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

**DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)

****

Mirmex GR

Product type 18

Cypermethrin as included in the Union list

of approved active substances

Case Number in R4BP: BC-FX059378-01

Evaluating Competent Authority: Greece

Date: June 2022

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# CONCLUSION

**Conclusion for Physico-chemistry:**

Mirmex is a granule insecticide (PT 18), containing nominal (pure) active ingredient of 0.6 % w/w cypermethrin.

Its physicochemical properties are considered acceptable for granular product. The product is not expected to have explosive or oxidising properties, nor to be self-heating or flammable; thus has no classification according to CLP criteria.

Acceptable data from accelerated storage stability study indicate that the product is anticipated to be stable for up to two years at ambient temperature when stored in the proposed commercial packaging.

Acceptable analytical method was provided for the determination of the four isomers of the active substance in the formulation.

**Post-authorization data requirement:** The long term storage stability study at ambient temperature should be provided, for the product Mirmex GR, when completed.

**Conclusion for Efficacy:**

Based on the results of the submitted efficacy lab and field studies, the product was proved efficacious as:

* Crack and crevice treatment by professionals and non-professionals, indoors for the control of ants (*Lasius niger,* workers), and outdoors around buildings, at sites protected from the rain, for the control of ants (*Lasius niger,* workers and nests) by spreading the granules of the product at 8 g/m2. The product has a residual period of 4 weeks. After the non-professional use, knockdown of ant workers is expected within 60 minutes after exposure of insects to the treated surfaces (Intented uses 1 & 2).
* Ant nest treatment by professionals and non-professionals, indoors and outdoors around buildings, for the control of ants (*Lasius niger,* workers and nests) by spreading of granules onto the nest, and for the control of ants (*Lasius niger,* workers) by application of wet product (after dilution of 8 g product in 4 ml water) onto the nest at 8 g product/nest. The product has a residual period of 4 weeks. After the non-professional use, knockdown of ant workers is expected within 60 minutes after exposure of insects to the treated surfaces (Intented uses 3 & 4).

**Conclusion for Human Health:**

Regarding human health hazards the biocidal product Mirmex GR should not be classified.

Regarding risk assessment, the primary exposure of trained professional and non-professional users does not entail unacceptable risk for human health.

With respect to secondary exposure of the general public, a risk has been identified for infants and toddlers entering into treated areas and touching with their hands the contaminated surfaces. A specific risk mitigation measure is proposed to be included in the product label, hence, no concern arises for this population group.

**Conclusion for Environment:**

According to the environmental risk assessment, the risk for all relevant environmental compartments (STP, terrestrial, aquatic, primary and secondary poisoning) is acceptable when the product is used for all indoor and outdoor uses (except nest treatment), according to label instruction.

Nest treatment (Scenario 5) **cannot be authorised** since the risk assessment for the terrestrial compartment is unacceptable.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| Identifier[[1]](#footnote-1) | Country (if relevant) |
| --- | --- |
| Mirmex GR | Greece |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| Name and address of the authorisation holder | Name | VEBI ISTITUTO BIOCHIMICO SRL |
| Address | VIA DESMAN 43, 35010 BORGORICCO (PD) |
| Authorisation number |  | |
| Date of the authorisation |  | |
| Expiry date of the authorisation |  | |

#### Manufacturer of the product

|  |  |
| --- | --- |
| Name of manufacturer | VEBI ISTITUTO BIOCHIMICO SRL |
| Address of manufacturer | VIA DESMAN 43, 35010 BORGORICCO (PD) |
| Location of manufacturing sites | VIA DESMAN 43, 35010 BORGORICCO (PD) |

#### Manufacturer of the active substance

|  |  |
| --- | --- |
| Active substance | CYPERMETHRIN TECHNICAL 40/60 |
| Name of substance supplier (according to art. 95) | LIMARU NV (acting for Tagros Chemicals India Ltd) |
| Address of substance supplier (according to art. 95) | Business Center Mezzo  Paalsesteenweg 170 Bus 7,  B-3583 BERINGEN, Belgium |
| Name of manufacturer | Tagros Chemicals India Private Ltd. |
| Address of manufacturer | “Jhaver Centre”, Rajah Annamalai Building, IV Floor, 72, Marshalls Road, 600 008 Egmore, Chennai, India |
| Location of manufacturing site | A-4/1 & 2, Sipcot Industrial Complex,  Pachayankuppam, Cuddalore,  607 005, Tamil Nadu, India  The address of the manufacturing plant for the active substance has been evaluated in the technical equivalence of Tagros Chemicals. |

### Product composition and formulation

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

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

Yes

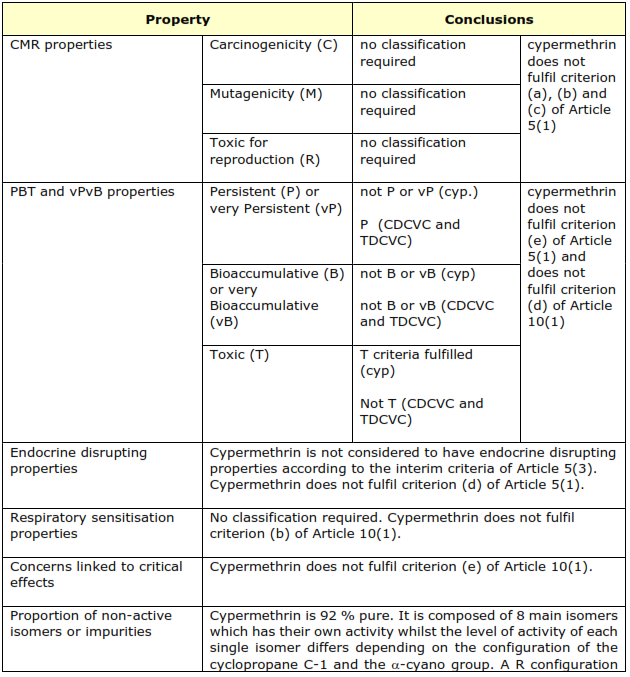
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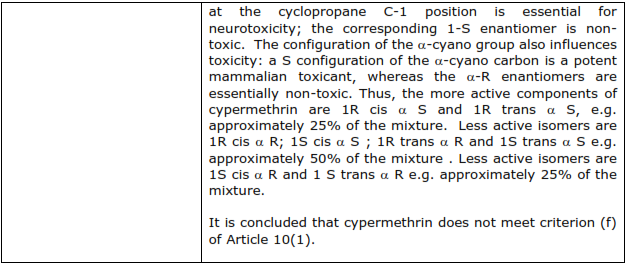
#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | CYPERMETHRIN TECHNICAL 40/60 |
| **IUPAC or EC name** | (RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; alphacyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; cyclopropanecarboxylic acid,  3(2,2-dichloroethenyl)-2,2-dimethyl-, cyano(3-phenoxyphenyl)methyl ester; cypermethrin cis/trans +/-  Cis/trans 40/60; cypermethrin, technical |
| **EC number** | 257-842-9 |
| **CAS number** | 52315-07-8 |
| **Index number in Annex VI of CLP** | 607-421-00-4 |
| **Minimum purity / content** | Minimum purity according to Commission Implementing Regulation (EU) 2018/1130: 92% w/w  Minimum purity from the technical of source used for the preparation of the product Mirmex: 95 % w/w (Tagros) |
| **Structural formula** |  |
| **Molecular weight** | 416.3 g/mol |
| **Molecural formula** | C22H19Cl2NO3 |

#### Candidate(s) for substitution

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

******

******

Cypermethrin does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012. Cypermethrin does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

Results from Opinion on the application for approval of the active substance (ECHA/BPC/153/2017):

Cypermethrin does not meet the conditions laid down in Article 10 of Regulation (EU) No. 528/2012, and is therefore not considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the “Note on the principles for taking decisions on the approval of active substances under the BPR” and in line with “Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR” agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation No. 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1) (a, b, d, e and f).

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content** |
| --- | --- | --- | --- | --- | --- |
| Cypermethrin  (min. purity 95% w/w) | (RS)-α-cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopro-panecarboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.6 % w/w  (pure)  0.632 % w/w  (technical) |
| Acetic acid | acetic acid | pH adjuster | 64-19-7 | 200-580-7 | 0.012 % w/w |
| Non-active substance | Confidential information. Please refer to the confidential information annex | | | | Up to 100 |

#### Information on technical equivalence

The source of the active substance cypermethrin in MIRMEX GR biocidal formulation is Tagros Chemicals India Ltd., which has been assessed to be technical equivalent to the reference source by ECHA on December 2020 (case number BC-UA059575-34, decision number TAP-D-1477453-13-00/F).

The active substance supplier LIMARU NV is the approved supplier of Cypermethrin active substance in accordance with Article 95 of Regulation (EU) No. 528/2012. The respective Letter of Access/Supply has been submitted.

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

|  |  |
| --- | --- |
| IUPAC name or other accepted chemical name | Acetic acid |
| EC number | 200-580-7 |
| CAS number | 64-19-7 |
| Concentration (minimum and maximum, g/kg or g/l) | ≤ 0.12 g/kg |
| Classification and Labelling according to Regulation (EC) No 1272/2008: | Flam. Liq. 3, H226  Skin Corr. 1A, H314  Eye Damage 1, H318 |
| Relevant toxicological/ecotoxicological information | European IOEL according to Commission Directive (EU) 2017/164:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | LIMIT VALUES | | | | Notation | | 8 hours | | Short-term | | | mg/m3 | ppm | mg/m3 | ppm | | 25 | 10 | 50 | 20 | - | |
| Other grounds for concern | Not expected to have PBT, vPvB, POP and ED properties. |

Please see the Confidential Annex for further details.

#### Type of formulation

|  |
| --- |
| GR - Granule |

### Hazard and precautionary statements[[2]](#footnote-2)

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

| Classification | |
| --- | --- |
| Hazard category | Aquatic Acute category 1  Aquatic Chronic category 1 |
| Hazard statement | H400: Very toxic to aquatic life.  H410: Very toxic to aquatic life with long lasting effects. |
|  | |
| Labelling | |
| Signal words | Warning GHS09 |
| Hazard statements | H410 Very toxic to aquatic life with long lasting eﬀects. |
| Precautionary statements | P101 If medical advice is needed, have product container or label at hand.  P102 Keep out of reach of children.  P103 Read label before use.  P273 Avoid release to the environment.  P391 Collect spillage.  P501 Dispose of contents and container in accordance with applicable regulations. |
|  | |
| Special provisions: | ND |
| Contains | - |
| Note | - |

### Authorised use(s)

#### General public

Table 1. Use # 1 – General public

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | For the control of ants (workers and nests) indoors  For the control of ants (workers) outdoors around buildings only on terraces and balconies |
| **Target organism (including development stage)** | Lasius niger Ants Adults |
| **Field of use** | Indoor, outdoor around building |
| **Application method(s)** | Spreading  Ready to use product  Crack and crevice treatment.  For indoor use: Apply in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities (partition between walls, holes, etc.).  For outdoor around building treatment: Apply in cracks and crevices only on paved surfaces and roof covered areas (protected from rain) on terraces and balconies. |
| **Application rate(s) and frequency** | 8 g/m2  Treatment can be performed up to 2 times per year with a minimum interval of 4 weeks between applications. |
| **Category(ies) of users** | General public (non-professionals) |
| **Pack sizes and packaging material\** | Envelope:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 350 g  Envelope material:  -plastic: PP MAT20 + PET MET 12 + PE45  -plastic: PP 25+PET MET 12 +PE60  -plastic: PP MAT20 + PET MET 12 + PE60  -plastic: PP25+PE80  -plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 350 g  bottle : LDPE, HDPE  cap:PP; LDPE  Bottle with applicator:  50 g, 100 g, 150 g, 200g, 250 g, 300 g, 350 g,  bottle: HDPE  cap: PP; LDPE |

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

|  |
| --- |
| The product is a granule against ants formulated with micro-encapsulated cypermethrin.  8 grams of product equals to 2 teaspoons approximately. Disposable or dedicated teaspoon should be used.  A careful pre-detection of the areas where the insects use to pass or hidden increases the efficacy of the treatment. Particular care should be taken for dark and warm places, in basements and warehouses. Also, in areas around water pipes, heating and ventilation, under cupboards and other bulky items.  Always read the label or package leaflet before use and follow all instructions provided.  If the infestation persists despite the instructions on the label, contact a pest control operator.  Knockdown of ant workers is expected within 60 minutes after exposure of insects to the treated surfaces.  The product has a residual period of 4 weeks.  Remove (clean) product after the residual period.  Remove dead insects after the treatment. |

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

|  |
| --- |
| Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For indoor use, the product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc). Do not apply to areas susceptible to routine wet cleaning.  For around building treatment: apply only on paved surfaces and roof covered area. Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| The product contains: cypermethrin. May cause paraesthesia.  IF ON SKIN: If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  There is no antidote, symptomatic treatment is advised.  No adverse effects expected when comply with the instructions for use.  Poison center phone number:  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

##### 

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

|  |
| --- |
| Waste treatment methods:  • Dispose of waste and residues in accordance with local authority requirements.  • Do not allow runoff to sewer, waterway or ground.  Residues and empty containers should be taken care of as hazardous waste according to local and national provisions. |

##### 

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

|  |
| --- |
| Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, animals, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

#### Professional user

Table 2. Use # 2 – Professional user

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | For the control of ants (workers and nests) indoors  For the control of ants (workers) outdoors around buildings only on terraces and balconies. |
| **Target organism (including development stage)** | Lasius niger Ants Adults |
| **Field of use** | Indoor, outdoor around building |
| **Application method(s)** | Spreading  Ready to use product  Crack and crevice treatment.  For indoor use:  Apply in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities (partition between walls, holes, etc.).  For outdoor around building treatment: Apply in cracks and crevices only on paved surfaces and roof covered areas (protected from rain) on balconies and terraces. |
| **Application rate(s) and frequency** | 8 g/m2  Treatment can be performed up to 2 times per year with a minimum interval of 4 weeks between applications. |
| **Category(ies) of users** | Trained professional\* |
| **Pack sizes and packaging material\** | Envelope:  0.5 kg, 1 kg, 1.5 kg, 2 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  -plastic: PP MAT20 + PET MET 12 + PE45  -plastic: PP 25+PET MET 12 +PE60  -plastic: PP MAT20 + PET MET 12 + PE60  -plastic: PP25+PE80  -plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 375 g 500 g, 750 g, 1000 g  bottle : LDPE, HDPE  cap:PP; LDPE  Bottle with applicator:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 375 g 500 g, 750 g  bottle: HDPE  cap: PP; LDPE  Bucket CPP:  5 Kg, 10 Kg |

\* It is noted that in Greece the users of biocidal products are either licensed professionals (i.e., trained) or non-professionals (amateur users). There is no separate risk assessment conducted for the category of professional users (other than pest control operators) that may be allowed to use the biocidal products in the context of their profession. It is noted, however, that for MS where the category of professional users is relevant, the risk assessment might be considered as covered either from the risk assessment conducted for the trained professional users or the non-professional ones.

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

|  |
| --- |
| Do not mix with other chemicals or products.  The product is a granule against ants formulated with micro-encapsulated cypermethrin.  8 grams of product equals to 2 teaspoons approximately. Disposable or dedicated teaspoon should be used.  Always read the label or package leaflet before use and follow all instructions provided.  The product has a residual period of 4 weeks.  Remove (clean) product after the residual period.  Remove dead insects after the treatment. |

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

|  |
| --- |
| Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For indoor use, the product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc).  Do not apply to areas susceptible to routine wet cleaning.  For around building treatment: apply only on paved surfaces and roof covered area.  Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  In case of use with applicator tool: Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| The product contains: cypermethrin. May cause paraesthesia.  IF ON SKIN: If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  There is no antidote, symptomatic treatment is advised.  No adverse effects expected when comply with the instructions for use.  Poison center phone number:  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

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

|  |
| --- |
| When use non-disposable (reusable) equipment: clean equipment with damp paper and after cleaning dispose the paper used for cleaning in solid wastes.  Waste treatment methods:  • Dispose of waste and residues in accordance with local authority requirements.  • Do not allow runoff to sewer, waterway or ground.  Residues and empty containers should be taken care of as hazardous waste according to local and national provisions. |

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

|  |
| --- |
| Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, animals, food or feed.  Avoid light and sunlight exposure  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

### General directions for use

#### Instructions for use

|  |
| --- |
| The product is a granule against ants formulated with micro-encapsulated cypermethrin.  Always read the label or package leaflet before use and follow all instructions provided.  A careful pre-detection of the areas where the insects use to pass or hidden increases the efficacy of the treatment. Particular care should be taken for dark and warm places, in basements and warehouses. Also, in areas around water pipes, heating and ventilation, under cupboards and other bulky items.  Do not mix with other chemicals or products.  Remove (clean) product after the residual period. Remove dead insects after the treatment.  Strategies for managing the development of resistance:  - Where possible, application treatments should be recommended to be combined with non-chemical measures.  - Where an extended period of control is required, treatments should be alternated with products containing active substances with different mode of action.  - In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing active substances with the same mode of action should cease.  - The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management. |

#### 

#### Risk mitigation measures

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| --- |
| Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  For indoor use,  the product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc). Do not apply to areas susceptible to routine wet cleaning.  For around building treatment: apply only on paved surfaces and roof covered area.  Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| The product contains: cypermethrin. May cause paraesthesia.  IF ON SKIN: If symptoms occur call a POISON CENTRE or a doctor.  IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.  There is no antidote, symptomatic treatment is advised.  No adverse effects expected when comply with the instructions for use.  Poison center phone number:  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

#### 

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

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| --- |
| Waste treatment methods:  • Dispose of waste and residues in accordance with local authority requirements.  • Do not allow runoff to sewer, waterway or ground.  Residues and empty containers should be taken care of as hazardous waste according to local and national provisions. |

#### 

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

|  |
| --- |
| Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, animals, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature. |

### Other information

|  |
| --- |
| The product contains the following nanomaterial: ‘’Silicon dioxide, chemically prepared (nano)’.’ |

### 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)** |
| Plastic envelope | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 350 g | PP MAT20 + PET MET 12 + PE45 | heat-sealed | General public (non-professional) | Yes |
| Plastic envelope | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 350 g | PP 25+PET MET 12 + PE60 | heat-sealed | General public (non-professional) | Yes |
| Plastic envelope | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 350 g | PP MAT20 + PET MET 12 + PE60 | heat-sealed | General public (non-professional) | Yes |
| Plastic envelope | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 350 g | PP25+PE80 | heat-sealed | General public (non-professional) | Yes |
| Plastic envelope | 50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 350 g | PP25 + PET12+ PE60 | heat-sealed | General public (non-professional) | Yes |
| Spreader Bottle | 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 350 g | bottle: LDPE, HDPE  cap: PP; LDPE | Pressure cap with spreader | General public (non-professional) | Yes |
| Bottle with applicator | 50 g, 100 g, 150 g, 200g, 250 g, 300g, 350 g | bottle: HDPE  cap: PP; LDPE | Pressure cap with tip applicator | General public (non-professional) | Yes |
| Plastic envelope | 0.5 kg, 1 kg, 1.5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg | PP MAT20 + PET MET 12 + PE45 | heat-sealed | Trained professional | Yes |
| Plastic envelope | 0.5 kg, 1 kg, 1.5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg | PP 25 + PET MET 12 + PE60 | heat-sealed | Trained professional | Yes |
| Plastic envelope | 0.5 kg, 1 kg, 1.5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg | PP MAT20 + PET MET 12 + PE60 | heat-sealed | Trained professional | Yes |
| Plastic envelope | 0.5 kg, 1 kg, 1.5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg | PP25+PE80 | heat-sealed | Trained professional | Yes |
| Plastic envelope | 0.5 kg, 1 kg, 1.5 kg, 2.0 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg | PP25+PET12+  PE60 | heat-sealed | Trained professional | Yes |
| Spreader Bottle | 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g, 750 g, 1000 g | bottle: LDPE, HDPE  cap: PP; LDPE | Pressure cap with spreader | Trained professional | Yes |
| Bottle with applicator | 50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g, 750 g | bottle: HDPE  cap: PP; LDPE | Pressure cap with tip applicator | Trained professional | Yes |
| Bucket | 5 kg, 10 kg | CPP (Copolymer Polypropylene) | Pressure cap with seal | Trained professional | Yes |

Please refert to IUCLID section 12 for additional details about packaging.

|  |
| --- |
| **Conclusion on the packaging of the biocidal product** |
| Accelerated storage stability test for 14 days at 54°C demonstrated compatibility with the packaging material plastic envelope from PP MAT20 + PET MET 12 + PE45. A statement has been submitted by the applicant regarding the effect of stacking for the flexible packages.  According to Guidance on the BPR (Volume I Parts A+B+C) for solid preparations extrapolation to all types of packaging is acceptable.Therefore, all the above-mentioned proposed packaging is considered acceptable for commercial use. |

### Documentation

#### Data submitted in relation to product application

Data on the active substance are available through Letter of access (IUCLID, section 13). Data on the product are available in theIUCLID dossier and are listed in Annex 3.1 to this document.

#### Access to documentation

The applicant submits the Letter of Access granted by the manufacturers of the active substance; this cover the studies owned by the companies and other information that have been used for including the active substance in the Union list of approved active substances under the Biocidal Products Regulation.

With such Letter of Access the applicant is authorized to use, refer to and rely on active substance data in order to apply for the authorization of the biocidal product.

## Assessment of the biocidal product

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

**Table 1. Use # 1 – General public**

|  |  |
| --- | --- |
| Product Type | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of ants (workers and nests) - General public – |
| Target organism (including development stage) | Lasius niger Ants Adults |
| Field of use | Indoor, outdoor around building |
| Application method(s) | Spreading  Ready to use product  Crack and crevice treatment. Voids and cavities  Apply in thin layers in cracks and crevices (under furniture, in corners and other hiding places) |
| Application rate(s) and frequency | 8g/m2  Crack and crevice treatment: The application rate is 8 g/m².​  Treatment can be performed up to 2 times per year with a minimum interval of 4 weeks between applications. |
| Category(ies) of users | General public (non-professional) |
| Pack sizes and packaging material\ | Envelope:  50 g, 100 g, 150 g, 200 g, 300 g, 400 g, 250 g, 500 g, 1000 g  Envelope material:  -plastic: PP MAT20 + PET MET 12 + PE45  -plastic: PP 25+PET MET 12 +PE60  -plastic: PP MAT20 + PET MET 12 + PE60  -plastic: PP25+PE80  -plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 375 g, 500 g, 750 g, 1000 g  bottle : LDPE, HDPE  cap:PP; LDPE  Bottle with applicator:  50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g  bottle: HDPE  cap: PP; LDPE |

#### Instructions for use

|  |
| --- |
| The product is a granule against ants formulated with micro-encapsulated cypermethrin. The special formulation attract and kill ants present nearby.  A careful pre-detection of the areas where the insects use to pass or hidden increase the efficacy of the treatment. Particular care should be taken for dark and warm places, in basements and warehouses. Also, in areas around water pipes, heating and  ventilation, under cupboards and other bulky items.  Apply 8 g/m2 of product in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities(partition between walls, holes, etc...).  Always read the label or package leaflet before use and follow all instructions provided.  If the infestation persists despite the instructions on the label, contact a pest control operator. Remove (clean) product and dead insects, when the presence of live insects is stopped.  The product has a residual period of 4 weeks. |

#### Risk mitigation measures

|  |
| --- |
| Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  The application is allowed only in areas that are not usually wet cleaned.  Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| The product contains: cypermethrin. May cause paraesthesia  IF ON SKIN: Wash with plenty of water and soap. If skin irritation or rashoccurs: Get medical advice/attention. Wash contaminated clothing before reusing them.  IF IN EYES: Rinse cautiously with water for several minutes. Seek medical advice if irritation develops. No adverse effects expected when comply with the instructions for use.  IF INHALED: Remove person to fresh air. If symptoms persist, seek medical advice. No adverse effects expected when comply with the instructions for use.  IF SWALLOWED: Rinse mouth. Get medical advice. There is no antidote, symptomatic treatment is advised. No adverse effects expected when comply with the instructions for use.  Poison center phone number:  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

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

|  |
| --- |
| Waste treatment methods:  • Dispose of waste and residues in accordance with local authority requirements.  • Do not allow runoff to sewer, waterway or ground.  Residues and empty containers should be taken care of as hazardous waste according to local and national provisions. |

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

|  |
| --- |
| Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, animals, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature |

**Table 2. Use # 2 – Professional user**

|  |  |
| --- | --- |
| Product Type | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of ants (workers and nests) – professional user |
| Target organism (including development stage) | Lasius niger Ants Adults |
| Field of use | Indoor, outdoor around building |
| Application method(s) | Spreading  Ready to use product  Crack and crevice treatment. Voids and cavities  Apply in thin layers in cracks and crevices (under furniture, in corners and other hiding places). |
| Application rate(s) and frequency | 8g/m2  Dilution %: 0.  Crack and crevice treatment: The application rate is 8 g/m².​  Treatment can be performed up to 2 times per year with a minimum interval of 4 weeks between applications. |
| Category(ies) of users | Industrial Trained professional Professional |
| Pack sizes and packaging material\ | Envelope:  0.5 kg, 1 kg, 1.5 kg, 2 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  -plastic: PP MAT20 + PET MET 12 + PE45  -plastic: PP 25+PET MET 12 +PE60  -plastic: PP MAT20 + PET MET 12 + PE60  -plastic: PP25+PE80  -plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 375 g 500 g, 750 g, 1000 g  bottle : LDPE, HDPE  cap:PP; LDPE  Bottle with applicator:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 375 g 500 g, 750 g  bottle: HDPE  cap: PP; LDPE  Bucket CPP:  5 Kg, 10 Kg |

#### Instructions for use

|  |
| --- |
| Codes of good practice should be followed. Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated. Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).Avoid exclusive repeated use of insecticides from the same chemical subgroup, alternate products containing active substances with different mode of action Do not mix with other chemicals or products. If the infestation persists despite the instructions on the label, you are probably dealing with a resistant population. We suggest using a non-pyrethroid active ingredient The product is a granule against ants formulated with micro-encapsulated cypermethrin. The special formulation attract and kill ants present nearby. It is intended to be used as it is. Apply 8 g/m2  of product in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities(partition between walls, holes, etc...) Always read the label or package leaflet before use and follow all instructions provided. Remove (clean) product and dead insects, when the presence of live insects is stopped.  The product has a residual period of 4 weeks. |

#### Risk mitigation measures

|  |
| --- |
| Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for  the feeding of livestock.  The application is allowed only in areas that are not usually wet cleaned.  Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  In case of use with applicator tool:Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| The product contains: cypermethrin. May cause paraesthesia  IF ON SKIN: Wash with plenty of water and soap. If skin irritation or rashoccurs: Get medical advice/attention. Wash contaminated clothing before reusing them.  IF IN EYES: Rinse cautiously with water for several minutes. Seek medical advice if irritation develops. No adverse effects expected when comply with the instructions for use.  IF INHALED: Remove person to fresh air. If symptoms persist, seek medical advice. No adverse effects expected when comply with the instructions for use.  IF SWALLOWED: Rinse mouth. Get medical advice. There is no antidote, symptomatic treatment is advised. No adverse effects expected when comply with the instructions for use.  Poison center phone number:  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

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

|  |
| --- |
| When use non-disposable (reusable) equipment: clean equipment with damp paper and after cleaning dispose the paper used for cleaning in solid wastes.  Waste treatment methods:  • Dispose of waste and residues in accordance with local authority requirements.  • Do not allow runoff to sewer, waterway or ground.  Residues and empty containers should be taken care of as hazardous waste according to local and national provisions. |

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

|  |
| --- |
| Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, animals, food or feed.  Avoid light and sunlight exposure.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature |

**Table 3. Use # 3 – General public-treatment of nest**

|  |  |
| --- | --- |
| Product Type | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of ants (workers and nests) - General public – |
| Target organism (including development stage) | Lasius niger Ants Adults |
| Field of use | Indoor, outdoor around building |
| Application method(s) | **Spreading**  Ant nest treatment: Apply 8 g of product in a thin layers around and on nest entrances. If ants appear from multiple entrance holes, the total amount of granules (8 g) must be divided for the number of entrance (for example if 4 entrances are present on the nest apply 2 g of product/ entrance).  Remove (clean) product and dead insects, when the presence of live insects is stopped.  **Other:Application of wet product**  Direct application of wet product  Ant nest treatment : Apply 12 g of diluted product (equivalent to 8 g of non diluted product) in thin layers on nest entrances.  If ants appear from multiple entrance holes, the total amount of product must be divided for the number of entrance.  In situations of reduced availability of water, a moistened product may have a higher efficacy than the granule as it is.  Add 4 g of warm water to 8 g of product and mix gentle with a disposable stick. The mixture thus obtained will have the appearance of a mush, that can be distributed. |
| Application rate(s) and frequency | 8 g nest  Nest treatment: The application rate is 8 g/nest.​  Treatment can be performed up to 2 times per year with a minimum interval of 4 weeks between applications. |
| Category(ies) of users | General public (non-professional) |
| Pack sizes and packaging material\ | Envelope:  50 g, 100 g, 150 g, 200 g, 300 g, 400 g, 250 g, 500 g, 1000 g  Envelope material:  -plastic: PP MAT20 + PET MET 12 + PE45  -plastic: PP 25+PET MET 12 +PE60  -plastic: PP MAT20 + PET MET 12 + PE60  -plastic: PP25+PE80  -plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 375 g, 500 g, 750 g, 1000 g  bottle : LDPE, HDPE  cap:PP; LDPE  Bottle with applicator:  50 g, 100 g, 150 g, 200g, 250 g, 300 g, 375 g, 500 g  bottle: HDPE  cap: PP; LDPE |

#### Instructions for use

|  |
| --- |
| The product is a granule against ants formulated with micro-encapsulated cypermethrin. The special formulation attract and kill ants present nearby.  It is intended to be used as it is or after dilution in water.  A careful pre-detection of the areas where the insects use to pass or hidden increase the efficacy of the treatment. Particular care should be taken for dark and warm places, in basements and warehouses. Also, in areas around water pipes, heating and ventilation, under cupboards and other bulky items.  For nest treatment: Apply 8 g of product in a thin layers around and on nest entrances. If ants appear from multiple entrance holes, treat all of them by evenly distributing the granules into all nest entries. If ants appear from multiple entrance holes, the total amount of granules must be divided for the number of entrance.  In situations of reduced availability of water, a moistened product may have a higher efficacy than the granule as it is. Add 4 g of warm water to 8 g of product and mix gentle with a disposable stick. The mixture thus obtained will have the appearance of a mush, that can be distributed.  Always read the label or package leaflet before use and follow all instructions provided.  If the infestation persists despite the instructions on the label, contact a pest control professional.  Remove (clean) product and dead insects, when the presence of live insects is stopped. |

#### Risk mitigation measures

|  |
| --- |
| Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.  The application is allowed only in areas that are not usually wet cleaned.  Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes |

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

|  |
| --- |
| The product contains: cypermethrin. May cause paraesthesia  IF ON SKIN: Wash with plenty of water and soap. If skin irritation or rashoccurs: Get medical advice/attention. Wash contaminated clothing before reusing them.  IF IN EYES: Rinse cautiously with water for several minutes. Seek medical advice if irritation develops. No adverse effects expected when comply with the instructions for use.  IF INHALED: Remove person to fresh air. If symptoms persist, seek medical advice. No adverse effects expected when comply with the instructions for use.  IF SWALLOWED: Rinse mouth. Get medical advice. There is no antidote, symptomatic treatment is advised. No adverse effects expected when comply with the instructions for use.  Poison center phone number:  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

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

|  |
| --- |
| Waste treatment methods:  • Dispose of waste and residues in accordance with local authority requirements.  • Do not allow runoff to sewer, waterway or ground.  Residues and empty containers should be taken care of as hazardous waste according to local and national provisions. |

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

|  |
| --- |
| Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, animals, food or feed.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature |

**Table 4. Use # 4 – Professional-nest treatment**

|  |  |
| --- | --- |
| Product Type | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | For kill and control of ants (workers and nests) - professional |
| Target organism (including development stage) | Lasius niger Ants Adults |
| Field of use | Indoor, outdoor around building |
| Application method(s) | **Spreading**  Ant nest treatment: Apply 8 g of product in a thin layers around and on nest entrances. If ants appear from multiple entrance holes, the total amount of granules (8 g) must be divided for the number of entrance (for example if 4 entrances are present on the nest apply 2 g of product/ entrance).  Remove (clean) product and dead insects, when the presence of live insects is stopped.  **Other:Application of wet product**  Direct application of wet product  Ant nest treatment : Apply 12 g of diluted product (equivalent to 8 g of non diluted product) in thin layers on nest entrances.  If ants appear from multiple entrance holes, the total amount of product must be divided for the number of entrance.  In situations of reduced availability of water, a moistened product may have a higher efficacy than the granule as it is.  Add 4 g of warm water to 8 g of product and mix gentle with a disposable stick. The mixture thus obtained will have the appearance of a mush, that can be distributed. |
| Application rate(s) and frequency | 8 g nest of product.  Nest treatment: The application rate is 8 g/nest.​  Treatment can be performed up to 2 times per year with a minimum interval of 4 weeks between applications. |
| Category(ies) of users | Industrial Trained professional Professional |
| Pack sizes and packaging material\ | Envelope:  0.5 kg, 1 kg, 1.5 kg, 2 kg, 2.5 kg, 3 kg, 5 kg, 10 kg, 20 kg  Envelope material:  -plastic: PP MAT20 + PET MET 12 + PE45  -plastic: PP 25+PET MET 12 +PE60  -plastic: PP MAT20 + PET MET 12 + PE60  -plastic: PP25+PE80  -plastic: PP25+PET12+PE60  Spreader Bottle:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 375 g 500 g, 750 g, 1000 g  bottle : LDPE, HDPE  cap:PP; LDPE  Bottle with applicator:  50 g, 100 g, 150 g, 200 g, 250 g, 300 g, 375 g, 500 g, 750 g  bottle: HDPE  cap: PP; LDPE  Bucket CPP:  5 Kg, 10 Kg |

#### Instructions for use

|  |
| --- |
| Codes of good practice should be followed. Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated. Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).Avoid exclusive repeated use of insecticides from the same chemical subgroup, alternate products containing active substances with different mode of action Do not mix with other chemicals or products. If the infestation persists despite the instructions on the label, you are probably dealing with a resistant population. We suggest using a non-pyrethroid active ingredient.  The product is a granule against ants formulated with micro-encapsulated cypermethrin. The special formulation attract and kill ants present nearby. It is intended to be used as it is. Apply 8 g of product in a thin layers around and on nest entrances. If ants appear from multiple entrance holes, the total amount of granules (8 g) must be divided for the number of entrance (for example if 4 entrances are present on the nest apply 2 g of product/ entrance).  In situations of reduced availability of water, a moistened product may have a higher efficacy than the granule as it is. Add 4 g of warm water to 8 g of product and mix gentle with a disposable stick. The mixture thus obtained will have the appearance of a mush, that can be distributed.  The product has a residual period of 4 weeks. |

#### Risk mitigation measures

|  |
| --- |
| Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for  the feeding of livestock.  The application is allowed only in areas that are not usually wet cleaned.  Do not apply near bodies of surface water or in the area of water protection zones.  For use only in areas that are inaccessible to infants, children, companion and farm animals.  In case of use with applicator tool:Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor.  No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the damp papers used as solid wastes. |

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

|  |
| --- |
| The product contains: cypermethrin. May cause paraesthesia  IF ON SKIN: Wash with plenty of water and soap. If skin irritation or rashoccurs: Get medical advice/attention. Wash contaminated clothing before reusing them.  IF IN EYES: Rinse cautiously with water for several minutes. Seek medical advice if irritation develops. No adverse effects expected when comply with the instructions for use.  IF INHALED: Remove person to fresh air. If symptoms persist, seek medical advice. No adverse effects expected when comply with the instructions for use.  IF SWALLOWED: Rinse mouth. Get medical advice. There is no antidote, symptomatic treatment is advised. No adverse effects expected when comply with the instructions for use.  Poison center phone number:  Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes. |

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

|  |
| --- |
| When use non-disposable (reusable) equipment: clean equipment with damp paper and after cleaning dispose the paper used for cleaning in solid wastes.  Waste treatment methods:  • Dispose of waste and residues in accordance with local authority requirements.  • Do not allow runoff to sewer, waterway or ground.  Residues and empty containers should be taken care of as hazardous waste according to local and national provisions. |

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

|  |
| --- |
| Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, animals, food or feed.  Avoid light and sunlight exposure.  The product is stable for 2 years when stored in the original intact package, protected by light and sunlight exposure, and when stored at room temperature |

### Physical, chemical and technical properties

Test item MIRMEX GR (Batch no.: 909199 and LAB18012021) has been used for the submitted experimental test. Composition of the formulation MIRMEX GR is reported in the confidential section.

| **Property** | **Guideline and Method** | **Purity of the test substance**  **(% w/w)** | **Results** | **Reference** | **GLP** | **Acceptability** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C | Visual  OPPTS 830.6303 | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | Blue solid (granular) | CH-0127/2020 | Yes | Acceptable |
| Colour at 20 °C | Visual  OPPTS 830.6302 | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | Blue, (Shortcode BL 6) | CH-0127/2020 | Yes | Acceptable |
| Odour at 20 °C | Organoleptic method  OPPTS 830.6304 | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | characteristic odour | CH-0127/2020 | Yes | Acceptable |
| Acidity / alkalinity | CIPAC MT 75.3,  OECD No. 122 | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | 6.2 (1% w/v aqueous dispersion at 20°C; water HPLC grade)  Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed. | CH-0127/2020 | Yes | Acceptable |
| Bulk density | CIPAC MT 186 | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | Pour density: 0.90 g/mL  Bulk density: 0.98 g/mL | CH-0127/2020 | Yes | Acceptable |
| Storage stability test – accelerated storage | CIPAC MT 46 “Accelerated storage procedure”  (54°C for 14 days)  Please see table below for additional information on test methods. | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | From the obtained results it can be concluded that no significant change was found in the Cypermethrin active ingredient content, no change in the sample appearance, colour or odour, no loss of sample and no evidence on corrosion phenomena.  Moreover, no significant changes in physical properties (pH value, dustiness, particle size distribution by laser diffraction, dry sieve test and attrition resistance of dispersible granules) were found for the sample stored in the plastic composite envelope: PP MAT20 + PET MET 12 + PE45 for 14 days of storage at 54°C, comparing the obtained results at the beginning of the storage stability.  Please see table below for additional information on results.  **Substance of concern:**  Acetic acid has been considered a substance of concern in the formulation Mirmex GR.  No data submitted for the determination of substance of concern before and after storage in MIRMEX GR formulation. Furthermore, no analytical method for its determination is available.  **RefMS:** In general, storage stability data and analytical methods for the determination of identified substances of concern is a requirement according to Annex III Title I of the BPR Guidance. However, no further data are required since SoC cannot be formed during storage and its concentration remain unchanged. | CH-0151/2020 | Yes | Acceptable  No significant variation of physicochemical and technical properties appears during storage.  The biocidal product Mirmex GR is considered stable when stored in its initial commercial packaging under the tested accelerated storage conditions (54°C for 14 days). |
| Storage stability test – long term storage at ambient temperature | GIFAP Monograph No. 17, 2  edition, June 2009: Guidelines for Specifying the Shelf Life  of Plant Protection Products  36 months of storage at ambient warehouse  Temperature  Cypermethrin a.i. content:  Method No. 0128/2020  Appearance (Colour, odour and physical state):  OPPTS 830.6302  OPPTS; 830.6303;  OPPTS 830.6304  pH value (1% w/v aqueous dilution):  MT 75.3  Weight variation (%): technical balance  Compatibility (resistance) of the packaging material (corrosion characteristics): internal and external visual examination of the packaging  Dustiness of granular products – gavimetric method: CIPAC MT 171.1  Particle size distribution  (laser diffraction): CIPAC MT 187, OECD No. 110  Attrition resistance of dispersable granules CIPAC MT 178.2  Particle size distribution  (sieve analysis): CIPAC MT 59.2, CIPAC MT 170, OECD No. 110 | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | The study is ongoing.  Results will be added as soon as available. | Study Plan CH - 0152/2020 | Yes | The long-term storage stability study at ambient temperature is ongoing and should be submitted when completed, to confirm the proposed shelf-life of the biocidal product **(post authorisation data requirement)**  However, the acceptable accelerated storage stability test indicates that the product is anticipated to be stable for up to two years when stored in its initial commercial packaging. |
| Storage stability test – low temperature stability test for liquids |  |  | Not applicable since the product is solid. | - |  | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - light |  |  | Study waived: packaging material is not transparent and no effect of light is expected. Furthermore envelopes are made of a coextruded material which contains a metalized foil inside to protect the product from light. | - |  | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity | CIPAC MT 46 “Accelerated storage procedure”  (54°C for 14 days) | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | From the results obtained from the accelerated storage stability study for 2 weeks at 54°C, no change in active ingredient content was observed.  From the above reported data, it can be concluded that the formulation Mirmex GR is stable in its commercial packaging under the tested accelerated storage conditions. | CH-0151/2020 | Yes | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | CIPAC MT 46 “Accelerated storage procedure”  (54°C for 14 days) | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | From the results obtained from the accelerated storage stability study for 2 weeks at 54°C, no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena. | CH-0151/2020 | Yes | Acceptable |
| Wettability |  |  | Not applicable sinceThe product is a granular solid. | - |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable sinceThe product is a granular solid. | - |  |  |
| Wet sieve analysis and dry sieve test | CIPAC:  MT 59.2 (MT 58) “Sieve analysis”  MT 170 “Dry sieve analysis of water dispersible granules” | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number:  LAB18012021 | Granular material collected:  on 0.850 mm (850 µm) to 0.250 mm (250 µm) test sieves (inclusive): 99.42%.  Dust fraction collected:  through 0.250 mm (250 µm) and retained on 0.150 mm (150 µm) test sieve: 0.31% (\*);  through 0.150 mm (150 µm) in receiver pan (including loss during sieving): 0.27% (\*\*).  Apparent density after compaction without pressure:  0.91 g/mL (\*\*\*)  (\*) No more than 4%;  (\*\*) No more than 1%.  (\*\*\*) Not less than 0.4 g/mL | GLP Study No. CH – 0189/2021 | yes | Acceptable |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not applicable since the product is a granular solid. | - |  |  |
| Disintegration time |  |  | Not applicable, the product is not a tablet. | - |  |  |
| content of dust/fines, attrition, friability  Attrition resistance of  dispersible granules | CIPAC MT 178.2 | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | 99.97 % | CH – 0127/2020 | Yes | Acceptable |
| Particle size distribution | CIPAC MT 187;  OECD No. 110 | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | Dv 10 (µm): 509  Dv 50 (µm) also known as the Mass Median Diameter (MMD) or the median of the volume distribution: 802  Dv 90 (µm): 1330  % < 50 µm: 0.00%  % > 75 µm: 100.00 % | CH – 0127/2020 | Yes | Acceptable |
| Dustiness of granular products | CIPAC MT 171.1 | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | 2.0 mg (nearly dust-free) | CH – 0127/2020 | Yes | Acceptable |
| Persistent foaming |  |  | Not applicable, the product is a granular solid ready to use. | - |  | - |
| Flowability/Pourability/Dustability |  |  | Flowability: the product has not to be applied through application equipment that would subject the granules to pressure and/or heat.  Pourability: not applicable, the product is a granular solid.  Dustability: not applicable, the product is not a dust, but a granular solid. | - |  | - |
| Burning rate — smoke generators |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Burning completeness — smoke generators |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Composition of smoke — smoke generators |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Spraying pattern — aerosols |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Physical compatibility |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Chemical compatibility |  |  | Not applicable since the product is not intended to be used with other products. | - |  | - |
| Degree of dissolution and dilution stability |  |  | Not applicable since the product is not intended to be diluted. The possible dilution with water has just the intent to increase the palatability of the granules and water is not intended to dissolve the granules. | - |  | - |
| Surface tension |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Viscosity |  |  | Not applicable since the product is a granular solid. | - |  | - |

**Storage stability test – accelerated storage procedure MT 46 details:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Test** | **Guidelines**  **and Methods** | **Initial**  **characterisation**  (study report CH-127/2020) | **After 14 days**  **of storage at 54°C**  (study report CH-151/2020) |
| Packaging of the test items | -- | Plastic composite: PP MAT20 + PET MET 12 + PE45, 100 g | Plastic composite: PP MAT20 + PET MET 12 + PE45 |
| Weight variation (%) | By technical balance | - | Mean of 20 packs:  -0.12% |
| Cypermethrin active  ingredient content | Method No. 0128/2020 | 0.62 ± 0.01 % w/w  *Cis isomer:* 0.25 ± 0.01 % w/w  *Trans isomer:* 0.37 ± 0.01 % w/w  (study report CH-128/2020) | 0.63 ± 0.01 % w/w  *Cis isomer:* 0.25 ± 0.004 % w/w  *Trans isomer:* 0.38 ± 0.003 % w/w  **Delta** (%) from T0: 1.61 |
| Appearance  (Colour, odour and  physical state) (1) | OPPTS 830.6302;  OPPTS 830.6304;  OPPTS 830.6303 | Blue solid (granular)  with characteristic odour | Blue solid (granular)  with characteristic odour  (Shortcode BL 6) |
| Compatibility (resistance) of the packaging material | internal and external visual examination of the packaging | - | The pack didn’t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena |
| pH value (2)  (1% w/v aqueous dispersion at 20° C; water HPLC grade) | CIPAC MT 75.3,  OECD No. 122 | 6.2  Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed. | 6.6  Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed. |
| Dustiness of granular products | CIPAC MT 171.1 | 2.0 mg  (nearly dust-free) | 1.8 mg  (nearly dust-free) |
| Particle size distribution  (laser diffraction) | CIPAC MT 187,  OECD No. 110 | Dv 10 (μm): 509  Dv 50 (μm) (MMD): 802  Dv 90 (μm): 1330  % < 50 μm: 0.00%  % > 75 μm: 100.00 % | Dv 10 (μm): 555  Dv 50 (μm) (MMD): 866  Dv 90 (μm): 1410  % < 50 μm: 0.00%  % > 75 μm: 100.00 % |
| Attrition resistance of dispersible granules | CIPAC MT 178.2 | 99.97 % | 99.89 % |
| Wet sieve analysis and dry sieve test | CIPAC MT 59.2  CIPAC MT 58 | (study report CH-189/2021)  Granular material collected:  on 0.850 mm (850 µm) to 0.250 mm (250 µm) test sieves (inclusive): 99.42%.  Dust fraction collected:  through 0.250 mm (250 µm) and retained on 0.150 mm (150 µm) test sieve: 0.31% (\*);  through 0.150 mm (150 µm) in receiver pan (including loss during sieving): 0.27% (\*\*).  Apparent density after compaction without pressure:  0.91 g/mL (\*\*\*)  (\*) No more than 4%;  (\*\*) No more than 1%.  (\*\*\*) Not less than 0.4 g/mL | (study report CH-189/2021)  Granular material collected:  on 0.850 mm (850 µm) to 0.250 mm (250 µm) test sieves (inclusive): 99.69%.  Dust fraction collected:  through 0.250 mm (250 µm) and retained on 0.150 mm (150 µm) test sieve: 0.19% (\*);  through 0.150 mm (150 µm) in receiver pan (including loss during sieving): 0.13% (\*\*).  Apparent density after compaction without pressure:  0.91 g/mL (\*\*\*)  (\*) No more than 4%;  (\*\*) No more than 1%.  (\*\*\*) Not less than 0.4 g/mL |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| Physical-chemical properties:  The preparation is a blue granule with characteristic odour, containing 0.6 % w/w (pure) cypermethrin. pH value of a 1 % w/v aqueous dispersion of was 6.2 at 20°C. Bulk density of Mirmex GR is 0.98 g/mL at 20°C. The product can be considered as nearly dust-free due to a dustiness of granular products value of 2.0 mg. The attrition resistance of dispersible granules is 99.97%.  Storage stability:  After storage at 54°C for 14 days (in plastic composite: PP MAT20 + PET MET 12 + PE45), the test item did not show any significant difference in terms of active ingredient content, pH, dustiness and particle size, compared to the initial conditions.  The long-term storage stability study at ambient temperature (for 36 months) is ongoing and should be submitted when completed, to confirm the proposed shelf-life of the biocidal product. **(post authorisation data requirement)**  However, the acceptable accelerated storage stability test indicates that the product is anticipated to be stable for up to two years when stored in its initial commercial packaging.  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. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** | **GLP** | **Acceptability** |
| --- | --- | --- | --- | --- | --- | --- |
| Explosives | Assessment of the potential oxidizing and explosive behaviour using thermodynamics data obtained from the molecular structure of the main components of the formulation by the computer software CHETAH (Chemical Thermodynamic And Hazard evaluation), version 7.3 (ASTM 2002). | Mirmex GR formulation (see confidential annex) | From the criteria results obtained with CHETAH software based on the molecular structure of the active substances and main co-formulants of the test item, it can be concluded that the Mirmex GR sample should not have an explosive behaviour. | CH-0129/2020 | Yes | Acceptable  The product is not expected to have explosive properties |
| Flammable gases |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Flammable aerosols |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Oxidising gases |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Gases under pressure |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Flammable liquids |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Flammable solids  Flammability (solids) | EC 440/2008 No. A.10 | Test item: Mirmex GR  Cypermethrin: 0.6 % w/w (pure)  Batch number: 909199 | The test item, blue granular solid, melted when the Bunsen burner flame came close, but the combustion did not propagated.  Since test item did not propagate combustion, no further testing was required. Therefore from the experimental data, it can be concluded that the test item formulation sample is not a flammable solid. | CH –0127/2020 | Yes | Acceptable  The preliminary test performed is similar/comparable to the test of the CLP guidance.  The product is not expected to be flammable. |
| Self-reactive substances and mixtures |  |  | The ADR states that self-reactive materials are materials that are thermically instable and that can undergo to exothermic decomposition.  None of the ingredients is listed in the list of self-reactive substances in the ADR.  In the flammability study, the test item did not propagate combustion and according to the accelerated storage stability study, as reported in the study report CH – 0151/2020, Mirmex GR formulation was stable in its commercial packaging (14 days at 54°C).  Please also refer to confidential PAR for more details.  Therefore, the mixture is not expected to have self-reactive properties. | - |  | Acceptable |
| Pyrophoric liquids |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Pyrophoric solids |  |  | Study waived. Experience in manufacture or handling shows that the mixture does not ignite spontaneously on coming into contact with air at normal temperatures (CLP guidance) | - |  | Acceptable |
| Self-heating substances and mixtures |  |  | Study waived. Experience in manufacture or handling shows that the mixture does not have self-heating properties. | - |  | Acceptable |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Study waived.  The chemical structure of the mixture does not contain metals or metalloids and experience in handling and use shows that the mixture does not react with water (CLP guidance). | - |  | Acceptable |
| Oxidising liquids |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Oxidising solids |  | Mirmex GR formulation (see confidential annex) | As reported on Guidance on the Application of the CLP Criteria Version 5.0 – July 2017, for organic mixtures the classification procedure for this hazard class need not be applied if the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.  None of the components of Mirmex GR are classified as oxidizing agent.  Therefore it is not expected that Mirmex GR will show oxidant properties.  Please also refer to confidential PAR for more details. | - |  | Acceptable  The product is not expected to have oxidising properties |
| Organic peroxides |  |  | Study waived. There are no peroxides in the chemical structures of the substances into the mixture. | - |  | - |
| Corrosive to metals |  | Mirmex GR formulation (see confidential annex) | We propose a weight-of-evidence approach, and consider that melting point of Mirmex GR higher than 55°C.  Please also refer to confidential PAR for more details.  Corrosive to metals properties are not expected for solid formulations. | - |  | Acceptable |
| Auto-ignition temperatures of products (liquids and gases) |  |  | Not applicable since the product is a granular solid. | - |  | - |
| Relative self-ignition temperature for solids |  |  | Study waived.  Most of mixture’s components flash-points are above 100°C. During normal condition of production and use of the b.p. no sources of ignition or conditions suitable for combustion will be expected. Mirmex GR is not considered flammable or subject to autoignition,  and the flash-point study was waived. | - |  | Acceptable |
| Dust explosion hazard |  |  | Not applicable since the product is a granular solid. | - |  | - |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is not expected to have explosive or oxidising properties, nor to be self-heating, self-reactive or flammable. None of the components is known to evolve any flammable gases in contact with water/humid air or to be pyrophoric. The product is not expected to be corrosive to metals. Thus, has no classification according to CLP criteria. |

### Methods for detection and identification

**Analytical methods for the analysis of the product as such including the active substance, impurities and residues**

**Scope**

This method is applicable to the quantitative determination of Cypermethrin active ingredient in Mirmex GR formulation samples.

The method has been validated by the analysis of reference material and test item solutions.

Principle of the method

The determination of the active ingredient was performed by HPLC using an external standard and a UV detector.

The quantification of active ingredient, as Cypermethrin, is performed by comparing the sum of the four peak areas of Cypermethrin (Cypermethrin Cis I, Cypermethrin Cis II, Cypermethrin Trans I, Cypermethrin Trans II) analytical standard versus the sum of the four peaks areas in Mirmex GR test item solutions.

**Preparation of the eluent (iso octane/ethyl acetate at 99.5/0.5 % v/v)**

Into 2 L volumetric flask add, using volumetric pipette, 10.00 mL of ethyl acetate and make to volume with iso-octane.

**Preparation of the stock reference material solution**

Using an analytical balance, a volumetric flask and a volumetric pipette, prepare a stock reference material solution in eluent as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| Reference material | Stock reference material solution (SRMS) | | |
| Nominal weight  (mg) (1) | Volume  (mL) (2) | Nominal concentration  (μg/mL) |
| Cypermethrin | 20 | 20.00 | 1000 |

(1) Reference material nominal weight

(2) Volume of the stock reference material solution.

**Preparation of the working standard solutions**

Using volumetric flasks and volumetric pipettes, prepare three working standard solutions for linear calibration in eluent as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Working  Standard  Solution | Stock reference material solution (SRMS) (mL) | Final Volume (mL) | Nominal concentration  (μg/mL) | Nominal  linearity range  (% w/w) (1) |
| Blank | 0 | 10.00 | 0 | 0 |
| WSS 1 | 0.60 | 10.00 | 60 | 0.30 – 0.90 |
| WSS 3 | 1.20 | 10.00 | 120 |
| WSS 5 | 1.80 | 10.00 | 180 |

(1) Calculated with respect to the nominal test item weight in repeatability (2000 mg).

All the stock and working standard solutions have been stored in a refrigerator.

***Preparation of the test item solutions***

Using the analytical balance, weigh about 2000 mg of the test item into 100.00 mL volumetric flask, make to volume with eluent and place in an ultrasonic bath for 15 minutes.

After thermal equilibrium at room temperature, filter an aliquot of the stock test item solution using PTFE syringe filter at 0.45 μm and then, transfer an aliquot of the filtered test item solution into a vial for the HPLC analysis.

The summary of test item preparation procedure is presented in the table here below.

|  |  |  |
| --- | --- | --- |
|  | Stock test item solution (STIS) | |
| Nominal weight (mg) | Volume (mL) |
| Test item | 2000 | 100.00 |

NOTE: Perform the test item weights mixing the granular formulation contained in five commercial packaging

Test item solutions have been stored in a refrigerator.

***Chromatographic conditions***

|  |  |
| --- | --- |
| HPLC column | Agilent Technologies or equivalent |
|  | Zorbax RX-SIL, 150 x 4.60 mm i.d., 5.0 μm |
| Detector | UV/Vis operating at 278 nm |
| Column temperature | 35°C |
| Eluent B | iso octane/ethyl acetate = 99.5 / 0.5 % v/v |
| Eluent (isocratic) | 100% eluent B |
| Eluent flow | 2.0 mL/min |
| Volume of injection | 10 μL |
| Cypermethrin Cis I ret. time | about 12 minutes |
| Cypermethrin Cis II ret. Time | about 13 minutes |
| Cypermethrin Trans I ret. Time | about 17 minutes |
| Cypermethrin Trans II ret. time | about 19 minutes |
| Total analysis time | 30 minutes |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |
| Cypermethrin (active substance in Mirmex GR) | HPLC/UV  (HPLC mod. 1200 equipped with UV detector, autosampler, managed by Chemstation software).  detector wavelength 278 nm | Using the analytical balance and volumetric pipettes, the fortified placebo solutions were prepared in eluent.  Spike A:  Cypermethrin C added 5.93 g/kg  Spike B:  Cypermethrin C added 5.92 g/kg  Number of measurements: 2. | Five working standard solutions were prepared and each solution was analysed by HPLC/UV.  The injected range and the relevant linearity range for the active ingredient were:  Cypermethrin  No. of WSS: 5  Injected range:  60.59 – 181.76 μg/mL  Linearity Range:  0.30 – 0.91 % w/w  y = 15065x + 14434  r = 0.99974  Cypermethrin Cis isomer  No. of WSS: 5  Injected range:  26.38 – 79.13  μg/mL  y = 15004x + 9027  r = 0.99960  Cypermethrin Trans isomer  No. of WSS: 5  Injected range:  34.21 – 102.63 μg/mL  y = 15113x + 5407  r = 0.99983 | The Cypermethrin active ingredient peaks were well separated and interferences with the Placebo peak were not evidenced.  Therefore, by using the conditions stated in the method, interferences can be avoided and the active ingredient can be reliably determined in test item samples. | Spike A:  Cypermethrin C added 5.93 g/kg  Cypermethrin C found 5.85 g/kg  Test No.: 1 det.  Cypermethrin Recovery (%) 98.75  Spike B:  Cypermethrin C added 5.92 g/kg  Cypermethrin C found 5.89 g/kg  Test No.: 1 det.  Cypermethrin Recovery (%) 99.50 | Total mean recovery (%):99.1 | - | Not required | CH – 0128/2020 |

**Specificity**

The analytical method, using the HPLC/UV instrument with quantification by external standard, was shown to be specific for Cypermethrin active ingredient in the test item formulation samples.

**Linearity**

Five working standard solutions were prepared as described in the Experimental section and each solution was analysed by HPLC/UV.

The injected range and the relevant linearity range for the active ingredient are detailed in the table here below.

|  |  |  |  |
| --- | --- | --- | --- |
| **Active ingredient** | **No. of**  **WSS** | **Injected range**  **(μg/mL)** | **Linearity Range**  **(% w/w) (1)** |
| Cypermethrin | 5 | 60.59 – 181.76 | 0.30 – 0.91 |
| Cypermethrin Cis isomer | 5 | 26.38 – 79.13 | - |
| Cypermethrin Trans isomer | 5 | 34.21 – 102.63 | - |

(1) Calculated with respect to the nominal test item weight and preparative in repeatability.

No significant memory signal was detected in the washing injected after the highest working standard solution and the range tested for the active ingredient was found to be linear (correlation coefficient r > 0.99).

**Precision**

The precision test was performed by five determinations of the test item (labelled A to E).

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Active ingredient** | **Test No.** | **Mean**  **value**  **(% w/w) (1)** | **Standard deviation (S.D.)**  **(% w/w)** | **Relative Standard Deviation (RSD%)** | **Horwitz**  **RSDr (2)** | **Horrat value (3)** |
| Cypermethrin | 5 | 0.62 | 0.01 | 2.33 | 2.88 | 0.81 |
| Cypermethrin Cis isomer | 5 | 0.25 | 0.01 | 2.22 | 3.30 | 0.67 |
| Cypermethrin Trans isomer | 5 | 0.37 | 0.01 | 2.41 | 3.11 | 0.78 |

(1) Calculated with respect to the weighed test item.

(2) % RSDr = % RSDR x 0.67; % RSDR = 2(1-0.5 log C), based on the Horwitz equation.

(3) Horrat value = RDS% / RSDr

Cypermethrin: 0.62 ± 0.01 % w/w

Cypermethrin Cis isomer: 0.25 ± 0.01 % w/w

Cypermethrin Trans isomer: 0.37 ± 0.01 % w/w

From data obtained, the Horrat value resulted to be lower than 1 for the active ingredient and therefore the precision of the analytical method is considered acceptable.

**Recovery**

For the recovery, the mean recovery values obtained comply with the SANCO/3030/99 rev. 5 guideline’s requirement, as below:

in the range 80 to 120 % for active ingredient content between 0.1 % w/w and 1.0 % w/w.

Since all recovery values were in the correct range, these criteria were fulfilled and therefore recovery of the analytical method is considered acceptable.

|  |  |  |  |  |
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| **Active ingredient** | **Level** | **Tests No.** | **Recovery value (%)** | |
| Cypermethrin | Spike A | 1 det. | 98.75 | |
| Spike B | 1 det. | | 99.50 |

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| **Conclusion on the methods for detection and identification of the product** |
| The HPLC-UV analytical method was found to be valid in terms of linearity, precision, accuracy in accordance with ECHA guidance, for the determination of Cypermethrin (including its isomers), in Mirmex GR formulation. |

**Analytical methods for monitoring**

Monitoring methods were reported in the Cypermethrin Assessment Report, and they are available through the Letter od Access attached to the IUCLID dossier:

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| Soil (principle of method and LOQ) | GC with MS detection, LOQ = 0.05 mg/kg (LOQ = 0.5 μg/kg for sediment) |
| Air (principle of method and LOQ) | GC with MS detection, LOQ = 0.375 μg/m3 |
| Water (principle of method and LOQ) | GC with electron capture detection, LOQ = 0.01 μg/L |
| Body fluids and tissues (principle of method and LOQ) | Cypermethrin is not indicated to be toxic or highly toxic. Therefore, analytical methods for the determination of Cypermethrin in animal and human body fluids and tissues are not required. |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | GC with electron capture detection, LOD = 0.05 mg/kg (oilseed rape) and 0.025 mg/kg (wheat) |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | GC with MS detection, LOQ = 0.05 mg/kg (bovine tissue), 0.005 mg/kg (bovine milk), 0.01 mg/kg (hen eggs). |

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| **Conclusion on the methods for monitoring** |
| Acceptable validated analytical methods for monitoring are available for the detection of cypermethrin in soil, air, water and residues in food and feeding stuff, reported in the CAR for cypermethrin (Belgium, 2017).  A letter of access covering the complete dossier of Agriphar Sprl (now Arysta LifeScience Benelux Sprl) for the active substance Cypermethrin, product type 18, is available from Limaru representing Tagros Chemicals India Ltd on the Article 95 list.  Analytical methods for the detection of Cypermethrin in animal and human body fluids and tissues or further data are not required. |

**Analytical methods for substances of concern**

Acetic acid have been considered a substance of concern in this product. No analytical methods and storage stability data have been added since it is not expected that it can be formed during storage and its concentration will increase. Moreover it is not possible to develop analytical method that can be sufficiently specific to detect and analyse the negligible amount present in the product. For further information refer to the production method in the confidential section.

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| **Conclusion on the methods for Substances of Concern in the product.** |
| Analytical method for the determination of Substance of Concern in the formulation MIRMEX GR have not been submitted, nor required since SoC cannot be formed during storage. |

### Efficacy against target organisms

#### Function and field of use

Function: Insecticide

Field of use (General public, non-professional):

Indoor, outdoor around building as crack and crevice treatment by spreading granules.

Field of use (Trained professional, Professional):

Indoor, outdoor around building as crack and crevice treatment by spreading granules.

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

Lasius niger  
Ants  
Adults

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

The product exerts knockdown and killing effect against the target otganisms.

#### Mode of action, including time delay

According to the Assessment Report of Cypermethrin, Cypermethrin cis:trans/40:60 is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon. Typically, this intoxication results in a rapid “knockdown”. The affected insect shows uncoordinated movements and finally dies.

#### Efficacy data

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| **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| MIRMEX GR (0.6 % w/w pure Cypermethrin) | *Lasius niger* (ant) | Lab study  (non-choice test) | The test was conducted on 20 x 20 cm ceramic tiles (non-porous surface) with the granule and with the granule diluted with water. The granule was weighed and homogeneously distributed on the tiles. The granule diluted with water was applied using a pipette; the product was then smeared on the whole surface with a plastic brush. 5 treated replications with 20 adults each were used both for granule and for granule diluted with water. 5 replications with 20 adults without insecticide were as used as negative control. The insects were placed for 60 minutes on the tiles under transparent plastic cups to prevent escaping and, thus, ensuring the contact with the treated surface. After 60 minutes since the beginning of the contact the insects were moved to a healthy environment to observe mortality at 24 hours.  Application rate:  8g/m2 for both granule and granule diluted application.  The dilution rate for the granule diluted with water (wet application) was 10g/5ml. | GRANULE: 100% knockdown after 25 minutes, 100% mortality in 24h in the treated replications; in the control replications knockdown and mortality were 0%.  GRANULE DILUTED:  100% knockdown after 25 minutes, 100% mortality  In 24h in the treated replications; in the control replications knockdown and mortality were 0%. | Andrea Drago; 2019 |
| MIRMEX GR (0.6 % w/w pure Cypermethrin) | *Lasius niger* (ant) | Lab study  (non-choice test) | The test was conducted on 20 x 20 cm non-porous (vitrified) and porous surfaces (granite) with the granule and with the granule diluted with water. The granule was weighed and homogeneously distributed on the tiles. The granule diluted with water was applied using a pipette; the product was then smeared on the whole surface with a plastic brush. 5 treated replications with 20 adults each were used both for granule and for granule diluted with water. 5 replications with 20 adults without insecticide were as used as negative control. The insects were placed for 60 minutes on the tiles under transparent plastic cups to prevent escaping and, thus, ensuring the contact with the treated surface. After 60 minutes since the beginning of the contact the insects were moved to a healthy environment to observe mortality at 24 hours (T0).  To assess residual activity treated samples were stored at 25° C, 60% of R.H. under a photoperiod of 12 hours of light, for 2 (T2) & 4 (T4) weeks.  Application rate:  8g/m2 for both granule and granule diluted application.  The dilution rate for the granule diluted with water (wet application) was 8g/4ml. | -Granule: On non-porous surface, 100% knockdown was reached in 25 minutes at T0, 15 minutes at T2 and 10 minutes at T4; mortality was always 100%. On porous surface, 100% knockdown was reached in 25 minutes at T0, 15 minutes at T2 and 20 minutes at T4; mortality was always 100%.  -Granule diluted: On non-porous surface, 100% knockdown was reached in 20 minutes at T0 and in 25 minutes at T2. At T4, knockdown after 60 minutes was 96.00±4.00%. Mortality was 100% at T0, 97.00±3.00% at T2 and 91.00±4.00% at T4. On porous surface, 100% knockdown was reached in 30 minutes at T0 and in 50 minutes at T2. At T4, knockdown after 60 minutes was 98.00±2.00%. Mortality was 100% at T0, 95.00±3.87% at T2 and 96.00±1.87% at T4.  In the control replications, knockdown was always 0% and mortality was 0-1% for all treatment cases | Andrea Drago; 2021 |
| MIRMEX GR (0.6 % w/w pure Cypermethrin) | *Lasius niger* (Nest and ant) | Field test.  In naturally infested indoor and outdoor areas of a retirement house located in the North of Italy. | The product was applied by 4 different application ways (Application Way Test - AWT):  - AWT 1: Test indoor, granular product applied on the ant pathways around building in crack and crevices.  - AWT 2: Test outdoor, granular product applied on the ant pathways around building in crack and crevices. Outdoor sites frequented by ants and protected from the rain by roofs were selected.  - AWT 3: Granular product applied in ant nests outdoors.  - AWT 4: Wet granules application in ant nests outdoors.  The test was performed with 3 replicates for each AWT. For the AWT 1 and 2 each replicate was an area where the present ants originated by a specific nest. Each replicate was far enough from the other replicates to be sure that ants from different replicates were not from the same nest. For the AWT indoor, the ants were observed both infesting the indoor area as well as on the nest from where they come from. This nest was not directly treated. The same was for the AWT outdoor, the product was applied just on the ant pathways but the observation of the ant activity was done both on the pathways and on the nest entrance.  *Ant pathway* (or path) is a term used by the applicant to refer to ant frequented areas (even if *Lasius niger* doesn’t form columns when foraging). The product was applied in the areas where ants are usually encountered, not onto the ants.  For AWT 1&2, in each site, three observation points were chosen where ant population was measured (though photographs) at each assessment counting the insects within a 30 x 30 cm squares, drowned on the floor.  For ant nest treatment (AWT 3&4), the number of ants present on the nest entrance was counted.  As pre-treatment assessments for all AWT, ants were counted in each site 24 hours before treatment.  The post-treatment assessments were done 48 hours, 3, 7, 14, 21 and 28 days after treatment.  The application rate:  - Indoor around building: 8 g / m2 of the pathway (ant frequented areas), applied along the pathway in cracks and crevices.  - Outdoor around building: 8 g / m2 of the pathway (ant frequented areas), applied directly along the pathway in cracks and crevices.  - Direct application on nest outdoors: 8 g / nest for both granule and water diluted granule. The dilution rate for water diluted granule was 10g product/ 5ml water.  Three untreated control sites were included in the test with 3 observation points each, for each AWT. | AWT 1&2 [granular product applied on the ant pathways around building indoors (AWT 1) and outdoors (AWT 2)]  Ant activity on nests  Indoor: Percentage of Reduction in the treated replications was 100% after 28 days. - Outdoor: Percentage of Reduction in the treated replications was 100% after 28 days  Ant activity on ant pathways  Indoor: Percentage of Reduction in the treated replications was 100% 28 days after treatment. - Outdoor: Percentage of Reduction in the treated replications was 98.1% 28 days after treatment.    AWT 3&4 [granules (AWT 3) and granules after dilution in water (AWT 4) applied on ant nests outdoors]  Granules: Percentage of Reduction in the treated replications was 100% after 28 days.  Granules diluted in water: Percentage of Reduction in the treated replications was 100% after 28  days.  In the untreated control sites, ant population 28 days after treatment remained almost the same or increased when compared to pre-treatment situation, in all cases. | Andrea Drago; 2019 |

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| **Conclusion on the efficacy of the product** |
| Based on the results of the submitted lab and field studies, the product was proved efficacious as:   * Crack and crevice treatment by professionals and non-professionals, indoors for the control of ants (*Lasius niger,* workers), and outdoors around buildings, at sites protected from the rain, for the control of ants (*Lasius niger,* workers and nests) by spreading the granules of the product at 8 g/m2. The product has a residual period of 4 weeks. After the non-professional use, knockdown of ant workers is expected within 60 minutes after exposure of insects to the treated surfaces (Intented uses 1 & 2). * Ant nest treatment by professionals and non-professionals, indoors and outdoors around buildings, for the control of ants (*Lasius niger,* workers and nests) by spreading of granules onto the nest, and for the control of ants (*Lasius niger,* workers) by application of wet product (after dilution of 8 g product in 4 ml water) onto the nest at 8 g product/nest. The product has a residual period of 4 weeks. After the non-professional use, knockdown of ant workers is expected within 60 minutes after exposure of insects to the treated surfaces (Intented uses 3 & 4). |

#### Occurrence of resistance and resistance management

According to the Assessment Report for Cypermethrin, resistance to pyrethroid insecticides has been reported for a number of pests both in agriculture and public health. Strategies such as alteration of insecticides with different modes of action and avoidance of over frequent use are standard practises in agriculture and should be applied also to biocide uses of cypermethrin.

The following principles of strategies for managing the development of resistance as for other synthetic pyrethroids-based products are proposed:

- Where possible, application treatments should be recommended to be combined with non-chemical measures

- Where an extended period of control is required, treatments should be alternated with products containing active substances with different mode of action.

- In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing active substances with the same mode of action should cease.

- The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

#### Known limitations

There are no known limitations.

#### Evaluation of the label claims

According to the submitted by the applicant PAR and SPC, the claimed intended uses are as follows:

Intended uses 1&2 for professional and non-professional use:

The product is a ready to use product intended for the kill and control of ants (*Lasius niger*) (workers and nests) indoors, and outdoors around buildings, as crack and crevice treatment by spreading at 8 g/m2. The product has a residual period of 4 weeks.

Intented uses 3&4 for professional and non-professional use:

The product is a ready to use product intended for the kill and control of ants (*Lasius niger*) (workers and nests) indoors, and outdoors around buildings as nest treatment by spreading or applying wet product (after adding 4 g of water to 8 g product) at 8 g/nest. The product has a residual period of 4 weeks.

**Trials submitted by the applicant to substantiate the claimed intended uses:**

Lab study by Drago 2019

In the lab study by Drago 2019, the product was applied as surface treatment in a forced contact test using non-porous surfaces (ceramic tiles) against ant adults (*Lasius niger*). The product was applied by spreading dry granules or by applying granules diluted in water (10g/5 ml) at 8 g product/m2. According to the results,the product exerted 100% knockdown in 25 minutes and 100% mortality in 24h after exposure of the insects to the treated non-porous surfaces.

Lab study by Drago 2021

In the lab study by Drago 2019, the product was applied as surface treatment in a forced contact test using non-porous and porous surfaces against ant adults (*Lasius niger*). The product was applied by spreading dry granules or by applying granules diluted in water (8g/4 ml) at 8 g product/m2. To evaluate the residual activity, the ants were exposed to 2 and 4 weeks aged treated tiles. According to the results,the exposure of antsto porous and non-porous surfaces treated with dry granules for up to 4-weeks resulted in 100% knockdown in 10-25 minutes and 100% mortality in 24h after exposure of the insects to the treated surfaces.The exposure of antsto porous and non-porous surfaces treated with granules diluted in water for up to 4-weeks resulted in 96-100% knockdown in 20-60 minutes and 91-100% mortality in 24h after exposure of the insects to the treated surfaces [91-96% (<100%) mortality in 4 weeks].

Field study by Drago 2019

In the field study by Drago 2019, the effectiveness of the product was evaluated in naturally infested areas by *Lasius niger*, indoors and outdoors by 4 diferrent application way tests (AWT)*.*

- AWT 1: Test indoor, granular product applied on the ant pathways (ant frequented areas) around building in crack and crevices.

- AWT 2: Test outdoor, granular product applied on the ant pathways (ant frequented areas) around building in crack and crevices. Outdoor sites frequented by ants and protected from the rain by roofs were selected.

- AWT 3: Granular product applied on ant nests outdoors.

- AWT 4: Wet granules application on ant nests outdoors.

For the AWT 1 & 2, the ants were observed both infesting the indoor area as well as on the nest from where they come from. This nest was not directly treated.

For ant nest treatment (AWT 3 & 4), the number of ants present on the nest entrance was counted.

According to the results, the product when applied in granular form as a crack and crevice treatment indoors around building at 8 g/m2, provided 100% ant population reduction in the ant frequented areas and in the nests where the ants came from, 4 weeks after treatment. When applied outdoors in granular form as a crack and crevice treatment around building at 8 g/m2, the product provided 98% ant population reduction in the ant frequented areas and 100% population reduction in the nests where the ants came from, 4 weeks after treatment.

The outdoor application of granule and wet form after dilution of granules in water (10g/5lt water) on nests at 8 g product/nest resulted in 100% reduction of ant activity on the ant nest entrances where the product was applied, 4 weeks after treatment.

Efficacy of the product in the field test as ant nest treatment outdoors can be extrapolated to the claimed appllication of ant nests indoors considering the outdoor conditions as worst case scenario in terms of efficacy.

Efficacy of the product in the field test as crack and crevice treatment indoors around building can be extrapolated to the claimed appllication of crack and crevice treatment indoors considering the indoor treatment only around the building as worst case scenario in terms of efficacy.

Taking into account the submitted efficacy studies, the intended uses as applied for by the applicant (section 2.2.1) are acceptable from an efficacy point of view, noting however the following:

* In the intended uses 3 & 4, the wet form of the product (after dilution of granules in water) is intended for ant nest treatment with a claim for “kill and control of nests”.

In the lab study by Drago 2021, the exposure of antsto porous and non-porous surfaces treated with the wet form of the product resulted in <100% (91-96%) mortality at the end of the claimed residual period of 4-weeks. However, in the guidance, for products with a claim for “nest kill”, in lab tests 100% mortality at the end of the residual period is required.

Hence, the claim “kill and control of nests” for the wet form of the product in the intended uses 3 & 4 (ant nest treatment) is not sufficiently supported and therefore we propose to remove it, while the control of ant workers is proved. This is addressed in the field “Where relevant, an exact description of the authorised use” in tables 3 & 4.

* For the intended uses 1 & 3 (non-professional use) against ant workers (not nests), the requirements of the guidance for surface treatment for consumers should normally be fulfilled, i.e. in lab tests >90% knockdown in 5-10 minutes (or according to the claim), direct after sprayingthe ants and at the end of residual period.

However, according to the lab study by Drago 2021, the exposure of antsto porous and non-porous surfaces treated with dry and wet form of the product for up to 4-weeks resulted in 100% knockdown in 10-60 minutes after exposure of the insects to the treated surfaces.

Hence, the following limitation is proposed to be added in the instructions for use for intented uses 1 & 3 (non-professionals), to be in line with results of this study: “Knockdown of ant workers is expected within 60 minutes after exposure of insects to the treated surfaces”.

* In the claimed intended uses 1 & 2, the product is applied in the dry form by spreading granules as a crack and crevice treatment outdoors around buildings at 8 g/m2 for the “kill and control of ant nests”.

In the field study by Drago 2019, the product when applied outdoors in granular form as a crack and crevice treatment around building at 8 g/m2 provided 98% ant population reduction in the ant frequented areas and 100% population reduction in the nests where the ants came from, 4 weeks after treatment. It is noted that according to the guidance for products intended for nest kill, in the field tests a population reduction of 100% is required, while in case of lower efficacy it has to be shown that the queen in the test nest is killed. However, in the nests where the ants came from (field study by Drago 2019) although no activity was observed (100% reduction) it was not examined if the queen was killed to ensure the elimination of the nest and support the “nest kill” claim.

The applicant provided the following justification to support the nest kill claim for the granule product application outdoors around buildings, despite <100% ant population reduction in the field study:

*The results showed always the complete reduction of ant presence except for the AWT 2 outdoor respect to the claim “Ant killing” where just a few ants were observed walking around the area. Because norms and criteria require a reduction of 90% for the claim “killing ants” while 98.01% was detected, the norms are fulfilled. In this regard it must be emphasized that the area where the treatment was carried out was quite far from the nest of origin identified and that in the surroundings there were other nests, even if quite far away. Since only a few ants were observed despite the nest showing no activity, it can be assumed that the ants observed may have come from other nests, not included in the test. In fact, once the entire nest has been killed, the area becomes vacant and other ants from nearby nests may attempt to colonize the area. We underline that the product itself, while acting by contact, manifests attractive properties and may have favored the process of approach by other colonies.*

The eCA opposing applicant’s view proposes to remove the claim for the control and kill of ant nests by outdoor crack and crevice treatment with the dry granular form around buildings in the intended uses 1 & 2. This is addressed in the field “Where relevant, an exact description of the authorised use” in tables 1 & 2.

* Considering the fact that in the field study by Drago 2019 the product was applied outdoors around building in crack and crevices at sites protected from the rain by roofs, we propose to add a relevant limitation in Intented uses 1&2 that for the outdoor application around buildings the product should be applied on sites protected from the rain.
* The claim “kill and control of ants” is proposed to be changed to “control of ants” as more appropriate.
* In the specific instructions for use the claim “Remove (clean) product and dead insects, when the presence of live insects is stopped”, is changed to “Remove (clean) product after the residual period. Remove dead insects after the treatment” as more appropriate from an efficacy point of view considering the residual action in case of re-infestation.

Overall, based on the submitted efficacy studies and after evaluation process in all sections, the eCA concludes into the proposed authorized uses of the product as described in 2.1.4.

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

The products are not intended to be used in combination with 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 irritant to skin. |
| Justification for the value/conclusion | No data for MIRMEX GR is provided. The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product.  The biocidal product MIRMEX GR contains an ingredient classified for skin corrosion (H314) and an ingredient classified for skin irritation (H315). However, the concentration of both ingredients is well below the generic concentration limits set out in Regulation (EC) No. 1272/2008 (CLP). As a consequence, no classification for skin corrosion/irritation is triggered for MIRMEX GR. |
| Classification of the product according to CLP | Not classified. |

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| **Data waiving** | |
| Information requirement | Skin corrosion and irritation.  Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | No data for MIRMEX GR is provided. The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product.  The biocidal product MIRMEX GR contains an ingredient classified for skin corrosion (H314) and an ingredient classified for skin irritation (H315). However, the concentration of both ingredients is well below the generic concentration limits set out in Regulation (EC) No. 1272/2008 (CLP). As a consequence, no classification for skin corrosion/irritation is triggered for MIRMEX GR and no further testing is required to assess the hazard. |

***Eye irritation***

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| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not irritant to eyes. |
| Justification for the value/conclusion | No data for MIRMEX GR is provided. The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product.  The biocidal product MIRMEX GR contains three ingredients classified for eye damage (H318). However, the concentration of all three ingredients is well below the generic concentration limit set out in Regulation (EC) No. 1272/2008 (CLP). As a consequence, no classification for eye damage/irritation is triggered for MIRMEX GR. |
| Classification of the product according to CLP | Not classified. |

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| **Data waiving** | |
| Information requirement | Eye irritation.  Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | No data for MIRMEX GR is provided. The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product.  The biocidal product MIRMEX GR contains three ingredients classified for eye damage (H318). However, the concentration of all three ingredients is well below the generic concentration limit set out in Regulation (EC) No. 1272/2008 (CLP). As a consequence, no classification for eye damage/irritation is triggered for MIRMEX GR and no further testing is required to assess the hazard. |

***Respiratory tract irritation***

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| **Conclusion used in Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not irritating to the respiratory tract. |
| Justification for the value/conclusion | There are no designated tests for the determination of respiratory tract irritation. No data for MIRMEX GR is available.  The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product.  The active substance and another ingredient of MIRMEX GR are classified as STOT SE Cat. 3, H335. As the active substance has a concentration of 0.6% in the whole mixture and the other ingredient has a concentration well below the generic concentration limits set out in Annex I of Regulation (EC) No. 1272/2008, the product is not expected to exert respiratory tract irritation.  Therefore, the biocidal product is not classified as a respiratory tract irritant, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified. |

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| **Data waiving** | |
| Information requirement | Respiratory tract irritation.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Please refer to the Confidential Annex of this PAR. |
| Justification | There are no designated tests for the determination of respiratory tract irritation. No data for MIRMEX GR is available.  The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product.  The active substance and another ingredient of MIRMEX GR are classified as STOT SE 3, H335. As the active substance has a concentration of 0.6% in the whole mixture and the other ingredient has a concentration well below the generic concentration limits set out in Annex I of Regulation (EC) No. 1272/2008, the product is not expected to exert respiratory tract irritation.  Therefore, the biocidal product is not classified as a respiratory tract irritant according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  The available information is sufficient to assess this hazard and no additional studies are required. |

***Skin sensitization***

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| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to skin. |
| Justification for the value/conclusion | No data for MIRMEX GR is provided. The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product.  Neither the active substance nor the co-formulants of MIRMEX GR are classified for skin sensitisation, hence no classification is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified. |

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| **Data waiving** | |
| Information requirement | Skin sensitisation.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |
| Justification | No data for MIRMEX GR is provided. The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product.  Neither the active substance nor the co-formulants of MIRMEX GR are classified for skin sensitisation, hence no classification is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  The available information is sufficient to assess this hazard and no additional studies are required. |

***Respiratory sensitization (ADS)***

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| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not a respiratory sensitizer. |
| Justification for the value/conclusion | There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation and there is no testing requirement for this endpoint under the BPR.  No study is available for MIRMEX GR.  The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product.  Neither the active substance nor the co-formulants of MIRMEX GR are classified as respiratory sensitizers. Therefore, the biocidal product does not meet the criteria for classification for respiratory sensitisation according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified. |

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| **Data waiving** | |
| Information requirement | Respiratory sensitization (ADS).  Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Justification | No study is available for MIRMEX GR. The classification of the product was conducted by the calculation method, based on the RAC opinion of cypermethrin (December 2019) and the MSDS of the other components of the product.  Neither the active substance nor the co-formulants of MIRMEX GR are classified as respiratory sensitizers. As a consequence, the biocidal product does not meet the criteria for classification for respiratory sensitisation according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  No additional information is deemed necessary and the study was waived. |

***Acute toxicity***

***Acute toxicity by oral route***

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| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Non-toxic *via* the oral route. |
| Justification for the selected value | No data for MIRMEX GR is provided. Application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  Cypermethrin and two co-formulants of MIRMEX GR are classified for acute oral toxicity (H302). However, as their concentration in the biocidal product is below 1%, no classification for acute oral toxicity is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute oral toxicity.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |
| Justification | No data for MIRMEX GR is provided. Application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  Cypermethrin and two co-formulants of MIRMEX GR are classified for acute oral toxicity (H302). However, as their concentration in the biocidal product is below 1%, no classification for acute oral toxicity is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  No additional information is required to investigate this hazard and therefore the study was waived. |

***Acute toxicity by inhalation***

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation** **toxicity** | |
| Value | Non-toxic *via* the inhalation route. |
| Justification for the selected value | No data for MIRMEX GR is provided. Application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  Cypermethrin and a co-formulant of MIRMEX GR are classified for acute inhalation toxicity (H332). However, as their concentration in the biocidal product is below 1%, no classification for acute inhalation toxicity is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP). |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute inhalation toxicity.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |
| Justification | No data for MIRMEX GR is provided. Application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  Cypermethrin and a co-formulant of MIRMEX GR are classified for acute inhalation toxicity (H332). However, as their concentration in the biocidal product is below 1%, no classification for acute inhalation toxicity is triggered for the biocidal product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).  No additional information is required to investigate this hazard and therefore the study was waived. |

***Acute toxicity by dermal route***

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Non-toxic *via* the dermal route. |
| Justification for the selected value | No data for MIRMEX GR is provided. Application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  Just one of the ingredients of MIRMEX GR is classified for the acute dermal toxicity hazard, but its concentration is well below the generic concentration limits set out in Regulation (EC) No. 1272/2008 (CLP). Therefore, the biocidal product is not classified for acute dermal toxicity. |
| Classification of the product according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute dermal toxicity.  Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |
| Justification | No data for MIRMEX GR is provided. Application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).  Just one of the ingredients of MIRMEX GR is classified for the acute dermal toxicity hazard, but its concentration is well below the generic concentration limits set out in Regulation (EC) No. 1272/2008 (CLP). Therefore, the biocidal product is not classified for acute dermal toxicity.  No additional information is required to set out the hazard related to this endpoint and therefore the acute dermal toxicity study was waived. |

***Information on dermal absorption***

Dermal absorption data for MIRMEX GR is not available; therefore, default values of dermal absorption have to be used in the risk assessment, as proposed in the current EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873].

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Cypermethrin |
| Value(s) | 50% |
| Justification for the selected value(s) | A dermal study has not been performed with the biocidal product MIRMEX GR, therefore a default value of dermal absorption has to be used.  According to EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873], in order to choose the suitable default value, the formulation category of the product and the concentration of the active substance in the product must be taken into consideration.  MIRMEX GR is a solid formulation and the concentration of cypermethrin in the biocidal product is 0.632%. As the percentage of the active substance in the product is below 5%, that is the threshold used to identify dilutions according to the previous EFSA Guidance on Dermal Absorption (2012, section 6.1), a default dermal absorption value of 50% will be considered in the risk assessment, as proposed in the current EFSA Guidance for dilutions of solid formulations. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal absorption |
| Justification | In the absence of relevant dermal absorption data with MIRMEX GR, the default value of 50% will be considered in the risk assessment for the active substance, as proposed in the current EFSA Guidance on dermal absorption for dilutions of solid formulations [EFSA Journal, 2017; 15(6): 4873]. |

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

The biocidal product MIRMEX GR contains the co-formulant acetic acid (CAS No. 64-19-7). Based on the submitted MSDS, acetic acid is classified for skin corrosion (H314) and eye damage (H318). The concentration of acetic acid in the product is below the generic concentration limits set out in Regulation (EC) No. 1272/2008 (CLP), therefore there is no impact on the classification of the biocidal product MIRMEX GR.

However, according to the Guidance on the Biocidal Product Regulation (Volume III Human Health – Part B and C Risk Assessment– Version 4.0 – December 2017), acetic acid should be considered as a Substance of Concern (SoC), as there is available European Union-agreed Occupational Exposure Limit (OEL). The long-term (8 hours) occupational exposure limit of acetic acid is 25 mg/m3 (<https://echa.europa.eu/el/indicative-oelvs-dir-2017-164/-/legislationlist/details/EU-IOELV_LIST_4-ANX_I-100.000.528-VSK-5F41D1>).

According to the BPR Guidance (p. 424), *for SoCs for which Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) have been set, a quantitative inhalation risk assessment for the professional operator against the IOELV should always be conducted*. Therefore, an inhalation quantitative risk assessment has been undertaken for this co-formulant.

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

The biocidal product MIRMEX GR contains only one mixture: Denatonium benzoate (CAS No. 3734-33-6). Available toxicological data relating to the mixture contained in the biocidal product MIRMEX GR is provided in the MSDS attached to current submission.

***Other***

Not applicable.

***Screening non-active substance(s) for endocrine-disrupting potential***

The assessment of the endocrine-disrupting properties of the co-formulants in the biocidal product MIRMEX GR has been performed according to the instructions described in the document agreed in the Coordination Group (CG-39-2020-11 AP 16.4 e-c ED co-formulant assessment by MS).

To assess the endocrine-disrupting (ED) potential of each co-formulant in the biocidal product, a step-wise approach was performed, which included screening of relevant databases and searching for freely available information in reliable literature sources.

The sources of information, the databases consulted as well as the results of the screening for endocrine-disrupting properties of the co-formulants in the biocidal product MIRMEX GR are presented in detail in the Confidential Annex.

#### Exposure assessment

Identification of main paths of human exposure towards active substance and substance 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 | yes | yes | n.a | no | yes | n.a |
| **Dermal** | n.a | yes | yes | n.a | no | yes | n.a |
| **Oral** | n.a | no | no | n.a | no | yes | n.a |

\* It is noted that in Greece the users of biocidal products are either licensed professionals (i.e., trained) or non-professionals (amateur users). There is no separate risk assessment conducted for the category of professional users (other than pest control operators) that may be allowed to use the biocidal products in the context of their profession. It is noted, however, that for MS where the category of professional users is relevant, the risk assessment might be considered as covered either from the risk assessment conducted for the trained professional users or the non-professional ones.

***List of scenarios***

| **Summary table: scenarios of intended uses of the biocidal product MIRMEX GR** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Application | **Primary exposure: direct**  Scattering powder from a hand held duster against ants. Crack and crevice/spot application. | Trained professional users |
| 2. | Mixing and loading | **Primary exposure: direct**  Loading of the powder into the application device. | Trained professional users |
| 3. | Application | **Primary exposure: direct**  Scattering powder from a hand held duster against ants. Crack and crevice application/spot application. | Non-professional users |
| 4. | Post-application | **Primary exposure: indirect**  Adult professional users laundering work clothes at home. | Trained professional users |
| 5. | Post-application | **Secondary Exposure**  Secondary exposure is relevant to the general public entering to treated areas after the product application and is derived *via* inhalation, dermal and oral route. | General public: infants, toddlers, children, adults |

***Industrial exposure***

The modelling of exposure and subsequent risk characterisation during production and formulation of Mirmex GR is addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under Regulation 528/2012 (this principle was agreed at Biocides Technical Meeting TMI06). Therefore, industrial exposure from production of the biocidal product is out of the scope of this assessment.

***Professional exposure***

MIRMEX GR may be used by trained professionals both indoors and outdoors around buildings and is a ready-to-use granules formulation containing 0.632% w/w of cypermethrin as active substance and 0.012% of Acetic acid as Substance of Concern.

The recommended application rate of the product is 8 g product/m2. Treatment can be performed up to 2 times per year with a minimum interval of 4 weeks between applications.

The product should be applied by spreading in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities (partition between walls, holes).

It is considered that the direct exposure estimates for indoor treatments encompass those for outdoor treatments (i.e., it is considered to be within the ‘risk envelope’ as defined by the indoor use).

Primary exposure of trained professional users will be *via* inhalation and dermal route. The exposure is anticipated to be chronic in nature.

The model and the parameters used for the professional exposure to MIRMEX GR are summarised below, while the calculations are presented in the Annex 3.2 of this document.

*Scenario 1*

| **Description of Scenario 1:** **Application of MIRMEX GR by trained professional users** | | |
| --- | --- | --- |
| Model:Biocides Human Health Exposure Methodology, ECHA, October 2015, p.126: “Scattering powder against ants from a hand-held flexible duster/hand-held canister by consumers and professionals”; Approach 2: Hand-held flexible Duster (TNsG 2007, p. 63). | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Trained professional users | - |
| Scenario | Application | - |
| Application rate | 8 g/m2 | Product label claim. |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction of cypermethrin | 0.632% | Concentration of cypermethrin in the biocidal product. |
| Application duration | 60 minutes | The application duration default value for spreading/scattering a granule formulation is 60 min, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Exposure duration | 240 minutes | The exposure duration is a sum of the time required for application and the time of the user remaining in the room after application.  According to RIVM report 320005002/2006 (p.70) a total time of 4 hours is set as the default value for the exposure duration assuming that the user stays in the treated room for 4 hours after the application. |
| **Dermal exposure** | | |
| Indicative dermal exposure:  hand/forearm: 2.73 mg/min  legs/feet/face: 2.74 mg/min | 2.73 + 2.74 = 5.47 mg/min | Worst case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Dermal absorption | 50% | Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |
| Penetration to skin | no PPE: 100% | As a worst case, it was assumed that the professional user wears no personal protective equipment during application of the biocidal product MIRMEX GR. |
| **Inhalation exposure** | | |
| Indicative inhalation exposure | 2.47 mg/m3 | Default value according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Inhalation absorption | 100% | Assessment report of cypermethrin. |
| Inhalation rate | 1.25 m³/hour | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |

*Scenario 2*

| **Description of Scenario 2: Loading of the granules into smaller application containers.** | | |
| --- | --- | --- |
| Model: Mixing and loading model 5 ”Professional pouring formulation from a container into a fixed receiving vessel” (TNsG part 2, p 137). | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Trained professional users | - |
| Scenario | Loading | - |
| Application rate | 8 g/m2 | Product label claim. |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction of cypermethrin | 0.632% | Concentration of cypermethrin in the biocidal product. |
| Area treated/day | 100 m2 | It is assumed that the professional user treats approximately 1000 m of 10 cm crack/crevice per day, therefore the surface of the treated area is 100 m2. The selection of this value is considered precautionary given that the product is a crack and crevice, voids and cavities treatment. |
| Amount of a.s. handled/day | 0.005056 kg a.s/day | The amount of a.s. handled per day is calculated as follows:  8 g product/m2 x 100 m2 x 0.632% a.s./product = 5.056 g a.s. per day = 0.005056 kg a.s/day. |
| Penetration to skin | no PPE: 100% | As a worst case, it was assumed that the professional user wears no personal protective equipment during application of the biocidal product MIRMEX GR. |
| **Dermal exposure** | | |
| Indicative dermal exposure | Hands: 10.2 mg a.s./kg a.s. | Default value for dermal exposure according to Mixing and loading model 5” (TNsG part 2, p 137). |
| Dermal absorption | 50% | Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |
| Dermal uptake | 0.00043 mg/kg bw/day | The dermal uptake is calculated as follows: 10.2 mg a.s./kg a.s x 0.005056 kg a.s/day x 50% / 60 kg = 0.00043 mg/kg bw/day. |
| **Inhalation exposure** | | |
| Indicative inhalation exposure | 0.66 mg a.s./kg a.s. | Default value for inhalation exposure according to Mixing and loading model 5” (TNsG part 2, p 137). |
| Inhalation absorption | 100% | Assessment report of cypermethrin. |
| Inhalation uptake | 0.000056 mg/kg bw/day | The inhalation uptake is calculated as follows: 0.66 mg a.s./kg a.s x 0.005056 kg a.s/day x 100% / 60 kg = 0.000056 mg/kg bw/day. |

*Scenario 4*

| **Description of Scenario 4:** **Adult trained professional users laundering contaminated work clothes at home.** | | |
| --- | --- | --- |
| Exposure of adult trained professional users to the product MIRMEX GR can potentially occur *via* contact with the contaminated coveralls, during laundering at home. The worst-case exposure is *via* the dermal route – mainly to the hands – from handling the contaminated clothing prior to introduction into the washing machine.  The amount of product contaminating the coverall is considered to be equivalent to the potential dermal exposure estimated by the scenario “Scattering powder against ants from a hand held flexible duster/hand-held canister by consumers and professionals (TNsG 2007, p. 63). The indicative exposure value for the total body of the adult user is 5.47 mg/min. With an estimated duration of the application of 60 minutes for professional users and a.s. concentration in the product of 0.632%, the potential contamination is 2.074 mg a.s./day. It is assumed that the coverall is washed weekly, after 5 days wear.  Please refer to Annex 3.2 for the detailed calculations. | | |
| Parameters | Value | Comments |
| Exposed group | Trained professional users |  |
| Scenario | Laundering work clothes |  |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction of cypermethrin | 0.632% | Concentration of cypermethrin in the biocidal product. |
| Application duration | 60 minutes | The application duration default value for spreading/scattering a granule formulation is 60 min, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Indicative dermal exposure:  hand/forearm: 2.73 mg/min  legs/feet/face: 2.74 mg/min | 2.73 + 2.74 = 5.47 mg/min | Worst case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Dermal absorption | 50% | Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |
| Total outer surface area of a medium sized coverall | 22700 cm2 | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Total area of both hands of an adult | 820 cm2 | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Dislodgeable fraction | 30% | The default value for the dislodgeable fraction is set at 30%, according to RIVM report 320005002 (p.71). |

**Calculations for Scenarios 1-2-4 for cypermethrin**

| **Summary table: estimated exposure from 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/no PPE | 0.000325 | 0.0173 | - | 0.01763 |
| Scenario 2 | 1/no PPE | 0.000056 | 0.00043 | - | 0.000486 |
| Scenario 4 | 1/no PPE | - | 0.00019 | - | 0.00019 |

**Further information and considerations on Scenarios 1 and 2**

Mirmex GR is formulated with acetic acid (CAS No. 64-19-7), which is used as pH adjuster in the early steps of manufacturing process (for additional information about manufacturing process, please see the Confidential Annex). The low concentration and function of acetic acid and the manufacturing method as a whole, make a possible user’s inhalation exposure highly difficult. Furthermore, the manufacturing process leads by its nature to a significant and relevant evaporation of acetic acid from the final product.

However, as acetic acid has a European Union-agreed IOELV (25 mg/m3), a quantitative inhalation risk assessment for the professional operator against the IOELV has been conducted. Therefore, for scenarios 1 and 2, the inhalation exposure of professional users to acetic acid has been calculated.

The parameters used for the inhalation exposure of trained professional users to acetic acid during the application (Scenario 1) and loading (Scenario 2) of MIRMEX GR are summarised below, while the calculations are presented in the Annex 3.2 of this document.

***Scenario 1***

| **Scenario 1: Inhalation exposure of trained professional users to acetic acid during the application of MIRMEX GR** | | |
| --- | --- | --- |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Trained professional users | - |
| Scenario | Application | - |
| Application rate | 8 g/m2 | Product label claim. |
| Concentration of acetic acid | 0.012% | Concentration of acetic acid in the biocidal product. |
| Body weight of adult | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Inhalation rate of adult | 1.25 m3/h | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Penetration to skin | no PPE: 100% | As a worst case, it was assumed that the professional user wears no personal protective equipment during application of the biocidal product MIRMEX GR. |
| Indicative inhalation exposure | 2.47 mg/m3 | Default value according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Inhalation absorption | 100% | Worst-case assumption. |
| Application duration | 60 min | The application duration default value for spreading/scattering a granule formulation is 60 min, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |

***Scenario 2***

| **Scenario 2: Inhalation exposure of trained professional users to acetic acid during loading of the granules into smaller application containers** | | |
| --- | --- | --- |
| Model: Mixing and loading model 5 ”Professional pouring formulation from a container into a fixed receiving vessel” (TNsG part 2, p 137). | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Trained professional users | - |
| Scenario | Loading | - |
| Application rate | 8 g/m2 | Product label claim. |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Concentration of acetic acid | 0.012% | Concentration of acetic acid in the biocidal product. |
| Area treated/day | 100 m2 | It is assumed that the professional user treats approximately 1000 m of 10 cm crack/crevice per day, therefore the surface of the treated area is 100 m2. The selection of this value is considered precautionary given that the product is for treatment in cracks and crevices, voids and cavities. |
| Amount of acetic acid handled/day | 0.000096 kg/day | The amount of acetic acid handled per day is calculated as follows:  8 g product/m2 x 100 m2 x 0.012% = 0.096 g acetic acid per day = 0.000096 kg acetic acid/day. |
| Penetration to skin | no PPE: 100% | As a worst case, it was assumed that the professional user wears no personal protective equipment during application of the biocidal product MIRMEX GR. |
| Indicative inhalation exposure | 0.66 mg substance/kg substance | Default value for inhalation exposure according to Mixing and loading model 5” (TNsG part 2, p 137). |
| Inhalation absorption | 100% | Worst-case assumption. |
| Inhalation uptake | 1.1x10-6 mg/kg bw/day | The inhalation uptake is calculated as follows: 0.66 mg/kg x 0.000096 kg/day x 100% / 60 kg = 1.1x10-6 mg/kg bw/day. |

**Calculations for Scenarios 1-2 for acetic acid.**

| **Summary table: estimated exposure from 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/no PPE | 6 x 10-6 | - | - | **6 x 10-6** |
| Scenario 2 | 1/no PPE | 1.1 x 10-6 | n.a. | - | **1.1 x 10-6** |

**Additional considerations on scenarios**

Post-application phase is not expected for this kind of product. No cleaning of the equipment is expected as most of the containers are for ready-to-use products and those to be filled with granules from bags are not expected to be cleaned after application.

Cleaning of the crack and crevices is not expected. Corners or point that could be cleaned are cleaned by dry cleaning (vacuum) as the product is a granule, therefore no contact with the product is expected.

In addition, secondary exposure due to re-entry is not expected, as the product is applied in cracks and crevices, voids and cavities. Also inhalation exposure due to evaporation is not expected as the active substance in these granules is a substance with an extremely low vapour pressure, and therefore not very volatile. The inhalation exposure due to evaporation is therefore considered to be negligible.

Dermal exposure may occur considering that professional workers may launder their work clothes at home in a domestic, automatic washing machine. Therefore, exposure of the professional user will occur by the dermal route, *via* the hands, from handling the contaminated clothing prior to and during introduction of the clothing into the washing machine (Scenario 4).

Combined exposure (combined scenarios 1+2+4 for cypermethrin and scenarios 1+2 for acetic acid) has been assessed for the professional user who is exposed to the active substance cypermethrin and the SoC acetic acid during the application of the product (primary direct exposure – Scenario 1), during the loading of the granules into application containers (primary direct exposure – Scenario 2) and during the laundering of the contaminated work clothes at home (primary indirect exposure – Scenario 04).

*Combined scenarios*

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  | **mg/kg bw/day** | | | |
| Scenarios [1,2,4]  Tier 1  Cypermethrin | 0.000381 | 0.01792 | - | 0.0183 |
| Scenarios [1,2]  Tier 1  Acetic acid | 7.1 x 10-6 | - | - | 7.1 x 10-6 |

Aggregated exposure of the active substance with acetic acid is not relevant, as the exposure to cypermethrin is expected to lead to systemic effects, while exposure to acetic acid is expected to lead to local effects (irritation of the respiratory tract).

***Non-professional exposure***

MIRMEX GR may be used by non-professionals both indoors and outdoors around buildings and is a ready-to-use granules formulation containing 0.632% w/w of cypermethrin as active substance and 0.012% of Acetic acid as Substance of Concern.

The recommended application rate of the product is 8 g product/m2. Treatment can be performed up to 2 times per year with a minimum interval of 4 weeks between applications.

The product should be applied by spreading in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities (partition between walls, holes).

It is considered that the direct exposure estimates for indoor treatments encompass those for outdoor treatments (i.e., it is considered to be within the ‘risk envelope’ as defined by the indoor use).

Primary exposure of non-professional users will be *via* inhalation and dermal route.

The model and the parameters used for the exposure of non-professionals to MIRMEX GR are summarised below, while the calculations are presented in the Annex 3.2 of this document.

*Scenario 3*

| **Description of Scenario 3:** **Application of MIRMEX GR by non-professional users** | | |
| --- | --- | --- |
| Model:Biocides Human Health Exposure Methodology, ECHA, October 2015, p.126: “Scattering powder against ants from a hand-held flexible duster/hand-held canister by consumers and professionals”; Approach 2: Hand-held flexible Duster (TNsG 2007, p. 63). | | |
| **Parameters** | **Value** | **Comments** |
| Exposed group | Non-professionals | - |
| Scenario | Application | - |
| Application rate | 8 g/m2 | Product label claim. |
| Body weight | 60 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction of cypermethrin | 0.632% | Concentration of cypermethrin in the biocidal product. |
| Application duration | 15 minutes | For dusting powders, the only available data for quantity of dust applied per min is an assumption of dusting 60 g/m2 in 5 min equivalent to 12 g/min (TNsG, 2002, p.280).  Based on this and taking into account the application rate of MIRMEX GR (8 g/m2), the default value of 22 m2 for surface broadcast dusting of powder (TNsG, 2002, p.279), the application duration for MIRMEX GR is calculated as follows: (8 g/m2  x 22 m2) / 12 g/min = 14.67 min.  Therefore, an application duration of 15 min was selected as a worst-case value**.** |
| Exposure duration | 240 minutes | The exposure duration is a sum of the time required for application and the time of the user remaining in the room after application.  According to RIVM report 320005002/2006 (p.70) a total time of 4 hours is set as the default value for the exposure duration assuming that the user stays in the treated room for 4 hours after the application. |
| **Dermal exposure** | | |
| Indicative dermal exposure:  hand/forearm: 2.73 mg/min  legs/feet/face: 2.74 mg/min | 2.73 + 2.74 = 5.47 mg/min | Worst case dermal exposure, according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Dermal absorption | 50% | Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |
| **Inhalation exposure** | | |
| Indicative inhalation exposure | 2.47 mg/m3 | Default value according to Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. |
| Inhalation absorption | 100% | Assessment report of cypermethrin. |
| Inhalation rate | 1.25 m³/hour | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |

**Calculations for Scenario 3**

| **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 3 | Tier 1/no PPE | 0.00008 | 0.0043 | - | **0.0044** |

**Further information and considerations on Scenario 3**

Post-application phase is not expected for this kind of product. No cleaning of the equipment is expected because containers are for ready-to-use products.

Cleaning of the crack and crevices is not expected. Corners or points that could be cleaned are cleaned by dry cleaning (vacuum) as the product is a granular formulation, therefore no contact with the product is expected.

***Exposure of the general public***

Subsequent to the use of the biocidal product, indirect secondary exposure of general public could occur in the residential environment. Secondary exposure is derived *via* inhalation, dermal and oral route.

Inhalation exposure to volatilised residues of cypermethrin is expected to occur for infants, toddlers, children and adults entering to treated areas.

Dermal exposure is expected to occur for the general public *via* direct contact to deposits of the biocide on the surface of contact after product application. Dermal exposure may occur to infants, toddlers and children crawling on floor or playing around treated surfaces for a significant time period.

It is noted that the biocidal product MIRMEX GR contains a bittering agent that prevents it from being ingested by the children. Therefore, the oral exposure of infants and toddlers from hand-to-mouth contact would be negligible.

It is assumed that infants, toddlers and children would not be permitted to be present during the application operation and therefore, there would be no acute exposure.

Secondary exposure for the general puclic is considered as a medium-term event, because it is estimated that the duration of exposure is more important than a single event, among others considering inhalation exposure. The exposure time would be high, 8 hours for inhalation of the residues and a dermal contact of one hour for children, toddlers and infants playing on the treated floor.

The models used for the secondary exposure assessment for the general public are summarized in the following table.

|  |  |  |
| --- | --- | --- |
| **Overview of models used for secondary human health exposure assessment.** | | |
| **Inhalation route** | **Models** | **Population** |
| Vapours (volatilised residues) | HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocidal active substances. | Infant  Toddler  Child  Adult |
| **Dermal route** | **Model** | **Population** |
| Dermal contact with treated surfaces | ConsExpo Web, version 1.0.6 - RIVM Pest Control Products Fact Sheet, 2006 - Secondary exposure - Rubbing off. | Infant  Toddler  Child |

**Assessment of Inhalation Exposure of Volatilised Biocidal Active Substances**

Inhalation exposure to volatilised residues of cypermethrin is expected to occur for infants, toddlers, children and adults entering to treated areas.

Volatization of cypermethrin is expected to be minimal due to low vapour pressure, low Henry’s Law constant and high adsorption potential. Therefore, inhalation exposure due to evaporation is considered to be negligible. However, the assessment of inhalation exposure of volatilised residues of active substances was performed for completeness.

*Tier-1 screening tool*

As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed in HEEG Opinion 13 (Assessment of Inhalation Exposure of Volatilised Biocide Active Substance).

Let mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa). For toddler (based on an inhalation rate of 8 m3/24 hr and body weight of 10 kg) and using an AEL in mg a.s./kg bw/d, if

0.328 × [(mw x vp) / AELlong-term] ≤ 1

then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is

negligible, then the inhalation risk for the infant, child and for the adult can also be considered to be negligible.

Tier-1 screening tool has been applied for the active substance as detailed in the following table.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Screening tool of inhalation exposure of volatilised biocidal active substance** | | | | | |
| **Active substance** | **MW (g/mol)** | **vp**  **(Pa)** | **AELlong-term**  **(mg/kg bw/d)** | **0.328 × mw x vp/AELlong-term** | **Result** |
| cypermethrin | 416.3 | 6 x 10-7 | 0.022 | 0.0037 | <1  risk from inhalation exposure for the toddler is negligible |

As a result of the application of Tier-1 screening tool, the risk from the inhalation exposure for toddlers is negligible in long-term exposure. Therefore, the inhalation risk for infants, children and adults is also considered negligible.

**Dermal exposure to residues on the floor – infants, toddlers and children**

Secondary dermal exposure due to the entering in areas treated with the product is not expected for the general public, as the product is applied in cracks and crevices, voids and cavities. In addition, secondary exposure of children, toddlers and crawling infants is not expected as the product is used in areas that are inaccessible to infants, toddlers and children, according to the product label.

However, as a worst case, a scenario for the secondary dermal exposure of infants, toddlers and childeren has been included in the risk assessment.

The models and the parameters used to calculate the secondary exposure assessment for the general public are described in detail in the following table, while the calculations are presented in the Annex 3.2 of this document.

*Scenario 5*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 5:** **Secondary dermal exposure of the general public.** | | |
| The assessment for the dermal exposure of the general public has been performed using ConsExpo Web, version 1.0.6, considering the application rate of the product (8 g/m2).  The parameters used were from the RIVM report 320005002/2006, Chapter 7, Dusting powders, Exposure after application (p. 71-73). | | |
| **Parameter** | **Value** | **Comments** |
| Exposed group | General public:  infant, toddler, child | - |
| Product database | Pest control products | - |
| Product category | Dusting powders | - |
| Product | Dusting powders | - |
| Scenario | Post-application (child) | - |
| Application rate | 8 g/m2 | Product label claim. |
| Body weight | Infant: 8 kg  Toddler: 10 kg  Child: 23.9 kg | HEEG Opinion “Default human factor values for use in exposure assessments of biocidal products”. |
| Weight fraction substance | 0.632% | Concentration of cypermethrin in the biocidal product. |
| **Dermal exposure** | | |
| Model | Direct product contact | - |
| Loading | Rubbing off | - |
| Exposure frequency | 70 per year | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 73). |
| Exposed area  (palms and backs of both hands) | Infant: 196.8 cm2  Toddler: 230.4 cm2  Child: 427.8 cm2 | HEEG Opinion “Default human factor values for use in exposure assessments for biocidal products”. |
| Transfer coefficient | Infant/toddler/child: 0.2 m2/hr | Recommendation no. 12 of the BPC Ad hoc Working Group on Human Exposure: “New default values for indoor Transfer Coefficient” (agreed at the Human Health Working Group V on 22 November 2016). |
| Dislodgeable amount  (product) | 2.04 g/m2 | Dislodgeable amount has been calculated as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 71), using the application rate of MIRMEX GR (8 g/m2).  According to RIVM report 320005002 (p.71), “the default value for the dislodgeable fraction is set at 30%. The airborne fraction is taken to be 15%, so 85% of the powder is sprinkled onto 1 m2”.  Therefore, the dislodgeable amount for MIRMEX GR is calculated as follows:  8 g/m2 x 0.85 x 0.3 = 2.04 g/m2 |
| Contact time | 60 min/day | Default value, as reported in RIVM report 320005002/2006: “Pest Control Products Fact Sheet” (p. 73). |
| Rubbed surface | 2 m2 | Spot treatment and cracks/crevices treatment for a domestic house is 2 m2 (Technical Agreements for Biocides (TAB) - ENV v.2.0, ENV 142). |
| Dermal absorption | 50% | Default dermal absorption value for cypermethrin, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for solid-formulated products. |

**Calculations for Scenario 5**

| **Summary table: systemic exposure for general public** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Exposed group** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
|  |  | mg/kg bw/day | | | |
| Scenario 5 | Infant | - | 0.16 | - | **0.16** |
| Scenario 5 | Toddler | - | 0.13 | - | **0.13** |
| Scenario 5 | Child | - | 0.054 | - | **0.054** |

***Monitoring data***

Not available.

***Dietary exposure***

Not applicable, due to the intended use.

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

Not applicable.

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

Not relevant.

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

Not relevant, in normal conditions of use the product does not come into contact with food.

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

Not relevant, in normal conditions of use the product does not come into contact with food.

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

Please, refer to the “Industrial exposure” paragraph.

***Aggregated exposure***

N.A.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | | |
| --- | --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Substance** | **Estimated total uptake**  (mg/kg bw/day) |
| 1. | Professional users | 1/no PPE | Cypermethrin | **0.01763** |
| Acetic acid | **6 x 10-6** |
| 2. | Professional users | 1/no PPE | Cypermethrin | **0.000486** |
| Acetic acid | **1.1 x 10-6** |
| 3. | Non-professional users | 1/no PPE | Cypermethrin | **0.0044** |
| 4. | Professional users | 1/no PPE | Cypermethrin | **0.00019** |
| 5. | Infant | 1/no PPE | Cypermethrin | **0.16** |
| 5. | Toddler | 1/no PPE | Cypermethrin | **0.13** |
| 5. | Child | 1/no PPE | Cypermethrin | **0.054** |
| 1+2+4 | Professional users | 1/no PPE | Cypermethrin | **0.0183** |
| 1+2 | Professional users | 1/no PPE | Acetic acid | **7.1 x 10-6** |

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | Rat, acute delayed neurotoxicity | 20 mg/kg bw/day | 100 | 44% | 0.088 mg/kg bw/day |
| AELmedium-term | Dog, 90-days | 12.5 mg/kg bw/day | 100 | 44% | 0.055 mg/kg bw/day |
| AELlong-term | Rat, 2-year | 5 mg/kg bw/day | 100 | 44% | 0.022 mg/kg bw/day |

The following values for ADI and ARfD were agreed (based on derivation made for the Plant Protection Products regulation; DAR Cypermethrin, EFSA Feb 2005):

ADI = 0.05 mg/kg bw/day

ARfD = 0.2 mg/kg bw/day

**Reference values to be used in Risk Characterisation for acetic acid**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| European IOELV according to Commission Directive (EU) 2017/164: | | | | Notation |
| Long-term (8 hours) | | Short-term | |
| mg/m3 | ppm | mg/m3 | ppm |
| 25 | 10 | 50 | 20 | - |

The critical effect of occupational exposure to acetic acid is irritation of the skin and mucous membrane. There is reliable dose-response data on sensory irritation in human volunteers and this can be used to set limits for exposure. Minor subjective irritant effects have been reported in two volunteer studies at 10-ppm exposures (Ernstgård et al 2006, HVBG 2007). Although Ernstgård et al (2006) noted a non-significant increase in eye blink frequency at 10 ppm, this response was not observed in the larger study on volunteers observed over 4 hours and reported by HVBG (2007). Neither the Ernstgård nor the HVBG studies observed any physiological changes compatible with irritation at 10-ppm exposures.

Ernstgård et al studied 11 volunteers in a 2-hour exposure and HVBG 24 subjects over 4 hours. The results reported in the two studies are comparable. Given the minor subjective effects reported at 10 ppm, the absence of any physiological measurements of irritation at this concentration, the possibility that smell may be affecting some self-reported ratings of irritation by the volunteers and a laterilisation (irritation) threshold of 40 ppm it is possible to recommend an 8-hour OEL of 10 ppm. Assuming 100 % respiratory uptake the inhaled dose over a working shift would be about 250 mg (25 mg/m3 x 10 m3). Given that the daily turnover of the acetate ion (the ionic form of acetic acid) is estimated to be about 45 g/day, no systemic effects are expected at the proposed OEL. With an irritation (laterilisation) threshold identified at 40 ppm, it is unlikely that at exposures half of this there will be noticeable irritation over the short term and therefore a 20 ppm STEL can also be recommended (Recommendation from the Scientific Committee on Occupational Exposure Limits for acetic acid (SCOEL/SUM/98; June 2012).

The European IOELV (25 mg/m3) has been converted in the systemic inhalation uptake of 0.5208 mg/kg bw/day, considering an inhalation rate of 1.25 m3/h, body weight of 60 kg, 100% inhalation absorption and1 h duration of exposure for the professional user (25 mg/m3 x 1.25 m3/h x 1 h x 100% / 60kg = 0.5208 mg/kg bw/day).

**Maximum residue limits or equivalent**

Not applicable

**Specific reference value for groundwater**

Not applicable

***Risk for industrial users***

The modelling of exposure and subsequent risk characterisation during production and formulation of Mirmex GR is addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under Regulation 528/2012 (this principle was agreed at Biocides Technical Meeting TMI06). Therefore, industrial exposure from production of the biocidal product is out of the scope of this assessment.

**Conclusion**

It is possible to conclude that occupational health risk is minimal.

***Risk for professional users***

**Systemic effects for cypermethrin**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AELmedium-term**  **(mg/kg bw/day)** | **Estimated uptake**  **(mg/kg bw/day)** | **Estimated uptake/AEL** | **Acceptable**  **(yes/no)** |
| Application Professional users Scenario 1 | 1 | 0.022 | 0.01763 | 80.14% | yes |
| Loading Professional users Scenario 2 | 1 | 0.022 | 0.000486 | 2.2% | yes |
| Laundering of working clothes  Professional users Scenario 4 | 1 | 0.022 | 0.00019 | 0.8636% | yes |

**Systemic effects for acetic acid**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **IOELV mg/m3/8h** | **Converted reference value**  **(mg/kg bw/day)** | **Estimated uptake**  **(mg/kg bw/day)** | **Estimated uptake/ reference value** | **Acceptable**  **(yes/no)** |
| Application Professional users Scenario 1 | 25 | 0.5208 | 6 x 10-6 | 0.00115% | yes |
| Loading Professional users Scenario 2 | 25 | 0.5208 | 1.1 x 10-6 | 0.00021% | yes |

**Combined scenarios for cypermethrin**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AELmedium-term**  **mg/kg bw/day** | **Estimated uptake**  **mg/kg bw/day** | **Estimated uptake/AEL** | **Acceptable**  **(yes/no)** |
| Loading,application and laundering Professional users Scenarios 1, 2, 4 | 1 | 0.022 | 0.0183 | 83.18% | yes |

**Combined scenarios for acetic acid**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **IOELV mg/m3/8h** | **Converted reference value**  **(mg/kg bw/day)** | **Estimated uptake**  **(mg/kg bw/day)** | **Estimated uptake/ reference value** | **Acceptable**  **(yes/no)** |
| Loading and application Professional users  Scenarios 1, 2 | 25 | 0.5208 | 7.1 x 10-6 | 0.00136% | yes |

**Local effects**

Local effects are not expected for this product.

**Conclusion**

For Scenarios 1, 2 and 4 exposure of professional users is considered acceptable, as the total internal dose is below the long-term AEL. Also combined exposure of Scenarios 1, 2 and 4 is considered acceptable.

Therefore, there is no concern for the professionals using the biocidal product MIRMEX GR.

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

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AELshort-term**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| Application  Non-professional users  Scenario 3 | 1 | 0.088 | 0.0044 | 5% | yes |

**Combined scenarios**

N.A.

**Local effects**

Local effects are not expected for this product.

**Conclusion**

For Scenario 3, the total internal dose is well below the short-term AEL. Therefore, there is no concern for non-professional users, using the biocidal product MIRMEX GR.

***Risk for the general public***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AELmedium-term**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| Infant  Scenario 5 | 1 | 0.055 | 0.16 | 291% | **no** |
| Toddler  Scenario 5 | 1 | 0.13 | 236.36% | **no** |
| Child  Scenario 5 | 1 | 0.054 | 98.18% | yes |

**Local effects**

Local effects are not expected for this product.

**Conclusion**

Secondary inhalation exposure due to evaporation of the active substance is considered to be negligible for the general public.

Secondary dermal exposure due to the entering in areas treated with the product is not expected for the general public, as the product is applied in cracks and crevices, voids and cavities. In addition, secondary exposure of children, toddlers and crawling infants is not expected as the product is used in areas that are inaccessible to infants, toddlers and children, according to the product label. However, as a worst case, a scenario for the secondary dermal exposure of infants, toddlers and childeren has been performed.

For adults and children, there is no concern for indirect secondary exposure from the use of the biocidal product MIRMEX.

In contrast, a risk has been identified for infants and toddlers. However, considering the label implication that the product should be used in areas inaccessible to infants and children, no concern arises for these populations groups.

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

Not applicable, due to the intended use.

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

No combined exposure is foreseen.

### Risk assessment for animal health

In and around buildings application

Terrestrial fauna

Cypermethrin cis:trans/40:60 has limited acute effect on terrestrial organisms such as earthworms. The EC50 is found >100 mg/Kg.

In a chronic test on earthworms, a NOEC mortality > of 100 mg/Kg was determined. A NOEC biomass of 30.8 mg/Kg and a NOEC reproduction of 5.2 mg/Kg where determined in the same study. Based on the measured concentration the NOEC (reproduction) for earthworms is 4 mg/kgdw.

In addition to these tests on earthworms, field trials provided information on the effect of 14d apart applications of cypermethrin 100 g/L (250ml/ha) on non-target arthropod fauna. No adverse effects were identified on Linyphiidae; Collembolla; Diptera; Braconidae/ Ichneumonidae+ Aphidius Sp.; Gamebird-chick food populations. The observed effects on Carabid and Staphilinid populations were only transient allowing populations to recover within a crop season. (Evaluation Report of AS)

Terrestrial micro organisms:

Cypermethrin has moderate effect on soil microorganisms on mineralisation process. A NOEC of 52.0 mg/Kg dry soil was determined. (Evaluation Report of AS)

Toxicity to birds:

Cypermethrin cis:trans/40:60 shows oral acute toxicity to bird a dose above 1376mg a.i. /Kg/d or 5620 mg/Kg feed. Chronic effects (21d) investigated up to 1000mg/Kgfood don’t show any significant results up to 92.0 mg as/Kgbw. There were no treatment-related effects upon reproductive performance at any of the concentrations tested and no treatment-related macroscopic abnormalities were observed in any birds examined at autopsy. The NOEC was set to 1000 mg/Kgfoodor 92.0 mg as/Kgbw. (Evaluation Report of AS)

### Risk assessment for the environment

#### Effects assessment on the environment

The results of the mesocosm study cannot be used to derive the PNEC water. The value of the assessment factor (10) was chosen according to the TGD based on the available dataset. The lowest NOEC calculated is 0.04 μg/l for daphnia. Therefore, using the AF of 10, the PNEC water is 0.004 μg/L.

**PNECwater = 0.004 μg/L**

No study allow for the derivation of a PNEC sed.

Using the equilibrium partitioning method and a value of koc of 575000 to calculate Ksusp-water.

PNECsed= 0.050 mg/kg

Using the equilibrium partitioning method (epm) with a Koc of 575000, the highest Koc within those derived (see doc IIA), and an additional Af of 10 necessary due to the strong biding of the active to the sediment particles, no risk is identified for the sediment.

**PNECsed= 0.005 mg/kg**

The result of the microbial activity inhibition test is provided as an EC50. According to the TGD, an assessment factor of 100 is applied to the 163 mg/l EC50 to derive the PNEC.

**PNECstp= 1.63mg/L**

Two acute tests on earthworms was provided, which both presented small deficiencies. The study presenting the most conservative value for the earthworms was kept as key study with an LC50 of 100 mg/Kg dry soil . A reproduction study with earthworms provided a NOEC of 4.0 mg/Kg dry soil based on measured concentration.

The field trial on mineralization of nitrogen in soil performed by Servajean, provided a NOEC of 52.0 mg/Kg ww.

Additional studies on plant and non-target arthropods indicated that cypermethrin has minor and transient effect on the evaluated organisms at PPP application rate (250ml/ha) following two sequential applications (14 or 19 days).

According to the TGD, an assessment factor of 50 can be used from the earthworm’s acute test, the chronic earthworms test and microbial inhibition test (two NOEC from two trophic levels). However, the result from the study on plant and the tests on non target arthropod which are non key studies does not normally allowed to further lower the AF. However the results of the tests enhance the confidence on the overall picture of the toxicity of cypermethrin on soil and terrestrial organisms. The resulting Pnec is 0.08 mg/Kg dw (equivalent to 0.07 mg/kg ww) soil from the chronic earthworm NOEC reproduction using and AF of 50.

**PNECsoil = 0.08 mg/Kgsoil dw ( = 0,0708 mg/kg ww)**

***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***

The product contains 0.6% of pure a.s. (cypermethrin) which is classified for the environmental hazards as Aquatic Acute 1, H400 (M = 100) and Aquatic Chronic 1, H410 (M = 1000). Therefore according to Regulation (EC) n. 1272/2008 (CLP), the product is classified as Aquatic Acute 1, H400 and Aquatic Chronic 1, H410.

***Further Ecotoxicological studies***

**No data available.**

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further Ecotoxicological studies |
| Justification | No further information is required.  Data available through letter of access. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Effects on any other specific, non-target organisms |
| Justification | Refer to 2.2.7 paragraph |

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

No data available.

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

No data available.

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

No data available.

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

Data available through letter of access.

***Leaching behaviour (ADS)***

Not applicable.

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

Data available through letter of access.

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

Data available through letter of access.

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

Data available through letter of access.

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

Not applicable.

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

Not applicable.

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | **Scenario 1**: non-professional indoor insecticide against ants  **Scenario 2**: professional indoor insecticide against ants  **Scenario 3**: non-professional outdoor around buildings insecticide against ants  **Scenario 4**: professional outdoor around buildings insecticide against ants  **Scenario 5**: non-professional and professional outdoor spot application against ants |
| ESD(s) used | Emission Scenario Document for Product Type 18:  OECD SERIES ON EMISSION SCENARIO DOCUMENTS  Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses |
| Approach | All scenarios: Average consumption |
| Distribution in the environment | * Emission Scenario Document (ESD) PT 18 No 18 (2008) * Guidance on the BPR, Vol. IV, Part B+C (2017) * Technical Agreements on Biocides (TAB), v. 2.1 (2019) |
| Groundwater simulation | none |
| Confidential Annexes | Not applicable |
| Life cycle steps assessed | Scenarios n:1 to 5  Production: No  Formulation No  Use: Yes  Service life: Yes |
| Remarks | none |

***Emission estimation***

**Scenario 1**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Insecticide, acaricides and products to control other arthropods. Indoor, powders/dusting. Non-professional use. Dust/powders – crack and crevices. The product has to be applied in thin layers in cracks and crevices where insects hide (under furniture, corners, etc.). | | | |
| Application rate of biocidal product | 8 | g/m² |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Cover mixing and loading | no | - |  |
| Number of emission days | 90 |  | Season treatment |
| Area treated in a standard house | 2 | m² | (spot treatment; TAB 2.1, ENV 142) |
| Frequency of application in standard houses | 1-2 times a year |  |  |
| Cleaning efficiency | 0.25 | - | (Dust/powders – crack and crevice; TAB ENV 149) |
| Washable coveralls or disposable coveralls? | Washable coveralls | - |  |
| Dry or wet cleaning of treated surfaces? | Dry cleaning | - |  |

Calculations for Scenario 1

For calculations of scenario 1 EUSES 2.2 has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: scenario for dusting powders indoor, application in crack and crevices, spot treatment (as defined in TABs, ENV 144). Non-professional use.

For the application indoor of voids and cavities no specific scenario was developed as no release into the environment is expected.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 3.72E-05 | Local emission to wastewater entering the STP |
| Air | 1.65E-05 |  |
| Soil | 0 |  |
| Groundwater | 0 |  |

**Scenario 2**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Insecticide, acaricides and products to control other arthropods. Indoor, powders/dusting. Professional use. Dust/powders – crack and crevices. | | | |
| Application rate of biocidal product | 8 | g/m² |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Cover mixing and loading | no | - | Cover the floor when loading the product in the application tools and dispose the material in solids wastes, in order to avoid releases on floor |
| Number of emission days | 90 |  | Season treatment |
| Area treated in a standard house | 2 | m² | (spot treatment; TAB 2.1, ENV 142) |
| Area treated in a large building | 9.3 | m² | (spot treatment; TAB 2.1, ENV 142) |
| Frequency of application in standard houses | 1-2 times a year |  |  |
| Frequency of application in large buildings | 1-2 times a year |  |  |
| Cleaning efficiency | 0.25 | - | (Dust/powders – crack and crevice; TAB ENV 149) |
| Washable coveralls or disposable coveralls? | Washable coveralls | - |  |
| Dry or wet cleaning of treated surfaces? | Dry cleaning | - |  |

Calculations for Scenario 2

For calculations of scenario 2 EUSES 2.2 has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: scenario for dusting powders indoor, application in crack and crevices, spot treatment (as defined in TABs, ENV 144). Professional use.

For the application indoor of voids and cavities under floating floors, no specific scenario was developed as no release into the environment is expected.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 5.01E-05 | Local emission to wastewater entering the STP |
| Air | 2.23E-05 |  |
| Soil | 0 |  |
| Groundwater | 0 |  |

**Scenario 3**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: non-professional outdoor around houses on paved ways, balconies and terraces treatment insecticide against ants. Apply the product in crack and crevices in ant frequented areas.  In case of spot application on paved surfaces around domestic premises the terrace scenario has been selected (no release to sewer/STP is assumed, only releases to soil compartment around a terrace; ENV 159).  Bait boxes scenario in terrace is used.  According to ENV 154, it was agreed to use a default area for the terrace of 30 m2 and assume a receiving area of 8.5 m2 (taking into account three sides of a terrace). In addition, a default value of 4 application sites should be used if no data on the application is provided by the applicant, substantiated with efficacy tests.  This can be considered a worst case, as powder are not expected to spread away from the site of application and the treated zone is covered by roof, which prevents the washout on the surrounding soil.  According to ENV 153, the soil depth is set to 0.5 m.  Application 8g/m2 = 8g/application site. | | | |
| Quantity of commercial product applied/nest | 8 | g |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Fraction emitted to soil during application | 0.9 |  | Worst case (as for powder in outdoor spot application) |
| Number of application sites | 4 | - | The default value for of 4 bait boxes per terrace was considered representative also for this use. |
| Number of applications during a campaign | 1 | - |  |
| Area exposed to the insecticide | 8.5 | m2 | See explanation above. |

Calculations for Scenario 3

For calculations of scenario 3 **EUSES 2.2** has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: outdoor spot application and according to ENV TABs. Non-professional use.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 0 |  |
| Air | 0 |  |
| Soil | 1.82E-04 | Kg (direct emission to soil) |
| Groundwater | 0 |  |

**Scenario 4**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: professional outdoor around houses on paved ways, balconies and terraces treatment insecticide against ants. Apply the product in crack and crevices in ant frequented areas.  In case of spot application on paved surfaces around domestic premises, this scenario is covered by scenario 3. In case of application on paved surfaces around large buildings, the terrace scenario has been adapted considering a perimeter of 100 m (ENV 159) and 14 application sites (re-proportioned from 4 application sites of the terrace scenario (30 m2). No release to sewer/STP is assumed, only releases to soil compartment around a terrace (ENV 159).  It should be noted that this is a worst case, as granules are not expected to spread away from the site of application and, according to the label instructions, the treated zone is covered by roof, which prevents the washout on the surrounding soil. Indeed note that according to ENV 158, for products “intended (..) for any professional use, but only used on paved surfaces, and not on bare soil and (…) to be applied in roof-covered areas, which cannot be affected by flooding, and which are protected from rain fall or  cleaning wash”, no risk assessment is needed.  As a worst case, however, it is supposed that, the paved perimeter of the building is large 1 m, therefore the paved application area is 100 m2. As for the terrace scenario, a strip of soil 0.5 m wide adjacent to the paved perimeter is exposed to the product, therefore 100 m perimeter x 0.5 m width = 50 m2. 50 m2 is the soil exposed area.  According to ENV 153, the soil depth is set to 0.5 m.  Application 8 g/m2 = 8 g/application site. | | | |
| Quantity of commercial product applied/nest | 8 | g |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Fraction emitted to soil during application | 0.9 |  | Worst case (as for powder in outdoor spot application) |
| Number of application sites | 14 | - | The default value for of 4 bait boxes per terrace was considered representative also for this use. |
| Number of applications during a campaign | 1 | - |  |
| Area exposed to the insecticide | 50 | m2 | See explanation above. |

Calculations for Scenario 4

For calculations of scenario 4 **EUSES 2.2** has been used. The scenario was developed in accordance with OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses: outdoor spot application and according to ENV TABs. Non-professional use.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 0 |  |
| Air | 0 |  |
| Soil | 6.37E-04 | Kg (direct emission to soil) |
| Groundwater | 0 |  |

**Scenario 5**

|  |
| --- |
| EL CA:  At the exposure assessment initially performed by the applicant, the fraction emitted to soil during application was set to 0.2 considering bait as the type of spot application.  According to the applicant, the emission to soil of bait scenario was considered appropriate, based on the composition of the product, the high affinity of Cypermethrin to soil which prevents the product from diffusing in the surrounding soil and indications from observation period of efficacy studies where no residues of the products were observed on the treated nest.  EL CA does not agree with this approach.  The bait scenario is based on bait stations/traps which are designed so that spill of substance around the trap is not allowed. Also, at the end of the efficacy period, traps and the potentially remaining product are disposed to municipal wastes.  The use pattern of granules is basically similar to that of powders. Thus, it is not current practice to collect unconsumed product, and it is considered that the fraction released during powder application to the environment is 90%, either directly or through ultimate releases after target insect death.  Therefore, the exposure assessment was performed with the fraction emitted to soil during application set to 0.9, as for powder in outdoor spot application. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: non-professional and professional outdoor insecticide against ants. The product is to be applied directly into the holes of soil, in the ants nest.  EUSES scenario: outdoor spot application. | | | |
| Quantity of commercial product applied/nest | 2 | g/nest entry |  |
| Concentration of active substance in the product | 0.632 | % w/w (technical) |  |
| Type of spot application | powder | - |  |
| Number of application sites | 4 | - | The product is intended to be treated just one nest per application.  Maximum of 4 nest entrance to be treated per nest. |
| Number of applications during a campaign | 1 | - | Usually one application is sufficient to eradicate the ant nest |

**Calculations for Scenario 5**

In this scenario direct application to soil nests is foreseen.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment)** | **Remarks** |
| Freshwater | 0 |  |
| Freshwater sediment | 0 |  |
| Seawater | 0 |  |
| Seawater sediment | 0 |  |
| STP | 0 |  |
| Air | 0 | (not relevant) |
| Soil | 0.214 | (mg/kg wwt)  Direct release to soil |
| Groundwater | 2.11E-05 | mg/L |

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

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Fresh-water** | **Freshwater sediment** | **STP** | **Air** | **Soil** | **Ground-water** | **Other** |
| Scenario 1 | Yes | Yes | Yes | *“not relevant”* | Yes | yes | No |
| Scenario 2 | Yes | Yes | Yes | *“not relevant”* | Yes | yes | No |
| Scenario 3 | No | No | No | *“not relevant”* | Yes | Yes | No |
| Scenario 4 | No | No | No | *“not relevant”* | Yes | Yes | No |
| Scenario 5 | No | No | No | *“not relevant”* | Yes | Yes | No |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| Calculation tool: |  | EUSES 2.2.0 |  |
| Input | Value | Unit | Remarks |
| Molecular weight | 416.3 | [g.mol-1] |  |
| Melting point | 41.2 | °C |  |
| Vapour pressure at 20 [oC] | 2.3E-07 | [Pa] |  |
| Vapour pressure at 25 [oC] | 6E-07 | [Pa] |  |
| Water solubility at 20 [oC] | 4 | [µg.l-1] |  |
| Water solubility at 25 [oC] | 4.2849E-03 | [mg.l-1] |  |
| Log Octanol/water partition coefficient | 5.45 | Log 10 |  |
| Chemical class for Koc-QSAR | Predominantly hydrophobic |  |  |
| Organic carbon/water partition coefficient (Koc) | 5.75E+05 | [l.kg-1] |  |
| Henry's law constant at test temperature | 0.024 | [Pa.m3.mol-1] |  |
| Bioconcentration factor for fish | 373.4 | [l.kgwwt-1] |  |
| Biodegradability | Not biodegradable |  |  |
| Rate constant for hydrolysis in surface water | 98.9 | [d] (DT50,12[oC]) |  |
| Rate constant for photolysis in surface water | 0.0469 | [d-1] |  |
| Total rate constant for degradation in bulk soil | 17.2 | [d],  (DT50, 12[oC]) |  |

Distribution in STP is foreseen for all scenario with the exception of the outdoor ground ant nest treatment in which direct emission to soil is foreseen.

The distribution is STP followed the standard inputs as for the OECD Emission Scenario for PT18 and EUSES 2.2, which includes in this latest release SimpleTreat 4.0.

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP** | | | |
| Compartment | Percentage [%] | | Remarks |
| Scenario 1 | Scenario 2 |
| Air | 5.44E-04 | 5.44E-04 | Scenario 3, 4 and 5: direct release to soil |
| Water | 8.356 | 8.356 |
| Primary settler | 66.15 | 66.15 |
| Sludge | 25.5 | 25.5 |
| Degraded in STP | 0 | 0 |

***Calculated PEC values***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | |
|  | PECSTP | PECwater | PECsed | PECsoil | PECGW | PECair |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | [mg/m3] |
| Scenario 1 | 1.55E-06 | 8.34E-08 | 1.04E-03 | 3.57E-05 | 8.35E-07 | 1.13E-09 |
| Scenario 2 | 2.09E-06 | 1.12E-07 | 1.41E-03 | 4.81E-05 | 1.13E-06 | 1.53E-09 |
| Scenario 3 | n.a. | n.a. | n.a. | 0.025 | 2.48E-03 | n.a. |
| Scenario 4 | n.a. | n.a. | n.a. | 0.015 | 1.48E-03 | n.a. |
| Scenario 5 | n.a. | n.a. | n.a. | 0.214 | 0.021 | n.a. |

***Primary and secondary poisoning***

Primary poisoning may occur when a non target animal swallows the granular product. According to the use of the product, this eventuality may occur outdoor, around buildings and when treating ant nests in soil.

Secondary poisoning may occur when non-target vertebrates eat ants which eaten the product.

Secondary poisoning is concerned with toxic effects in the higher members of the food chain, either living in the aquatic or terrestrial environment, which result from ingestion of organisms from lower trophic levels that contain accumulated substances.

Since the PECwater and the PECporewater are not negligible, and as cypermethrin tends to bioaccumulate in water organisms (although it has nor B neither vB properties) and as the substance has the potential to cause toxic effects (it is classified as STOT RE 2, H273 for neurotoxicity and liver toxicity), secondary exposure assessment has been carried out according to Guidance on BPR: Vol IV Environment Parts B+C (Version 2.0 October 2017).

Outdoor scenarios (i.e. professional and non-professional outdoor around buildings application and outdoor nest treatment) were considered for secondary poisoning for fish-eating predators and for earthworm-eating predators (scenarios 3, 4 and 5).

The following calculations and inputs where used:

*PECoral, fish-eating predator=PECwater x BCFfish x BMF*

Where:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable/parameter (unit)** | **Symbol** | **Unit** | **Value** | **Source** |
| Predicted Environmental Concentration in fish-eating predators | *PECoral, fish-eating predator* | [mg.kgwet fish-1] | X | Output |
| Predicted Environmental Concentration in water Scenario 3 | *PECwater* | [mg.L-1] | 1 | Input |
| Predicted Environmental Concentration in water Scenario 4 | *PECwater* | [mg.L-1] | 1 | Input |
| Bioconcentration Factor for fish on wet weight basis | *BCFfish* | [L.kgwet fish-1] | 417 2 | Input |
| Biomagnification factor in fish | *BMF* | [-] | 10 3 | Default |

1 For Scenarios 3 and 4 no release to sewer/STP is assumed, they concern releases only to soil compartment around a terrace. In Scenario 5 no emission to water is expected.

2 According to cypermethrin AR.

3 According to cypermethrin AR and Table 23 of ECHA Guidance on the BPR (Volume IV Environment –Version 2.0, October 2017) (worst case)

*PECoral, earthworm-eating predator=*

*Cearthworm = (BCFearthworm x Cporewater + Csoil x Fgut x CONVsoil) / (1 + Fgut x CONVsoil)*

Where:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable/parameter (unit)** | **Symbol** | **Unit** | **Value** | **Source** |
| Predicted Environmental Concentration in earthworm-eating predators | *PECoral, earthworm-eating predator* | [mg.kgwet earthworm-1] | X | Output |
| Concentration in earthworm on wet weight basis | *Cearthworm* | [mg.kgwet earthworm-1] | X | Output |
| Bioconcentration Factor for earthworms on wet weight basis | *BCFearthworm* | [mg.kgwet earthworm-1] | 3382.9 1 | Input |
| Concentration in porewater scenario 3 | *Cporewater* | [mg.L-1] | 2.48E-06 | Input |
| Concentration in porewater scenario 4 | *Cporewater* | [mg.L-1] | 1.48E-06 | Input |
| Concentration in porewater scenario 5 | *Cporewater* | [mg.L-1] |  | Input |
| Concentration in soil scenario 3 | *Csoil* | [mg.kg wwt-1] | 2 | Input |
| Concentration in soil scenario 4 | *Csoil* | [mg.kg wwt-1] | 2 | Input |
| Concentration in soil scenario 5 | *Csoil* | [mg.kg wwt-1] | 2 | Input |
| Fraction of gut loading in worm | *Fgut* | [kgdwt.kgwwt-1] | 0.1 3 | Default |
| Conversion factor for soil concentration wet-dry weight soil | *CONVsoil* | [kgwwt.kgdwt-1] | 1.13 3 | Default |

1 Calculated according to ECHA Guidance on the BPR (October 2017) equation 104d.

2 For Scenarios 3, 4 and 5 the direct release to soil concentration is used. This can be considered a worst case with respect to 180 days TWA PECsoil.

3 Default values were obtained from ECHA Guidance on the BPR (October 2017)

Based on the above the Predicted Environmental Concentration in fish-eating and earthworm-eating predators are presented in the following table.

|  |  |  |
| --- | --- | --- |
| **Summary table on estimated theoretical exposition values (ETE) via food chain** | | |
| **Scenario** | ***PECoral, fish-eating predator*** | ***PECoral, earthworm-eating predator*** |
| 3 | Not applicable | 1.09E-02 |
| 4 | Not applicable | 6.53E-03 |
| 5 | Not applicable | 9.28E-02 |

#### Risk characterisation

***Atmosphere***

Conclusion:

Direct emission in atmosphere is considered not relevant using the product.

No risk for the atmosphere was foreseen.

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

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 9.51E-07 |
| Scenario 2 | 1.28E-06 |
| Scenario 3 | No release in STP |
| Scenario 4 | No release in STP |
| Scenario 5 | No release in STP |

Conclusion: According to the obtained PEC/PNEC ratios, the use of MIRMEX is safe for the microorganisms involved in biodegradation processes in the STP, since the ratio between the predicted environmental concentration and the predicted no-effect concentration is below 0 for all scenarios.

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Scenario 1 | 2.09E-02 | 2.08E-01 |
| Scenario 2 | 2.80E-02 | 2.82E-01 |
| Scenario 3 | No release expected | |
| Scenario 4 | No release expected | |
| Scenario 5 | No release expected | |

Conclusion: According to the obtained PEC/PNEC ratio, the use of MIRMEX is safe for the aquatic environment and the sediment drewlling organisms, since the PECsw/PNECsw and the PECsed/PNECsed ratio are < 1.

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | PEC/PNECsoil |
| Scenario 1 | 5.04E-04 |
| Scenario 2 | 6.79E-04 |
| Scenario 3 | 3.53E-01 |
| Scenario 4 | 2.12E-01 |
| Scenario 5 | **3.02E+00** |

Conclusion: According to the obtained PEC/PNEC ratio, the use of MIRMEX is safe for the soil compartment in all scenarios except for scenario 5 (nest treatment) in which the PECsoil/PNECsoil ratio is higher than 1. Thus, the outdoor use (nest treatment, scenario 5) is **NOT AUTHORISED.**

***Groundwater***

|  |  |
| --- | --- |
| **Summary table on calculated PEC values** | |
|  | PECgw  [μg/l] |
| Scenario 1 | 8.35E-07 |
| Scenario 2 | 1.13E-06 |
| Scenario 3 | 2.48E-03 |
| Scenario 4 | 1.48E-03 |
| Scenario 5 | 0.021 |

Conclusion: all PEC values calculated for groundwater are lower than the threshold value of 0.1 micrograms per litre (μg/L), therefore no risk for groundwater compartment is expected.

***Primary and secondary poisoning***

Primary poisoning may occur when a non target animal swallows the granular product. According to the use of the product, this eventuality may occur outdoor, around buildings and when treating ant nests in soil.

Secondary poisoning may occur when non-target vertebrates eat ants which eaten the product.

**Primary poisoning**

As stated in the label, the product has a targeted application and should not be applied on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.

When applied around buildings, pet should not be allowed to enter the treated areas. The risk for other vertebrates i.e. birds, is not expected to be relevant.

Ant nests treatment is a targeted application and, as specified in the label, once the product exerted his action, it has to be removed together with dead insects (“Remove (clean) product and dead insects, when the presence of live insects is stopped”).

In addition the product is formulated with a bittering agent, that should make not palatable the product for non-target animals.

Therefore the type of use and the risk management measures to be taken should avoid the primary poisoning of non-target animals.

**Secondary poisoning**

Secondary poisoning occurs when non-target vertebrates eat ants which were poisoned by the product. According to the risk management measures to be undertaken stated in the label (i.e. “Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock “ and “Remove (clean) product and dead insects, when the presence of live insects is stopped”), secondary poisoning is not expected to occur. However, the following risk characterization of secondary poisoning via the terrestrial food chain was performed as a worst case. Secondary poisoning via the aquatic food chain is not expected to occur.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on secondary poisoning via the aquatic food chain** | | | | | | |
| **Scenario** | ***PECoral, fish-eating predator*** | **PNECbirds1** | **PNECmammals 2** | **PEC/ PNECbirds** | **PEC/ PNECmammals** |  |
| 3 | Not applicable | 33.3 mg/kg/d | 3.3 mg/kg/d | Not applicable | Not applicable |  |
| 4 | Not applicable | 33.3 mg/kg/d | 3.3 mg/kg/d | Not applicable | Not applicable |  |
| 5 | Not applicable | 33.3 mg/kg/d | 3.3 mg/kg/d | Not applicable | Not applicable |  |
| **Summary table on secondary poisoning via the terrestrial food chain** | | | | | | |
| **Scenario** | ***PECoral, earthworm-eating predator*** | **PNECbirds1** | **PNECmammals 2** | **PEC/ PNECbirds** | **PEC/ PNECmammals** |  |
| 3 | 1.09E-02 | 33.3 mg/kg/d | 3.3 mg/kg/d | 2.52E-01 | 3.31E-03 |  |
| 4 | 6.53E-03 | 33.3 mg/kg/d | 3.3 mg/kg/d | 1.50E-01 | 1.98E-03 |  |
| 5 | 9.28E-02 | 33.3 mg/kg/d | 3.3 mg/kg/d | 2.79E-03 | 2.81E-02 |  |

1 PNECbird is 33.3 mg/kg food based on 21d NOEC dietary toxicity study on birds, as reported on the AR of cypermethrin.

2 PNECmammal is 3.3 mg/kg food based 2-year oral toxicity study on rats, as reported on the AR of cypermethrin.

Conclusion: As it can be observed, the PEC/PNEC ratio is below 1 for all scenarios, indicating an acceptable risk of secondary poisoning through the terrestrial food-chain.

***Mixture toxicity***

Please, refer to the Exposure assessment and Risk characterisation sections. The product is classified for environmental hazards according to the rules laid down by Regulation 1272/2008 as Aquatic Acute 1, H400 and Aquatic Chronic 1, H410.

The substance leading to the classification of the mixture is the active substance, which is classified as Aquatic Acute 1, H400 and Aquatic Chronic 1, H410 (Macute = 100; Mchronic = 1000). Just two of the co-formulants are classified for environmental hazards: one is classified Aquatic Acute 1, H400 and Aquatic Chronic 1, H410 (M = 10), but, considering the M factor, it is not in such a concentration to lead to C&L classification, and the other is classified as Aquatic Chronic 3, H412 and its concentration is well below the concentration limits set out in annex I or Regulation (EC) n. 1272/2008 (CLP) to classify the mixture.

Please refer to composition in the confidential annex.

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

The overall exposure to humans and the environment, to the A.S. is not due to different products belonging to the same PT or different PTs. Therefore, it was not investigated.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| **Atmosphere**  Emissions and PECs in air are considered as negligible. It can be concluded that the use of this product will not pose a significant risk to the atmospheric compartment.  According to the environmental risk assessment, the risk for all relevant environmental compartments (STP, terrestrial, aquatic, primary and secondary poisoning) is acceptable when the product is used for all indoor and outdoor uses (except nest treatment), according to label instruction.  Nest treatment (Scenario 5) **cannot be authorised** since the risk assessment for the terrestrial compartment is unacceptable. |

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

**Instructions for use**

The product is a granule against ants formulated with micro-encapsulated cypermethrin.

A careful pre-detection of the areas where the insects use to pass or hidden increase the efficacy of the treatment. Particular care should be taken for dark and warm places, in basements and warehouses. Also, in areas around water pipes, heating and ventilation, under cupboards and other bulky items.

Apply 8 g/m2 of product in thin layers in cracks and crevices (under furniture, in corners and other hiding places), voids and cavities(partition between walls, holes, etc...).

Always read the label or package leaflet before use and follow all instructions provided.

If the infestation persists despite the instructions on the label, contact a pest control operator. Remove (clean) product and dead insects, when the presence of live insects is stopped.

Knockdown of ant workers is expected within 60 minutes after exposure of insects to the treated surfaces.

The product has a residual period of 4 weeks.

Always read the label or package leaflet before use and follow all instructions provided.

**Risk mitigation measures**

Do not apply the product on surfaces that may be in contact with animals, food or beverages intended for human consumption or for the feeding of livestock.

For indoor use, the product has to be applied only on restricted areas on surfaces not regularly cleaned (i.e. under furniture, corners, etc).

For around building treatment, apply  only on paved surfaces and roof covered areas.

Do not apply to areas susceptible to routine wet cleaning.

Do not apply near bodies of surface water or in the area of water protection zones.

For use only in areas that are inaccessible to infants, children, companion and farm animals.

No use of wet cleaning procedures. Use only dry-cleaning procedures (vacuum or broom) or use damp paper. After cleaning, dispose the collected in the dry cleaner materials or the  
damp papers used as solid wastes.

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

The product contains: cypermethrin. May cause paraesthesia.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

Poison center phone number:

Prevent entry into drains, sewers and watercourses. Pick up and arrange disposal without creating dust cloud. Collect spills and place them in suitable containers well sealed for disposal. Clean contaminated surfaces with damp paper and after cleaning disposed it in solid wastes.

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

Waste treatment methods:

• Dispose of waste and residues in accordance with local authority requirements.

• Do not allow runoff to sewer, waterway or ground.

Residues and empty containers should be taken care of as hazardous waste according to local and national provisions.

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

Keep containers tightly closed in a dry, cool and well-ventilated place, away from children, animals, food or feed.

Avoid light and sunlight exposure

The product is stable for 2 years at ambient temperature.

### Assessment of a combination of biocidal products

The product is not intended to be authorised for the use with other biocidal products.

# Annexes[[3]](#footnote-3)

## List of studies for the biocidal product

| **Author(s)** | **Year** | **Title** | **Reference** | **Testing Company** | **Report No.** | **GLP Study (Yes/No)** | **Data Protection Claimed (Yes/No)** | **Data Owner** | **Section No. in IUCLID** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Andrea Drago; | 2019 | EFFICACY EVALUATION OF  “MIRMEX GR”  AGAINST LASIUS NIGER  (FORCED CONTACT TEST ON NON-POROUS SURFACE) | Andrea Drago; 2019 | ENTOSTUDIO S  .r.l. | - | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7 |
| Andrea Drago; | 2019 | EVALUATION OF THE EFFICACY OF  “MIRMEX GR”  AGAINST LASIUS NIGER - FIELD TEST | Andrea Drago; 2019 | ENTOSTUDIO S.r.l. | - | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7 |
| Andrea Drago; | 2021 | EFFICACY EVALUATION OF  “MIRMEX GR”  AGAINST LASIUS NIGER  (FORCED CONTACT TEST ON NON-POROUS AND POROUS SURFACE) | Andrea Drago; 2021 | ENTOSTUDIO S  .r.l. | - | No | Yes | Vebi Istituto Biochimico S.r.l. | 6.7 |
| Simona Nichetti | 2020 | Mirmex GR:  Validation of the Analytical Method for the  Determination of the Active Ingredient Content | CH – 0128/2020 | ChemService S.r.l. Controlli e Ricerche | CH – 0128/2020 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 5 |
| Simona Nichetti | 2020 | Mirmex GR:  Determination of the Physico-chemical Properties | CH – 0127/2020 | ChemService S.r.l. Controlli e Ricerche | CH – 0127/2020 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 3.1  3.2  3.3 |
| Simona Nichetti | 2020 | Mirmex GR:  Determination of the Accelerated Storage Stability  and Corrosion Characteristics | CH - 0151/2020 | ChemService S.r.l. Controlli e Ricerche | CH - 0151/2020 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 3.4.1 |
| Simona Nichetti | 2020 | Mirmex GR:  Three Years Storage Stability and Corrosion  Characteristics | CH - 0152/2020 | ChemService S.r.l. Controlli e Ricerche | CH - 0152/2020 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 3.4.1 |
| Simona Nichetti | 2021 | Mirmex GR: Determination of the Accelerated Storage Stability (Particle Size Distribution - Sieve Analysis) | CH – 0189/2021 | ChemService S.r.l. Controlli e Ricerche | CH – 0189/2021 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 3.4.1 |
| Simona Nichetti | 2021 | Mirmex GR:  Determination of the Oxidizing properties | CH – 0188/2021 | ChemService S.r.l. Controlli e Ricerche | CH – 0188/2021 | Yes | Yes | Vebi Istituto Biochimico S.r.l. | 4.4 |

## Output tables from exposure assessment tools



## New information on the active substance

N.A

## 3.4 Residue behaviour

N.A

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

Refer to the IUCLID dossier.

## 3.6 Confidential annex

See separate file.

## 3.7 Other

N.A

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-2)
3. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-3)