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

**Final PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



COMPO Ameisen-Stop

(COM 116 02 I AL)

Product type 18

*Lambda*-cyhalothrin as included in the Union list of approved active substances

Case Number in R4BP: BC-ND000941-57

Evaluating Competent Authority: Austria

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# CONCLUSION

Data on the biocidal product have demonstrated sufficient efficacy against garden ants (*Lasius niger*), silverfishes (*Lepisma saccharina*), wood lice (*Porcellio scaber*) and cockroaches (*Blattella germanica, Blatta orientalis,* and *Periplaneta americana*). *Lambda*-cyhalothrin has a specific mode of action that disrupts the nervous system causing paralysis or death. The risk of resistance developing is reduced due to the localised treatment (no massive or big areas treated) and in the case of garden ants no resistance is possible since the whole colony will not survive.

The physico-chemical properties of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

The overall conclusion from the evaluation of the biocidal product, COM 116 02 I AL, containing 0.05% w/w of the active substance *lambda*-cyhalothrin, is that the active substance will not present an unacceptable risk to humans during and after the intended use of the product.

The environmental risk assessment has demonstrated that the intended uses lead to acceptable risk for STP micro-organisms, groundwater and for secondary poisoning.

For soil non-target organisms acceptable risk was calculated in most scenarios, a slight risk was identified for 3 scenarios.

In the aquatic compartment unacceptable risk was calculated for all scenarios for surface water and sediment.

Risk mitigation measures are proposed in order to reduce the calculated risk in the aquatic and terrestrial compartment to acceptable levels.

Direct treatment of target organisms is not authorised as the proposed restriction to areas that are not wet cleaned is not feasible for the mobile species and the non-professional user.

# ASSESSMENT REPORT

## Summary

### Presentation of the biocidal product

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | *lambda*-cyhalothrin |
| **IUPAC or EC name** | Reaction mass of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (1:1) |
| **EC number** | 415-130-7 |
| **CAS number** | 91465-08-6 |
| **Index number in Annex VI of CLP** | 607-252-00-6 |
| **Minimum purity / content** | min. 900 g/kg |
| **Structural formula** |  |

#### Product composition and formulation

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

The active substance *lambda-*cyhalothrin is contained in the substance at 0.05% w/w.

Please see the confidential annex for further details.

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

The product does not contain substances of concern. For further information please refer to the confidential annex.

#### Authorised use

**Use 1 - Insecticide and product to control other arthropods – garden ants, silverfishes, woodlice and cockroaches – non-professionals – spraying - indoor**

|  |  |
| --- | --- |
| Product Type | PT 18 Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Insecticide and product to control other arthropods |
| Target organism (including development stage) | Scientific name: Formicinae: *Lasius sp.*  Common name: **garden ants**  Development stage: ant colony  Scientific name: Lepismatidae: *Lepisma saccharina*  Common name: Lepismatid: **silverfishes**  Development stage: larvae and adults  Scientific name: Porcellionidae: *Porcellio scaber*  Common name: **woodlice**  Development stage: larvae and adults  Scientific name: Blattodea: *Blattella germanica, Blatta orientalis, Periplaneta americana*  Common name: **cockroaches**  Development stage: larvae (nymphal stage) |
| Field of use | Indoor use |
| Application method(s) | Method of application: **spraying**  Detailed description of the method:  Ants:  For killing ant nests, COM 116 02 I AL is sprayed on ant routes on indoor hard surfaces.  Silverfishes, woodlice and cockroaches:  Application is conducted on spots of ground areas (residual treatment) where target organisms have been observed. |
| Application rate(s) and frequency | **The application rate:**  Ants:  10 strokes for 1 m route correspond to 10 g product (44.5 g/m²)  Silverfishes, Woodlice and Cockroaches:  Residual treatment:  Treat surfaces from a distance of ca. 30 cm with the trigger sprayer applying spotwise 5 to 6 strokes (100 g/m²). Apply only where insects are expected running over.  **Number and timing of application:**  Against ants:  Maximum once per month during season of ant activity.  Against silverfishes:  Every 2 weeks, if pest occurs again.  Against woodlice:  Every 26 weeks, if pest occurs again.  Against cockroaches:  Every week (porous ground e.g.vinyl);  every 24 weeks (non-porous ground e.g. glazed tiles), if pest occurs again. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Please see the relevant section. |

**Use 2 – Insecticide – garden ants – non-professionals – spraying - outdoor**

|  |  |
| --- | --- |
| Product Type | PT 18 Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Insecticide |
| Target organism (including development stage) | Scientific name: Formicinae: *Lasius sp.*  Common name: **garden ants**  Development stage: ant colony |
| Field of use | Outdoor use |
| Application method(s) | Method of application: **spraying**  Detailed description of the method:  For killing ant nests, COM 116 02 I AL is sprayed on ant routes and nest entries on paved surfaces like terraces.  Best application time is in the morning or evening when ants are staying in the nests. |
| Application rate(s) and frequency | **The application rate:**  10 strokes for 1 m route and nest entries correspond to 10 g product (44.5 g/m2).  **Number and timing of application:**  Maximum once per month during season of ant activity. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Please see the relevant section. |

#### Hazard and precautionary statements

**Classification and Labelling according to Regulation (EC) No 1272/2008:**

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute 1 |
| Hazard statement | H400: Very toxic to aquatic life. |
| Hazard category | Aquatic Chronic 1 |
| Hazard statement | H410: Very toxic to aquatic life with long lasting effects. |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Pictogram | GHS09 Environment |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects.  EUH208: Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction. |
| Precautionary statements | P102: Keep out of reach of children.  P103 Read label before use.  P270: Do not eat, drink or smoke when using the product.  P273: Avoid release to the environment.  P501: Dispose of contents/container to … in accordance with local/regional/national/international regulation (to be specified). |
| Note | **‒** |

#### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Trigger bottle | 200 ml;  250 ml;  300 ml;  400 ml;  500 ml;  750 ml;  900 ml;  1000 ml; | PET | Trigger is made of PP | non-professional | Yes |

### Summary of the physical, chemical and technical properties

The biocidal product COM 116 02 I AL is a slightly milky liquid with slightly sweetish odor. It has no explosive, oxidizing or flammable properties. No flash point was detected below 101°C, the onset of boiling and no auto-ignition temperature was detected below 650°C. The pH value of the neat formulation is 6.1 and 6.5 of a 1% suspension in water. Its acidity is 0.01% calculated as H2SO4. The density of the biocidal product is 0.999 g/cm3 at 20°C and the surface tension 37.1 mN/m at 20°C. The formulation is stable at 54°C for 2 weeks and for 4 years at 20°C. It has a shelf life of 4 years. Store in a cool, dry and frost-protected place" "Storage temperature: 5-30°C".

It is concluded therefore, that there are no hazards associated with the physico-chemical properties of COM 116 02 I AL under normal conditions of use.

### Summary of the Human Health Risk Assessment

|  |  |
| --- | --- |
| **Endpoint** | **Brief description** |
| Skin corrosion and irritation | Not irritating.\* |
| Eye irritation | Not irritating. |
| Skin sensitisation | Not sensitising. |
| Respiratory sensitization (ADS) | No study available. |
| Acute toxicity by oral route | Not toxic/Not harmful.\* |
| Acute toxicity by dermal route | Not toxic/Not harmful.\* |
| Acute toxicity by inhalation | Not toxic/Not harmful.\* |
| Dermal absorption | 1%. |
| Other effects | No study available. |
| Available toxicological data relating to non-active substance(s) | Not applicable |
| Available toxicological data relating to a mixture | Not applicable |
| Other relevant information | Not applicable |

\* Classification based on the general rules for classification of mixtures according to Regulation (EC) No. 1272/2008.

**Reference values**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Study** | **NOAEL/ LOAEL** | **Overall assessment factor** | **Value** |
| AELshort-term | Dog, 6 week | 0.75 mg/kg bw/day | 100 | 0.0038 mg/kg bw/day\* |
| AELmedium-term | Dog, 1 year | 0.5 mg/kg bw/day | 100 | 0.0025 mg/kg bw/day\* |
| AELlong-term | Dog, 1 year | 0.5 mg/kg bw/day | 100 | 0.0025 mg/kg bw/day\* |
| AELinhalation | Rat, 21-day | 0.08 mg/kg bw  (0.3 μg/L) | 100 | 0.0008 mg/kg bw (0.003 μg/L) |
| ARfD | Dog, 6 week | 0.75 mg/kg bw/day | 100 | 0.0075 mg/kg bw/day |
| ADI | Dog, 1 year | 0.5 mg/kg bw | 100 | 0.005 mg/kg bw/day |

\* An oral absorption of 50% was considered.

**Risk characterisation**

COM 116 02 I AL is a liquid formulation applied by trigger spray devices. It contains 0.05% of the a.s., *lambda*-cyhalothrin (product type 18). The product is efficacious against garden ants and it will be used by non-professional users of the general public. The product is sprayed on the ground or directly on the target pest or is activated during absorption of the active substance by the target organisms. Due to the application type exposure of the user occurs by dermal and inhalation route. The vapour pressure of *lambda*-cyhalothrin is only 2×10–7 Pa so that exposure to *lambda*-cyhalothrin vapours in treated rooms can be ruled out; only primary exposure to spray mist is possible.

The potential for exposure to *lambda*-cyhalothrin is summarised in the table below.

|  |  |  |
| --- | --- | --- |
| **Exposure path** | **General public** | **Via the environment** |
| Inhalation | Relevant | Not relevant |
| Dermal | Relevant | Not relevant |
| Oral | Relevant for infants | Not relevant |

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Brief description of scenario** | **Exposed group** |
| 1. | Spot treatment, trigger spray | Primary exposure of non-professionals applying liquid formulation by trigger spray devices. | Non-professionals |
| 2. | Child playing on floor | Secondary exposure of children crawling on the floor after application. | Non-professional (child) |
| 3. | Reverse scenario: Infant ingesting product from treated surface | Secondary exposure of infant taking up the product on the floor | Non-professionals (infant) |
| 4. | Reverse scenario: Companion animal ingesting product from treated surface | Secondary exposure of animal licking the product on the floor | Non-professionals (animal) |

Conclusion of risk characterisation for industrial user

The biocidal product is intended for non-professional users only.

Conclusion of risk characterisation for professional user

The biocidal product is intended for non-professional users only.

Conclusion of risk characterisation for non-professional user

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **AEL  [mg/kg bw/day]** | **Estimated uptake [mg/kg bw/day]** | **% AEL** | **NOAEL [mg/kg bw/day]** | **MoE** | **Acceptable**  (yes/no) |
| Spot treatment, trigger spray, systemic (oral and dermal) | 0.0038 | 6.7E-5 | 1.8 | 0.75 | 11 194 | Yes |
| Spot treatment, trigger spray, inhalation | 0.0008 | 1.9E-5 | 2.4 | 0.08 | 4 211 | Yes |
| Sum of % AEL | | | 4.2 | n.r. | | Yes |

Conclusion of risk characterisation for indirect exposure

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **AEL  [mg/kg bw/day]** | **Systemic dose [mg/kg bw/day]** | **% AEL** | **NOAEL [mg/kg bw/day]** | **MoE** | **Acceptable**  (yes/no) |
| Child playing on floor | 0.0038 | 0.00134 | 35.3 | 0.75 | 560 | Yes |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **Scenario No.** | **AEL  [mg/kg bw/day]** | **bw [kg]** | **% a.s. in b.p. [%]** | **[gram b.p./ day]** | **[%] of application to 1 m route\*** | **Acceptable**  **(yes/no)** |
| Reverse scenario: Infant ingesting product from treated surface | 3 | 0.0075 | 10 | 0.05 | 0.15 | ≤0.33 | No |
| Reverse scenario: pet (dog) ingesting product from treated surface | 4 | 0.075 | 10 | 0.05 | 1.5 | ≤3.3 | No |

\*from 44.5 for ants to 170 g/m2 for wood lice

The AEL is neither reached nor exceeded by the estimated exposures and the Margins of Exposure (MoEs) are sufficiently high.

However the reverse scenarios for infants and for pets indicate an unacceptable risk. Therefore a specific labelling is necessary: *Due to the risk of poisoning the product may only be applied, where access of pets, livestock and children can be excluded.*

No dietary risk assessment was carried out. However the product is not intended for direct application to foods or feeding stuff or to surfaces and areas where foods or feeding stuff are prepared or stored. A specific labelling is required: *The product may only be applied, where contamination of food, feed, drinks and edible plants as well as growing areas for edible plants can be excluded.*

Under use restrictions indicated with these labels the use of the b.p. represents an acceptable risk for human health.

### Summary of the Environmental Risk Assessment

***Fate and behaviour in the environment***

* + - 1. **Degradation of *lambda*-cyhalothrin in the aquatic compartment**

As summarized in the CAR (Sweden, 2011) *lambda*-cyhalothrin is (essentially) stable to aqueous **hydrolysis** at pH 5 and 7 and hydrolysis is uncertain at pH 9 with a DT50 of 8.6 days, at 25°C. Hydrolysis is therefore not expected to be a significant degradation route at environmentally relevant pHes (around 7). Hence, no major hydrolysis products were identified.

The available studies on **photolysis** indicate a potential for photochemical transformation of *lambda-*cyhalothrin in pure water (only little adsorption above 290 nm wave-length), but the half-lives are not considered reliable and representative for environmental conditions. Photo-transformation in water is therefore not expected to be a significant route of degradation in water.

There are no data available on **ready biodegradability**.

In a **water/sediment test system** *lambda*-cyhalothrin disappears rapidly from the water column via adsorption to the sediments with dissipation DT50s of 5.6 and 14 hours. *Lambda*-cyhalothrin is also expected to adsorb to aquatic plants. A geometric mean DT50 value for degradation of 32 days (12°C) in the whole water/sediment system was calculated. *Lambda*-cyhalothrin was degraded by ring hydroxylation and cleavage of the ester link followed by mineralisation. The major metabolite formed was Compound Ia (cyclopropane acid), reaching a maximum of 29% of applied in the water phase on day 14 and a maximum of 11% of applied in the sediment on day 30.

There are no data available for (an)aerobic biodegradation in sewage sludge.

Due to the lack of data on aerobic and anaerobic biodegradation in sewage sludge, as a worst case approach it was assumed that no biodegradation takes place in sewage treatment plants.

* + - 1. **Degradation of *lambda*-cyhalothrin in soils**

According to the CAR on *lambda*-cyhalothrin (Sweden, 2011), **photochemical trans-formation** processes are considered to be negligible in soil.

A DT50 value of 36 days was determined for *lambda*-cyhalothrin in one laboratory **soil degradation study** (69 days at 12°C). This value was used for the estimation of PECsoil. *Lambda*-cyhalothrin dissipation in soils was found to vary between different soils. The route of degradation in soil was the same as in water; *lambda*-cyhalothrin was degraded by ring hydroxylation and cleavage of the ester link followed by mineralisation. Compound XV (hydroxylated *lambda*-cyhalothrin) was the only metabolite identified as >10% of the applied radioactivity (max. 12% at day 60). The non-extractable residues are a "sink" for *lambda*-cyhalothrin in soil. In studies which used 14C-labelled substance 17-32% of the applied radioactivity was non-extractable.

The CAR on *lambda*-cyhalothrin (Sweden, 2011) shows that *lambda*-cyhalothrin adsorbs strongly to soils and sediments, and that the **adsorption** generally can be expected to be non-reversible. All results from the studies on *lambda*-cyhalothrin are more or less uncertain mainly due to indirect measurement of adsorption in most of the experiments and also due to the inherent difficulties to accurately determine the adsorption for such a hydrophobic substance. The results were accepted as best available estimates of the magnitude of adsorption. The mean Koc values for *lambda*-cyhalothrin from different studies were in the range of 70100-724000 ml/g. To take account of the uncertainty of the estimated Koc values, the lowest Koc value of 70100 ml/g was used for calculation of PECsurface water and of PECgroundwater, to provide worst case estimates of exposure. From the data on adsorption of metabolites, it is concluded that Compound XV (hydroxylated *lambda*-cyhalothrin) adsorbs strongly onto soil (Koc of 58000-92000 ml/g, n=6), and that adsorption of Compound Ia (cyclopropane acid) is weak, but with a slightly higher degree of adsorption in acidic soils (Koc of 14-16 ml/gat pH 7.1-7.6 and of 92 ml/gat pH 5.4).

* + - 1. **Degradation of *lambda*-cyhalothrin in air**

*Lambda*-cyhalothrin has a low vapour pressure (2x10-7 Pa at 20°C) and the Henry’s law constant is 1.8x10-2 Pa m3/mol (20°C), indicating a negligible volatilisation potential from aqueous and terrestrial compartments.

Direct **photolysis** in air is unlikely to occur as only little absorption at wave-lengths above 290 nm was measured.

The **photo-oxidative degradation** in air was estimated with T½ of 0.51 days (12.2 hours), based on rate constant for gas-phase reaction with hydroxyl radicals 31.46 cm³/molecule x sec and assuming a global (day + night) annual average OH-radical concentration of 0.5x106 molecules/cm³.

Therefore, *lambda*-cyhalothrin is virtually 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.

|  |  |  |
| --- | --- | --- |
| **Summary table on compartments exposed and assessed** | | |
| **Compartment** | **Exposed (Y/N)** | **Assessed (Y/N)** |
| STP | Y | Y |
| Surface water | Y | Y |
| Sediment | Y | Y |
| Soil | Y | Y |
| Groundwater | Y | Y |

|  |  |  |
| --- | --- | --- |
| **Summary table on relevant metabolites** | | |
| **Metabolite/transformation- or reaction product** | **Compartment** | **% Active Substance** |
| Compound Ia (cyclopropane acid) | water/sediment  soil | 29% (day 14) water phase  11% (day 30) sediment phase  6.2% (day 30) soil |
| Compound XV (hydroxylated *lambda*-cyhalothrin) | Soil | 12% (day 60) |

Compound Ia was found to be rapidly biodegradable in soil studies with DT50s of 3.1, 4.0 and 16 days in 3 different soils. Adsorption of Compound Ia onto soil is weak, with a slightly higher degree of adsorption in acidic soils (Koc of 14-16 ml/gat pH 7.1-7.6 and Koc of 92 ml/gat pH 5.4). Therefore some leaching could be expected, although Compound Ia is rapidly degradable in soil. For Compound Ia acute toxicity tests with fish are available showing less toxicity (96h LC50 >10 800 µg/l) than *lambda*-cyhalothrin (96h LC50 of 0.078 µg/l). Acute toxicity data are also available for daphnia showing similar results (Compound Ia 48h EC50 of 105 000 µg/l; *lambda*-cyhalothrin 48h EC50 of 0.002 µg/l).

Compound XV decreased in soil, after reaching its maximum, to 4.2% at the end of incubation at day 90. Compound XV adsorbs strongly onto soil (Koc of 58000-92000 ml/g, n=6). Therefore leaching would not be expected.

On the basis of the available data these two major metabolites were not considered further for RA in the CAR on *lambda*-cyhalothrin (Sweden, 2011) and in the currently presented PAR.

***Effects assessment***

| **Summary table on calculated PNEC values** | |
| --- | --- |
| **Compartment** | **PNEC** |
| STP | 5x10-3 mg/l (water solubility limit) |
| Surface water | 2x10-7 mg/l |
| Sediment | 9.3x10-4 mg/kg wwt |
| Soil | 2.9x10-3 mg/kg wwt |

***Exposure assessment***

Various phases in the life cycle of a product may cause emissions and environmental exposure. In this report emissions from active substance production and product formulation are considered less relevant compared to emissions from the application phase, in service and waste phase of the product.

COM 116 02 I AL is a liquid formulation applied by a trigger spray device (ready-to-use). The product is intended to be used indoors and outdoors in areas were the paved surfaces join the house (e.g. terraces).

The major emission route after indoor application of insecticides concerns the waste phase, which is emission of waste water from cleaning activities. In the European ESD document on insecticide applications for household and professional uses (OECD, 2008[[1]](#footnote-2)), the STP is therefore considered as the main “receiving compartment”. Consequently, PECs for the directly exposed STP and the indirectly exposed compartments water, sediment and agricultural soil from sludge application and groundwater are calculated.

Emission routes after outdoor application of insecticides on paved surfaces are direct release to the soil compartment as a major receiving compartment in rural areas as well as direct release to the STP in urban areas. In urban areas, PECs for the directly exposed STP and the indirectly exposed compartments water, sediment and agricultural soil from sludge application and groundwater are calculated. In rural areas direct contamination of soil and groundwater are considered.

The table below summarizes the calculated PEC values. For detailed information on potential of possible emissions to the environment please see Chapter 2.3.7/B of this document.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | |
| **Scenarios** | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |  |
| **Spraying indoors, residual treatment** | | | | | | has not been predicted |
| **Ants, max. 11 appl./year** | 3.28E-5 | 2.97E-6 | 4.53E-3 | 1.08E-3 | 8.72E-4 |
| **Silverfish & Cockroaches, weekly** | 0.25E-3 | 2.24E-5 | 34.09E-3 | 8.13E-3 | 6.57E-3 |
| **Wood lice & Cockroaches, twice a year** | 1.82E-5 | 1.65E-6 | 2.52E-3 | 0.60E-3 | 4.85E-4 |
| **Spraying indoors, direct treatment of target organisms** | | | | | |
| **Silverfish & Cockroaches, weekly** | 0.30E-3 | 2.75E-5 | 41.96E-3 | 10.00E-3 | 8.08E-3 |
| **Cockroaches, twice a year** | 2.26E-5 | 2.04E-6 | 3.11E-3 | 0.74E-3 | 6.00E-4 |
| **Wood lice, twice a year** | 3.10E-5 | 2.81E-6 | 4.28E-3 | 1.02E-3 | 8.24E-4 |
| **Spraying, outdoors, residual treatment** | | | | | |
| **Ants** (urban area), **max. 11 appl./year** | 2.6E-5 | 2.35E-6 | 3.95E-3 | 0.85E-3 | 6.91E-4 |
| **Ants** (rural area), **max. 11 appl./year** | - | - | - | 3.74E-3 | 3.03E-3 |

- Compartment not exposed

Due to the spray application, primary poisoning of birds or mammals is not relevant. Nevertheless, the secondary poisoning to biota is assessed, since animals may be poisoned secondarily through the ingestion of contaminated organisms (e.g. ants and worms) from the treated areas.

***Risk characterization***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
| **Scenarios** | **PEC/PNECSTP** | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECsoil** |
| **Spraying indoors, residual treatment** | | | | |
| **Ants, max. 11 appl./year** | 6.56E-3 | **14.85** | **4.87** | 0.37 |
| **Silverfish & Cockroaches, weekly** | 5.0E-2 | **112** | **36.66** | **2.80** |
| **Wood lice & Cockroaches, twice a year** | 3.64E-3 | **8.25** | **2.71** | 0.21 |
| **Spraying indoors, direct treatment of target organisms** | | | | |
| **Silverfish & Cockroaches, weekly** | 6.0E-2 | **137.5** | **45.12** | **3.45** |
| **Cockroaches, twice a year** | 4.52E-3 | **10.2** | **3.34** | 0.26 |
| **Wood lice, twice a year** | 6.20E-3 | **14.05** | **4.60** | 0.35 |
| **Spraying, outdoors, residual treatment** | | | | |
| **Ants,** (urban area), **max. 11 appl./year** | 5.2E-3 | **11.75** | **4.25** | 0.29 |
| **Ants,** (rural area), **max. 11 appl./year** | - | - | - | **1.29** |

- Compartment not exposed

**Conclusion:**

Acceptable risk (PEC/PNEC <1) was calculated for all scenarios in STP.

All calculated groundwater PEC values are <0.1 µg/l, also indicating acceptable risk.

Additionally acceptable risk was proven for soil for residual treatment, indoors against ants (max. 11 applications a year), wood lice and cockroaches (application twice a year), for direct treatment of target organisms, indoors for woodlice and cockroaches (application twice a year) and for outdoor residual treatment against ants in urban areas.

PEC/PNEC values indicating unacceptable risk (slightly >1) were calculated for soil for weekly indoor residual and direct treatment of target organisms against silverfish and cockroaches and for residual treatment of ants, outdoors in rural areas.

For surface water and sediment all calculated risk ratios, are >1, indicating unacceptable risk for aquatic and sediment non-target organisms in all scenarios.

Calculated risk ratios for secondary poisoning, through the consumption of directly contaminated ants and earthworms as well as for the potential of bioaccumulation via the aquatic and terrestrial food chain were <1 for birds and mammals for all calculated scenarios.

The following risk mitigation measures are proposed in order to reduce the calculated risk in the aquatic and terrestrial compartment to acceptable levels:

* Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain floods and cleaning water.
* The application is restricted to areas that are not wet cleaned e.g. in cracks and crevices, closed bath tubes, areas next to, behind and under furniture.
* Do not use, where release to drains (sewers) cannot be prevented.

Direct treatment of target organisms is not authorised as the proposed restriction to areas that are not wet cleaned is not feasible for the mobile species and the non-professional user.

## General information about the product application

### Administrative information

#### Trade name of the product

| **Trade name[[2]](#footnote-3)** | **Country (if relevant)** |
| --- | --- |
| COMPO Ameisen-Stop | Austria |
| COMPO Ungeziefer-Stop | Austria |
| COMPO Ungeziefer-Spray | Austria |
| COMPO Ameisen-Spray | Austria |
| Ameisen-Spray | Austria |
| Ungeziefer-Spray | Austria |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| Name and address of the authorisation holder | Name | COMPO Austria GmbH |
| Address | Hietzinger Hauptstrasse 119  1131 Wien  AUSTRIA |
| Telephone: |  | |
| Fax: | +43 1 876 6393-116 | |
| E-mail address: | info@compo.at | |
| Pre-submission phase started on: |  | |
| Pre-submission phase concluded on: |  | |
| Case number in R4BP3: | BC-ND000941-57 | |

#### Applicant (if different from authorisation holder)

|  |  |
| --- | --- |
| Company Name: | COMPO GmbH |
| Address: | Gildenstr. 38 |
| City: | Münster |
| Postal Code: | 48157 |
| Country: | Germany |
| Telephone: | + 49 (0) 251 3277 368 |
| Fax: | + 49 (0) 251 3277 1368 |
| E-mail address: | eva.mandrisch@compo.de |
| Letter of appointment for the applicant to represent the authorisation holder provided (yes/no): | no |

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

|  |  |
| --- | --- |
| Name: | Eva Mandrisch |
| Function: |  |
| Address: |  |
| City: |  |
| Postal Code: |  |
| Country: |  |
| Telephone: | + 49 (0) 251 3277 368 |
| Fax: |  |
| E-mail address: | eva.mandrisch@compo.de |

#### Manufacturer(s) of the product

|  |  |
| --- | --- |
| Name of manufacturer | COMPO GmbH |
| Address of manufacturer | Address: Gildenstr. 38  Postal code: 48157  Town: Münster  Country: Germany |
| Location of manufacturing sites | BiB  Address: Randweg 7  Postal code: 6045 JK  Town: Roermond  Country: Netherlands |
|  | FormiChem GmbH  Address: Anna-von-Philipp-Str. B33  Postal code: 86633  Town: Neuburg a.d. Donau  Country: Germany |
|  | Schirm GmbH  Address: Standort Baar-Ebenhausen  Dieselstraße 8  Postal code: 85107  Town: Baar-Ebenhausen  Country: Germany |

#### Candidate(s) for substitution

The active substance is a candidate for substitution according to Article 10, 1(d) of Regulation (EU) No. 528/2012. It meets the criteria for being B and T in accordance with Annex XIII to Regulation (EC) No. 1907/2006.

### Product composition and formulation

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | *lambda*-cyhalothrin |
| **IUPAC or EC name** | Reaction mass of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (1:1) |
| **EC number** | 415-130-7 |
| **CAS number** | 91465-08-6 |
| **Index number in Annex VI of CLP** | 607-252-00-6 |
| **Minimum purity / content** | min. 900 g/kg |
| **Structural formula** |  |

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

Please see the confidential annex for further details.

#### Information on technical equivalence

Not applicable because the source of active substance was the same as was evaluated for inclusion in the Union list of approved active substances.

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

The biocidal product does not contain substances of concern. For further information please refer to the confidential annex.

#### Type of formulation

|  |
| --- |
| AL Any other liquid; ready to use spray |

### 

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

**Table 1: Use 1 – Insecticide and product to control other arthropods – garden ants, silverfishes, woodlice and cockroaches – general public – spraying – indoor**

|  |  |
| --- | --- |
| Product Type | PT 18 Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Insecticides and product to control other arthropods |
| Target organism (including development stage) | Scientific name: Formicinae: *Lasius niger*  Common name: **garden ant**  Development stage: ant colony  Scientific name: Lepismatidae: *Lepisma saccharina*  Common name: Lepismatid: **silverfishes**  Development stage: larvae and adults  Scientific name: Porcellionidae: *Porcellio scaber*  Common name: **woodlice**  Development stage: adults (larvae and adults)  Scientific name: Blattodea: *Blattella germanica, Blatta orientalis, Periplaneta americana*  Common name: **cockroaches**  Development stage: adult |
| Field of use | Indoor use |
| Application method(s) | Method of application: **spraying**  Detailed description of the method:  Application is conducted on the target organism or on spots of ground floor area where target organisms have been observed.  For killing ant nests, COM 116 02 I AL is sprayed on routes and nest entries of ants in areas protected from cleaning wash. Best application time is in the morning or evening when ants are staying in the nests. |
| Application rate(s) and frequency | **The application rate:**  Ants: 10 strokes for 1 m route correspond to 10 g product  Silverfishes, Wood lice, Cockroaches:  Treat spotwise surfaces from a distance of ca. 30 cm with the trigger sprayer applying 5 to 6 strokes. Apply only where insects are expected running over or treat individuals directly.  **Number and timing of application:** One application provides long-lasting protection (between 1 and 26 weeks depending on the pest and the type of surface, s. table below) if left until no insects appear any longer. Treated areas should be protected from cleaning to provide the long lasting effect of the product.   |  |  |  |  | | --- | --- | --- | --- | | **Pest species** | **Knockdown after direct application on pest species** | **Time until 100% control (treatment of surface area)** | **Time until which product remains efficient on treated areas** | | **Ants** | not tested | nest kill within 21 d | not relevant since application will result in complete nest destruction => no re-colonisation | | **Silverfish** | within 3 min | 20 min (e.g. glazed tiles) - 60 Min (e.g. vinyl flooring) | at least 2 weeks | | **Wood lice** | 70% knock down efficacy was given within 15 minutes.  After 24 hours mortality was 100% | 2h (e.g. glazed tiles) - 24 h (e.g. vinyl flooring) | at least 26 weeks (vinyl flooring) | | **Cockroaches** | within 33 min (*Blatta orientalis*) | 15 min (e.g. glazed tiles) - 36 h (e.g. vinyl flooring) | at least 24 weeks (e.g. glazed tiles)  at least 1-6 week (e.g. vinyl flooring) | |
| Category(ies) of users | General public (non-professional) |
| Pack sizes and packaging material | Please see the relevant section. |

**Table 2: Use 2 – Insecticide – garden ants – general public – spraying - outdoor**

|  |  |
| --- | --- |
| Product Type | PT 18 Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Insecticide |
| Target organism (including development stage) | Scientific name: Formicinae: *Lasius niger*  Common name: **garden ant**  Development stage: ant colony |
| Field of use | Outdoor use |
| Application method(s) | Method of application: **spraying**  Detailed description of the method:  Application is conducted on the target organism or on spots of ground area where target organisms have been observed.  For killing ant nests, COM 116 02 I AL is sprayed on routes and nest entries of ants. The product shall only be applied on paved surfaces like terraces. Best application time is in the morning or evening when ants are staying in the nests. |
| Application rate(s) and frequency | **The application rate:**  10 strokes for 1 m route correspond to 10 g product  **Number and timing of application:** One application provides long-lasting protection (s. table below) if left until no insects appear any longer. Treated areas should be protected from cleaning to provide the long lasting effect of the product.   |  |  |  |  | | --- | --- | --- | --- | | **Pest species** | **Knockdown after direct application on pest species** | **Time until 100% control (treatment of surface area)** | **Time until which product remains efficient on treated areas** | | **Ants** | not tested | nest kill within 21 d | not relevant since application will result in complete nest destruction => no re-colonization | |
| Category(ies) of users | General public (non-professional) |
| Pack sizes and packaging material | Please see the relevant section. |

### Authorised use

**Use 1 - Insecticide and product to control other arthropods – garden ants, silverfishes, woodlice and cockroaches – non-professionals – spraying - indoor**

|  |  |
| --- | --- |
| Product Type | PT 18 Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Insecticide and product to control other arthropods |
| Target organism (including development stage) | Scientific name: Formicinae: *Lasius sp.*  Common name: **garden ants**  Development stage: ant colony  Scientific name: Lepismatidae: *Lepisma saccharina*  Common name: Lepismatid: **silverfishes**  Development stage: larvae and adults  Scientific name: Porcellionidae: *Porcellio scaber*  Common name: **woodlice**  Development stage: larvae and adults  Scientific name: Blattodea: *Blattella germanica, Blatta orientalis, Periplaneta americana*  Common name: **cockroaches**  Development stage: larvae (nymphal stage) |
| Field of use | Indoor use |
| Application method(s) | Method of application: **spraying**  Detailed description of the method:  Ants:  For killing ant nests, COM 116 02 I AL is sprayed on ant routes on indoor hard surfaces.  Silverfishes, woodlice and cockroaches:  Application is conducted on spots of ground areas (residual treatment) where target organisms have been observed. |
| Application rate(s) and frequency | **The application rate:**  Ants:  10 strokes for 1 m route correspond to 10 g product (44.5 g/m²)  Silverfishes, woodlice and cockroaches:  Residual treatment:  Treat surfaces from a distance of ca. 30 cm with the trigger sprayer applying spotwise 5 to 6 strokes (100 g/m²). Apply only where insects are expected running over.  **Number and timing of application:**  Against ants:  Maximum once per month during season of ant activity.  Against silverfishes:  Every 2 weeks, if pest occurs again.  Against woodlice:  Every 26 weeks, if pest occurs again.  Against cockroaches:  Every week (porous ground e.g. vinyl);every 24 weeks (non-porous ground e.g. glazed tiles), if pest occurs again. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Please see the relevant section. |

* + - 1. Use-specific instructions for use

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* + - 1. Use-specific risk mitigation measures

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* + - 1. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| --- |

* + - 1. Where specific to the use, the instructions for safe disposal of the product and its packaging

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| --- |
| --- |

* + - 1. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| --- |

**Use 2 – Insecticide – garden ants – non-professionals – spraying - outdoor**

|  |  |
| --- | --- |
| Product Type | PT 18 Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Insecticide |
| Target organism (including development stage) | Scientific name: Formicinae: *Lasius sp.*  Common name: **garden ants**  Development stage: ant colony |
| Field of use | Outdoor use |
| Application method(s) | Method of application: **spraying**  Detailed description of the method:  For killing ant nests, COM 116 02 I AL is sprayed on ant routes and nest entries on paved surfaces like terraces.  Best application time is in the morning or evening when ants are staying in the nests. |
| Application rate(s) and frequency | **The application rate:**  10 strokes for 1 m route and nest entries correspond to 10 g product (44.5 g/m2).  **Number and timing of application:**  Maximum once per month during season of ant activity. |
| Category(ies) of users | Non-professionals |
| Pack sizes and packaging material | Please see the relevant section. |

* + - 1. Use-specific instructions for use

|  |
| --- |
| --- |

* + - 1. Use-specific risk mitigation measures

|  |
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| --- |

* + - 1. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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* + - 1. Where specific to the use, the instructions for safe disposal of the product and its packaging

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* + - 1. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| --- |

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

|  |
| --- |
| --- |

### Hazard and precautionary statements

#### Proposed classification and labelling of the biocidal product

***Classification and Labelling according to Regulation (EC) No 1272/2008:***

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute 1 |
| Hazard statement | H400: Very toxic to aquatic life. |
| Hazard category | Aquatic Chronic 1 |
| Hazard statement | H410: Very toxic to aquatic life with long lasting effects. |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Pictogram | GHS09 |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects.  EUH208: Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction. |
| Precautionary statements | P102: Keep out of reach of children.  P103 Read label before use.  P270: Do not eat, drink or smoke when using the product.  P273: Avoid release to the environment.  P501: Dispose of contents/container to … in accordance with local/regional/national/international regulation (to be specified). |
|  | |
| Note | **‒** |

#### 

#### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Trigger bottle | 200 ml;  250 ml;  300 ml;  400 ml;  500 ml;  750 ml;  900 ml;  1000 ml | PET | Trigger is made of PP | non-professional | Yes |

### 

### General directions for use

#### Instructions for use

|  |
| --- |
| Avoid any unnecessary contact with the product or treated surface. Misuse can cause damage to one’s health.  Avoid contact with the skin.  Do not breathe spray.   * May only be applied where contamination of food, feed, drinks and edible plants as well as growing areas for edible plants can be excluded.   Wash hands after use.  Keep away product, its remaining as well as emptied container and packages from water bodies.  Treated areas should be protected from cleaning to provide the long lasting effect of the product.   * Inform the authorisation holder if the treatment is ineffective. * If the infestation persists despite following the instructions of the label, contact a pest control professional. * Adopt integrated pest management methods such as alternation between treatment strategies during the treatment regime (biological, chemical and mechanical), taking into account local specificities (climatic conditions, target species, conditions of use, etc. |

#### Risk mitigation measures

|  |
| --- |
| * The application is restricted to areas that are not wet cleaned, e.g. in cracks and crevices, closed bath tubes, areas next to, behind and under furniture * Do not use where release to drains (sewer) cannot be prevented. * Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain floods and cleaning water.   Due to the risk for poisoning the product may only be applied, where access of pets, livestock and children can be excluded. |

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

|  |
| --- |
| **Particulars of likely direct or indirect effects:**   * Not known if the product is used properly according to the product label.   **First aid instructions:**   * If inhaled: Keep patient calm, remove to fresh air, seek medical attention. * After contact with skin: Wash thoroughly with soap and water. * May cause temporary and reversible itching, tingling, burning, or numbness of exposed skin, called paraesthesia. These skin contact paresthesia effects are transient, and normally disappear within 24 hours. Treat symptomatically. * After eye contact: Rinse with plenty of water. * If swallowed: Seek medical advice immediately and show this container or label.   **Emergency measures to protect the environment:**  --- |

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

|  |
| --- |
| * Dispose of unused product in its container according to national and local requirements. |

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

|  |
| --- |
| **Requirements for storage areas and containers**:  Keep product in original container only, tightly closed, in a safe place. Store in a cool, dry and frost-protected place. Keep away from direct sunlight.  **Further information on storage conditions:**  Keep away from food, drink and animal feed.  Storage period: 4 years.  Storage temperature: 5-30°C |

### Documentation

#### Data submitted in relation to product application

Please see the List of new data submitted in support of the evaluation of the biocidal product in this report, Annex 3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

#### Access to documentation

The applicant has submitted a letter of access from Syngenta Crop protection AG. Data access is granted to the dossier that supported the registration of the active substance *lambda*-cyhalothrin under the Biocidal Product Directive 98/8/EC to get Annex I inclusion and to product data owned by Syngenta Crop protection AG.

### Other information

|  |
| --- |
| Application codes:  I b: Target organisms to be controlled  I.2 Crustacea Crustaceans  I.2.1 Isopoda Isopods  I.2.1.1 Porcellionidae Woodlice (e.g. Common rough woodlouse)  I.3 Insecta Insects  I.3.1 Zygentoma Silverfishes  I.3.1.1 Lepismatidae Lepismatid silverfishes (e.g. Common silverfish, Firebrat)  I.3.4 Blattodea Cockroaches  I.3.4.1 Blattellidae Blattellid Cockroaches (e.g. German Cockroach, Brown-banded Cockroach)  I.3.4.2 Blattidae Blattid Cockroaches (e.g. Common cockroach, American Cockroach, Australian cockroach)  I.3.10 Hymenoptera: Formicidae Ants  I.3.10.3 Formicinae (e.g. Garden Ant, Red Ant)  II: Developmental stages of target organisms to be controlled  II.1.2 Larvae  II.1.3 Nymphs  II:1.4 Pupae  II.1.5 Imagines, Adults  III: Function/Mode of action of a.s./b.p./ type of effect  III.1 Mode of exposure  III.1.1 ingestion (bait)  III.1.3 contact  III.2 Type of effect (on individual pests)  III.2.1 Kill effect  III.2.2 Knock-Down Effect  III.3 Type of effect (on populations of pests)  III.3.2 Trophallaxis (e.g. in ants)  III.3.3 Can control entire colonies (Eradication)  III.4 Duration of effect  III.4.1 Acute/short acting toxins  III.4.2 Residual activity (long time effect)  IV: Field of use  IV.1 indoor use:  IV.1.1. potential for contamination outdoors  IV.1.1.1 yes  IV.1.2. potential for contamination of food  IV.1.2.2. no  IV 1. 3 To be used in /at:  IV 1.3.2 Households / private areas  IV.2 outdoor use in/at:  IV 2.5. Others (specifiy) paved surfaced like terraces, in roof covered areas  V: User category  V.1 non-professional user / consumer  VI: Method of application  VI a Method:  VI.1 Spraying  VI.1.1 Surface Spraying  VII: Application aim  VII.2 Health protection  VIII: Type of formulation  VIII 3.2 Ready-for-use  VIII 3.2.1 Suspension / capsule suspension CS |

## 

## Assessment of the biocidal product

### Physical, chemical and technical properties

Note: The percentage given in column “Purity of the test substance” refers to the amount of product formulation used for the tests. As a matter of fact all tests for the physico-chemical properties reported in this section have been performed with the undiluted product formulation. Therefore 100% is given as purity value.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20°C and 101.3 kPa | Visual inspection | 100% | Before and after storage for 2 weeks at 54°C and 2 years at 20°C: Liquid | Wochner, 2009 and 2012a |
| Colour at 20°C and 101.3 kPa | Visual inspection | 100% | Before and after storage for 2 weeks at 54°C and 2 years at 20°C: Slightly milky | Wochner, 2009 and 2012a |
| Odour at 20°C and 101.3 kPa | Olfactory inspection | 100%. | Before and after storage for 2 weeks at 54°C and 2 years at 20°C: Slightly sweetish | Wochner, 2009 and 2012a |
| Acidity / alkalinity | CIPAC method 75.3  CIPAC method MT 191 | 100% | Results of pH at 25°C: 6.1 (neat formulation) 6.5 (1% suspension in water)  Acidity: 0.01% (calculated as H2SO4) | Martin-Keusch, 2009a |
|  | CIPAC method 75.3 | 100% | Results of pH at 25°C: After storage for 2 weeks at 54°C: 6.0 (neat formulation, PET) 6.7 (1% suspension in water, PET)  After storage for 2 years at 20°C: 6.0 (neat formulation, PET) 6.5 (1% suspension in water, PET) | Wochner, 2009 and 2012a |
|  | CIPAC method 75.3  The test was performed with the commercial packages of the formulation (Transparent PET- bottle 500 ml with trigger sprayer) | 100% | Results of pH at 20°C:  Undiluted at 20°C:  Before storage: 5.59  After 24 months storage: 5.78  After 36 months storage: 5.67  After 48 months storage: 5.78  Diluted (1% in water) at 20°C:  Before storage: 6.01  After 24 months storage: 6.19  After 36 months storage: 5.94  After 48 months storage: 5.81 | Schieck, 2018 |
| Relative density / bulk density | OECD 109 | 100% | Result for density at 20°C before and after storage for 2 weeks at 54°C and 2 years at 20°C: 0.999 g/cm3 (PET) | Wochner, 2009 and 2012a |
|  | − | − | Determination of the bulk density is not applicable because the biocidal product is liquid. | − |
| Storage stability test – **accelerated storage** | CIPAC method MT 46.3  The test was performed with commercial packages of the formulation (PET trigger bottle). | 100% | The formulation is stable at 54°C for 2 weeks. No significant changes of physical-chemical properties and packaging stability occurred during the test. The a.s. content was 0.0533% w/w before and 0.0531% w/w after the storage. The appearance, pH value, relative density, persistent foaming, wet sieving and pourability were measured before and after storage. Results for these tests were considered acceptable before and after storage and are discussed under the relevant section points. | Wochner, 2009 |
| Storage stability test – **long term storage at ambient temperature** | Storage stability for 2 years at 20°C (comparable to GIFAP Monograph No. 17)  The test was performed with commercial packages of the formulation (PET trigger bottle) | 100% | The formulation is stable for 2 years at 20°C. No significant changes of physical-chemical properties and packaging stability occurred during the test. The a.s. content was 0.0533% w/w before and 0.0516% w/w after the storage. The appearance, pH value, relative density, persistent foaming, wet sieving and pourability were measured before and after storage. Results for these tests were considered acceptable before and after storage and are discussed under the relevant section points. | Wochner, 2012a |
| Storage stability test -long term storage at ambient temperature | Storage stability for 4 years at 20°C (GIFAP Monograph No. 17)  The test was performed with the commercial packages of the formulation (Transparent PET- bottle 500 ml with trigger sprayer) | 100% | The formulation is stable for 4 years at 20°C.  The a.s. content:  Before storage: 0.501g/L  After 24 months storage: 0.513g/L  After 36 months storage: 0.514g/L  After 48 months storage: 0.514g/L  After storage at 20°C for 48 months no significant alteration of the ingredient content was determined. (+2.66%)  Appearance of formulation: During storage, no changes occurred.  Stability of packaging: During storage for 36 and 48 months, the bottle has contracted slightly. | Schieck, 2018 |
| Storage stability test – **low temperature stability test for liquids** | FAO/WHO  4 freeze/thaw cycles:  20°C (±2°C) and -10°C (±2°C) in all four 18-hour-freeze/6-hour-melt cycles | 100% | The following tests were performed with the freeze/thaw stored formulation:  -pH value, 1% in deion. water: 6.2  -pH value, neat (undiluted): 6.0  -Wet sieve test, 75 µm sieve: <0.01%  -Pourability:  Pour residue: 0.23% Rinsed residue: 0.15% | Martin-Keusch, 2009b |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | − | − | Not applicable as the packaging is light-proof. Therefore, the formulation is not exposed to light during storage. | − |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | − | − | Not applicable because according to the label instructions the biocidal product has to be kept in original container, tightly closed, in a safe place. It has to be stored in a cool, dry and frost free place. | − |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Accelerated storage at 54°C for 2 weeks and for 2 years at 20°C (CIPAC method MT 46.3 and GIFAP Monograph No. 17) | 100% | The formulation is stable at 54°C for 2 weeks and for 2 years at 20°C. No significant changes of packaging stability occurred during the test. | Wochner, 2009 and 2012a |
| Wettability | − | − | The wettability must be determined for solid biocidal products. Since the biocidal product is liquid the wettability does not need to be performed. | − |
| Suspensibility, spontaneity and dispersion stability | − | − | The suspensibility, spontaneity and dispersion stability must be determined for solid biocidal products or suspensions, respectively. Since the biocidal product is not solid and no suspension these tests do not need to be performed. | − |
| Wet sieve analysis and dry sieve test | CIPAC method MT 185 | 100% | The tests were performed using a 75 μm sieve.  Before storage and after storage for 2 weeks at 54°C: <0.01% (PET)  After storage for 2 years at 20°C: 0.03% (PET) | Wochner, 2009 and 2012a |
|  | CIPAC method MT 185  The test was performed with the commercial packages of the formulation (Transparent PET- bottle 500 ml with trigger sprayer) | 100% | Residue on 75 µm sieve:  Before storage: 0.0003%  After 24 months storage: 0.0073%  After 36 months storage: 0.0071%  After 48 months storage:0.0075% | Schieck, 2018 |
| Emulsifiability, re-emulsifiability and emulsion stability | − | − | The data on emulsifiability, re-emulsifiability and emulsion stability are required to determine whether a preparation forms and maintains a stable emulsion. Since the biocidal product is a ready-to-use product these tests do not need to be performed. | − |
| Disintegration time | − | − | The disintegration time must be determined for biocidal products supplied as tablets. Since the biocidal product is liquid this test does not need to be performed. | − |
| Particle size distribution, content of dust/fines, attrition, friability | − | − | The data on particle size distribution, content of dust/fines, attrition, and friability are required for solid biocidal products. Since the biocidal product is liquid these tests do not need to be performed. | − |
| Persistent foaming | CIPAC method MT 47.2 | 100% | Values given below refer to volume measured after 1 minute  Before storage: 44 ml (PET)  After storage for 2 weeks at 54°C: 20 ml (PET)  After storage for 2 years at 20°C: 3 ml (PET) | Wochner, 2009 and 2012a |
|  | CIPAC method MT 47.2  The test was performed with the commercial packages of the formulation (Transparent PET- bottle 500 ml with trigger sprayer) | 100% | Before storage:  Foaming could be observed  (up to 44 mL)  12 min after agitation 3 mL of foam remained  After 24 months storage:  Foaming could be observed  (up to 7 mL)  12 min after agitation 1 mL of foam remained  After 36 months storage:  After inverting the sample for 30 times foam could be observed (30-40 mL)  The foam has dissolved completely in the first 10 seconds.  After 48 months storage:  Foaming could be observed  (up to 29 mL)  12 min after agitation 2 mL of foam remained | Schieck, 2018 |
| Flowability/Pourability/Dustability | CIPAC method MT 148 | 100% | Before storage: Pour residue: 0.42% (PET) Rinsed Residues: 0.17% (PET)  After storage for 2 weeks at 54°C: Pour residue: 0.44% (PET) Rinsed Residues: 0.14% (PET)  After storage for 2 years at 20°C: Pour residue: 0.43% (PET) Rinsed Residues: 0.17% (PET) | Wochner, 2009 and 2012a |
|  | CIPAC method MT 148  The test was performed with the commercial packages of the formulation (Transparent PET- bottle 500 ml with trigger sprayer) | 100% | Before storage: Pour residue: 0.39%  Rinsed Residues: 0.10%  After 24 months storage at 20°C:  Pour residue: 0.28%  Rinsed Residues: 0.21%  After 36 months storage at 20°C:  Pour residue: 0.24%  Rinsed Residues: 0.14%  After 48 months storage at 20°C:  Pour residue: 0.17%  Rinsed Residues: 0.13% | Schieck, 2018 |
| Burning rate — smoke generators | − | − | The burning rate must be determined for biocidal products intended to be used as smoke generators. Since the biocidal product is not a smoke generator this test does not need to be performed. | − |
| Burning completeness — smoke generators | − | − | The burning completeness must be determined for biocidal products intended to be used as smoke generators. Since the biocidal product is not a smoke generator this test does not need to be performed. | − |
| Composition of smoke — smoke generators | − | − | The composition of smoke must be determined for biocidal products intended to be used as smoke generators. Since the biocidal product is not a smoke generator this test does not need to be performed. | − |
| Spraying pattern — aerosols | − | − | No significant changes of the parameter clogging, spray diameter and discharge rate were observed before and after the storage at 20°C for two years.  Clogging has been performed according Manual on development and use of FAO and WHO Specifications for Pesticides  No clogging has been observed in the beginning and after 2 years storage at 20°C  The discharge rate has been determined according to PSD, Data Requirements Handbook.  The initial discharge rate was 0.78 g (one stroke)/3.92 g (5 strokes) and 0.74 g (one stroke)/3.72 g (5 strokes) after two year storage at 20°C  Spray diameter has been determined according to PSD, Data Requirements Handbook.  The initial result was 24 cm and 22 cm after two year storage at 20°C | Wochner, 2012b |
|  |  |  | No significant changes of the parameter clogging, spray diameter and discharge rate were observed before and after the storage for four years.  Clogging has been performed according Manual on development and use of FAO and WHO Specifications for Pesticides  No clogging has been observed in the beginning and after four years storage at 20°C  The discharge rate has been determined according to PSD, Data Requirements Handbook.  The discharge rate was 1.27 g before storage, 1.30 g after two years storage, 1.29 g after three years storage and 1.19 g after four years storage.  Spray diameter has been determined according to PSD, Data Requirements Handbook.  The initial result was 30.1 cm, 32.7 cm after two year storage, 30.1 cm after two three years storage and 29.4 cm after four years storage. | Schieck, 2018 |
| Physical compatibility | − | − | The biocidal product is not intended to be used with other products including other biocidal products. Therefore no information is submitted about its physical compatibility with other products. | − |
| Chemical compatibility | − | − | The biocidal product is not intended to be used with other products including other biocidal products. Therefore no information is submitted about its chemical compatibility with other products. | − |
| Degree of dissolution and dilution stability | − | − | The degree of dissolution must be determined for water soluble bags and tablets, the dilution stability for water-soluble preparations. Since the biocidal product is not a water soluble bag, tablet or a water-soluble preparation these tests do not need to be performed. | − |
| Surface tension | EC Method A.5 | 100% | 37.1 mN/m at 20°C | Martin-Keusch, 2009a |
| Viscosity | OECD guideline 114 CIPAC method MT 192 | 100% | 1.1 mPa\*s at 20°C  0.8 mPa\*s at 40°C | Martin-Keusch, 2009a |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | EC method A.14 |  | The substance did not explode when exposed to heat or mechanical shock.  With regard to mechanical shock the test was carried out in accordance with EC Test A.14, Reference 6.2, using the BAM Fall Hammer apparatus. Limiting Impact Energy >40 joules. The test substance is not classified as explosive in terms of its mechanical sensitivity with respect to shock.  With regard to thermal sensitivity the test was carried out based on EC Test A.14, Reference 6.2, using the Koenen steel tube apparatus. No explosions were observed using the 2 mm orifice plates, i.e. Limiting Diameter <2 mm. The test substance is not classified as explosive in terms of its thermal sensitivity. | Jackson, 2009a |
| Flammable gases | − | − | The parameter flammable gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed. | − |
| Flammable aerosols | − | − | The parameter flammable aerosols must be determined for biocidal products that are supplied as aerosols. Since the biocidal product is not an aerosol this test does not need to be performed. | − |
| Oxidising gases | − | − | The parameter oxidising gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed. | − |
| Gases under pressure | − | − | The parameter gases under pressure must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed. | − |
| Flammable liquids | EC method A.9 |  | No flash point was detected below 101°C, the onset of boiling. | Jackson, 2009c |
| Flammable solids | − | − | The oxidising properties have to be determined for solid biocidal products. Since the biocidal product is liquid this test does not need to be performed. | − |
| Self-reactive substances and mixtures | − | − | There are no ingredients with explosive or self-reactive properties present in the biocidal product. Therefore the formulation is not self-reactive. | − |
| Pyrophoric liquids | − | − | The study does not need to be conducted as based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected. | − |
| Pyrophoric solids | − | − | Pyrophoric properties have to be determined for solid biocidal products. Since the biocidal product is liquid this test does not need to be performed. | − |
| Self-heating substances and mixtures | − | − | The study does not need to be conducted as the biocidal product is liquid. A liquid shows not self-heating behaviour if it is not absorbed on a large surface. | − |
| Substances and mixtures which in contact with water emit flammable gases | − | − | The biocidal product contains water. Therefore an emission of flammable gases is not expected when the preparation comes in contact with water. | − |
| Oxidising liquids | EC method A.21 |  | The test was carried out in accordance with EC Test A.21, "Oxidising Properties (Liquids)", Reference 6.2.  The test mixtures failed to create a sufficient pressure increase to enable the rise time to be measured.  (In accordance with the criteria of EC Test A.21, the test substance is not classified as an oxidising substance.) | Jackson, 2009b |
| Oxidising solids | − | − | The oxidising properties have to be determined for solid biocidal products. Since the biocidal product is liquid this test does not need to be performed. | − |
| Organic peroxides | − | − | Since the biocidal product is not an organic peroxide, tests do not need to be performed. | − |
| Corrosive to metals | − | − | The product has been known since many years. It has never been reported any significant corrosion with tank or applicability material which are partially made of metal. In addition, the active substance and all the co-formulants of the recipe are not known to be corrosive to metals. In conclusion, the product is not significantly corrosive to metals. | − |
| Auto-ignition temperatures of products (liquids and gases) | EC method A.15 |  | No auto-ignition temperature was detected below 650°C. | Jackson, 2009d |
| Relative self-ignition temperature for solids | − | − | The relative self-ignition temperature has to be determined for solid biocidal products. Since the biocidal product is liquid this test does not need to be performed. | − |
| Dust explosion hazard | − | − | The dust explosion hazard must be determined for powders or biocidal products containing, or able to produce, dust. Since the biocidal product is liquid this test does not need to be performed. | − |

### Methods for detection and identification

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *lambda*-cyhalothrin | HPLC-UV | Laboratory prepared co-formulant mixes to which known amounts of active substance have been added, were prepared and analysed. The synthetic formulations prepared have a concentration like the formulation to be examined, +30% and −30%. Each concentration level was prepared and analysed four times. | Six standard solutions over the range 0.00025% to 0.0025% (equivalent to app. 0.01% to 0.1% in formulation) were measured.  Each concentration was measured twice.  Correlation coefficient: 0.999958 | No interferences with other peaks were observed. | The mean recovery rates ranged from 96.32% to 97.42% (n=4). The overall mean recovery was 96.80% (n=12).  The relative standard deviations ranged from 1.905% to 3.987% (n=4). The overall relative standard deviation was 2.811% (n=12). | | | Limit of quantification: 0.0043%  Limit of detection: 0.0014% | Schieck, 2008 |

Analytical methods for the determination of *lambda*-cyhalothrin residues in relevant environmental media (soil, air and water) as well as in animal and human body fluids and tissues were not submitted for the biocidal product since this point is covered by the data set of the active substance. Please refer to the CAR of the active substance.

An exposure of *lambda*-cyhalothrin to food and feedstuffs can be excluded when applied according to the intended use as described in section 2.2.3 and by applying the risk mitigation measures as described in section 2.2.6. An analytical method for the determination of active substance residues in/on food and feedstuffs is therefore not necessary.

### Efficacy against target organisms

#### Function and field of use

The biocidal product is a ready-to-use liquid insecticidal formulation (PT18) and is applied by trigger spray devices. It is effective against garden ants (*Lasius niger*) outdoors and indoors for several weeks. Also silverfishes, wood lice and cockroaches are controlled.

As other pyrethroids it acts as a sodium channel modulator. By disrupting the nervous system of insects, *lambda*-cyhalothrin may cause paralysis or death.

In the specific case the product is a microcapsule formulation of the active substance. The ready-to-use microencapsulated active substance is released after contact and ingestion by the insects. The main effect is due to the cleaning procedure of the insect. By licking its body the capsules unfold their efficacy on the way to /through the bowel. After release the a.s. acts very fast.

If the capsules are on the skin of the insect they are transmitted by contact to another insect, so it is possible e.g. for ants that the whole nest is destroyed or that the whole population of the insects is killed. From this, the delayed and desired release in the nest is explained.

Due to this described process the efficacy of the product is slower compared to other products with the active substance Lambda-Cyhalothrin without microcapsules.

Application is intended by the general public directly on the insect or on the target area where the insects occur.

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

Target organisms to be controlled are garden ants (*Lasius niger*), silverfishes (*Lepisma saccharina*), wood lice (*Porcellio scaber*), cockroaches (*Blattella germanica, Blatta orientalis, Periplaneta americana*).

Organisms (to be protected) or treated materials: Areas in and around domestic buildings.

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

*Lambda*-cyhalothrin may cause paralysis or death by disrupting the nervous system of insects.

Regarding garden ants the effect does not appear immediately but after a few hours. Since a great part of worker ants will not be able to transfer food to the nest colony after contamination, this will lead to nest killing within 2-3 weeks. Furthermore, ants which might be able to reach the nest with the microcapsules containing the active ingredient, adhered to their body, can contribute to nest killing.

#### Mode of action, including time delay

*Lambda*-cyhalothrin belongs to a class of insecticides known as synthetic pyrethroids. *Lambda*-cyhalothrin, as other pyrethroids, acts as a sodium channel modulator. By disrupting the nervous system of insects, *lambda*-cyhalothrin may cause paralysis or death.

Due to the microencapsulation of the active substance, the product is intended to be released only upon contact and ingestion by the target organism.

#### Efficacy data

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | |
| **Test substance** | **Test organism(s)** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| COM 116 02 I AL, 0.5 g/l *lambda*-cyalothrin | Insects:  *Lasius niger* | Field tests (exposure time 21 days) of the efficacy of different experimental products intended to control ants in garden and house environment were conducted.  Nests were found in large meadows in 6 fields in the country or private gardens with no human intervention during the trial.  Experimental design: 3 untreated nests, 3 nests treated with each experimental factor.  Register of temperature during the trial are given in the report.  0.5 g/l a.s.  (*lambda*-cyhalothrin) | % reductions of the frequency of ants in surface   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **+2 D** | **+7 D** | **+14 D** | **+21 D** | | Untreated | -9.8 | 23.2 | -8.8 | -10.1 | | COM 116 02 I AL spray | 66.9 | 90.7 | 98.9 | 100 | | Standard AFOURMI SG “strewing” | 78.9 | 92.4 | 100 | 100 | | Standard AFOURMI SG “drenching” | 93.5 | 100 | 100 | 100 |   Final counts on ant nests (in number of insects)   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Trial** | **Content a.i.** | **Application method** | **Dose** | **Final count of alive ants after 3 weeks** | | COM 116 02 I AL spray | 0.5 g/l a.s.  (*l*-cyhalothrin) | spray | 10 g/linear meter | 0 | | AFOURMI SG Standard granules | 0.02% a.s. (fipronil) | strewing | 40 g/nest | 0 | | drenching | 40 g/2000 ml | 0 | | Control | - | - | - | >1500 |   Conclusion: In this field test, COM 116 02 I AL (spray) has proved a complete and fast efficacy towards the ant *Lasius niger*. | Serrano, 2007a |

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| --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | |
| **Test substance** | **Test organism(s)** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| COM 116 02 I AL, 0.5 g/l *lambda*-cyhalothrin | Insects:  Lasius niger | Laboratory tests (exposure time 8 days) of the efficacy of different experimental products intended to control ants in garden and house environment were conducted.  The tests were carried out in 30 cm×30 cm×15 cm plastic arenas with 5 cm ground retrieved from the nest with or without competition food.  0.5 g/l a.s. *(lambda-*cyhalothrin*)* | Arena trial with food: % mortality (mean of 3 replicates)   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | **+1 D** | **+2 D** | **+3 D** | **+4 D** | **+5 D** | **+6 D** | **+7 D** | **+8 D** | | Untreated | 0.3 | 1.0 | 1.6 | 1.6 | 2.3 | 2.6 | 2.6 | 3.0 | | COM 116 02 I AL spray | 0.0 | 0.3 | 15.2 | 31.5 | 55.4 | 75.2 | 99.0 | 100 | | Standard AFOURMI SG “strewing” | 0.0 | 0.0 | 23.3 | 64.5 | 100 | 100 | 100 | 100 | | Standard AFOURMI SG “drenching” | 0.0 | 0.0 | 16.5 | 45.2 | 77.7 | 94.0 | 98.0 | 100 |   Arena trial without food: % mortality (mean of 3 replicates)   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | **+1 D** | **+2 D** | **+3 D** | **+4 D** | **+5 D** | **+6 D** | **+7 D** | **+8 D** | | Untreated | 0.3 | 1.0 | 1.6 | 1.6 | 2.3 | 2.6 | 2.6 | 3.0 | | COM 116 02 I AL spray | 0.0 | 0.3 | 16.3 | 30.6 | 53.5 | 74.1 | 100 | 100 | | Standard AFOURMI SG “strewing” | 0.0 | 0.3 | 22.9 | 70.9 | 100 | 100 | 100 | 100 | | Standard AFOURMI SG “drenching” | 0.0 | 0.7 | 16.1 | 42.5 | 78.2 | 96.7 | 99.7 | 100 |   Conclusion: In this laboratory test, COM 116 02 I AL (spray) has proved a complete and fast efficacy towards the ant *Lasius niger*. | Serrano, 2007b |

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| --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | |
| **Test substance** | **Test organism(s)** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| COM 116 02 I AL, 0.05% w/w *lambda*-cyhalothrin | Insects:  *Blattella germanica, Blatta orientalis, Periplaneta americana* | Laboratory tests of the efficacy of different experimental products intended to control cockroaches in house environment were conducted.  a) Direct spray treatment (exposure time 48 hours)  b) Residual test (exposure of 72 hours, residues aged up to 24 weeks)  Type of test chamber:  a) Direct spray treatment: glass rings (9.5 cm in diameter, 5.5 cm height)  b) Residual effects: Spray robot, glazed tiles or PVC  Bag-on-valve system (0.05% w/w *lambda-*cyhalothrin*)* | a) Direct spray treatment:  100% knock down efficacy was given with all tested cockroach species. Mortality after 24 hours was 100% in all cases.  Against German cockroaches it took ca. 10 min to achieve 100% of knock down efficacy (ca. 8-11 min. range). Against Oriental cockroaches it took ca. 33 min to achieve 100% of knock down efficacy (ca. 25-47 min. range). Against American cockroaches it took ca. 27 min to achieve 100% of knock down efficacy (ca. 23-36 min. range).  b) Residual effects on glazed tiles:  Against German cockroaches it took 15 min up to 60 min to achieve 100% of efficacy for the complete test period of 24 weeks, in 1 out of 39 cases 2 hours. Against Oriental cockroaches, depending on the age of the residues, it took 30 min up to 12 hours to achieve 100% of efficacy. Against American cockroaches, for residues aged 1 day up to 16 weeks, it took 30 min up to 12 hours to achieve 100% of efficacy. At the end of the test period (for residues aged 20 and 24 weeks), in 2 out of 39 cases, 100% efficacy was not achieved during the exposure time of 72 hours.  Residual effects on PVC: The efficacy was weaker.  Against German cockroaches 100% efficacy was achieved for residues up to 3 weeks (within 60 min up to 72 hours after start of exposure).  Against Oriental cockroaches 100% efficacy was achieved for residues aged 1 day, in parts for residues aged 1 week and 3 weeks (within 6 hours up to 72 hours after start of exposure).  Against American cockroaches 100% efficacy was achieved for residues aged 6 weeks (within 60 min. up to 6 hours after start of exposure).  Conclusion: In this laboratory test, COM 116 02 I AL (spray) has proved a complete and fast efficacy towards the cockroach species *Blattela germanica, Blatta orientalis and Periplaneta americana.* | Lüpkes, 2009 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | |
| **Test substance** | **Test organism(s)** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| COM 116 02 I AL, 0.05% w/w *lambda*-cyhalothrin | Insects:  *Lepisma saccharina* | Laboratory tests of the efficacy of different experimental products intended to control silverfishes in garden and house environment were conducted.  a) Direct spray treatment (exposure time 48 hours )  b) Residual test (exposure of 72 hours, residues aged up to 2 weeks)  Type of test chamber:  a) Direct spray treatment: glass rings (9.5 cm in diameter, 5.5 cm height)  b) Residual effects: Spray robot, glazed tiles or PVC  Bag-on-valve system (0.05% w/w *lambda-*cyhalothrin) | a) Direct spray treatment (mean of 10 replicates)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Product | **100% knock down after minutes (‘) and seconds (‘’)** | | **% knock down after** | **100% mortality after** | | | mean | range | 2h | 24h | 48h | | COM 116 02 I AL spray | 2’47’’ | 2’05’’–3’24’’ | 100 | 100 | 100 | | Untreated | - | - | 0 | 0 | 0 |   b) Residual efficacy (mean of 3 replicates)   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Product | Tiles | **100% knock down followed by mortality after minutes during an exposure time of 72 hours after:** | | | | 1 day | 1 week | 2 weeks | | COM 116 02 I AL spray | Glazed Tiles | 25 | 25 | 20 | | PVC | 60 | 60 | 50 | | Untreated | Glazed Tiles | 72h (20%) | 72h (0%) | 72h (0%) | | PVC | 72h (0%) | 72h (0%) | 72h (0%) |   Conclusion: In this laboratory test, COM 116 02 I AL (spray) has proved a complete and fast efficacy towards the silverfish Lepisma saccharina. | Lüpkes, 2008 |

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| --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | |
| **Test substance** | **Test organism(s)** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| COM 116 02 I AL, 0.05% w/w *lambda*-cyhalothrin | Insects:  *Porcellio scaber* | Laboratory tests of the efficacy of different experimental products intended to control woodlice in garden and house environment were conducted.  a) Direct spray treatment (exposure time 72 hours days)  b) Residual test (exposure of 72 hours, residues aged up to 26 weeks)  Type of test chamber:  a) Direct spray treatment: Product was sprayed directly on the woodlice  b) Residual effects: Ceramic or PVC tiles (19.5×19.5 cm) were sprayed with the product  0.05% w/w *lambda-*cyhalothrin | a) Direct spray treatment:  70% knock down efficacy was given within 15 minutes. After 24 hours mortality was 100%.  b) Residual effects on glazed tiles:  It took 2h (for residues aged 1 or 2 weeks) up to 6h (for all other residues) to achieve 100% of efficacy (knock down and / or mortality).  Residual effects on PVC:  The efficacy was weaker. It took 1h (for residues aged 1 day or 1 week) or up to 24h (for residues aged 22 weeks) to achieve 100% of efficacy (knock down and /or mortality).  Conclusion: In this laboratory test, COM 116 02 I AL (spray) has proved a complete and fast efficacy towards the woodlice *Porcellio scaber*. | Felke, 2009 |

**Calculation of application rates**

In the efficacy tests submitted the application of COM 116 02 I AL was executed with a spray can (BOV system):

1. Efficacy of BOV (Bag-on-Valve) System COM 116 02 I AL / Ameisen Stop (0.05% *lambda*-cyhalothrin) against cockroaches, Study No. Mo3684 Author K.-H. Lüpkes including Amendment No. 1, Author K.-H. Lüpkes
2. Efficacy of BOV (Bag-on-Valve) System COM 116 02 I AL / Ameisen Stop (0.05% *lambda*-cyhalothrin) against silverfishes, Study No. Mo3611 Author K.-H. Lüpkes, 2008-07-09
3. Contact toxicity and residual activity of COM 116 02 I AL on woodlice (*Porcellio scaber*), Dr. Martin Felke, 20.05.2009

Summing up the results of these biological test reports and taking into account the parameters discharge rate and spray diameter of the system trigger sprayer and bottle, described in study A16132A Impact of batch LOT 06/002 on Trigger Sprayer Clogging, Discharge Rate and Spray Diameter, Author Dr. F. Wochner, 18-Jun-2009, Study No. 120025, a relationship for the product applied for contact and residual toxicity could be drawn.

The treatment for direct spraying and residual spray in study no. Mo3684 and study no. Mo3611 are almost the same, so only study no. Mo3684 is taking into consideration.

**References**

The reports cited have been referenced in the text above. All reports have already been submitted along with the product dossier for COM 116 02 I AL with exception of the following new report which will be submitted as part of this statement:

Lüpkes, K.-H (2009): Biological Test Report, Efficacy against cockroaches. Study No. Mo3684, Report No. BIO027/09

Lüpkes, K.-H (2015): Amendment No. 1 to Biological Test Report, Efficacy of a product against cockroaches, Study No. Mo3684, Report No. BIO027/09

Lüpkes, K.-H (2008): Biological Test Report, Efficacy of a product against silverfish. Study No. Mo3611, Report No. BIO048/08

Felke, Dr. Martin (2009): Study Report, Contact toxicity and residual activity of COM 116 02 I AL on woodlice (*Porcellio scaber*)

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|  | **study no. Mo3684**  **K.-H. Lüpkes** | **study Dr. M. Felke** | **study no. 120025,**  Study A16132A, Report Nr. 10394896, Archiv Nr 120025  **Dr. F. Wochner** |
| **direct spray treatment** |  |  |  |
| quantity of product, average | 2.8 g (2 seconds spray) | 2.8 g | 0.78 g/stroke |
| distance of spray | 60 cm | 40 cm | 30 cm |
| spray diameter | 17 cm | N/S | 24 cm |
| ***surface covered:***  insects kept inside: | glass ring, 9 cm diameter  surface inside: 63.6 cm²  treated with 0.78 g product | petri dishes, diameter 14.5 cm  surface inside: 165.1 cm²  treated with: 2.8 g product | 452.4 cm²  0.78 g/stroke |
| grams product / cm² | 0.0123 g/cm² | 0.017 g/cm² | 0.0017 g/cm² per stroke |
|  |  |  |  |
| **residual spray treatment** |  |  |  |
| quantity of product | 7 g (5 seconds spray) | 2.8 g | 0.78 g/stroke |
| distance of spray | 25 cm | 40 cm | 30 cm |
| spray diameter | n.a. | 11 cm | 24 cm |
| surface covered | Tiles 1 linear meter treated with 7.0 g product, 1 tile 15 cm, application per tile 1.05 g  diameter of the glass ring on the tile 9 cm  surface inside: 63.6 cm²  treated with: 0.63 g | Not the whole tiles (19.5 x 19.5 cm) were treated as tiles had to be fixed by adhesive tape, so it could be assumed that a surface of 17 x 17 cm, equal to 289 cm² was treated. | Actuating the trigger sprayer from a distance of ca 30 cm a surface of 452 cm² is treated with 0.78 g: 452 cm²= 0.0017 g/cm² by one stroke |
| **grams product / cm²** | **0.010 g/cm²** | **0.010 g/cm²** | **0.0017 g/cm² per stroke**  **0.010 : 0.0017 = 5.88 strokes** |
| **Result: Treat spot wise surfaces from a distance of ca. 30 cm with the trigger sprayer. Apply only where insects are expected running over or treat target organisms directly.** | | | |

**Conversion of application rates from BOV system to trigger sprayer**

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| **Conclusion on the efficacy of the product** |
| Ants: According to the field test (Serrano, 2007a), the biocidal product shows sufficient efficacy against garden ants (*Lasius niger*): Nestkill is shown within 3 weeks. Instruction of use: 10 strokes on ant routes for 1 m route and nest entries corresponding to 10 g product.  Residual efficacy is shown against silverfishes *(Lepisma saccharina),* wood lice (*Porcellio scaber*) and cockroaches (*Blattella germanica, Blatta orientalis, Periplaneta americana*)  at an application rate of 100mg/cm². The treatment should be spot wise on surfaces from a distance of ca. 30 cm with the trigger sprayer applying 5 to 6 strokes. Application should only be done where insects are expected running over.  For direct treatment of target organisms, following application rates showed sufficient mortality:  Against cockroaches, and silverfishes: 7 strokes spot wise  Against wood lice: 10 strokes spot wise   |  |  |  |  | | --- | --- | --- | --- | | **Pest species** | **Knockdown after direct application on pest species** | **Time until 100% control (treatment of surface area)** | **Time until which product remains efficient on treated areas** | | **Ants** | not tested | Nest kill within 21 d | Application will result in complete nest destruction | | **Silverfish** | within 3 min | 25 min (e.g. glazed tiles) - 60 min (e.g. vinyl flooring, PVC) | at least 2 weeks | | **Wood lice** | 70% knock down efficacy was given within 15 minutes.  After 24 hours mortality was 100% | 2h - 6h (e.g. glazed tiles) –  1- 24h (e.g. vinyl flooring, PVC) | at least 25 weeks (glaced tiles) | | **Cockroaches** | 10 min (German cockroach) up to 33 min (*Blatta orientalis*) | 15 min (e.g. glazed tiles) -  6 h (e.g. vinyl flooring, PVC) | at least 1 week (e.g. vinyl flooring, PVC)  every 24 weeks (non-porous ground e.g. glazed tiles) |   The current guidance for PT 18 (2012) was not available at the time of the initial application. At the renewal stage, new data to address the requirements in the most up to date guidance will be required.  In accordance with the TNsG (2012) it is necessary to provide simulated use tests against the claimed target species. However, the application was made before the TNsG were available for 2 years (the application has been submitted in September 2013).  The previous guideline (TNsG on Product evaluation Feb 08) does not provide clear statements. As a compromise, an authorisation of the product on the basis of the available data and the ambiguous guidance is done, provided that an application for change will be submitted within 1 year post authorisation which is based on new data. The data for the change should comply with the current guidelines. |

#### Occurrence of resistance and resistance management

As the treatment is very local (no massive or big areas treated), and the strategic spraying around the nest or on limited ground areas avoids dispersing the substance into the environment. This further reduces the risk of resistance developing.

For the biocidal use of *lambda*-cyhalothrin against Lasius spp. (garden ants) the probability of resistance is very low due to the eusocial lifestyle of ants. The individuals of this species are social insects from which only the queen can reproduce. A great part of worker ants will not be able to transfer food to the nest colony after contamination whereas other ants might be able to reach the nest with the microcapsules. Therefore, even if some worker ants would survive, the colony would disappear if the queen is dead, i.e. the resistance could then not be passed on to offspring.

To avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

- Inform the authorisation holder if the treatment is ineffective.

- If the infestation persists despite following the instructions of the label, contact a pest control professional.

- Adopt integrated pest management methods such as alternation between treatment strategies during the treatment regime (biological, chemical and mechanical), taking into account local specificities (climatic conditions, target species, conditions of use, etc.).

#### Known limitations

No undesirable or unintended side effects e.g. on beneficial and other non-target organisms were observed.

#### Evaluation of the label claims

The label claims reflect the efficacy of the biocidal product.

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

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

### Risk assessment for human health

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not irritating to skin. |
| Justification for the value/conclusion | A skin irritation test with COM 116 02 I AL has not been conducted. Testing of the pure active substance *lambda*-cyhalothrin revealed no skin-irritating potential. Other components of the formulation do not give rise to skin-irritating properties. It is therefore concluded that the b.p. also has no skin-irritating potential. |
| Classification of the product according to CLP | According to CLP no classification for skin irritation is necessary. |

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| **Data waiving** | |
| Information requirement | Study scientifically unjustified |
| Justification | The b.p. does not contain ingredients classified for primary skin irritation. The b.p. contains >99% water. In addition, the b.p. has been tested for eye-irritating properties and was found to be not irritating. Therefore, no classification for primary skin irritation is necessary. Due to the composition of the b.p., a skin irritation test with the b.p. is scientifically unjustified. |

For skin corrosion and irritation no human data is available.

***Eye irritation***

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| --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on serious eye damage and eye irritation** | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance,Dose levels, Duration of exposure** | **Results**  *Average score (24, 48, 72h)/*  *observations and time point of onset, reversibility* | **Remarks** | **Reference** |
| Eye irritation,  OECD 405,  GLP Study,  RL 1 | Rabbit,  New Zealand White,  Male/female,  3 | COM 116 02 I AL,  Neat substance,  Single application, No rinse | Cornea: 0  Iris: 0  Conjunctivae: 0  Chemosis: 0  Reversibility: n.a. | not irritating | Giannini, 2008a |

For eye damage and eye irritation no human data is available.

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| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not irritating to eyes. |
| Justification for the value/conclusion | COM 116 02 I AL was not irritating to rabbits eyes. |
| Classification of the product according to CLP | According to CLP no classification for eye irritation is necessary. |

***Respiratory tract irritation***

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| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not irritating to the respiratory tract. |
| Justification for the conclusion | COM 116 02 I AL is neither irritating to eyes nor to the skin. |
| Classification of the product according to CLP | According to CLP no classification for respiratory tract irritation is necessary. |

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| **Data waiving** | |
| Information requirement | Study scientifically unjustified |
| Justification | The b.p. COM 116 02 I AL contains >99% water and is not irritating to eyes. The average 24, 48, 72h score in a reliable OECD Guideline study for each parameter was 0. Therefore an irritation test with the b.p. is scientifically unjustified. |

***Skin sensitization***

| **Summary table of animal studies on skin sensitisation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline, GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle,**  **Dose levels,  duration of exposure Route of exposure** | **Results**  *(Number of sensitised animals at induction dose)* | **Remarks** | **Reference** |
| GPMT,  OECD 406  GLP Study,  RL 1 | Guinea pig,  Dunking Hartley,  Male/female,  10 | COM 116 02 I AL;  Water,  Intradermal induction: 50% topical induction and challenge: 100%, | 24h: 0/10;  48h: 0/10; | Not sensitising | Giannini, 2008b |

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| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising. |
| Justification for the value/conclusion | The liquid formulation COM 116 02 I AL was tested in the Guinea Pig Maximisation Test. There were no skin reactions at any examined time point following challenge. |
| Classification of the product according to CLP | According to CLP no classification as a skin sensitizer is necessary.  However application of “EUH208: Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.” is necessary. |

For skin sensitisation no human data is available.

***Respiratory sensitization (ADS)***

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| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising |
| Justification for the value/conclusion | The b.p. COM 116 02 I AL contains >99% water and is not sensitising to skin. None of the ingredients is classified for sensitisation. |
| Classification of the product according to CLP | According to CLP no classification for respiratory sensitisation is necessary. |

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| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified |
| Justification | The b.p. COM 116 02 I AL contains >99% water and is not sensitising to skin. None of the ingredients is classified for sensitisation. No publications with regard to respiratory sensitisation are available. Therefore no data for this additional data set are provided. |

***Acute toxicity***

*Acute toxicity by oral route*

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| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not harmful |
| Justification for the selected value | Acute toxicity studies with COM 116 02 I AL have not been conducted. The b.p. mainly consists of water (>99%). Only the a.s. is toxicologically relevant. The content of *lambda*-cyhalothrin in the preparation (0.05% w/w) does not exceed 0.1% (w/w). |
| Classification of the product according to CLP | According to CLP no classification for acute oral toxicity is necessary. |

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| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified |
| Justification | The b.p. contains only one ingredient classified for acute oral toxicity. The a.s., *lambda*-cyhalothrin is classified as Acute Tox.3, H301 according to CLP.  However, the b.p. contains only 0.05% of the a.s. and >99% water. Due to the composition of the b.p., an acute oral toxicity test with the b.p. is scientifically unjustified. |

For acute oral toxicity no human data is available.

*Acute toxicity by inhalation*

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| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not harmful |
| Justification for the selected value | Acute toxicity studies with COM 116 02 I AL have not been conducted. The b.p. mainly consists of water (>99%). Only the a.s. is toxicologically relevant. The content of *lambda*-cyhalothrin in the preparation (0.05% w/w) does not exceed 0.1% (w/w). |
| Classification of the product according to CLP | According to CLP no classification for acute inhalation toxicity is necessary. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified |
| Justification | The b.p. contains only one ingredient classified for acute inhalation toxicity. The a.s., *lambda*-cyhalothrin is classified as Acute Inhal 2, H330. However, the b.p. contains only 0.05% of the a.s. and >99% water. Therefore, no classification for acute inhalation toxicity is necessary. Due to the composition of the b.p., an acute inhalation test with the b.p. is scientifically unjustified. For acute inhalation toxicity no human data is available. |

*Acute toxicity by dermal route*

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| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not harmful |
| Justification for the selected value | Acute toxicity studies with COM 116 02 I AL have not been conducted. The b.p. mainly consists of water (>99%). Only the a.s. is toxicologically relevant. The content of *lambda*-cyhalothrin in the preparation (0.05% w/w) does not exceed 0.1% (w/w). |
| Classification of the product according to CLP | According to CLP no classification for acute dermal toxicity is necessary. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified |
| Justification | The b.p. contains only one ingredient classified for acute percutaneous toxicity. The a.s., *lambda*-cyhalothrin is classified as Acute Tox.4, H312 according to CLP. However, the b.p. contains only 0.05% of the a.s. and >99% water. Due to the composition of the b.p., an acute dermal toxicity test with the b.p. is scientifically unjustified. |

For acute dermal toxicity no human data is available.

*Other dermal effects*

*Lambda*-cyhalothrin is a synthetic type II pyrethroid insecticide. The principal effect of pyrethroids is to delay sodium channel closure on nerve axons which in turn delays membrane repolarisation following an action potential. In this sense, synthetic pyrethroids affect the nervous system of insects by prolonging the deactivation of voltage-gated sodium channels, which results in prolonged excitation of nerve fibers. There is evidence that synthetic pyrethroids containing an alpha-cyano group (such as *lambda*-cyhalothrin) are more potent in eliciting neurotoxic effects, in comparison to pyrethroids that do not contain an alpha-cyano group.

While synthetic pyrethroids have a higher level of selectivity and toxicity for the insect nervous system, local effects on human skin resulting in paresthesias can occur in association with overexposure. Systemic intoxication is uncommon in humans, as the dermal absorption of these chemicals appears to be minimal. However, cases of subjective facial sensation (also known as 'SFS' or paraesthesia) have occurred at all stages of *lambda*-cyhalothrin handling, from small-scale laboratory work to commercial synthesis and formulation operations. The paresthesia has been described as ranging from a mild itch to a stinging sensation, with progression to numbness in some cases. The duration of symptoms varies, ranging from several hours to approximately 24 hours.

According to the technical statement of Syngenta no information regarding that paraesthesia may happen also at 0.05% a.s. is available. Additionally it is considered unlikely that entry into a treated home would result in sufficient exposure to *lambda-*cyhalothrin to cause paraesthesia. Additionally, the likelihood of exposure is reduced by encapsulation of the formulation and use of personal protective equipment. Nonetheless, personal protective equipment cannot normally be considered for non-professional users and in order to cover vulnerable population. Therefore a statement should be added: “May cause temporary and reversible itching, tingling, burning, or numbness of exposed skin, called paraesthesia. These skin contact paresthesia effects are transient, and normally disappear within 24 hours. Treat symptomatically”.

References:

*Soderlund DM, Clark JM, Sheets LP, Mullin LS, Piccirillo 1. VJ, Sargent D, Stevens JT,Weiner ML. Mechanisms of pyrethroid neurotoxicity: implications for cumulative risk assessment. Toxicology 2002, 171: 3-59.*

*Flannigan SA, Tucker SB, Key MM, Ross CE, Fairchild EJ, Grimes BA,Harrist RB. Synthetic pyrethroid insecticides: a dermatological evaluation. Br J Ind Med 1985, 42: 363-372.*

*Woollen BH, Marsh JR, Laird WJ,Lesser JE. The metabolism of cypermethrin in man: differences in urinary metabolite profiles following oral and dermal administration. Xenobiotica 1992, 22: 983-991.*

*Williams RL, Bernard CE,Krieger RI. Human exposure to indoor residential cyfluthrin residues during a structured activity program. J Expo Anal Environ Epidemiol 2003, 13: 112-119.*

*Tucker SB,Flannigan SA. Cutaneous effects from occupational exposure to fenvalerate. Arch Toxicol 1983, 54: 195-202.*

*Knox JM, Tucker SB,Flannigan SA. Paresthesia from cutaneous exposure to a synthetic pyrethroid insecticide. Arch Dermatol 1984, 120: 744-746.*

***Information on dermal absorption***

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| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | *lambda*-cyhalothrin |
| Value(s) | 1% |
| Justification for the selected value(s) | According to the Guidance on the BPR: Volume III. Part A Chapter III: Requirements for Biocidal Products (ECHA 2014), information on dermal absorption is needed if exposure occurs to the biocidal product. The assessment of this endpoint shall proceed using a tiered approach. It is not always mandatory to submit experimental data. Dermal absorption can be estimated on the basis of existing information. According to the Note for Discussion Paper on Approach for Dermal Absorption (CA-July13-Doc.6.2.b) one can use data from the Assessment Report for Annex I inclusion or for product authorisation provided that conditions 1 and 2 are met:  1. It is justified that the formulations presented in dermal absorption studies submitted for Annex I inclusion or for product authorisation have a similar composition as compared to the biocidal product to be authorised.  2. The applicant holds a letter of access (LoA) from the data owner of the dermal absorption study which is relevant for the biocidal product to be authorised.  Data of the active substance (a.s.) *lambda*-cyhalothrin were evaluated by the Rapporteur Member State (RMS) Sweden and published as Assessment Report (AR, RMS Sweden, 2011). One of the representative biocidal products used is Demand 10 CS, a capsule suspension formulation containing 9.6% w/w *lambda*-cyhalothrin. Demand 10 CS is also used as the active substance concentrate formulation in the present biocidal product (b.p.) COM 116 02 I AL.  **Summary of available in vitro dermal absorption data**  The sponsor of the study provided information on in vitro data on dermal absorption of *lambda-*cyhalothrin through human skin for a CS formulation to the applicant.  The study was conducted according OECD Guideline 428 “Dermal Absorption (human skin)”. The tested CS formulation contains the same amount of *lambda*-cyhalothrin as the formulation Demand 10 CS used in the b.p., i.e. 9.6% w/w *lambda*-cyhalothrin. The physical/chemical properties of the tested CS formulation indicate that data obtained for this formulation could be considered conservative for Demand 10 CS (RMS Sweden, 2011). The formulation was applied to the skin membranes as the concentrate (100 g/L) and as 0.4 g *lambda*-cyhalothrin/l aqueous spray strength dilution. The total exposure time was 48 h with analyses of samples made at 6, 8, 10, 24 h.  The mean absorption rate for lambda-cyhalothrin from the concentrate formulation during the first 10 h of exposure was 0.018 µg/cm2/h. This increased to give an essentially unchanging mean rate of 0.036 µg/cm2/h between 12-48 h. From the concentrate formulation, a mean of 0.006% of applied dose was absorbed by 6 h, 0.0013% by 10 h and 0.059% was absorbed over a 24 h period. From the spray dilution, no absorbed *lambda*-cyhalothrin was detected during the first 10 h of exposure. After 12 h, absorption was just detectable. A mean of 0.315% was absorbed by 24 h. The relatively high percentage of the dose absorbed from the aqueous solution at 24 h (0.315%) reflects the fact that only a very slow dose (4.12 µg *lambda*-cyhalothrin/cm²) was applied. Thus, the study indicate that **lambda**-cyhalothrin is absorbed very slowly from the CS concentrate formulation and even more slowly from the 0.4 g/L aqueous solution through human epidermis.  Since residues remaining in skin and overall recovery was not analysed and since a steady state level was not reached, a conservative value of 1% was suggested for both the undiluted and the diluted Demand 10 CS formulation (AR, RMS Sweden, 2011).  **Evaluation of the similarity of formulations**  According to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) data on another (reference) formulation can be used if the formulation to be assessed is closely related. In the AR it is stated, that the data obtained for the tested CS formulation could be considered conservative for Demand 10 CS. The b.p. COM 116 02 I AL contains 0.52% w/w Demand 10 CS, i.e. exactly the reference formulation in the AR. Demand 10 CS contains 9.7% of the insecticidal a.s. *lambda*-cyhalothrin kept inside the capsules. Thus, COM 116 02 I AL contains 0.05% w/w (0.5 g/l considering a density of approx. 1 g/cm³) of the a.s. lambda-cyhalothrin. Hence, COM 116 02 I AL and the tested aqueous dilution of 0.4 g lambda-cyhalothrin/l contain comparable amounts of a.s. The b.p. COM 116 02 I AL mainly consists of water (>99%). Other co-formulants are (1) the surfactant castor oil, ethoxylated (<0.1%), (2) a preserver containing up to 20% 1,2-benzisothiazolin-3-one (BIT), up to 10% sodium hydroxide and organic solvent (<0.1%), and (3) citric acid as pH adjuster (<0.1%).  Thus, the major difference between the aqueous solutions of Demand 10 CS, for which a conservative dermal absorption value of 1% is established, and the b.p. COM 116 02 I AL is the existence of a surfactant (<0.1%), a preserver (<0.1%) and a pH adjuster (<0.1%) in very low concentrations. Surfactants, dermal irritants and skin sensitizer are known to affect dermal absorption. The surfactant is not added to the formulation to solubilize lipophilic ingredients but to lower the surface tension between the solid surface and the liquid to allow a more homogeneous distribution of the formulation on the floor. Generally, surfactants have the ability to solubilize lipids in stratum corneum and to interact with keratin. However non-ionic surfactants, such as the ethoxylated castor oil derivate, have minimal effects compared with ionic surfactants (Guidance Notes on Dermal Absorption ENV/JM/MONO(2011)36). Considering the minimal effects of non-ionic surfactants and taking into account the concentration of the surfactant in the b.p. <0.1%) the ability to solubilize lipids in stratum corneum and to interact with keratin is virtually excluded.  Sodium hydroxide and citric acid might increase dermal absorption by their irritating properties. However, the concentration of sodium hydroxide and citric acid is well below the specific concentration limits (SCL) and the generic concentration limits, respectively, for classifying a mixture for eye and/or skin irritation. Additionally, both co-formulants neutralize each other. In fact, citric acid is applied to adjust the pH value of the product. Taking into account that the b.p. is not irritating to skin and eyes and that the pH value of the neat formulation and of a 1% suspension in water is 6.1 and 6.5, respectively, both co-formulants will not affect dermal absorption of the a.s.  The preserver BIT is classified for skin sensitization. A SCL for this hazard is established at or exceeding a concentration of 0.05%. The concentration of BIT in the b.p. COM 116 02 I AL is clearly below the SCL. Thus, no sensitizing reaction that may enhance dermal absorption needs to be expected.  A not further specified organic solvent (<0.1%) is part of the preservative and might therefore influence the dermal absorption of *lambda*-cyhalothrin from the b.p. COM 116 02 I AL compared to the reference formulation. It is well known that dermal absorption of a.s. from solvent based-formulations can be higher compared to water based-formulations. However, the b.p. contains >99% water and therefore represents clearly a water based formulation. Independently of the nature of organic solvent the low concentration of the solvent will not significantly increase the dermal absorption of the a.s. from the b.p.  Taking together, due to the very low content of the co-formulants in the b.p. (each well below 0.1%), potential effects enhancing the dermal absorption like irritancy and/or solubilisation of the lipid layer is virtually excluded.  In conclusion, the b.p. formulation and an aqueous solution of Demand 10 CS are sufficiently similar to conclude that the dermal absorption of 1% *lambda*-cyhalothrin given in the AR is suited for the risk assessment of the b.p. COM 116 02 I AL.  **Further considerations**  A dermal absorption of 0.315% within 24 h was observed when the skin was exposed to the diluted test preparation for 24 h. After 12 h, absorption was just detectable. Therefore, the dermal absorption value of 1% represents a clear worst case when considering the duration of skin contact during primary exposure but also during secondary exposure.  Additionally, the type of formulation, i.e. a capsule suspension, and the kind of likely exposure to the b.p. should be taken into account to assess whether the dermal absorption value provided in the assessment report is valid for the b.p. The liquid b.p. is applied on surfaces. The solvent (water) evaporates and the dried a.s. kept inside the capsules is attached to the treated surfaces. The a.s. is liberated when the capsules are punctured, e.g. in a secondary scenario by a child crawling over the surface. Under this condition the child is in contact to the concentrated b.p. Due to the reverse relationship between dermal absorption and concentration in a formulation, the relative dermal absorption decreases with increasing concentrations. Thus, the dermal absorption value of 1% derived for an aqueous solution of a CS formulation distinctly overestimates the dermal penetration of the a.s. from a dried solution and therefore represents a worst case.  For primary exposure it should be noted that the capsules cannot pass through the skin and that therefore the majority of the a.s. contained within the capsules will not be available for dermal penetration. However, the a.s. might be released when the capsule is opened via mechanical breakage. This primary exposure scenario is modelled by the application of the formulation to the human skin. The dermal absorption value of 1% derived for the CS formulation should be considered for exposure assessment of the b.p. COM 116 02 I AL, instead of default values that do not taken into account the type of formulation.  The low dermal penetration of the pyrethroid *lambda*-cyhalothrin as determined in the dermal absorption study using human skin in vitro is supported by additional data available in the public literature. The UKPID Monograph “Pyrethroids” reported that based on excretion studies, dermal absorption of pyrethroids is in general low, reaching a maximum of 1.5% (Nassif et al., 1980 as cited in UKPID Monograph “Pyrethroids”). Only about 0.0001% (54 µg) of *lambda*-cyhalothrin handled and sprayed each day by spraymen was absorbed, based on estimation of metabolites in urine and serum (Chester et al, 1992 as cited in UKPID Monograph “Pyrethroids”). Even data on a solvent-based pyrethroid formulation (cypermethrin in a hydrocarbon solvent, Eadsforth et al, 1988 as cited in UKPID Monograph “Pyrethroids”) also suggest that pyrethroid absorption is limited. Also, the Bavarian Health and Food Safety Authority (2005) reported for pyrethroids a low cutaneous absorption of 0.3-1.8% in animal and in in vitro studies using intact skin.  **Conclusion**  Based on an in vitro dermal absorption study, a conservative dermal absorption value of 1% was provided in the AR for both the undiluted and the diluted Demand 10 CS formulation (AR, RMS Sweden, 2011). It is justified, to consider the dermal absorption value of 1% for the b.p. COM 116 02 I AL in the relevant scenarios of the human health exposure and risk assessment due to the following reasons:  1. The b.p. COM 116 02 I AL and an aqueous dilution of Demand 10 CS formulation are sufficiently similar with respect to dermal absorption.  2. Since the skin was continuously exposed for 24 h, the dermal absorption value of 1% represents a clear worst case when considering the duration of skin contact during primary and secondary exposure.  3. Considering secondary exposure towards the dried solution, the dermal absorption value of 1% represents a worst case.  4. Additional data available in the public literature support a dermal absorption value in the range of 1% for pyrethroids. For *lambda*-cyhalothrin the dermal absorption values are even lower. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Other justification |
| Justification | See above, justification for the selected value. |

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

The b.p. mainly consists of water (>99%). No substances of concern were identified.

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

Available toxicological data relating to a mixture that a substance(s) of concern is a component of are not required as no substances of concern were identified.

***Other***

The biocidal product is not intended for direct application to foods or feeding stuff or to surfaces and areas where foods or feeding stuff are prepared or stored. Hence, an exposure of food and feeding stuff to *lambda*-cyhalothrin can be excluded when applied according to the recommended uses. Additional food or feeding stuffs studies are not required.

#### Exposure assessment

The b.p. is sold as a trigger pump spray for non-professional use. It is used by spraying for spot treatment.

Based on the intended use, exposure to generated aerosol leading to inhalation and dermal exposure is considered to be relevant for users. Oral exposure is expected to be not significant in comparison to the previous routes.

Secondary exposure is considered to be possible assuming contact with treated surfaces. Inhalation exposure due to gaseous release is expected to be not relevant, as only small areas are treated (spot treatment) and due to the low vapour pressure of the a.s. Dermal and oral exposure might be relevant as reasonable worst case for secondary exposure, assuming infants crawling over treated areas.

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

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

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Spot treatment, trigger spray | Primary exposure of non-professionals applying liquid formulation by trigger spray devices. | Non-professionals |
| 2. | Child playing on floor | Secondary exposure of children crawling on the floor after application. | General public (child) |

***Industrial exposure***

No industrial exposure is foreseen.

***Professional exposure***

No professional exposure is foreseen.

***Non-professional exposure***

*Scenario [1]*

*Application of liquid formulation by trigger spray devices*

| **Scenario 1**: Primary exposure of non-professionals applying liquid formulation by trigger spray devices |
| --- |
| The exposure of non-professionals to *lambda*-cyhalothrin during application of the insecticide is assessed by the software ConsExpo 5.0. The b.p. is sold as a trigger pump spray. The scenario for spot treatment is based on a non-professional user who is controlling crawling insects on the floor.  The user is assumed to stay in the treated room for 4 h after application. To calculate the exposure of the user during the application, the 'spray' model is used for the inhalatory exposure and the ‘constant rate’ model is used for the dermal exposure. The respiration rate is ConsExpo's default for a 60-kg individual under light exercise (33 m³/day ≅ 1.37 m³/h). The oral exposure is handled in the 'spray' model. ConsExpo assumes that the non-respirable fraction is taken in orally; oral absorption is 50%. The default particle size distribution for trigger sprays is adopted. The default scenarios were adapted in terms of body weight (adult: 60 kg) according to the TNsG and of non-volatile density (1 g/cm³), due to the 99.3% water content of the formulation. The use frequency was set to “1 per day” so that the reported exposures reflect the acute exposure on the day of use. The exposed skin surface is comprised of the back of the one hand holding the bottle/can. This is approximately 210 cm², i.e. 1/4 of the surface of both hands as given in the RIVM Fact Sheet (Bremmer & van Veen, 2000). A dermal penetration of 1% was determined for diluted solutions (0.04%) of *lambda*-cyhalothrin by RMS Sweden.  No personal protective equipment was considered. For details on the exposure assessment please refer to Annex 3.2. |

**Calculations for Scenario 1:** Primary exposure of non-professionals applying liquid formulation by trigger spray devices

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| mg/kg bw/day | | | |
| Scenario 1 | 1 / None | 1.9x10-5 | 1.5x10-5 | 5.2x10-5 | 8.7x10-5 |

***Exposure of the general public***

*Scenario 2: Child playing on floor*

Secondary exposure is considered to be possible assuming contact with treated surfaces. Inhalation exposure due to gaseous release is expected to be not relevant, as only small areas are treated (spot treatment) and due to the low vapour pressure of the a.s. Dermal and oral exposure might be relevant as reasonable worst case for secondary exposure, assuming infants crawling over treated areas.

| **Scenario 2: Child playing on floor – dermal exposure** | | |
| --- | --- | --- |
| The exposure after spot treatment is described for crawling children present in the room after the treatment has been carried out. It is assumed that a child/toddler (=10 kg) plays inside the treated room for 1 h/day. The treated surface within this room is only a small fraction of the total surface and the infant touches the actual treated surface only by chance. In common, only ant trails are also found at easily accessible areas. Treatment against silverfish and cockroaches will only require application behind furniture or along baseboards. These areas will be less likely to be touched by children than ant trails that may run across the middle of a room. Treatment against ants therefore represents the worst case in terms of secondary exposure potential.  Within the small default room of 8 m², it is assumed that the b.p. is sprayed only onto 1 m². This is equivalent to a swath with a length of 5 m at a width of 20 cm.  Referring to information provided by the applicant, when the b.p. is sprayed from a distance of 30 cm the diameter of one stroke is 24 cm. 0.78 g b.p. are released per stroke(please refer to the overview table on page 53 in the PAR). However, assuming 10g b.p. per running meter with a spray width of 24 cm an application rate of 44.5 g/m2 can be calculated.  It is assumed that the probability of a child touching a given spot on the floor is uniformly distributed across the entire room. Thus, it is justified to assume an average amount of b.p. equivalent to 1/8 of the application rate on the treated swath (44.5 g b.p./m²). Hence, the effective application rate (AR) is  AR = 1/8 × 44.5 g/m² = 5.56 g/m²  The scenario was adopted in terms of body weight according to the SOPs from the US-EPA (1997), a source which is cited by ConsExpo itself regarding the transfer coefficient. The dislodgeable floor residues can be estimated using the maximum value of 60% for dried fluids from various types of surface (TNsG 2007- Annex 6, p. 102) giving a dislodgeable residue of 1.56 mg a.s./m². For details on the exposure assessment please refer to Annex 3.2. | | |
|  | Parameters | Value |
| Tier 1 | Dislodgeable residue [mg a.s./m²] | 1.67 |
| Transfer coefficient [m²/h] | 0.2 |
| Contact duration [h/day] | 1 |
| Dermal absorption [%] | 1 |
| Body weight of toddler[kg] | 10 |

| **Scenario 2: *Child playing on floor* – oral exposure** | | |
| --- | --- | --- |
| Small children exhibit a great deal of hand-to-mouth (HTM) contact. Therefore, a part of the a.s. residues present on the hands will be dislodged by saliva and eventually ingested. The a.s. will not be completely removed via saliva and mouthing (simulated by wiping in Camann et al., 1995) based on data for other pesticides. Thus, one would expect the saliva removal efficiency of the a.s. to be not higher than 50%. The bioavailability (oral absorption) of ingested *lambda*-cyhalothrin is 50%. HESI (2004) contains data on the frequency of hand-to-mouth events for children during indoor play. For 1-2-year olds, toddlers, a mean hand-to-mouth frequency of 18 events per hour was determined for the contact time. For details on the exposure assessment please refer to Annex 3.2. | | |
|  | Parameters | Value |
| Tier 1 | Dermal load [mg a.s./cm²] | 0.000167 |
| Hand area contacting the mouth [cm²] | 4.5 |
| Efficiency of removal by saliva from skin [%] | 50 |
| Number of hand to mouth contacts [day–1] | 18 |
| Oral absorption [%] | 50 |
| Body weight of toddler[kg] | 10 |

**Calculations for Scenario 2: Child playing on floor**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| mg/kg/ bw/day | | | |
| Scenario 2 | 1 / None | Not relevant | 0.000334 | 0.000338 | 0.00067 |

*Combined scenarios*

Combined exposure from the direct and indirect scenarios does not occur.

***Monitoring data***

No further information on surveys or studies with the actual product or with a surrogate is available.

***Dietary exposure***

Food, drinking water or livestock exposure of *lambda*-cyhalothrin can be excluded when applied according to the recommended uses.

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

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1. | veterinary use\* | Fat | 0.5 mg/kg[[3]](#footnote-4) |
| Milk / Kidney | 0.05 mg/kg |
| 2. | plant protection products | MRL range of different crops | 0.02–10 mg/kg[[4]](#footnote-5) |

\* Established for cyhalothrin.

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

Food, drinking water or livestock exposure of *lambda*-cyhalothrin can be excluded when applied according to the recommended uses.

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

Food, drinking water or livestock exposure of *lambda*-cyhalothrin can be excluded when applied according to the recommended uses.

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

Food, drinking water or livestock exposure of *lambda*-cyhalothrin can be excluded when applied according to the recommended uses.

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

Exposure during the production and formulation of the active substance should be addressed under other EU legislation (e.g. REACH) and not repeated under Regulation EU (No.) 528/2012. The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for *lambda*-cyhalothrin which is an existing biocidal active substance within the EU.

***Aggregated exposure***

Currently no methodology has been developed how an aggregated exposure assessment shall be performed. This was not addressed.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake [mg/kg bw/day]** |
| 1. | Non-professionals | 1/None | 0.000087 |
| 2. | Non-professionals (child) | 1/None | 0.00067 |

#### Risk characterisation for human health

**Reference values to be used in Risk Characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)**  **[mg/kg bw/day]** | **AF1** | **Correction for oral absorption** | **Value**  **[mg/kg bw/day]** |
| AELshort-term | Dog, 6 week | 0.75 | 100 | 50% | 0.0038 |
| AELmedium-term | Dog, 1 year | 0.5 | 100 | 50% | 0.0025 |
| AELlong-term | Dog, 1 year | 0.5 | 100 | 50% | 0.0025 |
| AELinhalation | Rat, 21-day | 0.08  (0.3 μg/l) | 100 | n.a. | 0.0008 (0.003 μg/l) |
| ARfD | Dog, 6 week | 0.75 | 100 | n.a. | 0.0075 |
| ADI | Dog, 1 year | 0.5 | 100 | n.a. | 0.005 |

1 compensating for inter/intra species variations

**Specific reference value for groundwater**

No specific reference value for groundwater was established. Thus, the European standard value of 0.1 µg/l for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC), does apply.

***Risk for industrial users***

Not relevant

***Risk for professional users***

Not relevant

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

The product is only used sporadically and therefore the acute AEL is used for assessing primary exposures. Since the acute AEL is actually based on a 6-week study, even repeated exposures would be covered. The inhalation route (only relevant for primary exposure) is separately assessed using the AEL for inhalation since this appears to be lower compared to the AEL for oral exposure. (The CAR for the active substance explains: “Although the systemic absorption is higher following inhalation, it cannot fully explain the difference between the rat effect levels following inhalation (LOAEL 0.9 mg/kg bw) and oral administration (LOAEL 35 mg/kg bw). The apparently higher sensitivity following inhalation and dermal exposure to *lambda*-cyhalothrin could be a consequence of a first-pass effect of the liver being avoided. This first-pass effect may be specific for the Wistar-derived rat but is difficult to verify since all but one of the rat studies were performed with this strain”.) Note that the respiratory route of exposure was not considered relevant for the active substance evaluation, since the representative product was a microencapsulated formation leading to no/very low respirable fractions.

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **[mg/kg bw/d]** | **AEL**  **[mg/kg bw/d]** | **Estimated uptake**  **[mg/kg bw/d]** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Spot treatment, trigger spray, systemic (oral and dermal) / Scenario 1 | 1 | 0.75 | 0.0038 | 6.7E-5 | 1.8 | yes |
| Spot treatment, trigger spray, inhalation / Scenario 1 | 1 | 0.08 | 0.0008 | 1.9E-5 | 2.4 | yes |
| Sum of % AEL | | | | | 4.2 | yes |

**Combined scenarios**

No combined exposure is foreseen.

**Local effects**

The b.p. is not classified for local effects. Therefore, risk characterisation for local effects is not required.

**Conclusion**

The AEL is neither reached nor exceeded by the estimated exposures and the MoEs are sufficiently high.

***Risk for the general public***

The product is only used sporadically and therefore the acute AEL is used for assessing secondary exposures. Since the acute AEL is actually based on a 6-week study, even repeated exposures would be covered.

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **[mg/kg bw/d]** | **AEL**  **[mg/kg bw/d]** | **Estimated uptake**  **[mg/kg bw/d]** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Child playing on floor / Scenario 2 | 1 | 0.75 | 0.0038 | 0.00067 | 17.6 | yes |

However considering a reverse scenario, the risk that infants ingest inacceptable amounts appears obvious: The content of the active substance in the product is 0.05%. Application rate is 44.5 b.p./m2, resulting in 22.25 mg a.s./m2. Assuming an AEL of 0.0075 mg/kg bw day (not corrected for oral absorption, since the study and the exposure would be oral) an infant weighing 10 kg should not take up more than what is applied to 0.0033 m2 or 33 cm2 (10 [kg bw] \* 0.0075 [mg/kg bw day] /22.25 [mg a.s./m2])This corresponds to 0.33% of one application to one square-meter.

Nevertheless, the product should be labelled with: “*Due to the risk of poisoning the product may only be applied, where access of pets, livestock and children can be excluded*”. This is considered to represent an adequate risk mitigation measure.

**Local effects**

The b.p. is not classified for local effects. Therefore, risk characterisation for local effects is not required.

**Conclusion**

The reverse scenario indicates an inacceptable risk for infants. The proposed labelling is considered to represent an adequate risk mitigation measure.

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

The product will be labelled with the following risk mitigation measure: “May only be applied, where contamination of food, feed, drinks and edible plants as well as growing areas for edible plants can be excluded.” Therefore no unacceptable risk to consumer health via residues in food needs to be expected.

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

The b.p. mainly consists of water (>99%). No substances of concern were identified. Therefore exposure to several active substances or substances of concern within a product is not relevant.

### Risk assessment for animal health

The content of the active substance in the product is 0.05%. Application rate is 44.5 b.p./m2, resulting in 22.25 mg a.s./m2.

Assuming a dog specific AEL of 0.075 mg/kg bw day (only factor 10 for intra-species uncertainty to NOAEL of 0.75 mg/kg bw day) a dog weighing 12.7 kg should not lick more than 0.043 m2 = 430 cm2 treated floor (12.7 [kg bw] \* 0.075 [mg/kg bw day] /22.25 [mg a.s./m2]). This corresponds to 4.3% of one application to 1 square-meter.

For cats at least an (inter- and intraspecies) uncertainty factor of 100 would be relevant (considering also the known sensitivity of cats to pyrethroids). This means that a cat with a body weight of 3 kg should not lick more than 0.001 m2 or 10 cm2. (3 [kg bw] \* 0.0075 [mg/kg bw day] /22.25 [mg a.s./m2]).

This reverse scenario indicates an unacceptable risk for pets. Consequently the product should be labelled with: “Due to the risk the product may only be applied, where access of pets, livestock and children can be excluded”. This is considered to represent an adequate risk mitigation measure.

### Risk assessment for the environment

Authorisation is requested for the product COMPO Ameisen-Stop (COM 116 02 I AL) as a PT18 insecticide. Active substances and products intended for PT 18 purposes are used as 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 (ESD PT18; OECD, 2008[[5]](#footnote-6)).

COM 116 02 I AL is a liquid formulation containing 0.05% w/w *lambda*-cyhalothrin (0.5 g/l). The product is efficacious against garden ants, silverfishes, wood lice, and cockroaches and will be used by non-professional users. The product is intended to be applied indoors and outdoors, around domestic buildings on paved surfaces like terraces.

The active ingredient *lambda*-cyhalothrin is sealed in micro-small polymer capsules and is released after contact and ingestion by the insects. Due to microencapsulation, the product is stable over several weeks upon application and provides a long-lasting effect of the active substance. The product is ready-to-use (RTU) and can be applied by direct spraying either on the target area where insects occur or on the insect.

#### Effects assessment on the environment

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

Acute and/or chronic toxicity studies with COM 116 02 I AL have not been conducted. According to the 1st ATP to Regulation (EC) No 1272/2008 the pure active substance *lambda*-cyhalothrin has a harmonised classification for its environmental effects as Aquatic Acute 1, H400: Very toxic to aquatic life and Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects, M=10 000 (acute and chronic).

According to the content of *lambda*-cyhalothrin in the biocidal product (0.05% w/w) the formulation is very toxic to aquatic organisms and it may cause long-term adverse effects in the aquatic environment. Therefore the biocidal product COM 116 02 I AL has to be labelled, according to CLP, with the pictogram GHS09, the signal word “Warning” and the hazard statement H410 (H400 may be omitted).

In the product there is no other co-formulant contributing to the proposed classification and labelling of COM 116 02 I AL.

***Further Ecotoxicological studies***

No new data was submitted for the active substance and the biocidal product.

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

No new data was submitted for the active substance and the biocidal product.

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

No new data was submitted for the active substance and the biocidal product.

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

Since the product is applied by spraying no further data is considered necessary.

No new data was submitted.

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

The biocidal product is not intended to be applied in a large proportion of a specific habitat type. Therefore secondary ecological effects are considered to be negligible and no new data was submitted.

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

For the environmental risk assessment, the relevant compartments for emissions have to be defined and an assessment of the potential residues in each area of importance has to be conducted. Emission Scenario Documents (ESD) had been prepared for a number of product types, among them for products used as insecticides for household and professional uses (ESD PT18; OECD, 2008[[6]](#footnote-7)). The environmental risk assessment for the biocidal product COM 116 02 I AL is based on this document.

The ESD for PT18 on insecticides for household and professional users covers the following life-cycle steps as being potentially relevant for environmental emissions:

- Mixing/loading

- Application

- Releases from indoor treated surfaces by cleaning and outdoor treated surfaces by weathering.

The ready-to-use biocidal product COM 116 02 I AL is intended to be used in- and out-doors. It is typically sprayed onto confined grounds, where the target organisms appear, i.e. insect routes, nest entries, and hiding places of ants, silverfishes, wood lice and cockroaches. A large-scale application covering widespread surfaces of rooms, paths and terraces is not foreseen. Therefore the treatment is limited to a small target area of the whole ground surface.

COM 116 02 I AL is sold as a trigger pump spray. Volatile solvents are not used in this product variety. Also the release of a propellant is not indicated for this mode of application. The technique produces rather large droplets not expected to remain airborne but to settle on the ground. Furthermore, the product is used by non-professionals, dealing with commercially available household amounts of the biocidal product, not intended to be employed extensively.

Due to this kind of formulation, the following release pathways can be excluded or can be identified to be relevant for environmental exposure:

**Use # 1 – Indoor**

**- Mixing/loading**

COM 116 02 I AL is a ready-to-use product. Mixing and loading is therefore not necessary. The vapour pressure of lambda-cyhalothrin is only 2×10–7 Pa so that exposure to vapours can be ruled out. An exposure of environmental compartments during this life-cycle step is therefore not relevant.

**- Application and cleaning step**

For the indoor application, the product is sprayed locally on insect routes, nest entries and hiding places or directly on the insects. Insecticides applied indoors via spraying will generally reach the treated surface, the floor, the applicator and the indoor air. The ESD for PT 18 proposes emission factors for each of these receiving compartments.

Emissions to wastewater via cleaning of treated surfaces (incl. floors) or applicators’ clothes are considered as the most relevant route of emission for indoor use. There, the main compartments potentially exposed are the STP, the adjacent surface water and sediment compartment and subsequently, soil and groundwater from sewage sludge application. During trigger pump spray application, liquid droplets sprayed are not expected to remain airborne but to settle on the ground. Exposure of the air compartment is thus limited in time and restricted to a very local scale. Consequently, relevant emission to air is not considered.

In view of the emission estimation of *COM 116 02 I AL* for indoor application by spraying the emission scenario for indoor “Spray application” (chapter 3.3.1. of the ESD PT18) is used. For worst case considerations, wet cleaning of the applicators’ clothes (fraction of emission to the applicator=0.006) is assumed with the total fraction of product being emitted to the wastewater (Fapplicator,ww=1). It is assumed that 50% (FCE=0.5) of the remaining product is directed to waste water during cleaning of treated surfaces (incl. floors).

**Use # 2 – Outoor**

**- Mixing/loading**

Cf. indoor application.

**- Application and weathering**

The product *COM 116 02 I AL* is used for the control of ants in close proximity to buildings, e.g. on terraces. According to the ESD for PT 18 it is proposed to assess two theoretical environments, one where 100% of the releases end up in soil in a rural environment and another one where 100% of the releases are sent to sewers in a city environment. Releases can then occur to surface water and sediment from STP discharge, to agricultural soil from sludge application and eventually to groundwater. The fractions of the product emitted directly on unpaved soil (rural environment) will eventually end up to groundwater as well.

*Direct emissions to soil as a result of wash-off by rainfall (rural environment):*

The specific application practice for *COM 116 02 I AL* foresees spraying of the ready to use product on hard surfaces only on ant pathways or on nest entries. The product must not be used for treatment on bar soil.

Therefore, direct exposure of soil is considered as a result of wash-off by rainfall from treated surfaces after the application step. In view of the emission estimations of *COM 116 02 I AL* by spraying the emission scenario for crawling insects (chapter 4.4.2.2 of the ESD PT 18) is adopted, which proposes scenarios for the application step and further for wash-off of treated surfaces by rainfall. It is assumed that 70% of the product applied remains on the surface after application, whereas 30% are emitted to soil. The quantity of substance that is washed off by rainfall is dependent to some extent on the type of surface that is treated (e.g. concrete, cement, tiles). In accordance with the ESD PT18, it is assumed that 50% of the applied substance is washed off the surface during the first rain event.

*Direct release to the STP by treatment on hard surfaces (urban environment):*

An emission scenario is included in the environmental risk assessment, considering primary emission to the sewage treatment plant and hence, secondary emission to the aquatic surface water, the sediment compartment and soils via application of sewage sludge.

In absence of a specialized scenario the soil emission scenario described above (ESD PT 18, chapter 4.4.2.2 Emission scenario for crawling insects) was used. Thereby, it was assumed that the releases from hard surfaces are directed to the rainwater/sewage system during the first rain event following application.

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

No new data was submitted.

***Leaching behaviour (ADS)***

Data on the leaching behaviour is considered not relevant for the intended use of COM 116 02 I AL and thus, is not available.

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

No new data was submitted.

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

No new data was submitted.

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

No new data was submitted.

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

The product is intended for in- and outdoor use via spray application in restricted areas. Outdoor use is restricted to paved surfaces in roof-covered areas, protected from rain-fall or cleaning wash according to label instructions. Thus direct emissions to surface water and sediment are not expected.

No new data was submitted.

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

The product is intended to be applied outdoors on hard, paved surfaces, in areas protected from wash-off by weathering. During spray application, liquid droplets or solid particles sprayed outdoors are not expected to remain airborne but will settle on the ground. A large scale formation of dust is not likely. Effects on non-target species are expected to be low because of instant dilution and turbulence in air (OECD, 2008).

No new data was submitted.

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT18 |
| Assessed scenarios | Scenario 1: Spray application; indoor use  Scenario 2: Spray application; outdoor use, application on paved surfaces e.g.: terraces |
| ESD(s) used | Emission Scenario Document for Product Type 18: Insecticides, acaricides and products to control other arthropods (ENV/JM/MONO(2008)14) |
| Approach | No tonnage based scenario available.  A consumption based approach has been used as a suitable protective measure at the local level. |
| Distribution in the environment | Distribution in the environment is calculated based on TGD[[7]](#footnote-8) for Risk Assessment (EC, 2003) |
| Groundwater simulation | Not relevant |
| Confidential Annexes | No confidential Annexes |
| Life cycle steps assessed | Scenario n: 1 + 2  Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks | No remarks |

***Emission estimation***

COM 116 02 I AL is a biocidal product in PT18 (BPR, Regulation (EU) No 528/2012) for non-professional use as an insecticide against garden ants, silverfishes, wood lice and cockroaches, containing the active substance *lambda*-cyhalothrin.

For a detailed description of foreseeable routes of entry into the environment on the basis of the use envisaged please see the chapter above (cf. Foreseeable routes of entry into the environment on the basis of the use envisaged).

No substances of concern were identified for the environment, since there are no co-formulants in COM 116 02 I AL which contribute to the classification of the biocidal product on the basis of their hazards for the environment. Therefore, in the provided environmental exposure assessment only the active substance *lambda*-cyhalothrin has been considered.

***Emission calculations***

**Use 1: Scenario 1- Spray application; indoor use**

Environmental exposure may arise either due to washing of contaminated clothes from the applicator or due to wet cleaning of treated surfaces and the respective surrounding floors. Both pathways will subsequent lead to release of contaminated waste water to the STP system.

Default values for the relevant treated area and the application frequency were taken from the emission scenario “Spray application” (chapter 3.3.1. of the ESD PT 18). Due to the proposed use pattern of COM 116 02 I AL, the application mode can be described as target spot application.

Moreover, the ESD PT 18 states that 85% of the emissions are released to the target surface, 11% reach the surrounding floor surface and 2% of the emission release to the applicator and the air, respectively. During trigger pump spray application, liquid droplets sprayed are not expected to remain airborne but to settle on the ground. Exposure of the air compartment is thus not considered but emissions released to the floor are increased. In the case of hand-held trigger sprays, the emission factor to the applicator can be reduced to 0.6% also increasing the fraction emitted to the floor. Fractions emitted to wastewater were taken from the emission scenario “Cleaning step” (chapter 3.5.1. of the ESD PT 18). In case of use in wet cleaned areas it is assumed that 50% of the product may end-up in the sewer, which is the cleaning efficiency for spray surface application according to the ESD for PT18.

According to ESD PT 18 4000 public buildings are connected to one STP. Furthermore, simultaneity factors are proposed in the ESD PT 18 that considers the simultaneity of treatments by the houses connected to the same STP.

The simultaneity factors were calculated based on the frequency of product uses, which are twice a year or weekly application (including treatment every 2 weeks) for treatment of wood lice or silverfish and cockroaches, respectively.

Treatment against ants is limited to once per month during season of ant activity (worst case assumption: 9 month). This would result in up to 9 applications per year. Therefore, the product application frequency is assumed on a “3 to 11 applications per year” basis.

The input parameters for determining releases to the environment as well as the calculated emission rates to relevant environmental compartments are summarised in the tables below. The calculations were separated according to the authorised use into Scenario 1a – Residual treatment (ants, silverfishes, cockroaches and wood lice) and Scenario 1b – Direct treatment of target organisms (silverfishes, cockroaches and wood lice).

Scenario 1a - Residual treatment:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emissions of *lambda*-cyhalothrin during indoor spray application of COM 116 02 I AL** | | | | | |
| **Input** | **Unit** | **Definition** | **Indoor use (houses)** | | |
| **Ants** | **Silverfish & Cockroaches** | **Wood lice** |
| Quantity of commercial applied | [g/m2] | Qprod | 44.5 | 100 | |
| Fraction of active substance in the commercial product | [-] | FAI | 0.0005 | | |
| Number of applications per day | [d] | Nappl, building | 1 | | |
| Area treated with the product | [m²] | AREAtreated | 2.0 | | |
| Fraction emitted to applicator during application | [-] | Fapplication, applicator | 0.006 | | |
| Fraction emitted to wastewater from applicator after the application | [-] | Fapplicator, ww | 1 | | |
| Fraction emitted to floor during application | [-] | Fapplication, floor | 0.124 | | |
| Fraction emitted to treated surfaces during application | [-] | Fapplication, treated | 0.85 | | |
| Fraction emitted to wastewater from treated surfaces after the application (incl. floor) | [-] | Fww | 1 | | |
| Cleaning efficiency | [-] | FCE | 0.5 | | |
| Number of buildings connected to STP | [-] | Nbuildings | 4000 | | |
| Simultaneity factor | [%] | Fsimultaneity | 0.815 | 2.75 | 0.204 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Resulting emission to relevant environmental compartments during spray application step** | | | | | |
| **Compartment** | **Unit** | **Definition** | **Indoor use (houses)** | | |
| **Ants** | **Silverfish & Cockroaches** | **Wood lice** |
| Emission to applicator | [g/d] | Eapplication, applicator = Nappl, building x Fapplication, applicatorx Qprod x FAI x AREAtreated | 2.67E-04 | 6.00E-04 | |
| Emission to floor | [g/d] | Eapplication, floor = Nappl, building x Fapplication, floorx Qprod x FAI x AREAtreated | 5.52E-03 | 1.24E-02 | |
| Emission to treated surface | [g/d] | Eapplication, treated = Nappl, building x Fapplication, treated x Qprod x FAI x AREAtreated | 3.78E-02 | 8.5E-02 | |
| Emission from applicator to wastewater during cleaning | [g/d] | Eapplicator, ww = Eapplication, applicator x Fapplicator, ww | 2.67E-04 | 6.00E-04 | |
| Emission from floor/treated surface to wastewater during cleaning | [g/d] | Etreated, ww = (Eapplication, floor + Eapplication, treated) x Fww x Fce | 2.17E-02 | 4.87E-02 | |
| **Emission to wastewater** | **[g/d]** | **Eww, houses = (Eapplicator, ww + Etreated, ww) x NHouses x Fsimultaneity** | **0.72** | **5.42** | **0.40** |

Scenario 1b - Direct treatment of target organisms:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emissions of *lambda*-cyhalothrin during indoor spray application of COM 116 02 I AL** | | | | |
| **Input** | **Unit** | **Definition** | **Indoor use (houses)** | |
| **Silverfish & Cockroaches** | **Wood lice** |
| Quantity of commercial applied | [g/m2] | Qprod | 123 | 170 |
| Fraction of active substance in the commercial product | [-] | FAI | 0.0005 | |
| Number of applications per day | [d] | Nappl, building | 1 | |
| Area treated with the product | [m²] | AREAtreated | 2.0 | |
| Fraction emitted to applicator during application | [-] | Fapplication, applicator | 0.006 | |
| Fraction emitted to wastewater from applicator after the application | [-] | Fapplicator, ww | 1 | |
| Fraction emitted to floor during application | [-] | Fapplication, floor | 0.124 | |
| Fraction emitted to treated surfaces during application | [-] | Fapplication, treated | 0.85 | |
| Fraction emitted to wastewater from treated surfaces after the application (incl. floor) | [-] | Fww | 1 | |
| Cleaning efficiency | [-] | FCE | 0.5 | |
| Number of buildings connected to STP | [-] | Nbuildings | 4000 | |
| Simultaneity factor | [%] | Fsimultaneity | 2.75 | 0.204 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Resulting emission to relevant environmental compartments during spray application step** | | | | |
| **Compartment** | **Unit** | **Definition** | **Indoor use (houses)** | |
| **Silverfish & Cockroaches** | **Wood lice** |
| Emission to applicator | [g/d] | Eapplication, applicator = Nappl, building x Fapplication, applicatorx Qprod x FAI x AREAtreated | 7.38E-04 | 1.02E-03 |
| Emission to floor | [g/d] | Eapplication, floor = Nappl, building x Fapplication, floorx Qprod x FAI x AREAtreated | 1.53E-02 | 2.11E-02 |
| Emission to treated surface | [g/d] | Eapplication, treated = Nappl, building x Fapplication, treated x Qprod x FAI x AREAtreated | 0.11 | 0.15 |
| Emission from applicator to wastewater during cleaning | [g/d] | Eapplicator, ww = Eapplication, applicator x Fapplicator, ww | 7.38E-04 | 1.02E-03 |
| Emission from floor/treated surface to wastewater during cleaning | [g/d] | Etreated, ww = (Eapplication, floor + Eapplication, treated) x Fww x Fce | 5.99E-02 | 8.28E-02 |
| **Emission to wastewater** | **[g/d]** | **Eww, houses = (Eapplicator, ww + Etreated, ww) x NHouses x Fsimultaneity** | **6.67** | **0.68** |

**Use 2: Scenario 2 - Spray application; outdoor use, application on paved surfaces**

For outdoor use the residual treatment against ants was requested only. Environmental exposure may arise via run-off of during the application step or due to wash-off from contaminated impervious surfaces during the first rain event following application either to unpaved soil or to rainwater/sewage system. Releases can then occur to surface water and sediment from STP discharge, to agricultural soil from sludge application and eventually to groundwater. The fractions of the product emitted directly on unpaved soil will eventually end up to groundwater.

Default values for the fractions emitted to soil during outdoor foundation spray application and foundation wash-off by rainfall were taken from the emission scenario “Spray application” (chapter 4.4.2.2 Emission scenario for crawling insects of the ESD PT 18). The ESD PT 18 states in the case of private houses, 25 m² foundation are treated per day. However, the target area, in which a garden ant colony population is aimed to be reduced, is limited on parts of terraces around private houses, where ants have established their nests or ant pathways. COM 116 02 I AL is not foreseen for the treatment of the complete area of a terrace. Therefore, adaption of the ESD assumption for crawling insects is made concerning the treated area. According to the ESD, the typical size of a pathway or terrace is about 25 m² (area of foundation) or 30 m² (area of a terrace), respectively. In this assessment a rectangular terrace of 6 m × 5 m (30 m²) of a private house is assumed. One of the longer sides of the terrace is adjacent to one side of the house (6 m).

For application on ant pathways a band of approx. 25 cm width along the house wall across the terrace from one end to the other, representing an ant pathway (approx. 6 m × 0.25 m=1.5 m²), might need treatment with the biocidal product.

For application on ant nests, it is assumed that the receiving compartment is a square with dimension of 0.5 m x 0.5 m. Considering 4 application sites on a terrace (according to the ESD PT18) a nest infested area of 4 x 0.25 m²=1 m² is conceivable on a terrace.

Since the treated area for application on ant pathways is higher than for treatment of nests, the typical area that is treated for ant control is adapted to 1.5 m² in the exposure assessment as a worst case figure.

Following the MOTA (V6, 2013), the number of houses per STP (N house) was assumed to be 2500 for outdoor use. Furthermore, simultaneity factors are proposed in the ESD PT 18 that considers the simultaneity of treatments by the houses connected to the same STP.

The simultaneity factor is calculated based on the frequency of product uses, which is limited to once per month during season of ant activity (worst case assumption: 9 month). This would result in up to 9 applications per year. Therefore, the product application frequency is assumed on a “3 to 11 applications per year” basis.

The input parameters for determining releases to the environment are summarised in the tables below.

| **Input parameters for calculating the local emissions of *lambda*-cyhalothrin during outdoor spray application of COM 116 02 I AL** | | | |
| --- | --- | --- | --- |
| **Input** | **Unit** | **Definition** | **Outdoor use** |
| **Ants** |
| Quantity of commercial applied | [g/m2] | Qprod | 44.5 |
| Fraction of active substance in the commercial product | [-] | FAI | 0.0005 |
| Area of foundation treated per day – private house | [m²] | AREAtreated | 1.5\* |
| Fraction emitted to soil during outdoor foundation spray application | [-] | Fspray,terrace | 0.3 |
| Fraction emitted to soil due to foundation wash-off by rainfall | [-] | Fspray,wash-off | 0.5 |
| Number of houses connected to STP | [-] | Nbuildings | 2500 |
| Simultaneity factor | [%] | Fsimultaneity | 0.815 |

\* Adaption of the ESD PT18 assumption is made. The typical area that is treated for ant control is adapted to 1.5 m² as treatment is only required for restricted infested zones.

Direct emissions to soil as a result of wash-off by rainfall (rural areas):

During spray application on hard surfaces, a fraction of the solution actually applied on the surface may eventually reach the soil via run-off. In line with the emission factors in ESD for outdoor spray applications, it is assumed that 70% of the product applied remains on the surface after application. It should be noted that, 30% loss due to deposition and runoff can be considered as worst case as it is more related to vertical surfaces.

The quantity of substance that is washed off by rainfall is dependent to some extent on the type of surface that is treated (e.g. concrete, cement, tiles). In the absence of validated model, the ESD PT18 proposes to use default value of 50% of the applied substance washed of the surface during the first rain event.

|  |  |  |  |
| --- | --- | --- | --- |
| **Resulting emissions to soil during application phase, i.e. run-off** | | | |
| **Compartment** | **Unit** | **Definition** | **Outdoor use** |
| **Ants** |
| Emission to soil from outdoor spray application on terraces | g | Espray,terrace = Qprod × FAI × AREAtreated × Fspray,terrace | 0.010 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Resulting emissions to soil during post-application phase, i.e. wash-off** | | | |
| **Compartment** | **Unit** | **Symbol** | **Outdoor use** |
| **Ants** |
| Local emission from outdoor spray application on terrace due to wash-off | g | Espray,terrace,wash-off = AREAtreated × Qprod × FAI × Fspray,wash-off | 0.017 |

Total emissions (application plus wash-off) are calculated according to ESD PT18, equation 51, as follows:

Espray,crawlinginsects = Espray,terrace + Espray,terrace,wash-off

Note: The parameter “Espray,soil” (see ESD PT18, equation 51) is omitted here, since it describes direct spraying to soil (soil treatment), which is not relevant for the spray application onto terraces for the biocidal product.

**Espray,crawlinginsects,Soil = 0.027 g**

*Release to the STP by treatment on hard surfaces (urban area):*

For the calculation of the emission to the STP via terraces, which may have a connection to the sewer system, the soil emission scenario was used in the absence of a specialised scenario. The intended application rates are 44.5 g/m² for both scenarios (i.e. emission to soil or emission to STP). Also the input parameters relevant for determining the release per terrace are the same. Hence, emission to the rainwater/sewage system per terrace is equal to the emission to soil.

Espray,crawlinginsects,Soil = Espray,crawlinginsects,STP = 0.027 g

In order to take into account that a number of households are treated at the same time, this emission rate has to be multiplied by the number of houses connected to STP and the percentage of this houses which are treated simultaneously.

|  |  |  |  |
| --- | --- | --- | --- |
| **Resulting emission to rainwater/sewage system during outdoor use** | | | |
| **Compartment** | **Unit** | **Definition** | **Outdoor use** |
| **Ants** |
| **Emission to wastewater** | [g/d] | Eww, houses = Espray,crawlinginsects,STP x Nhouse x Fsimultaneity | **0.55** |

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

In the following table the environmental compartments are summarised which might be exposed to the active substance *lambda*-cyhalothrin via indoor spray application (scenario 1) and outdoor spray application on hard surfaces (scenario 2). Due to the low volatilisation of *lambda*-cyhalothrin the compartment air has not to be addressed.

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Main  scenario | Sub-scenario | Freshwater1 | STP | Soil | Air | Secondary poisoning |
| Spraying, indoor | - | + | ++ | +2 | (Q) | + |
| Spraying, outdoor | Rural area | - | - | ++3 | (Q) | (+) |
| Urban area | + | ++ | +2 | (Q) | + |

++ Compartment directly exposed, + Compartment indirectly exposed, (+) Compartment potentially exposed (but unlikely significant concern due to minimal scale of exposure), (Q) Qualitative assessment, depending on application or substance-specific properties. - Compartment not exposed

1 Including sediment, 2 including soil and groundwater via STP surplus sludge application, 3 including groundwater

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 449.9 | g/mol |  |
| Melting point | 48.2 | °C |  |
| Boiling point | Not relevant | °C |  |
| Vapour pressure (at 20° C) | 2 x 10-7 | Pa |  |
| Water solubility (at 20 °C) | 5 | µg/l |  |
| Log Octanol/water partition coefficient (log Kow) | 7.0 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 70,100-724,000 | l/kg |  |
| Henry’s Law Constant | 1.8 x 10-2 | Pa/m3/mol |  |
| Biodegradability | n.d. |  |  |
| Rate constant for STP | n.d. | h-1 |  |
| DT50 for biodegradation in surface water | n.d. | d or hr (at 12ºC) |  |
| DT50 for hydrolysis in surface water | Stable | at 25ºC /pH 5 |  |
| DT50 for hydrolysis in surface water | 8.6 | d (at 25ºC /pH 9) |  |
| DT50 for photolysis in surface water | n.d. | d or hr |  |
| DT50 for degradation in soil | No significant degradation observed | d or hr (at 12ºC) |  |
| DT50 for degradation in air | 12.2 | hr |  |

***Calculated PEC values***

***PEC in air***

In view of the limited volatility of *lambda*-cyhalothrin, emissions to the air compartment are regarded to be insignificant. Thus, the PEC of *lambda*-cyhalothrin in air is considered to be negligible.

***PEC for STP***

Based on the ESD PT 18, emissions to STP are relevant following both, indoor and outdoor product use on hard surfaces (e.g. terraces) considering subsequent wash-off. The distribution of the active substance *lambda*-cyhalothrin in the environment after release to the sewer system is calculated according to the distribution obtained from Simple Treat 3.1. The calculations are separated according to the authorised use into residual treatment and direct treatment of target organisms.

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP** | | |
| Compartment | Percentage [%] | Remarks |
| Scenarios 1-2 |
| Air | 1.38E-03 | --- |
| Water | 9.12 | --- |
| Sludge | 90.9 | --- |
| Degraded in STP | 0 | --- |

Residual treatment:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Calculation of the STP influent concentration (*cf.* TGD, 2003, Equation 32)** | | | | | |
| **Parameter** | **Definition** | **Indoor use** | | | **Outdoor use** |
| **Ants** | **Silverfish & Cockroaches** | **Wood lice** | **Ants** |
| Local emission rate to wastewater  [g/d] | Elocalwater | 0.72 | 5.42 | 0.40 | 0.57 |
| Capacity of the STP [eq] | CAPACITYstp | 10000 | | | |
| Sewage flow per inhabitant  [l/d\*eq] | WASTEWinhab | 200 | | | |
| Effluent discharge rate [l/d] | EFFLUENTstp = CAPACITYstp x WASTEWinhab | 2000000 | | | |
| **Cumulative concentration in untreated wastewater [µg/l]** |  | **0.36** | **2.71** | **0.20** | **0.285** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Calculation of the STP effluent concentration (*cf.* TGD, 2003, Tier 1: Equation 33)** | | | | | |
| **Parameter** | **Definition** | **Indoor use** | | | **Outdoor use** |
| **Ants** | **Silverfish & Cockroaches** | **Wood lice** | **Ants** |
| Cumulative concentration in untreated wastewater [µg/l] | Clocalinf | 0.36 | 3.34 | 0.34 | 0.285 |
| Fraction of emission directed to water by STP [-] | Fstpwater | 0.0912 | | | |
| **Concentration of substance in the STP effluent [µg/l]** | **Clocaleff =**  **Clocalinf x Fstpwater** | **3.28E-2** | **0.25** | **1.82E-2** | **2.60E-2** |

Direct treatment of target organisms:

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculation of the STP influent concentration (*cf.* TGD, 2003, Equation 32)** | | | |
| **Parameter** | **Definition** | **Indoor use** | |
| **Silverfish & Cockroaches** | **Wood lice** |
| Local emission rate to wastewater  [g/d] | Elocalwater | 6.67 | 0.68 |
| Capacity of the STP [eq] | CAPACITYstp | 10000 | |
| Sewage flow per inhabitant  [l/d\*eq] | WASTEWinhab | 200 | |
| Effluent discharge rate [l/d] | EFFLUENTstp = CAPACITYstp x WASTEWinhab | 2000000 | |
| **Cumulative concentration in untreated wastewater [µg/l]** |  | **3.34** | **0.34** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculation of the STP effluent concentration (*cf.* TGD, 2003, Tier 1: Equation 33)** | | | |
| **Parameter** | **Definition** | **Indoor use** | |
| **Silverfish & Cockroaches** | **Wood lice** |
| Cumulative concentration in untreated wastewater [µg/l] | Clocalinf | 3.34 | 0.34 |
| Fraction of emission directed to water by STP [-] | Fstpwater | 0.0912 | |
| **Concentration of substance in the STP effluent [µg/l]** | **Clocaleff =**  **Clocalinf x Fstpwater** | **0.30** | **3.10E-2** |

The parameter Clocaleff can be regarded as the PECSTP of *lambda*-cyhalothrin (*cf*. TGD, 2003, Equation 38), under the prerequisite that only the dissolved concentration is bioavailable, i.e., it is the actual concentration to which the microorganisms in a sewage treatment plant are exposed to.

***PEC for Surface Water***

The effluent of the sewage treatment plant is diluted into the surface water. For the calculation of Predicted Environmental Concentrations for this compartment complete mixing of the effluent in surface water is assumed. Because of the short distance between the point of effluent discharge and the exposure location, volatilisation, degradation and sedimentation are ignored.

As summarised in chapter 2.1.4, Koc values determined for different test concentrations in nine soils and five sediments varied between 70100 ml/g and 724000 mL/g (n=14). In the CA report it is suggested to take the lower value for calculating the PECsw (70100 mL/g).

|  |  |  |
| --- | --- | --- |
| **Calculation of the partition coefficient solid-water in suspended matter (*cf.* TGD, 2003, Equation 23)** | | |
| **Parameter** | **Definition** | **Value** |
| Weight fraction organic carbon in susp. solids [kg/kg] | Focsusp | 0.1 |
| Partition coefficient organic carbon-water [L/kg] | KOC | 70100 |
| **Partition coefficient solid-water in suspended matter [l/kg]** | ***Kpsusp = Focsusp x KOC*** | **7010** |

In order to assess the adsorption to suspended matter, the solid-water partition coefficient (Kpsusp) is calculated from the KOC value. A default value of 0.1 kg/kg for Focsusp (according to the TGD, 2003, Chapter 3, Table 5) and a Koc value of 70100 L/kg (see above) are used for the calculation.

The resulting Kpsusp is used to calculate the local concentration in surface water (Clocalwater corresponding to PECsurface water). According to the TGD (2003), a default value of 15 mg/l is taken for the concentration of suspended matter in the river (SUSPwater) and a dilution factor of 10 is used.

Residual treatment:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Calculation of the Clocalwater concentration (corresponding to PEClocalwater) for *lambda*-cyhalothrin (cf. TGD, 2003, Equation 45)** | | | | | |
| **Parameter** | **Definition** | **Indoor use** | | | **Outdoor use** |
| **Ants** | **Silverfish & Cockroaches** | **Wood lice** | **Ants** |
| Concentration of substance in the STP effluent [µg/l] | Clocaleff | 3.28E-2 | 0.25 | 1.82E-2 | 2.60E-2 |
| Solids-water partitioning coefficient of suspended matter [l/kg] | Kpsusp | 7010 | | | |
| Concentration of suspended matter in the river [mg/l] | SUSPwater | 15 | | | |
| Dilution factor [-] | DILUTION | 10 | | | |
| **Local concentration in surface water during emission episode [µg/l]** | **Clocalwater =**  **Clocaleff** x **((1+Kpsusp** x **SUSPwater** x **10-6) DILUTION)-1** | **2.97E-3** | **2.24E-2** | **1.65E-3** | **2.35E-3** |

Direct treatment of target organisms:

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculation of the Clocalwater concentration (corresponding to PEClocalwater) for *lambda*-cyhalothrin (cf. TGD, 2003, Equation 45)** | | | |
| **Parameter** | **Definition** | **Indoor use** | |
| **Silverfish & Cockroaches** | **Wood lice** |
| Concentration of substance in the STP effluent [µg/l] | Clocaleff | 0.30 | 3.10E-2 |
| Solids-water partitioning coefficient of suspended matter [l/kg] | Kpsusp | 7010 | |
| Concentration of suspended matter in the river [mg/l] | SUSPwater | 15 | |
| Dilution factor [-] | DILUTION | 10 | |
| **Local concentration in surface water during emission episode [µg/l]** | **Clocalwater =**  **Clocaleff** x **((1+Kpsusp** x **SUSPwater** x **10-6) DILUTION)-1** | **2.75E-2** | **2.81E-3** |

The calculated Clocalwater concentrations correspond to the PEClocalwater in the case of non-existing background concentrations.

***PEC for Sediment***

Following the TGD (2003), the PEC in sediment is assessed for freshly deposited sediments. Therefore, the properties of suspended matter are used. Accordingly, the bulk density of (wet) suspended matter (RHOsusp) and the suspended matter-water partitioning coefficient (Ksusp-water) are calculated respectively, and the PEClocal for sediment is assessed.

The bulk density of (wet) suspended matter (RHOsusp) is calculated taking the following default values: 0.1 m³/m³ for Fsolidsusp (fraction solids in suspended matter), 2500 kg/m³for RHOsolid (bulk density of the solid phase), 0.9 m³/m³for Fwatersusp (fraction water in suspended matter) and 1000 kg/m³for RHOwater (density of the water phase).

|  |  |  |
| --- | --- | --- |
| **Calculation of RHOsusp (*cf.* TGD, 2003, Equation 18)** | | |
| **Parameter** | **Definition** | **Value** |
| Fraction solids in suspended matter  [m³/m3] | Fsolidsusp | 0.1 |
| Bulk density of the solid phase [kg/m3] | RHOsolid | 2500 |
| Fraction water in suspended matter [m³/m3] | Fwatersusp | 0.9 |
| Density of the water phase [kg/m3] | RHOwater | 1000 |
| **Bulk density of (wet) suspended matter [kg/m3]** | ***RHOsusp = Fsolidsusp x RHOsolid + Fwatersusp x RHOwater*** | **1150** |

The suspended matter-water partitioning coefficient (Ksusp-water) is derived taking default values of 0.9 m³/m³ for Fwatersusp, 0.1 m³/m³for Fsolidsusp and 2500 kg/m³ for RHOsolid. The Kpsusp figure is taken from above.

|  |  |  |
| --- | --- | --- |
| **Calculation of Ksusp-water (*cf.* TGD, 2003, Equation 24)** | | |
| **Parameter** | **Definition** | **Value** |
| Fraction water in suspended matter [m³/m3] | Fwatersusp | 0.9 |
| Fraction solids in suspended matter[m³/m3] | Fsolidsusp | 0.1 |
| Partition coefficient solid-water in suspended matter [l/kg] | Kpsusp | 7010 |
| Density of the solid phase [kg/m3] | RHOsolid | 2500 |
| **Suspended matter-water partitioning coefficient  [m³/m3]** |  | **1753.4** |

Residual treatment:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Calculation of PEClocal in sediment (*cf.* TGD, 2003, Equation 50)** | | | | | |
| **Parameter** | **Definition** | **Indoor use** | | | **Outdoor use** |
| **Ants** | **Silverfish & Cockroaches** | **Wood lice** | **Ants** |
| Concentration in surface water during emission episode [µg/l] | PEClocalwater | 2.97E-3 | 2.24E-2 | 1.65E-3 | 2.35E-3 |
| Suspended matter-water partitioning coefficient  [m³/m3] | Ksusp-water | 1753.4 | | | |
| Bulk density of suspended matter [kg/m3] | RHOsusp | 1150 | | | |
| **Predicted Environmental Concentration in sediment [µg/kg]** | **PEClocalsed = (Ksusp-water / RHOsusp) x PEClocalwater x 1000** | **4.53** | **34.09** | **2.52** | **3.95** |

Direct treatment of target organisms:

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculation of PEClocal in sediment (*cf.* TGD, 2003, Equation 50)** | | | |
| **Parameter** | **Definition** | **Indoor use** | |
| **Silverfish & Cockroaches** | **Wood lice** |
| Concentration in surface water during emission episode [µg/l] | PEClocalwater | 2.75E-2 | 2.81E-2 |
| Suspended matter-water partitioning coefficient  [m³/m3] | Ksusp-water | 1753.4 | |
| Bulk density of suspended matter [kg/m3] | RHOsusp | 1150 | |
| **Predicted Environmental Concentration in sediment [µg/kg]** | **PEClocalsed = (Ksusp-water / RHOsusp) x PEClocalwater x 1000** | **41.96** | **4.28** |

***PEC in soils***

*PEC in soil as a result of wash-off to soil by rainfall (direct exposure, rural area):*

For outdoor applications on terraces in rural areas, it is considered, that soil adjacent to the terraces is directly exposed following wash-off of the treated areas by rainfalls.

A rectangular terrace of 6 m × 5 m (30 m²) of a private house is assumed. One of the longer sides of the terrace is adjacent to one side of the house (6 m). In accordance with scenarios recommend in ESD PT18, a 0.5 m soil strip adjacent to the other sides of the terrace with a 0.5 m default value for soil depth is defined as the receiving compartment and a volume of the two soil corners of 0.5 m side length and 0.5 m soil depth is added.

Hence, the soil volume for wash-off is calculated as:

Vsoil, wash-off = [2\*(5\*0.5\*0.5)] + (6\*0.5\*0.5) + [2\*(0.5\*0.5\*0.5)] = 4.25 m³

The PEC of *lambda*-cyhalothrin in the receiving soil around treated terraces is estimated as follows:

|  |  |  |
| --- | --- | --- |
| **Calculation of the concentration in the receiving soil as a result of wash-off to soil by rainfall** | | |
| **Parameter** | Definition | **Outdoor use** |
| **Ants** |
| Emission from outdoor application on terraces [mg/d] | Elocalsoil,washoff | 27 |
| Soil volume for wash-off at [m³] | Vsoil, wash-off | 4.25 |
| Bulk density of wet soil [kg/m³] | RHOsoil | 1700 |
| **Concentration in the receiving soil as a result of wash-off to soil by rainfall [mg/kgwwt]** | **Clocal,soil,washoff = Elocalsoil,washoff / (Vsoil,washoff × *RHOsoil*)** | 3.74E-3 |

*PEC in soil via the application of STP sludge (indirect exposure, urban area):*

Soil contamination can arise indirectly, via the application of STP sludge; hence, the concentration in STP sludge has to be assessed at first.

The rate of sewage sludge production (SLUDGERATE) is estimated from the outflows of primary and secondary sludge. According to the TGD (2003), the following default values were chosen: 0.45 kg/m³ for SUSPCONCinf (concentration of suspended matter in STP influent), 0.011 kg/d for SURPLUSsludge (surplus sludge per inhabitant equivalent), and 10000 inhabitant equivalents for CAPACITYstp (capacity of the STP). The resulting SLUDGERATE amounts to 790 kg/d.

|  |  |  |
| --- | --- | --- |
| **Calculation of the rate of sewage sludge production in a model STP (TGD, 2003, Equation 37)** | | |
| **Parameter** | **Definition** | **Value** |
| Concentration of suspended matter in STP influent [kg/m3] | SUSPCONCinf | 0.45 |
| Effluent discharge rate of STP [m³/d] | EFFLUENTSTP | 2000 |
| Surplus sludge per inhabitant equivalent  [kg/d\*eq] | SURPLUSsludge | 0.019 |
| Capacity of the STP [eq] | CAPACITYSTP | 10000 |
| **Rate of sewage sludge production [kg/d]** | **SLUDGERATE = 2/3 × SUSPCONCinf × EFFLUENTSTP + SURPLUSsludge × CAPACITYSTP** | **790** |

Residual treatment:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Calculation of the sludge concentration (TGD, 2003, Equation 36)** | | | | | |
| **Parameter** | **Definition** | **Indoor use** | | | **Outdoor use** |
| **Ants** | **Silverfish & Cockroaches** | **Wood lice** | **Ants** |
| Local emission rate to water during episode [g/d] | Elocalwater | 0.72 | 5.42 | 0.40 | 0.57 |
| Fraction of emission directed to sludge by STP [-] | Fstpsludge | 0.909 | | | |
| Rate of sewage sludge production  [kg/d] | SLUDGERATE | 790 | | | |
| **Concentration in dry sewage sludge  [µg/kg]** | **Csludge = Fstpsludge × Elocalwater × 106 × SLUDGERATE -1** | **828** | **6236** | **460** | **656** |

According to the TGD, default values were taken for the sludge application rate (5000 kg dry weight/ha/yr, corresponding to 0.5 kg/m²/yr), the soil depth (0.2 m) and the bulk density of the soil (1700 kg/m³).

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Calculation of concentrations in the soil following a single STP sludge concentration (TGD, 2003, equation 60)** | | | | | | | | |
| **Parameter** | **Definition** | **Indoor use** | | | | | **Outdoor use** | |
| **Ants** | **Silverfish & Cockroaches** | | **Wood lice** | | **Ants** | |
| Concentration in dry sewage sludge  [µg/kg] | Csludge | 828 | 6236 | | 460 | | 656 | |
| Dry sludge application rate  [kg/m2\*yr] | APPLsludge | 0.5 | | | | | | |
| Mixing depth of soil [m] | DEPTHsoil | 0.2 | | | | | | |
| Bulk density of soil [kg/m3] | RHOsoil | 1700 | | | | | | |
| **Concentration in soil due to sludge in first year at t=0 [µg/kg]** |  | **1.22** | | **9.17** | | **0.68** | | **0.96** |

As a worst-case assumption for exposure, it is assumed that sludge applications take place for 10 consecutive years, each with one application. The fraction of lambda-cyhalothrin that remains in the top soil layer one year after an application is given in the table below. For the calculation of the rate (k), a DT50 in soils of 69 days is considered.

|  |  |  |
| --- | --- | --- |
| **Calculation of the accumulated active substance fraction remaining in soils one year following a sludge application (TGD, 2003, equation 61)** | | |
| **Parameter** | **Definition** | **Value** |
| First order rate constant for removal from top soil [1/d] | k | 0.01005 |
| **Fraction accumulation in one year [-]** | **Facc = e-365k** | **0.025562** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Calculation of soil concentrations following a one-fold sludge application in each of ten years (concentration immediately after the tenth application, TGD, 2003, equation 62)** | | | | | | |
| **Parameter** | Definition | **Indoor use** | | | **Outdoor use** | |
| **Ants** | **Silverfish & Cockroaches** | **Wood lice** | **Ants** | |
| Concentration in soil due to sludge in first year at t=0  [µg/kg] | Csludgesoil1 (0) | 1.22 | 9.17 | 0.68 | 0.96 | |
| Fraction accumulation in one year [-] | Facc | 0.025562 | | | | |
| **Concentration in soil due to sludge after 10 applications at=0 [µg/kg]** | ***Csludgesoil 10 (0) =***  ***Csludgesoil1 (0) × [1 + Faccn]*** | **1.25** | **9.41** | **0.69** | | **0.99** |

The initial concentrations following 10 sludge applications are used to calculate average residues in soils of terrestrial ecosystems, i.e., over a time period of 30 days. The rate constant k only compasses the biodegradation, whereas volatilisation and leaching were not considered as relevant routes for removal.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Calculation of the average concentration in soils of terrestrial ecosystems (Clocalsoil, TGD, 2003, equation 55)** | | | | | |
| **Parameter** | Definition | **Indoor use** | | | **Outdoor use** |
| **Ants** | **Silverfish & Cockroaches** | **Wood lice** | **Ants** |
| First order rate constant for removal from top soil [1/d] | k | 0.01005 | | | |
| Averaging time [d] | T | 30 | | | |
| Initial concentration after sludge application [µg/kg] | Csoil (0) | 1.25 | 9.41 | 0.69 | 0.99 |
| **Average concentration in soil over T days [µg/kgwwt]** | **Clocalsoil = (1/kT) x Csoil (0) x (1-e-kT)** | 1.08 | 8.13 | 0.60 | 0.85 |

Under the prerequisite that a background concentration for *lambda*-cyhalothrin does not exist, the Clocalsoil values represent the PEClocalsoil values.

Direct treatment of target organisms:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Calculation of the sludge concentration (TGD, 2003, Equation 36)** | | | | |
| **Parameter** | **Definition** | **Indoor use** | | **Outdoor use** |
| **Silverfish & Cockroaches** | **Wood lice** | |
| Local emission rate to water during episode [g/d] | Elocalwater | 6.67 | 0.68 | |
| Fraction of emission directed to sludge by STP [-] | Fstpsludge | 0.909 | | |
| Rate of sewage sludge production  [kg/d] | SLUDGERATE | 790 | | |
| **Concentration in dry sewage sludge  [µg/kg]** | **Csludge = Fstpsludge × Elocalwater × 106 × SLUDGERATE -1** | **7674** | **782** | |

According to the TGD, default values were taken for the sludge application rate (5000 kg dry weight/ha/yr, corresponding to 0.5 kg/m²/yr), the soil depth (0.2 m) and the bulk density of the soil (1700 kg/m³).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Calculation of concentrations in the soil following a single STP sludge concentration (TGD, 2003, equation 60)** | | | | |
| **Parameter** | **Definition** | **Indoor use** | | |
| **Silverfish & Cockroaches** | **Wood lice** | |
| Concentration in dry sewage sludge  [µg/kg] | Csludge | 7674 | 782 | |
| Dry sludge application rate  [kg/m2\*yr] | APPLsludge | 0.5 | | |
| Mixing depth of soil [m] | DEPTHsoil | 0.2 | | |
| Bulk density of soil [kg/m3] | RHOsoil | 1700 | | |
| **Concentration in soil due to sludge in first year at t=0 [µg/kg]** |  | **11** | | **1.15** |

As a worst-case assumption for exposure, it is assumed that sludge applications take place for 10 consecutive years, each with one application. The fraction of lambda-cyhalothrin that remains in the top soil layer one year after an application is given in the table below. For the calculation of the rate (k), a DT50 in soils of 69 days is considered.

|  |  |  |
| --- | --- | --- |
| **Calculation of the accumulated active substance fraction remaining in soils one year following a sludge application (TGD, 2003, equation 61)** | | |
| **Parameter** | **Definition** | **Value** |
| First order rate constant for removal from top soil [1/d] | k | 0.01005 |
| **Fraction accumulation in one year [-]** | **Facc = e-365k** | **0.025562** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculation of soil concentrations following a one-fold sludge application in each of ten years (concentration immediately after the tenth application, TGD, 2003, equation 62)** | | | |
| **Parameter** | Definition | **Indoor use** | |
| **Silverfish & Cockroaches** | **Wood lice** |
| Concentration in soil due to sludge in first year at t=0  [µg/kg] | Csludgesoil1 (0) | 11.28 | 1.15 |
| Fraction accumulation in one year [-] | Facc | 0.025562 | |
| **Concentration in soil due to sludge after 10 applications at=0 [µg/kg]** | ***Csludgesoil 10 (0) =***  ***Csludgesoil1 (0) × [1 + Faccn]*** | **11.58** | **1.18** |

The initial concentrations following 10 sludge applications are used to calculate average residues in soils of terrestrial ecosystems, i.e., over a time period of 30 days. The rate constant k only compasses the biodegradation, whereas volatilisation and leaching were not considered as relevant routes for removal.

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculation of the average concentration in soils of terrestrial ecosystems (Clocalsoil, TGD, 2003, equation 55)** | | | |
| **Parameter** | Definition | **Indoor use** | |
| **Silverfish & Cockroaches** | **Wood lice** |
| First order rate constant for removal from top soil [1/d] | k | 0.01005 | |
| Averaging time [d] | T | 30 | |
| Initial concentration after sludge application [µg/kg] | Csoil (0) | 11,58 | 1.18 |
| **Average concentration in soil over T days [µg/kgwwt]** | **Clocalsoil = (1/kT) x Csoil (0) x (1-e-kT)** | 10,00 | 1.02 |

Under the prerequisite that a background concentration for *lambda*-cyhalothrin does not exist, the Clocalsoil values represent the PEClocalsoil values.

***PEC in groundwater***

The Koc values determined for lambda-cyhalothrin (70100 ml/g - 724000 ml/g, n=14) indicate a very strong adsorption in soils and therefore a very low potential for transport into deeper soil layers. However, for reasons of completeness, the soil pore water concentration will be assessed as an indicator of potential residues occurring in groundwater.

Most of the parameters used for the PEC calculation in soil pore water have default values, which are provided in the TGD (TGD, 2003). For characterisation of the adsorption potential of *lambda*-cyhalothrin in soils, the lowest Koc value of 70100 ml/g has been used for worst case considerations with regards to compound mobility in soil.

|  |  |  |
| --- | --- | --- |
| **Calculation of the solids-water partition coefficient in soil (*cf.* TGD, Equation 23)** | | |
| Parameter | **Definition** | **Value** |
| Weight fraction of organic carbon in compartment soil [kg/kg] | Focsoil | 0.02 |
| Partition coefficient organic carbon-water [l/kg] | Koc | 70100 |
| **Partitioning coefficient solid-water in soil [l/kg]** |  | **1402** |

|  |  |  |
| --- | --- | --- |
| **Calculation of the air-water partitioning coefficient (*cf.* TGD, Equation 22)** | | |
| Parameter | **Definition** | **Value** |
| Henry´s Law constant [Pa\*m³/mol] | HENRY | 1.80 x 10-2 |
| Gas constant [Pa\*m³/mol\*k] | R | 8.314 |
| Temperature at the air-water interface [K] | TEMP | 285 |
| **Air-water partitioning coefficient [-]** |  | **7.60 x 10-6** |

|  |  |  |
| --- | --- | --- |
| **Calculation of the soil-water partitioning coefficient (cf. TGD, Equation 24)** | | |
| **Parameter** | **Definition** | **Value** |
| Fraction air in compartment soil [m³ x m-3] | Fairsoil | 0.2 |
| Air-water partitioning coefficient [-] | Kair-water | 7.58 x 10-6 |
| Fraction water in compartment soil [m³ x m-3] | Fwatersoil | 0.2 |
| Fraction solids in compartment soil [m³ x m-3] | Fsolidsoil | 0.6 |
| Solids-water partitioning coefficient in compartment soil [l x kg-1] | Kpsoil | 1402 |
| Density of the solid phase (kg x m-3) [kg x m-3] | RHOsolid | 2500 |
| **Soil-water partitioning coefficient [m³ x m-3]** |  | **2103.2** |

As result, the soil-water partitioning coefficient is calculated and used as input parameter to calculate the local pore water concentration. Degradation of *lambda*-cyhalothrin in soils is not considered.

Residual treatment:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Calculation of the predicted environmental concentration in pore water (*cf.* TGD, Equation 67)** | | | | | | |
| **Parameter** | | **Definition** | **Indoor use** | | | **Outdoor use** |
| **Ants** | **Silverfish & Cockroaches** | **Wood lice** | **Ants** |
| Local concentration in soil [µg/kg] | sludge application | PEClocalsoil | 1.08 | 8.13 | 0.60 | 0.85 |
| wash-off to soil | - | - | - | 3.74 |
| Bulk density of wet soil [kg/m3] | | RHOsoil | 1700 | | | |
| Soil-water partitioning coefficient  [m³/m3] | | Ksoil-water | 2103.2 | | | |
| **Predicted Environmental Concentration in pore water  [µg/l]** | sludge application\* |  | **8.72E-4** | **6.57E-3** | **4.85E-4** | **6.91E-4** |
| wash-off to soil | **-** | **-** | **-** | **3.03E-3** |

\*According to guidance the concentration in pore water of agricultural soil after an averaging time of 180 days should be used as an indication for potential groundwater levels. However, the approach to use the concentration in pore water of the terrestrial ecosystem represents the worst case resulting in low pore water levels and an adaption would not change the outcome of the environmental risk assessment in this report.

Direct treatment of target organisms:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Calculation of the predicted environmental concentration in pore water (*cf.* TGD, Equation 67)** | | | | |
| **Parameter** | | **Definition** | **Indoor use** | |
| **Silverfish & Cockroaches** | **Wood lice** |
| Local concentration in soil [µg/kg] | sludge application | PEClocalsoil | 10 | 1.02 |
| Bulk density of wet soil [kg/m3] | | RHOsoil | 1700 | |
| Soil-water partitioning coefficient  [m³/m3] | | Ksoil-water | 2103.2 | |
| **Predicted Environmental Concentration in pore water  [µg/l]** | sludge application |  | **8.08E-3** | **8.24E-4** |

Predicted environmental concentrations in pore water are well below 0.1 µg/l, indicating relevant concentrations in groundwater are not to be expected.

***Summary tables on calculated PEC values***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | |
| **Scenarios** | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |  |
| **Spraying indoors, residual treatment** | | | | | | has not been predicted |
| **Ants** | 3.28E-5 | 2.97E-6 | 4.53E-3 | 1.08E-3 | 8.72E-4 |
| **Silverfish & Cockroaches, weekly** | 0.25E-3 | 2.24E-5 | 34.09E-3 | 8.13E-3 | 6.57E-3 |
| **Wood lice** | 1.82E-5 | 1.65E-6 | 2.52E-3 | 0.60E-3 | 4.85E-4 |
| **Spraying indoors, direct treatment of target organisms** | | | | | |
| **Silverfish & Cockroaches, weekly** | 0.30E-3 | 2.75E-5 | 41.96E-3 | 10.00E-3 | 8.08E-3 |
| **Wood lice, twice a year** | 3.10E-5 | 2.81E-6 | 4.28E-3 | 1.02E-3 | 8.24E-4 |
| **Spraying, outdoors, residual treatment** | | | | | |
| **Ants** (urban area) | 2.6E-5 | 2.35E-6 | 3.95E-3 | 0.85E-3 | 6.91E-4 |
| **Ants** (rural area) | - | - | - | 3.74E-3 | 3.03E-3 |

- Compartment not exposed

Risk from treatment against cockroaches has been assessed considering applications every two weeks (simultaneity factor 2.75%), which is the worst case assumption according to the number and timing of application given in the intended use. However, in view of the treatment of non-porous ground e.g. glazed tiles, the Austrian Competent Authority considers that a simultaneity factor of 2.75% will overestimate environmental releases as the time until which product remains efficient on non-porous ground is at least 24 weeks. A refined simultaneity factor of 0.204%, as proposed for applications only twice a year, has been considered for a second Tier release estimation. The table below summarizes revised PEC values for indoor applications against cockroaches calculated using the same calculation method and input parameter as described above but based on the lower frequency of product use according to the intended use.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on revised PEC values for indoor applications against Cockroaches, when the product is used twice a year** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| **Cockroaches, residual treatment twice a year** | 1.82E-5 | 1.65E-6 | 2.52E-3 | 0.60E-3 | 4.85E-4 |
| **Cockroaches, direct treatment twice a year** | 2.26E-5 | 2.04E-6 | 3.11E-3 | 0.74E-3 | 6.00E-4 |

***Primary and secondary poisoning***

Primary poisoning

**Primary poisoning via direct consumption of insecticide by birds or mammals**

According to the ESD for PT 18 (OECD, 2008[[8]](#footnote-9)), primary poisoningvia direct consumption of insecticide by birds or mammals is only a matter of concern if insecticides are applied together with food attractant or the insecticide is applied as granular formulation.

COM 116 02 I AL is typically sprayed outdoors onto confined areas, where ants appear, like entrances of nests, ant trails or loop holes. Therefore, the treatment is limited to a small fraction of the whole surface area.

In the case of COM 116 02 I AL, a primary poisoning of non-target organisms is no matter of concern and a risk assessment for non-target animals primary exposed to *lambda*-cyhalothrin is not deemed reasonable.

Secondary poisoning

**Secondary poisoning for insectivorous species via the consumption of contaminated ants**

For insectivorous species, the estimated theoretical exposure (ETE) is calculated, representing the estimated daily intake and corresponding to the PECoral per day. The theoretical exposure of vertebrates is a function of the estimated concentration of the insecticide found in food sources (ants) of insectivorous birds and mammals. Concentrations are derived from the exposure scenario established for plant protection products in the EU (EC, 2002[[9]](#footnote-10)).

Insectivorous mammals always are assumed to eat large insects; therefore an assessment for mammals is not indicated in this context. Small birds are assumed to prefer small insects, so the residues for small insects are the default values in the case of birds in order to cover the worst case. According to the guidance document for plant protection products (EC, 2002) typical residues in contaminated small insects are 52 mg/kg wet weight for the acute situation and 29 mg/kg wet weight for the short term toxicity assessment (both values are normalised for an application rate of 1 kg a.s./ha). These figures are defined as RUD values (RUD=Residue per Unit Dose). They have to be multiplied by the actual application rate (Tappl) to obtain the concentration per wet weight. The application rate of household insecticides is provided as kg/m². Therefore, an additional factor of 10-4 has to be added to convert Tappl into kg/ha.

As a first step, the actual application rate is calculated. As explained above, a spotwise application on paved surfaces close to houses (e.g. terraces) of 1.5 m² per house is assumed. Considering that the worst case application against ants for outdoor treatment is 44.5 g/m² a total of 66.75 g product containing in total 0.005 mg *lambda*-cyhalothrin are calculated to be potentially applied on this specific area. According to the ESD, the typical size of a terrace is about 30 m².

|  |  |  |
| --- | --- | --- |
| **Calculation of the *lambda*-cyhalothrin application rate** | | |
|  | **Definition** | **Value** |
| Amount of product used [g/terrace] | Qprod | 66.75 |
| Fraction of active substance in product [-] | FAI | 0.0005 |
| Area of the treated terrace [m²] | AREAterrace | 30 |
| **Application rate [kg/m2]** | **Tappl = ((Qprod x FAI) / AREAterrace) / 1000)** | **1.12 x 10-6** |

In a second step, the lambda-cyhalothrin concentration in the fresh diet is assessed for acute and short-term exposure, and the estimated theoretical exposure is calculated for the corresponding indicator species (insectivorous birds).

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculation of the *lambda*-cyhalothrin concentration in the fresh diet** | | | |
|  | **Definition** | **Value** | |
| **Acute exposure** | **Short-term exposure** |
| Application rate [kg x m-2] | Tappl | 1.12 x 10-6 | |
| Residue per unit dose [mg x kg-1] | RUD | 52 | 29 |
| Predicted environmental concentration in ants [mg × kg-1]\*\* | Cant = RUD x Tappl x 10-4 | 5.82 x 10-9 | 3.25 x 10-9 |
| Food intake rates per body weight-Small insectivorous bird I [d-1] | FIR /bw | 1.04 | |
| Food intake rates per body weight- Small insectivorous bird II [d-1] | FIR /bw | 0.2 | |
| Avoidance factor of contaminated food (AV=1, no avoidance) [-] | AV | 1 | |
| Proportion of diet obtained in treated area [-] | PT | 1 | |
| Proportion of food type (vegetation or insects) in the diet of specie of concern [-] | PD | 1 | |
| **Estimated theoretical exposure- Small insectivorous bird I**  **[mg x kg-1x d-1]\*** | **ETE= Cant x (FIR/bw) x AV x PT x PD** | **6.05 x 10-9** | **3.38 x 10-9** |
| **Estimated theoretical exposure- Small insectivorous bird II**  **[mg x kgbw-1x d-1]** | **1.17 x 10-9** | **0.65 x 10-9** |

\*Worst-case value for risk assessment

\*\* For household insecticides, the application rate is usually provided as kg/m². Therefore, an additional factor of 10-4 has to be added to convert Tappl into kg/ha.

**Secondary poisoning via the consumption of contaminated worms**

The assessment of secondary poisoning via the consumption of contaminated worms is calculated according to the TGD (2003).

As input parameter worst case estimates of concentrations in the receiving soil compartment after STP sludge applications and after wash-off to soil by rainfall are included as well as the BCF in earthworms, the concentration in pore water, the fraction of gut loading in worm and the conversion factor for soil concentration wet-dry/weight soil. A reduction of the concentrations in soil or pore water due to use of the biocide on a limited area was not considered. For calculating the bioconcentration factor, an octanol/water partition coefficient of log Kow=7 is taken.

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| **Worst case calculation of the predicted environmental concentration in earthworms (*cf*. TGD, Equation 82b-d)** | | | | | | | | | | |
| **Parameter** | **Definition** | **Indoor use\*** | | | | | **Outdoor use** | | | |
| **Ants** residual treatmant | **Silverfish & Cockroaches** on target organisms, weekly | | **Wood lice** on target organisms, twice a year | | **Ants**  (urban area), residual treatment | | **Ants**  (rural area), residual treatment | |
| Local concentration in soil due to sludge application [mg/kgwwt] | PEClocalsoil | 1.08E-3 | 10.00E-3 | | 1.02E-3 | | 0.85E-3 | | 3.74E-3 | |
| Octanol/water partition coefficient [-] | Kow | 10,000,000 | | | | | | | | |
| Density of earthworm [kgwwt/l] | RHOearthworm | 1 | | | | | | | | |
| Bioconcentration factor for earthworm on wet weight basis  [l/kgwet earthworm] | BCF = (0.84 + 0.012 Kow)/RHOearthworm | 120001 | | | | | | | | |
| Fraction of gut loading in worm [kgdwt/kgwwt earthworm] | Fgut | 0.1 | | | | | | | | |
| Conversion factor for soil concentration wet-dry weight soil  [kgwwt/kgdwt] | CONVsoil | 1.133333 | | | | | | | | |
| Predicted Environmental Concentration in pore water [mg/l] | PEClocalsoil,porewater | 8.72E-7 | | 8.08E-6 | | 8.24E-7 | | 6.91E-7 | | 3.03E-6 |
| **Predicted Environmental Concentration in earthworms [mg/kgwet earthworm]** |  | **1.08E-3** | | **10.00E-3** | | **1.02E-3** | | **8.51E-4** | | **3.74E-03** |

\*According to guidance the local concentrations in soil or pore water of agricultural soil after an averaging time of 180 days should be used as an indication for potential groundwater levels. However, the approach to use the concentrations of the terrestrial ecosystem represents the worst case and an adaption would not change the outcome of the environmental risk assessment in this report.

According to the ESD for PT 18 (OECD, 2008), direct emissions to soil the Cearthworm have to be replaced by the estimated theoretical exposure (ETE). For the food chain from earthworm to earthworm-eating mammals and birds, the estimated residues in earthworm is converted to daily dose by multiplying a factor that relates the food intake rates and the body weight (FIR/bw). This factor corresponds to 1.4 for mammals and 1.1 for birds and it is derived from the exposure scenario established for plant protection products in the EU (European Commission, 2002).

The ETE values are calculated as a function of the content of the active substance *lambda-*cyhalothrin in worms and assuming the standardised worst-case scenario for the rest of the parameters.

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| **Calculation of the estimated theoretical exposure (ETE) for earthworm-eating mammals and birds** | | | |
| **Parameter** | **Definition** | **Outdoor use**  **Ants**  (rural area) | |
| **Mammals** | **Birds** |
| **Predicted Environmental Concentration in earthworms [mg x kg-1]** | Cearthworm | 3.74E-3 | |
| **Food intake rates per body weight [d-1] [-]** | FIR /bw | 1.44 | 1.1 |
| **Avoidance factor of contaminated food (AV=1, no avoidance)** | AV | 1 | |
| **Proportion of diet obtained in treated area [-]** | PT | 1 | |
| **Proportion of food type (vegetation or insects) in the diet of specie of concern [-]** | PD | 1 | |
| **Estimated theoretical exposure [mg x kg-1x d-1]** | **ETE= Cearthworm x (FIR/bw) x AVx PT x PD** | **5.39E-3** | **4.11E-3** |

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| **Worst case calculation of the predicted environmental concentration in fish (*cf*. TGD, Equation 76)** | | | | | |
| **Parameter** | **Definition** | **Indoor use** | | | **Outdoor use** |
| **Ants**  residual treatment | **Silverfish & Cockroaches**  on target organisms, weekly | **Wood lice** on target organisms, twice a year | **Ants**  (urban area), residual treatment |
| Predicted environmental concentration in surface water [mg/l] | PECwater | 2.97E-6 | 2.75E-5 | 2.81E-6 | 2.35E-6 |
| Bioconcentration factor for fish on wet weight basis  [l/kgwet fish] | BCFfish | 4982 | | | |
| biomagnification factor in fish [-] | BMF | 2 | | | |
| **Predicted Environmental Concentration in fish [mg/kgwet fish]** |  | **2.96E-2** | **0.274** | **2.80E-2** | **2.34E-2** |

**Secondary poisoning via the consumption of contaminated fish**

The assessment of secondary poisoning via the consumption of contaminated fish is calculated according to the TGD (2003).

The concentration of contaminant in food (fish of fish-eating predators (PECoralpredator) is calculated from worst case exposure estimates for surface water, the BCF for fish and the biomagnification factor (BMF) proposed in the CAR on lambda-cyhalothrin (Sweden, 2011). A reduction of the concentration in water due to the assumption that 50 % of the diet comes from a local area and 50 % of the diet comes from a regional area was not considered in this report.

#### Risk characterisation

***Atmosphere***

The active substance is virtually 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.

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

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
| **Scenarios** | **PECSTP** [**mg/l]** | **PEC/PNECSTP** |
|  | **PNECSTP = 5.0E-3 mg/l** | |
| **Spraying indoors, residual treatment** | | |
| Ants, max. 11 appl./year | 3.28E-5 | 6.56E-3 |
| Silverfishes & Cockroaches, weekly | 0.25E-3 | 5.00E-2 |
| Woodlice & Cockroaches, twice a year | 1.82E-5 | 3.64E-3 |
| **Spraying indoors, direct treatment of target organisms** | | |
| Silverfishes & Cockroaches, weekly | 0.30E-3 | 6.00E-2 |
| Cockroaches, twice a year | 2.26E-5 | 4.52E-3 |
| Woodlice, twice a year | 3.10E-5 | 6.20E-3 |
| **Spraying outdoors, residual treatment** | | |
| Ants, urban area | 2.60E-5 | 5.20E-3 |
| Ants, rural area | - | - |

**Conclusion:**

All calculated PEC/PNEC ratios are <1, showing that the intended uses of the biocidal product COM 116 02 I AL lead to acceptable risk for STP micro-organisms.

***Aquatic compartment***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
| **Scenarios** | **PECwater** [**mg/l]** | **PEC/PNECwater** | **PECsed** [**mg/kgwwt]** | **PEC/PNECsed** |
|  | **PNECwater = 2.0E-7 mg/l** | | **PNECsed = 9.3E-4 mg/kgwwt** | |
| **Spraying indoors, residual treatment** | | | | |
| Ants, max. 11 appl./year | 2.97E-6 | **14.85** | 4.53E-3 | **4.87** |
| Silverfishes & Cockroaches, weekly | 2.24E-5 | **112** | 34.09E-3 | **36.66** |
| Woodlice & Cockroaches, twice a year | 1.65E-6 | **8.25** | 2.52E-3 | **2.71** |
| **Spraying indoors, direct treatment of target organisms** | | | | |
| Silverfishes & Cockroaches, weekly | 2.75E-5 | **137.5** | 41.96E-3 | **45.12** |
| Cockroaches, twice a year | 2.04E-6 | **10.2** | 3.11E-3 | **3.34** |
| Woodlice, twice a year | 2.81E-6 | **14.05** | 4.28E-3 | **4.60** |
| **Spraying outdoors, residual treatment** | | | | |
| Ants, urban area | 2.35E-6 | **11.75** | 3.95E-3 | **4.25** |
| Ants, rural area | - | **-** | - | **-** |

**Conclusion:**

All calculated PEC/PNEC ratios for indirect exposure of surface water and sediment via STP are >1, indicating unacceptable risk for aquatic and sediment dwelling organisms.

The highest risk ratios for surface water (112 and 137.5) were calculated for silverfishes and cockroaches after weekly residual or direct treatment of target organisms.

In sediment PEC/PNEC ratios for silverfishes and cockroaches after weekly residual or direct treatment of target organisms are 36.66 and 45.12.

Direct treatment of target organisms indoors and weekly residual and direct treatment of silverfishes & cockroaches turn out to be the worst case scenarios.

All these results are based on very conservative assumptions for the intended small scale application of the product. According to the ESD for PT 18 for indoor spraying it is assumed that through wet cleaning of floors 50% of the sprayed product is emitted to the STP. For outdoor spraying in urban areas it is assumed that 80% of the applied product will end up in STP during a rain event.

The calculated risk may therefore be overestimated.

*However,* risk mitigation measures are proposed in order to reduce the calculated risk to acceptable levels in the aquatic compartment:

* Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain floods and cleaning water.
* The application is restricted to areas that are not wet cleaned, e.g. in cracks and crevices, closed bath tubes, areas next to, behind and under furniture.
* Do not use, where release to drains (sewers) cannot be prevented.

Direct treatment of target organisms is not authorised as the proposed restriction to areas that are not wet cleaned is not feasible for the mobile species and the non-professional user.

***Terrestrial compartment***

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| --- | --- | --- |
| **Calculated PEC/PNEC values** | | |
| **Scenarios** | **PECsoil** **[mg/kgwwt]** | **PEC/PNECsoil** |
|  | **PNECsoil = 2.9E-3 mg/kgwwt** | |
| **Spraying indoors, residual treatment** | | |
| Ants, max. 11 appl./year | 1.08E-3 | 0.37 |
| Silverfishes & Cockroaches, weekly | 8.13E-3 | **2.80** |
| Woodlice & Cockroaches,  twice a year | 0.60E-3 | 0.21 |
| **Spraying indoors, direct treatment of target organisms** | | |
| Silverfishes & Cockroaches, weekly | 10.00E-3 | **3.45** |
| Cockroaches, twice a year | 0.74E-3 | 0.26 |
| Woodlice, twice a year | 1.02E-3 | 0.35 |
| **Spraying outdoors, residual treatment** | | |
| Ants, urban area | 0.85E-3 | 0.29 |
| Ants, rural area | 3.74E-3 | **1.29** |

**Conclusion:**

PEC/PNEC ratios are <1 for soil organisms, when indirectly exposed via sludge application, after indoor residual treatment against ants, woodlice and cockroaches (treatment twice a year) and after indoor direct treatment of target organisms against cockroaches and woodlice, when treated twice a year only.

Outdoor treatment against ants in urban areas leads to PEC/PNEC ratios <1, too.

For all these scenarios the biocidal product COM 116 02 I AL poses acceptable risk for non-target soil organisms.

PEC/PNECsoil ratios slightly >1 were calculated for indirect exposure via sludge application, after weekly indoor residual and direct treatment against silverfishes & cockroaches.

Direct exposure of soil after outdoor treatment against ants in rural areas also leads to risk ratios slightly >1.

Again these results are based on worst case assumption for the intended small scale application of the product. According to the ESD for PT 18 for indoor spraying of the product it is assumed that through wet cleaning of floors 50% of the sprayed product is emitted to the STP. For outdoor spraying it is assumed that 80% of the applied product will end up in soil through wash off in a rain event.

The calculated risk may therefore be overestimated; however, risk mitigation measures are proposed in order to reduce the calculated risk in the terrestrial compartment to acceptable levels:

* Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain floods and cleaning water.
* The application is restricted to areas that are not wet cleaned.

***Groundwater***

No specific reference value for *lambda-*cyhalothrinfor groundwater was established. Thus, the European standard value of 0.1 µg/l for the maximum admissible concentration of pesticides in drinking-water (Council Directive 98/83/EC), applies.

PECgroundwater values for indirect exposure of soil via sewage sludge application after indoor residual treatment against ants, silverfishes & cockroaches (weekly) and woodlice & cockroaches (twice a year) were 8.72E-4 µg/l, 6.57E-3 µg/l and 4.85E-4 µg/l, respectively.

For indirect exposure of soil via sludge application after indoor direct treatment of target organisms PECgroundwater values were 8.08E-3 µg/l for silverfishes & cockroaches (weekly), 6.00E-4 µg/l for cockroaches (twice a year) and 8.24E-4 µg/l for woodlice (twice a year).

The PECgroundwater value for indirect exposure of soil via sludge application after outdoor treatment against ants (urban area) was 6.91E-4 µg/l. For direct exposure of soil after treatment of ants (rural area) the PECgroundwater value was 3.03E-3 µg/l.

**Conclusion:**

All calculated PECgroundwater values are <0.1 µg/l, indicating acceptable risk for groundwater.

***Primary and secondary poisoning***

Primary poisoning

Due to spray application, primary poisoning of birds or mammals is not relevant.

Secondary poisoning

According to the ESD for PT 18, secondary poisoning is also defined as an “indirect exposure scenario” whereas a “direct exposure” corresponds to primary poisoning.

Thus, birds and mammals may be poisoned secondarily through the ingestion of contaminated ants.

Insectivorous mammals always are assumed to eat large insects therefore an assessment for mammals is not indicated in this context.

Small birds are assumed to prefer small insects, thus the residues for small insects are the default values for birds in order to cover the worst case. Thus, acute and short term poisoning of birds through ingestion of contaminated ants from treated surfaces were assessed.

Additionally poisoning of birds and mammals, through consumption of fish or earthworms, which were contaminated by poisoned surface water or soil, was calculated.

The calculated chronic Predicted No Effect Concentrations (PNECoral) for birds and mammals were taken from Doc II-C of the CAR of *lambda*-cyhalothrin (SE, 2011):

PNECoral birds: 0.6 mg ai/kg bw/d, PNECoral mammals: 0.12 mg/mg ai/kg bw/d

Risk ratios for consumption of directly exposed diet (ants and earthworms) were calculated using ETE values, in order to avoid conversion of the PNEC values to mg/kgbw/d. The risk ratios are therefore expressed as ETE/PNEC values.

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| **Summary table on secondary poisoning, consumption of directly exposed diet** | | | | | | | |
| **Scenario** | | | **ETE oral predator** | | | **ETE/PNEC** | |
|  | | | **PNEC birds = 0.6 mg ai/kg bw/d** | | | | |
| Small insectivorous bird I (worst case) (fresh diet: ants) | | | | | | | |
| * Acute toxicity | | | 6.05E-9 | | | 1.01E-8 | |
| * Short term toxicity | | | 3.38E-9 | | | 5.63E-9 | |
|  | | | **PNEC birds = 0.6 mg ai/kg bw/d**  **PNEC mammals = 0.12 mg ai/kg bw/d** | | | | |
| Predators (fresh diet: earthworms, rural area) | | | | | | | |
| * Birds | | | 4.11E-3 | | | 6.85E-3 | |
| * Mammals | | | 5.39E-3 | | | 4.49E-2 | |

Birds and mammals may also be poisoned by *lambda-*cyhalothrin through the consumption of fish or earthworms exposed to indirectly contaminated surface water or soil. For these cases the potential for bioaccumulation via the aquatic and terrestrial food chain was assessed for the worst case scenarios from the aquatic and terrestrial compartments. Hence, concentrations in the food of earthworm- and fish-eating predators were calculated and a risk assessment was performed.

To be comparable with the daily dose value, the exposure also needs to be based on daily intake of contaminated food. Therefore, the PECoral, predator was used to calculate the ETE (estimated theoretical exposure, expressed as mg ai/kg bw per day).

Thereof in order to calculate the risk in the aquatic food chain, the estimated residues in fish are converted to daily dose by multiplying with FIR/bw (feed intake rate per body weight) of 0.13 and 0.21 for mammals and birds, respectively.

In order to calculate the risk in the terrestrial food chain, the estimated residues in earthworms are converted to daily dose by multiplying with FIR/bw of 1.4 and 1.1 for mammals and birds, respectively (Doc II-C of CAR SE, 2011, SANCO/4145).

PECoral, predator = Cfish

ETE = FIR/bw × PEC *oral, predator*

FIR/bw

0.13 for fish-eating mammals

0.21 for fish-eating birds

PECoral, predator = Cearthworm

ETE = FIR/bw × Cearthworm

FIR/bw

1.4 for earthworm-eating mammals

1.1 for earthworm-eating birds

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| **Calculation of ETE (estimated theoretical exposure)** **from PEC (predicted environmental concentration)** | | | | | |
| **Parameter** | **Definition** | **Indoor** | | | **Outdoor** |
| **Ants** residual treatment | **Silverfish & Cockroaches**  on target organisms, weekly | **Wood lice** on target organisms, twice a year | **Ants** (urban area), residual treatment |
| **PEC [mg/kgwet fish]** | *PEC oral, predator = Cfish* | **2.96E-2** | **0.274** | **2.80E-2** | **2.34E-2** |
| FIR/bw\* | | 0.21 for fish-eating birds | | | |
| FIR/bw\* | | 0.13 for fish-eating mammals | | | |
| **ETE in birds**  **[mg ai/kg bw/d]** | ETE = FIR/bw × PEC *oral, predator* | 6.21E-3 | 5.75E-2 | 5.88E-3 | 4.91E-3 |
| **ETE** **in mammals [mg ai/kg bw/d]** | ETE = FIR/bw × PEC *oral, predator* | 6.22E-3 | 3.56E-2 | 3.64E-3 | 3.04E-3 |
| **PEC in earth-worm [mg/kgwet earthworm]** | *PEC oral, predator = Cearthworm* | **1.08E-3** | **10.00E-3** | **1.02E-3** | **8.51E-4** |
| FIR/bw\* | | 1.1 for earthworm-eating birds | | | |
| FIR/bw\* | | 1.4 for earthworm-eating mammals | | | |
| **ETE in birds**  **[mg ai/kg bw/d]** | ETE = FIR/bw × Cearthworm | 1.18E-3 | 1.1E-2 | 1.12E3 | 9.36E-4 |
| **ETE** **in mammals [mg ai/kg bw/d]** | ETE = FIR/bw × Cearthworm | 1.51E-3 | 1.4E-2 | 1.42E-3 | 1.19E-3 |

\* Feed Intake Rate per body weight

|  |  |  |
| --- | --- | --- |
| **Summary table on worst case scenarios for bioaccumulation via the aquatic food chain** | | |
| **Scenario** | **ETE** | **ETE/PNEC** |
|  | **PNEC birds = 0.6 mg ai/kg bw/d**  **PNEC mammals = 0.12 mg ai/kg bw/d** | |
| **Indoor use** | | |
| Ants, residual treatment |  | |
| * Fish-eating birds | 6.21E-3 | 1.03E-2 |
| * Fish-eating mammals | 6.22E-3 | 5.18E-2 |
| Silverfishes & Cockroaches, direct treatment of target organisms, weekly |  | |
| * Fish-eating birds | 5.75E-2 | 9.59E-2 |
| * Fish-eating mammals | 3.56E-2 | 0.296 |
| Woodlice, direct treatment of target organisms, twice a year |  | |
| * Fish-eating birds | 5.88E-3 | 9.8E-3 |
| * Fish-eating mammals | 3.64E-3 | 3.03E-2 |
| **Outdoor use** | | |
| Ants (urban area), residual treatment |  | |
| * Fish-eating birds | 4.91E-3 | 8.18E-3 |
| * Fish-eating mammals | 3.04E-3 | 2.52E-2 |

|  |  |  |
| --- | --- | --- |
| **Summary table on worst case scenarios for bioaccumulation via the terrestrial food chain** | | |
| **Scenario** | **PECoral predator** | **PEC/PNEC** |
|  | **PNEC birds = 0.6 mg ai/kg bw/d**  **PNEC mammals = 0.12 mg ai/kg bw/d** | |
| **Indoor use** | | |
| Ants, residual treatment |  | |
| * Earthworm-eating birds | 1.18E-3 | 1.98E-3 |
| * Earthworm-eating mammals | 1.51E-3 | 1.26E-2 |
| Silverfishes & Cockroaches, direct treatment of target organisms, weekly |  | |
| * Earthworm-eating birds | 1.1E-2 | 1.83E-2 |
| * Earthworm-eating mammals | 1.4E-2 | 0.116 |
| Woodlice, direct treatment of target organisms, twice a year |  | |
| * Earthworm-eating birds | 1.12E-3 | 1.87E-3 |
| * Earthworm-eating mammals | 1.42E-3 | 1.19E-2 |
| **Outdoor use** | | |
| Ants (urban area), residual treatment |  | |
| * Earthworm-eating birds | 9.36E-4 | 1.56E-3 |
| * Earthworm-eating mammals | 1.19E-3 | 9.92E-3 |

**Conclusion:**

Calculated risk ratios for secondary poisoning, through the consumption of directly contaminated ants and earthworms as well as for the potential of bioaccumulation via the aquatic and terrestrial food chain were <1 for birds and mammals for all calculated scenarios.

Thus, acceptable risk is assumed for secondary poisoning of non-target organisms.

***Mixture toxicity***

Mixture toxicity is not relevant since the biocidal product only contains one active substance (*lambda*-cyhalothrin) and no substances of concern.

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

#### Recommended methods and precautions

Handling:

Advice on safe handling: Keep only in the original container.

Advice on protection against fire and explosion: The product is not flammable.

Storage:

Requirements for storage areas and containers: Keep product in original container only, tightly closed, in a safe place.Store in a cool, dry and frost-protected place. Keep away from direct sunlight.

Further information on storage conditions: Keep away from food, drink and animal feed.

Storage period: 4 years.

Storage temperature: 5-30°C.

Disposal:

Dispose of product residues in its container according to local and national requirements.

Transport:

UN number: 3082

Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (*lambda*-cyhalothrin)

Transport hazard class: 9

Packing group: III

Environmental hazards: IMDG: Marine Pollutant Check Reqd

Special precautions for user: Tunnel restriction code (E)

Fire:

Suitable extinguishing media: Water, carbon dioxide (CO2), foam, dry chemical.

Special protective equipment for firefighters: Wear self-contained breathing apparatus and chemical protective clothing.

Further information: Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

#### Identity of relevant combustion products in cases of fire

Evolution of toxic gases/vapours: carbon monoxide, carbon dioxide (CO2).

#### Specific treatment in case of an accident

First aid measures:

If inhaled: Keep patient calm, remove to fresh air, seek medical attention.

After contact with skin: Wash thoroughly with soap and water.

After eye contact: Rinse with plenty of water.

If swallowed: Seek medical advice immediately and show this container or label.

Emergency measures to protect the environment: Do not flush into surface water or sanitary sewer system.

#### Possibility of destruction or decontamination following release

Air:

The biocidal product contains 0.05% w/w *lambda*-cyhalothrin which has a low vapour pressure (2x10-7 Pa at 20°C). It is therefore very unlikely that it volatilises and the potential for exposure to the air compartment would be limited.

There are no specific procedures available for destruction or decontamination of the biocidal product following its release to air.

Water:

There are no specific procedures available for destruction or decontamination of the biocidal product following its release in water due to accidental misuse; focus should be on prevention of contamination.

Soil:

Methods for cleaning up: Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Dispose of promptly.

#### Procedures for waste management of the biocidal product and its packaging

Dispose unused product in its container according to national and local requirements

#### Procedures for cleaning application equipment where relevant

Not applicable.

#### Specify any repellents or poison control measures included in the product

The biocidal product does not include any repellents or poison control measures that are present to prevent action against non-target organisms.

### Assessment of a combination of biocidal products

Not applicable.

### Comparative assessment

**Background:**

The biocidal product COM 116 02 I AL contains the active substance *lambda*-cyhalothrin, which meets the criteria for substitution pursuant to Article 10(1) of the Biocides Regulation (EU) No 528/2012 (BPR). *Lambda*-cyhalothrin is considered to be bioaccumulative (B) and toxic (T), but not persistent (P). Therefore it meets two of the three criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006. Consequently, in line with Article 23(1) of the Biocides Regulation the Austrian Competent Authority has performed a comparative assessment for the biocidal product COM 116 02 I AL, based on the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a).

For this comparative assessment the Austrian Competent Authority used the list of biocidal products authorised in Austria for PT 18 (in the version of 10.02.2016), accessible on <http://www.biozide.at/>, which is maintained by the Environment Agency Austria (Umweltbundesamt) on behalf of the Austrian Federal Ministry of Sustainability and Tourism (BMNT). This was done due to the lack of a tool in the current version of R4BP3 to search SPCs, pursuant to the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a).

**Authorised uses for the relevant biocidal product in the application**

The biocidal product COM 116 02 I AL is an insecticide (PT 18) which contains the active substance *lambda*-cyhalothrin. The product is used by the general public (non-professionals) in order to control garden ants, silverfishes, woodlice and cockroaches indoors as well as garden ants outdoors, respectively. It is a ready-to-use product in a PET-trigger bottle with packaging sizes from 200 up to 1000 ml. Application is conducted on the target organism or on spots of ground area where target organisms have been observed.

|  |  |
| --- | --- |
| Product Type | PT 18 Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Insecticide and products to control other arthropods |
| Target organism(s), development stage | Indoor and outdoor use:  Scientific name: Formicinae: *Lasius sp.*  Common name: **garden ants**  Development stage: ant colony   Indoor use:  Scientific name: Lepismatidae: *Lepisma saccharina*  Common name: Lepismatid: **silverfishes**  Development stage: larvae and adults   Scientific name: Porcellionidae: *Porcellio scaber*  Common name: **woodlice**  Development stage: larvae and adults  Scientific name: Blattodea: *Blattella germanica, Blatta orientalis, Periplaneta americana*  Common name: **cockroaches**  Development stage: larvae (nymphal stage) |
| Field(s) of use | Indoor use, outdoor use |
| Application method(s) | Method of application: **spraying**  Detailed description of the method:  Ants:  For killing ant nests, COM 116 02 I AL is sprayed on ant routes on indoor hard surfaces or on outdoor ant routs and nest entries on paved surfaces like terraces.  Silverfishes, woodlice and cockroaches: Application is conducted on spots of ground areas (residual treatment) where target organisms have been observed.  The application is restricted to areas that are not wet cleaned. |
| Category(ies) of users | General public (non-professional) |

*Table: Intended uses of the biocidal products*

Mode of action:

The active substance *lambda*-cyhalothrin belongs to a class of insecticides known as synthetic pyrethroids. It acts by contact and by ingestion resulting in knock-down or death of the target organism. As other pyrethroids *lambda*-cyhalothrin acts as a sodium channel modulator by disrupting the nervous system of insects.

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

**Identified eligible alternative biocidal products:**

For this comparative assessment the Austrian Competent Authority used the list of biocidal products authorised in Austria for PT 18 (in the version of 10.02.2016), as mentioned above. Active substances presently authorised in Austria for PT 18 are indoxacarb, spinosad and nitrogen. Biocidal products based on Nitrogen and indoxacarb are restricted to professional use only.

According to the information available, there are currently no biocidal products against silverfish and woodlice authorised in Austria, just two biocidal products against cockroaches – both based on indoxacarb and being restricted to professional use. 13 biocidal products to control ants are available for non-professionals, however all of these are based on the active substance spinosad.

**Screening phase:**

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

Chemical diversity

Article 23(3) (b) BPR refers to the adequate chemical diversity of the available active substances within a given product type/use/target organism combination as one of the two sine qua non conditions to be met in order to allow a restriction or prohibition of a biocidal product subject to comparative assessment. During the screening phase it shall be checked whether the diversity of the active substance, product type and mode of action combination in authorised biocidal products is adequate to minimise the occurrence of resistance in the target organisms. The screening phase shall allow through a simple assessment to judge whether it is required or not to perform a comprehensive comparative assessment. As a general rule, at least three different and independent active substance/mode of action - combinations should be available through authorised products.

As outlined above, no products have been authorised in Austria against silverfish and woodlice and just two BPs against cockroach but none of these for non-professional use. All of the 13 BPs to control ants are authorised for non-professionals, however all based on the active substance spinosad. As such the chemical diversity cannot be considered to be adequate.

**Consideration on whether the CFS meets at least one of the exclusion criteria listed in Article 5(1) but can benefit from derogation in accordance with Article 5(2) of the BPR**

The active substance *lambda*-cyhalothrin is neither carcinogenic, mutagenic or reprotoxic, nor is it a PBT or vPvB substance and therefore it does not meet any of the exclusion criteria in Article 5(1) of Regulation (EU) No 528/2012. But as mentioned before, it meets two of the three criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006 and thus it becomes a candidate substitution pursuant to Article 10(1) of the BPR.

**Conclusion of the screening phase:**

Stop comparative assessment. As there are currently in Austria no biocidal products against silverfish and woodlice authorised, just two biocidal products against cockroaches - both being restricted to professional use, and thirteen products against ants, but all based on the active substance spinosad, the Austrian Competent Authority concludes that an adequate chemical diversity to minimise the occurrence of resistance is not given yet. Consequently there are no eligible alternative biocidal products and therefore a comparison of the significant economic or practical disadvantages was deemed unnecessary. Therefore the comparative assessment is stopped and finalised at this stage.

The biocidal product COM 116 02 I AL will be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation (EU) No 528/2012.

# Annexes

## List of studies for the biocidal product

| **Author(s)** | **Year** | **Title** | **Testing Company** | **Report No.** | **GLP Study (Yes/No)** | **Published (Yes/No)** | **Data Protection Claimed (Yes/No)** | **Data Owner** | **Section No. in IUCLID /  Non-key study/ Published** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bremmer, H.J. and van Veen, M.P. | 2000 | Factsheet algemeen –Randvoorwaarden en betrouwbaarheid, ventilatie, kamergrootte, lichaamsoppervlak. | – | RIVM rapport 612810 009 | n.a. | Yes | No | – | published |
| Camann, D.E., Majumdar, T.K., Harding, H.J. | 1995 | Determination of Pesticide Removal Efficiencies from Human Hand Wiped with Gauze Moistened with Three Salivary Fluids (EXPERIMENT I.3). | Southwest Research Institute, San Antonio, Texas National Exposure Research Laboratory, Research Triangle Park, NC | 78228-0510. SwRI Project 01-7131; ManTech P.O. 95LP0047 Task 004; USEPA Contract Number 68 | No | Yes | No | – | published |
| Felke, M. | 2009 | Contact toxicity and residual activity of COM 116 02 I AL on woodlice (*Porcellio scaber*).  Date: 2009-05-23 | Institut für Schädlingskunde, Groß-Zimmern, Germany | None | No | No | Yes | COMPO GmbH & Co. KG | 6.7\_05 |
| xxxxx. | 2008a | Primary Eye Irritation Study in Rabbits – COM 116 02 I AL.  Date: 2008-07-11 | RCC Ltd, Füllinsdorf, Switzerland | B85296 | Yes | No | Yes | COMPO GmbH & Co. KG | 8.2 |
| xxxxx | 2008b | Contact Hypersensitivity in Albino Guinea Pigs, Maximization-Test – COM 116 02 I AL.  Date: 2008-07-11 | RCC Ltd, Füllinsdorf, Switzerland | B85307 | Yes | No | Yes | COMPO GmbH & Co. KG | 8.3 |
| Jackson, W.A. | 2009a | A16132A – Explosive properties.  Date: 2009-06-25 | Syngenta Technology and Projects, Process Hazards Section, Huddersfield, UK | HT09/190 | Yes | No | Yes | Syngenta Crop Protection Münchwilen AG | 4.1 |
| Jackson, W.A. | 2009b | A16132A – Oxidising properties.  Date: 2009-06-25 | Syngenta Technology and Projects, Process Hazards Section, Huddersfield, UK | HT09/192 | Yes | No | Yes | Syngenta Crop Protection Münchwilen AG | 4.4 |
| Jackson, W.A. | 2009c | A16132A – Flash point.  Date: 2009-06-25 | Syngenta Technology and Projects, Process Hazards Section, Huddersfield, UK | HT09/189 | Yes | No | Yes | Syngenta Crop Protection Münchwilen AG | 4.2 |
| Jackson, W.A. | 2009d | A16132A – Auto-ignition temperature.  Date: 2009-06-25 | Syngenta Technology and Projects, Process Hazards Section, Huddersfield, UK | HT09/191 | Yes | No | Yes | Syngenta Crop Protection Münchwilen AG | 4.17.1 |
| Lüpkes, K.-H. | 2008 | Efficacy of a product against silverfish, Efficacy after direct spray treatment and residual efficacy of a product against silverfish.  Date: 2008-09-09 | BioGenius GmbH, Bergisch Gladbach, Germany | BIO048/08 | No | No | Yes | COMPO GmbH & Co. KG | 6.7\_04 |
| Lüpkes, K.-H. | 2009 | Efficacy of a product against cockroaches, Efficacy after direct spray treatment and residual efficacy of a product against cockroaches.  Date: 2009-04-24  Amended: 2015-01-21 | BioGenius GmbH, Bergisch Gladbach, Germany | BIO027/09 | No | No | Yes | COMPO GmbH & Co. KG | 6.7\_03 |
| Lüpkes, K.-H | 2015 | Amendment No. 1 to Biological Test Report, Efficacy of a product against cockroaches | BioGenius GmbH, Bergisch Gladbach, Germany | Mo3684, Report No. BIO027/09 | Yes | No | Yes | COMPO GmbH & Co. KG | 6.7\_03 |
| Martin-Keusch, Ch. | 2009a | A16132A – Physical properties of batch LOT 06/002.  Date: 2009-07-16 | Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland | 119810 | Yes | No | Yes | Syngenta Crop Protection Münchwilen AG | 3.2\_01 3.8 3.9 |
| Martin-Keusch, Ch. | 2009b | A16132A – Technical properties of batch LOT 06/002.  Date: 2009-05-26 | Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland | 119819 | Yes | No | Yes | Syngenta Crop Protection Münchwilen AG | 3.4\_02 |
| Schieck, S. | 2008 | COM 116 02 I AL Validation of an analytical method: Determination of *lambda*-cyhalothrin in formulation COM 116 02 I AL by HPLC.  Date: 2008-05-13 | Intertek biodata GmbH, Linden, Germany | Study No. 48690 | No | No | Yes | COMPO GmbH & Co. KG | 5 |
| Serrano, B. | 2007a | Field trial of the efficacy of insecticide products against garden ants.  Date: 2007-09-11 | T.E.C. Laboratory, Anglet, France | 1204b/0707R | No | No | Yes | Compo GmbH & Co. KG | 6.7\_01 |
| Serrano, B. | 2007b | Laboratory trial of the efficacy of insecticide products against garden ants.  Date: 2007-09-11 | T.E.C. Laboratory, Anglet, France | 1204a/0707R | No | No | Yes | COMPO GmbH & Co. KG | 6.7\_02 |
| Serrano, B. | 2011 | Serrano, B. |  |  | No | No | Yes | COMPO GmbH & Co. KG | 6.7\_06 |
| van Engelen, J.G.M. and Prud’homme de Lodder, L.C.H. | 2007 | Non-food products: How to assess children’s exposure? | – | RIVM report 320005005/2007 | n.a. | Yes | No | – | published |
| Wochner, F. | 2009 | A16132A – Storage stability and shelf life statement (2 weeks 54°C) in packaging made of PET (trigger bottle).  Date: 2009-07-20 | Syngenta Crop Protection Münchwilen AG, Analytical Development & Product Chemistry, Münchwilen, Switzerland | 10395223 | Yes | No | Yes | Syngenta Crop Protection Münchwilen AG | 3.1\_01 3.2\_02 3.3\_01 3.4\_01 3.5\_01 |
| Wochner, F. | 2012a | A16132A – Storage stability and shelf life statement (2 years 20°C) in packaging made of PET (trigger bottle).  Date: 2012-07-05 | Syngenta Crop Protection Münchwilen AG, Analytical Development & Product Chemistry, Münchwilen, Switzerland | 10485617 | Yes | No | Yes | Syngenta Crop Protection Münchwilen AG | 3.1\_02 3.2\_03 3.3\_02 3.4\_03 3.5\_02 |
| Schieck, S. | 2018 | 4 years storage stability test COM 116 02 I AL | Intertek Food Service GmbH, Linden, Germany | Study no: 75617 | Yes | No | Yes | COMPO GmbH & Co. KG |  |
| Wochner, F. | 2012b | A16132A – Impact of storage (2 years 20°C) of batch LOT 06/002 on trigger sprayer regarding clogging, spray diameter and discharge rate.  Date: 2012-07-05 | Syngenta Crop Protection Münchwilen AG, Analytical Development & Product Chemistry, Münchwilen, Switzerland | 10487530  10394896 | Yes | No | Yes | Syngenta Crop Protection Münchwilen AG | 3.5\_08  4.17 |

## Output tables from exposure assessment tools

Scenario 1: Primary exposure of non-professionals applying liquid formulation by trigger spray devices

|  |
| --- |
| **Adult**  body weight 60 kilogram  **Product**  **COM 116 02 I AL – Trigger Spray**  **Aggregate Exposures**  **Aggregate exposure for Adult :**  Total chronic potential dose (mg/kg/day): 0.0017  **Total chronic systemic dose (mg/kg/day): 8.7E-5**  Inhalation chronic potential dose (mg/kg/day): 1.9E-5  **Inhalation chronic systemic dose (mg/kg/day): 1.9E-5**  Dermal chronic potential dose (mg/kg/day): 0.0015  **Dermal chronic systemic dose (mg/kg/day): 1.5E-5**  Oral chronic potential dose (mg/kg/day): 5.2E-5  **Oral chronic systemic dose (mg/kg/day): 5.2E-5**  **Details for scenario: Adult, COM 116 02 I AL – Pump spray : application (trigger spray)**  **Inhalation model: Exposure to spray : spraying**  weight fraction compound 0.05 %  exposure duration 2.4E2 minute  room volume 20 m³  ventilation rate 0.6 1/h  mass generation rate 0.38 g/sec  spray duration 4 minute  airborne fraction 0.2 fraction  weight fraction non-volatile 1 fraction  density non-volatile 1 g/cm³  room height 2.5 meter  inhalation cut-off diameter 15 micrometer  non-respirable uptake fraction 0.5 fraction  **Uptake model: Fraction**  uptake fraction 1 fraction  inhalation rate 33 m³/day  **Dermal model: Direct dermal contact with product : constant rate**  weight fraction compound 0.05 %  exposed area 2.1E2 cm²  contact rate 46 mg/min  release duration 2.4E2 second  **Uptake model: fraction**  uptake fraction 1 % |
|  |

Scenario 2: Child playing on floor

As described in 2.3.5, Part B of this document the effective application rate (AR) is assessed to be 5.56 g/m². The scenario was adopted in terms of body weight according to the SOPs from the US-EPA (1997), a source which is cited by ConsExpo itself regarding the transfer coefficient. The dislodgeable floor residues can be estimated using the maximum value of 60% from various types of surface (TNsG 2007- Annex 6, p. 102) giving a dislodgeable residue of 1.67 mg a.s./m².

Calculation of dislodgeable residue of a.s.

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Definition** | **Value** |
| Effective application rate [g b.p./m²] | AR | 5.56\* |
| Transfer efficiency [%] | TE | 60 |
| Concentration of a.s. in b.p. (w/w) [%] | C | 0.05 |
| Dislodgeable residue [mg a.s./m²] | DR = A × EA × TE × C | 1.67 |

\* application rate of 44.5 g/m2 (as established in the document on application rates) divided by the surface area of 8 m2 as done in the PAR.

Dermal exposure of children via treated surfaces

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Definition** | **Value** |
| Dislodgeable residue [mg a.s./m²] | DR | 1.67 |
| Transfer coefficient [m²/h] | TC | 0.2 |
| Contact duration [h/day] | T | 1 |
| Dermal absorption [%] | DA | 1 |
| Body weight [kg] | BW | 10 |
| Systemic dermal exposure [mg/kg/day] | Idermal = DR × TC × T × DA × SRE × BW-1 | 0.000334 |

Calculation of acute systemic exposure of infants via HTM contact

Small children exhibit a great deal of hand-to-mouth (HTM) contact. Therefore, a part of the a.s. residues present on the hands will be dislodged by saliva and eventually ingested. To provide a realistic estimate of this exposure, data on the frequency and extent of HTM contact of small children was used for the exposure estimate.

Observations of children by videotape and subsequent analyses have shown that the average hand area contacting the mouth is 4.5 cm² per mouthing event for 1-2-year olds (reviewed in HESI, 2004, see following table).

Table: Surface area contacting the mouth per event as a function of age (from HESI, 2004)

|  |  |  |
| --- | --- | --- |
| Age [years] | Hand area contacted per HTM event [cm²/event] | |
| Average | Range |
| 1 | 4.1 | 2.6 - 5.8 |
| 2 | 4.9 | 4.0 - 6.7 |
| 1 – 2 | 4.5 | 2.6 - 6.7 |
| 3 | 7.9 | 6.5 - 10.3 |
| 4 | 7.4 | 4.0 - 10.0 |
| 3 – 4 | 7.7 | 4.0 - 10.3 |

This dislodgeable amount can either penetrate through skin or being ingested following hand-to-mouth contact. The low water solubility of the a.s. will not allow for efficient saliva dislodgeability.

Measurements of the removal efficiency of pesticide residues by saliva have been carried out for several different chemical classes (Camann et al., 1995). Because saliva is predominantly water, a reasonable assumption is that water solubility may be an important rate limiting factor in saliva removal efficiency; however, competing for solubilisation by saliva is the chemical's adsorption to skin and, to some degree, absorption through skin.

Clearly, the amount of a chemical that is adsorbed (e.g., bound to the stratum corneum) and dermally absorbed would no longer be available for saliva removal, and thus, the degree of adsorption is in competition with saliva solubilisation and incidental ingestion. As shown in the following table, summary data for several pesticides suggest that removal efficiency by human saliva or artificial saliva is similar.

Table: Saliva removal efficiency for several compounds

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Pesticide | Water Solubility [mg/L] | Reference | Saliva Removal [%] | Reference |
| Pyrethrins I | 0.2 (temp. not specified) | HSDB\* | 50 | Camann et al., 1995 |
| PBO | 14.3 at 25°C | HSDB\* | 50 | Camann et al., 1995 |
| Chlorpyrifos | 1.4 at 25°C | HSDB\* | 50 | Camann et al., 1995 |
| *Lambda*-cyhalothrin | 0.005 at 20°C | Doc IIA | 50 | assumption |

\*<http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>

Based on the data shown it is surmised that the a.s. will not be completely removed via saliva and mouthing (simulated by wiping in Camann et al., 1995) based on data for other pesticides. Thus, one would expect the saliva removal efficiency of the a.s. to be not higher than 50%.

The bioavailability (oral absorption) of ingested *lambda*-cyhalothrin is 50%. HESI (2004) contains data on the frequency of hand-to-mouth events for children during indoor play. In a 2002 study, HTM behaviour in 72 children (37 male, 35 female) was examined. Children (11-60 months) were observed for 5-60 minutes per day for 1-6 days. Eating events were specifically excluded from the post videotaping quantitation of HTM frequency. Children older than 24 months had a lower mouthing frequency than younger children. Therefore, only children below that age were considered for the present exposure assessment. For 1-2-year olds, a mean hand-to-mouth frequency of 18 events per hour was determined for the estimated contact time.

With these assumptions oral exposure (Ioral) of infants via HTM contact can be calculated as presented in the following table.

|  |  |  |
| --- | --- | --- |
| Parameter | Definition | Value |
| Dermal load [mg a.s./cm²] | DL = DR | 0.000167 |
| Hand area contacting the mouth [cm²] | SA | 4.5 |
| Efficiency of removal by saliva from skin [%] | RE | 50 |
| Number of hand to mouth contacts [day–1] | F | 18 |
| Oral absorption [%] | OA | 50 |
| Body weight [kg] | BW | 10 |
| Systemic oral dose [mg/kg bw/day] | Ioral = DL × SA × RE × F × OA× BW –1 | 0.000338 |

The combined oral and dermal exposure after application for infants amounts to

Itotal = Ioral + Idermal = 0.00134 mg/kg bw/day.

## New information on the active substance

Not applicable

## Residue behaviour

Not applicable

## Summaries of the efficacy studies (B.5.10.1-5)

| Section B5.10 Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6 | Efficacy Data  5.10. Effects on target organisms (PT 18; Study 1) |  |
| --- | --- | --- |
|  |  |  |
|  | 1. Reference | **Official use only** |
| * 1. Reference | Serrano, B. (2007a): Field trial of the efficacy of insecticide products against garden ants. T.E.C. Laboratory, Anglet, France, Report No. 1204b/0707R, Date: 2007-09-11 (unpublished) |  |
| * 1. Data protection | Yes |  |
| * + 1. Data owner | Compo GmbH & Co. KG |  |
| * + 1. Companies with Letter of Access | – |  |
| * + 1. Criteria for data protection | Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation. |  |
| * 1. Guideline study | The methodology was based on the French official registration protocol C.E.B no. 1 "Methodology for field testing of a specialty against ants". |  |
| * 1. Deviations | none |  |
|  | 1. Method |  |
| * 1. Test Substance | COM 116 02 I AL |  |
| * + 1. Purity | The biocidal product contains 0.5 g/kg of the active substance lambda-cyhalothrin. |  |
| * + 1. Physical state and nature | Liquid formulation: cloudy liquid with whitish colour |  |
| * + 1. Method of analysis | As described in Section 5 of dossier. |  |
| * 1. Reference substance | AFOURMI SG (0.02 % fipronil, batch 1834Y EMB, AMM 9900344) |  |
| * 1. Testing procedure |  |  |
| * + 1. Test population /  inoculum / test organism | Lasius niger |  |
| * + 1. Test system | Effectiveness of insecticide hand sprayer was tested against garden ants. |  |
| * + 1. Application of TS | Hand sprayer: 10 g/m ant pathway (10 strokes per linear meter) and coarse spray directly on nest entries | x |
| * + 1. Test conditions | Climatic conditions: 18.9 – 19.9°C (mean values, measured over 3 month)  The trial was conducted in areas like gardens or orchards where ant nests are well isolated. |  |
| * + 1. Duration of the test / Exposure time | 3 weeks |  |
| * + 1. Number of replicates performed | 3 replicates |  |
| * + 1. Controls | Yes (untreated) |  |
| * 1. Examination |  |  |
| * + 1. Effect investigated | The frequency of ants on surface during the test period and mortality of the ants after test termination |  |
| * + 1. Method for recording / scoring of the effect | Alive: the insects are able to move properly Dead: the insects are unable to move properly |  |
| * + 1. Intervals of examination | *–* |  |
| * + 1. Statistics | – |  |
| * + 1. Post monitoring of the test organism | No |  |
|  | 1. Results |  |
| * 1. Efficacy |  |  |
| * + 1. Dose/Efficacy curve | *–* |  |
| * + 1. Begin and duration of effects | – |  |
| * 1. Tabular and/or graphical presentation of the summarised results | See Table B5.10\_1 and Table B5.10\_2. |  |
| * 1. Efficacy limiting factors |  |  |
| * + 1. Occurrences of resistances | Not applicable |  |
| * + 1. Other limiting factors | Not applicable |  |
|  | 1. Relevance of the results compared to field conditions |  |
| * 1. Reasons for laboratory testing | *–* |  |
| * 1. Intended actual scale of biocide application | – |  |
| * 1. Relevance compared to field conditions |  |  |
| * + 1. Application method | Yes |  |
| * + 1. Test organism | Yes, ant Lasius niger is a typical pest in gardens. |  |
| * + 1. Observed effect | A complete efficacy (no alive ants after 3 weeks) against the ant *Lasius niger* could be determined. |  |
| * 1. Relevance for read-across | Yes |  |
|  | 1. Applicant's Summary and conclusion |  |
| * 1. Materials and methods | Assessment of the efficacy of speciality products under field conditions to control garden ants. |  |
| * 1. Reliability | 1 |  |
| * 1. Assessment of efficacy, data analysis and interpretation | In the conditions of this trial, COM 116 02 I AL applied with hand sprayer have proved: - a complete and fast efficacy towards the ant Lasius niger - an equal efficacy compared to the registered standard product AFOURMI SG (0.02 % fipronil, AMM 9900344), granules applied in drenching or by strewing. |  |
| * 1. Conclusion | The results show that COM 116 02 I AL has a strong efficacy against Lasius niger. |  |
| * 1. Proposed efficacy specification | *–* |  |

| Section B5.10 Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6 | Efficacy Data  5.10. Effects on target organisms (PT 18; Study 1) |  |
| --- | --- | --- |
|  |  |  |
|  | Evaluation by Competent Authorities |  |
|  | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |  |
|  | **Evaluation by Rapporteur Member State** | |
| **Date** | July 2018 | |
| **Comments** | 2.3.3 Application of TS:  For application 10 strokes per linear meter and nest entries are used. | |
| **Summary and conclusion** | Agree with applicants version | |

**Table B5.10\_1: Percentage reductions of the frequency of ants on surface**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Treatment** | **Days of exposure** | | | |
| 2 | 7 | 14 | 21 |
| Untreated | -9.8 | 23.2 | -8.8 | -10.1 |
| COM 116 02 I AL | 66.9 | 90.7 | 98.9 | 100 |
| AFOURMI SG, strewing | 78.9 | 92.4 | 100 | 100 |
| AFOURMI SG, strewing | 93.5 | 100 | 100 | 100 |

**Table B5.10\_2: Number of alive ants after 3 weeks\***

|  |  |  |
| --- | --- | --- |
| **Treatment** | **Application** | **Number of alive ants** |
| Untreated | - | > 1500 |
| COM 116 02 I AL | 10 g/L | 0 |
| AFOURMI SG, strewing | 40 g/nest | 0 |
| AFOURMI SG, strewing | 40 g/2000 mL | 0 |

\* The nest was open and parts of ground are retrieved and observed in the laboratory for insect counts.

| Section B5.10 Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6 | Efficacy Data  5.10. Effects on target organisms (PT 18; Study 2) |  |
| --- | --- | --- |
|  |  |  |
|  | 1. Reference | **Official use only** |
| * 1. Reference | Serrano, B. (2007b): Laboratory trial of the efficacy of insecticide products against garden ants. T.E.C. Laboratory, Anglet, France, Report No. 1204a/0707R, Date: 2007-09-11 (unpublished) |  |
| * 1. Data protection | Yes |  |
| * + 1. Data owner | Compo GmbH & Co. KG |  |
| * + 1. Companies with Letter of Access | – |  |
| * + 1. Criteria for data protection | Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation. |  |
| * 1. Guideline study | The methodology was based on the French official registration protocol C.E.B no. 196 "Méthode d'étude de l'efficacité des préparations appâts inseciticides sur les espèces communes de fourmis, Novembre 1997". |  |
| * 1. Deviations | The trial was conducted with and without competition food (sugar wet cotton), the species chosen is Lasius niger. |  |
|  | 1. Method |  |
| * 1. Test Substance | COM 116 02 I AL (batch 45061H) |  |
| * + 1. Purity | The biocidal product contains 0.5 g/kg of the active substance lambda-cyhalothrin. |  |
| * + 1. Physical state and nature | Liquid formulation |  |
| * + 1. Method of analysis | As described in Section 5 of dossier. |  |
| * 1. Reference substance | AFOURMI SG (0.02 % fipronil, batch 1834Y EMB, AMM 9900344) |  |
| * 1. Testing procedure |  |  |
| * + 1. Test population /  inoculum / test organism | Lasius niger |  |
| * + 1. Test system | Effectiveness of insecticide hand sprayer was tested against garden ants. |  |
| * + 1. Application of TS | Hand sprayer: 5 g are sprayed onto the ground in arenas. |  |
| * + 1. Test conditions | Climatic conditions: 25 °C±1 °C / 65% RH±4% RH / light 1500 lux 8/16 photoperiod  The tests were conducted in plastic arenas 30 cm × 30 cm × 15 cm with 5 cm ground retrieved from the nest with or without competition food (sugar wet cotton). Only workers are exposed to the product. |  |
| * + 1. Duration of the test / Exposure time | 8 days |  |
| * + 1. Number of replicates performed | 3 replicates |  |
| * + 1. Controls | Yes (untreated) |  |
| * 1. Examination |  |  |
| * + 1. Effect investigated | Mortality of ants |  |
| * + 1. Method for recording / scoring of the effect | Alive: the insects are able to move properly Dead: the insects are unable to move properly |  |
| * + 1. Intervals of examination | Daily |  |
| * + 1. Statistics | – |  |
| * + 1. Post monitoring of the test organism | No |  |
|  | 1. Results |  |
| * 1. Efficacy |  |  |
| * + 1. Dose/Efficacy curve | *–* |  |
| * + 1. Begin and duration of effects | – |  |
| * 1. Tabular and/or graphical presentation of the summarised results | See Table B5.10\_1 and Table B5.10\_2. |  |
| * 1. Efficacy limiting factors |  |  |
| * + 1. Occurrences of resistances | Due to the mode of action a development of resistance is neither to be expected nor has ever been observed. |  |
| * + 1. Other limiting factors | Not applicable |  |
|  | 1. Relevance of the results compared to field conditions |  |
| * 1. Reasons for laboratory testing | It is easier and more precisely to test a product against ants in a laboratory arena. The conditions are comparable and controllable; the number of organisms is defined. The observations and counting are easier and more correct. |  |
| * 1. Intended actual scale of biocide application | For application in and around domestic and commercial premises. |  |
| * 1. Relevance compared to field conditions |  |  |
| * + 1. Application method | Yes, applied according to the label recommendations. |  |
| * + 1. Test organism | Yes, ant Lasius niger is a typical pest in gardens. |  |
| * + 1. Observed effect | A complete efficacy against the ant *Lasius niger* could be determined. |  |
| * 1. Relevance for read-across | Yes |  |
|  | 1. Applicant's Summary and conclusion |  |
| * 1. Materials and methods | Assessment of the efficacy of speciality products under laboratory conditions to control garden ants. |  |
| * 1. Reliability | 1 |  |
| * 1. Assessment of efficacy, data analysis and interpretation | In the conditions of this trial, COM 116 02 I AL applied with hand sprayer have proved: - a complete and fast efficacy towards the ant Lasius niger - an equal efficacy compared to the registered standard product AFOURMI SG (0.02 % fipronil, AMM 9900344), granules applied in drenching or by strewing. |  |
| * 1. Conclusion | The results show that COM 116 02 I AL has a complete and fast efficacy against Lasius niger. |  |
| * 1. Proposed efficacy specification | *–* |  |

| Section B5.10 Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6 | Efficacy Data  5.10. Effects on target organisms (PT 18; Study 2) |  |
| --- | --- | --- |
|  |  |  |
|  | Evaluation by Competent Authorities |  |
|  | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |  |
|  | **Evaluation by Rapporteur Member State** | |
| **Date** | July 2015 | |
| **Comments** | - | |
| **Summary and conclusion** | Agree with applicants version | |

**Table B5.10\_1: Percentage of mortality in arena trials with competition food**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Treatment** | **Mortality (%)** | | | | | | | |
| 1 d | 2 d | 3 d | 4 d | 5 d | 6 d | 7 d | 8 d |
| Untreated | 0.3 | 1.0 | 1.6 | 1.6 | 2.3 | 2.6 | 2.6 | 3.0 |
| COM 116 02 I AL | 0.0 | 0.3 | 15.2 | 31.5 | 55.4 | 75.2 | 99.0 | 100.0 |
| AFOURMI SG, strewing | 0.0 | 0.0 | 23.3 | 64.5 | 100.0 | 100.0 | 100.0 | 100.0 |
| AFOURMI SG, strewing | 0.0 | 0.0 | 16.5 | 45.2 | 77.7 | 94.0 | 98.0 | 100.0 |

**Table B5.10\_2: Percentage of mortality in arena trials without competition food**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Treatment** | **Mortality (%)** | | | | | | | |
| 1 d | 2 d | 3 d | 4 d | 5 d | 6 d | 7 d | 8 d |
| Untreated\* | 0.3 | 1.0 | 1.6 | 1.6 | 2.3 | 2.6 | 2.6 | 3.0 |
| COM 116 02 I AL | 0.0 | 0.3 | 16.3 | 30.6 | 53.5 | 74.1 | 100.0 | 100.0 |
| AFOURMI SG, strewing | 0.0 | 0.3 | 22.9 | 70.9 | 100.0 | 100.0 | 100.0 | 100.0 |
| AFOURMI SG, strewing | 0.0 | 0.7 | 16.1 | 42.5 | 78.2 | 96.7 | 99.7 | 100.0 |

**\* same as for trial with competition food**

| Section B5.10 Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6 | Efficacy Data  5.10. Effects on target organisms (PT 18; Study 3) |  |
| --- | --- | --- |
|  |  |  |
|  | 1. Reference | **Official use only** |
| * 1. Reference | Lüpkes, K.-H. (2009): Efficacy of a product against cockroaches, Efficacy after direct spray treatment and residual efficacy of a product against cockroaches. BioGenius GmbH, Bergisch Gladbach, Germany, Report No. BIO027/09, Date: 2009-04-29 (unpublished) |  |
| * 1. Data protection | Yes |  |
| * + 1. Data owner | Compo GmbH & Co. KG |  |
| * + 1. Companies with Letter of Access | – |  |
| * + 1. Criteria for data protection | Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation. |  |
| * 1. Guideline study | The methodology was based on the following in-house methods:  Method BioG B 200-01 (modified): Test of spray can and trigger direct treatment of cockroaches by manual spraying  Method BioG B008-02 (modified): Test method for finding the residual effect of spray cans (using spray robot) |  |
| * 1. Deviations | Not applicable |  |
|  | 1. Method |  |
| * 1. Test Substance | COM 116 02 I AL (batch 05/024) |  |
| * + 1. Purity | The biocidal product contains 0.05% of the active substance lambda-cyhalothrin. |  |
| * + 1. Physical state and nature | Liquid formulation, bag-on-valve system |  |
| * + 1. Method of analysis | As described in Section 5 of dossier. |  |
| * 1. Reference substance | no |  |
| * 1. Testing procedure |  |  |
| * + 1. Test population /  inoculum / test organism | Blattella germanica (larvae), Blatta orientalis (larvae), Periplaneta americana (larvae) |  |
| * + 1. Test system | Effectiveness of insecticide bag-on-valve system was tested against garden ants in rooms (indoor). |  |
| * + 1. Application of TS | a) Direct spray treatment: Cockroaches were sprayed with the product for 2 seconds (= 2.6 – 3.0 gram, average 2.8 g) out of a distance of 60 cm.  b) Residual effects: Surfaces type glazed tiles or PVC were sprayed with a spray rate of 7.0 g per 5 seconds per meter (distance of 25 cm). |  |
| * + 1. Test conditions | Climatic conditions:  Temperature: a) 21 °C, b) 23 – 25 °C Rel. humidity: a) 28%, b) 55-70%  Light cycles during test: a, b) Artificial light during hours of work, additionally day light is given.  Type of test chamber:  a) Direct spray treatment: glass rings (9.5 cm in diameter, 5.5 cm height) b) Residual effects: Spray robot, residual racks, glazed tiles or PVC |  |
| * + 1. Duration of the test / Exposure time | 24 weeks |  |
| * + 1. Number of replicates performed | a) 10 replicates b) 3 replicates |  |
| * + 1. Controls | Yes, untreated controls: a) 3 replicates, b) 1 replicate |  |
| * 1. Examination |  |  |
| * + 1. Effect investigated | a) and b) Knock-down and mortality |  |
| * + 1. Method for recording / scoring of the effect | Visual observation of test animals |  |
| * + 1. Intervals of examination | a) Continuously up to 2 hours maximum for knock down and for mortality after 24 and 48 hours.  b) Exposure of the cockroaches for 72 hours to residues aged 1 day as well as 1, 2, 3, 4, 6, 8, 10, 12, 14, 16, 20 and 24 weeks, evaluation of knock down and mortality was done after 15 and 30 min as well as 1, 2, 6, 12, 24, 48 and 72 hours. |  |
| * + 1. Statistics | – |  |
| * + 1. Post monitoring of the test organism | No |  |
|  | 1. Results |  |
| * 1. Efficacy |  |  |
| * + 1. Dose/Efficacy curve | *–* |  |
| * + 1. Begin and duration of effects | a) Direct spray treatment:  100% knock down efficacy was given with all tested cockroach species. Mortality after 24 hours was 100% in all cases. Against German cockroaches it took ca. 10 min to achieve 100% of knock down efficacy (ca. 8-11 min. range). Against Oriental cockroaches it took ca. 33 min to achieve 100% of knock down efficacy (ca. 25-47 min. range). Against American cockroaches it took ca. 27 min to achieve 100% of knock down efficacy (ca. 23-36 min. range).  b) Residual effects on glazed tiles: Against German cockroaches it took 15 min up to 60 min to achieve 100% of efficacy for the complete test period of 24 weeks, in 1 out of 39 cases 2 hours. Against Oriental cockroaches, depending on the age of the residues, it took 30 min up to 12 hours to achieve 100% of efficacy. Against American cockroaches, for residues aged 1 day up to 16 weeks, it took 30 min up to 12 hours to achieve 100% of efficacy. At the end of the test period (for residues aged 20 and 24 weeks), in 2 out of 39 cases, 100% efficacy was not achieved during the exposure time of 72 hours.  Residual effects on PVC: The efficacy was weaker. Against German cockroaches 100% efficacy was achieved for residues up to 3 weeks (within 60 min up to 72 hours after start of exposure). Against Oriental cockroaches 100% efficacy was achieved for residues aged 1 day, in parts for residues aged 1 week and 3 weeks (within 6 hours up to 72 hours after start of exposure). Against American cockroaches 100% efficacy was achieved for residues aged 6 weeks (within 60 min up to 6 hours after start of exposure). |  |
| * 1. Tabular and/or graphical presentation of the summarised results | See Table B5.10\_1 |  |
| * 1. Efficacy limiting factors |  |  |
| * + 1. Occurrences of resistances | Due to the mode of action a development of resistance is neither to be expected nor has ever been observed. |  |
| * + 1. Other limiting factors | Not applicable |  |
|  | 1. Relevance of the results compared to field conditions |  |
| * 1. Reasons for laboratory testing | It is easier and more precisely to test a product against cockroaches in a laboratory arena. The conditions are comparable and controllable; the number of organisms is defined. The observations and counting are easier and more correct. |  |
| * 1. Intended actual scale of biocide application | For application in and around domestic and commercial premises. |  |
| * 1. Relevance compared to field conditions |  |  |
| * + 1. Application method | Yes, applied according to the label recommendations. |  |
| * + 1. Test organism | Yes, the cockroaches Blattella germanica, Blatta orientalis, Periplaneta americana are typical pests in homes. |  |
| * + 1. Observed effect | A complete efficacy against the different cockroach species could be determined. |  |
| * 1. Relevance for read-across | Yes |  |
|  | 1. Applicant's Summary and conclusion |  |
| * 1. Materials and methods | Assessment of the efficacy of speciality products under laboratory conditions to control cockroaches by measuring the knock down effect and mortality after direct spray treatment and assessing the residual effects (up to 24 weeks) after spraying of glazed tiles or PVC tiles. |  |
| * 1. Reliability | 1 |  |
| * 1. Assessment of efficacy, data analysis and interpretation | In the conditions of the trial, COM 116 02 I AL (spray) has proved a complete and fast efficacy towards the cockroach species Blattela germanica, Blatta orientalis and Periplaneta americana. |  |
| * 1. Conclusion | The results show that COM 116 02 I AL has a complete and fast efficacy against Blattela germanica, Blatta orientalis and Periplaneta americana |  |
| * 1. Proposed efficacy specification | *–* |  |

| Section B5.10 Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6 | Efficacy Data  5.10. Effects on target organisms (PT 18; Study 3) |  |
| --- | --- | --- |
|  |  |  |
|  | Evaluation by Competent Authorities |  |
|  | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |  |
|  | **Evaluation by Rapporteur Member State** | |
| **Date** | July 2015 | |
| **Comments** | - | |
| **Summary and conclusion** | Agree with applicants version | |

**Table B5.10\_1: Percentage of knock down after direct spray treatment against cockroaches**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Treatment** | **Test species  (5th larval stage)** | **% knock down after minutes (’) and seconds (’’)** | | **% knock down  after** |
| **mean** | **range** | **2 h** |
| COM 116 02 I AL | *Blattella germanica* | 9’31’’ | 7’30 -10’50’’ | 100 |
| COM 116 02 I AL | *Blatta orientalis* | 32’44’’ | 25’10 – 47’10’’ | 100 |
| COM 116 02 I AL | *Periplaneta americana* | 27’28’’ | 23’20 – 35’40’’ | 100 |

| Section B5.10 Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6 | Efficacy Data  5.10. Effects on target organisms (PT 18; Study 4) |  |
| --- | --- | --- |
|  |  |  |
|  | 1. Reference | **Official use only** |
| * 1. Reference | Lüpkes, K.-H. (2008): Efficacy of a product against silverfish, Efficacy after direct spray treatment and residual efficacy of a product against silverfish. BioGenius GmbH, Bergisch Gladbach, Germany, Report No. BIO048/08, Date: 2008-08-19 (unpublished) |  |
| * 1. Data protection | Yes |  |
| * + 1. Data owner | Compo GmbH & Co. KG |  |
| * + 1. Companies with Letter of Access | – |  |
| * + 1. Criteria for data protection | Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation. |  |
| * 1. Guideline study | The methodology was based on the following in-house methods:  Method BioG B 200-01 (modified): Test of spray can and trigger direct treatment of silverfish by manual spraying  Method BioG B008-02 (modified): Test method for finding the residual effect of spray cans (using computer controlled spraying apparatus) |  |
| * 1. Deviations | Not applicable |  |
|  | 1. Method |  |
| * 1. Test Substance | COM 116 02 I AL (batch 05/024) |  |
| * + 1. Purity | The biocidal product contains 0.05% of the active substance lambda-cyhalothrin. |  |
| * + 1. Physical state and nature | Liquid formulation, bag-on-valve system |  |
| * + 1. Method of analysis | As described in Section 5 of dossier. |  |
| * 1. Reference substance | no |  |
| * 1. Testing procedure |  |  |
| * + 1. Test population /  inoculum / test organism | Lepisma saccharina (adults) |  |
| * + 1. Test system | Effectiveness of insecticide bag-on-valve system was tested against silverfishes in rooms (indoor). |  |
| * + 1. Application of TS | a) Direct spray treatment: Silverfishes were sprayed with the product for 2 seconds (= 2.6 – 3.0 gram, average 2.8 g) out of a distance of 60 cm.  b) Residual effects: Surfaces type glazed tiles or PVC were sprayed with a spray rate of 7.0 g per 5 seconds per meter (distance of 25 cm). |  |
| * + 1. Test conditions | Climatic conditions:  Temperature: a) 22 °C, b) 24 – 26 °C Rel. humidity: a) 68%, b) 50-70%  Light cycles during test: a, b) Additionally to the day light about 10 hours of artificial light (day light for about 14 hours), rest darkness.  Type of test chamber:  a) Direct spray treatment: glass rings (9.5 cm in diameter, 5.5 cm height), 1 silverfish per test unit b) Residual effects: Spray robot, residual racks, glazed tiles or PVC, 5 silverfish per surface |  |
| * + 1. Duration of the test / Exposure time | 2 weeks |  |
| * + 1. Number of replicates performed | a) 10 replicates b) 3 replicates |  |
| * + 1. Controls | Yes, untreated controls: a) 3 replicates, b) 1 replicate |  |
| * 1. Examination |  |  |
| * + 1. Effect investigated | a) and b) Knock-down and mortality |  |
| * + 1. Method for recording / scoring of the effect | Visual observation of test animals |  |
| * + 1. Intervals of examination | a) Continuously up to 2 hours maximum for knock down and for mortality after 24 and 48 hours.  b) Exposure of the silverfishes for 72 hours to residues aged 1 day as well as 1 and 2 weeks, evaluation of knock down and mortality was done after 15 and 30 min as well as 1, 2, 6, 12, 24, 48 and 72 hours. |  |
| * + 1. Statistics | – |  |
| * + 1. Post monitoring of the test organism | No |  |
|  | 1. Results |  |
| * 1. Efficacy |  |  |
| * + 1. Dose/Efficacy curve | *–* |  |
| * + 1. Begin and duration of effects | a) Direct spray treatment:  100% knock down efficacy was achieved 2 minutes and 47 seconds after treatment. Mortality was 100% after 24 hours.  b) Residual effects: On glazed tiles 100% of knock down followed by mortality was given after 15 min up to 30 min, on PVC after 30 min up to 60 min. |  |
| * 1. Tabular and/or graphical presentation of the summarised results | See Table B5.10\_1 and Table B5.10\_2 |  |
| * 1. Efficacy limiting factors |  |  |
| * + 1. Occurrences of resistances | Due to the mode of action a development of resistance is neither to be expected nor has ever been observed. |  |
| * + 1. Other limiting factors | Not applicable |  |
|  | 1. Relevance of the results compared to field conditions |  |
| * 1. Reasons for laboratory testing | It is easier and more precisely to test a product against silverfishes in a laboratory arena. The conditions are comparable and controllable; the number of organisms is defined. The observations and counting are easier and more correct. |  |
| * 1. Intended actual scale of biocide application | For application in and around domestic and commercial premises. |  |
| * 1. Relevance compared to field conditions |  |  |
| * + 1. Application method | Yes, applied according to the label recommendations. |  |
| * + 1. Test organism | Yes, the silverfishes Lepisma saccharina are typical pests in homes. |  |
| * + 1. Observed effect | A complete efficacy against silverfishes could be determined. |  |
| * 1. Relevance for read-across | Yes |  |
|  | 1. Applicant's Summary and conclusion |  |
| * 1. Materials and methods | Assessment of the efficacy of speciality products under laboratory conditions to control silverfishes by measuring the knock down effect and mortality after direct spray treatment and assessing the residual effects (up to 2 weeks) after spraying of glazed tiles or PVC tiles. |  |
| * 1. Reliability | 1 |  |
| * 1. Assessment of efficacy, data analysis and interpretation | In the conditions of the trial, COM 116 02 I AL (spray) has proved a complete and fast efficacy towards the silverfish species Lepisma saccharina. |  |
| * 1. Conclusion | The results show that COM 116 02 I AL has a complete and fast efficacy against Lepisma saccharina. |  |
| * 1. Proposed efficacy specification | *–* |  |

| Section B5.10 Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6 | Efficacy Data  5.10. Effects on target organisms (PT 18; Study 4) |  |
| --- | --- | --- |
|  |  |  |
|  | Evaluation by Competent Authorities |  |
|  | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |  |
|  | **Evaluation by Rapporteur Member State** | |
| **Date** | July 2015 | |
| **Comments** | - | |
| **Summary and conclusion** | Agree with applicant´s version | |
|  |  | |

**Table B5.10\_1: Percentage of knock down after direct spray treatment against adults of silverfishes**

|  |  |  |  |
| --- | --- | --- | --- |
| **Treatment** | **% knock down after minutes (’) and seconds (’’)** | | **% knock down** |
| **mean** | **range** | **after 2 h** |
| COM 116 02 I AL | 2’47’’ | 2’05 -3’24’’ | 100 |

**Table B5.10\_2: Residual efficacy after spray treatment against adults of silverfishes**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Treatment | Tiles | 100% knock down, followed by mortality, after minutes during an exposure time of 72 h after | | |
| 1 day | 1 week | 2 weeks |
| COM 116 02 I AL | Glazed tiles | 25 \* | 25 \* | 20 \* |
| COM 116 02 I AL | PVC | 60 \* | 60 \* | 50 \* |
| Untreated control | Glazed tiles | 72 h 20% | 72 h 0% | 72 h 0% |
| Untreated control | PVC | 72 h 0% | 72 h 0% | 72 h 0% |

**\* mean value of 3 replicates**

| Section B5.10 Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6 | Efficacy Data  5.10. Effects on target organisms (PT 18; Study 5) |  |
| --- | --- | --- |
|  |  |  |
|  | 1. Reference | **Official use only** |
| * 1. Reference | Felke, M. (2009): Contact toxicity and residual activity of COM 116 02 I AL on woodlice (*Porcellio scaber*). Institut für Schädlingskunde, Groß-Zimmern, Germany, Date: 2009-05-23 (unpublished) |  |
| * 1. Data protection | Yes |  |
| * + 1. Data owner | Compo GmbH & Co. KG |  |
| * + 1. Companies with Letter of Access | – |  |
| * + 1. Criteria for data protection | Data submitted to the MS after 13 May 2000 on existing b.p. for the purpose of its authorisation. |  |
| * 1. Guideline study | No |  |
| * 1. Deviations | Not applicable |  |
|  | 1. Method |  |
| * 1. Test Substance | COM 116 02 I AL |  |
| * + 1. Purity | The biocidal product contains 0.05% of the active substance lambda-cyhalothrin. |  |
| * + 1. Physical state and nature | Liquid formulation |  |
| * + 1. Method of analysis | As described in Section 5 of dossier. |  |
| * 1. Reference substance | no |  |
| * 1. Testing procedure |  |  |
| * + 1. Test population /  inoculum / test organism | Porcellio scaber (adults) |  |
| * + 1. Test system | Effectiveness of insecticide spray treatment was tested against woodlice in rooms (indoor). |  |
| * + 1. Application of TS | a) Direct spray treatment: Product was sprayed directly on the woodlice for 2 seconds from a distance of 40 cm.  b) Residual effects: Ceramic or PVC tiles (19.5 × 19.5 cm) were sprayed with the product for 2 seconds (distance of 40 cm). | x  x |
| * + 1. Test conditions | Climatic conditions:  Temperature: a, b) 20 – 25 °C  Light cycles during test: a, b) Natural daylight  Type of test chamber:  a) Petri dishes (145 mm diameter, 20 mm height), after 2 hours transfer of test animals to other petri dishes (90 mm diameter, 15 mm height), containing a moistened paper circle, a carrot slice and a shelter (moistened piece of paper formed as cave).  b) Ceramic or PVC tiles (19.5 × 19.5 cm) were placed inside covered plastic boxes (20 × 20 cm × 7 cm), the gap between edge of tile and plastic box was sealed up with adhesive tape. |  |
| * + 1. Duration of the test / Exposure time | 26 weeks |  |
| * + 1. Number of replicates performed | a, b) 5 replicates |  |
| * + 1. Controls | Yes, untreated controls: a, b) 5 replicates |  |
| * 1. Examination |  |  |
| * + 1. Effect investigated | a, b) Knock-down and mortality |  |
| * + 1. Method for recording / scoring of the effect | Visual observation of test animals |  |
| * + 1. Intervals of examination | a) 15 min, 30 min, 1 h, 2 h, 24, 48 and 72 hours  b) Intervals of examination: evaluation of knock down and mortality was done after 15 and 30 min as well as 1, 2, 6, 12, 24, 48 and 72 hours  Ceramic tiles: Assessment of residues aged 1 day as well as 1, 2, 4, 6, 9, 13, 17, 21 and 25 weeks after treatment,  PVC tiles: Assessment of residues aged 1 day as well as 1, 2, 4, 6, 9, 14, 18, 22 and 26 weeks after treatment |  |
| * + 1. Statistics | – |  |
| * + 1. Post monitoring of the test organism | No |  |
|  | 1. Results |  |
| * 1. Efficacy |  |  |
| * + 1. Dose/Efficacy curve | *–* |  |
| * + 1. Begin and duration of effects | a) Direct spray treatment:  70% knock down efficacy was given within 15 minutes. After 24 hours mortality was 100%.  b) Residual effects on glazed tiles:  It took 2 h (for residues aged 1 or 2 weeks) up to 6 h (for all other residues) to achieve 100% of efficacy (knock down and / or mortality).  Residual effects on PVC:  The efficacy was weaker. It took 1 h (for residues aged 1 day or 1 week) or up to 24 h (for residues aged 22 weeks) to achieve 100% of efficacy (knock down and / or mortality). |  |
| * 1. Tabular and/or graphical presentation of the summarised results | Graphical presentation of the results is shown in the report. |  |
| * 1. Efficacy limiting factors | – |  |
| * + 1. Occurrences of resistances | Due to the mode of action a development of resistance is neither to be expected nor has ever been observed. |  |
| * + 1. Other limiting factors | Not applicable |  |
|  | 1. Relevance of the results compared to field conditions |  |
| * 1. Reasons for laboratory testing | It is easier and more precisely to test a product against woodlice in a laboratory arena. The conditions are comparable and controllable; the number of organisms is defined. The observations and counting are easier and more correct. |  |
| * 1. Intended actual scale of biocide application | For application in and around domestic and commercial premises. |  |
| * 1. Relevance compared to field conditions |  |  |
| * + 1. Application method | Yes, applied according to the label recommendations. |  |
| * + 1. Test organism | Yes, woodlice Porcellio scaber as would be encountered under field conditions. |  |
| * + 1. Observed effect | A complete efficacy against woodlice could be determined. |  |
| * 1. Relevance for read-across | Yes |  |
|  | 1. Applicant's Summary and conclusion |  |
| * 1. Materials and methods | Assessment of the efficacy of speciality products under laboratory conditions to control woodlice by measuring the knock down effect and mortality after direct spray treatment and assessing the residual effects (up to 26 weeks) after spraying of ceramic or PVC tiles. | x |
| * 1. Reliability | 2 | x |
| * 1. Assessment of efficacy, data analysis and interpretation | In the conditions of the trial, COM 116 02 I AL (spray) has proved a complete and fast efficacy towards the woodlice species Porcellio scaber. |  |
| * 1. Conclusion | The results show that COM 116 02 I AL has a complete and fast efficacy against Porcellio scaber. |  |
| * 1. Proposed efficacy specification | *–* |  |

| Section B5.10 Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6 | Efficacy Data  5.10. Effects on target organisms (PT 18; Study 5) |  |
| --- | --- | --- |
|  |  |  |
|  | Evaluation by Competent Authorities |  |
|  | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |  |
|  | **Evaluation by Rapporteur Member State** | |
| **Date** | July 2015 | |
| **Comments** | 2.3.3 Application of TS: 2 seconds spray corresponds to an application of 2.8g product (information of the applicant)  5.1 5.1 Materials and methods Ceramic tiles were assessed for a maximum of 25 and 26 weeks, respectively. In both cases all test animals were reported as dead after 12 h  5.2. Reliability: Agreed, because of the weak documentation. | |
| **Summary and conclusion** | Agree with applicant´s version. | |

## Confidential annex

See final PAR COM 116 02 I AL confidential Annex

## Other

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. [↑](#footnote-ref-2)
2. In case the product would have more than one name, all names can be provided in this field, if the other elements of the SPC are identical. Otherwise additional SPCs would have to be provided (one SPC per name). [↑](#footnote-ref-3)
3. Committee for veterinary Medicinal Products, Cyhalothrin, Summary Report, 2001, EMEA/MRL/699/99-Final (http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/document/document\_detail.jsp?webContentId=WC500013070&mid=) [↑](#footnote-ref-4)
4. EU Pesticides data base, Reg. (EU) No 834/2013, (http://ec.europa.eu/sanco\_pesticides/public/?event=pesticide.residue.CurrentMRL&language=EN&pestResidueId=140) [↑](#footnote-ref-5)
5. 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. [↑](#footnote-ref-6)
6. 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. [↑](#footnote-ref-7)
7. Technical Guidance Document on Risk Assessment. European Commission Joint Research Centre, EUR 20418 [↑](#footnote-ref-8)
8. 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. [↑](#footnote-ref-9)
9. European Commission, 2002: Guidance document on risk assessment for birds and mammals under council directive 91/414/EEC; SANCO/4145 2002 [↑](#footnote-ref-10)