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

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

(submitted by the evaluating Competent Authority)



GEL ATTRACTIF ANTI-FOURMIS

Product type 18

Cypermethrin, D-Fructose

Case Number in R4BP: BC-SM059300-33

Evaluating Competent Authority: France

Date: [15/11/2022]

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# CONCLUSION

The product GEL ATTRACTIF ANTI-FOURMIS is an insecticide gel bait (PT18) containing 0.217% w/w cypermethrin cis:trans 40:60 (CAS No. 52315-07-8) as active substance and D-fructose as Annex I active substance to control ants, for non-professional users, indoor. It is used for curative and preventive treatment.

**Conclusion on physico-chemical properties and analytical methods:**

The physico-chemical properties of the product GEL ATTRACTIF ANTI-FOURMIS have been described and considered acceptable in the conditions of use detailed in the SPC.

The content of active substance cypermethrin decrease more than 10% after accelerated storage stability. Therefore, a 6 months shelf life can be granted at this step based on the shelf life storage stability study. The accelerated storage stability at 35°C show that the product is not stable. The mitigation measure, store the product at temperature below 25°C should be added on the label. Moreover, the packaging cannot be considered as barrier to light, therefore a mitigation measure, protect to light should be added on the label.

The product is not classified as explosive, oxidising and corrosive to metal. An SADT test has been provided and show that the product is not classified self-reactive.

A test for auto-ignition should be provided in post-authorization within 1 year.

Analytical methods for the determination of the active substance cypermethrin have been developed and validated for this determination in the biocidal product GEL ATTRACTIF ANTI-FOURMIS.

**Conclusion on efficacy:**

The bait product GEL ATTRACTIF ANTI-FOURMIS has shown a sufficient efficacy (drops as spot application) indoors to control ants with the destruction of nests at the application rate of 0.5 g /m², against the following species:

* Black garden ant (*Lasius niger*),
* Argentine ant (*Linepithema humile*)
* Pharaoh ant (*Monomorium pharaonis*)

The time delay is 2 weeks for the reduction of population and 28 days for nest destruction.

The product has a residual efficacy up to 4 weeks.

**Conclusion on Human Health:**

For the product GEL ATTRACTIF ANTI-FOURMIS, the risk is considered acceptable for non-professional users and the general public, with the application of the following risk mitigation measure (RMM):

* Apply only in areas inaccessible to children and pets.

**Conclusion on Food Safety:**

No specific residue data were submitted in the context of this dossier. To prevent dietary exposure the following risk mitigation measure should apply:

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

**Conclusion on Environment:**

The environmental risk assessment has been conducted for the active substance cypermethrin only.

It has been demonstrated that the intended use of the biocidal product GEL ATTRACTIF ANTI-FOURMIS applied indoor until 11 times per year by non-professionals in private houses as gel droplets where ants pass and near the entries of the nest does not pose a risk to the environmental compartments. No specific risk mitigation measure is required.

**OVERALL CONCLUSION**

FR CA considers that the product GEL ATTRACTIF ANTI-FOURMIS shall be authorized according to Article 19(1) for the following uses:

|  |  |  |  |
| --- | --- | --- | --- |
| **Target organisms** | **Application rates** | **Use conditions** | **Conclusions** |
| Black garden ant *(Lasius niger)*  Pharaoh ant *(Monomorium pharaonis)*  Argentine ant *(Linepithema humile)* | 0.5 g/m² (5 drops of 0.1 g)  In areas where ants pass or in nest entrances | Non-professional users.  Indoor.  Application by spot treatment. | Acceptable |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| GEL ATTRACTIF ANTI-FOURMIS  FOURMI GEL  SUBITO GEL ANTI-FOURMIS  GEL APPAT ANTI-FOURMIS  EXIT RB | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | SPRING |
| **Address** | 4, rue Blaise Pascal  Z.I. du Bois de Leuze  13310 Saint-Martin-de-Crau  France |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | SPRING |
| **Address of manufacturer** | 4, rue Blaise Pascal  Z.I. du Bois de Leuze  13310 Saint-Martin-de-Crau  France |
| **Location of manufacturing sites** | 4, rue Blaise Pascal  Z.I. du Bois de Leuze  13310 Saint-Martin-de-Crau  France |

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

|  |  |
| --- | --- |
| **Active substance** | Cypermethrin |
| **Name of manufacturer n°1** | Tagros Chemicals India Private Limited |
| **Address of manufacturer** | Jhaver Centre, Raja Annamalai  Building IVth Floor  72 Marshall Road  Egmore  6000 008 Chennai  India |
| **Location of manufacturing sites** | A-4/1&2, Sipcot Industrial Complex  Pachayankuppam  Cuddalore  607 005 Tamilnadu  India |

|  |  |
| --- | --- |
| **Active substance** | Cypermethrin |
| **Name of manufacturer n°2** | Arysta LifeScience Benelux SPRL |
| **Address of manufacturer** | Rue de Renory 26/1  B-4102 Ougrée  Belgium |
| **Location of manufacturing sites** | D, ½, MIDC  Lote Parshuram Tal. Khed Dist.  Ratnagiri  415 722 Maharashtra  India |
|  |  |
| **Active substance** | Fructose |
| **Name of manufacturer** | Belgosuc |
| **Address of manufacturer** | Industriepark 20  B-8730 Beernem  Belgium |
| **Location of manufacturing sites** | Industriepark 20  B-8730 Beernem  Belgium |

### Product composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Cypermethrin cis/trans 40/60 |
| **IUPAC or EC name** | α-cyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate |
| **EC number** | 257-842-9 |
| **CAS number** | 52315-07-8 |
| **Index number in Annex VI of CLP** | 607-421-00-4 |
| **Minimum purity / content** | ≥ 92% w/w |
| **Structural formula** | C22H19Cl2NO3  Image illustrative de l’article Cyperméthrine |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Fructose |
| **IUPAC or EC name** | (3S,4R,5R)-2-(hydroxymethyl)oxane-2,3,4,5-tetrol |
| **EC number** | 200-333-3 |
| **CAS number** | 7660-25-5 |
| **Index number in Annex VI of CLP** | 57-48-7 |
| **Minimum purity / content** | 84% w/w |
| **Structural formula** | C6H12O6  D-Fructose Keilstrich.svg |

#### Candidate(s) for substitution

The active substance cypermethrin cis:trans 40:60 contained in the biocidal product GEL ATTRACTIF ANTI-FOURMIS does not meet any exclusion criteria listed in Article 5 of Regulation (EU) No.528/2012 (CMR Cat 1A or 1B, endocrine disruptor, PBT, vPvB) or substitution criteria listed in Article 10 and at that time, is not a candidate for exclusion or substitution in accordance with Articles 5(1) and 10 of Regulation (EU) No.528/2012.

D-Fructose is not a candidate for exclusion or substitution as it is an active substance in category 4 of Annex I of Regulation (EU) No.528/2012.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Technical Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Cypermethrin | (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.217 |
| D-Fructose | (3S,4R,5R)-2-(hydroxymethyl)oxane-2,3,4,5-tetrol | Active substance | 57-48-7 | 200-333-3 | 69.383 |
|  |  |  |  |  |  |

#### Information on technical equivalence

A technical equivalence application has been submitted at ECHA to demonstrate the equivalence of the source used in this dossier and the source of the original active substance.

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

No substance of concern has been identified in the product GEL ATTRACTIF ANTI-FOURMIS.

Please refer to the Confidential annex for further information.

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

The biocidal product contains the active substance cypermethrin, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

Please refer to the Confidential Annexe for further details.

#### Type of formulation

|  |
| --- |
| RB : Bait (ready to use) |

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

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

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic acute 1  Aquatic chronic 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 | P102: Keep out of reach of children  P103: Read label before use  P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of the contents and its container to appropriate waste disposal in accordance to national regulations. |
|  | |
| Note |  |

### Authorised use(s)

#### Use description[[4]](#footnote-5)

Table 1. Use # 1 – Ant Bait – Non-professional

|  |  |
| --- | --- |
| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Black garden ant *(Lasius niger)*  Pharaoh ant *(Monomorium pharaonis)*  Argentine ant *(Linepithema humile)*  All developement stage  Nest killing |
| **Field of use** | Indoor |
| **Application method(s)** | Spot treatment |
| **Application rate(s) and frequency** | Application rate: 0.5 g/m² (5 drops of 0.1g) in areas where ants pass or in nest entrances.  Population control two weeks after application and nest destruction 28 days after application.  The product has a residual effect until 4 weeks.  Maximal application frequency: 11 times a year |
| **Category(ies) of users** | Non-professional |
| **Pack sizes and packaging material** | Pipette in LDPE (65 mL) |

#### Use-specific instructions for use[[5]](#footnote-6)

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

### General directions for use

#### Instructions for use[[6]](#footnote-7)

|  |
| --- |
| * Comply with the instructions for use. * Inform the authorisation holder if the treatment is ineffective. * Do not apply the product on absorbent surfaces. * Check the bait point once a week. * Do not expose bait drops to sunlight or heat (i.e radiator). * Before treatment, remove all natural source of food from the infested area to encourage the ingestion of the gel. * Retreat in case of new infestation without exceeding the maximum number of applications per year. * Avoid continuous use of the product. * If the infestation persists contact a professional. |

#### Risk mitigation measures

|  |
| --- |
| * Apply only in areas inaccessible to children and pets. * Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock. |

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

|  |
| --- |
| * If medical advice is needed, have product container or label at hand. * IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor. * IF SWALLOWED: 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: not applicable. |

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

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

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

|  |
| --- |
| * Keep out of reach of children and non-target animals/pets. * Do not store the product at temperature above 25°C. * Protect to light. * Shelf-life: 6 months. |

### Other information

|  |
| --- |
| * The biocidal product contains cypermethrin which is dangerous to bees. |

### 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)** |
| Pipette | 65 mL | LDPE (opaque) | - | Non professional | Yes (results of stability studies will be provided when available) |

### Documentation

#### Data submitted in relation to product application

Physico-chemical properties studies and analytical methods on the biocidal product GEL ATTRACTIF ANTI-FOURMIS were provided by SAS SPRING.

#### Access to documentation

SAS SPRING has access to data on the active substance Cypermethrin with a Letter of Access of LIMARU NV representing TAGROS INDIA PRIVATE LIMITED, one applicant of the active substance Cypermethrin.

SAS SPRING has access to data on the active substance Cypermethrin with a Letter of Access of Arysta ScienceLife Benelux SPRL, one applicant of the active substance Cypermethrin and products.

## Assessment of the biocidal product

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

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 0.217% of technical active substance Cypermethrin and 0.200% of pure active substance Cypermethrin and 58.282% of pure active substance D-fructose.

The product contains PT6 preservative which are authorized.

The product is a ready-to-use.

Formulation type: Bait (RB)

Table 1 Intended use # 1 – PT18 Ants

|  |  |
| --- | --- |
| Product Type(s) | 18 |
| Where relevant, an exact description of the authorised use | Bait for the control of ants |
| Target organism (including development stage) | Ants (all stages), including their nests.  - *Lasius niger*: black garden ant  - *Monomorium pharaonis*: Pharaoh ant  - *Linepithema humile*: Argentine ant |
| Field of use | Indoor |
| Application method(s) | Spot treatment |
| Application rate(s) and frequency | Application rate: 0.5 g/m² (5 drops of 0.1 g) |
| Category(ies) of user(s) | Non-professional |
| Pack sizes and packaging material | Pipette in LDPE (65mL) |

### Physical, chemical and technical properties

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | Visual observation  No guideline required Organoleptic observation | GEL ATTRACTIF ANTI-FOURMIS | |  |  |  | | --- | --- | --- | |  | T0 | After accelerated storage 35°C for 12 weeks | | Appearance | Viscous and homogeneous liquid | Viscous and homogeneous liquid | | Colour | RAL 1013 White Oyster | RAL 1015 Light ivory | | Odour | Characteristic | Characteristic | | Acceptable | Bartocci M., 2021  Final report no. BT305/20,  Bio |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa |
| Acidity / alkalinity | CIPAC MT 75.3 (2000) | GEL ATTRACTIF ANTI-FOURMIS | pH ( at 22°C)  undiluted : 5.05  diluted 1%w/v : 5.12 | Acceptable | Bartocci M., 2021  Final report no. BT305/20,  Bio |
| Relative density / bulk density | EU Method A.3 (2008), OECD Guideline No.109 (2012) | GEL ATTRACTIF ANTI-FOURMIS | Relative Density at 20°C: 1.246 | Acceptable | Bartocci M., 2021  Final report no. BT304/20,  Bio |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 method (storage stability) (2000)  CIPAC MT 75.3  CIPAC MT 191  Validated method in  GLP Study BT302/20  OECD 114 | GEL ATTRACTIF ANTI-FOURMIS Packaging: 65 mL LDPE pipette | Before and after an accelerated storage procedure at 35 ± 2°C for 12 weeks in its commercial packaging (50 mL plastic bottle (no more information of the nature of plastic has been provided) with measuring spout):   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | After accelerated storage 35°C for 12 weeks | | | Appearance | Viscous and homogeneous liquid | Viscous and homogeneous liquid | | | Colour | RAL 1013 White Oyster | RAL 1015 Light ivory | | | Odour | Characteristic | Characteristic | | | Packaging | 50 mL plastic bottle with measuring spout | 50 mL plastic bottle with measuring spout: no modification observed | | | Weight loss% | n.a. | 0.65 ( see note 1) | | Cypermethrin totalcontent | 1.9617 ± 0.0292 g/kg 0.196 ± 0.003% w/w 2.444 ± 0.036 g/L | 1.6985 ± 0.0357 g/kg 0.170 ± 0.004% w/w 2.116 ± 0.044 g/L | | % variation AS content | / | -13.4% | | CypermethrinCIS/TRANS ratio (content obtained by calculation) | 40.71 ± 0.09% (cis-cypermethrin) 59.29 ± 0.09% (trans-cypermethrin) | 41.65 ± 0.09% (cis-cypermethrin) 58.35 ± 0.09% (trans-cypermethrin) | | Fructose content | 597.24 ± 8.66 g/kg 59.724 ± 0.866% w/w 744.16 ± 10.79 g/L | 602.10 ± 6.74 g/kg 60.210 ± 0.674% w/w 750.21 ± 8.40 g/L | | pH ( at 22°C)  undiluted  diluted 1%w/v | 5.05  5.12 | 3.81  4.51 | | | Acidity calculated asH2SO4 (% w/w) | n.a. | 0.057 | |   At T=0 :    At T=12 weeks at 35°C: | Not acceptable  The nature of the plastic should be specified.  After storage, the pH decrease and the content of active substance decrease by more than 10%.  The product is not stable at 35°C. | Bartocci M., 2021  Final report no. BT305/20,  Bio |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No.17, 2nd edition, CropLife  GLP Study BT302/20 | GEL ATTRACTIF ANTI-FOURMIS Packaging: 65 mL LDPE pipette | The study to determine the stability of the test item GEL ATTRACTIF ANTI FOURMIS in its commercial packaging (65 mL LDPE pipette) after 24 months at 20 ± 2°C is still on-going. Intermediate results are reported after 6 months: Results will be provided when available     |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T0 | After 6 months storage at 20°C | After 12 months storage at 20°C | After 18 months storage at 20°C | | Appearance | Viscous and homogeneous liquid | Viscous and homogeneous liquid | Viscous liquid.  Dark spots are visible  in some areas of the  container | Viscous liquid.  Dark spots are visible  in some areas of the  container | | Colour | RAL 1013 White Oyster | RAL 1013 White Oyster | Heterogeneous  colours | Heterogeneous  colours | | Odour | Characteristic | Characteristic | Characteristic | Characteristic | | Packaging | 50 mL plastic bottle with measuring spout | 50 mL plastic bottle with measuring spout: no modification and no leak observed | 50 mL plastic bottle  with measuring spout.  No modification or  leak observed | 50 mL plastic bottle  with measuring spout.  No modification or  leak observed | | Weight loss% | n.a. | 0.07 | 0.13 | 0.16 | | Cypermethrin totalcontent | 1.9617 ± 0.0292 g/kg 0.196 ± 0.003% w/w 2.444 ± 0.036 g/L | 1.8900 ± 0.0587 g/kg 0.189 ± 0.006% w/w 2.355 ± 0.073 g/L | 1.7261 ±0.0233 g/kg  0.173 ±0.002% w/w  2.150 ± 0.029 g/L | 1.6663 ±0.0561 g/kg  0.167 ±0.006% w/w  2.076 ± 0.070 g/L | | % variation AS content | / | -3.7% | -12% | -15% | | CypermethrinCIS/TRANS ratio (content obtained by calculation) | 40.71 ± 0.09% cis-cypermethrin) 59.29 ± 0.09% rans-cypermethrin) | 42.08 ± 0.07% (cis-cypermethrin) 57.92 ± 0.07% (trans-cypermethrin) | 41.93 ± 0.12%  (cis-cypermethrin)  58.07 ± 0.12%  (trans-cypermethrin) | 41.78 ± 0.05%  (cis-cypermethrin)  58.22 ± 0.05%  (trans-cypermethrin) | | Fructose content | 597.24 ± 8.66 g/kg 59.724 ± 0.866% w/w 744.16 ± 10.79 g/L | 603.22 ± 8.71 g/kg 60.322 ± 0.871% w/w 751.61 ± 10.85 g/L | 588.53 ± 5.74 g/kg  58.853 ± 0.574% w/w  733.31 ± 7.16 g/L | 575.23 ± 7.20 g/kg  57.523 ± 0.720% w/w  716.74 ± 8.98 g/L | | pH ( at 22°C)  undiluted  diluted 1%w/v | Not determined | Not determined | Not determined | Not determined | | Acidity calculated asH2SO4 (% w/w) | Not determined | Not determined | Not determined | Not determined | | Acceptable  The intermediate data show that the product is not stable after 6 months. Indeed the content of Cypermethrin decrease more than 10% after 12 months. Moreover, the pH is not determined.  Palatability test is provided but no information on the identity of the degradation products has been provided.  Therefore, the shelf life is set at 6 months. Moreover, as the accelerated storage study shows that the product is not stable at 35°C during 12 weeks, a mitigation measure “do not store the product at temperature above 25°C” should be added on the label. | Bartocci M., 2021  Interim report no. BT306/20 |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 (Handbook J, 2000) | GEL ATTRACTIF ANTI-FOURMIS | The study to determine the cold stability (7 days at 0 ± 2°C) of the test item GEL ATTRACTIF ANTI-FOURMIS is available. The pH and acidity/   |  |  |  | | --- | --- | --- | |  | T0 | After 7 days storage at 0°C | | Appearance | Viscous and homogeneous liquid | Viscous and homogeneous liquid | | Colour | RAL 1013 White Oyster | RAL 1013 White Oyster | | Odour | Characteristic | Characteristic | | Packaging | 50 mL plastic bottle with measuring spout | - | | pH ( at 20°C)  undiluted  diluted 1%w/v | 5.13  5.10 | 5.28  5.48 | | Acceptable  The product is stable 7 days at 0°C. | Bartocci M., 2021  Final report no. BT304/20,  Bio |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | The study for stability to sunlight is not required as the commercial packaging of the product GEL ATTRACTIF ANTI-FOURMIS is opaque. | While the packaging is opaque this does not lead that the packaging is barrier to light. A mitigation measure : “protect to light” should be added on the label | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | - | Data on temperature have been provided in the accelerated storage stability study and in the low temperature stability study. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | - | Data on packaging have been provided in the long term stability study. | - |
| Wettability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Suspensibility, spontaneity and dispersion stability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Wet sieve analysis and dry sieve test | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Disintegration time | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | Not required as the product is a ready-to-use liquid, not applied by spraying. | - | - |
| Persistent foaming | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Flowability/Pourability/Dustability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Burning rate — smoke generators | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Burning completeness — smoke generators | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Composition of smoke — smoke generators | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Spraying pattern — aerosols | - | - | Not required as the product is a ready-to-use liquid, not applied by spraying. | - | - |
| Physical compatibility | - | - | Not applicable. The product GEL ATTRACTIF ANTI-FOURMIS is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical compatibility of the product GEL ATTRACTIF ANTI-FOURMIS with other biocidal products, chemicals or active substances is required. | *-* | *-* |
| Chemical compatibility | - | - | Not applicable. The product GEL ATTRACTIF ANTI-FOURMIS is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. Hence, no data on the chemical compatibility of the product GEL ATTRACTIF ANTI-FOURMIS with other biocidal products, chemicals or active substances is required. | Acceptable | *-* |
| Degree of dissolution and dilution stability | - | - | Not required as the product is a ready-to-use liquid. | - | - |
| Surface tension | EU Method A.5 (2008), OECD Test Guideline115 (1195) | GEL ATTRACTIF ANTI-FOURMIS | The mean surface tension of the pure test item at 20°C was 48.1 mN/m.  The test item is considered as surface active. | Acceptable | Bartocci M., 2021  Final report no. BT304/20,  Bio |
| Viscosity | OECD Test Guideline 114 (2012) | GEL ATTRACTIF ANTI-FOURMIS | Before the accelerated storage procedure at 35 ± 2°C for 12 weeks, taking into account the results obtained at 20.0°C and 40.0°C, the test item was considered to have non-newtonian properties in the experimental conditions used. The dynamic viscosity varied as following:  At 20.0 ± 0.2°C, from 1 rpm = 14187 mPa.s to 12 rpm = 2141.7 mPa.s.  At 40.0 ± 0.2°C, from 1 rpm = 12303 mPa.s to 12 rpm = 1785.4 mPa.s.  After the accelerated storage procedure at 35 ± 2°C for 12 weeks, taking into account the results obtained at 20.0°C and 40.0°C, the test item was considered to have non-newtonian properties in the experimental conditions used. The dynamic viscosity varied as following:  At 20.0 ± 0.2 °C, from 3 rpm = 3628.4 mPa.s to 60 rpm = 552.2 mPa.s.  At 40.0 ± 0.2 °C, from 3 rpm = 2331.6 mPa.s to 60 rpm = 370.2 mPa.s. | Acceptable | Bartocci M., 2021  Interim report no. BT306/20 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product GEL ATTRACTIF ANTI FOURMIS is a bait ready-to-use (RB) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable except for the accelerated storage stability study.  The appearance of the product is a white viscous and homogeneous liquid with a characteristic odour. After 12 weeks at 35°C, the content of active substance decrease by more than 10% and the pH decrease of one unit. The product is not stable at 35°C. After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Shelf life storage study is provided. The content of cypermethrin decrease by more than 10% after 12 months. Palability test after 18 months has been provided but no information on the identity of degradation products has been provided. Therefore, the shelf life is set at 6 months. Moreover, based on these results of accelerated storage, a mitigation measure “Do not store the product at temperature above 25°C should be added on the label.  Its technical characteristics are acceptable for an RB formulation.  Shelf life : 6 months  Risk mitigation measure:  Do not store at temperature above 25°C. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | - | The product GEL ATTRACTIF ANTI-FOURMIS contains:  - 0.20% w/w of cypermethrin cis:trans 40:60 (pure) (CAS No. 52315-07-8) is not explosive according to its Document I. Evaluation Report (Product-Type 18, February 2017) and based on chemical structure, no chemical structure alert is present according to the table A2 and A3 of the UN RTDG.  58.282% w/w of fructose (pure) (CAS No. 57-48-7) and 10.407% w/w of dextrose (CAS No. 50-99-7) which have no chemical group associated with explosive properties.  The product contains 28% w/w water, an inert ingredient without explosives properties. The other components (less than 3.2% w/w of the composition) are not classified as explosive according to their chemical structures.  In addition, a DSC test (An aliquot of test item was placed into a crucible. The lid was fitted and the crucible was placed in the DSC analyser. Two phases of heating were programmed. The heating procedure was performed at 5°C/min from room temperature to 550°C.) has been provided: an exothermic peak was observed at 197°C. The enthalpy difference is 314.6 J/g. | Acceptable  The product is not classified as explosive. | Detrimont H., 2022 Report  No.22-919062-001 |
| Flammable gases | Statement | - | - | Not relevant as the product is a liquid. | IUCLID |
| Flammable aerosols | Statement | - | - | Not relevant as the product is a liquid. | IUCLID |
| Oxidising gases | Statement | - | - | Not relevant as the product is a liquid. | IUCLID |
| Gases under pressure | Statement | - | - | Not relevant as the product is a liquid. | IUCLID |
| Flammable liquids | EC Method A9 | Gel attractif anti-fourmis  Batch 3137 | The product GEL ATTRACTIF ANTI-FOURMIS has been determined not to have a flash point below its boiling temperature (~123°C). | Acceptable  The product is not a flammable liquid. | Tremain.S.P. 2021, labcorp study n°: 8473650 |
| Flammable solids | Statement | - | - | Not relevant as the product is a liquid. | IUCLID |
| Self-reactive substances and mixtures | Statement | - | A DSC test (An aliquot of test item was placed into a crucible. The lid was fitted and the crucible was placed in the DSC analyser. Two phases of heating were programmed. The heating procedure was performed at 5°C/min from room temperature to 550°C, has been provided: an exothermic peak was observed at 197°C. The enthalpy difference is 314.6 J/g. | Not Acceptable  The enthalpy measured for the second peak is over 300J/g. In consequence, according to the CLP guidance, a SADT should be provided.  The data available do not allow to conclude on the classification. | Detrimont H., 2022 Report  No.22-919062-001 |
|  | UN test H4. | Batch number : 3137  Cypermethrine : 0.196% w/w  Fructose : 59.724 % w/w | SADT : ambient to 400°C  Quantity : 400 mL  The test item was observed to take 118.3 hours to reach a temperature 2°C below the oven  temperature. Over the following 168 hours (7 days) the test item reached a maximum  temperature of 74.1°C. The test item did not reach a temperature of more than 6°C above the  oven temperature therefore the SADT of the substance is > 75°C. The substance is therefore  exempt from classification as a self-reactive substance of UN Class 4, Division 4.1. | Acceptable. The product is not classified self-reactive | Porte P, 2022, Report 3016012158R1/2022  GLP |
| Pyrophoric liquids | Statement | - | Test is not required as the product GEL ATTRACTIF ANTI-FOURMIS does not contain any components classified as pyrophoric according to their safety data  sheets. Moreover, experience in manufacture and handling shows that the product GEL ATTRACTIF ANTI-FOURMIS do not ignite spontaneously on coming into contact with air at normal temperature. The product GEL ATTRACTIF ANTIFOURMIS is not expected to be a pyrophoric liquid and test is not required. | Acceptable | IUCLID |
| Pyrophoric solids | Statement | - | - | Not relevant as the product is a liquid. | IUCLID |
| Self-heating substances and mixtures | Statement | - | Test not required the product is a liquid. | Acceptable | IUCLID |
| Substances and mixtures which in contact with water emit flammable gases | Statement | - | Test is not required as the product GEL ATTRACTIF ANTI-FOURMIS does not contain any components classified as substances which in contact with water emit flammable gases. Therefore, the product GEL ATTRACTIF ANTI-FOURMIS is not expected to emit flammable gases in contact with water and test is not required. | Acceptable | IUCLID |
| Oxidising liquids | Statement | - | The product GEL ATTRACTIF ANTI-FOURMIS contains: - 0.20% w/w of cypermethrin cis:trans 40:60 (pure) (CAS No. 52315-07-8) is not classified for oxidising properties according to its Document I. Evaluation Report (Product-Type 18, February 2017) and based on chemical structure, the substance contains oxygen and chlorine but they are only bonded with carbon or hydrogen.  - 58.282% w/w of fructose (pure) (CAS No. 57-48-7) and 10.407% w/w of dextrose (CAS No. 50-99-7) which contain oxygen atoms but these elements are chemically bonded only to carbon and/or hydrogen atoms.  The product contains 28% w/w water, an inert ingredient without oxidising properties. The other components (less than 3.2% w/w of the composition), are not classified as oxidising according based on their chemical composition (see PAR conf). | Acceptable.  Based on the chemical composition of the product, no chemical structure associated with oxidizing properties are identified, therefore, the product is not classified as oxidizing. | IUCLID |
| Oxidising solids | Statement | - | - | Not relevant as the product is a liquid. | IUCLID |
| Organic peroxides | Statement | - | The product GEL ATTRACTIF ANTI-FOURMIS is not concerned by the physical hazard “organic peroxides” as its components are not expected to form or contain Organic peroxides. | Acceptable | IUCLID |

| Corrosive to metals | method C.1 | Gel attractif anti-fourmis batch 3137 | Principle of the test:  2 mm thickness aluminium and steel plates are prepared, weighed and exposed to the test item in defined conditions for 7 days at 55 ± 1°C. After the end of the test, the plates are rinsed off, cleaned, dried and weighed. The type of corrosion is determined and the loss of weight of the plates is calculated in percentage. In case of localised corrosion, the minimum intrusion depth is determined.  Results:  **\*Steel plates**  -Immersed plate | Acceptable  The test of corrosion is acceptable, there is neither localized nor uniform corrosion. The product GEL ATTRACTIF ANTI-FOURMIS is not classified as corrosive. | Detrimont H. 2021, report N° 21-919062-007 |
| --- | --- | --- | --- | --- | --- |
|  |  |  | -half way immersed plate:    -plate placed in the gaseous phase: |  |  |
|  |  |  | **\*for aluminium plates**  -immersed plate    -half way immersed plate: |  |  |
|  |  |  | -plate placed in the gaseous phase: |  |  |
|  |  |  | Conclusion:  Neither localised nor uniform corrosion was observed after the test; the test item GEL ATTRACTIF ANTI-FOURMIS is not classified as corrosive to metals according to the United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria and according to Regulation EC No.1272/2008 (CLP). |  |  |
| Auto-ignition temperatures of products (liquids and gases) | Statement | - | The product GEL ATTRACTIF ANTI-FOURMIS contains 0.20% w/w of cypermethrin cis:trans 40:60 (pure) (CAS No. 52315-07-8), which has no self-ignition temperature up to 400°C according to its Document I. Evaluation Report (Product-Type 18, February 2017) and to its safety datasheet. The main constituents of the product GEL ATTRACTIF ANTI-FOURMIS are fructose (pure) (CAS No. 57-48-7) and dextrose (CAS No. 50-99-7) (respectively 58.282% w/w and 10.407% w/w of the composition); these two ingredients, found in many plants (fruits, vegetables), are not self-flammable properties and do not require safety data sheets according to Art. 31 in connection with Appendix II of the Regulation No. 1907/2006 of the European Parliament and the Council (REACH) of the 18th of December 2006. The product contains 28% w/w water, an inert ingredient which is not self-flammable. Data is lacking on the self-ignition temperatures of some of the other components (less than 3.2% w/w of the formulation), although they are not expected to present a significant hazard for auto-flammability according to their safety data sheets. Therefore, the product GEL ATTRACTIF ANTI-FOURMIS is not expected to present a significant hazard for auto-flammability and test is not required. | Not Acceptable  A test for auto-ignition is required. | IUCLID |
| Relative self-ignition temperature for solids | Statement | - | - | Not relevant as the product is a liquid. | IUCLID |
| Dust explosion hazard | Statement | - | - | Not relevant as the product is a liquid. | IUCLID |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties. The DSC analysis provided show an exothermic peak with an enthalpy higher than 300 J/g. According to the CLP regulation, an SADT has been provided. Results show that the product is not self-reactive.  The product is not classified for physical hazard.  A test for auto-ignition is required post-authorisation within 1 year. |

### Methods for detection and identification

**Determination of cypermethrin cis/trans 40/60 content in the product:**

Report: Bartocci M 2020 Analytical method validation for the determination of cypermethrin cis/trans 40/60 content in the test item GEL ATTRACTIF ANTIFOURMIS (SANCO/3030/99 rev.5 from 22/03/2019).

Report no BT302/20

Test facilities: BioTechnologie BT srl (Todi, Italy)

Principle of the method:

An analytical method for the determination of cypermethrin cis/trans 40/60 content in the product GEL ATTRACTIF ANTI-FOURMIS will be validated during this study by definition of the specificity, the linearity, the accuracy and the precision of the method. Furthermore, this method will allow determining the ratio of cis- and trans-cypermethrin isomers.

Cypermethrin cis:trans 40:60 will be analysed after extraction from the formulation GEL ATTRACTIF ANTI-FOURMIS with hexane and will be quantified by HPLC-UV/DAD (λ = 210 nm).

The validation of this method was considered in compliance with SANCO/3030/99 rev.5.

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * cis- and trans-cypermethrin standard solutions * blank Formulation * blank formulation spiked with cypermethrin * Test item of the product   No interference was found: no peak appears in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item.  All chromatograms were available.  To identify the chromatographic peaks related to cis- and trans- isomers, specific analytical standards solutions were used. Solutions prepared for confirmation of analyte were injected once after the linearity solutions. Matching the retention times (Rt) of chromatograms obtained from linearity solutions (prepared with the cypermethrin technical active substance) and from precision solutions (prepared with test item), with the chromatograms of CYP\_CIS and CYP\_TRANS solutions, it was possible to identify the different  isomers peaks by the elution chronology. Moreover the UV spectra of the isomers found in the test item and the UV spectra of the same isomers in the linearity solutions were obtained and matched with the UV spectra, respectively, extracted from CYP\_CIS and CYP\_TRANS solutions chromatograms. | |
| Linearity | Linearity was studied by carrying out five concentrations between 50% and 150% (from 11.7549 mg/L to 117.5486 mg/L, equivalent to 0.0470 - 0.4702% w/w in the test item of the reference item.)  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| Active substance: cypermethrin | 0.047%-0.4702% w/w Y = 12.6012X – 35.6545  r= 0.9992  n=5 |
| Precision | Repeatability was evaluated by analyzing five test item solutions. | |
| Compound | Repeatability (RSD) |
| Active substance: cypermethrin at 0.196%w/w | RSD = 1.41% |
| The percent area (%) of cis- and trans-cypermethrin was calculated:  40.71 ± 0.09% of cis-cypermethrin and 59.29 ± 0.09% of trans-cypermethrin. | |
| Accuracy | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 0.1% w/w | 94.31%; 91.72%; 92.77%; 93.97%; 88.96% | 92.35% | 2.33% | 5 | | 1% w/w | 90.71%; 89.83%; 89.89%; 90.36%; 94.42% | 91.04% | 2.11% | 5 | | |

The analytical method is fully validated for the determination of the active substance cypermethrin in the product.

**Determination of fructose content in the product**

Report: Bartocci M 2020 Analytical method validation for the determination of d-fructose content in the test item GEL ATTRACTIF ANTIFOURMIS (SANCO/3030/99 rev.5 from 22/03/2019).

Report no BT303/20

Test facilities: BioTechnologie BT srl (Todi, Italy)

Principle of the method:

Fructose is analysed after dilution from the formulation with water and quantified by liquid chromatography using a MS/MS detector (two mass transitions monitored).

Q1 transition (quantification): 179.0 → 89.0 m/z

Q2 transition (qualification): 179.0 → 161.1 m/z

The validation of this method was considered in compliance with SANCO/3030/99 rev.5.

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * calibration solutions * blank Formulation * blank spiked with fructose * Test item of the product   No interference was found: no peak appears in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item.  All chromatograms and mass spectra were available. | |
| Linearity | Linearity was studied by carrying out five concentrations between 50% and 150% of the reference item (from 0.9862 – 15.3409 mg/L, equivalent to 9.17 – 142.71% w/w in test item).  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| Active substance | 50% to 150%  Q1 Transition (quantification): 179.0 → 89.0 m/z  y = 400.284327x + 561.392028  r = 0.9939  Q2 Transition (qualification): 179.0 → 161.1 m/z  y = 130.321283x + 166.982654  r = 0.9925  n=5 |
| Precision | Repeatability was evaluated by analyzing five test item solutions. | |
| Compound | Repeatability (RSD) |
| Active substance fructose (59.72% w/w) | RSD = 1.45% |
| Accuracy | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 50% w/w | 96.35; 98.05; 99.05;  99.32;99.63 | 99.48 | 1.35 | 5 | | 70% w/w | 99.15;101.79;99.81;102.6;100.47 | 100.76 | 1.41 | 5 | | |

The analytical method is fully validated for the determination of the active substance d-fructose in the product.

Analytical methods for Cypermethrin residues in soil, air, water (drinking water) and sediment are available in Assessment Report of Cypermethrin Product-type 18, February 2017. The applicant SAS SPRING has a Letter of Access from LIMARU NV (Acting for Tagros Chemicals India Private Limited) and Arysta LifeScience Benelux SPRL for these data.

As the active substance Cypermethrin is not classified Toxic or Very Toxic, an analytical method for the determination of Cypermethrin residue in human body fluids and tissues is unnecessary.

As the product GEL ATTRACTIF ANTI-FOURMIS is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of Cypermethrin residue in food/feed of plant and animal origin is unnecessary. However, analytical methods for the determination of cypermethrin residues in Food/feed of plant and animal origin are available in Document I, Evaluation Report of Cypermethrin, Product-type 18 (Insecticides), February 2017.

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes):

LOD = 0.05 mg/kg (oilseed rape),

0.025 mg/kg (wheat).

Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes):

LOQ = 0.05 mg/kg (bovine tissue),

0.005 mg/kg (bovine milk),

0.01 mg/kg (hen eggs)

**Fructose**Analytical methods for the determination of fructose residues in soil, air and water are not required as it is an active substance in category 4 of Annex I of Regulation (EU) No.528/2012.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is fully validated for the determination of the active substance Cypermethrin in the product.  Analytical methods were provided at EU level for the determination of Cypermethrin residue in soil, air and water with respectively LOQ = 0.05 mg/kg, 0.375 µg/m3 and 0.01 µg/L.  Cypermethrin is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.  As the product GEL ATTRACTIF ANTI-FOURMIS is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of Cypermethrin in food/feed of plant and animal origin is not required. However, analytical methods for the determination of cypermethrin residues in Food/feed of plant and animal origin are available in Document I, Evaluation Report of Cypermethrin, Product-type 18 (Insecticides), February 2017. |

### Efficacy against target organisms

#### Function and field of use

Main Group 03: Pest Control

Product Type 18: Insecticides, acaricides and products to control other arthropods.

The product GEL ATTRACTIF ANTI-FOURMIS is a ready to use gel bait applied as spot for the control of ants, for non-professional users, indoor in privative areas.

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

The product GEL ATTRACTIF ANTI-FOURMIS is intended to be used for the control of ants in order to protect public health and also materials.

GEL ATTRACTIF ANTI-FOURMIS is used to control the following species ants:

* Black garden ants *Lasius niger*;
* Argentine ant *Linepithema humile*;
* Pharaoh ant *Monomorium pharaonis*;

The developement stage is all stage including nests.

Objects to be protected: Indoor of buildings.

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

Cypermethrin is a synthetic pyrethroid insecticide which acts by contact and ingestion.

Pyrethroids should be expected to exert a rapid knockdown efficacy against target species, following by a killing effect. This effect is expected to be shown a few minutes after contact, although may take longer with larger fewer sensitive species.

Fructose has an attractant effect based on olfactory attraction.

#### Mode of action, including time delay

Cypermethrin 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.

D-Fructose (Annex I active substance) is present is in the product as attractant.

#### Efficacy data

The following table summarises the efficacy studies submitted with the product GEL ATTRACTIF ANTI-FOURMIS by the applicant.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | |
| **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Indoor | GEL ATTRACTIF ANTI-FOURMIS  (cypermethrin 0.217% w/w,)  Batch 2725 | *Lasius niger*  *Linepithema humile, Monomorium pharaonis*  25 workers | Laboratory trial (Palatability test)  According to C.E.B. method No. 196 | Laboratory test was carried out in arenas (30 cm x 30 cm x 15 cm) with a competition food (2% sugar) and a shelter.  Application rate: 0.5 g/m²  The gel was placed into a Petri dish on the floor of the arena.  Exposure: 10 days Daily counting of dead ants and calculation of mortality percentage.  Replicates: 5 replicates per test species.  Non-treated controls: 5 replicates per species, with the same procedure but without any treatment  Temperature:25 °C +/-1 °C  Hygrometry :65 % RH +/-4%RH  Light 1500 lux 8/16 photoperiod | % of mortality of *L. niger*   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | Days of exposure | | | | | | | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | Test product | 0 | 4 | 28 | 51 | 66 | 78 | 87 | 95 | 100 | 100 | | Untreated control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.8 | 0.8 | 1.6 |   % of mortality of *L. humile*   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | Days of exposure | | | | | | | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | Test product | 0 | 2.40 | 18 | 38 | 54 | 66 | 76 | 84 | 96 | 100 | | Untreated control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.8 |   % of mortality of *M. pharaonis*   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | Days of exposure | | | | | | | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | Test product | 0 | 0 | 6.4 | 22 | 37 | 53 | 70 | 83 | 98 | 100 | | Untreated control | 0 | 0 | 0 | 0 | 0 | 0.8 | 0.8 | 3.2 | 3.2 | 4 |   The product showed 95% mortality against *L. niger*, *L. humile* and *M. pharaonis* at the application rate of 0.5 g/m² within 8-9 days.  However, the reliability of the test is 3, because the composition of the product tested contains more fructose than GEL ATTRACTIF ANTI-FOURMI. (see confidential annex). | Serrano B. 2020. Study No. 2541c/0120  RI= 3 |
| Indoor | GEL ATTRACTIF ANTI-FOURMIS  Aged 12 weeks at 35°C cypermethrin 0.17% w/w (pure), 13.3% decreased from an initial content of 0.196% w/w D-fructose 60.2% w/w  Batch 3137 | *Lasius niger*  *Linepithema humile, Monomorium pharaonis*  25 workers | Laboratory trial (Palatability test)  According to C.E.B. method No. 196 | Laboratory test was carried out in arenas (30 cm x 30 cm x 15 cm) with a competition food (2% sugar) and a shelter.  Application rate: 0.5 g/m²  The gel was placed into a Petri dish on the floor of the arena.  Exposure: 12 days Daily counting of dead ants and calculation of mortality percentage.  Replicates: 5 replicates per test species.  Non-treated controls: 5 replicates per species, with the same procedure but without any treatment  Temperature:25 °C +/-1 °C  Hygrometry :65 % RH +/-4%RH  Light 1500 lux 8/16 photoperiod | % of mortality of *L. niger*   |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | Days of exposure | | | | | | | | | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | | Test product | 0 | 1 | 6 | 35 | 60 | 81 | 86 | 98 | 100 | 100 | 100 | 100 | | Untreated control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 2 | 2 | 2 |   % of mortality of *L. humile*   |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | Days of exposure | | | | | | | | | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | | Test product | 0 | 0 | 0 | 12 | 26 | 35 | 46 | 58 | 73 | 83 | 95 | 100 | | Untreated control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 2 |   % of mortality of *M. pharaonis*   |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | Days of exposure | | | | | | | | | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | | Test product | 0 | 1 | 2 | 20 | 42 | 55 | 72 | 82 | 98 | 100 | 100 | 100 | | Untreated control | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 1 |   The product showed 95% mortality against *L. niger*, *L. humile* and *M. pharaonis* at the application rate of 0.5 g/m² within 8-11 days. | Serrano B. 2021. Study No. 2672/0521  RI = 1 |
| Indoor | GEL ATTRACTIF ANTI-FOURMIS (0.217 % w/w cypermethrin, 58.28 % w/w fructose )  Batch 3137 | *Lasius niger*  *Linepithema humile, Monomorium pharaonis* | Field trial  According to C.E.B. method No. 196 | The trial is conducted in  gardens, orchards or everywhere as soon as the ant nests are well isolated.  The principle was to measure the activity of ants through frequency of ants' passage in surface before and after the treatment, and then to open the nest after 4 weeks to check any alive insect.  7 assessments were done:  one before treatment: D-1,  6 after treatment: 1, 3, 7, 14, 21 and 28 days after treatment.  The criteria was the FCS = Frequency of Crossing in Surface. The FCS was measured by counting the number of ants moving in a defined place and always in the same place along the trial  The observation was done in a square of 1 m² around the main nest entry, by setting a frame on the ground.  Dose: 0.5 g/m² near the nest entries or on the ants' tracks if the nest entries are not visible  The experimenter recorded the number of ants in this area at each assessment date, in the morning (more activity) and always at the same hour. The duration of each assessment was 5 minutes, and the count was done only once (this was not a dynamic count along time, this was a kind of “photo shoot” of the number of ants walking around the nest at each date).  The treatment was not repeated.  5 nests (sites) were monitored for each species and each treatment (treated / untreated). The species present on each site was determined by a specialist.  At the end of the trial (4 weeks), the nest is open to check if there is any activity inside and alive adults, larvae, queen, cocoons etc. | Percentages of reductions of the frequency of crossing in surface (FCS) in comparison with the activity before the treatment  *L. niger*   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Site | D-1 | D+1 day | D+3 days | D+7 days | D+14 days | D+21 days | D+28 days | | 1 | 188 | 11.2 (167)\*\* | 30.9 (130) | 91 (17) | 100 | 100 | 100 | | 2 | 65 | 13.8 (56) | 20 (52) | 92.3 (5) | 100 | 100 | 100 | | 3 | 39 | 17.9 (32) | 23.1 (30) | 92.3 (3) | 100 | 100 | 100 | | 4 | 41 | 9.8 (37) | 31.7 (28) | 97.6 (1) | 100 | 100 | 100 | | 5 | 46 | -10.9 (51) | 13 (40) | 100 (0) | 100 | 100 | 100 | | Control\* | 50.2 | 7.9 | 8.4 | 4.3 | -4.6 | -1 | -11.4 |   \*: mean of 5 untreated sites  \*\*: FCS  Note: a negative percentage of reduction means an increase of the FCS  The product showed more than 90% reduction population of *L. niger* after 7 days and 100% within 14 days and up to 28 days after treatment, on all sites and the complete nest destruction (with death of queen) after 28 days at the application rate of 0.5 g/m²  *L. humile*   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Site | D-1 | D+1 day | D+3 days | D+7 days | D+14 days | D+21 days | D+28 days | | 1 | 106 | -7.5 (114)\*\* | 9.4 (96) | 64.2 (38) | 98.1 (2) | 100 | 100 | | 2 | 32 | -3.1 (33) | 12.5 (28) | 81.3 (6) | 100 (0) | 100 | 100 | | 3 | 59 | -11.9 (66) | -1.7 (60) | 64.4 (21) | 100 | 100 | 100 | | 4 | 117 | 9.4 (106) | 32.5 (79) | 93.2 (8) | 100 | 100 | 100 | | 5 | 64 | 3.1 (62) | 56.3 (28) | 98.4 (1) | 100 | 100 | 100 | | Control\* | 40.2 | -0.5 | 2.3 | 3.4 | -1.7 | 3.3 | -3.9 |   \*: mean of 5 untreated sites  \*\*: FCS  Note: a negative percentage of reduction means an increase of the FCS  The product showed more than 98-100% reduction population of *L. humile* after 14 days and 100% up to 28 days after treatment, on all sites and the complete nest destruction (with death of queen) after 28 days at the application rate of 0.5 g/m²  *M. pharaonis*   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Site | D-1 | D+1 day | D+3 days | D+7 days | D+14 days | D+21 days | D+28 days | | 1 | 36 | -5.6 (38)\*\* | 13.9 (31) | 83.3 (6) | 100 | 100 | 100 | | 2 | 27 | 11.1 (24) | 7.4 (25) | 100 (0) | 100 | 100 | 100 | | 3 | 44 | 6.8 (41) | -4.5 (46) | 90.9 (4) | 100 | 100 | 100 | | 4 | 60 | -5 (63) | 13.3 (52) | 85 (9) | 100 | 100 | 100 | | 5 | 51 | -9.8 (56) | 15.7 (43) | 80.4 (10) | 100 | 100 | 100 | | Control\* | 33.2 | 4.6 | 1.2 | -8.6 | -8.6 | -2.9 | -12.1 |   \*: mean of 5 untreated sites  \*\*: FCS  Note: a negative percentage of reduction means an increase of the FCS  The product showed 100% reduction population of *M. pharaonis* after 14 days and up to 28 days after treatment, on all sites and the complete nest destruction (with death of queen) after 28 days at the application rate of 0.5 g/m² | Serrano B. 2018. Study No. 2672/0521  RI = 2 |

Laboratory and field tests have been conducted with the product GEL ATTRACTIF ANTI-FOURMIS to demonstrate the efficacy of the product to control ants (*Lasius niger*, *Linepithema humile*, *Monomorium pharaonis*).

Laboratory test (palatability test) conducted with the fresh product GEL ATTRACTIF ANTI-FOURMIS (0.217 % w/w), but with a different content of palatable agent that the one claimed, showed 95% mortality within 8-9 days after exposure at the rate application of 0.5 g/m² against *Lasius niger*, *Linepithema humile*, *Monomorium pharaonis*).

As the composition of the product tested is not similar to the product GEL ATTRACTIF ANTI-FOURMIS on its content of palatable agent (see confidential annex). Therefore this test is not suitable to support the efficacy of the product GEL ATTRACTIF ANTI-FOURMIS as claimed in the dossier.

The applicant provides another palatability test with accelerated aged product GEL ATTRACTIF ANTI-FOURMIS (12 weeks at 35 °C), that showed 95% mortality within 8-11 days after exposure at the rate application of 0.5 g/m² against *Lasius niger*, *Linepithema humile*, *Monomorium pharaonis*.

eCA accepts the demonstration of the bait palatability with accelerated aged product because it was conducted in worst conditions.

According to the TAB, additional efficacy test are required for bait product which the degradation of the active content is >10% and assessment of the degradation on the efficacy is needed to substantiate the shelf life claim.

Nevertheless, it should be highlighted that for bait product, efficacy test with accelerated aged product are not acceptable to support the shelf-life of the product in case where an active degradation of more than 10% is observed.

This study is then not suitable to support the efficacy of the product for a shelf-life of 2 years.

In field test, conducted in outdoor, the product GEL ATTRACTIF ANTI-FOURMIS (0.196 % w/w) showed more than 90% mortality against *Lasius. niger*, *Linepithema humile*, *Monomorium pharaonis*, after 1 to 2 weeks for the reduction of population and 28 days for the destruction of nest and has a residual effect up to 4 weeks after the treatment.

According to the efficacy guidance, for bait products, simulated-use test should be normally provided. Considering the robustness of field tests, e-CA agree with the applicant to waive it.

The field test demonstrates the efficacy of the product outdoor, however the use is intended for indoor. Nevertheless, as the application at the entrance of nest and its destruction are claimed, eCA considers this test relevant and robust and covers the use indoor.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities consider that the elements submitted in the dossier demonstrated the efficacy of the bait product GEL ATTRACTIF ANTI-FOURMIS indoor to control, with destruction of nest at the application rate of 0.5 g /m²,against the following species:   * Black garden ant (*Lasius niger*), * Argentine ant (*Linepithema humile*) and * Pharaoh ant (*Monomorium pharaonis*)   The time delay is 2 weeks for the reduction of population and 28 days for nest destruction.  The product has a residual efficacy up to 4 weeks. |

#### Occurrence of resistance and resistance management

Cypermethrin belongs to the pyrethroid family. Resistance phenomena to cypermethrin have been reported for a number of pests both in agriculture and public health.

However no resistance phenomenon of ants species claimed to cypermethrin has been reported up to date in scientific literature.

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

Resistance is not expected for D-fructose since its mode of action is based on olfaction.

#### Known limitations

None.

#### Evaluation of the label claims

See Efficacy conclusion.

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

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

### Risk assessment for human health

No toxicological studies have been submitted for the product GEL ATTRACTIF ANTI-FOURMIS.

The classification of the product has been set according to the calculation rules laid down in the CLP regulation 1272/2008/EC.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not corrosive to skin |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not irritant for the eyes |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value/ Conclusion | Not irritating for the respiratory tract |
| Justification for the conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to skin |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising for the respiratory tract |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via oral route |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic via inhalation |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via dermal route |
| Justification for the selected value | Based on intrinsic properties of individual components of the biocidal product. |
| Classification of the product according to CLP | No classification required. |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Cypermethrin |
| Value | 70% |
| Justification for the selected value | Default dermal absorption value for ready for use bait (RB) with a concentration in active substance below 5%, based on the EFSA Guidance on dermal absorption (2017). |

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

No substance of concern has been identified for HH.

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

Not relevant.

***Other***

Not relevant.

#### Exposure assessment

The product GEL ATTRACTIF ANTI-FOURMIS is a ready-to-use gel bait (PT18) for the control of ants, as a preventive and curative treatment. It is applied as gel droplets with a pipette in areas where ants pass, indoor, by non-professional users.

For the primary exposure to the product, the user is only exposed via dermal route.

Secondary exposure (dermal and oral) may occur from the toddler crawling on the floor after the application.

The D-fructose is an active substance in category 4 of Annex I of Regulation (EU) No.528/2012. No effect on human health is expected.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: main paths of human exposure** | | | | |  |
| **Exposure path** | **Primary (direct) exposure** | | **Secondary (indirect) exposure** | |  |
| **Professional users** (including industrial users and trained professional users) | **Non-**  **professional users** | **Professional users**  (including industrial users and trained professional users) | **Non-**  **professional bystanders/ General public** | **Via food** |
| Oral | n/a | No | n/a | Yes |  |
| Dermal | n/a | Yes | n/a | Yes |  |
| Inhalation | n/a | No | n/a | No | No |

***List of scenarios***

| **Summary table: exposure scenarios** | | |
| --- | --- | --- |
| **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| Scenario 1 | Primary exposure  Application of droplets of gel | Non-professionals |
| Scenario 2 | Secondary exposure  Inhalation of volatised residues | General public |
| Scenario 3 | Secondary exposure  Toddler crawling on the floor and hand-to-mouth transfer | General public (toddlers) |

***Professional users (including industrial users)***

Not relevant. The product is intended to be used by non-professionals only.

***Non-professional users***

**Primary exposure**

*Scenario [1] – Application of droplets of gel*

| **Description of Scenario [1] – Application of droplets of gel** | | | |
| --- | --- | --- | --- |
| The product is applied by non-professionals as gel drops, using a pipette.  An approach is proposed in Ad hoc Recommendation 6 – Methods and models to assess exposure to biocidal products in different product types, to estimate the potential dermal exposure using different parameters of the gel drop. As the height of the beads for this product is not known, this approach cannot be used and a reverse scenario is used to determine the amount of drops of gel the user can be in contact with to reach an exposure level equal to the AELmedium-term (according to the applicant, the product is to be used maximum 11 times per year).  The weight of a drop of gel is equal to 0.1g and the concentration of active substance in the product is 0.217% w/w.  The exposure by inhalation is not expected in this scenario. | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of active substance | 0.217% | Applicant’s data |
| AEL medium-term | 0.054 mg/kg/d | CAR on Cypermethrin |
| Dermal absorption value | 70% | Default value according to EFSA Guidance 2017 |
| Body weight | 60 kg | Ad hoc Recommendation 14 |
| Weight of a drop of gel | 0.1 g | Applicant’s data |

**Calculations for Scenario [1]**

| **Summary table: systemic exposure from non-professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Acceptable external exposure (g product)** | **Number of drops of product to touch to reach the AELmedium-term** |
| Scenario [1] | 1/ No PPE | 2.17 | 21 |

**Secondary exposure - Exposure of the general public**

*Scenario [2] – Inhalation of volatised residues*

| **Description of Scenario [2] – Inhalation of volatised residues** |
| --- |
| As the product is applied indoor in closed area, the general public can be exposed to volatised residues of the product. No risk is expected via inhalation route, but a risk assessment is performed to demonstrate the low exposure.  In the HEEG Opinion 13, on the Assessment of Inhalation Exposure of Volatised Biocide Active Substance, a calculation is developed and determined if the risk from inhalation exposure is negligible or should be included in the risk assessment.  This formula is based on the toddler representing the worst-case and covering every age group:  With *mw* being the molecular weight and *vp* the vapour pressure.  If the result is below 1, then the risk from inhalation exposure is considered negligible.  For Cypermethrin:   * Mw = 416.3 g/mol * Vp = 2.30x10-7 Pa * AEC long-term = 0.022 mg/kg bw/d   For the cypermethrin, the result is **< 1**. Therefore, the inhalation exposure is negligible after the application and not taken into account in the risk assessment. |

*Scenario [3] – Toddler crawling on the floor and hand-to-mouth transfer*

| **Description of Scenario [3] – Toddler crawling on the floor and hand-to-mouth transfer** | | | |
| --- | --- | --- | --- |
| After the application of the product, toddlers can crawl into the room and be dermally exposed to the product by contact with the drops on the floor. Oral exposure to the active substance after hand-to-mouth transfer is also expected.  It is assumed in the assessment that the toddler can touch the drops applied on 1m², with the application rate of 0.5 g/m² of product.  According to the ConsExpo Pest Control Products Fact Sheet, 10% of the dermal exposure is taken orally due to hand-to-mouth transfer. | | | |
|  | Parameters | Value | Justification |
| Tier 1 | Concentration of active substance | 0.217% | Applicant’s data |
| Application rate | 0.5 g/m2 | Applicant’s data |
| Dermal absorption value | 70% | Default value according to EFSA Guidance 2017 |
| Oral absorption | 57% | Data on active substance |
| Body weight | 10 kg | Ad hoc Recommendation 14 |

**Calculations for Scenario [3]**

| **Summary table: estimated exposure from general public** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [3] | Tier 1/No PPE | negligible | 7.6x10-2 | 6.18x10-3 | 8.21x10-2 |

***Dietary exposure***

The product GEL ATTRACTIF ANTI-FOURMIS is only applied as gel droplets indoor. It is not intended to be used near food, feed, drinks or livestock, and on surfaces and facilities in the vicinity of or likely to be in contact with food, feed, drinks and livestock. No direct or indirect contact with food, feed, drinks or livestock is expected. Therefore, an investigation of residues in food does not appear to be justified. The following risk mitigation measures is applied:

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

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

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1. | Plant protection product | Insecticide for use on crops | **Residue definition:** Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers))  **MRLs** of 0.05 - 3 mg/kg depending upon commodity (Reg. (EU) 2017/626) |
| 2. | Veterinary medicine | Antiparasitic agent for use against ectoparasites | **Residue definition:**  Cypermethrin (sum of isomers)  **MRL (all ruminants):**  20µg/kg – muscle, kidney, milk  200µg/kg - fat,  **MRL (*Salmonidae*):**  50 µg/kg - muscle and skin in natural proportions  (Regulation (EU) 37/2010) |

*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

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

Not relevant

*Maximum residue limits or equivalent*

No specific biocide MRLs are established for this active substance. Nevertheless, MRLs are established in Regulation (EU) 1107/2009 and Regulation (EU) 37/2010 (See paragraph above “Information of non-biocidal use of the active substance*”).*

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation – Cypermethrin

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AELshort-term | Rat, acute delayed neurotoxicity, oral behavioural effects | 20 mg/kg/d | 100 | 44% | 0.088 mg/kg/d |
| AELmedium-term | Dog, 90-days, oral | 12.5 mg/kg/d | 100 | 44% | 0.055 mg/kg/d |
| AELlong-term | Rat, 2-years, oral | 5 mg/kg/d | 100 | 44% | 0.022 mg/kg/d |
| ARfD |  |  |  |  | 0.2 mg/kg bw |
| ADI |  |  |  |  | 0.05 mg/kg bw/d |

***Risk for industrial users***

The product is intended to be used by non-professionals only.

***Risk for professional users***

The product is intended to be used by non-professionals only.

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

| **Summary table: systemic exposure from non-professional uses** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Acceptable external exposure (g product)** | **Number of drops of product to touch to reach the AELmedium-term** |
| Scenario [1] | 1/ No PPE | 2.17 | 21 |

To reach the medium-term AEL, a dermal contact with 21 droplets is necessary.

**Local effects**

Not applicable. The product is not classified.

**Conclusion**

According to the reverse scenario calculations, a maximum of 21 droplets of gel can be touched by the non-professional user to reach the AELshort-medium. Considering that the application rate claimed by the applicant is 5 drops of gel per m² to be applied on ants path, a dermal contact with 21 drops of gel during application is considered an unrealistic worst-case and the risk is deemed acceptable.

***Risk for the general public***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** |
| **Scenario [3]** | 1/no PPE | 0.088 | 8.21x10-2 | 93 |

**Local effects**

Not applicable. The product is not classified.

**Conclusion**

The risk is considered acceptable (%AEL <100) taking into account that the product contains a bittering agent. Moreover, in order to minimize the potential secondary exposure the following risk mitigation measure (RMM) is proposed:

* Apply only in areas inaccessible to children and pets.

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

Not relevant. See details in paragraph above.

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

Not relevant.

### Risk assessment for animal health

In the risk assessment for human health, the risk is considered acceptable for toddlers exposed to drops of products applied on the floor, with the application of RMM.

Therefore, the risk for animal health is covered by the risk for human health and the same RMM is required to minimize animal exposure:

* Apply only in areas inaccessible to children and pets.

### Risk assessment for the environment

The product GEL ATTRACTIF ANTI-FOURMIS is a ready-to use gel containing 0.217% w/w cypermethrin (CAS No. 52315-07-8) as active substance and 58.282 % w/w D-fructose- (CAS No. 57-48-7) as annex I active substance, intended to be applied indoor against ants by non-professionals in private houses as gel droplets where ants pass and near the entries of the nest.

The product does not contain any substance of concern. The D-fructose is included in Annex I, therefore the risk assessment is provided on the active substance cypermethrin only. The data on active substance are provided by the competent authority report (CAR) of cypermethrin for PT18. The available ecotoxicological information from the CAR are used for the environmental risk assessment.

#### **Effects assessment on the environment**

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

The biocidal product does not contain any co-formulants that are classified for the environment. The fructose is not classified for the environment. Therefore, product classification is driven only by the active substance cypermethrin. According to the ATP 17 of the CLP Regulation, cypermethrin is classified as Aquatic Acute 1, H400 (with an M-factor of 100 000) and Aquatic Chronic 1, H410 (with an M-factor of 100 000).

The product contains 0.217% w/w cypermethrin. Therefore it is classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) under the CLP Regulation (EC) No 1272/2008.

***Further Ecotoxicological studies***

No new data is available.

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant. |
| Justification | Available ecotoxicity data on cypermethrin are considered sufficient to assess the ecotoxicity of the product as there is no substance of concern for the environment in the product.  Therefore, no additional ecotoxicological study with the product GEL ATTRACTIF ANTI-FOURMIS was conducted to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant. |
| Justification | Available ecotoxicity data on cypermethrin are considered sufficient to assess the ecotoxicity of the product as there is no substance of concern for the environment in the product.  Therefore, no additional ecotoxicological study with the product GEL ATTRACTIF ANTI-FOURMIS was conducted to address this point. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. The product GEL ATTRACTIF ANTI-FOURMIS is a gel used indoor only, where poisoning of non-target organisms is negligible.  Moreover, available ecotoxicity data on cypermethrin are considered sufficient to assess the ecotoxicity of the product as there is no substance of concern for the environment in the product.  No further data on the product GEL ATTRACTIF ANTI-FOURMIS is deemed necessary. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant. |
| Justification | The product GEL ATTRACTIF ANTI-FOURMIS is a gel used indoor only. The product is therefore not intended to be applied directly in a specific habitat such as water body, wetland, forest or field.  Therefore, no secondary ecological effect is expected when using the product GEL ATTRACTIF ANTI-FOURMIS according to the label recommendations.  No further data on the product GEL ATTRACTIF ANTI-FOURMIS is deemed necessary. |

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

The product GEL ATTRACTIF ANTI-FOURMIS is a ready-to use gel containing 0.217% w/w cypermethrin as active substance and 58.282 % w/w D-fructose, as Annex I active substance, intended to be applied indoor by non-professionals in private houses as gel droplets where ants pass and near the entries of the nest.

According to the intended uses, the following releases may occur:

* After gel drops indoor application and wet cleaning of treated or contaminated area, the Sewage Treatment Plant (STP) is considered as the main receiving compartment. Then, the final environmental compartment will be surface water, including sediment (through STP effluent), the soil and the groundwater (from sludge application).

Therefore, there is indirect emission into the environment following the use of the product GEL ATTRACTIF ANTI-FOURMIS.

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Not relevant. |
| Justification | The product is intended to use indoor only as gel droplets on spots against ants and is a ready-to use gel containing 0.217% w/w cypermethrin and 58.282 % w/w D-fructose. The product contains a two active substances and does not contain any environmentally relevant substances of concern or co-formulants which are likely to alter the environmental fate and behaviour (degradation or mobility) of the active substance, cypermethrin. The environmental fate and behaviour of the products may therefore be extrapolated from information available on the active substance. |

***Leaching behaviour (ADS)***

Not relevant.

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

Not relevant.

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

Not relevant.

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

Not relevant.

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

Not relevant.

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

Not relevant.

**PNEC values summary table**

Based on the cypermethrin assessment report, the relevant PNECs for the environmental risk characterisation are reported below.

|  |  |  |
| --- | --- | --- |
| **PNEC** | | **Justification** |
| PNECSTP | 1.63 mg/L | An EC50 of 163 mg/L from a microbial activity inhibition test is reported in the CAR (2019). An assessment factor (AF) of 100 was applied to the EC50 to derive the PNEC. |
| PNECwater | 4.00E-06 mg/L | The PNECwater presented in the CAR (2019) was derived from the NOEC of 0.04 µg/L for daphnia and an AF of 10. |
| PNECsediment,EPM | 0.005 mg/kg wwt | Equilibrium partitioning method. This value already considers the additional factor of 10 needed in case of high Koc value |
| PNECsoil | 0.07 mg/kg wwt | The PNECsoil presented in the CAR (2019) was derived from the chronic earthworm NOEC reproduction (4 mg/kg dwt) with an AF of 50. |
| PNECoral bird | 33.3 mg/kg food | - |
| PNECoral mammal | 3.3 mg/kg food | - |

#### **Exposure assessment**

The biocidal product GEL ATTRACTIF ANTI-FOURMIS is a product type 18 as a ready-to use gel. It is intended to be applied indoor against ants by non-professionals in private houses as gel droplets where ants pass and near the entries of the nest.

After the biocidal product indoor application, a wet cleaning can be considered leading to the exposure of the STP as a primary receiving environmental compartment. Then, the final environmental compartment will be surface water, including sediment (through STP effluent), the soil and the groundwater (from sludge application).

One emission scenario was assessed in order to cover the intended use. This represents a medium scale application on a surface of 20 m2.

General information

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: Indoor gel application (including cleaning) on surface |
| ESD(s) used | ESD PT18 for household and professional uses (2008).  Technical Agreement on Biocides (TAB), December 2019 |
| Approach | Scenario 1: Average consumption |
| Distribution in the environment | Calculated based on ECHA Guidance on the BPR Vol IV Part B; 2017 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks | - |

***Emission estimation***

**Scenario 1: Indoor gel application (including cleaning)**

Local emission due to the gel droplets application was calculated using ESD for PT18 Insecticides, Acaricides and products to control other arthropods for household and professional uses (2008).

A medium scale area treated with the product of 20 m2 (corresponding to a wet cleaned area of 5.9 m²) was used for a standard house (default value according the entry 142 of the Technical Agreements for Biocides – ENV – 09 November 2021). The calculations are based on the application of the product on surfaces. These values are considered as a worst case largely covering the intended use. The biocidal product contains 0.217% w/w cypermethrin. The application rate claimed is 0.5 g/m² (i.e. 5 drops of 0.1 g).

The product is ready to use; no emission during the preparation phase is foreseen.

All parameters used for emission calculation are summarised in the following tables:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Symbol** | **Value** | **Unit** | **Remarks** |
| **Scenario 1: Indoor gel application (including cleaning)** | | | | |
| Number of private houses connected to the same STP | Nhouse | 4000 | [-] | D |
| Fraction of active substance in the commercial product | FAI | 0.00217 | [-] | S |
| Wet cleaned area | AREAwet\_cleaned | 5.9 | m² | TAB ENV 142 |
| Number of application per day per building (standard house) | Napp | 1 | d-1 | D |
| Number of gel point per square meter | Npoint | 5 | point.m-² | S |
| Quantity of commercial product applied per point of gel | Qprod,point | 0.1 | g.point-1 | S |
| Fraction emitted to applicator during application step | Fapplication,applicator | 0 | [-] | D (gel form) |
| Fraction emitted to treated surfaces during application step | Fapplication,treated | 1 | [-] | D |
| Simultaneity factor for indoor uses of insecticide in standard houses | Fsimultaneity | 0.008151 | [-] | S - Frequency of application : 3-11 times a year |
| Cleaning efficiency | FCE | 0.25 | [-] | Corresponding to a gel use on surface |

Calculations for Scenario 1:

Elocalwater = Qprod,point \* Npoint \* FAI \* AREAwet\_cleaned \* Fapplication,treated \* Nappl \* 0.001 \* FCE \*Nhouse \* Fsimultaneity

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalwater) [kg/d]** | **Remarks** |
| Emission to wastewater | 5.22E-05 | - |

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

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario 1** | | | | | | | | |
| Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Yes | Yes | No | No | Yes | No | Yes | Yes | Not relevant |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 416.3 | g.mol-1 | - |
| Vapour pressure (at 25°C) | 6.00E-07 | Pa | - |
| Water solubility (at 20°C) | 4.00E-03 | mg/l | - |
| Log Octanol/water partition coefficient | 5.45 | Log 10 | - |
| Organic carbon/water partition coefficient (Koc) | 575000 | l/kg | - |
| Henry’s Law Constant (at 20°C) | 2.40E-02 | Pa/m3/mol | - |
| Biodegradability | Not readily biodegradable | *-* | - |
| DT50 for degradation in soil | 17.20 | d (at 12ºC) | - |
| k biosoil | 4.03E-02 | d-1 |  |
| k volat (arable land) | 3.10E-07 | d-1 |  |
| k leach (arable land) | 1.39E-07 | d-1 |  |
| k total (arable land) | 4.03E-02 | d-1 |  |
| BCF fish | 417 | L.kgwwt-1 | - |
| BCF earthworm | 3383 | L.kgwwt-1 | - |
| BMF | 1 | - | - |

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP** | | |
| Compartment | Percentage [%] | Remarks |
| Scenario 1 |
| Air | 6.74E-04 | Simple Treat v4.0, considering a concentration suspended solids effluents (Css) of 30 mg/L or 0.03 kg/m3 (TAB 07/2021, ENV9) |
| Water | 8.36E+00 |
| Sludge | 9.17E+01 |
| Degraded in STP | 0 |

***Calculated PEC values***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values – Scenario 1** | | | | |
| **PECSTP** | **PECwater** | **PECsed** | **PECsoil twa 30d** | **PECGW** |
| [mg/l] | [mg/l] | [mg/kg wwt] | [mg/kg wwt] | [μg/l] |
| 2.18E-06 | 1.17E-07 | 1.46E-03 | 5.17E-05 | 1.21E-06 |

*n.r.: not relevant*

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning, *i.e.* the direct consumption of insecticide by birds or mammals and also honeybees is relevant only for outdoor uses. The biocidal product GEL ATTRACTIF ANTI-FOURMIS is used only indoor. Therefore, primary poisoning is not considered as relevant for this product.

Secondary poisoning

As cypermethrin has a log Kow > 3 (log Kow = 5.45 at 25°C) and a BCF > 100 (BCF in fish = 417 L/kg and BCF in earthworm = 3380 L/kg), secondary poisoning may occur *via* the aquatic food chain and *via* the terrestrial food chain.

The concentrations were calculated according to the biocidal guidance Vol IV Part B+C.

|  |  |  |
| --- | --- | --- |
| **Summary table on estimated theoretical exposition** | | |
|  | **Concentration in fish** | **Concentration in earthworm** |
| [mg/kg] | [mg/kg] |
| Scenario 1 | 2.44E-05 | 2.46E-06 |

#### **Risk characterisation**

***Atmosphere***

Conclusion: Emissions to air during gel application are considered to be negligible. Moreover, due to the non-volatility of cypermethrin (vapour pressure equal to 2.3\*10-7 Pa at 20°C), the risk of contamination of the atmosphere can be considered as negligible and this foreseeable route of entry in the environment is not of concern.

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

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 1.34E-06 |

Conclusion: The PEC/PNEC ratios are below the trigger value of 1. Then, risk for STP microorganisms is acceptable for the intended use of this biocidal product.

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Scenario 1 | 2.93E-02 | 2.93E-01 |

Conclusion: The PEC/PNEC ratios are below the trigger value of 1. Then, risks for the aquatic compartment are acceptable for the intended use of this biocidal product.

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| Scenario 1 | 7.38E-04 |

Conclusion: The PEC/PNEC ratio is below the trigger value of 1. Then, risk for terrestrial compartment is acceptable for the intended use of this biocidal product.

***Groundwater***

|  |  |
| --- | --- |
|  | **PEClocalgroundwater (µg/l)** |
| Scenario 1 | 1.21E-06 |

Conclusion: The calculated value for groundwater contamination doesn’t exceed the limit value of 0.1 μg.L-1 for biocides (Directives 2006/118/EC and 98/83/EC). Therefore, risks are acceptable for groundwater.

***Primary and secondary poisoning***

Primary poisoning

As the proposed use of the biocidal product is indoor and therefore will not result in direct exposure to birds and mammals, the risk for the primary poisoning is considered acceptable.

Secondary poisoning

As cypermethrin has a log Kow > 3 (log Kow = 5.45 at 25°C) and a BCF > 100 (BCF in fish = 417 L/kg and BCF in earthworm = 3380 L/kg), secondary poisoning may occur *via* the aquatic food chain and *via* the terrestrial food chain.

|  |  |  |
| --- | --- | --- |
| **Summary table on secondary poisoning** | | |
| **Scenario** | **PEC/PNECbirds** | **PEC/PNECmammals** |
| Aquatic food chain | 7.33E-07 | 7.40E-06 |
| Terrestrial food chain | 7.39E-08 | 7.46E-07 |

Conclusion: All the calculated risk characterisation ratios are below the trigger value of 1. Therefore, risks for the secondary poisoning are acceptable.

***Mixture toxicity***

The biocidal product GEL ATTRACTIF ANTI-FOURMIS contains two substance actives. The D-fructose is included in Annex I, therefore, a mixture assessment is not relevant.

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

There is only one use for product GEL ATTRACTIF ANTI-FOURMIS. The aggregated exposure is not relevant.



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

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The environmental risk assessment has been conducted for the active substance cypermethrin only.  It has been demonstrated that the intended use of the biocidal product GEL ATTRACTIF ANTI-FOURMIS applied indoor until 11 times per year by non-professionals in private houses as gel droplets where ants pass and near the entries of the nest does not pose a risk to the environmental compartments. No specific risk mitigation measure is required. |

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

See summary of the product assessment

### Assessment of a combination of biocidal products

Not relevant

### Comparative assessment

Not relevant

# Annexes[[7]](#footnote-8)

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Serrano. B | 2020 | PALATABILITY TRIAL OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS Gel Attractif Anti-Fourmis  T.E.C. Laboratory, 2541c/0120. Unpublished. | Yes | SPRING |
| Serrano. B | 2021 | PALATABILITY TRIAL OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS  T.E.C. Laboratory, 2672a/0521. Unpublished. | Yes | SPRING |
| Serrano. B | 2021 | FIELD TRIAL OF AN INSECTICIDAL GEL BAIT AGAINST ANTS  T.E.C. Laboratory, 2672/0521. Unpublished. | Yes | SPRING |
| Bartocci M. | 2020 | Physical-chemical characterization and accelerated storage stability  (12 weeks/35 ± 2°C) of test item GEL ATTRACTIF ANTI-FOURMIS (CIPAC MT 46.3  (2000))  Report no. BT305/20  Unpublished. | Yes | SPRING |
| Bartocci M. | 2020 | Relative density, surface tension and low temperature  storage stability (1 week/0 ± 2°C) of test item GEL  ATTRACTIF ANTI-FOURMIS  (OECD 109 (2012), OECD 115 (1995) and CIPAC MT 39.3  (2000))  Report no. BT304/20  Unpublished. | Yes | SPRING |
| Bartocci M. | 2020 | Physical-chemical  characterization of test item GEL ATTRACTIF ANTI-FOURMIS after 2 years shelf  life (2 years/20 ± 2°C) (Technical Monograph No.17,  2nd edition CropLife  International)  Report no. BT306/20  Unpublished. | Yes | SPRING |
| Tremain S. P. | 2021 | Gel attractif anti-fourmis: Determination of Flash Point  according to EC Method A9  Report no. 8473650  Unpublished. | Yes | SPRING |
| Bartocci M. | 2020 | Analytical method validation  for the determination of cypermethrin cis/trans 40/60  content in the test item GEL  ATTRACTIF ANTI-FOURMIS(SANCO/3030/99  rev.5 from 22/03/2019)  Report no. BT302/20  Unpublished. | Yes | SPRING |
| Bartocci M. | 2020 | Analytical method validation  for the determination of  fructose content in the test item GEL ATTRACTIF ANTI-FOURMIS (SANCO/3030/99  rev.5 from 22/03/2019)  Report no. BT303/20  Unpublished. | Yes | SPRING |
| Porte P. | 2022 | UN Heat Accumulation Storage Test (SADT - H.4 Test) on a Sample of GEL ATTRACTIF ANTI-FOURMIS DEKRA UK Ltd - Report 3016012158R1/2022  GLP | Yes | SPRING |

## Output tables from exposure assessment tools

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## Confidential annex

See separate document.

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. Please delete as appropriate. [↑](#footnote-ref-3)
3. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-4)
4. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-5)
5. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-6)
6. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-7)
7. 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-8)