$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} \text{ x } SUSP_{water} \text{ x } 10^{-6}) \text{ x } DILUTION}$$

**Table 2.8.3.10-1: Determination of the predicted environmental concentration in surface water via STP ($PEClocal_{water}$ via STP)**

| Parameter | | Description | | Value |
|---|---|---|---|---|
| $Clocal_{eff}$ | = | Total concentration of a.s. in the STP effluent [mg × $L^{-1}$]<br>*TGD, equation 33* | = | 0.0123 |
| $Foc_{susp}$ | = | Weight fraction organic carbon in susp. soils [kg × $kg^{-1}$] | = | 0.1 (Default)[1] |
| *$Kp_{susp}$* | = | Partition coefficient solid-water in suspended matter [L × $kg^{-1}$] | = | 137.6 |
| $SUSP_{water}$ | = | Conc. of suspended matter in the river [mg × $L^{-1}$] | = | 15 (Default)[1] |
| DILUTION | = | Dilution factor [-] | = | 10 (Default)[1] |
| **$Clocal_{water}$** | = | Local conc. of a.s. in surface water during emission episode [mg × $L^{-1}$]<br>*TGD, equation 45* | | **0.0012** |
| **$PEClocal_{water}$** | = | Predicted environmental concentration during episode [mg × $L^{-1}$]<br>*TGD, equation 48 (no PECregional)* | = | **0.0012**<br>**= 1.2 µg/L** |
| [1] Default value from general TGD on Risk Assessment. | | | | |

**PECsediment via STP**

The potential concentration of the active substance in sediment is determined by calculating the concentration in freshly deposited sediment i.e. suspended matter, this is achieved using the equation 50 from the TGD and the values of $Kp_{susp}$ and $PEClocal_{water}$ as input parameters (confer section 2.8.3.5).
The calculation is presented in the following table:

**Table 2.8.3.10-2: Determination of the PEC in sediment via STP ($PEC_{sed}$ via STP)**

| Parameter | | Description | | Value |
|---|---|---|---|---|
| $Fwater_{susp}$ | = | Volume fraction of water in suspended matter ($m^3/m^3$). | = | 0.9 (default) [1] |
| $Fsolid_{susp}$ | = | Volume fraction of solids in suspended matter ($m^3/m^3$). | = | 0.1 (default) [1] |
| $Kp_{susp}$ | = | Partition coefficient organic carbon-water (L/kg), | = | 137.6 |
| RHOsolid | = | Bulk density of the solid phase ($kg/m^3$) | = | 2500 (default) [1] |
| $K_{susp-water}$ | = | Suspended matter-water partitioning coefficient ($m^3/m^3$),<br>*calculated using the equation given (TGD 23, 24).* | | 35.3 |
| RHOsusp | = | Bulk density of (wet) suspended matter ($kg/m^3$) | = | 1150 (default) [1] |
| $PEClocal_{surface\ water}$ | = | Predicted environmental concentration in surface water (mg/L)<br>*Value taken from table 2.8.3.10-1* | = | 0.0012 mg/L |
| **$PEClocal_{sed}$** | = | Resulting predicted environmental concentration in freshly deposited sediment (mg/kg wwt), from arable land or grassland<br>*Using the equation above (TGD 50)* | = | **0.04**<br>**= 36.8 µg/kg wwt** |
| [1] Default value from general TGD on Risk Assessment. | | | | |

#### 2.8.3.11 $PEClocal_{soil}$ and $PEC_{groundwater}$ via sludge application

Guidance for calculating PEClocal in soil due to application of sewage sludge in agriculture is given in the TGD.
When soil is fertilised with sludge from the STP, a concentration of spinosad is transferred into this compartment.
For sludge application to agricultural soil an application rate of 5,000 kg/ha dry weight per year is assumed while for grassland a rate of 1,000 kg/ha dry weight per year should be used. Sludge application is treated as a single event once a year.
For the calculation of spinosad in soil via sludge application, the rate of sewage sludge production can be estimated using equation 37 of the TGD:

$$SLUDGERATE = \frac{2}{3} \times SUSPCONC_{inf} \times EFFLUENT_{stp} + SURPLUSsludge \times CAPACITY_{stp}$$

The obtained value is then used in the equation below for the calculation of the spinosad concentration contained in sewage sludge (equation 36 of TGD).

$$C_{sludge} = \frac{\mathrm{Fstp}_{\mathrm{sludge}} \times Elocal_{water} \times 10^6}{\mathrm{SLUDGERATE}}$$

The concentration in soil just after the first application can be derived with the equation below (TGD equation 60):

$$Csludge_{soil\ 1}\ (0) = \frac{\mathrm{C}_{\mathrm{sludge}} \times APPL_{sludge}}{\mathrm{DEPTH}_{\mathrm{soil}} \times \mathrm{RHO}_{\mathrm{soil}}}$$

Using the equations above, the concentration of spinosad in soil via sludge application (1 event) is calculated in the table below:

**Table 2.8.3.11-1: Determination of the initial predicted environmental concentration in soil via sludge application ($PECsoil_1(0)$ via STP)**

| **Parameter** | | **Description** | | **Value** |
|---|---|---|---|---|
| $SUSPCONC_{inf}$ | = | Conc. of suspended matter in STP influent [kg × $m^{-3}$] | = | 0.45(Default)[1] |
| $EFFLUENT_{stp}$ | = | Effluent discharge rate of STP [$m^3$ × $d^{-1}$] | = | 2000(Default)[1] |
| SURPLUSsludge | = | Surplus sludge per inhabitant equivalent [kg × $d^{-1}$ × $eq^{-1}$] | = | 0.011(Default)[1] |
| $CAPACITY_{stp}$ | = | Capacity of the STP [eq] | = | 10,000(Default)[1] |
| SLUDGERATE | = | Rate of sewage sludge production [kg × $d^{-1}$] *TGD, equation 37* | = | 710 (Default)* |
| $Elocal_{water}$ | = | Local emission rate to (waste) water during episode [kg × $d^{-1}$] *Taken from table 2.8.3.9-2* | = | 0.0383 |
| $Fstp_{sludge}$ | = | Fraction of emission directed to sludge by STP [-] *Appendix II of TGD, no biodegradability* | = | 0.64 |
| Csludge | = | Concentration in dry sewage sludge [mg × $kg^{-1}$] *TGD, equation 36, see equation above* | = | 34.58 |
| $APPL_{sludge}$ | = | Dry sludge application rate [kg × $m^{-2}$ × $yr^{-1}$] | = | 0.5(Default)[1] |
| $DEPTH_{soil}$ | = | Mixing depth of soil [m] | = | 0.2(Default)[1] |
| $RHO_{soil}$ | = | Bulk density of soil [kg × $m^{-3}$] | = | 1700(Default)[1] |
| **$Csludge_{soil\ 1}$ (0)** | = | Conc. in soil due to sludge in first year at t = 0 [mg × $kg^{-1}$] *TGD, equation 60, see equation above* | = | **0.051 = 50.9 µg/kg ww** |

[1] Default value from general TGD on Risk Assessment.
* Value based on default values

The concentration obtained for $Csludge_{soil\ 1}$ is considered the initial PEC value in soil without considering accumulation and degradation.

**Derivation of the initial soil concentration after 10 years of sludge application**

Once in soil, potentially residues of the active substance spinosad could accumulate following yearly applications of sludge to land each year. However, as seen in other chapters, under aerobic conditions the average degradation rates of the active substance i.e. $DT_{50}$ values are clearly under 70 days at 12℃ (for both spinosyn A and spinosyn D) and therefore any year on year accumulation is considered unlikely.
Since the PECsoil which is relevant for the terrestrial ecosystem is the one which considers the accumulation of substances over the years, in the following, the concentration of spinosad is calculated after 10 consecutive years of sludge application.
Similarly to the $PEClocal_{soil}$ obtained via the manure application (confer section 2.8.3.2), an estimation of the concentration average for a 30 days period just after the last application is needed. For the ecosystem a period of 30 days is taken as a relevant time period with respect to chronic exposure of soil organisms.
Using equations 29, 61, 62 and 63 (confer section 2.8.3.2) the initial concentration after application of sludge over 10 years is calculated to be **42 µg/kg wwt.**

**$PEClocal_{soil}$ via STP**

$PEClocal_{soil}$ is derived from the average concentration in soil over 30 days ($Clocal_{soil}$) using the equation below (equation 55 from TGD). For the calculation, aerial deposition flux is not considered ($D_{air}$ = 0) and an averaging time (T) of 30 days is taken for the ecosystem as relevant time period with respect to chronic exposure of soil organisms (TGD 2003, Table 11).

$$\mathrm{Clocal}_{\mathrm{soil}} = \frac{\mathrm{D}_{\mathrm{air}}}{\mathrm{k}} + \frac{1}{kT}\left[C_{soil}(0) - \frac{D_{air}}{k}\right] \times \left[1 - e^{-kT}\right]$$

Using the equation given above, the average concentration in soil over 30 days is estimated to be **7 µg/kg wwt.**

**$PEClocal_{soil}$ via STP of major soil metabolites**

According to laboratory studies, degradation of the active substance in soil leads to the formation of two significant soil metabolites under aerobic conditions, spinosyn B (molecular weight 717.9 g/mol) and N-demethylated spinosyn D (molecular weight 753.0 g/mol). In studies conducted at relevant dose rates, the metabolite spinosyn B was observed at a maximum level of 39 to 67% of initial levels after 28 to 182 days and the metabolite N-demethylated spinosyn D was observed at a maximum level of 28 to 68% of initial levels after 28 to 237 days. Therefore the maximum potential concentrations of the metabolites in soil (wet weight) can be calculated as below:

$$\text{Concentration of spinosyn B in soil} = 0.007 \times \frac{67}{100} \times \frac{717.9}{731.98} = 4.60 \mu\text{g/kg wwt}$$

$$\text{Concentration of N} - \text{demethylated spinosyn D in soil} = 0.007 \times \frac{68}{100} \times \frac{753.0}{746.00} = 4.80 \mu\text{g/kg wwt}$$

The maximum concentration of the metabolites spinosyn B and N-demethylated spinosyn D are **4.60 µg/kg (wet weight) and 4.80 µg/kg (wet weight)**, respectively.
In laboratory soil degradation studies, the metabolites spinosyn B and N-demethylated spinosyn D are shown to be degraded in soil with average DT50 values of 194 and 531 days at 25℃, respectively. However, there is also available field data for the degradation of the metabolites spinosyn B and N-demethylated spinosyn D in soil and this information shows that under more representative conditions the metabolites degrade with an average

DT50 value of 2.11 and 3.77 days, respectively. Therefore it is not expected that significant residues of the metabolites will accumulate.

**PECgroundwater due to emissions via STP**

The predicted concentration in groundwater (PECgw) has been calculated according to the general TGD (Technical Guidance Document) on Risk Assessment. Please confer section 2.8.3.3 for the formulae given.

**Table 2.8.3.11-2: Determination of the PEC in groundwater ($PEC_{GW}$ via STP)**

| Parameter | | Description | | Value |
|---|---|---|---|---|
| $PEClocal_{soil}$ | = | Predicted environmental concentration in soil (mg/kg wwt) | = | 0.007 |
| $RHOsoil_{wet}$ | = | Bulk density of wet soil (kg wet wt/$m^3$). | = | 1700 (default) [1] |
| $Fair_{soil}$ | = | Fraction of air in soil compartment ($m^3/m^3$) | = | 0.2(default) [1] |
| HENRY | = | Henry's law constant (Pa $m^3$/mol) | = | $1.89 \times 10^{-7}$ Pa |
| R | = | Gas constant (Pa $m^3$/mol/k) | = | 8.314 (default) [1] |
| TEMP | = | Temperature of the air-water interface | = | 285 (default) [1] |
| $Fwater_{soil}$ | = | Fraction of water in soil compartment ($m^3/m^3$). | = | 0.2 (default) [1] |
| $Fsolid_{soil}$ | = | Fraction of solids in soil compartment ($m^3/m^3$). | = | 0.6 (default) [1] |
| Kpsoil | = | Partition coefficient organic carbon-water (L/kg), | = | 137.6 |
| RHOsolid | = | Density of the solid phase (kg/$m^3$) | = | 2500 (default) [1] |
| $K_{soil-water}$ | = | Soil-water partitioning coefficient ($m^3/m^3$), *calculated using the equation given.* | | 206.6 |
| **$PEClocal_{soil, porew}$** | = | Resulting soil porewater concentration, (mg/L). | = | **$5.76 \times 10^{-5}$ = 0.058 µg/L** |
| [1] Default value from general TGD on Risk Assessment. | | | | |

### 2.8.3.12 PECbiota

Taking into account the formulae given in section 2.8.3.7, the PECbiota for fish eating predators and worm eating predators was calculated as follows:

**Table 2.8.3.12-1: Determination of the predicted environmental concentration in earthworms ($PECbiota_{worm}$ via STP)**

| Parameter | | Description | | Value |
|---|---|---|---|---|
| $C_{soil}$ | = | 50% of the local concentration in soil [mg x $kg^{-1}$ wwt] ~ $PEClocal_{soil}$ / 2 *Value taken from table 2.8.4.11-2 and adapted to the 50% diet assumption (expressed as wwt)* | = | 0.0035 |
| $K_{ow}$ | = | Octanol/water partition coefficient [-] for the active substance (see note below) | = | 23988 |
| $RHO_{earthworm}$ | = | Density of earthworm [$kg_{wwt}$ x $L^{-1}$] | = | 1 (Default)[1] |
| $BCF_{earthworm}$ | = | Bioconcentration factor for earthworm on wet weight basis [L × $kg_{wet\ earthworm}^{-1}$] *TGD, Equation 82d* | = | 289 |
| $F_{gut}$ | = | Fraction of gut loading in worm [$kg_{dwt}$ x $kg_{wwt}^{-1}$] | = | 0.1 (Default)[1] |
| $CONV_{soil}$ | = | Conversion factor for soil concentration wet-dry weight soil [$kg_{wwt}$ x $kg_{dwt}^{-1}$] | = | 1.133333 (Default)[1] |
| $C_{,porewater}$ | = | Predicted Environmental Concentration in pore water [mg x $L^{-1}$] ~ $PEClocal_{soil,porewater}$ *Value taken from table 2.8.4.11-2* | = | $5.76 \times 10^{-5}$ |
| ***Cearthworm*** | = | Predicted Environmental Concentration in earthworms [mg × $kg_{wet\ earthworm}^{-1}$] *TGD, Equation 82c* | = | **$1.5 \times 10^{-2}$ =15 µg/kg** |

[1] Default value from general TGD on Risk Assessment.
Note: Maximal value obtained in unbuffered water (log Kow = 4.38 for spinosad D).

**Table 2.8.3.12-2: Determination of the predicted environmental concentration in fish (($PECbiota_{fish}$ via STP)**

| Parameter | | Description | | Value |
|---|---|---|---|---|
| $PEC_{surface\ water}$ | = | 50% of the Predicted Environmental Conc. in water [mg × $L^{-1}$] *Value taken from table 2.8.3.10-1, adapted to the 50% diet assumption* | = | 0.0006 |
| BCF | = | Bioconcentration factor for fish on wet weight basis [L × $kg_{wet\ fish}^{-1}$] *Experimental value* | = | 115 |
| BMF | = | Biomagnification factor in fish [-] | = | 1 (Default)[1] |
| **$PEC_{oral,\ predator}$** | = | Concentration in the food of the predator [mg × $kg_{wet\ fish}^{-1}$] | = | **0.069 = 69 µg/kg** |

[1] Default value from general TGD on Risk Assessment.
Note: Maximal value obtained in the bioconcentration study

#### 2.8.3.13 Summary of PEC values via manure and via STP

For the calculation of the PEC values via manure application, the recommended application rates of the product Elector for each target organism according to the user's instructions were considered. As a first step, the concentration of spinosad in soil resulting from the application of manure from stables or poultry houses was estimated. This concentration varies depending on the animal species, the surface area to be treated, and also the type of the receiving soil (arable land or grassland).

The worst case $PIEC_{soil}$ obtained was then used for the calculation of the $PEClocal_{soil}$ and subsequently the other PEC values for the relevant compartments.
For the calculation of the PEC values via sewage treatment plant, the worst case application rate according to the user's instructions was considered. This is the application rate of 30 mL on 250 $m^2$ of surface to be treated against darkling beetles/mealworms/red mites. The $Elocal_{water}$ was calculated for the animal categories i= 8, 11, 12, 16, 17, 18 according to the ESD. The STP and other compartments (surface water, soil, groundwater and sediment via STP) were also calculated.
Both groups of PEC-values are summarised in the table below:

**Table 2.8.3.13-1: Summary of calculated PEC values for environmental compartments**

| Compartment | Manure route | | | STP route | |
|---|---|---|---|---|---|
| | PEC value | | Comment | PEC value | Comment |
| | grassland | arable land | | | |
| $C_{soil\ 1}(0)$ [µg/kg wwt] | 4.1[1] | 2.0[1] | cf. Section 2.8.3.2 | 50.9 | cf. Section 2.8.3.11 |
| $C_{soil\ 10}(0)$ [µg/kg wwt] | 0.84 | 1.64 | cf. Section 2.8.3.2 | 42 | cf. Section 2.8.3.11 |
| $PEClocal_{soil}^{*}$ [µg/kg wwt] spinosad | 0.14 | 0.28 | cf. Section 2.8.3.2 | 7 | cf. Section 2.8.3.11 |
| $PEClocal_{soil}^{*}$ [µg/kg wwt] spinosyn B | 0.09 | 0.18 | cf. Section 2.8.3.2 | 4.60 | cf. Section 2.8.3.11 |
| $PEClocal_{soil}^{*}$ [µg/kg wwt] N-demthylated spinosyn D | 0.10 | 0.19 | cf. Section 2.8.3.12.8.3.1 | 4.80 | cf. Section 2.8.3.11 |
| $PEC_{groundwater}$ [µg/L] | 0.0012 | 0.0023 | cf. Section 2.8.3.32.8.3.3 | 0.058 | cf. Section 2.8.3.11 |
| PECstp [µg/L] | n.a. | n.a. | -- | 12.3 | cf. Section 2.8.3.9 |
| $PEC_{surface\ water}$ [µg/L] | 0.00012 | 0.00023 | cf. Section 2.8.3.4 | 1.2 | cf. Section 2.8.3.10 |
| $PEC_{sediment}$ [µg/kg wwt] | 0.0037 | 0.0071 | cf. Section 2.8.3.5 | 36.8 | cf. Section 2.8.3.10 |
| $PEC_{sediment}$ [µg/kg wwt] refinement, 2-tier | -- | 0.0004 (extrapolation) | cf. Section 2.8.3.52.8.3.5 | -- | -- |
| $PEC_{biota}$ [µg/kg $_{wet\ earthworm}$] | 0.6 | 0.33 | cf. Section 2.8.3.7 | 15 | cf. Section 2.8.3.12 |
| $PEC_{biota}$ [µg/kg $_{wet\ fish}$] | 0.007 | 0.013 | cf. Section 2.8.3.7 | 69 | cf. Section 2.8.3.12 |

[1] worst case is for Veal calves after application against flies
* average concentration in soil over 30 days

## 2.8.4 Risk Assessment

The risk characterisation and the underlying assumptions presented here are also confirmed in the summary dossier for the product Elector from the applicant and the final Assessment Report of the active substance spinosad of May 2010 (RMS NL).
(Product Type 18).

#### 2.8.4.1 Aquatic Compartment (including sewage treatment plants)

**Sewage treatment plant**

In the CA report for spinosad a **$PNEC_{STP}$** > 10 mg/L was derived from an $EC_{10}$ obtained in a respiration inhibition test with activated sludge and the application of an assessment factor of 10.

In general it is believed that in the EU it is prohibited to discharge waste water containing manure as well as water from wet cleaning operations to the public (municipal) sewer, although local authorities might allow livestock farms to discharge diluted waste streams to the public sewer if they are able to treat the extra pollution load. However, the risk characterisation for this compartment was done for the sake of completeness.

**Table 2.8.4.1-1:PEC/PNEC ratio concerning exposure of microorganisms in sewage treatment plants**

| Compartment | $PEC_{STP}$ [µg a.s./L] | $PNEC_{microorganisms}$ [µg a.s./L] | $\frac{PEC}{PNEC}$ |
|---|---|---|---|
| Sewage treatment plant | 12.3 | 10.000 | 0.001 |

The derived risk quotient is clearly < 1. Thus, it is considered that there is no relevant risk for the microorganisms in a STP caused by spinosad used in an insecticidal product.

**Surface water**

In the CA report for spinosad a **$PNEC_{water}$** = 0.062 µg/L was derived from the acute core data set with the application of an AF of 10.

Due to the indoor use of spinosad as insecticide, surface waters are no compartments for direct emissions. Based on potential spinosad residues following field applications of manure/slurry to soils, an indirect contamination via run-off in surface water bodies or via the STP is possible.

From the exposure and effect data for spinosad, the following risk quotients were derived (see Table 2.8.4.1-2):

**Table 2.8.4.1-2: PEC/PNEC ratios for spinosad in surface water**

| Compartment | PEC value [µg/L] | | PNEC [µg/L] | PEC/PNEC | |
|---|---|---|---|---|---|
| | **Arable land** | **Grassland** | | **Arable land** | **Grassland** |
| Surface water – via runoff | 0.00012 | 0.00023 | 0.062 | 0.0019 | 0.004 |
| Surface water –via STP | 1.2 | | 0.062 | **19.3** | |

The derived risk quotient is < 1 for surface water exposed via run off. For surface water exposed via STP the risk quotient is 19.3 based on emissions from poultry houses to the STP. The worst-case treatment (0.058 g a.i./$m^2$) is for the control of darkling beetles/mealworms/red mites for animal category 16 (turkeys in free range with litter floor) which are housed in stables with a floor area of 3330 $m^2$. The risk quotient will be < 1 in case the floor surface of stables in poultry houses treated for the control of of darkling beetles/mealworms/red mites is < 170 $m^2$ which is realistic for non-professional use.

Thus, it is considered that there is no relevant risk for the aquatic environment caused by spinosad used in an insecticide product in case the following risk mitigation measure is included in the proposed label:

*To protect soil and water living organisms, residues (such as dirt and waste water containing the product) need to be removed to the manure deposit.*

**Risk Assessment for sediment**

In the CA report for spinosad a **PNECsed** = 0.23 µg/kg wwt was calculated from the results of a chronic test with *Chironomus riparius* using an assessment factor of 100.
Due to the indoor use of spinosad as insecticide the sediment compartment does not receive direct emissions. Based on potential spinosad residues following field applications of manure/slurry to soils, an indirect contamination via run-off in surface water bodies or via the STP and the subsequent deposition onto freshly deposited sediment is possible. This was calculated with the procedure outlined in the general TGD on Risk Assessment.
Since initially a potential risk was identified for sediment organisms, higher tier assessment was considered based on the FOCUS surface water modelling tool SWASH (MACRO, PRZM, TOXSWA). A FOCUS calculation was already submitted for spinosad in Sweden in the context of the national registration. This study was used to assess spinosad concentrations in sediment due to soil run-off.

**Table 2.8.4.2-1:PEC/PNEC ratio concerning exposure of the sediment compartment**

| Compartment | $PEC_{sed}$ [µg a.s./kg sediment] | | $PNEC_{sed}$ [µg a.s./kg sediment] | $\frac{PEC}{PNEC}$ | |
|---|---|---|---|---|---|
| | Arable land | Grassland | | Arable land | Grassland |
| Sediment, 1-tier – via run off | 0.0037 | 0.0071 | 0.23 | 0.02 | 0.03 |
| Sediment, 2-tier – via runoff | -- | 0.0004 | 0.23 | -- | 0.002 |
| Sediment, 1-tier – via STP | 36.8 | | 0.23 | **160.00** | |

The derived risk quotient for both the 1-tier and 2-tier approach is below 1. Thus, it is considered that there is no relevant risk for the sediment environment caused by spinosad used in an insecticidal product.

The derived risk quotient for sediment exposed via run off is < 1 for both the 1-tier and 2-tier approach. For sediment exposed via STP the risk quotient is 160 based on emissions from poultry houses to the STP. The worst-case treatment (0.058 g a.i./$m^2$) is for the control of darkling beetles/mealworms/red mites for animal category 16 (turkeys in free range with litter floor) which are housed in stables with a floor area of 3330 $m^2$. The risk quotient will be < 1 in case the floor surface of stables in poultry houses treated for the control of of darkling beetles/mealworms/red mites is < 21 $m^2$ which is realistic for non-professional use. Thus, it is considered that there is no relevant risk for the aquatic environment caused by spinosad used in an insecticide product in case the following risk mitigation measure is included in the proposed label:
*To protect soil and water living organisms, residues (such as dirt and waste water containing the product) need to be removed to the manure deposit.*

#### 2.8.4.2 Terrestrial Compartment

### Risk Assessment for soil

*Active substance*

In the CA report for spinosad a **$PNEC_{soil}$ = 2.27 µg/kg wwt soil** (2.57 µg/kg dw soil) was calculated with the equilibrium partitioning method and the PNECaquatic values.
Following use of Elector to suitable surfaces in animal houses, the active substance is potentially collected along with the manure and stored according to normal farming practices. Subsequent land application of the manure after storage potentially releases the active substance to soil. The amount of manure that is permitted to be applied to land is effectively controlled by the nitrogen content of the manure.
The use of Elector against red mites according to user's instructions for turkeys in free range with litter floor was identified as the worst case initial soil concentration. The risk characterisation for the compartment soil and further compartments is based on this value. Potential accumulation following repeated applications of manure to land was considered over a 10 year time period.

**Table 2.8.4.3-1:PEC/PNEC ratio concerning exposure of the soil compartment**

| **Compartment** | **$PEC_{soil}$ [µg a.s./kg wwt soil]** | | **$PNEC_{soil}$ [µg a.s./kg soil]** | **$\frac{PEC}{PNEC}$** | |
|---|---|---|---|---|---|
| | **Arable land** | **Grassland** | | **Arable land** | **Grassland** |
| Soil – via manure | 0.28 | 0.14 | 2.27 | 0.12 | 0.06 |
| Soil – via STP sludge | 7 | | 2.27 | **3.08** | |

The derived risk quotient is < 1 for soil exposed via manure. For soil exposed via STP sludge the risk quotient is 3.08 based on emissions from poultry houses to the STP. The worst-case treatment (0.058 g a.i./$m^2$) is for the control of darkling beetles/mealworms/red mites for animal category 16 (turkeys in free range with litter floor) which are housed in stables with a floor area of 3330 $m^2$. The risk quotient will be < 1 in case the floor surface of stables in poultry houses treated for the control of of darkling beetles/mealworms/red mites is < 1081 $m^2$ which is realistic for non-professional use.
Thus, it is considered that there is no relevant risk for the terrestrial environment caused by spinosad used in an insecticide product in case the following risk mitigation measure is included in the proposed label:
*To protect soil and water living organisms, residues (such as dirt and waste water containing the product) need to be removed to the manure deposit.*

<u>*Metabolites*</u>
According to laboratory studies, degradation of the active substance in soil leads to the formation of two significant soil metabolites under aerobic conditions, spinosyn B and N-demethylated spinosyn D.
No unacceptable effects were observed at relatively high dosages on the nitrification processes and soil respiration as well as in the earthworm toxicity tests.
The CA-report gives a $PNEC_{soil}$ for the major metabolites spinosyn B and N-demethylated spinosyn D based on equilibrium partitioning:
**$PNEC_{soil}$ (spinosyn B) =** 1.43 µg/kg wwt
**$PNEC_{soil}$ (N-demethylated spinosyn D) =** 0.35 µg/kg wwt

**Table 2.8.4.3-2: PEC/PNEC ratio concerning exposure of the soil compartment**

| Compartment | Metabolite | $PEC_{soil}$ [µg a.s./kg wwt soil] | | $PNEC_{soil}$ [µg a.s./kg wwt soil] | $\frac{PEC}{PNEC}$ | |
|---|---|---|---|---|---|---|
| | | Arable land | Grassland | | Arable land | Grassland |
| Soil-via manure | **spinosyn B** | 0.09 | 0.18 | 1.43 | 0.06 | 0.13 |
| | **N-demethylated spinosyn D** | 0.1 | 0.19 | 0.35 | 0.29 | 0.54 |
| Soil – via STP sludge | **spinosyn B** | 4.6 | | 1.43 | **3.22** | |
| | **N-demethylated spinosyn D** | 4.8 | | 0.35 | **13.71** | |

The derived risk quotient is < 1 for soil exposed via manure. For soil exposed via STP sludge the worst-case risk quotient is 13.71 based on emissions from poultry houses to the STP. The worst-case treatment (0.058 g a.i./$m^2$) is for the control of darkling beetles/mealworms/red mites for animal category 16 (turkeys in free range with litter floor) which are housed in stables with a floor area of 3330 $m^2$. The risk quotient will be < 1 in case the floor surface of stables in poultry houses treated for the control of of darkling beetles/mealworms/red mites is < 242 $m^2$ which is realistic for non-professional use.
Thus, it is considered that there is no relevant risk for the terrestrial environment caused by spinosad used in an insecticide product in case the following risk mitigation measure is included in the proposed label:
*To protect soil and water living organisms, residues (such as dirt and waste water containing the product) need to be removed to the manure deposit.*

#### 2.8.4.3 Risk Assessment for groundwater

*Spinosad is a mixture of two structurally similar molecules spinosyn A and D. The sorption characteristics of spinosyn A and D indicate a strong sorption to soil components and a very low potential for mobility.*
*However, for reasons of completeness the soil pore water concentration is assessed as an indicator of potential residues occurring in groundwater. On the basis of the calculation as provided in the TGD, a soil pore water concentration of 0.0012 and 0.0023 µg/L was calculated for arable and grassland respectively, which is below 0.1 µg/L, the European standard value for single pesticides fixed in the Drinking Water Directive 98/83/EC.*

#### 2.8.4.4 Atmosphere

Spinosyn A and D have a low vapour pressure (spinosyn A: 3.0 x $10^{-8}$ Pa at 25℃ and spinosyn D: 2.0 x $10^{-8}$ Pa at 25℃). The Henry's law constant was calculated as 1.89 x $10^{-7}$ Pa x m³ x $mol^{-1}$ (25℃) for spinosyn A and 2.32 x $10^{-5}$ Pa x m³ x $mol^{-1}$ (25℃) for spinosyn D indicating that the compounds are not volatile from aqueous surfaces.
A calculation of the atmospheric half-live of spinosad in the troposphere resulted in half-lives of 20 min for spinosyn A and 19 min for spinosyn D. An experiment on the volatilisation of spinosad from plant and soil surfaces yielded < 2% exhalation of spinosyn A or D within 24 h. Therefore, spinosad is not volatile and even when entering the atmosphere the compound is rapidly degraded by photochemical processes. Thus, neither accumulation in the air nor transport over longer distances is to be expected.
A risk assessment for the atmosphere is therefore not considered necessary.

#### 2.8.4.5 Non compartment specific effects relevant to the food chain (secondary poisoning)

After the application of Elector, predatory birds and mammals may be poisoned secondarily through the ingestion of contaminated fish or by the consumption of earthworms from contaminated soils.
The assessment of secondary poisoning via the consumption of contaminated fish or earthworms is done according to the TGD.
A **$PNEC_{oral}$** of 3.3 mg a.s./kg food was derived for fish- or eartworm eating mammals covering the less sensitive birds.

**Table 2.8.4.6-1:PEC/PNEC ratio concerning fish- and worm eating predators**

<table>
<tr><th rowspan="2">Route</th><th rowspan="2">Compartment</th><th colspan="2">$PEC_{biota}$ [µg /kg wet fish or earthworm]</th><th rowspan="2">$PNEC_{oral, birds}$ [µg a.s./kg food]</th><th colspan="2">$\frac{PEC}{PNEC}$</th></tr>
<tr><th>Arable land</th><th>Grassland</th><th>Arable land</th><th>Grassland</th></tr>
<tr><td rowspan="2">Via manure: run off to water and spreading on land</td><td>Fish eating predator (aquatic food chain)</td><td>0.007</td><td>0.013</td><td rowspan="2">3300</td><td>$2.12 \times 10^{-6}$</td><td>$3.94 \times 10^{-6}$</td></tr>
<tr><td>Earthworm eating predator (terrestrial food chain)</td><td>0.33</td><td>0.6</td><td>$1.00 \times 10^{-4}$</td><td>$1.82 \times 10^{-4}$</td></tr>
<tr><td rowspan="2">Via STP: emission of effluent to surface water and spreading of sludge on land</td><td>Fish eating predator (aquatic food chain)</td><td colspan="2">69</td><td rowspan="2">3300</td><td colspan="2">$2.09 \times 10^{-2}$</td></tr>
<tr><td>Earthworm eating predator (terrestrial food chain)</td><td colspan="2">15</td><td colspan="2">$4.55 \times 10^{-3}$</td></tr>
</table>

The assessment reveals PEC/PNEC ratios far below 1. Hence, no adverse effects for earthworm or fish-eating predators are to be expected.

### 2.8.5 Overall conclusion regarding the environment

The environmental risk assessment has demonstrated that manure/slurry storage systems are the only compartment for direct spinosad emissions, whereas soils, groundwater and surface water are indirect targets via the application of manure/slurry as fertilizer to agricultural fields. According to the PT18 ESD for stables and manure, in some housing types for poultry emissions of waste water to municipal sewage treatment plants can occur during professional use, although national regulations throughout the EU do not allow discharge to the municipal sewage system. When spinosad enters the environment via waste water unacceptable effects are expected during professional use in all the relevant environmental compartments except for the STP where no risk for the micro-organisms could be identified. Therefore the following risk mitigation measure needs to be included in the proposed label:
*To protect soil and water living organisms, residues (such as dirt and waste water containing the product) need to be removed to the manure deposit.*
In contrast, non-professionals can discharge waste water containing manure/slurry to the public (municipal) sewer. The risk to all relevant compartments will be acceptable (PEC/PNEC < 1) in case the floor surface of stables in poultry houses treated for the control of of darkling beetles/mealworms/red mites is < 21 $m^2$ which is realistic for non-professional use...

With regard to the main emission pathway via the application of liquid waste/manure containing spinosad as fertilizer to soil, employing reasonable worst case assumptions, the concentrations calculated for the affected compartments are below threshold values for aquatic and terrestrial organisms (PEC/PNEC < 1), indicating that there is no risk for these organisms due to the use of spinosad for PT 18 purposes. Besides, no risk of secondary poisoning was determined.
As far as the two major metabolites are concerned (degradation products > 10% AR were only detected in the soil compartment) no adverse effects were observed for the soil compartment (PEC/PNEC < 1).
The toxicity of spinosad to terrestrial organisms is low whereas it is very toxic to aquatic organisms (R50/53). However, as the surface water compartment only receives low amounts of spinosad, the risk to aquatic organisms is acceptable (PEC/PNEC ratios < 1).
Finally, it can be concluded that no unacceptable risk is expected for all contemplated environmental compartments due to the use of spinosad applied as an insecticidal biocidal product in stables.

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

- Do not apply directly onto livestock. Animals are allowed to stay in the stable during application
- Avoid run-off.
- Avoid contamination of food, feed and drinking water
- Do not apply as fog
- Do not mix with other products in the spraying equipment

The instructions for use must contain the following indications in order to prevent emission to water, sediment and soil via the STP for professional use:

- To protect soil and water living organisms, residues (such as dirt and waste water containing the product) need to be removed to the manure deposit.

# 3 Proposal for decision

Elector has been evaluated as an insectide for the control of poultry red mites, house flies, stable flies and darkling beetles/mealworms in animal production facilities including intensive poultry/pig/cattle housing (poultry houses and some livestock animal housings).

The Dutch CA considers that sufficient data have been provided to verify the outcome and conclusions, and permits the authorisation of Elector for both professional and non-professional use.

**ANNEXES CONTAIN CONFIDENTIAL DATA: This information should not be disclosed to third parties**

**Annex:**

1. **Summary of product characteristics**
2. **List of studies reviewed**
3. **Analytical methods residues – active substance**
4. **Toxicology and metabolism –active substance**
5. **Toxicology – biocidal product**
6. **Safety for professional operators**
7. **Safety for non-professional operators and the general public**
8. **Residue behaviour**
9. **Efficacy tests provided to demonstrate the efficacy of Elector against stable fly, house fly and lesser mealworm.**

## Annex 1: Summary of product characteristics

**(a) Product trade name:** Elector

**(b) (i) Qualitative and quantitative information on the composition of the biocidal product**

NB: This information is confidential and should not be disclosed to third parties

| **Active substance(s)** | | | | **Contents** | | | | |
|---|---|---|---|---|---|---|---|---|
| **Common name** | **IUPAC name** | **CAS number** | **EC number** | **Concentration** | **Unit**[8] | **w/w (%)** | **Minimum purity (% w/w)** | **Same source as for Annex I inclusion** |
| spinosad | mixture of 50–95% (2*R*,3a*S*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-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-1*H*-*as*-indaceno[3,2-*d*]oxacyclododecine-7,15-dione and 50–5% (2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*S*)-2-(6- deoxy-2,3,4-tri-*O*-methyl-α-L-mannopyranosyloxy)-13-(4- dimethylamino-2,3,4,6-tetradeoxy-β-D- | 168316-95-8 | 434-300-1 | 480,0 | g/L | 44.2 | 85,00 | ☒ **yes** ☐ **no** |

8 g/l, g/kg, other. For biological products, the concentration should state the number of activity units/units of potency (as appropriate) per defined unit of formulation (e.g. per gramme or per litre).

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | erythropyranosyloxy)-9- ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b- hexadecahydro-4,14-dimethyl-1*H*-*as*-indaceno[3,2-*d*]oxacyclododecine-7,15-dione | | | | | | | |

| **Co-formulants** | | | | | **Contents** | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Concentration** | **Unit** | **w/w (%)** | **Classification** | **Substance of concern** |
| Pluronic P105 | | wetting agent | 9003-11-6 | | 21.8 | **g/L** | 2.0 | **-** | ☐ **yes** ☒ **no** |
| Agnique NSC 4AL | | dispersant | 9069-80-1 | | 21.8 | **g/L** | 2.0 | - | ☐ **yes** ☒ **no** |
| Antifoam B | | antifoam | 9004-67-5 | | 10.9 | **g/L** | 1.0 | - | ☐ **yes** ☒ **no** |
| Proxel GXL | | preservative | 2634-33-5 | | 2.18 | **g/L** | 0.2 | R22, R34, R43, R50 | ☐ **yes** ☒ **no** |
| Propylene glycol | | antifreeze | 57-55-6 | | 43.6 | **g/L** | 4.0 | - | ☐ **yes** ☒ **no** |
| Kelzan | | thickening agent | 11138-66-2 | | 0.76 | **g/L** | 0.07 | - | ☐ **yes** ☒ **no** |
| Veegum | | thickener | 12199-37-0 | | 4.58 | **g/L** | 0.42 | - | ☐ **yes** ☒ **no** |
| water | | solvent | 7732-18-5 | | 419.7 | **g/L** | 38.5 | - | ☐ **yes** ☒ **no** |

| | | | |
|---|---|---|---|
| **Sum** | **1005.32** | | **100.0** |

**(b) (ii) Is the product identical to the representative product, assessed for the purpose of the Annex I inclusion?**

☐ **yes** ☒ **no** ☐ **unknown**

**If not, briefly describe the difference.**

| |
|---|
| The product is identical to NAF-85, which was used in some of the studies used for Annex I inclusion. Compared to the representative product, GF-739, Elector does not contain bittering agent, dyes, attractant, binding agent, antioxidant, disintegrant, anti-caking agent or carrier. |

**(b) (iii) Does the biocidal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?**

☐ **yes** ☒ **no**

If yes, does the product comply with Directive 2001/18/EC?

☐ **yes** ☐ **no**

A copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive was provided.

(c) Manufacturer of the active substance (name and address including location of plant)

| | | | | | |
|---|---|---|---|---|---|
| Name of the active substance: spinosad | | | | | |
| Manufacturer | | | | | |
| Company Name: Dow AgroSciences | | | | | |
| Address: | 305 North Huron Avenue | | | | |
| City: | Harbor Beach | Postal Code: | Michigan 48441 | Country: | USA |
| Telephone: | + 1 989-479-5231 | Fax: | + 1 517-479-9410 | E-Mail: | |
| Intra-Community VAT number or, for non EU companies, company registration number: 62719-MI-001 | | | | | |

(d) Formulators of the biocidal product (names and addresses including location of plants)

| | | | | | |
|---|---|---|---|---|---|
| Formulator | | | | | |
| Site 1: | | | | | |
| Company Name: Bold Formulators | | | | | |
| Address: | 364 Fitzgerald Highway | | | | |
| City: | Ocilla | Postal Code: | GA 31774 | Country: | USA |
| Telephone: | +1 229 468 5895 | Fax: | +1 229 468 7253 | E-Mail: | |
| | Jerry.flint@boldformulatorsllc.com | | | | |
| Intra-Community VAT number or, for non EU companies, company registration number: 37429-GA-02 | | | | | |
| Site 2: | | | | | |
| Company Name: CJB Industries, Inc. | | | | | |
| Address: | 2114 Cypress Street | | | | |
| City: | Valdosta | Postal Code: | GA 31603-1362 | Country: | USA |
| Telephone: | +1 229 293 0800 | Fax: | +1 229 293 0103 | E-Mail: | |
| Intra-Community VAT number or, for non EU companies, company registration number: 70815-GA-001 | | | | | |

***Physical state and nature of the biocidal product:***

(e) Type of formulation:

SC

(f) Ready-to-use product: ☒no ☐ yes

***Classification and labelling statements of the biocidal product:***

(g) Product classification:

N Dangerous for the environment

(h) Risk and Safety Phrases:

Professional use: R50/53, S36/37, S42, S60, S61

Non-professional use: R50/53, S29

(i) Product classification according to GHS:

GHS09 Aquatic acute 1, Aquatic chronic 1

(j) Hazard statement according to GHS:

Professional use: H400, H410, P280c, P284, P273, P391, P501

Non-professional use: H400, H410, P273, P391, P501

***Intended uses and efficacy:***

| | | |
|---|---|---|
| (k) | PT: | 18 |
| (l) | Target harmful organisms: | *Stomoxys calcitrans* (stable flies),<br>*Musca domestica* (house fly)<br>*Alphitobius diaperinus (lesser mealworm/darkling beetle)*<br>*Dermanyssus gallinae (poultry red mite)* |
| (m) | Development stage of target organisms: | Juveniles and adults |
| (n) | Function/mode of action: | Insecticide |
| (o) | Field of use: | In animal production facilities including intensive poultry/pig/cattle housing and domestic animal housing |
| (p) | Application aim: | Control of flies, beetles and poultry red mite |
| (q) | User category | Professional and non-professional |

| | | |
|---|---|---|
| (r) | Application method: | dilute product and spray on surfaces,<br><br>cracks and crevices, but avoid run-off |

***Directions for use:***

(s) Manner and area of use:

Elector is a biocidal product containing the active substance spinosad (480g/L, 44.2% w/w) as an insecticide for the control of pest species in agricultural and domestic animal premises. Elector can be used after dilution of the product in water by spraying surfaces. The diluted product can be used as a surface treatment or by application to cracks and around feeders. The product is efficacious against poultry red mites, house flies, stable flies and darkling beetles/mealworms in animal production facilities including intensive poultry/pig/cattle housing (poultry houses and some livestock animal housings). For non-professional use the product is used mainly for treatment against poultry red mites in hobby aviaries for domestic birds or small-scale chicken houses owned by non-professionals. The general use dosages are 30 ml in 3.5-18 litres of water per 250-500 $m^2$.

The product is intended for both professional and non-professional use.

Elector falls in the category of product type 18 according to the BP-directive.

(t) Conditions of use:.

General use:
The product is an SC formulation containing 44.2% (w/w) a.s. which is diluted before use.

Dose:
house fly / stable fly
30 ml product in 18-36 litres water (equivalent to 0.04-0.08% spinosad) to spray 500 $m^2$, sprayed onto flies and the resting areas of the flies

darkling beetle/mealworm
30 ml product in 9-18 litres water (equivalent to 0.08-0.16% spinosad) to spray 250 $m^2$, sprayed onto cracks and around feeders

poultry red mite:
30 ml product in 3.5-7 litres water (equivalent to 0.2-0.4% spinosad) to spray 250 $m^2$, sprayed onto cages and cracks.

Application:
The diluted product is applied as coarse, low-pressure spray or a low volume high pressure spray.

(u) Instructions for safe use of the product:

- The instructions for use must contain the following indications in order to prevent emission to water, sediment and soil via the STP for professional use: To protect soil and water living organisms, residues (such as dirt and waste water containing the product) need to be removed to the manure deposit.
- Do not apply directly onto livestock. Animals are allowed to stay in the stable during application
- Avoid run-off.
- Avoid contamination of food, feed and drinking water
- Do not apply as fog

- Do not mix with other products in the spraying equipment

(v) Particulars of likely direct or indirect adverse effects and first aid instructions

If ingested: if conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a physician immediately.

(w) Instructions for safe disposal of the product and its packaging

See SDS.

(x) Conditions of storage and shelf-life of the product under normal conditions of storage:

The specified shelf life is three years in the original HDPE packaging, which is supported by ambient temperature storage stability data

(y) Additional information:

None.

## Annex 2: List of studies reviewed

***List of <u>new data</u> submitted in support of the evaluation of the active substance***
No new date is submitted in support of the evaluation of the active substance.

***List of <u>new data</u> submitted in support of the evaluation of the biocidal product***

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Yes | No | Yes | No |
| **B3.1(01) IIB, III 3.1**<br>**also filed B3.5(01) also filed B3.6(01) also filed B3.7(01) also filed B3.8(01) also filed B3.10(02) also filed B3.11(01)** | **GHE-P-6018** | **McGrath, G.** | **1997a** | **Determination of physico-chemical data (accelerated storage CIPAC MT 46.1) for spinosad (480 g/L) SC insecticide, NAF-85.**<br>**Date: 1997-08-27** | **DowElanco Europe** | ☐ | ☒ | ☒ | ☐ |
| **B3.2(01) IIB, III 3.2**<br>**also filed B3.4(01) also filed B3.10(01)** | **GHE-P-6494** | **McGrath, G.** | **1997b** | **Determination of physico-chemical properties of spinosad 480 g/L SC insecticide, NAF-85.**<br>**Date: 1997-07-29** | **DowElanco Europe** | ☐ | ☒ | ☒ | ☐ |

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| B3.4(01) IIB, III 3.4<br>filed B3.2(01) | GHE-P-6494 | McGrath, G. | 1997b | Determination of physico-chemical properties of spinosad 480 g/L SC insecticide, NAF-85.<br>Date: 1997-07-29 | DowElanco Europe | ☐ | ☒ | ☒ | ☐ |
| B3.5(01) IIB, III 3.5<br>filed B3.1(01) | GHE-P-6018 | McGrath, G. | 1997a | Determination of physico-chemical data (accelerated storage CIPAC MT 46.1) for spinosad (480 g/L) SC insecticide, NAF-85.<br>Date: 1997-08-27 | DowElanco Europe | ☐ | ☒ | ☒ | ☐ |
| B3.6(01) IIB, III 3.6<br>filed B3.1(01) | GHE-P-6018 | McGrath, G. | 1997a | Determination of physico-chemical data (accelerated storage CIPAC MT 46.1) for spinosad (480 g/L) SC insecticide, NAF-85.<br>Date: 1997-08-27 | DowElanco Europe | ☐ | ☒ | ☒ | ☐ |
| B3.7(01) IIB, III 3.7<br>filed B3.1(01) | GHE-P-6018 | McGrath, G. | 1997a | Determination of physico-chemical data (accelerated storage CIPAC MT 46.1) for spinosad (480 g/L) SC insecticide, NAF-85.<br>Date: 1997-08-27 | DowElanco Europe | ☐ | ☒ | ☒ | ☐ |

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| **B3.7(02)<br>IIB, III 3.7** | **NAFST131** | **Krause, R.E.** | **1999** | **Storage stability of spinosad SC formulation NAF-85 - Two years study results in commercial type containers.**<br>**Date: 1999-10-27** | **Dow AgroSciences LLC** | ☐ | ☒ | ☒ | ☐ |
| **B3.7(03)<br>IIB, III 3.7** | **Document number DN0020968**<br>**PTR number 15355159** | **Boucher, R.E.** | **2006** | **Chemical stability of spinosad 480 g/L SC.**<br>**Date: 2006-07-18** | **Dow AgroSciences** | ☐ | ☒ | ☒ | ☐ |
| B3.7<br>IIB, III 3.7 | FOR-08-006 | Stock, M. | 2012 | Storage Stability and Package Corrosion Characteristics of GF-976 in PET and HDPE; Three Year<br>Ambient Study | Dow AgroSciences LLC | ☐ | ☒ | ☒ | ☐ |
| **B3.8(01)<br>IIB, III 3.8**<br>**filed B3.1(01)** | **GHE-P-6018** | **McGrath, G.** | **1997a** | **Determination of physico-chemical data (accelerated storage CIPAC MT 46.1) for spinosad (480 g/L) SC insecticide, NAF-85.**<br>**Date: 1997-08-27** | **DowElanco Europe** | ☐ | ☒ | ☒ | ☐ |
| **B3.10(01) –**<br>**filed B3.2(01)** | **GHE-P-6494** | **McGrath, G.** | **1997b** | **Determination of physico-chemical properties of spinosad 480 g/L SC insecticide, NAF-85.**<br>**Date: 1997-07-29** | **DowElanco Europe** | ☐ | ☒ | ☒ | ☐ |

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Yes | No | Yes | No |
| B5.10(01) IIB, V 10 | T9CAM0004 | Naylor, S. A. and Snyder, E. D. | 2001a | Efficacy evaluation of spinosad against adult stable fly (*Stomoxys calcitrans*) when applied as a premise spray to selected substrate surfaces under laboratory conditions.<br>Date: 2001-11-26 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |
| B5.10(02) IIB, V 10 | T9CAM0007 | Naylor, S. A. and Snyder, E. D. | 2001b | Efficacy evaluation of spinosad against adult stable fly (*Stomoxys calcitrans*) when applied as a premise spray to selected substrate surfaces under laboratory conditions.<br>Date: 2001-07-27 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |
| B5.10(03) IIB, V 10 | T9CAM0010 | Naylor, S. A. and Snyder, E. D. | 2001c | Efficacy evaluation of spinosad against adult stable fly (*Stomoxys calcitrans*) when applied as a premise spray to selected substrate surfaces under laboratory conditions.<br>Date: 2001-10-04 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| B5.10(04) IIB, V 10 | T9CAM9913 | Naylor, S. A. and Snyder, E. D. | 2000 | Efficacy evaluation of spinosad against adult stable fly (*Stomoxys calcitrans*) when applied as a premise spray under laboratory conditions.<br>Date: 2000-01-21 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |
| B5.10(05) IIB, V 10 | T9CAM0015 | Naylor, S. A. and Snyder, E. D. | 2001d | Efficacy evaluation of spinosad against adult stable fly (*Stomoxys calcitrans*) when applied as a premise spray to painted block walls and ceilings in an enclosed building.<br>Date: 2001-10-04 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |
| B5.10(06) IIB, V 10 | T9C060111 | TerHune, T. | 2002 | A dose evaluation of the efficacy of spinosad applied to facility premises for the control of naturally occurring infestations of house flies (*Musca domestica*).<br>Date: 2002-03-11 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |
| B5.10(07) IIB, V 10 | T9C390101 | Williams, R.E. | 2002 | A dose evaluation of the efficacy of spinosad applied to facility premises for the control of naturally occurring infestations of house flies (*Musca domestica).*<br>Date: 2002-03-08 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| B5.10(08)<br>IIB, V 10 | T9C010107 | Howard, D. D. | 2002 | A dose justification study of the efficacy of spinosad applied to poultry facility premises for the control of infestations of adult and larval forms of *Alphitobius diaperinus* (darkling beetles).<br>Date: 2002-06-25 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |
| B5.10(09)<br>IIB, V 10 | T9C010220 | Moore, G.M. | 2005a | A dose evaluation study of the efficacy of spinosad applied to poultry facility premises for the control of infestations of adult and larval forms of *Alphitobius diaperinus* (lesser Mealworms).<br>Date: 2005-04-19 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |
| B5.10(10)<br>IIB, V 10 | T9C130221 | Moore, G.M. | 2005b | A dose evaluation study of the efficacy of spinosad applied to poultry facility premises for the control of infestations of adult and larval forms of *Alphitobius diaperinus* (lesser mealworms).<br>Date: 2005-04-19 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| B5.10(11) IIB, V 10 | T9C060222 | Moore, G. M. | 2005c | A dose evaluation study of the efficacy of spinosad applied to poultry facility premises for the control of infestations of adult and larval forms of *Alphitobius diaperinus* (lesser mealworms).<br>Date: 2005-04-19 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |
| B5.10(12) IIB, V 10 | T9CAL0138 | Lambkin T. | 2002 | Field trial to compare and evaluate the efficacy of spinosad and cyfluthrin (Tugon® WP) (standard and modified applications) in controlling *Alphitobius diaperinus* (darkling beetle or lesser mealworm) in broiler sheds.<br>Date: 2002-02-04 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |
| B5.10(14) IIB, V 10 | T9CGB090002 | Knox, A. | 2009 | A dose determination study examining two doses of spinosad (Elector®) for the treatment of poultry red mite (*Dermanyssus gallinae*) in conventional cages stocked with laying hens.<br>Date: 2009-07-24 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |

| Section No | Reference No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|---|
| B5.10(15) IIB, V 10 | T9CDE090011 | Liebisch, G. | 2009 | Field study to evaluate Elector against poultry red mites (*Dermanyssus gallinae*).<br>Date: 2009-11-30 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |
| B5.10(16) IIB, V 10 | T9CANL0602 | Van der Klis, J. D. | 2007 | The *in vitro* efficacy of spinosad against poultry red mites (*Dermanyssus gallinae*).<br>Date: 2007-11-16 | Elanco Animal Health | ☐ | ☒ | ☒ | ☐ |

| Section No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Yes | No | Yes | No |
| 6.7.1. | Spurlock-Brouwer, L. Et al. | 2000 | Magnitude of the Residue of Spinosad in Meat and Milk from Dermal Applications to Dairy Cattle. Elanco Animal Health, Greenfield, IN, USA | Elanco Animal Health | ☒ | ☐ | ☒ | ☐ |

| Section No | Author | Year | Title | Owner of data | Letter of Access | | Data protection claimed | |
|---|---|---|---|---|---|---|---|---|
| 6.7.2. | Rosser SW, Shackleford DD | 2008 | Pesticide Development Study (GLP): Magnitude of Spinosad Residues in Poultry tissues and Eggs Resulting from Applications of Spinosad Directily to Chickens for Contro of Northern Fowl Mites along with Premise Sprays for Control of Certain Poultry House Insects. Dow AgroSciences LLC, Indianapolis, IN, USA (analytical part)<br>HMS Veterinary Development, Inc. Tulare, CA, USA (in-life phase)<br>Study No. T9C180534, date: 2008-03-28, (unpublished). | Elanco Animal Health | ☒ | ☐ | ☒ | ☐ |

### Annex 3: Analytical methods residues – active substance

| spinosad |
|---|

The analytical methods for residues are taken from the CA report to support the inclusion of spinosad in annex I of Directive 98/8/EC.

**Analytical methods for residues**

| | |
|---|---|
| Soil (principle of method and LOQ) (Annex IIA, point 4.2) | The relevant residues for monitoring of soil are spinosyn A, D, B and N-demethyl spinosyn D.<br><br>Extraction with methanol/5% sodium chloride/1N sodium hydroxide, analysis by LC/MS/MS.<br>LOQ 0.005 mg/kg (spinosyn A, spinosyn D, spinosyn B and N-demethyl spinosyn D individually) |
| Air (principle of method and LOQ) (Annex IIA, point 4.2) | Residues relevant for air are spinosyn A and D.<br><br>Adsorption on TENAX tube, extraction with a solution of methanol/acetonitrile and aqueous ammonium acetate, analysis by LC/MS/MS.<br>LOQ is 0.73 µg/$m^3$ for spinosyn A and spinosyn D, respectively [method GRM 02.18]). |
| Water (principle of method and LOQ) (Annex IIA, point 4.2) | Residues relevant for water are spinosyn A and D.<br><br>Extraction with methyl tert-butyl ether, analysis by LC/MS/MS. LOQ 0.01 µg/L (spinosyn A, spinosyn D, each individually in drinking, surface and groundwater) |
| Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2) | not required, since spinosad is not classified as toxic or very toxic. |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1) | not required, since the biocidal product will not be used on any food or feed of plant origin. |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1) | The residue definition for enforcement/monitoring for animal commodities (tissues, milk, eggs) consists of spinosyn A and D.<br><br>HPLC-UV method GRM 95.03 is valid for the determination of spinosyns A and D in ruminant tissues and milk.<br>Valid range 0.01-10.0 mg/kg for beef fat and cream, and 0.01-1.0 mg/kg for milk, beef liver, lean beef, and beef kidney. LOQ = 0.01 mg/kg<br><br>Immunoassay method GRM 95.14 is valid for the determination of total spinosad residue in ruminant tissues and milk.<br>Valid range 0.01-0.50 mg/kg for bovine kidney, lean muscle, and whole milk and 0.01- 5.0 mg/kg for bovine liver. LOQ = 0.01 mg/kg. Fat samples were not validated. Method GRM 95.14 is valuable as a screening method to establish the presence of spinosyns. |

Revised HPLC-UV method GRM 95.15.R1 is valid for the determination of spinosyns A and D in poultry tissues and eggs.
Valid range 0.01-1.0 mg/kg for eggs and poultry tissues (liver, meat and meat with overlying skin and associated fat), LOQ = 0.01 mg/kg.
Valid range 0.02-2.0 mg/kg for poultry fat, LOQ =0.02 mg/kg.

## Spinosad

Threshold Limits and other Values for Human Health Risk Assessment

| **Summary** | | | |
|---|---|---|---|
| | Value | Study | SF |
| AEL long-term | 0.012 mg/kg bw/day | 24-month rat | 100 |
| AEL medium-term | 0.024 mg/kg bw/day | 90-day dog | 100, 50% correction for oral absorption |
| AEL acute | Not derived, no acute effects | | |
| ADI (if residues in food or feed) | 0.024 mg/kg bw/day | 24-month rat | 100 |
| Drinking water limit | 0.1µg/L | | |

| | |
|---|---|
| Inhalative absorption | No data; 100% used as a default |
| Oral absorption | 50% |
| Dermal absorption | 0.1% for the concentrated product<br>2% for a concentration comparable to the spray liquid |

| **Classification** | |
|---|---|
| with regard to toxicological data (according to the criteria in Dir. 67/548/EEC) | |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | |

## Elector

**General information**

| | |
|---|---|
| Formulation Type | Suspension concentrate |
| Active substance(s) (incl. content) | Spinosad (48%) |
| Category | PT18 |

| **Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)** | |
|---|---|
| Rat LD50 oral (OECD 420) | > 5000 mg/kg bw |
| Rat LD50 dermal (OECD 402) | > 2000 mg/kg bw |
| Rat LC50 inhalation (OECD 403) | Not acceptable* |
| Skin irritation (OECD 404) | Not irritating |
| Eye irritation (OECD 405) | Not irritating |
| Skin sensitisation (OECD 429; LLNA) | Not acceptable** |

* the study was considered to be not acceptable due to inadequate concentration measurement, incorrect MMAD calculation and negative pressure in the exposure unit
** The study is considered not acceptable, as in accordance with OECD 406 10 control and 20 test animals should have been used.

| **Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)** | |
|---|---|
| Directive 1999/45/EC | Professional: S36/37, S42*<br>Non-professional: - |
| Regulation 1272/2008/EC | Professional: P280c, P284**<br>Non-professional: - |

*S36/37 and S42 are assigned based on the risk assessment for professional users
**P280c and P284 are assigned based on the risk assessment for professional users

# Elector

## Exposure assessment

### Exposure scenarios for intended uses (Annex IIIB, point 6.6 )

Primary exposure of professionals

Application of Elector solution (0.41% spinosad) by coarse spraying

| Product and intended use | Exposure scenario | Inhalational uptake Exposure (mg/m$^3$) | Dermal uptake Exposure (mg b.p. per handling) |
|---|---|---|---|
| Elector<br>Application in and around accommodations for livestock, pigs and poultry for the control of house flies, stable flies, beetles and blood louse | Application of a diluted solution (0.41% spinosad) by coarse spraying for 6 hours | Indicative exposure 104 mg/m$^3$ biocidal product. | Hands: 181 mg/min potential exposure without glove; 10.7 mg/min inside glove.<br>Body: 92 mg/min. Uncertainty is moderate |

| **Inhalation Exposure** | |
|---|---|
| Indicative exposure biocidal product | 104 mg/m$^3$ |
| Breating rate | 1.25 m$^3$/hour (default) |
| Task duration | 6 hours |
| Amount of biocidal product inhaled | 104 x 1.25 x 6 = 780 mg |
| Amount of active substance inhaled (0.41%) | 780 x 0.41% = 3.198 mg a.s. |
| Operator body weight | 60 kg |
| **Inhaled internal systemic dose (no RPE)** | **3.198/60 = 0.0533 mg/kg bw/day** |
| Reduction by RPE | 90% |
| **Inhaled internal systemic dose (RPE, 90% reduction)** | **5.33 x 10$^{-3}$ mg/kg bw/day** |

| **Dermal Exposure** | |
|---|---|
| Indicative exposure biocidal product (hands + body) | 181 + 92 = 273 mg/min |
| Task duration | 360 minutes |
| Amount of biocidal product on skin | 273 x 360 = 98280 mg |
| Amount of active substance on skin (0.41% w/w) | 98280 x 0.41% = 402.948 mg a.s |
| Dermal absorption of spinosad | 2% |
| Operator body weight | 60 kg |
| **Dermal internal systemic dose (no PPE)** | **402.948 x 2%/60 = 0.134 mg/kg bw/day** |
| Reduction by PPE (coveralls) | 90% |
| Indicative exposure biocidal product inside gloves | 10.7 mg/min |
| Amount of biocidal product on hands inside gloves | 10.7 x 360 = 3852 mg |
| Amount of active substance on hands inside gloves | 3852 x 0.41% = 15.79 mg |

| | |
|---|---|
| Amount of biocidal product on the body (coveral, 90% reduction) | 92 x 10% = 9.2 mg |
| Amount of active substance on the body (coverall, 90% reduction) | 9.2 x 0.41% = 0.038 mg |
| Amount of active substance on skin (gloves and coverall) | 15.79 + 0.038 = 15.83 mg |
| Dermal internal systemic exposure to spinosad (coverall, gloves) | 15.83 x 2% / 60 = 5.28 x $10^{-3}$ mg/kg bw/day |

| **Exposure scenario** | **Component** | **CAS** | **Dermal Total [mg/kg/d] (no PPE)** | **Dermal Total [mg/day] (gloves, coverall)** | **Inhalation Exposure [mg/kg/d] (no PPE)** | **Inhation exposure [mg/kg/d] (RPE, 90% reduction)** | **Total exposure [mg/kg/d] (no PPE)** | **Total exposure [mg/kg/d] (gloves, 90% reduction)** |
|---|---|---|---|---|---|---|---|---|
| Application of a diluted solution (0.41% spinosad) by coarse spraying for 6 hours | Spinosad | 168316-95-8 | 0.134 | 5.28 x $10^{-3}$ | 0.0533 | 5.33 x $10^{-3}$ | 0.1873 | 0.0106 |

Risk assessment

| **Component** | **CAS** | **AEL [mg/kg/d]** | **Absorption** | | **Inhalation internal exposure [mg/kg/bw]** | | **Dermal internal exposure [mg/kg/d]** | | **RCR** |
|---|---|---|---|---|---|---|---|---|---|
| spinosad | 168316-95-8 | 0.024 | inh | derm | Act. Expo | RCR | Act. Expo | RCR | |
| | | | 100% | 2% | 5.33 x $10^{-3}$ | 0.22 | 5.28 x $10^{-3}$ | 0.22 | 0.44 |

## Annex 7: Safety for non-professional operators and the general public

| Elector |
|---|

| General information | |
|---|---|
| Formulation Type | Suspension concentrate |
| Active substance(s) (incl. content) | Spinosad (48%) |
| Category | PT18 |
| Authorisation number | |

**Spinosad (48%)**

| Data base for exposure estimation | |
|---|---|
| according to | Appendix: Toxicology and metabolism – active substance/CAR |

| Exposure scenarios for intended uses (Annex IIIB, point 6.6 ) | |
|---|---|
| Primary exposure | Non-professional users, application in and around animal premises by coarse spraying |
| Secondary exposure, acute | Infant touching treated surfaces and ingesting the product by hand-to-mouth transfer |
| Secondary exposure, chronic | Exposure via residues in the products of animal origin |

Primary exposure of amateurs

Application of Elector solution (0.41% spinosad) by coarse spraying

| Product and intended use | Exposure scenario | Inhalational uptake Exposure (mg/m$^3$) | Dermal uptake Exposure (mg b.p. per handling) |
|---|---|---|---|
| Elector<br>Application in and around accommodations for livestock, pigs and poultry for the control of house flies, stable flies, beetles and blood louse | Application of a diluted solution (0.41% spinosad) by coarse spraying for 6 hours | Indicative exposure 104 mg/m$^3$ biocidal product. | Hands: 181 mg/min potential exposure without glove; 10.7 mg/min inside glove.<br>Body: 92 mg/min. |

| **Inhalation Exposure** | |
|---|---|
| Indicative exposure biocidal product | 104 mg/m$^3$ |
| Breating rate | 1.25 m$^3$/hour (default) |
| Task duration | 40 minutes |
| Amount of biocidal product inhaled | 104 x 1.25 x 40/60 = 86.7 mg |
| Amount of active substance inhaled (0.41%) | 86.7 x 0.41% = 0.355 mg a.s. |
| Operator body weight | 60 kg |
| **Inhaled internal systemic dose (no RPE)** | **0.355/60 = 5.92 x 10$^{-3}$ mg/kg bw/day** |
| **Dermal Exposure** | |
| Indicative exposure biocidal product (hands + body) | 181 + 92 = 273 mg/min |
| Task duration | 40 minutes |
| Amount of biocidal product on skin | 273 x 40 = 10920 mg |
| Amount of active substance on skin (0.41% w/w) | 10920 x 0.41% = 44.772 mg a.s |
| Dermal absorption of spinosad | 2% |
| Operator body weight | 60 kg |
| **Dermal internal systemic dose (no PPE)** | **44.772 x 2%/60 = 0.015 mg/kg bw/day** |

| Exposure scenario | Component | CAS | Dermal Total [mg/kg/d] (no PPE) | Inhalation Exposure [mg/kg/d] (no PPE) | Total exposure [mg/kg/d] (no PPE) |
|---|---|---|---|---|---|
| Application of a diluted solution (0.41% spinosad) by coarse spraying for 6 hours | Spinosad | 168316-95-8 | 0.015 | 5.92 x 10$^{-3}$ | 0.021 |

Risk assessment

| Component | CAS | AEL [mg/kg/d] | Absorption | | Inhalation internal exposure [mg/kg/bw] | | Dermal internal exposure [mg/kg/d] | | RCR |
|---|---|---|---|---|---|---|---|---|---|
| spinosad | 168316-95-8 | 0.024 | inh | derm | Act. Expo | RCR | Act. Expo | RCR | |
| | | | 100% | 2% | $5.92 \times 10^{-3}$ | 0.25 | 0.015 | 0.625 | 0.875 |

Indirect exposure: infants touching the treated surfaces and ingesting the product by hand-to-mouth transfer

| Product and intended use | Exposure scenario | Inhalational uptake | Dermal uptake | Oral uptake |
|---|---|---|---|---|
| | | **Exposure concentration ($mg/m^3$)** | **Exposure concentration ($mg/m^2$)** | **Exposure concentration (mg/event)** |
| Elector<br>Application in and around animal housing for the control of flyes, beetles, blood louse | Non-users (adults, children and infants) will not be present during application.<br>Infants may touch the treated surfaces and ingest the substance due to hand-to-mouth transfer | None. | $5.76 \times 10^{-3}$ mg spinosad/$cm^2$ | No direct oral exposure |

| **1. EXPOSURE ASSESSMENT FOR INFANTS BASED ON DEFAULT VALUES** | |
|---|---|
| Concentration of spinosad on the surface | $5.76 \times 10^{-3}$ mg/$cm^2$ |
| Surface area of both hands | 200 $cm^2$ |
| Percentage of hands contaminated | 20% |
| Amount of spinosad on the hands | 0.2292 mg |
| Oral absorption | 50% |
| Infant body weight | 10 kg |
| **Internal oral systemic exposure to spinosad (considering 100% hand-to-mouth transfer)** | **0.2292 x 50%/10 = 0.011 mg/kg bw/day** |

| Exposure scenario | Component | CAS | Oral Total [mg/day] | Oral Total [mg/kg/d] |
|---|---|---|---|---|
| | | | | |

| | | | | |
|---|---|---|---|---|
| | | | | |
| Infant touching the treated surfaces and ingesting the product by hand-to-mouth transfer | Spinosad | 168316-95-8 | 0.1146 | 0.011 |

Risk assessment

| Exposure scenario | Component | CAS | AEL [mg/kg/d] | Absorption | | Inhal internal [mg/kg/bw] | | Derm internal [mg/kg/d] | | RCR total |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | inh | derm | Act. Expo | RCR | Act. Expo | RCR | |
| Application of Elector in and around animal premises by coarse spraying | Spinosad | 168316-95-8 | 0.024 | No data; 100% chosen as default | 2% | $5.92 \times 10^{-3}$ | 0.25 | 0.015 | 0.625 | 0.875 |

| Exposure scenario | Component | CAS | AEL [mg/kg/d] | Oral exposure [mg/kg/d] | | RCR total |
|---|---|---|---|---|---|---|
| | | | | Act. Expo | RCR | |
| Infant touching the treated surfaces and ingesting the product by hand-to-mouth transfer | Spinosad | 168316-95-8 | 0.024 | 0.011 | 0.458 | 0.458 |

Conclusion:
Exposure of non-professionals and the general public to the biocidal product containing 48% spinosad as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

| Spinosad |
| --- |

## Calculation of the dietary burden

Dietary risk assessment for the MRLs proposed for spinosad in animal products was calculated using the EFSA Pesticide Residue Intake (PRIMo) Model rev. 2[1], in which all national EU diets are incorporated.

## Dietary Risk Assessment for the MRLs proposed for spinosad in animal products

| | | TMDI (range) in % of ADI minimum - maximum | | | | | |
|---|---|---|---|---|---|---|---|
| | | 86 | | | | | |
| | | **No of diets exceeding ADI:** | --- | | | | |
| Highest calculated TMDI values in % of ADI | MS Diet | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities |
| 86.1 | FR toddler | 82.5 | Milk and cream, | 1.7 | Bovine: Meat | 0.8 | Birds' eggs |
| 82.6 | UK Infant | 80.7 | Milk and cream, | 1.1 | Birds' eggs | 0.8 | Bovine: Liver |
| 65.4 | NL child | 61.1 | Milk and cream, | 1.5 | Bovine: Meat | 0.6 | Bovine: Liver |
| 55.3 | FR infant | 53.6 | Milk and cream, | 0.7 | Bovine: Meat | 0.5 | Poultry: Meat |
| 44.0 | UK Toddler | 43.0 | Milk and cream, | 0.7 | Birds' eggs | 0.2 | Bovine: Liver |
| 31.7 | DE child | 29.8 | Milk and cream, | 0.9 | Birds' eggs | 0.5 | Poultry: Meat |
| 30.5 | ES child | 26.1 | Milk and cream, | 1.8 | Bovine: Meat | 1.1 | Poultry: Meat |
| 28.1 | DK child | 26.3 | Milk and cream, | 1.1 | Bovine: Liver | 0.7 | Birds' eggs |
| 26.5 | SE general population 90th percentile | 25.8 | Milk and cream, | 0.7 | Birds' eggs | | FRUIT (FRESH OR FROZEN) |
| 15.8 | NL general | 13.7 | Milk and cream, | 0.9 | Bovine: Meat | 0.3 | Poultry: Meat |
| 14.4 | WHO regional European diet | 10.0 | Milk and cream, | 1.3 | Bovine: Meat | 0.7 | Poultry: Meat |
| 13.1 | WHO cluster diet D | 10.5 | Milk and cream, | 0.7 | Bovine: Meat | 0.3 | Birds' eggs |
| 12.7 | ES adult | 10.3 | Milk and cream, | 0.9 | Bovine: Meat | 0.5 | Poultry: Meat |
| 12.6 | DK adult | 11.2 | Milk and cream, | 0.7 | Bovine: Meat | 0.5 | Bovine: Liver |
| 12.0 | FI adult | 11.8 | Milk and cream, | 0.2 | Birds' eggs | | FRUIT (FRESH OR FROZEN) |
| 11.8 | WHO Cluster diet B | 6.6 | Milk and cream, | 1.0 | Bovine: Meat | 0.8 | Poultry: Meat |
| 11.0 | WHO Cluster diet F | 8.3 | Milk and cream, | 1.1 | Bovine: Meat | 0.4 | Birds' eggs |
| 10.0 | LT adult | 8.3 | Milk and cream, | 0.5 | Swine: Fat free of lean meat | 0.3 | Bovine: Meat |
| 10.0 | WHO cluster diet E | 6.2 | Milk and cream, | 0.9 | Bovine: Meat | 0.8 | Poultry: Meat |
| 7.7 | IE adult | 5.8 | Milk and cream, | 0.5 | Bovine: Meat | 0.5 | Sheep: Liver |
| 7.1 | FR all population | 5.6 | Milk and cream, | 0.6 | Bovine: Meat | 0.5 | Poultry: Meat |
| 7.1 | UK vegetarian | 6.8 | Milk and cream, | 0.3 | Birds' eggs | 0.0 | Poultry: Meat |
| 6.6 | UK Adult | 6.2 | Milk and cream, | 0.3 | Birds' eggs | 0.1 | Bovine: Liver |
| | IT adult | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |
| | IT adult | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |
| | IT adult | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |
| | IT adult | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |

## Dietary Risk Assessment for the measured spinosad residues in cattle and chicken products

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | TMDI (range) in % of ADI minimum - maximum 12 | | | | | |
| | | **No of diets exceeding ADI:** | | --- | | | |
| Highest calculated TMDI values in % of ADI | MS Diet | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities |
| 11.7 | NL child | 11.2 | Milk and milk products: Cattle | 0.2 | Bovine: Meat | 0.1 | Eggs: Chicken |
| 10.1 | FR infant | 9.9 | Milk and milk products: Cattle | 0.1 | Bovine: Meat | 0.1 | Eggs: Chicken |
| 5.7 | DE child | 5.5 | Milk and milk products: Cattle | 0.2 | Eggs: Chicken | 0.0 | Bovine: Meat |
| 5.2 | ES child | 4.8 | Milk and milk products: Cattle | 0.2 | Bovine: Meat | 0.1 | Eggs: Chicken |
| 4.9 | SE general population 90th percentile | 4.7 | Milk and milk products: Cattle | 0.2 | Eggs: Chicken | | FRUIT (FRESH OR FROZEN) |
| 2.7 | NL general | 2.5 | Milk and milk products: Cattle | 0.1 | Bovine: Meat | 0.1 | Eggs: Chicken |
| 2.3 | WHO regional European diet | 1.8 | Milk and milk products: Cattle | 0.1 | Bovine: Meat | 0.1 | Poultry: Fat |
| 2.1 | ES adult | 1.9 | Milk and milk products: Cattle | 0.1 | Bovine: Meat | 0.1 | Eggs: Chicken |
| 2.0 | WHO cluster diet D | 1.8 | Milk and milk products: Cattle | 0.1 | Bovine: Meat | 0.1 | Eggs: Chicken |
| 1.8 | WHO Cluster diet F | 1.5 | Milk and milk products: Cattle | 0.1 | Bovine: Meat | 0.1 | Eggs: Chicken |
| 1.6 | LT adult | 1.5 | Milk and milk products: Cattle | 0.1 | Eggs: Chicken | 0.0 | Bovine: Meat |
| 1.6 | WHO Cluster diet B | 1.1 | Milk and milk products: Cattle | 0.1 | Bovine: Meat | 0.1 | Eggs: Chicken |
| 1.4 | WHO cluster diet E | 1.1 | Milk and milk products: Cattle | 0.1 | Eggs: Chicken | 0.1 | Bovine: Meat |
| 1.2 | IE adult | 1.1 | Milk and milk products: Cattle | 0.1 | Bovine: Meat | 0.0 | Eggs: Chicken |
| 1.2 | FR all population | 1.0 | Milk and milk products: Cattle | 0.1 | Bovine: Meat | 0.1 | Eggs: Chicken |
| 0.4 | FR toddler | 0.2 | Bovine: Meat | 0.2 | Eggs: Chicken | 0.0 | Poultry: Meat |
| 0.1 | DK adult | 0.1 | Bovine: Meat | 0.0 | Bovine: Liver | | FRUIT (FRESH OR FROZEN) |
| 0.1 | DK child | 0.1 | Bovine: Liver | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |
| 0.1 | UK Infant | 0.1 | Bovine: Liver | 0.0 | Bovine: Kidney | | FRUIT (FRESH OR FROZEN) |
| 0.0 | UK Toddler | 0.0 | Bovine: Liver | 0.0 | Bovine: Kidney | | FRUIT (FRESH OR FROZEN) |
| 0.0 | UK Adult | 0.0 | Bovine: Liver | 0.0 | Bovine: Kidney | | FRUIT (FRESH OR FROZEN) |
| 0.0 | UK vegetarian | 0.0 | Poultry: Meat | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |
| | FI adult | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |
| | FI adult | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |
| | FI adult | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |
| | FI adult | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |
| | FI adult | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) | | FRUIT (FRESH OR FROZEN) |

## Consumer risk assessment

When using the MRLs of spinosad from Regulation (EC) 396/2005, the conversion factor for liver and egg for poultry products and the PRIMo Model, for the Total Mean Daily Intake (TMDI) calculation the ADI is used for 182.8%, maximally, for the NL children (1-6y). Assuming that the STMR (Supervised Trial Median Residue) values are 50% of the MRL maximally, the refined Estimated Daily Intake (EDI) calculation shows that 91.4% of the ADI is used maximally for the NL children (1-6y). All other national diets use less of the ADI.

If only the use as a biocide is taken into account, the contribution of the tMRLs of animal products (ruminant products, poultry products) alone, the TMDI calculation is 86.9% of the ADI, maximally, for FR toddlers (refinement is not necessary). In all other national diets the tMRLs for animal products alone use less of the ADI.

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the general public to spinosad as a result of the application of Elector.

## Annex 9: Efficacy tests provided to demonstrate the efficacy of Elector against stable fly, house fly and lesser mealworm.

<table>
<tr><th>Test substance</th><th>Test organism(s)</th><th>Test system / concentrations applied / exposure time</th><th>Test results: effects, mode of action, resistance</th><th>Reference</th></tr>
<tr>
<td>Spinosad<br><br>25 g/L SC<br><br>Spinosyn A (65-95%) and Spinosyn D (5-35%)</td>
<td>Stomoxys calcitrans</td>
<td>Test method OPPTS Guideline No. 810.3500<br><br>Test system: One foot (approx. 30 cm) squares of painted, non-pressure treated, wood siding were used as the premise surface in this study. Four pieces of painted, non-pressure treated, wood siding were assigned to each treatment. Four fly containers were attached to each piece of painted, non-pressure treated, wood siding after the surface was dry.<br><br>Test flies: 10 mixed sex adult stable flies were placed in each fly container on Day 0, Day 7, Day 14 and Day 21.<br><br>Application: Plastic spray bottles were used to spray each treatment and tap water was obtained from the local municipal water source.<br><br>Exposure time: 24 days<br><br>Replicates: 4,<br>Lab test</td>
<td>Spinosad applied to painted, non-pressure treated, wood siding gave similar short-term knockdown and residual control against adult stable flies when compared to a synthetic pyrethroid. While it did not perform as well as the longest post-treatment time point evaluated in this study, performance through Day 17-post treatment was very comparable.<br><br>
<table>
<tr><th></th><th colspan="2">Day 3</th><th colspan="2">Day 10</th><th colspan="2">Day 17</th><th colspan="2">Day 24</th></tr>
<tr><th>Treatment</th><th>Ave. No. live flies</th><th>% Efficacy</th><th>Ave. No. live flies</th><th>% Efficacy</th><th>Ave. No. live flies</th><th>% Efficacy</th><th>Ave. No. live flies</th><th>% Efficacy</th></tr>
<tr><td>Tap water control</td><td>8.3</td><td>NA</td><td>7.9</td><td>NA</td><td>7.6</td><td>NA</td><td>8.5</td><td>NA</td></tr>
<tr><td>Spinosad 25 g/L SC</td><td>0.25</td><td>97.0</td><td>0.1</td><td>98.4</td><td>1.6</td><td>78.7</td><td>5.9</td><td>30.1</td></tr>
<tr><td>Atroban® 11 % EC</td><td>0</td><td>100</td><td>0</td><td>100</td><td>2.1</td><td>73.0</td><td>2.6</td><td>69.1</td></tr>
<tr><td colspan="9">Ave No. live flies= Average number of live flies per substrate within a treatment / the number of substrates in a treatment<br><br>Percent efficacy= [(Average number of live flies in untreated controls – Average number of live flies in a treatment group)/(Average number of live flies in untreated controls)]*100</td></tr>
</table>
</td>
<td>Naylor and Snyder (2001a)<br><br>B5.10 (01)</td>
</tr>
</table>

<table>
<tr>
<td>Spinosad<br><br>25 g/L SC<br><br>Spinosyn A (65-95%) and Spinosyn D (5-35%)</td>
<td>Stomoxys calcitrans</td>
<td>Test method OPPTS Guideline No. 810.3500<br><br>Test system: Four, one-foot square, non-painted concrete blocks were assigned to each treatment. The four pieces of the premise surface for each treatment group were positioned vertically along the interior wall of a well-ventilated room and physically separated to avoid contamination. Each piece of the premise surface was sprayed on the labelled side with the appropriate treatment to the point of run-off.<br><br>Test flies: 10 mixed sex adult stable flies were placed in each fly container on Day 0, Day 7, Day 14 and Day 21.<br><br>Application: Plastic spray bottles were used to spray each treatment.<br><br>Exposure time: 31 days<br><br>Replicates: 4<br>Lab test</td>
<td>Spinosad applied to non-painted concrete blocks gave similar short-term knockdown and residual control against adult stable flies when compared to a synthetic pyrethroid. The spinosad treated blocks provided better control of adult stable flies than the synthetic pyrethroid to a full 31 days after initial treatment. Summary of results after fly exposure to non-painted concrete blocks.<br><br>
<table>
<tr><th></th><th colspan="2">Day 3</th><th colspan="2">Day 10</th><th colspan="2">Day 18</th><th colspan="2">Day 25</th><th colspan="2">Day 31</th></tr>
<tr><th>Treatment</th><th>Ave. no. live flies</th><th>% Eff.</th><th>Ave. no. live flies</th><th>% Eff.</th><th>Ave. no. live flies</th><th>% Eff.</th><th>Ave. no. live flies</th><th>% Eff.</th><th>Ave. no. live flies</th><th>% Eff.</th></tr>
<tr><td>Tap water control</td><td>8.6</td><td>NA</td><td>8.6</td><td>NA</td><td>9.3</td><td>NA</td><td>7.8</td><td>NA</td><td>7.7</td><td>NA</td></tr>
<tr><td>Spinosad 25 g/L SC</td><td>0.06</td><td>99.3</td><td>0.06</td><td>99.3</td><td>0</td><td>100</td><td>0.1</td><td>98.4</td><td>0.5</td><td>93.5</td></tr>
<tr><td>Atroban® 11 % EC</td><td>0</td><td>100</td><td>0.2</td><td>97.8</td><td>1.6</td><td>83.3</td><td>0.9</td><td>87.9</td><td>1.3</td><td>83.7</td></tr>
<tr><td colspan="11">Ave. no live flies = ave. no. live flies per substrate within a treatment/the number of substrates in a treatment<br><br>% Efficacy= [(Ave. no. live flies in untreated controls – Ave. no. live flies in a treatment group)/(Ave. no. live flies in untreated controls)] * 100</td></tr>
</table>
</td>
<td>Naylor and Snyder (2001b)<br><br>B5.10 (02)</td>
</tr>
</table>

| | | | | |
|---|---|---|---|---|
| Spinosad<br>25 g/L SC<br>Spinosyn A (65-95 %) and Spinosyn D (5-35 %) | *Stomoxys calcitrans* | ***Test method*** *OPPTS Guideline No. 810.3500*<br>***Test system****: Four painted concrete blocks were assigned to each treatment. The four pieces of the premise surface for each treatment group were positioned vertically along the interior wall of a well-ventilated room and physically separated to avoid contamination. Each piece of the premise surface was sprayed on the labelled side with the appropriate treatment to the point of run-off.*<br>*Test flies: 10 mixed sex adult stable flies were placed in each fly container on Day 0, Day 7 and Day 14.*<br>***Application:*** *Plastic spray bottles were used to spray each treatment.*<br>***Exposure time****: 17 days*<br>***Replicates****: 4*<br>Lab test | Spinosad applied to **non-painted concrete blocks** gave reasonable short-term knockdown when compared to a synthetic pyrethroid with similar test conditions. In addition, spinosad gave adequate residual control against adult stable flies when compared to a synthetic pyrethroid to a 17 days after initial treatment. | Naylor and Snyder (2001c)<br>B5.10 (03) |

| | **Day 3** | | **Day 10[4]** | | **Day 17** | |
|---|---|---|---|---|---|---|
| **Treatment** | **Ave. No. live flies[1]** | **% Efficacy[2]** | **Ave. no. live flies[1]** | **% Efficacy[2]** | **Ave. no. live flies[1]** | **% Efficacy[2]** |
| **Tap water control** | 9.1 | NA | 7.5 | NA | 8.0 | NA |
| **Spinosad 25 g/L SC** | 3.1 (1.5)[3] | 65.9 (83.5)[3] | 2.7 (1.7)[3] | 64.0 (77.3)[3] | 3.1 (2.3)[3] | 61.3 (71.3)[3] |
| **Atroban® 11 % EC** | 0.8 | 91.2 | 2.7 | 64.0 | 3.7 | 53.8 |

[1]Ave. No live flies = ave. no. live flies per substrate within a treatment/the number of substrates in a treatment

[2]% Efficacy= [(Ave. no. live flies in untreated controls – Ave. no. live flies in a treatment group)/(Ave. no. live flies in untreated controls)] * 100

[3] Ave. No. live flies and percent efficacy were recalculated without substrate number 17

[4] Added flies to only 3 of the 4 substrates due to low fly hatch. Efficacy was determined based on 3 substrates with 4 containers each and 12 containers total instead of 4 substrates with 4 containers each and 16 containers total.

<table>
<tr>
<td>Spinosad<br>25 g/L SC<br>Spinosyn A (65-95%) and Spinosyn D (5-35%)</td>
<td>Stomoxys calcitrans</td>
<td>Test method OPPTS Guideline No. 810.3500<br><br>Test system: One-foot (approx. 30 cm) squares of unpainted, pressure treated plywood were used as the premise surface. Twelve cutout were assigned to each treatment. The 12 cutouts were positioned vertically, outside along the exterior wall of the building, physically separated to avoid contamination and sprayed to the point of run-off.<br><br>Application: Plastic spray bottles were used to spray each treatment.<br><br>Exposure time: 15 days<br><br>Replicates: 4<br>Lab test</td>
<td>Spinosad applied to the surface of a common substrate found in agricultural and livestock facilities, namely unpainted pressure treated plywood, gave similar short-term knock-down and residual control against adult stable flies when compared to an organophosphate or a synthetic pyrethroid. While it did not perform as well at the longer post-treatment timepoints evaluated in this study, this new class of chemistry does have the added advantage of being able to control flies that have varying levels of resistance to older classes of chemistry.<br><br>
<table>
<tr><td></td><td colspan="2">Day 2</td><td colspan="2">Day 8</td><td colspan="2">Day 15</td></tr>
<tr><td>Treatment</td><td>Ave. no. dead flies[1]</td><td>% Mortality[2]</td><td>Ave. no. dead flies[1]</td><td>% Mortality[2]</td><td>Ave. no. dead flies[1]</td><td>% Mortality[2]</td></tr>
<tr><td>Tap water control</td><td>3.5</td><td>11.7</td><td>3.5</td><td>11.7</td><td>4.0</td><td>13.3</td></tr>
<tr><td>Rabon®50 WP</td><td>25.5</td><td>85.0</td><td>27.75</td><td>92.5</td><td>28.0</td><td>93.3</td></tr>
<tr><td>Atroban® 42.5 % EC</td><td>26.5</td><td>88.3</td><td>28.25</td><td>94.2</td><td>27.75</td><td>92.5</td></tr>
<tr><td>Spinosad 25 g/L SC</td><td>22.5</td><td>75.0</td><td>14.25</td><td>47.5</td><td>14.75</td><td>49.2</td></tr>
<tr><td colspan="7">Ave. no dead flies = (dead flies in Box A + dead flies in Box B + dead flies in Box C + dead flies in Box D)/4<br><br>% Mortality= (Ave. no. dead /30) * 100</td></tr>
</table>
</td>
<td>Naylor and Snyder (2000)<br><br>B5.10 (04)</td>
</tr>
</table>

| | | | | |
|---|---|---|---|---|
| *Spinosad*<br><br>*25 g/L SC*<br><br>Spinosyn A (65-95%) and Spinosyn D (5-35%) | *Stomoxys calcitrans* | ***Test method*** *OPPTS Guideline No. 810.3500*<br><br>***Test system****: Four separate and isolated rooms with screened entryways were used for this study. Each room was approximately 3 m × 5 m × 2.6 m. One wall of each room was screened from floor to ceiling. The cement block walls and ceiling of each animal room were painted with high gloss paint. The screened wall was not painted. All four walls and the ceilings were sprayed while the floors were not sprayed. There were 3 rooms sprayed with spinosad and one room sprayed with tap water. Each room was identified by room number.*<br><br>***Application:*** *The efficacy of spinosad 25 g/L SC was tested at 800 and 400 ppm.*<br><br>***Exposure time****: 8 days*<br><br>***Replicates****: 4*<br><br>**Simulated use test** | Spinosad applied at either 400 or 800 ppm to the **surfaces inside an enclosed animal facility** gave excellent short-term knockdown and one week residual control against adult stable flies. These results show that enclosed animal facilities could be sprayed with 400 or 800 ppm spinosad weekly to reduce stable fly infestations. | Naylor and Snyder (2001d)<br><br>B5.10 (05) |

<table>
<tr>
<td>Spinosad SC 480 g AI /L<br><br>AI: Spinosad Tech.l: 90% Spinosyn A and Spinosyn D (ratio A/D: 87/13)</td>
<td>Musca domestica</td>
<td>Test methods: OPPTS Guideline No. 810.1000 and 810.3500<br><br>Test system: Poultry facilities were treated Housing: caged layer houses.<br><br>Each house was treated with either the test substance, a negative control (0 ppm spinosad) or an approved product at approved levels and application rates.<br><br>Application: The concentrations of spinosad applied were 0 ppm spinosad, 800 ppm spinosad or 800 ppm spinosad with 5% white sugar by weight as an additive/attractant. Each solution was applied at a rate of two gallons per 1000 ft$^2$.(2.5 ml/m²)<br><br>Positive control: Tempo (20% Cyfluthrin)<br><br>Exposure time: 28 days<br><br>Replicates: 1<br><br>Field test</td>
<td>Spinosad 800 ppm and spinosad 800 ppm + sugar, when administered at a rate of 2 gallons per 1000 square feet, had comparable efficacy to the positive control product, Tempo, administered at 10 g/1000 square feet.<br><br>
<table>
<tr><td></td><td colspan="4">Test Substance</td></tr>
<tr><td></td><td>800 ppm Spinosad</td><td>800 ppm Spinosad+Sugar</td><td>Tempo</td><td>Negative Control</td></tr>
<tr><td>Study Day</td><td>Building Number 3</td><td>Building Number 4</td><td>Building Number 5[1]</td><td>Building Number 6[1]</td></tr>
<tr><td>-15 (baseline)</td><td>22</td><td>28</td><td>13</td><td>20</td></tr>
<tr><td>0</td><td>9</td><td>20</td><td>11.5</td><td>22.9</td></tr>
<tr><td>1</td><td>3</td><td>23</td><td>3.4</td><td>42.4</td></tr>
<tr><td>2</td><td>7</td><td>14</td><td>9.2</td><td>51.5</td></tr>
<tr><td>3</td><td>7</td><td>21</td><td>6.9</td><td>45.8</td></tr>
<tr><td>4</td><td>5</td><td>14</td><td>0.0</td><td>18.3</td></tr>
<tr><td>5</td><td>6</td><td>16</td><td>2.3</td><td>22.9</td></tr>
<tr><td>6</td><td>4</td><td>5</td><td>2.3</td><td>21.8</td></tr>
<tr><td>7</td><td>5</td><td>6</td><td>5.7</td><td>26.3</td></tr>
<tr><td>14</td><td>9</td><td>44</td><td>6.9</td><td>24.1</td></tr>
<tr><td>21</td><td>9</td><td>16</td><td>11.5</td><td>42.4</td></tr>
<tr><td>28</td><td>11</td><td>19</td><td>17.2</td><td>40.1</td></tr>
<tr><td>Average (Day 0-28)</td><td>6.8</td><td>18.0</td><td>7.0</td><td>32.6</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Percent Improvement[2]: Day 28 Sticky Fly Ribbon Counts - Total</td></tr>
<tr><td colspan="4">800 ppm Spinosad compared to Negative Control</td><td>79.1</td></tr>
<tr><td colspan="4">800 ppm Spinosad compared to Tempo</td><td>2.9</td></tr>
<tr><td colspan="4">800 ppm Spinosad+Sugar compared to Negative Control</td><td>44.8</td></tr>
<tr><td colspan="4">800 ppm Spinosad+Sugar compared to Tempo</td><td>-157.1</td></tr>
</table>
[1] In order to compare efficacy results on an equal building square foot basis, Sticky Fly Ribbon Counts were adjusted upward by a factor of 1.15 for Buildings 5 and 6 to account for their smaller floor area.<br>
[2] The following formula was used to determine percent improvement: % Improvement = ((Negative or Positive Control 28 day mean – Treatment Group mean)/Control Group mean)*100.</td>
<td>TerHune (2002)<br><br>B5.10 (06)</td>
</tr>
</table>

| | | | | |
|---|---|---|---|---|
| Spinosad SC 480 g AI /L<br><br>AI: Spinosad Tech.I: 90% Spinosyn A and Spinosyn D (ratio A/D: 87/13) | *Musca domestica* | ***Test methods:*** *OPPTS Guideline No. 810.1000 and 810.3500*<br><br>***Test system:*** *The type of confined poultry premises used included caged-egglayer houses. The houses selected had similar aged birds and stored manure conditions and with established house fly and beetle populations.*<br><br>***Application:*** *Spinosad was diluted to the appropriate concentration and applied to the poultry pit walls and facility support structures within the pit. Commercially available spraying equipment was used.*<br><br>*Reference substance: Positive control: Tempo 20 WP (20 % Cyfluthrin)*<br><br>***Exposure time****: 28 days*<br><br>***Replicates****: 1*<br><br>**Field test** | Based on the results of this study, the spinosad treatment with added sugar afforded observable control of house flies; whereas the other treatments (spinosad at 800 ppm and Tempo) kept adult fly numbers from increasing. In the untreated house, house fly numbers were observed to increase over the course of the 4 weeks post-treatment. | Williams (2002)<br><br>B5.10 (07) |

| | | | | |
|---|---|---|---|---|
| Spinosad 44.2 % (w/w) or 480 g/L SC<br><br>Spinosyn A (65-95%) and Spinosyn D (5-35%) | *Alphitobius diaperinus* (lesser mealworms) | ***Test methods:*** *OPPTS Guideline Nos. 810.1000 and 810.3500*<br><br>***Test system:*** *The poultry facility (litter only) was treated prior to the placement of birds so that no animals were exposed to the test substances. The type of confined poultry premises used in this study was a multi-pen poultry research house.*<br><br>*All pens had adequate and equivalent feeding and watering space per bird. The number of birds was adjusted to approximate a floor space of 4 $ft^2$ per bird.*<br><br>*The infection with the beetles was done artificially and the infestation period was 30 days.*<br><br>***Application****: There were four concentrations (400, 600, 800 and 1600 ppm) of spinosad applied to each of 8 pens at a rate of either 1 or 2 gallons per 1000 $ft^2$ per pen on day -1 of the live phase of this study.*<br><br>***Exposure time****: 49 days*<br><br>***Replicates****: 4*<br><br>**Field test** | Spinosad SC was effective at reducing **lesser mealworm infestations** at levels at and above 400 ppm, applied at either 1or 2 gal/1000 $ft^2$ (3.8- 7.6 L / 90 m2) up through 30 days of the last phase when compared to the positive control (Tempo). Spinosad SC was effective at reducing darkling beetle infestations at levels above 400 ppm, applied at either 1 or 2 gal/ 1000 $ft^2$ up through 49 days of the last phase when compared to the positive control (Tempo). All spinosad treatments were effective in reducing darkling beetle infestations when compared to the negative control over the 49 day live phase period. | Howard (2002)<br><br>B5 10.(08) |

| Pen No. | TA[1] | Conc. | ROA[2] | 19-Oct | 20-Oct | 22-Oct | 26-Oct | 2-Nov | 9-Nov | 16-Nov | 23-Nov | 30-Nov | 7-Dec | Totals (D0 - D49)[3] | Trt. Means | % of |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Ppm | | | | | | | | | | | | | | Control |
| 1 | Spinosad | 1600 | 0.5 | 0 | 0 | 0 | 16 | 10 | 3 | 23 | 7 | 4 | 16 | 79 | 8 | 97.19 |
| 2 | Spinosad | 800 | 0.5 | 0 | 0 | 0 | 9 | 12 | 8 | 30 | 9 | 19 | 6 | 93 | 9 | 96.70 |
| 3 | Tempo | 16ml/gal | 1 | 0 | 1 | 0 | 7 | 5 | 2 | 11 | 1 | 2 | 5 | 34 | 3 | 98.79 |
| 4 | Spinosad | 600 | 0.5 | 0 | 1 | 0 | 1 | 10 | 40 | 37 | 25 | 13 | 10 | 137 | 14 | 95.13 |
| 5 | Neg Cont | 0 | 1 | 0 | 3 | 1 | 66 | 61 | 125 | 130 | 258 | 722 | 1450 | 2816 | 282 | |
| 6 | Spinosad | 400 | 0.5 | 0 | 0 | 0 | 26 | 13 | 27 | 44 | 35 | 117 | 181 | 443 | 44 | 84.27 |
| 7 | Spinosad | 400 | 1 | 0 | 0 | 0 | 8 | 10 | 35 | 20 | 22 | 253 | 81 | 429 | 43 | 84.77 |
| 8 | Spinosad | 600 | 1 | 0 | 0 | 0 | 3 | 1 | 11 | 35 | 49 | 21 | 18 | 138 | 14 | 95.10 |
| 9 | Spinosad | 800 | 1 | 0 | 2 | 1 | 2 | 0 | 16 | 23 | 15 | 24 | 26 | 109 | 11 | 96.13 |
| 10 | Spinosad | 1600 | 1 | 0 | 3 | 0 | 1 | 0 | 2 | 2 | 1 | 5 | 11 | 25 | 3 | 99.11 |

1 TA = Test Article
2 ROA = Rate of Application
3 Total from October 19th through December 7th.
Note: All counts are a total of 4 tube traps per pen.

<table>
<tr>
<td>Spinosad 44.2% (w/w) or 480 g/L SC<br><br>Spinosyn A (65-95%) and Spinosyn D (5-35%)</td>
<td>Alphitobius diaperinus (lesser mealworms)</td>
<td>Test methods: OPPTS Guideline Nos. 810.1000, 810.3000, 810.3200 and 810.3500<br><br>Test system: An artificial infestation model for populating the pens with insects was used. The test system is comprised of Alphitobius diaperinus (the insect) and the poultry litter. A multiple floor-pen poultry research house was used. The study was conducted utilizing a randomized complete block design for the pens and treatments<br><br>Application: The treatment groups consisted of spinosad applied at 400, 800 or 1600 ppm, tap water (negative control) and Tempo SC Ultra (reference substance, 8 ml per 2 gallons approx. 126.59 ppm)<br><br>Exposure time: 49 days<br><br>Replicates 2<br><br>Field test</td>
<td>Spinosad SC was shown to be highly effective for the control of the lesser mealworm when administered at 800 ppm and 1600 ppm at a rate of 2 gallons per 1000 $ft^2$ as compared to both the negative control (tap water) and Tempo® (the reference substance). The mean percent improvement (% control) for the live and dead, adult and larval forms of A. diaperinus at Day 49 for the 800 ppm spinosad concentration (74.74%) and the 1600 ppm spinosad concentration (87.29%) was numerically superior to that of Tempo® (65.83%).<br><br>
<table>
<tr><th>Treatment</th><th>Day 0</th><th>Day 7</th><th>Day 14</th><th>Day 21</th><th>Day 28</th><th>Day 35</th><th>Day 42</th><th>Day 49</th></tr>
<tr><td>1600 ppm</td><td>88.24</td><td>0.00</td><td>78.22</td><td>98.29</td><td>99.41</td><td>93.62</td><td>84.20</td><td>87.29</td></tr>
<tr><td>800 ppm</td><td>94.12</td><td>0.00</td><td>76.56</td><td>96.77</td><td>97.72</td><td>87.71</td><td>59.66</td><td>74.74</td></tr>
<tr><td>400 ppm</td><td>88.24</td><td>0.00</td><td>32.37</td><td>80.34</td><td>81.16</td><td>80.68</td><td>42.35</td><td>58.17</td></tr>
<tr><td>Tempo® (126.59 ppm)</td><td>100.00</td><td>0.00</td><td>62.45</td><td>90.84</td><td>95.36</td><td>83.64</td><td>56.47</td><td>65.83</td></tr>
</table>
</td>
<td>Moore (2005a)<br><br>B5.10 (09)</td>
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| Spinosad 44.2% (w/w) or 480 g/L SC<br><br>Spinosyn A (65-95%) and Spinosyn D (5-35%) | *Alphitobius diaperinus* (lesser mealworms) | ***Test methods:*** *OPPTS Guideline Nos. 810.1000, 810.3000, 810.3200 and 810.3500*<br><br>***Test system:*** *The test system is comprised of Alphitobius diaperinus (the insect) and the poultry litter. A multiple floor-pen poultry research house was used. The study was conducted utilizing a randomized complete block design for the pens and treatments.*<br><br>***Application****: The treatment groups consisted of spinosad applied at 400, 800 or 1600 ppm, tap water (negative control) and Tempo SC Ultra (reference substance, 8 ml per 2 gallons, approx. 126.59 ppm)*<br><br>***Exposure time****: 49 days*<br><br>***Replicates*** *2*<br><br>**Field test** | Spinosad SC, applied at 400 and 800 ppm to poultry litter for the control of larval and adult forms of *A. diaperinus*, demonstrated variable efficacy by observation day. Spinosad SC was shown to be effective for the control of the lesser mealworm when administered at 1600 ppm at a rate of 2 gallons per 1000 $ft^2$ as compared to all other treatments. Spinosad SC applied at 1600 ppm performed comparable to the reference substance Tempo®. | Moore (2005b)<br><br>B5.10 (10) |

| **Treatment** | **Day 0** | **Day 7** | **Day 14** | **Day 21** | **Day 28** | **Day 35** | **Day 42** | **Day 49** |
|---|---|---|---|---|---|---|---|---|
| 1600 ppm | 20.27 | 74.55 | 89.00 | 70.06 | 66.32 | 65.50 | 57.55 | 49.83 |
| 800 ppm | 10.36 | 66.91 | 71.22 | 54.75 | 25.17 | 51.77 | 37.10 | 34.52 |
| 400 ppm | 5.41 | 75.27 | 64.57 | 28.34 | 62.65 | 61.37 | 44.78 | 26.02 |
| Tempo® (126.59 ppm) | 33.78 | 85.66 | 81.98 | 41.46 | 82.24 | 61.76 | 62.16 | 40.74 |

<table>
<tr>
<td>Spinosad 44.2% (w/w) or 480 g/L SC<br><br>Spinosyn A (65-95%) and Spinosyn D (5-35 %)</td>
<td>Alphitobius diaperinus (lesser mealworms)</td>
<td>Test methods: OPPTS Guideline Nos. 810.1000, 810.3000, 810.3200 and 810.3500<br><br>Test system: An artificial infestation model for populating the pens with insects was used. The test system is comprised of Alphitobius diaperinus (the insect) and the poultry litter. A multiple floor-pen poultry research house was used. The study was conducted utilizing a randomized complete block design for the pens and treatments.<br><br>Application: The treatment groups consisted of spinosad applied at 400, 800 or 1600 ppm, tap water (negative control) and Tempo® 20 WP (reference substance, 10 g per 2 gallons (approx. 264.17 ppm)<br><br>Exposure time: 49 days<br><br>Replicates 2<br><br>Field test</td>
<td>Spinosad SC applied at 400, 800 and 1600 ppm to poultry litter at a rate of 2 gallons per 1000 $ft^2$ was shown to be effective for the control of the lesser mealworm as compared to both the negative control (tap water) and Tempo® (the reference substance). The mean percent improvement (% control) for the live and dead, adult and larval forms of A. diaperinus at day 49 for the 400, 800 and 1600 ppm spinosad concentrations was 84.51%, 81.69% and 88.73% respectively and all were superior to Tempo® at 61.27% control.<br><br>
<table>
<tr><th>Treatment</th><th>Day 0</th><th>Day 7</th><th>Day 14</th><th>Day 21</th><th>Day 28</th><th>Day 35</th><th>Day 42</th><th>Day 49</th></tr>
<tr><td>1600 ppm</td><td>37.55</td><td>49.22</td><td>44.76</td><td>32.56</td><td>19.00</td><td>76.92</td><td>75.19</td><td>84.51</td></tr>
<tr><td>800 ppm</td><td>48.03</td><td>0.00</td><td>0.00</td><td>42.44</td><td>59.00</td><td>91.35</td><td>94.74</td><td>81.69</td></tr>
<tr><td>400 ppm</td><td>47.16</td><td>50.78</td><td>10.49</td><td>44.77</td><td>60.00</td><td>82.69</td><td>81.95</td><td>88.73</td></tr>
<tr><td>Tempo® (264.17 ppm)</td><td>33.19</td><td>22.48</td><td>0.00</td><td>44.77</td><td>38.00</td><td>39.42</td><td>78.95</td><td>61.27</td></tr>
</table></td>
<td>Moore (2005c)<br><br>B5.10 (11)</td>
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| Spinosad suspension (250 ppm)<br><br>Spinosyn A (65-95%) and Spinosyn D (5-35%) | *Alphitobius diaperinus* (lesser mealworms) | ***Test methods:*** *Commercial field trial*<br><br>***Test system:*** *The study was run in a commercial broiler farm in Queensland, Australia. Approx. 270 000 birds across seven sheds were used during the trial. Treatments were allocated to sheds at random and the investigators and co-operator were blinded to treatment.*<br><br>*Chickens were placed 1 day after spray treatment of the shed walls and earth floor. The study was run over three batches of birds and spraying was repeated at the beginning of each batch of birds. The sheds had compacted earth floors. The A. diaperinus populations were considered to be high to very high.*<br><br>***Application****: Following dose rates: 0, 125, 250 and 500 ml/m² of a 250 ppm spinosad suspension (0 mg, 31.25 mg, 62.5 mg and 125 mg spinosad / m² respectively) with Tugon® WP (100 g/ 50 L cyfluthrin).*<br><br>***Exposure time****: 49 to 56 days*<br><br>***Replicates****: no*<br><br>***Field test*** | *Mean numbers of live A. diaperinus and percentage dead A. diaperinus were plotted against time for each shed (treatment group). In all sheds, for all treatments, populations of beetles were very low just after clean out and treatment. Following placement of the chickens in the shed, beetle numbers increased and peaked when the chickens were two to three weeks old. At approx. 4 weeks the live beetle numbers dropped dramatically and at cleanout the numbers were again reduced to a very low level. Over each successive batch, beetle numbers declined in association with the change in seasons from summer to winter.*<br><br>The beetle numbers response to spinosad was dose dependent. Spinosad (250 ppm) applied at 500 ml/m² gave the lowest pest population growth rates of all batches in all sheds. The response to treatment in the 250 ppm at 250 ml/m² dose was not substantially different from the 500 ml/m² dose, particularly in the latter half of the study.<br><br>The highest application rate of spinosad (500 ml/m²) gave a consistently and significant suppression of A. diaperinus. All other doses rates of spinosad and the positive control gave unsatisfactory results. | Lambkin (2002)<br><br>B5.10 (12) |

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| Elector® spinosad 44.2% (w/w) SC or 480 g/L (w/v)<br><br>Spinosyn A (65-95%) and Spinosyn D (5-35%) | *Dermanyssus gallinae* | ***Test method:*** *The study aimed the determination of the optimal dose of Elector when applied to the cages of laying hens (with hens in situ) for the treatment and control of poultry red mite.*<br><br>***Test system:*** *A small commercial layer house was used for the trial. The house contained two rows of "Big Dutchman" layer cages. Each row had four tiers of cages set back-to-back. Each row was 24 cages long, providing a total of 192 cages per row. The uppermost tier was not populated with birds.*<br><br>*Each study cage was 500 mm wide, 460 mm deep and 460 mm high at the front and 400 mm high at the back and contained four nipple drinkers. Each cage contained four laying hens at the start of the study.*<br><br>***Application:*** *A single spray application on Day 1 was used. Cages were sprayed with spinosad diluted with water and administered via a hand-held lance sprayer (Hozelock 7 L Killaspray).*<br><br>***Exposure time:*** *28 days*<br><br>***Replicates****: 4* | *<u>Total number of mites</u>: Total mite populations were significantly different between treatments at all points with the exception of 21 days PS (post-spray). Significant differences between pairs of means confirm that total mite numbers following application of spinosad were significantly lower than in the control treatment. There was a consistent trend for lower mite numbers at the higher spinosad rate.*<br><br>*<u>Proportion of adult females</u>: The proportion of adult females was significantly different between treatments at all time points PS, with the exception of 3 days PS and 21 days PS. There was an initial drop in the proportion of females in spinosad-treated cages at 7 days PS, but at all later time points this trend was reversed.*<br><br>*<u>Nymphs and adult males per adult female</u>: There appeared to be an initial increase in the number of nymphs and adult males per adult female in spinosad treated cage groups, but at later time points this trend was reversed.*<br><br>*<u>Eggs per adult female</u>: The number of eggs per adult female was only significantly decreased in the spinosad-high treated group 3 days PS and varied inconsistently in other weeks.*<br><br>*<u>Proportion of the population unfed</u>: The proportion of the population unfed was significantly higher in the control treatment for 14 days PS data only. The proportion generally decreased progressively with increased spinosad application rate.* | Knox (2009)<br><br>B5.10 (14) |

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<tr>
<td>Elector® 44.2% (w/w) SC or 480 g/L (w/v)<br><br>Spinosyn A (65-95%) and Spinosyn D (5-35%)</td>
<td>Dermanyssus gallinae</td>
<td>Test method: A field study in which Elector's efficacy was evaluated under commercial conditions applied by commercial equipment.<br><br>Test system: The study consisted of one commercial facility with two poultry layer houses. A different facility served as an untreated control. The houses were of the aviary style or cage free birds. Two houses were treated with Elector one time and one house was not treated.<br><br>The poultry house (stable) was sampled for red mites from 10 locations throughout each house (treated and untreated).<br><br>Application: Study used the commercial Elector® formulation containing spinosad (480 g/L SC) which was diluted in water according to the following scheme: 30, 60 or 0 mL Elector® in 7 L water.<br><br>Exposure time: 93 days<br><br>Replicates: 2</td>
<td>Red mite count results showed that the 60 mL dose was more effective than the 30 mL dose. The duration of effectiveness was longer with the 60 mL dose than the 30 mL dose.<br><br>
<table>
<tr><th rowspan="2">Sampling Day</th><th colspan="3">Total number of red mites</th><th colspan="2">Reduction (%)</th></tr>
<tr><th>Stable 1 4 mg/mL</th><th>Stable 2 2 mg/mL</th><th>Control</th><th>Stable 1 4 mg/mL</th><th>Stable 2 2 mg/mL</th></tr>
<tr><td>0</td><td>10260</td><td>12010</td><td>12300</td><td>16.6</td><td>2.6</td></tr>
<tr><td>7</td><td>71</td><td>241</td><td>15720</td><td>99.5</td><td>98.5</td></tr>
<tr><td>14</td><td>0</td><td>38</td><td>14980</td><td>100</td><td>99.7</td></tr>
<tr><td>21</td><td>1</td><td>263</td><td>8750</td><td>99.9</td><td>97</td></tr>
<tr><td>28</td><td>1</td><td>81</td><td>18749</td><td>99.9</td><td>99.6</td></tr>
<tr><td>35</td><td>16</td><td>1117</td><td>16880</td><td>99.9</td><td>93.4</td></tr>
<tr><td>42</td><td>7</td><td>2248</td><td>10800</td><td>99.9</td><td>79.2</td></tr>
<tr><td>49</td><td>1</td><td>3110</td><td>12090</td><td>99.9</td><td>74.3</td></tr>
<tr><td>56</td><td>196</td><td>10310</td><td>14080</td><td>98.6</td><td>26.8</td></tr>
<tr><td>63</td><td>280</td><td>n.c.</td><td>13870</td><td>98</td><td>n.c.</td></tr>
<tr><td>70</td><td>444</td><td>n.c.</td><td>6410</td><td>93.1</td><td>n.c.</td></tr>
<tr><td>77</td><td>565</td><td>n.c.</td><td>9450</td><td>94</td><td>n.c.</td></tr>
<tr><td>84</td><td>3066</td><td>n.c.</td><td>7090</td><td>56.8</td><td>n.c.</td></tr>
<tr><td>93</td><td>11510</td><td>n.c.</td><td>7560</td><td>0</td><td>n.c.</td></tr>
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n.c = not collected</td>
<td>Liebisch (2009)<br><br>B5.10 (15)</td>
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| Elector®<br>44.2% (w/w) SC or 480 g/L (w/v)<br>Spinosyn A (65-95%) and Spinosyn D (5-35%) | *Dermanyssus gallinae* | ***Test method and test system:*** *Laboratory experiment in which red mites collected from a commercial layer facility were put in contact to glass vials treated with spinosad.*<br>***Application:****. Seven doses were tested including the negative control. Each dose consisted of three replicates with 20 to 25 red mites in a glass vial (chromacol)*<br>***Exposure time:*** *Max. 48 h*<br>***Replicates****: 3* | <u>*Main effect of exposure time*</u>*: It is clearly shown that the number of dead and moribund red mites increased with the time of incubation from 20 % after 2 hours to 80 % after 48 hours. After 48 hours approx. 72 % were classified as being dead.*<br><br><u>*Mean effect of dose*</u>*: The maximum efficacy was shown using a concentration of the test substance of 1000 mg Elector®/L. Furthermore a higher dose level reduced the efficacy as the maximum percentage of dead or dead plus moribund was obtained at a dose level of 1000 mg Elector®/L whereas higher dose levels resulted in a lower percentage of dead or dead plus moribund* | Van der Klis (2007)<br>B5.10 (16) |