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)



ADDICT GEL FOURMIS

Product type(s) 18

Dinotefuran

Case Number in R4BP: BC-WG049688-13

Evaluating Competent Authority: FR

Date: December 2021

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# CONCLUSION

France, as e-CA, received an application from LODI for national authorisation for the biocidal product ADDICT GEL FOURMIS.

The biocidal product ADDICT GEL FOURMIS, containing 0.0202% of dinotefuran, is a product type (PT) 18 uses against ants indoor, outdoor around houses, buildings and on terraces. The biocide product ADDICT GEL FOURMIS is a ready to use gel bait used by trained professional, professional and non-professional users.

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

The product ADDICT GEL FOURMIS is a ready to use gel bait. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The stability data indicate a shelf life of 2 years at ambient temperature when stored in PP high density and LDPE syringes, PEHD bottle and PP and PS bait stations. The long term storage stability study (24 months) is on-going and should be provided in post authorisation.

No test has been provided for the stability at 0°C. No data have been provided for the stability at light and some packaging are transparent.

Therefore, the product must be stored at temperature above 0°C and away from light.

An analytical method has been provided and validated for the determination of the active substance dinotefuran in the product.

***Conclusion Efficacy***

The product ADDICT GEL FOURMIS, has shown a sufficient efficacy for the following uses claimed:

* Use as bait application (drops or box) against the Black garden ant (*Lasius niger*), Argentine ant (*Linepithema humile*) and Pharaoh ant (*Monomorium pharaonis*) at the application rate of 0.2 g/m² indoor.
* Use as bait application (drops or box) against the Black garden ant (*Lasius niger*) and Argentine ant (*Linepithema humile*) at the application rate of 0.2 g/m² outdoor.

Submitted data are not sufficient to demonstrate the palatability of the product at the end of the claimed period of storage of 3 years, but only for 2 years.

***Conclusion on risk assessment for human health***

The risk for professional and non-professional users using the product ADDICT GEL FOURMIS is considered acceptable. The risk is considered acceptable for the general public.

***Conclusion on risk for consumers via residues in food***

Based on the intended uses, the acute and chronic exposure to residues are unlikely to cause a dietary risk to consumers. The product should not be applied directly on or near food, feed or drinks, nor on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock, nor on vegetable garden.

***Conclusion of risk assessment for Environment:***

Considering the intended use of ADDICT GEL FOURMIS, risks are acceptable whatever the way of environmental release considering the specific conditions of use (indoor and outdoor). Nevertheless, the product contains the active substance dinotefuran known to be toxic to bees and therefore a risk for bees cannot be excluded.

For these reasons, FR CA considers that when used outdoor, the product must be preferentially applied in pre-filled bait boxes to protect bees. When this is not feasible, crack and crevice applications are also foreseen in order to minimize access from non-target organisms. With respect to the condition of outdoor uses, honeybee exposure can be considered as negligible. The following RMM has been added by the FR CA:

* “For outdoor use, apply this biocidal product in bait boxes or in cracks and crevices only or directly to ant nests. Protect from bees by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait).”

***Overall conclusion***

|  |  |  |  |
| --- | --- | --- | --- |
| Target organism | Dose | Use conditions | Conclusion |
| * Black garden ant (*Lasius niger*);
* Pharaoh ant (*Monomorium pharaonis*)
* Argentine ant (*Linepithema humile*)

All developmental stagesNest killing | 0.2 g/m² | IndoorTrained professionalProfessionalGeneral public (non-professional) | Acceptable  |
| * Black garden ant (*Lasius niger*);
* Argentine ant (*Linepithema humile*)

All developmental stagesNest killing | 0.2 g/m² | Outdoor around houses, buildings and on terracesTrained professionalProfessionalGeneral public (non-professional) | Acceptable  |

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| ADDICT GEL FOURMIS |  |
| DIGRAIN GEL FOURMIS |  |
| PHOBI GEL FOURMIS |  |
| DN GEL FOURMIS |  |
| GEL FOURMIS 200 |  |
| GEL FOURMIS DINOTEFURAN |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | LODI S.A.S. |
| **Address** | Parc d'Activités des Quatre Routes35390 Grand FougerayFRANCE |
| **Authorisation number** |  |
| **Date of the authorisation** |  |
| **Expiry date of the authorisation** |  |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | LODI S.A.S. |
| **Address of manufacturer** | Parc d'Activités des Quatre Routes35390 Grand FougerayFRANCE |
| **Location of manufacturing sites** | LODI S.A.S.35390 Grand Fougeray France |

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

|  |  |
| --- | --- |
| **Active substance** | Dinotefuran |
| **Name of manufacturer** | Mitsui Chemicals Agro, Inc. |
| **Address of manufacturer** | Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chuo-ku, 103-0027 Tokyo Japan |
| **Location of manufacturing sites** | Mitsui Chemicals Inc./Omuta Works, 30 Asamuta-Machi, Ohmuta Shi, 836-8610 Fukuoka Japan |

### Product composition and formulation

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

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

Yes [ ]

No [x]

#### Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **ISO name** | Dinotefuran  |
| **IUPAC or EC name** | (RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine  |
| **EC number** | 605-399-0 |
| **CAS number** | 165252-70-0  |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | 99.1 % w/w (991 g/kg) |
| **Structural formula** | C7H14N4O3 |

#### Candidate(s) for substitution

According to the most recent scientific information available, the active substance in this biocidal product, dinotefuran, is considered as a candidate for substitution using the criteria in Article 10(1) of EU Regulation 528/2012, although it is not considered as meeting the exclusion criteria according to Article 5(1). This conclusion is based on section 1.4.4. of the Evaluation of Active Substances Assessment Report for dinotefuran under Product Type 18 and the European Union list (dated September 2020): List\_compilation\_exclusion\_substitution\_criteria\_version\_Sept\_2020.xls, which states that dinotefuran is proposed to be classified as persistent/very persistent (P/vP) and toxic (T) but not bio-accumulative. Therefore dinotefuran can be considered to meet the criteria in Article 10(1)(d), notably it meets two of the criteria for being PBT in accordance with Annex XIII to regulation (EC) No 1907/2006.

Please see section 2.2.11 for the overall conclusion of the comparative assessment.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%w/w)** |
| --- | --- | --- | --- | --- | --- |
| Dinotefuran technical | (RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine | Active substance | 165252-70-0 | 605-399-0 | 0.0202 |
| Isopentyl acetate |  | Co-formulant | 123-92-2 | 204-662-3 | 0.005 |
| Cyclohexane |  | Co-formulant | 110-82-7 | 203-806-2 | 0.01 |

Co-formulants[[1]](#footnote-2) are detailed in the confidentiel annex.

#### Information on technical equivalence

The source of the active substance is identical to the one indicated in the CAR.

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

Two co-formulants contained in the product ADDICT GEL FOURMIS are identified as substances of concern for human health.

Please see the confidential annex for further details.

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

None of the co-formulants contained in the biocidal product ADDICT GEL FOURMIS is regulatory identified as endocrine disruptors.

However, one co-formulant shows indications of endocrine activity (refer to confidential annex). The evaluation of endocrine activity of this co-formulant should be undertaken under REACH Regulation.

#### Type of formulation

|  |
| --- |
| Gel bait (ready to use) |

### Hazard and precautionary statements

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

| **Classification** |
| --- |
| Hazard category | None |
| Hazard statement | None |
|  |
| **Labelling** |
| Signal words | None |
| Hazard statements | None |
| Precautionary statements | P501: Dispose of contents/container according to local/regional/national/ international regulation |
|  |
| Note | EUH208: Contains 2-methyl-2H-isothiazole-3–one. May produce an allergic reaction. |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Bait application - Indoor

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **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 developmental stagesNest killing |
| **Field of use** | IndoorIndustrial, commercial or public premises and private area. |
| **Application method(s)** | Bait station or gel drops application |
| **Application rate(s) and frequency** | Dose: 0.2 g/m²Treatment with the syringe or bottle: Apply gel drops as spot or directly in cracks and crevices where insects hide, on the ants trail or close to the nest. Apply 2 drops of 0.1 g (0.5 cm diameter) per square meter. Treatment with the pre-baited station:Apply the pre-baited station adapted to the area of treatment respecting the dose of 0.2 g/m². For example one pre-baited station of 2 g to treat 10 m² or one pre-baited station of 5g to treat 25 m². Place the bait station along the ant trail or close to the nest if possible.  |
| **Category(ies) of users** | Trained professionalProfessionalNon-professional |
| **Pack sizes and packaging material** | Syringe in LDPE or PP high density : 1g to 50 gHDPE bottle: 1g to 500 gPP or PS bait station : 1g to 5 g |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### 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

|  |
| --- |
|  |

#### Use description

Table 2. Use # 2 – Bait application – Outdoor around houses, buildings and on terraces

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | * Black garden ant (*Lasius niger*);
* Argentine ant (*Linepithema humile*)

All developmental stagesNest killing |
| **Field of use** | OutdoorOutdoor around houses and buildingsOutdoor on terraces |
| **Application method(s)** | Bait station or gel drops application |
| **Application rate(s) and frequency** | Dose: 0.2 g/m²Treatment with the syringe or bottle: Apply gel drops as spot or directly in cracks and crevices where insects hide, on the ants trail or near to the nest.Apply 2 drops of 0.1 g (0.5 cm diameter) per square or linear metre. Treatment with the pre-baited station:Apply the prebaited station adapted to the area of treatment respecting the dose of 0.2 g/m². For example one prebaited station of 2 g to treat 10 m² or one prebaited station of 5 g to treat 25 m². Place the bait station along the ant trail or close to the nest if possible.  |
| **Category(ies) of users** | Trained professionalProfessionalNon-professional |
| **Pack sizes and packaging material** | Syringe in LDPE or PP high density : 1g to 50 gHDPE bottle: 1g to 500 gPP or PS bait station : 1g to 5 g |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply on vegetable garden.
 |

##### 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

|  |
| --- |
| * Always read the label or leaflet before use, and respect all instructions, which are indicated.
* Avoid continuous use of the product.
* Apply the product with accuracy on the ants trail or close to the nest.
* Respect the application doses of the product.
* Diminution of the population can be observed 7 days after application but complete eradication can take up to one month.
* Drops of gel and/or bait stations must be checked 7 days after first application and then once a week.
* Renew the consumed or dirty gel bait until complete eradication of the colony or one month after application if the infestation persists.
* Do not mix with other product and do not apply on surfaces already treated with another biocidal product.
* Always protect the product from rainfall, flooding and washing water.
* If the infestation persists contact a professional.
* Inform the registration holder if the treatment is ineffective.
* Do not apply the product on absorbing surfaces.
* Do not expose bait drops to sunlight or heat (i.e. radiator).
* In case of re-infestation, renew the application.
* Remove the bait at the end of the treatment period for following disposal.
 |

#### Risk mitigation measures

|  |
| --- |
| * Hazardous to bees.
* For outdoor use, apply this biocidal product in bait boxes or in cracks and crevices only or directly to ant nests. Protect from bees by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait).
* Do not apply directly on or near food, feed or drinks, nor on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
* Prevent access to bait by children and animals.
* Follow strict individual hygiene conditions: do not eat, drink or smoke during handling of the product and wash hands after use.
* Never apply gel bait for preventive treatment, only use it in case of proven infestation
 |

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

|  |
| --- |
| * Skin contact: Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
* Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
* Mouth contact: Wash out mouth with water. Contact poison treatment specialist.
* Keep the container or label available.
 |

#### 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 in a safe place out of reach of children and animals.
* Shelf-life: 2 years.
* Store the product at temperature above 0°C.
* Store the product away from light.
 |

### Other information

|  |
| --- |
| * The presence of 1,2-benzisothiazol-3(2H)-one, skin sensitizer that may produce an allergic reaction, must be mentioned on the label.
 |

### 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)** |
| Syringe | From 1g to 50 g | LDPE or PP high density | Cap or stopper | Professional and Non-professional |  |
| Baitbox | From 1g to 5 g | PP or PS | Sealed round box | Professional and Non-professional |  |
| Bottle | From 1g to 500g  | PEHD | cap | Professional and Non-professional |  |

### Documentation

#### Data submitted in relation to product application

Studies have been provided on the product ADDICT GEL FOURMIS for the physico-chemical properties and analytical methods.

*-* **Efficacy data**

The following efficacy studies were submitted:

***Lasius niger:***

* A laboratory study (plastic box) according to CEB N°196 method[[2]](#footnote-3) conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in syringe on one ant species black garden ant (*Lasius niger*).
* A laboratory study (plastic box) according to CEB N°196 method3 conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in bait station on one ant species black garden ant (*Lasius niger*).
* A laboratory study (plastic box) according to CEB N°196 method3 conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), aged formulation in syringe on one ant species black garden ant (*Lasius niger*).
* A field test (in and outdoor) conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in syringe on one ant species black garden ant (*Lasius niger*).
* A field test (in and outdoor) conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in bait box on one ant species black garden ant (*Lasius niger*).

***Linepithema humile:***

* A laboratory study (plastic box) according to CEB N°196 method3 conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in syringe on one ant species Argentine ant (*Linepithema humile*).
* A laboratory study (plastic box) according to CEB N°196 method3 conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in bait station on one ant species Argentine ant (*Linepithema humile*).
* A laboratory study (plastic box) according to CEB N°196 method3 conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), aged formulation in syringe on one ant species Argentine ant (*Linepithema humile*).
* A field test (in and outdoor) conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in syringe on one ant species Argentine ant (*Linepithema humile*).
* A field test (in and outdoor) conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in bait box on one ant species Argentine ant (*Linepithema humile*).

***Monomorium pharaonis:***

* A laboratory study (plastic box) according to CEB N°196 method3 conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in syringe on one ant species pharaoh ant (*Monomorium pharaonis*).
* A laboratory study (plastic box) according to CEB N°196 method3 conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in bait station on one ant species pharaoh ant (*Monomorium pharaonis*).
* A laboratory study (plastic box) according to CEB N°196 method3 conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), aged formulation in syringe on one ant species pharaoh ant (*Monomorium pharaonis*).
* A field test (indoor) conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in syringe on one ant species pharaoh ant (*Monomorium pharaonis*).
* A field test (indoor) conducted with the product ADDICT GEL FOURMIS (0.02% w/w Dinotefuran), fresh formulation in bait box on one ant species pharaoh ant (*Monomorium pharaonis*).

*-* **Toxicological data**

The following toxicological studies were submitted:

* ASSESSMENT OF ACUTE DERMAL IRRITATION/CORROSION
* ASSESSMENT OF ACUTE EYE IRRITATION/CORROSION
* ASSESSMENT OF THE SKIN SENSITISATION POTENTIAL IN THE MOUSE USING THE LOCAL LYMPH NODE ASSAY (LLNA:BrdU)
* EVALUATION OF ACUTE ORAL TOXICITY IN RATS – ACUTE TOXIC CLASS METHOD
* ACUTE INHALATION TOXICITY STUDY OF ADDICT GEL FOURMIS IN RATS
* EVALUATION OF ACUTE DERMAL TOXICITY IN RATS

#### Access to documentation

A letter of access from Mitsui Chemical Agro, Inc. is submitted to grant access to dossier related to approval of active subtance dinotefuran.

## Assessment of the biocidal product

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

Table 4. Intended use # 1 – Bait application - Indoor

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | - |
| Target organism (including development stage) | *Lasius niger* (Garden ant)Adults*Monomorium pharaonis (*Pharaoh ant)Adults*Linepithema humile* (Argentine ant)Adults |
| Field of use | IndoorIndustrial, commercial or public premises and private area. |
| Application method(s) | Bait applicationApply pre-baited stations or gel drops as spot or directly in cracks and crevices where insects hide, on the ants trail or close to the nest. |
| Application rate(s) and frequency | Dose: 0.2 g/m²Treatment with the syringe or bottle: Apply 2 drops of 0.1 g (0.5 cm diameter) per square or linear metre. Gel bait must be applied on the ant trails, close to the nest or in cracks and crevices where insects hide. Treatment with the pre-baited station:Apply the prebaited station adapted to the area of treatment respecting the dose of 0.2 g/m². For example one prebaited station of 2 g to treat 10 m² or one prebaited station of 5g to treat 25 m². Place the bait station along the ant trail or close to the nest if possible. Frequency: Drops of gel and/or bait stations must be checked 7 days after first application and then once a week until consumption stops. Renew the consumed or dirty gel bait until complete eradication of the colony.  |
| Category(ies) of user(s) | ProfessionalGeneral public (non-professional) |
| Pack sizes and packaging material | Syringe in LDPE or PP high density : 1g to 50 gHDPE bottle: 1g to 500 gPP or PS bait station : 1g to 5 g |

Table 5. Intended use # 2 – Bait application – Outdoor around houses and buildings

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | - |
| Target organism (including development stage) | *Lasius niger* (Garden ant)Adults*Linepithema humile* (Argentine ant)Adults |
| Field of use | OutdoorOutdoor around houses and buildings or on terraces |
| Application method(s) | Bait applicationApply pre-baited stations or gel drops as spot or directly in cracks and crevices where insects hide, on the ants trail or close to the nest. |
| Application rate(s) and frequency | Dose: 0.2 g/m²Treatment with the syringe or bottle: Apply 2 drops of 0.1 g (0.5 cm diameter) per square or linear metre. Gel bait must be applied along the ant trails, close to the nest or in cracks and crevices where insects hide.Treatment with the pre-baited station:Apply the prebaited station adapted to the area of treatment respecting the dose of 0.2 g/m². For example one prebaited station of 2 g to treat 10 m² or one prebaited station of 5 g to treat 25 m². Place the bait station along the ant trail or close to the nest if possible. Frequency: Drops of gel and/or bait stations must be checked 7 days after first application and then once a week until consumption stops. Renew the consumed or dirty gel bait until complete eradication of the colony.  |
| Category(ies) of user(s) | ProfessionalGeneral public (non-professional) |
| Pack sizes and packaging material | Syringe in LDPE or PP high density : 1g to 50 gHDPE bottle: 1g to 500 gPP or PS bait station : 1g to 5 g |

### Physical, chemical and technical properties

The product ADDICT GEL FOURMIS is a ready to use gel that contains 0.0202% of technical dinotefuran.

The product does not contain H304 co-formulants.

The product contains a bittering agent at the content of 0.001%.

The product is for professional and non-professional users.

| **Property** | **Guideline and Method** | **Purity of the test substance** **% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | EPA OPPTS 830.6303GLP | ADDICT GEL FOURMISBatch CL20180301Dinotefuran 0.0208% | Thick gel that doesn’t flow | Acceptable | Richerioux S.,2018LODI.11/2018 |
| Colour at 20 °C and 101.3 kPa | EPA OPPTS 830.6302GLP | ADDICT GEL FOURMISBatch CL20180301Dinotefuran 0.0208% | 7.5Y 8.5/2Light yellow | Acceptable | Richerioux S.,2018LODI.11/2018 |
| Odour at 20 °C and 101.3 kPa | EPA OPPTS830.6304GLP | ADDICT GEL FOURMISBatch CL20180301Dinotefuran 0.0208% | Sweet and Fruity | Acceptable | Richerioux S.,2018LODI.11/2018 |
| Acidity / alkalinity | CIPAC MT 75.3GLP | ADDICT GEL FOURMISBatch CL20180118G | Dilution: 10.43g/L (env 1%)Temperature: 19.0°CpH=6.3 | Acceptable | Leclercq S., 2018LODI.02/2018 |
| Relative density / bulk density | Method EC A.3 / OECD 109StereopycnometerGLP | ADDICT GEL FOURMISBatch 20171218Dinotefuran 0.02% | D=1.147±0.001 at 20.6°C | Acceptable | Demangel B.,201818-912011-001 |
| Storage stability test – **accelerated storage** | GIFAP Monograph n°17CIPAC MT 4614 days at 54°C in glass bottle for appearance / in PP cartridge for the active substance content and pHOPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304CIPAC MT 75.3HPLC-UV (validation data reported in 2.2.4)GLP | ADDICT GEL FOURMISBatch CL20180301 Dinotefuran 0.0208% | Appearance:

|  |  |  |  |
| --- | --- | --- | --- |
|  | T0 | T14d | T21d |
| Sample aspect | Thick gel that doesn't flow |
| Sample color | 7.5Y 8.5/2Light yellow | 7.5Y 8.5/4Light yellow | 7.5Y 8.5/4Light yellow |
| Sample odor | Sweet and fruity |
| Packaging aspect | Glass bottle closed with a white cap containing a LDPE joint |

 | AcceptableThe product is stable 14 days at 54°C. | Richerioux S.,2018LODI.11/2018 |
| ADDICT GEL FOURMISBatch CL20180118G | pH:

|  |  |  |  |
| --- | --- | --- | --- |
|  | T0 | T14d | T21d |
| pH | 6.3(at 10.43g/L and 19°C) | 6.3(at 9.95 g/L and 18.8°C) | 6.1(at 10.07 g/L and 20.5°C) |
| Packaging | Transparent PP cartridge with orange cap clean and dry outside |

 | Leclercq S., 2018LODI.02/2018 |
| ADDICT GEL FOURMISBatch CL20180301 Dinotefuran 0.0208% | Active substance content:

|  |  |  |  |
| --- | --- | --- | --- |
|  | T0 | T14d | T21d |
| Dinotefuran content | 0.0208% | 0.0189% | 0.0191% |
| Packaging | Transparent PP cartridge with orange cap clean and dry outside |

-9.13% of deviation for active substance content after 14d-8.17% of deviation for active substance content after 21d | Leclercq S., 2018LODI.07/2018 |
| Storage stability test – **long term storage at ambient temperature** | GIFAP Monograph n°173 years at 20°C in glass bottle for appearance / in 30 g PP cartridge for the active substance content and pH(study on-going, beginning March 2018)HPLC-UV (validation data reported in 2.2.4)3 years at 20°CHPLC-UV (validation data reported in 2.2.4)OPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304CIPAC MT 75.3GLP | ADDICT GEL FOURMISBatch CL20180301 Dinotefuran 0.0208% |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | T0 | T6m | T12m | T18m |
| Test item aspect | Light yellow gel |
| Dinotefuran content | 0.0208% | 0.0209% | 0.0212% | 0.02026% |
| Deviation | - | +0.48% | +1.92% | -2.60% |
| Packaging | Transparent PP cartridge with orange cap clean and dry outside |

 | Based on the data provided the product is stable 6 months, 12 months and 18 months at 20°C.Results after 24 months are not available and should be provided in post authorisation.A shelf-life of two years could be granted in PP packaging. | Leclercq S.,2018LODI.08/2018 |
| For chemical stability after 2 and 3 years only study plans are available. | Richerioux S.,2018LODI.09/2018LODI.10/2018 |
| Appearance:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | T0 | T6m | T12m | T18m |
| Sample aspect | Thick gel that doesn't flow |
| Sample color | 7.5Y 8.5/2Light yellow7.5Y 8.5/2Light yellow |
| Sample odor | Sweet and fruity |

 | Richerioux S., 2018LODI.12/2018 |
| pH:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | T0 | T6m | T12m | T18m |
| pH  | 6.7(at 9.92g/L and 19.3°C) | 6.9(at 10.15g/L and 20.2°C) | 6.2(at 10.26g/L and 21.0°C) | 6.2(at 10.06g/L and 18.3°C) |
| Packaging | Transparent PP cartridge with orange cap clean and dry outside |

 | Leclercq S., 2018LODI.03/2018 |
| Storage stability test – **low temperature stability test for liquids** |  |  | No data have been provided | Data is missing but in the SPC the applicant specify that the product should be protect from freeze.The risk mitigation measure “Do not store at temperature below 0°C” is added to SPC since no test is provided. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | No data have been provided | Data is missing but in the SPC the applicant specify that the product should be store away from light. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  |  | See data on the accelerated storage study 14 days at 54°C. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | GIFAP Monograph n°17CIPAC MT 4614 days at 54°CGLP | ADDICT GEL FOURMISBatch 20180702InPP syringeLDPE syringePEHD bottlePS ant bait stationPP ant bait station | Test item aspect:

|  |  |  |  |
| --- | --- | --- | --- |
|  | T0 | T14d | T21d |
| PP syringe | Light yellow gel |
| PP bait station |
| LDPE syringe | Sample not visible |
| HDPE bottle |
| PS bait station |

Packaging aspect:

|  |  |  |  |
| --- | --- | --- | --- |
|  | T0 | T14d | T21d |
| PP syringe | Clean, no leak | Clean, no leak neither at the piston nor at the cap |
| LDPE syringe |
| HDPE bottle | All is clean (bottle and cap), no leak |
| PS bait station | No spot, no leak |
| PP bait station |

Weight and deviation:

|  |  |  |  |
| --- | --- | --- | --- |
| g | T0 | T14d | T21d |
| PP syringe | 44.9547 | 44.7978(-0.35%) | 44.739(-0.48%) |
| LDPE syringe | 25.2913 | 24.7225(-2.26%) | 24.7217(-2.26%) |
| HDPE bottle | 60.2724 | 60.1654(-0.18%) | 60.1366(-0.23%) |
| PS bait station | 16.956 | 15.659(-7.65%) | 15.643 (-7.74%) |
| PP bait station | 15.428 | 14.799(-4.07 %) | 14.793(-4.11%) |

Weight deviation below 10% | AcceptableThe product is compatible with PP and LDPE syringes, PEHD bottle and PP and PS bait stations.Results after 18 and 24 months are not available and should be provided in post authorisation. | Richerioux S.,2018LODI.14/2018 |
| GIFAP Monograph n°173 years at 20 °C (on-going, beginning July 2018)GLP | ADDICT GEL FOURMISBatch 20180702InPP syringeLDPE syringePEHD bottlePS ant bait stationPP ant bait station | Test item aspect:

|  |  |  |
| --- | --- | --- |
|  | T0 | T6m |
| PP syringe | Light yellow gel |
| PP bait station |
| LDPE syringe | Sample not visible |
| HDPE bottle |
| PS bait station |

|  |  |  |
| --- | --- | --- |
|  | T0 | T12m |
| PP syringe | Light yellow gel |
| PP bait station |
| LDPE syringe | Sample not visible |
| HDPE bottle |
| PS bait station |

Packaging aspect:

|  |  |  |
| --- | --- | --- |
|  | T0 | T6m |
| PP syringe | Clean and dry, no leak |
| LDPE syringe |
| HDPE bottle | All is clean (bottle and cap), no leak |
| PS bait station | No leak, box is clean and dry |
| PP bait station |

|  |  |  |
| --- | --- | --- |
|  | T0 | T12m |
| PP syringe | Cartridge outside clean and dry, no leakSlight oozing at the piston (dry) |
| LDPE syringe |
| HDPE bottle | All is clean (bottle and cap), no leak |
| PS bait station | No leak, the box is clean and dry |
| PP bait station |

Weight and deviation:

|  |  |  |
| --- | --- | --- |
| Packaging | Weight deviation between T0 and T6 months | Weight deviation between T0 and T12 months |
| PP syringe | -0.54 % | -1.05% |
| LDPE Syringe | -0.09 % | -0.15% |
| HDPE bottle | -0.06 % | -0.11% |
| PS Ant bait station | -6.48 % | -6.11% |
| PP Ant bait station | -0.82 % | -0.18% |

Weight deviation below 10% | Leclercq S., 2018LODI.15/2018 |
| Wettability |  |  | Product is not intended to be dispersed in water, therefore determination of wettability is not relevant. | Acceptable |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not relevant because the product is a ready-to-use gel bait.  | Acceptable |  |
| Wet sieve analysis and dry sieve test |  |  | Not relevant because the product is not a wettable powder, suspension concentrate, water dispersible granules, aqueous capsule suspension, dispersible concentrate, suspo-emulsion, water soluble granule or water soluble powder. | Acceptable |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not relevant because the product is a ready-to-use.  | Acceptable |  |
| Disintegration time |  |  | Not relevant because the product is not a tablet.  | Acceptable |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not relevant because the product is a gel bait.  | Acceptable |  |
| Persistent foaming |  |  | Not relevant because the product is not intended to be diluted in water.  | Acceptable |  |
| Flowability/Pourability/Dustability |  |  | Not relevant because the product is a gel bait.  | Acceptable |  |
| Burning rate — smoke generators |  |  | Not relevant because the product is not a smoke generator.  | Acceptable |  |
| Burning completeness — smoke generators |  |  | Not relevant because the product is not a smoke generator. | Acceptable |  |
| Composition of smoke — smoke generators |  |  | Not relevant because the product is not a smoke generator. | Acceptable |  |
| Spraying pattern — aerosols |  |  | Not relevant because the product is not an aerosol. | Acceptable |  |
| Physical compatibility |  |  | Not applicable because the product is not intended to be used with other chemical products.  | Acceptable |  |
| Chemical compatibility |  |  | Not applicable because the product is not intended to be used with other chemical products. | Acceptable |  |
| Degree of dissolution and dilution stability |  |  | Not relevant because the product is not intended to be diluted. | Acceptable |  |
| Surface tension |  |  | Not relevant because the product is not a liquid.  | Acceptable |  |
| Viscosity | OECD 114GLP | ADDICT GEL FOURMISBatch 20171218Dinotefuran 0.02% | Dynamic viscosity:At 20 °C and 40 °C, the viscosity is higher than 6000000mPa.s (upper limit of the apparatus) | Acceptable | Demangel B., 201818-912011-001 |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product ADDICT GEL FOURMIS is a ready to use light yellow gel bait with a sweet and fruity odor. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. ADDICT GEL FOURMIS product has a pH of 6.3 at 1% dilution and a density of 1.147. Its viscosity is very high, (> 6000000 mPa.s.).There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of 2 years at ambient temperature when stored in PP high density and LDPE syringes, HDPE bottle and PP and PS bait stations (commercial packaging materials). The long term storage stability study (24 months) is on-going and should be provided in post authorisation. The 36 months storage stability study is also on-going and the results could be submitted in a minor-change application to increase the shelf-life.No test has been provided for the stability at 0°C, the product must be stored at temperature above 0°C. No data have been provided for the stability at light and some packaging are transparent. The product must be store away from light.Risk mitigation measure to be added:Store the product at temperature above 0°C.Store the product away from light. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Koenen TestBam Fallhammer TestGLP | ADDICT GEL FOURMISBatch 20180720Dinotefuran 0.02% | Negative result for the Koenen test as no effect on heating under confinement has been observed as the limiting diameter was less than 1.0mm.The result of the Bam Fallhammer test was “negative”, thus the test item was not considered to be too dangerous to transport in the tested form. | AcceptableThe product is not explosive. | Demangel B., 201818-912011-002 |
| Flammable gases |  |  | Not relevant | Acceptable, the product is not a gas |  |
| Flammable aerosols |  |  | Not relevant | Acceptable, the product is not a solid |  |
| Oxidising gases |  |  | Not relevant | Acceptable, the product is not a gas |  |
| Gases under pressure |  |  | Not relevant | Acceptable, the product is not a gas |  |
| Flammable liquids | Method EC A.9Closed cup methodGLP | ADDICT GEL FOURMISBatch 20171218Dinotefuran 0.02% | No flash-point was observed up to 170°C. | AcceptableThe product is not flammable. | Demangel B., 201818-912011-001 |
| Flammable solids |  |  | Not relevant | Acceptable, the product is not a solid |  |
| Self-reactive substances and mixtures | DifferentialScanning Calorimetry method (DSC)  | ADDICT GEL FOURMISBatch LAB20190909Dinotefuran 0.02% | In the temperature range used (room temperature to 600°C), no exothermic reaction was observed. This thermodynamic information allows knowing that the test item shall not be classified as explosive and the test on explosive properties according to EC A14 method or series 1 to 3 following EC No. 1272/2008 (CLP) and GHS should not be performed. | AcceptableThe product is not a self-reactive mixture. | Halbwachs P., 201919-912011-001 |
| Pyrophoric liquids | Method EC A13GLPManual of tests and Criteria - Sixthrevised edition (2015) - Test N.3 (Part III, Section 33.3.1.5) | ADDICT GEL FOURMISBatch CL20180301ADDICT GEL FOURMISBatch LAB20190924 | Test item doesn’t ignite spontaneously.The product is not considered as pyrophoric.The test item was not considered to be pyrophoric in our experimental conditions.According to EC No. 1272/2008 (CLP), the test item was not classified. | Acceptable However, for the CLP criteria, the UN test N.3 should be performed instead.Acceptable | Halbwachs P., 201919-912011-001 |
| Auto-ignition temperatures of products (liquids and gases) | Method EC A.15GLP | ADDICT GEL FOURMISBatch 20171218Dinotefuran 0.02% | The auto-ignition temperature of the test item was 464 °C ± 3 °C (corrected temperature). | Acceptable | Demangel B., 201818-912011-001 |
| Relative self-ignition temperature for solids |  |  | Not relevant | Acceptable, the product is not a solid |  |
| Dust explosion hazard |  |  | Not relevant | Acceptable, the product is not a powder |  |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product ADDICT GEL FOURMIS is not explosive and has no oxidizing properties. The product is not flammable and its auto-ignition temperature is 464°C. The product is not a pyrophoric liquid. It is not corrosive to metals. |

### Methods for detection and identification

Identification and quantification of the active substance dinotefuran in the product ADDDICT GEL FOURMIS:

|  |
| --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%) / Fidelity** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Dinotefuran* | HPLC-UV | Three samples were used as fortification range.Each sample was measured twice. Fortification levels: 160ppm, 200ppm and 240ppm corresponding to 80, 100 and 120 %. | Five concentration levels over the range 2.49 mg/L to 7.50 mg/L were measured. Each concentration was measured twice. Correlation coefficient: 0.99999. | Placebo is analysed. No peak appears at retention time of dinotefuran. Stressed sample (with acetic acid) is analysed : No interference appears at the retention time of dinotefuran. | Mean Recovery = 98.56 %Range = 80/100/120 %, Intralaboratory fidelity (ten samples solutions):RSD = 0.37 %RSDlim = 4.83 %Intermediate fidelity (5 sample solutions another day):RSD= 0.34 %RSDlim= 4.83 % | LOQ: 1.25 mg/LLOD: 0.25 mg/L | Richerioux S., 2018LODI.01/2018 |

Analytical methods for dinotefuran residues in soil and water are available in Assessment Report dinotefuran Product-type 18 (insecticides), June 2014. The applicant have a Letter of Access for these data.

A method is not required for air as the vapour pressure of dinotefuran was estimated to be < 1.7 x 10-6 Pa at 30 °C and no exposure is expected.

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

As the product ADDICT GEL 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 dinotefuran residue in food/feed of plant and animal origin is unnecessary.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| An analytical method has been provided for the determination of the active substance dinotefuran in the product.Analytical methods were provided at EU level for the determination of dinotefuran residue in soil and water with respectively LOQ = 0.01mg/kg, 0.1µg/L.A method is not required for air as the vapour pressure of dinotefuran was estimated to be < 1.7 x 10-6 Pa at 30 °C and no exposure is expected.Dinotefuran is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.Since the product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of dinotefuran residue in food/feed of plant and animal origin is not required. |

### Efficacy against target organisms

#### Function and field of use

PT18 - Insecticides, acaricides and products to control other arthropods (Pest control).

The biocidal product is a ready-to-use gel bait, it contains the insecticide active substance (PT 18) dinotefuran (0.02% w/w). The product is available in syringe, bottle (with applicator tip) or pre-baited stations. The syringe and bottle allow application of gel drops on surfaces or directly in cracks and crevices.

Product is intended to be used indoor and outdoor on impermeable surfaces such as terraces or around houses buildings in urban areas by non-professional and professional users.

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

According to the uses claimed by the applicant, ADDICT GEL FOURMIS is intented to be used to control:

• Black garden ant *Lasius niger* (all developmental stages);

• Argentine ant *Linepithema humile* (all developmental stages);

• Pharaoh ant *Monomorium pharaonis* (all developmental stages).

Objects to be protected: Indoor and outdoor of buildings.

Application rates recommended by the applicant are the following:

* For the bait gel in syringes or bottle: 0.2 g/m². 2 drops of 0.1 g per square meter.
* For the bait box: 0.2 g/m².For example one pre-baited station of 2 g to treat 10 m² or one pre-baited station of 5 g to treat 25 m².
* Place the bait station along the ant trail or close to the nest if possible.

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

Effects on target organisms occur after contact or ingestion of gel bait. Death occurs with a slight time delay to ensure that ants transport gel bait to the nest to kill the entire colony.

#### Mode of action, including time delay

Dinotefuran is a neonicotinoid in the nitroguanidine class. This active substance acts as an agonist of insect nicotinic acetylcholine receptors, but it is postulated that dinotefuran affects the nicotinic acetylcholine binding in a mode that differs from other neonicotinoid insecticides. Biocidal effect appears further days after application of the product according to laboratory and field studies. This time delay allows ants to transport gel bait to the nest and this permits to eradicate the entire colony.

#### Efficacy data

The applicant submitted fifteen studies (laboratory and field tests) to show the efficacy of the product ADDICT GEL FOURMIS.

Two laboratory tests with the gel in syringe and the gel in bait station have shown the efficacy of the bait gel application against each of the three ant species: Black garden ant (*L. niger*), Argentine ant (*L. humile*) and Pharaoh ant (*M. pharaonis*).

One laboratory test with the aged gel in syringe has shown the efficacy of the aged bait gel application against each of the three ant species: Black garden ant (*L. niger*), Argentine ant (*L. humile*) and Pharaoh ant (*M. pharaonis*).

The aged product have been aged by accelerated aging, 3 weeks at 54°C.

Two field tests indoor and outdoor with the gel in syringe and the gel in bait station have shown the efficacy of the bait gel application against each of the two ant species: Black garden ant (*L. niger*) and Argentine ant (*L. humile*).

Two field tests indoor with the gel in syringe and the gel in bait station have shown the efficacy of the bait gel application against Pharaoh ant (*M. pharaonis*).

|  |
| --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Indooroutdoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in syringe – Fresh product | *Lasius niger*100 workers per tray (laboratory breeding). | Laboratory Test according to C.E.B Method No. 196 | **Laboratory study on** **fresh bait (20°C) in syringe**.Exposure duration: 15 DaysPlastic box (30 x 30 x 5 cm), T°C 22-25°C, 52-58%RH.light 1500 lux 8/16 photoperiodFood source presentThe same procedure was used but without any treatment for controls.5 replicates were conducted for each treatment.Spots of gel were applied at the dose of 0.2 g/m² (spot of 0.5 cm, 1 application) | > 95 % mortality on all trays after 7 days of exposure:D0: 2,6%D1: 60,2%D2: 80,2%D3: 86 %D4: 88,2%D5: 92,8%D6: 94,6%D7: 99%D8: 100%For each control tray, the daily and mean mortality (considered as control series) was lower than 10% which validates the test (between 0 and 4% maximum for each control tray).The test has proved a good laboratory palatability efficacy against *Lasius niger.* | Guicherd A., 2018. 18LODLnLab001RI = 1 |
| Insecticide | Indooroutdoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in bait box – Fresh product | *L. niger*100 workers per tray (laboratory breeding). | Laboratory Test according to C.E.B Method No. 196 | **Laboratory study on fresh bait (20°C) in bait station**. Exposure duration: 15 DaysPlastic box (30 x 30 x 5 cm), T°C 22-25°C, 52-58%RH.light 1500 lux 8/16 photoperiodFood source presentThe same procedure was used but without any treatment for controls.5 replicates were conducted for each treatment.Spots of gel were applied at the dose of 0.2 g/m² (spot of 0.5 cm, 1 application) | > 95 % mortality on all trays after 6 days of exposure:D0: 6,4%D1: 42,4%D2: 60,2%D3: 74%D4: 88,8%D5: 93,6%D6: 97,8%D7: 99,6%D8: 100%For each control tray, the daily and mean mortality (considered as control series) was lower than 10%, which validates the test (between 0 and 3% maximum for each control tray).The test has proved a good laboratory palatability efficacy against *Lasius niger.* | Guicherd A., 2018. 18LODLnLab003RI = 1 |
| Insecticide | Indooroutdoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in syringe– Aged product (54°C 2 weeks) | *L. niger*100 workers per tray (laboratory breeding). | Laboratory Test according to C.E.B Method No. 196 | **Laboratory study on aged bait (54°C) in syringe**. Exposure duration: 15 DaysPlastic box (30 x 30 x 5 cm), T°C 22-25°C, 52-58%RH.light 1500 lux 8/16 photoperiodFood source presentThe same procedure was used but without any treatment for controls.5 replicates were conducted for each treatment.Spots of gel were applied at the dose of 0.2 g/m² (spot of 0.5 cm, 1 application) | >95 % mortality on all trays after 6 days of exposure:D0: 6,8%D1: 28,2%D2: 44,2%D3: 59,8%D4: 76,6%D5: 88,2%D6: 96,2%D7: 99%D8: 100%For each control tray, the daily and mean mortality (considered as control series) was lower than 10%, which validates the test (between 0 and 2% maximum for each control tray).The test has proved a good laboratory palatability efficacy against *Lasius niger.* | Guicherd A., 2018. 18LODLnLab002RI = 2accelerated ageing bait |
| Insecticide | Indooroutdoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in syringe– Fresh product | *L. niger* | Field trial according to ECHA Guidance on the Biocidal Products Regulation, Volume II, version 3.0 April 2018 | **Field study on** **fresh bait (20°C) in syringe.** Exposure duration: From D0 to D7 with 15 days of post-treatment period (D14 to D28).Application dose: 0.2 g/m²Three test sites were treated and three test sites were non-treated and used as controls. The trials were led on ant colonies nearby and entering residential homes causing inconvenients to the owners. The treated sites were located in Courzieu 1 (outer courtyard), Courzieu 2 (inside, living room) and Solaize (outer courtyard) near Lyon city (South East of France).3 ant trails per nest.Monitoring of the population before treatment and, 2 and 4 weeks after treatment.The nests were opened at the end of the test. | 90% reduction of surface activity of treated trays after D4 and 100% from D5 to D28.No re-infestations were noted on the treated sites 4 weeks after the application of the Test Item. The nests were killed. No reduction of activity of control trays is observed.The test has proved a complete efficacy against black ants *Lasius niger* within 28 days in the conditions of this field trial. | Guicherd A., 2018. 18LODLnF001RI = 1 |
| Insecticide | Indooroutdoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in bait box– Fresh product | *L. niger* | Field trial according to ECHA Guidance on the Biocidal Products Regulation, Volume II, version 3.0 April 2018 | **Field study on** **fresh bait (20°C) in bait station.** Exposure duration: From D0 to D7 with 15 days of post-treatment period (D14 to D28).Application dose: 0.2 g/m² in bait station (i.e. one bait station of 2 g to treat 10 m²). The three treated sites were located in Meximieux 1 (inside house), Meximieux 2 (outside) and Meximieux 3 (outside) near Lyon city (South East of France).3 ant trails per nest.Monitoring of the population before treatment and, 2 and 4 weeks after treatment.The nests were opened at the end of the test. | 90% reduction of surface activity of treated trays after D3 and 100% from D6 to D28.No re-infestations were noted on the treated sites 4 weeks after the application of the Test Item. The nests were killed. No reduction of activity of control trays is observed.The test has proved a complete efficacy against black ants *Lasius niger* within 28 days in the conditions of this field trial. | Guicherd A., 2018. 18LODLnF002RI=1 |
| Insecticide | Indooroutdoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in syringe – Fresh product | *Linepithema**humile*workers from a wild nest, 50 ants per replicate (laboratory breeding). | Laboratory Test according to C.E.B Method No. 196 | **Laboratory study on** **fresh bait (20°C) in syringe**.Exposure duration: 8 daysPlastic box (30 x 30 x 5 cm), T°C 25±1°C, 65±4%RH.light 1500 lux 8/16 photoperiodFood source presentThe same procedure was used but without any treatment for controls.5 replicates were conducted for each treatment.Application dose: 0.2 g/m² in two droplets of 0.1 g (0.5 cm diameter) = 18 mg per arena (0.09 m²). | >95 % mortality on all trays after 6 days of exposure:D1: 0%D2: 2%D3: 33%D4: 50%D5: 76%D6: 97%D7: 100%D8: 100%For each control tray, the daily and mean mortality (considered as control series) was lower than 10%, which validates the test (between 0 and 1% maximum for each control tray).The test has proved a good laboratory efficacy against *Linepithema humile*. | Serrano B., 2018.2323a-GEL-FRESH-LAB-LH/0418RRI=1 |
| Insecticide | Indooroutdoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in bait box – Fresh product | *L. humile*workers from a wild nest,50 ants per replicate (from wild nest). | Laboratory Test according to C.E.B Method No. 196 | **Laboratory study on** **fresh bait (20°C) in bait station.**Exposure duration: 8 daysPlastic box (30 x 30 x 5 cm), T°C 25±1°C, 65±4%RH.light 1500 lux 8/16 photoperiodFood source presentThe same procedure was used but without any treatment for controls.5 replicates were conducted for each treatment.Application dose: One bait box containing 0.2 g of product was applied per arena (0.09m²). | > 95 % mortality on all trays after 6 days of exposure:D1: 0%D2: 2%D3: 34%D4: 54%D5: 87%D6: 99%D7: 100%D8: 100%For each control tray, the daily and mean mortality (considered as control series) was lower than 10% which validates the test (between 0 and 1% maximum for each control tray).The test has proved a good laboratory efficacy against *Linepithema humile*. | Serrano B.,2018.2323c-BOX-FRESH-LAB-LH/0418RRI=1 |
| Insecticide | Indooroutdoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in syringe– Aged product (54°C 3weeks) | *L. humile*Workers from a wild nest, 50 ants per replicate (from wild nest). | Laboratory Test according to C.E.B Method No. 196 | **Laboratory study on** **aged bait (54°C) in syringe**.Exposure duration: 8 daysPlastic box (30 x 30 x 5 cm), T°C 25±1°C, 65±4%RH.light 1500 lux 8/16 photoperiodFood source presentThe same procedure was used but without any treatment for controls.5 replicates were conducted for each treatment.Application dose: 0.2 g/m² in two droplets of 0.1 g (0.5 cm diameter) = 18 mg per arena (0.09 m²). | 100% % mortality on all trays after 8 days of exposure:D1: 0%D2: 0%D3: 27%D4: 47%D5: 70%D6: 79%D7: 94%D8: 100%For each control tray, the daily and mean mortality (considered as control series) was lower than 10% which validates the test (between 0 and 1% maximum for each control tray).The test has proved a good laboratory efficacy against *Linepithema humile*. | Serrano B.,2018.2323e-GEL-AGED-LAB-LH/0418RRI=2accelerated ageing bait |
| Insecticide | Indooroutdoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in bait box– Fresh product | *L. humile*5 nests>1000 ants per treatment | Field study according to ECHA guidance on the Biocidal Products Regulation – Volume II efficacy – assessment and Evaluation (Parts B&C)C.E.B. method 196 and C.E.B. method MG1.EPPO guidelines | **Field study on** **fresh bait (20°C) in syringe.** Exposure duration: 28 days.Application dose: 0.2 g/m² in two droplets of 0.1 g (0.5 cm diameter) near the nest entry and/or on the tracks.The location of nests were the following :- Tarnos (40) - Industrial building / outdoor- Biarritz (64) - Office building / indoor- Anglet (64) - Food store / outdoor- Guéthary (64) - Industrial building / outdoor- Bayonne (64) - Food store / indoorThe sites are chosen according to the following requirements:- hard surfaces, terraces, pavements, urban environment, houses etc- significant activity of the ants- availability of the access along the trial- protected sites (not to be damaged)- Indoor and OutdoorThe criteria was the FCS = Frequency of Crossing in Surface.July & August, Average 22,2-21,5°C; Max 29,5-34,1°C; Min 15,4-17,8°C; Rain 169-61 mm; H of sun 237-253h.No treatment one month beforeMonitoring of the population before the treatment.The nests were opened at the end of the test. | >90% reduction of activity of treated trays between 7 and 28 days.% of reduction of the Frequency of Crossing in Surface of the ants in comparison with the activity before the treatment (means of replicates):D1: 0,2%D3: 59,4%D7: 91,2%D14: 92,5%D21: 100%D28: 100%The nests were killed.% of reduction of the Frequency of Crossing in Surface of the ants in comparison with the activity before the treatment (means of replicates) for control trays:D1: -2%D3: -1,6%D7: 5,1%D14: 5,7%D21: -2,4%D28: -4,1% The test has proved a complete efficacy against Argentine ants *Linepithema humile* within 28 days in the conditions of this field trial. | Serrano B., 2018.2323j-BOX-FRESH-FIELD-LH/0418RRI=1 |
| Insecticide | Indooroutdoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in syringe– Fresh product | *L. humile*5 nests>1000 ants per treatment | Field study according to ECHA guidance on the Biocidal Products Regulation – Volume II efficacy – assessment and Evaluation (Parts B&C)C.E.B. method 196 and C.E.B. method MG1.EPPO guidelines.  | **Field study on** **fresh bait (20°C) in bait station.** Exposure duration: 28 days.Application dose: 1 bait box containing 0.2 g per m² near the nest entry and/or on the tracks.The location of nests were the following :- Bayonne (64) - House terrace / outdoor- Hendaye (64) - House terrace / outdoor- Boucau (40) - Industrial building / indoor- St Martin (40) - Industrial building / indoor- Bayonne (64) - Industrial building / outdoorThe sites are chosen according to the following requirements:- hard surfaces, terraces, pavements, urban environment, houses etc- significant activity of the ants- availability of the access along the trial- protected sites (not to be damaged)- Indoor and OutdoorThe criteria was the FCS = Frequency of Crossing in Surface.July & August, Average 22,2-21,5°C; Max 29,5-34,1°C; Min 15,4-17,8°C; Rain 169-61 mm; H of sun 237-253h.No treatment one month beforeMonitoring of the population before the treatment.The nests were opened at the end of the test. | >90% reduction of activity of treated trays between 14 and 28 days% of reduction of the Frequency of Crossing in Surface of the ants in comparison with the activity before the treatment (means of replicates):D1: -3,6%D3: 57,1%D7: 79,2%D14: 96,6%D21: 98,6%D28: 100%The nests were killed.% of reduction of the Frequency of Crossing in Surface of the ants incomparison with the activity before the treatment (means of replicates) for control trays:D1: -2%D3: -1,6%D7: 5,1%D14: 5,7%D21: -2,4%D28: -4,1% The test has proved a complete efficacy against Argentine ants *Linepithema humile* within 28 days in the conditions of this field trial. | Serrano B., 2018.2323h-GEL-FRESH-FIELD-LH/0418RRI=1 |
| Insecticide | Indoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in syringe– Fresh product | *Monomorium pharaonis*Workers from a wild nest, 50 ants per replicate (from wild nest). | Laboratory Test according to C.E.B Method No. 196 | **Laboratory study on** **fresh bait (20°C) in syringe**.Exposure duration: 8 daysPlastic box (30 x 30 x 5 cm), T°C 25°C +/- 1°C, 65%RH +/- 4%RHlight 1500 lux 8/16 photoperiodFood source presentThe same procedure was used but without any treatment for controls.5 replicates were conducted for each treatment.Application dose: 0.2 g/m² in two droplets of 0.1 g (0.5 cm diameter) = 18 mg per arena (0.09 m²). | >95 % mortality on all trays after 7 days of exposure:D1: 0%D2: 1%D3: 27%D4: 46%D5: 70%D6: 91%D7: 98%D8: 100%For each control tray, the daily and mean mortality (considered as control series) was lower than 10% which validates the test (between 0 and 1% maximum for each control tray).The test has proved a good laboratory efficacy against *Monomorium pharaonis*. | Serrano B., 2018.2323b-GEL-FRESH-LAB-MP/0418RRI 1 |
| Insecticide | Indoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in bait box– Fresh product | *M. pharaonis*Workers from a wild nest, 50 ants per replicate (from wild nest). | Laboratory Test according to C.E.B Method No. 196 | **Laboratory study on** **fresh bait (20°C) in bait station**.Exposure duration: 8 daysPlastic box (30 x 30 x 5 cm), T°C 25°C +/- 1°C, 65%RH +/- 4%RHlight 1500 lux 8/16 photoperiodFood source presentThe same procedure was used but without any treatment for controls.5 replicates were conducted for each treatment.Application dose: 0.2 g/m² in two droplets of 0.1 g (0.5 cm diameter) = 18 mg per arena (0.09 m²). | >95 % mortality on all trays after 6 days of exposure:D1: 0%D2: 1%D3: 26%D4: 47%D5: 78%D6: 97%D7: 100%D8: 100%For each control tray, the daily and mean mortality (considered as control series) was lower than 10%, which validates the test (between 0 and 1% maximum for each control tray).The test has proved a good laboratory efficacy against *Monomorium pharaonis*. | Serrano B., 2018.2323d-BOX-FRESH-LAB-MP/0418RRI 1 |
| Insecticide | Indoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in syringe– Aged product (54°C 3 weeks) | *M. pharaonis*Workers from a wild nest, 50 ants per replicate (from wild nest). | Laboratory Test according to C.E.B Method No. 196 | **Laboratory study on** **aged bait (54°C) in syringe**.Exposure duration: 8 daysPlastic box (30 x 30 x 5 cm), T°C 25°C +/- 1°C, 65%RH +/- 4%RHlight 1500 lux 8/16 photoperiodFood source presentThe same procedure was used but without any treatment for controls.5 replicates were conducted for each treatment.Application dose: 0.2 g/m² in two droplets of 0.1 g (0.5 cm diameter) = 18 mg per arena (0.09 m²). | >95 % mortality on all trays after 7 days of exposure:D1: 0%D2: 0%D3: 21%D4: 35%D5: 65%D6: 80%D7: 96%D8: 100%For each control tray, the daily and mean mortality (considered as control series) was lower than 10%, which validates the test (between 0 and 1% maximum for each control tray).The test has proved a good laboratory efficacy against *Monomorium pharaonis*. | Serrano B., 2018.2323f-GEL-AGED-LAB-MP/0418RRI 2accelerated ageing bait |
| Insecticide | Indoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in syringe– Fresh product | *M. pharaonis*5 nests1000 ants per treatment | Field study according to ECHA guidance on the Biocidal Products Regulation – Volume II efficacy – assessment and Evaluation (Parts B&C)C.E.B. method 196 and C.E.B. method MG1.EPPO guidelines | **Field study on** **fresh bait (20°C) in syringe.** Exposure duration: 28 days.Application dose: 0.2 g/m² in two droplets of 0.1 g (0.5 cm diameter) near the nest entry and/or on the tracks.The location of nests were the following :- Boucau (40) - Industrial building / indoor- Anglet (64) - House / indoor- Anglet (64) - Office building / indoor- Bayonne (64) – House / indoor- Bayonne (64) - Bakery / indoorThe sites are chosen according to the following requirements:- hard surfaces, terraces, pavements, urban environment, houses etc- significant activity of the ants- availability of the access along the trial- protected sites (not to be damaged)- Indoor The criteria was the FCS = Frequency of Crossing in Surface.July & August, Average 22,2-21,5°C; Max 29,5-34,1°C; Min 15,4-17,8°C; Rain 169-61 mm; H of sun 237-253h.No treatment one month beforeThe nests were opened at the end of the test.  | 100% reduction of activity of treated trays between 14 and 28 days% of reduction of the Frequency of Crossing in Surface of the ants in comparison with the activity before the treatment (means of replicates):D1: -3,6%D3: 59,8%D7: 83,2%D14: 100%D21: 100%D28: 100%The nests were killed.% of reduction of the Frequency of Crossing in Surface of the ants incomparison with the activity before the treatment (means of replicates) for control trays:D1: -3,5%D3: -5,6%D7: 1,1%D14: -3,5%D21: -7,4%D28: -3,5% The test has proved a complete efficacy against Pharaoh ants *Monomorium pharaonis* within 28 days in the conditions of this field trial. | Serrano B., 2018.2323g-GEL-FRESH-FIELD-MP/0418RRI 1 |
| Insecticide | Indoor | ADDICT GEL FOURMISDinotefuran 0.02 % - Gel in bait box– Fresh product | *M. pharaonis*5 nests1000 ants per treatment | Field study according to ECHA guidance on the Biocidal Products Regulation – Volume II efficacy – assessment and Evaluation (Parts B&C)C.E.B. method 196 and C.E.B. method MG1.EPPO guidelines | **Field study on** **fresh bait (20°C) in bait station.** Exposure duration: 28 days.Application dose: 1 bait box containing 0.2 g per m² near the nest entry and/or on the tracks.The location of nests were the following :- Bayonne (64) - House / indoor- Bayonne (64) - House / indoor- Tarnos (40) - Industrial building / indoor- Tarnos (40) - House / indoor- Bayonne (64) - Office building / indoorThe sites are chosen according to the following requirements:- hard surfaces, terraces, pavements, urban environment, houses etc- significant activity of the ants- availability of the access along the trial- protected sites (not to be damaged)- Indoor The criteria was the FCS = Frequency of Crossing in Surface.July & August, Average 22,2-21,5°C; Max 29,5-34,1°C; Min 15,4-17,8°C; Rain 169-61 mm; H of sun 237-253h.No treatment one month beforeThe nests were opened at the end of the test.  | >90% reduction of activity of treated trays between 7 and 28 days% of reduction of the Frequency of Crossing in Surface of the ants in comparison with the activity before the treatment (means of replicates):D1: -0,8%D3: 54,1%D7: 91,4%D14: 97,5%D21: 100%D28: 100%The nests were killed.% of reduction of the Frequency of Crossing in Surface of the ants incomparison with the activity before the treatment (means of replicates) for control trays:D1: -3,5%D3: -5,6%D7: 1,1%D14: -3,5%D21: -7,4%D28: -3,5% The test has proved a complete efficacy against Pharaoh ants *Monomorium pharaonis* within 28 days in the conditions of this field trial. | Serrano B., 2018.2323i-BOX-FRESH-FIELD-MP/0418RRI 1 |

The efficacy data submitted are not compliant with the requirements of the Guidance on the BPR: Vol II Parts B+C, as only laboratory and field tests for each form of product and ant species was submitted, and no simulated use test was conducted as mentioned in the section 5.6.4.4.2.3 of this same Guidance. However, French competent authorities (FR CA) consider that simulated-use tests can be waived because robust field trials were submitted.

The efficacy data submitted demonstrate the efficacy of the product in syringe against ants with both laboratory and field tests when applied in gel drops as spot or directly in cracks and crevices:

* outdoor against Black garden ant (*L. niger*) and Argentine ant (*L. humile*)
* indoor against Black garden ant (*L. niger*), Argentine ant (*L. humile*) and Pharaoh ant (*M. pharaonis*)

The efficacy data submitted demonstrate the efficacy of the product in pre-baited station against ants with both laboratory and field tests when applied:

* outdoor against Black garden ant (*L. niger*) and Argentine ant (*L. humile*)
* indoor against Black garden ant (*L. niger*), Argentine ant (*L. humile*) and Pharaoh ant (*M. pharaonis*)

According to section 5.6.2.2.5 of ECHA guidance Vol.II part B/C and TAB «Shelf life of PT18 bait products (WGV2016)», accelerated ageing studies are not sufficient to demonstrate the efficacy of a product.

Thus, FR CA considers that the efficacy data with accelerated ageing studies (3 weeks at 54°C) are not sufficient to support a shelf life of 3 years. Therefore, as the product contains preservatives, a shelf life of 2 years is validated.

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| **Conclusion on the efficacy of the product** |
| In conclusion, in accordance with the requirement of the ECHA guidance Vol.II part B/C, FR CA consider that the elements presented in the dossier are sufficient to demonstrate the efficacy of the product ADDICT GEL FOURMIS in syringe or in pre-baited station against *Lasius niger*, *Monomorium pharaonis* and *Linepithema humile* indoors and against *Lasius niger* and *Linepithema humile* outdoors. However, efficacy data are not sufficient to support a shelf life of 3 years. |

#### Occurrence of resistance and resistance management

Dinotefuran is a nitroguanidine compound included with other insect nicotinic acetylcholine receptor (nAChRs) agonists in the Insect Resistance Action Committee (IRAC) group 4A. Detailed mode of action studies suggest that dinotefuran binds to the acetylcholine receptor site in a mode that differs to the chlorinated neonicotinic molecules included in IRAC group 4A. In common with all insecticides the possibility of the development of a cross resistance or a specific resistance to dinotefuran cannot be discounted.

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

However, the authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

#### Known limitations

Product must be applied only on hard non-absorbent surfaces and protected from rainfall during all the treatment period.

#### Evaluation of the label claims

The efficacy data submitted demonstrate the efficacy of the product in syringe against ants with both laboratory and field tests. Moreover, the efficacy of the bait in syringe has been proved with accelerated ageing studies (3 weeks at 54°C) when applied:

* In gel drops as spot or directly in cracks and crevices, outdoor against Black garden ants (*L. niger*) and Argentine ants (*L. humile*) and indoor against Black garden ants (*L. niger*), Argentine ants (*L. humile*) and Pharaoh ants (*M. pharaonis*)
* In pre-baited station, outdoor against Black garden ants (*L. niger*) and Argentine ants (*L. humile*) and indoor against Black garden ants (*L. niger*), Argentine ants (*L. humile*) and Pharaoh ants (*M. pharaonis*)

According to the ECHA guidance Vol.II part B/C and TAB « Shelf life of PT18 bait products (WGV2016) », accelerated ageing studies are not sufficient to demonstrate the efficacy of a product.

Thus, FR CA consider that the efficacy data with accelerated ageing studies (3 weeks at 54°C) are not sufficient to support a shelf life of 3 years. Therefore, as the product contains preservatives, a shelf life of 2 years is validated.

#### 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

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

| **Summary table of in vivo studies on skin corrosion/irritation** |
| --- |
| **Method, Guideline,****GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** | **Reference** |
| OECD 404, GLP | Albino New Zealand RabbitsOne male and two females  | 0.5 mL of the test item,No vehicle was used, 4 hours | No cutaneous reactions (erythema and oedema) were observed whatever the examination time (1, 24, 48 and 72 hours). | None | XXX |

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Not corrosive/irritant to the skin |
| Justification for the value/conclusion | Under experimental conditions, ADDICT GEL FOURMIS does not have to be classified. |
| Classification of the product according to CLP  | Not classified for skin corrosion/irritation. |

| ***Eye irritation* Summary table of in vivo studies on serious eye damage and eye irritation**  |
| --- |
| **Method,Guideline,****GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks**  | **Reference** |
| OECD 405, GLP  | Albino New Zealand rabbits 3 males | 0.1 mL of the test item,No vehicle was used  | The ocular reactions observed during the study have been slight to moderate and totally reversible:at the conjunctivae level: a slight to moderate redness noted 1 hour after the test item instillation in all animal and totally reversible between Days 1 and 2. This reaction was associated with a slight chemosis noted 1 hour after the test item instillation and totally reversible on Day 1. | None | XXX |

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| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | Not irritant to the eye |
| Justification for the value/conclusion | Under experimental conditions, ADDICT GEL FOURMIS does not have to be classified. |
| Classification of the product according to CLP  | Not classified for eye irritation. |

***Respiratory tract irritation***

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| **Conclusion used in the Risk Assessment – Respiratory tract irritation** |
| Justification for the conclusion | Not irritating to respiratory tract |
| Classification of the product according to CLP  | The classification has been determined according to the CLP Regulation. A coformulant is classified H335 but below the concentration of 20%. Therefore, no classification is required for irritation to the respiratory tract. |

***Skin sensitization***

| **Summary table of animal studies on skin sensitisation** |
| --- |
| **Method,Guideline, GLP status, . Reliability** | **Species,Strain,Sex,No/group** | **Test substance, Vehicle,****Dose levels, duration of exposure Route of exposure**  | **Results**  | **Remarks** | **Reference**  |
| OECD 442B and Test method B.51, GLP  | CBA/JRj strain mice3 groups of 4 females1 group for negative control  | Addict Gel Fourmis 3 concentrations: undiluted (100 %), diluted at 50 % and 25 % in N,N-dimethylformamideTopical application: 25 µL to the dorsal surface of each ear for 3 consecutive days | No mortality and no signs of systemic toxicity were noted in the test and control animals during the test.Stimulation Index (SI) was 1.13, 1.21 and 1.19 for the treated groups at 25 %, 50 % and 100 %, respectively.EC1.6 cannot be determined due to the absence of SI value higher than 1.6. | None | XXX |

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| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Not sensitising to the skin |
| Justification for the value/conclusion | Deviations from the guideline 442-B are noted: Stop solution was added to the test after 5 to 30 min, with a measurement at an absorbance of 450 nm with a reference wavelength of 690 nm, while an absorbance of 370 nm with a reference wavelength of 492 nm is proposed in the guideline without stop solution. These considerations come from ICCVAM Test method evaluation report on the Murine Local Lymph Node Assay: BrDu-ELISA, March 2010: “Measure an absorbance (ABS) at 370 nm with a reference wavelength of 492 nm. When using stop solution (1 M sulfuric acid, 25 µL/well), measure ABS at 450 nm with a reference wavelength of 690 nm.” Study is considered acceptable. Under experimental conditions, ADDICT GEL FOURMIS does not have to be classified. Moreover, the sensitizing substances present at a content superior to 1/10th to their threshold for skin sensitisation classification should be mentioned on the label. The sentence “EUH208: Contains 2-methyl-2H-isothiazole-3–one. May produce an allergic reaction” should be mentioned.The presence of 1,2-benzisothiazol-3(2H)-one, skin sensitizer that may produce an allergic reaction, must be mentioned on the label. |
| Classification of the product according to CLP  | Not classified for skin sensitisation. |

***Respiratory sensitization (ADS)***

|  |
| --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | Not sensitising to the respiratory system. |
| Justification for the value/conclusion | The classification has been determined according to the CLP Regulation. None of the coformulants are classified H334. Therefore, no classification is required for irritation to the respiratory sensitization. |
| Classification of the product according to CLP  | No classification for respiratory sensitisation is required. |

***Acute toxicity***

*Acute toxicity by oral route*

| **Summary table of animal studies on acute oral toxicity** |
| --- |
| **Method Guideline****GLP status, Reliability**  | **Species,Strain,Sex,No/group** | **Test substance****Dose levels, Type of administration**  | **Signs of toxicity** | **ValueLD50** | **Remarks** | **Reference**  |
| OECD 423, GLP | Sprague Dawley rats,6 females | Addict Gel Fourmis by gavage under a volume of 1.79 mL/kg bw (2 g/kg). | No mortality and no signs of toxicity | >2000 mg/kg body weight | None | XXX |

|  |
| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | LD50 > 2000 mg/kg bw |
| Justification for the selected value | Minor deviations: The maximum value measured for humidity was 75%. The maximum value for temperature measured was 27°C.ADDICT GEL FOURMIS was administered to a group of 6 females Sprague Dawley rats at the dose of 2000 mg/kg body weight. No clinical signs were observed during the study. |
| Classification of the product according to CLP  | Not classified.  |

*Acute toxicity by inhalation*

|  |
| --- |
| **Summary table of animal studies on acute inhalation toxicity** |
| **Method,Guideline,****GLP status , Reliability** | **Species,Strain,Sex,No/group** | **Test substance, form and particle size (MMAD)****Actual and nominal concentration, Type of administration** | **Signs of toxicity**  | **LC50** | **Remarks**  | **Reference** |
| OECD 436 and OECD series on testing and assessment No. 39., GLP | Wistar rats3 males and 3 females | Addict Gel Fourmis, aerosol form (30 %w/w)Particle size (MMAD): 1.45 μm.Nominal concentration: 10.07 mg/L Actual concentration: 5.04 mg/L (equivalent to 1.51 mg of ADDICT GEL FOURMIS).Administration: nose only, 4 hours. | No mortality, Reversible clinical signs (nasal discharge, hypoactivity and ruffled appearance). Animals were free of these signs on day 2 after exposure. | > 5.04 mg/L air | None | XXX |

|  |
| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | LC50 > 5.04 mg/L air |
| Justification for the selected value | Groups of three male and three female rats were subjected to a single inhalation exposure of the formulated test item, for a period of 4 hours at concentration of 5.04 mg/L (equivalent to 1.51 mg of ADDICT GEL FOURMIS). No clinical signs were observed along a period of 14 days. According to the composition, none of the component is identified as toxicologically relevant via inhalation route. |
| Classification of the product according to CLP  | Not classified. |

*Acute toxicity by dermal route*

|  |
| --- |
| **Summary table of animal studies on acute dermal toxicity** |
| **Method, Guideline,****GLP status,****Reliability** | **Species, strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity**  | **LD50** | **Remarks**  | **Reference** |
| OECD 402, GLP | Sprague Dawley rats,3 females  | Addict Gel Fourmis by topical application under non-occlusive porous gauze dressing (50 mmx 50 mm), under a volume of 1.79 mL/kg bw, 2000 mg/kg bw, 24 hours.  | No mortality and no signs of toxicity | >2000 mg/kg bw | None | XXX |

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | LD50 >2000 mg/kg bw |
| Justification for the selected value | Minor deviations: The maximum value measured for humidity was 75%. The maximum value for temperature measured was 27°C.The test item ADDICT GEL FOURMIS was applied onto the intact skin of 3 female Sprague Dawley rats at the dose of 2000 mg/kg bw. No systemic clinical sign related to the administration of the test item was observed.According to the composition, none of the component is identified as toxicologically relevant via dermal route. |
| Classification of the product according to CLP  | Not classified.  |

***Information on dermal absorption***

|  |
| --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Substance | Dinotefuran |
| Value | 70% |
| Justification for the selected value | According to EFSA guidance on dermal absorption 2017, a default dermal absorption value of 70% may be applied for other types of formulations from organic solvent-based and water-based/dispersed or solid formulations, such as gel for direct application. |

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

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, the following co-formulants have been identified as substances of concern:

| **Name and CAS** **SOC** | **Reason(s) for identification** | **Relation to band** | **Consequences on the Human Risk assessment** | **Community workplace exposure limit** (mg/m3) [[3]](#footnote-4) |
| --- | --- | --- | --- | --- |
| Isopentyl acetateCAS: 123-92-2 | Substances for which there are Community workplace exposure limits. | Band C | Quantitative inhalation risk assessment for the professional (EU OEL) | 270 mg/m3 |
| CyclohexaneCAS: 203-806-2 | Substances for which there are Community workplace exposure limits. | Band C | Quantitative inhalation risk assessment for the professional (EU OEL) | 700 mg/m3 |

Given that the low concentration of Isopentyl acetate and Cyclohexane (see Confidential annex) and the high EU-OEL values, a full quantitative risk characterisation is not needed. In addition, inhalation is considered negligible regarding the application methods.

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

No data.

***Other***

None.

#### Exposure assessment

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

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

The product ADDICT GEL FOURMIS is a ready-to-use insecticide gel bait supplied in syringe, bottle or pre-baited stations. Syringes and bottles have an applicator nozzle which is narrow to allow accurate delivering of the product. The product is applied as droplets of 0.1 g (0.5 cm diameter).

*Primary exposure:*

Professionals and non-professionals may be exposed during spot application for dermal exposure. Inhalation is considered negligible regarding the low vapour pressure of active substance (5 x 10-5 Pa at 25 °C) and the application methods.

*Secondary exposure:*

Bystanders (adults, children, toddlers or infants) can touch the product after application. Infants or toddlers can ingest the product after application. Inhalation is considered negligible regarding the low vapour pressure of active substance (5 x 10-5 Pa at 25 °C) and the application methods.

***List of scenarios***

| **Summary table: scenarios** |
| --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure** **Description of scenario** | **Exposed group** |
| 1. | Handling and applying gel bait | **Primary exposure – dermal exposure**Dermal exposure by touching the applicator tip of syringe (or bottle) during the opening and closing phases. | Professionals and non-professionals |
| 2. | Dermal exposure to the applied gel | **Secondary exposure – dermal exposure**Secondary exposure of adult, child, toddler or infant by touching the dislodged product. | Bystanders (adult, child, toddler and infant) |
| 3. | Oral exposure to the applied gel | **Secondary exposure – oral exposure**Secondary exposure of toddler or infant by ingestion of the dislodged product. | Bystanders (toddler and infant) |

***Industrial exposure***

No exposure is foreseen.

***Professional and non-professional exposure***

*Scenario [1] - Handling and applying gel bait*

| **Description of Scenario [1]** |
| --- |
| A reverse scenario approach is done to assess the amount of product needed on the skin to reach the AEL for professional and non-professional users, with the following parameters for dermal exposure:

|  |  |  |
| --- | --- | --- |
| **Parameters** | **Value** | **Reference** |
| AELlong-term and medium-term (mg/kg bw/d) | 0.22 | CAR 2014 |
| Concentration of dinotefuran | 0.0202% | Applicant’s data |
| Dermal absorption | 70% | Default value (EFSA 2017) |
| Adult body weight (kg) | 60 | HEAd Hoc Recommendation no. 14 |

 |

**Calculations for Scenario [1]**

Maximum quantity to reach the AELlong-term/medium term is equal to **93** **g** of the product that would be necessary for a professional or a non-professional to generate systemic effects due to the dermal primary exposure. This quantity corresponds to 933 drops.

***Exposure of the general public***

*Scenario [2] - Dermal exposure to the applied gel (adults, children, toddlers, infants)*

| **Description of Scenario [2]** |
| --- |
| A reverse scenario approach is done to assess the amount of product needed on the skin to reach the AEL (short-term) for adults, children, toddlers and infants, with the following parameters for dermal exposure:

|  |  |  |
| --- | --- | --- |
| **Parameters** | **Value** | **Reference** |
| AELshort-term (mg/kg bw/d) | 1.75 | CAR 2014 |
| Concentration of dinotefuran | 0.0202% | Applicant’s data |
| Dermal absorption | 70% | Default value (EFSA 2017) |
| Adult body weight (kg) | 60 | HEAd Hoc Recommendation no. 14 |
| Child body weight (kg) | 15.6 |
| Toddler body weight (kg) | 10 |
| Infant body weight (kg) | 8 |

  |

**Calculations for Scenario [2]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Adult** | **Child** | **Toddler** | **Infant** |
| Maximal amount of product to be touched (g) | 743 | 193 | 124 | 99 |

*Scenario [3] - Oral exposure to the applied gel (toddlers, infants)*

| **Description of Scenario [3]** |
| --- |
| A reverse scenario approach is done to assess the amount of product needed to be ingested to reach the AEL (short-term) for toddlers and infants, with the following parameters for oral exposure:

|  |  |  |
| --- | --- | --- |
| **Parameters** | **Value** | **Reference** |
| AELshort-term (mg/kg bw/d) | 1.75 | CAR 2014 |
| Concentration of dinotefuran | 0.0202% | Applicant’s data |
| Oral absorption | 100% | Default value |
| Toddler body weight (kg) | 10 | HEAd Hoc Recommendation no. 14 |
| Infant body weight (kg) | 8 |

  |

**Calculations for Scenario [3]**

|  |  |  |
| --- | --- | --- |
|  | **Toddler** | **Infant** |
| Maximal amount of product to be ingested (g) | 87 | 69 |

***Monitoring data***

None.

***Dietary exposure***

Food, drinking water or livestock exposure of dinotefuran can be excluded when applied according to the recommended uses.

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

Residue definitions

| **Summary table of other (non-biocidal) uses** |
| --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant protection products | The active substance is not approved. | Default MRL of 0.01 mg/kg applies according to Art 18(1)(b) of Reg 396/2005. |

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

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

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

Food, drinking water or livestock exposure of dinotefuran can be excluded when applied according to the recommended uses.

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

According to the recommended use, no transfer of biocidal active substance into food is foreseen.

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

According to the recommended use, no transfer of biocidal active substance into food is foreseen.

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

Not applicable

***Aggregated exposure***

Not performed

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** |
| --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake** |
| 1. | Professionals and non-professionals | Tier 1 | Maximum quantity to be touched: 93 g |
| 2. | Adults | Tier 1 | Maximum quantity to be touched: 743 g |
| 2. | Children | Tier 1 | Maximum quantity to be touched: 193 g |
| 2. | Toddlers | Tier 1 | Maximum quantity to be touched: 124 g |
| 2. | Infants  | Tier 1 | Maximum quantity to be touched: 99 g |
| 3. | Toddlers | Tier 1 | Maximum quantity to be ingested: 87 g |
| 3. | Infants  | Tier 1 | Maximum quantity to be ingested: 69 g |

#### Risk characterisation for human health

Reference values to be used in Risk Characterisation – Dinotefuran

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL** (mg/kg bw/day) | **AF1** | **Correction for oral absorption** | **Value**(mg/kg bw/day) |
| AELshort-term | Rabbit (NZW) oral developmental toxicity study | 175 | 100 | - | 1.75 |
| AELmedium-term | Dog oral (dietary) 1 year study | 22 | 100 | - | 0.22 |
| AELlong-term | Dog oral (dietary) 1 year study | 22 | 100 | - | 0.22 |
| ARfD | Rabbit (NZW) oral developmental toxicity study | 175 | 100 | - | 1.75 |
| ADI | Dog oral (dietary) 1 year study | 22 | 100 | - | 0.22 |

1 10 x 10 for inter- & intraspecific differences.

**Maximum residue limits or equivalent**

Not relevant

***Risk for professional users***

Maximum quantity to reach the AELlong-term is equal to 93 gof the product that would be necessary for a professional to generate systemic effects due to the dermal primary exposure. Considering that 2 drops of 0.1 g per square meter is applied for treatment with the syringe or bottle, these calculated amounts have been considered not relevant and the risk is acceptable.

Considering that the prebaited station is adapted to a dose of 0.2 g/m² (i.e. 2 g to treat 10 m² or 5 g to treat 25 m²), these calculated amounts have been considered not relevant and the risk is acceptable.

**Conclusion**

The exposure to such amount of product is not likely to occur, therefore the risk for professional users is considered as acceptable without gloves.

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

Maximum quantity to reach the AELmedium-term is equal to 93 gof the product that would be necessary for a professional to generate systemic effects due to the dermal primary exposure.

Considering that 2 drops of 0.1 g per square meter is applied for treatment with the syringe or bottle, these calculated amounts have been considered not relevant and the risk is acceptable.

Considering that the prebaited station is adapted to a dose of 0.2 g/m² (i.e. 2 g to treat 10 m² or 5 g to treat 25 m²), these calculated amounts have been considered not relevant and the risk is acceptable.

**Conclusion**

The exposure to such amount of product is not likely to occur, therefore the risk for non-professional users is considered as acceptable.

***Risk for the general public (adults, children, toddlers and infants)***

Maximum quantity to reach the AELshort term is equal to:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Adult** | **Child** | **Toddler** | **Infant** |
| Maximal amount of product to be touched (g) | 743 | 193 | 124 | 99 |
| Maximal amount of product to be ingested (g) | - | - | 87 | 69 |

Considering that 2 drops of 0.1 g per square meter is applied for treatment with the syringe or bottle, these calculated amounts have been considered not relevant and the risk is acceptable.

Considering that the prebaited station is adapted to a dose of 0.2 g/m² (i.e. 2 g to treat 10 m² or 5 g to treat 25 m²), these calculated amounts have been considered not relevant and the risk is acceptable.

**Conclusion**

The exposure to such amount of product is not likely to occur, therefore the risk for general public is considered as acceptable.

However, it is still recommended not to touch gel bait for children and the label includes the following risk mitigation measures:

* Prevent access to bait by children and animals.
* Keep in a safe place out of reach of children and animals.

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

Food, drinking water or livestock exposure of dinotefuran can be excluded when applied according to the recommended uses. Therefore no unacceptable risk to consumer health via residues in food needs to be expected.

The following risk mitigation measures are recommended:

* Do not apply directly on or near food, feed or drinks, nor on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
* Do not apply on vegetable garden.

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

Not applicable

### Risk assessment for animal health

Risk assessment for pets is covered by exposure to the general public.

The following RMM is proposed: “Keep in a safe place out of reach of children and animals”.

### Risk assessment for the environment

The following environmental exposure and risk assessment was conducted for the biocidal product (BP) ADDICT GEL FOURMIS that is a ready-to-use insecticide gel bait to be applied indoor or outdoor (around houses and buildings and on terraces), in the form of gel drops or in pre-baited station. The product contains 0.0202% w/w technical dinotefuran, as the active substance, with an insecticidal action. The application dose is of two gel drops of 0.1g per square or linear metre or a pre-baited station of 2 g to treat 10 m² in order to respect the dose of 0.2 g/m². The product must be applied on the path of ants or close to the nest. When applied outdoor, the gel bait must be placed on paved surfaces and protected from the rain and non target organisms.

The assessment has been conducted for the active substance and its relevant metabolite MNG only according to the CAR. No substance of concern was defined for the environment.

More details about the identification of co-formulants as potential SoC can be found in the confidential PAR.

No additional studies regarding ecotoxicity and environmental fate for the biocidal product have been performed.

#### Effects assessment on the environment

An overview for the PNECs for the active substance dinotefuran, its relevant metabolite MNG are given in the table below:

|  |  |  |
| --- | --- | --- |
| **Compartment** | **PNEC (dinotefuran)**  | **PNEC (MNG)** |
| STP microorganisms | 100 mg/l (CAR) | n.r. |
| Surface water | 0.254 µg/l (CAR) | n.r. |
| Sediment | n.r. (EPM) | n.r. |
| Soil | 0.0016 mg/kg wwt (revised in WG-V2019\_ENV\_7-4)  | 0.00016 mg/kg wwt |

With regard to the formation of metabolites in aquatic systems, only one major metabolite – DN – was detected in the CAR at significant concentrations (i.e. >10 %) in the water-sediment degradation study. Maximum formation of DN reached 32.6 % AR in total system whilst 6 other degradation products were all detected at levels <4 % AR. Comparison of surface water effects for dinotefuran and DN presented in the CAR indicates that the major metabolite is significantly less toxic to aquatic organisms than its parent (dinotefuran appears to be >300 times more toxic by comparison). This was verified in the CAR by the RCR values that were significantly lower for the metabolite than for the active substance. Therefore, it is clear that environmental risks are likely to be driven by the presence of the a.s. in aquatic systems rather than its degradation products and so calculation of DN concentrations in surface waters has not been considered relevant.

With regard to the formation of metabolites in the terrestrial compartment, only one major metabolite – MNG – was detected at significant concentrations (i.e. >10 %) under aerobic conditions in a soil degradation study using silt loam as test substrate. Maximum formation of MNG did not exceed 16 % AR.

For MNG metabolite, no effects data on terrestrial organisms are available to derive a PNEC, it is assumed that metabolites can be 10 times more toxic than their parent compound. The PNECsoil  for MNG is therefore of 1.60E-04 mg/kg wet soil.

**Bees:**

The active substance Dinotefuran is known to be toxic to bees (LD50 contact = 0.056 µg/bee, defined in WGVENV\_ENV\_7-4).

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

|  |
| --- |
| Classification for the environment of the Active Substance Dinotefuran |
| Value/conclusion | **Very toxic to aquatic life – H400 with M-factor = 10****Very toxic to aquatic life with long-lasting effects – H410 with M-factor = 10** |

|  |
| --- |
| Classification for the environment of the Product ADDICT GEL FOURMIS  |
| Value/conclusion | According to ecotoxicological data available for the active substance Dinotefuran and considering the criteria of Regulation (EC) 1272/2008, the product ADDICT GEL FOURMIS containing 0.0202 % of technical dinotefuran is **not classified for the environment*.*** |

***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)***

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

The product is intended to be used indoor or outdoor (on terraces or around houses and buildings) at the dose of 0.2 g/m². Gel drops are applied on surfaces, in bait stations, or in cracks and crevices. In case of indoor treatment, the active substance can reach the STP after wet cleaning of the treated surfaces. The active substance is then distributed at a local scale to surface water, sediment, agricultural soil and groundwater. In case of outdoor treatment in urban area, the active substance can reach the sewer system after a rain event and then be distributed through the environmental compartments as for indoor treatment. For outdoor use in rural area, the soil is the receiving compartment. Groundwater compartment is also exposed due to leaching of the substance through the soil. Concentration of active substance in pore water is calculated to estimate the potential concentration in groundwater and refinements are conducted using FOCUS Pearl modelling.

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

No new data is available.

***Leaching behaviour (ADS)***

No new data is available.

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

No new data is available.

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

No new data is available.

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

No new data is available.

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

The biocidal product is a gel bait applied in bait station or covered bait point. Therefore a risk assessment for spray application is 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)***

The biocidal product is a gel bait applied in bait station or covered bait point. Therefore a risk assessment for spray application is not relevant. The product ADDICT GEL FOURMIS (in gel form) contains the active substance Dinotefuran known to be toxic to bees (LD50 contact = 0.056µg/bee) and therefore a risk for bees cannot be excluded.

#### Exposure assessment

General information

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: Indoor application – Barrier treatmentScenario 2: Outdoor application around houses and buildings.Scenario 3: Outdoor application on terraces. |
| ESD(s) used | *Emission Scenario Document for Product Type 18:* Emission Scenario Document for Insecticides, acaricides and products to control other arthropods for household and professional uses, July 2008. |
| Approach | Scenario 1: Average consumptionScenario 2: Average consumptionScenario 3: Average consumption |
| Distribution in the environment | *Calculated based on ESD model, EUSES 2.1* |
| Groundwater simulation | Pore water calculations are first undertaken as screening approach. In case of unacceptable risk (PEC values > 0.1µg/L), a second tier using FOCUS PEARL is performed.  |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1, 2, 3:Production: NoFormulation NoUse: YesService life: Yes |
| Remarks | No |

***Emission estimation***

**Scenario [1] – Indoor, surface treatment as a barrier**

ADDICT GEL FOURMIS is a ready-to-use gel bait containing 0.0202% of technical dinotefuran intended to be applied indoor on the path of ants or close to the nest. Gel bait is applied indoor on surfaces as a barrier treatment along the path of ants or close to the nest at the dose of 0.2 g/m² (i.e. 2 drops of 0.1 g). The product is a ready to use gel bait, therefore no emission is calculated for the preparation step. Emissions to air and on the applicator are also not considered due to the form of the product and the mode of application. The product must be checked once a week and replaced if necessary until consumption stops (simultaneity factor of 2.74 %). ADDICT GEL FOURMIS is applied on surfaces, cleaning efficiency is therefore of 25 % assuming the product applied along the ant runways could be washed away and reach the STP by unexpected flooding or via accidental spillages. Drops of gel can be applied on surfaces or in cracks and crevices; this last application is covered by application on surfaces. No release to the environment is expected using pre-baited station considering that gel bait is protected from wet cleaning.

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario 1: Gel applied indoor on surfaces as a barrier treatment (houses and large buildings) |
| Number of application per day | 1 | d-1 |  |
| Number of gel point per area  | 2 | Point.m-2 |  |
| Fraction emitted to treated surfaces during application | 1 | - |  |
| Quantity of commercial product applied per point of gel | 0.1 | g.point-1 |  |
| Fraction of active substance in commercial product | 0.000202 | - | (technical) |
| Wet cleaned area of private houses  | 5.9 | m² | According to TAB (ENV) v 2.0 2018 (ENV 142). |
| Wet cleaned area of buildings | 27 | m² |
| Cleaning efficiency | 25 | % |  |
| Simultaneity factor | 0.0274 | - | 1 application per week |
| Number of houses connected to STP | 4000 | - | According to TM-I-2010 and WG-IV-2017 |
| Number of buildings connected to STP | 300 | - |

Calculations for Scenario [*1*]

| **Resulting local emission to relevant environmental compartments (gel bait application)** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
|  | **Dinotefuran** |  |
| STP - urban area, indirect release | 8.8E-06 | Houses **and** buildings |

**Scenario [2] – Outdoor application around houses and buildings.**

The product can be applied around houses and buildings in urban and rural areas to control ant infestations. In urban areas runoff of rainwater goes to the sewer system contrary to rural areas where runoff of rainwater goes to the surrounding unpaved soil.

The product is applied on the perimeter of houses and buildings. The application dose is 0.2 g/m² (equivalent to 2 drops of 0.1 g per linear metre). According to ESD PT18, the perimeter of a private house is 50 m (17.5 m x 7.5 m). For a larger building, the perimeter is 98.7 m based on the revised surface area of 609 m². According to ESD PT18, the size of the receiving compartment corresponds to a band of 50 cm around the treated zone. For private house the receiving compartment in rural area is defined as follows: (17.5 x 0.5 x 2)+(7.5x0.5x2)+(0.5x0.5x4) = 26 m². For larger buildings, the size of each side is calculated from the area of 609 m². Therefore the receiving area is (24,678x0.5x4)+(0.5x0.5x4) = 50.4 m².

The product need to be checked and renewed once a week (simultaneity factor of 0.03). According to ESD PT18, the fraction released during gel application to the environment is 90%, while it is of 20% when applied in bait stations or in cracks and crevices because gel bait is protected from flooding.

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario 2 : Outdoor application around houses and buildings (perimeter)  |
| Amount of product used per linear metre | 0.2 | g |  |
| Fraction of active substance in product  | 0.000202 | - | (technical) |
| Perimeter of a private house | 50 | m |  |
| Perimeter of a larger building | 98.7 | m |  |
| Number of application per day | 1 | d-1 |  |
| Fraction emitted to soil during outdoor application on paved surfaces | 0.9 | - |  |
| Fraction emitted to soil during outdoor bait box or cracks and crevices | 0.2 | - |  |
| Surface of receiving compartment for perimeter treatment of house in rural area | 26 | m² |  |
| Surface of receiving compartment for perimeter treatment of buildings in rural area | 50.4 | m² |  |
| Simultaneity factor | 0.03 | - |  |
| Number of houses | 2500 | - | According to TM-I-2010 |
| Number of buildings | 300 | - |

Calculations for Scenario [*2*]

| **Resulting local emission to relevant environmental compartments (gel bait application)** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
|  | **Dinotefuran** |  |
| Soil – rural area, direct release | 1.82E-06 | House |
| Soil – rural area, direct release | 3.59E-06 | Building |
| STP - urban area, indirect release | 1.69E-04 | Houses **and** buildings |

| **Resulting local emission to relevant environmental compartments (bait box or cracks and crevices application)** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
|  | **Dinotefuran** |  |
| Soil – rural area, direct release | 4.04E-07 | House |
| Soil – rural area, direct release | 7.98E-07 | Building |
| STP - urban area, indirect release | 3.75E-05 | Houses **and** buildings |

**Scenario [3] – Outdoor application on terraces**

ADDICT GEL FOURMIS can be applied on terraces of private houses to control ant infestations. The application dose is 0.2 g/m² on the path of ants, or near the nest (if located on a paved surface). It was agreed at WG-V-2016 that for terrace scenario, the default value for treated area is 30 m². The size of receiving compartment is 8.5 m², taking into account three sides of a terrace. The product need to be checked and renewed once a week (simultaneity factor of 0.03). According to ESD PT18, fraction released to soil after gel bait application on surface is 90%, while it is 20% when applied in bait box or cracks and crevices. At the end of the treatment period, the unconsumed product must be disposed in a waste centre. In case of treatment on surfaces, the remaining drops of product must be removed with absorbent paper.

For this scenario, it is considered that house covers application in large buildings for the releases to soil.

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario 3: Outdoor application on terraces. |
| Amount of product used per square meter | 0.2 | g |  |
| Fraction of active substance in product  | 0.000202 | - | (technical) |
| Fraction of MIT in the product (SoC) | 0.00001475 | - | (=2.5%\*0.059%) |
| Number of application | 1 | - |  |
| Fraction emitted to soil during outdoor application of gel spots | 0.9 | - |  |
| Fraction emitted to soil during outdoor application of bait box or in cracks and crevices | 0.2 | - |  |
| Surface of treated area (house and large buildings) | 30 | m² | According to WG-V-2016 |
| Surface of receiving compartment | 8.5 | m² |
| Depth of exposed soil | 0.5 | m | According to WG-V-2014 |
| Number of houses per STP | 2500 | -  | Default |
| Number of larger buildings per STP | 300 | - | Default |
| Simultaneity factor | 0.03 | - | Default as worst-case |

Calculations for Scenario [*3*]

| **Resulting local emission to relevant environmental compartments (gel bait application)** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
|  | **Dinotefuran** |  |
| Soil – rural area, direct release | 1.09E-06 | House **or** building |
| STP - urban area, indirect release | 9.16E-05 | House **and** building |

| **Resulting local emission to relevant environmental compartments (bait box and cracks and crevices application)** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
|  | **Dinotefuran** |  |
| Soil – rural area, direct release | 2.42E-07 | House **or** building |
| STP - urban area, indirect release | 2.04E-05 | House **and** building |

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

|  |
| --- |
|  | Fresh-water(covering seawater) | Freshwater sediment (covered by freshwater) | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | Yes | n.r. | Yes | n.r. | Yes | Yes | n.r. |
| Scenario 2 | Yes | n.r. | Yes | n.r. | Yes | Yes | n.r. |
| Scenario 3 | Yes | n.r. | Yes | n.r. | Yes | Yes | n.r. |

|  |
| --- |
| **Input parameters for calculating the fate and distribution in the environment - Dinotefuran** |
| Input  | Value  | Unit | Remarks |
| Molecular weight | 202.2 | g.mol-1 |  |
| Vapour pressure  | 5E-05  | Pa | 25°C |
| Water solubility | 39.83 | g/L | 20°C, unbuffered water |
| Log Octanol/water partition coefficient | -0.644 | Log 10 | At pH 7 and 25°C |
| Organic carbon/water partition coefficient (Koc) | 31.4 | L/kg |  |
| Biodegradability | Not Ready biodegradable | - |  |
| DT50 for degradation in soil | 19.2 | d (at 12ºC) |  |
| Henry’s law constant (at 25°C) | 2.37E-07 | Pa.m3.mol-1 | Calculated by EUSES taking into account vapour pressure and water solubility |
| Bioconcentration factor (BCF) | 0.06 (fish)0.843 (earthworm) | - | Calculated by QSAR  |

According to the dinotefuran CAR, the only relevant metabolite, 1-methyl-2-nitroguanidine (MNG), was formed in terrestrial compartment at 16.0 % AR.

|  |  |
| --- | --- |
| **Input parameters for calculating the fate and distribution in the environment** | **MNG** |
| Molecular weight (g.mol-1)\* | 118.10 |
| Solubility in water (mg.L-1) at 25°C\* | 1E+06 |
| Vapour pressure (Pa) at 25°C\* | 16.9 |
| Octanol-water partition coefficient (log Kow)\* | -1.17 |
| Organic carbon adsorption coefficient (Koc in L.kg-1)\* | **2.702 (Kow method)\*\***24.14 (MCI method) |
| Aquatic degradation DT50 (d at 12°C) | - |
| Aerobic soil degradation DT50 (d at 12°C) | 137 |
| BCF  | 0.84 (earthworm) |

\* All indicated endpoints have been determined by US-EPA EPISuite v4.11 modelling in the absence of actual supporting data (based on reasoned arguments due to restricted indoor use pattern of representative product and the likelihood of limited emissions to aquatic and terrestrial compartments). QSAR values have been derived using SMILES notations of NC(NC)=NN(=O)(=O) for MNG but if extension of use for a.s. is sought leading to an increase in emissions, then predicted values should be replaced by measured ones.

\*\* the lowest Koc value of 2.702 was considered in the risk assessment as a worst case for groundwater.

|  |
| --- |
| **Calculated fate and distribution in the STP – Dinotefuran (Simple Treat 4.0)** |
| Compartment | Percentage [%] |
| Scenario 1, 2 &3 |
| Air | 0 |
| Water | 99.6 |
| Sludge | 0.4 |
| Degraded in STP | 0 |

***Calculated PEC values***

|  |
| --- |
| **Summary table on calculated PEC values - Dinotefuran** |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** |
| [mg/L] | [mg/L] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Scenario 1 – Indoor application, barrier treatment |
| Gel bait  | 4.38E-06 | 4.38E-07 | n.r | 3.90E-08 | 1.42E-05 |
| Bait box | 0 | 0 | 0 | 0 | 0 |
| Scenario 2 – Outdoor application around houses and buildings (perimeter) |
| Gel bait, direct release | n.r. | n.r. | n.r. | House: 8.23E-05\*Building: 8.39E-05\* | House: **1.22E-01**Building:**1.25E-01** |
| Gel bait, indirect release | 8.40E-05 | 8.40E-06 | n.r. | 7.47E-07 | 2.72E-04 |
| Bait box, direct release | n.r. | n.r. | n.r. | House: 1.83E-05\*Building:1.86E-05\* | House: 2.72E-02Building:2.77E-02 |
| Bait box, indirect release | 1.87E-05 | 1.87E-06 | n.r. | 1.66E-07 | 6.03E-05 |
| Scenario 3 – outdoor application on terraces |
| Gel bait, direct release | n.r. | n.r. | n.r. | 1.51E-04 (house or building)\* | **2.25E-01** (house or building) |
| Gel bait, indirect release | 4.56E-05 | 4.56E-06 | n.r. | 4.06E-07 | 1.48E-04 |
| Bait box, direct release | n.r. | n.r. | n.r. | 3.36E-05 (house or building)\* | 4.99E-02 (house or building) |
| Bait box, indirect release | 1.01E-05 | 1.01E-06 | n.r. | 9.02E-08 | 3.28E-05 |

\* initial concentration

The dinotefuran concentrations in groundwater exceed the trigger value of 0.1 µg/L in case of direct release of non-protected gel used outdoor.

The PECs for the metabolite MNG are calculated taking into account its percentage of formation and the correction for differences in molecular weight.

MNG is a major metabolite in soil reaching a maximum level of 16.0%. The PECsoil for MNG is calculated from PECsoil of dinotefuran. The percentage of formation as well as differences in the molecular weight (118.1 : 202.2) are taken into account.

For calculation of PECgroundwater a Ksoil-water value of 0.281 m3.m-3 was used as a worst case considering the lowest Koc value of 2.7.

|  |
| --- |
| **Summary table on calculated PEC values – MNG** |
|  | **PECsoil (MNG)** | **PECGW(MNG)** |
| [mg/kgwwt] | [μg/l] |
| Scenario 1 – Indoor application, barrier treatment |
| Gel bait  | 5.01E-09 | 1.34E-05 |
| Bait box | 0 | 0 |
| Scenario 2 – Outdoor application around houses and buildings (perimeter) |
| Gel bait, direct release | House: 7.69E-06\*Building: 7.84E-05\* | House: 4.65E-02Building: 4.742E-02 |
| Gel bait, indirect release | 9.61E-08 | 2.58E-04 |
| Bait box, direct release | House: 1.71E-06\*Building:1.74E-06\* | House: 1.03E-02Building: 1.05E-02 |
| Bait box, indirect release | 2.14E-08 | 5.72E-05 |
| Scenario 3 – Outdoor application on terraces |
| Gel bait, direct release | 1.41E-05 (house or building)\* | 8.53E-02 (house or building) |
| Gel bait, indirect release | 5.22E-08 | 1.40E-04 |
| Bait box, direct release | 3.14E-06 (house or building)\* | 1.90E-02 (house or building) |
| Bait box, indirect release | 1.16E-08 | 3.11E-05 |

\* initial concentration

The MNG concentrations in groundwater do not exceed the trigger value of 0.1 µg/L.

***Primary and secondary poisoning***

**Bees:**

The product ADDICT GEL FOURMIS (in gel form) contains the active substance Dinotefuran known to be toxic to bees (LD50 contact = 0.056 µg/bee) and therefore a risk for bees cannot be excluded. The ant gel bait containing dinotefuran must be protected from bees when applied outdoor (either in bait box or covered bait point).

**Secondary poisoning:**

Considering the very low BCF value for the active substance and its metabolite, no secondary poisoning is foreseen.

#### Risk characterisation

***Atmosphere***

Conclusion:Dinotefuran is not volatile and is not expected to enter the atmosphere.

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

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECSTP** |
|  | **Dinotefuran** |
| **PNECSTP:** | **100 mg/l** |
| Scenario 1- Indoor application, barrier treatment |
| Gel bait | 4.38E-08 |
| Bait box | n.r. |
| Scenario 2– outdoor application around houses and buildings |
| Gel bait | 8.40E-07 |
| Bait box | 1.87E-07 |
| Scenario 3– outdoor application on terraces |
| Gel bait | 4.56E-07 |
| Bait box | 1.01E-07 |

Conclusion: PEC/PNEC for STP compartment is <1. The risk is therefore acceptable for all scenarios.

***Aquatic compartment***

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
| **PNEC** | **PEC/PNECwater covering sediment** |
| **Dinotefuran** |
| **0.254 µg/l** |
| Scenario 1- Indoor application, barrier treatment |
| Gel bait  | 1.73E-03 |
| Bait box | n.r. |
| Scenario 2– Outdoor application around houses and buildings |
| Gel bait, direct release | n.r. |
| Gel bait, indirect release | 3.31E-02 |
| Bait box, direct release | n.r. |
| Bait box, indirect release | 7.35E-03 |
| Scenario 3– Outdoor application on terraces |
| Gel bait, direct release | n.r. |
| Gel bait, indirect release | 1.80E-02 |
| Bait box, direct release | n.r. |
| Bait box, indirect release | 3.99E-03 |

Conclusion: The PEC/PNEC values for water compartment (covering sediment)) are < 1 for dinotefuran. The risk is acceptable for all scenarios.

***Terrestrial compartment***

|  |
| --- |
| **Calculated PEC/PNEC values** |
|  | **PEC/PNECsoil** |
|  | **Dinotefuran** | **MNG** |
| **PNECsoil** | **1.60E-03 mg/kgwwt** | **1.60E-04 mg/kgwwt** |
| Scenario 1- Indoor application, barrier treatment |
| Gel bait  | 2.44E-05 | 3.13E-05 |
| Bait box | n.r. | n.r. |
| Scenario 2– outdoor application around houses and buildings |
| Gel bait, direct release | House: 5.14E-02Building: 5.24E-02 | House: 4.80E-02Building: 4.90E-02 |
| Gel bait, indirect release | 4.67E-04 | 6.01E-04 |
| Bait box, direct release | House: 1.14E-02Building: 1.16E-02 | House: 1.07E-02Building: 1.09E-02 |
| Bait box, indirect release | 1.04E-04 | 1.33E-04 |
| Scenario 3– outdoor application on terraces |
| Gel bait, direct release | 9.44E-02 | 8.82E-02 |
| Gel bait, indirect release | 2.54E-04 | 3.26E-04 |
| Bait box, direct release | 2.10E-02 | 1.96E-02 |
| Bait box, indirect release | 5.64E-05 | 7.25E-05 |

Conclusion: The PEC/PNEC values are < 1 for dinotefuran and its relevant metabolite MNG. The risk is acceptable for the three scenarios.

***Groundwater***

The dinotefuran concentrations in groundwater exceed the trigger value of 0.1 µg/L in case of direct release of non-protected gel used outdoor. For the metabolite MNG, the concentrations in groundwater do not exceed the trigger value of 0.1 µg/L whatever the scenario.

FOCUS groundwater model PEARL (version 4.4.4) was used as a refinement for the groundwater assessment of the parent.

Concentrations in groundwater are expected to exceed the threshold limit value of 0.1 μg/L for scenario 2 and 3 in case of direct exposure of the product to soil.

A tier 2 approach was applied to calculate PECGW for the scenario 2 (worst-case compared to scenario 3) using FOCUS PEARL 4.4.4, and the following parameters:

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Unit** | **Value** | **Reference/Remark** |
|  |  | **Scenario 2 (house / rural area)** |  |
| Espot,soil | [kg.d-1] | 1.82E-06 | Scenario house/perimeter for one application |
| Number of houses treated per hectare | [houses.ha-1] | 16 | Point ENV157 (ENV-TAB, 2018) |
| Standard crop | [-] | Alfalfa | Point ENV157 (ENV-TAB, 2018) |
| Application depth | [cm] | 50 | Point ENV153 (ENV-TAB, 2018) |
| Date of application | [-] | 10 events evenly distributed over the year:* 10/01
* 15/02
* 24/03
* 29/04
* 05/06
* 11/07
* 17/08
* 22/09
* 29/10
* 04/12
 | ESD for PT08 – Supplement to Appendix 4 (paragraph 594c, p.178), cited in the point ENV157 (ENV-TAB, 2018) |
| Application rate | [kg.ha-1] | 1.46E-04 | 5 times the application rate (as the product can be applied once a week and the interval between date of application are around 5/application) |
| Molar Mass | [g.mol-1] | 202.2 |  |
| Solubility in water at 20°C | [g.L-1] | 39.83 |  |
| Molar enthalpy of dissolution | [KJ.mol-1] | 27 | Point ENV23 (ENV-TAB, 2018)  |
| Vapour pressure at 25°C | [Pa] | 5E-05 |  |
| Molar enthalpy of vaporisation | [KJ.mol-1] | 95 | Point ENV23 (ENV-TAB, 2018) |
| Diffusion coefficient in water | [m².d-1] | 4.3E-05 | Point ENV23 (ENV-TAB, 2018) |
| Gas diffusion coefficient | [m².d-1] | 0.43 | Point ENV23 (ENV-TAB, 2018) |
| Reference temperature to degradation, vaporization and dissolution | [°C] | 20 | Point ENV23 (ENV-TAB, 2018) |
| Exponent for the effect of liquid (degradation moisture relationship) | [-] | 0.7 | Point ENV23 (ENV-TAB, 2018) |
| Sorption to soil organic carbon | [dm3.kg-1]  | 18.21 | Kom = Koc / 1.724(Point ENV23 (ENV-TAB, 2018)) |
| Exponent of the Freundlich-isotherm (1/n) | [-] | 1 | Point ENV23 (ENV-TAB, 2018) |
| DT50 (12°C) | [d] | 19.2 |  |
| Arrhenius activation energy | [KJ.mol-1] | 65.4 | Point ENV23 (ENV-TAB, 2018) |
| Plant uptake factor | [-] | 0 | Point ENV23 (ENV-TAB, 2018) |

The PECGW (tier 2) are summarized in the table below:

|  |
| --- |
| **Summary table on PECGW(tier2) [µg/L]** |
|  | **Scenario 2 (around house / rural area)** |
| Chateaudun | 0.00052 |
| Hambourg | 0.00226 |
| Jokioinen | 0.00193 |
| Kremsmuenster | 0.00059 |
| Okehampton | 0.00254 |
| Piacenza | 0.00177 |
| Porto | 0.00240 |
| Sevilla | 0.00059 |
| Thiva | 0.00033 |

Conclusion: PECGW (tier2) does not exceed the regulatory threshold of 0.1 μg/L. The risk is acceptable for all scenarios. MNG has also been included in the FOCUS simulation and risk is also acceptable for groundwater.

***Primary and secondary poisoning***

Due to the intended use of the product, the physico-chemical properties of the active substance and the very low BCF value for the active substance and its metabolite, it is assumed that no primary or secondary poisoning may occur. The risk is therefore not assessed.

Concerning bees, considering the high level of risk for bees, when used outdoors, the product must be used in pre-filled bait boxes to protect from non-target organisms. When this is not practically possible, crack and crevice gel applications are also permitted in order to minimize access from non-target organisms. With respect to the condition of outdoor uses, the risk for bees can be considered as negligible. The following RMM have been added by the FR CA:

* “For outdoor use, apply this biocidal product in bait boxes or in cracks and crevices only or directly to ant nests. Protect from bees by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait)”.

***Mixture toxicity***

As no substance of concern has been identified, mixture toxicity is not relevant.

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

Considering that:

- guidelines to conduct an aggregated exposure assessment are still under development as cited at page 207 of Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0 October 2017;

- the active substance dinotefuran, is approved for use in products only within a single product type (PT18) under BPR;

- the authorised uses (outdoor application restricted to bait boxes, cracks and crevices and places protected from rainfall),

emissions sources from outdoor and indoor uses are not expected to cumulate in the STP compartment.



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

Conclusion: On the basis of the consideration mentioned above, no aggregated exposure assessment is deemed necessary for this biocidal product. A qualitative assessment is deemed sufficient to conclude that no overlap in time and space for the simultaneous use of the product and its active substance will occur on a regular (daily) basis.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| FR CA concludes the product ADDICT GEL FOURMIS poses no risk to the terrestrial or aquatic environmental compartments for indoor and outdoor uses, whatever the way of application, taking into account the intended application rate and the use recommendations. Nevertheless, the product contains the active substance Dinotefuran known to be toxic to bees and therefore a risk for bees cannot be excluded. For these reasons, when used outdoors, the product must be pre-filled bait boxes to protect from bees. When this is not practically possible, crack and crevice applications are also permitted in order to minimize access from non-target organisms. With respect to the condition of outdoor uses, honeybee exposure can be considered as negligible. The following RMM has been added by the FR CA:* “For outdoor use, apply this biocidal product in bait boxes or in cracks and crevices only or directly to ant nests. Protect from bees by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait)”.

Overall conclusion on the risk assessment for the environment of the product is summarized in the table below:

|  |
| --- |
| Summary table for the risk assessment of the product Insecticides for home use  |
|  | Emission | PEC/PNEC STP | PEC/PNEC water | PEC/PNEC sediment | PEC/PNEC soil | PEC/PNEC GW |
| **Indoor** |
| **1** (gel) | STP | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable |
| **1** (box) | n.r. | n.r. | n.r. | n.r. | n.r. | n.r. |
| **Oudoor** |
| **2** (gel perimeter) | STP | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable |
| Soil | n.r. | n.r. | n.r. | Acceptable | Acceptable (tier 2) |
| **2** (box perimeter) | STP | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable |
| Soil | n.r. | n.r. | n.r. | Acceptable | Acceptable |
| **3** (gel terrace) | Soil | n.r. | n.r. | n.r. | Acceptable | Acceptable (tier 2) |
| **3** (box terrace) | STP | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable |
| Soil | n.r. | n.r. | n.r. | Acceptable | Acceptable |

 |

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

*[Please refer to summary of the product assessment and to the relevant sections of the assessment report.]*

### Assessment of a combination of biocidal products

Not relevant

### Comparative assessment

**Overall conclusion:**

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

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

Considering that only one product have been identified as potential alternatives with an active substances acting with a different mode of action than dinotefuran, FR CA concludes that there is not an adequate chemical diversity in line with Article 23(3)(b) and the technical guidance note on comparative assessment.

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

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

# Annexes[[4]](#footnote-5)

## 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)** |
| RICHERIOUX S.  | 2018  | Aspect, color and odor of Addict gel fourmis after acceleratedstorage Testing Lab: LODI SAS Report: LODI.11/2018 | Yes | LODI SAS  |
| DEMANGEL B.  | 2018  | Physico-chemical tests on ADDICT GEL FOURMISTesting Lab: DEFITRACESReport: 18-912011-001 | Yes | LODI S.A.S.  |
| LECLERCQ S  | 2018  | pH of Addict gel fourmis after accelerated storageTesting Lab: LODI SASReport: LODI.02/2018 | Yes | LODI SAS  |
| RICHERIOUX S.  | 2018  | Aspect, color and odor of Addict gel fourmis after acceleratedstorageTesting Lab: LODI SASReport: LODI.11/2018 | Yes | LODI SAS  |
| LECLERCQ S  | 2018  | pH of Addict gel fourmis after accelerated storageTesting Lab: LODI SASReport: LODI.02/2018 | Yes | LODI SAS  |
| LECLERCQ S.  | 2018  | Chemical stability of dinotefuran in Addict gel fourmis afteraccelerated storageTesting Lab: LODI SASReport: LODI.07/2018 | Yes | LODI SAS  |
| RICHERIOUX S.  | 2018  | Compatibility between Addict gel fourmis and packaging afteraccelerated storageTesting Lab: LODI SAS Report: LODI.14/2018 | Yes | LODI SAS  |
| LECLERCQ S  | 2018 | Chemical stability of dinotefuran in Addict gel fourmis after oneyear of storage at 20°C ±2 °C (Analysis after 6 months ofstorage)Testing Lab: LODI SASReport: LODI.08/2018 | Yes | LODI SAS  |
| RICHERIOUX S.  | 2018  | Chemical stability of dinotefuran in Addict gel fourmis after twoyears of storage at 20°C ± 2°CTesting Lab: LODI SASReport: LODI.09/2018 | Yes | LODI SAS  |
| RICHERIOUX S.  | 2018  | Chemical stability of dinotefuran in Addict gel fourmis after threeyears of storage at 20°C ± 2°C Testing Lab: LODI SASReport: LODI.10/2018 | Yes | LODI SAS  |
| LECLERCQ S  | 2018  | pH of Addict gel fourmis after 3 years of storage at 20°C ± 2°C(After 6 months) Testing Lab: LODI SASReport: LODI.03/2018 | Yes | LODI SAS  |
| RICHERIOUX S.  | 2018  | Aspect, color and odor of Addict gel fourmis after three years ofstorage at 20°C ± 2°C (After 6 months of storage) Testing Lab: LODI SASReport: LODI.12/2018 | Yes | LODI SAS  |
| LECLERCQ S.  | 2018  | Compatibility between Addict gel fourmis and packagings afterthree years of storage at 20°C ± 2°C Testing Lab: LODI SASReport: LODI.15/2018 | Yes | LODI SAS  |
| DEMANGEL B.  | 2018  | Physico-chemical tests on ADDICT GEL FOURMIS Testing Lab: DEFITRACESReport: 18-912011-001 | Yes | LODI S.A.S.  |
| DEMANGEL B.  | 2018  | Explosive properties of liquids on ADDICT GEL FOURMIS Testing Lab: DEFITRACESReport: 18-912011-002 | Yes | LODI S.A.S.  |
| RICHERIOUX S.  | 2018  | Pyrophoric properties of Addict gel fourmis Testing Lab: LODI SASReport: LODI.04/2018 | Yes | LODI SAS  |
| DEMANGEL B.  | 2018  | Test for oxidizing liquids on ADDICT GEL FOURMIS Testing Lab: DEFITRACESReport: 18-912011-003 | Yes | LODI S.A.S.  |
| DEMANGEL B.  | 2018  | Physico-chemical tests on ADDICT GEL FOURMIS Testing Lab: DEFITRACESReport: 18-912011-001 | Yes | LODI S.A.S.  |
| DEMANGEL B.  | 2018  | Physico-chemical tests on ADDICT GEL FOURMIS Testing Lab: DEFITRACESReport: 18-912011-001 | Yes | LODI S.A.S.  |
| GUICHERD A. | 2018 | STUDY ON THE EFFICACY OF THE “ADDICT GEL FOURMIS” ON BLACK GARDEN ANT (LASIUS NIGER) | Yes | LODI GROUP |
| GUICHERD A. | 2018 | STUDY ON THE EFFICACY OF THE “ADDICT GEL FOURMIS (20°C)” DISTRIBUTED IN BAIT STATION ON BLACK GARDEN ANT (LASIUS NIGER) | Yes | LODI GROUP |
| GUICHERD A. | 2018 | STUDY ON THE EFFICACY OF THE “ADDICT GEL FOURMIS 54°C” ON BLACK GARDEN ANT (LASIUS NIGER) | Yes | LODI GROUP |
| GUICHERD A. | 2018 | EVALUATION OF THE EFFICACY OF THE “ADDICT GEL FOURMIS 20°C” FOR THE CONTROL OF BLACK GARDEN ANT (LASIUS NIGER) INFESTATIONS | Yes | LODI GROUP |
| GUICHERD A. | 2018 | EVALUATION OF THE EFFICACY OF THE “ADDICT GEL FOURMIS 20°C” DISTRIBUTED IN BAIT STATION FOR THE CONTROL OF BLACK GARDEN ANT (LASIUS NIGER) INFESTATIONS | Yes | LODI GROUP |
| SERRANO B. | 2018 | LABORATORY TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS – Palatability trial | Yes | LODI GROUP |
| SERRANO B. | 2018 | LABORATORY TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS – Palatability trial | Yes | LODI GROUP |
| SERRANO B. | 2018 | LABORATORY TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS – Palatability trial | Yes | LODI GROUP |
| SERRANO B. | 2018 | FIELD TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS | Yes | LODI GROUP |
| SERRANO B. | 2018 | FIELD TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS | Yes | LODI GROUP |
| SERRANO B. | 2018 | LABORATORY TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS – Palatability trial | Yes | LODI GROUP |
| SERRANO B. | 2018 | LABORATORY TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS – Palatability trial | Yes | LODI GROUP |
| SERRANO B. | 2018 | LABORATORY TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS – Palatability trial | Yes | LODI GROUP |
| SERRANO B. | 2018 | FIELD TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL  | Yes | LODI GROUP |
| SERRANO B. | 2018 | FIELD TRIAL OF THE EFFICACY OF AN INSECTICIDAL GEL BAIT INTENDED TO CONTROL ANTS | Yes | LODI GROUP |
| XXX | XXX | ASSESSMENT OF ACUTE DERMAL IRRITATION/CORROSION | Yes | XXX |
| XXX | XXX | ASSESSMENT OF ACUTE EYE IRRITATION/CORROSION | Yes | XXX |
| XXX | XXX | ASSESSMENT OF THE SKIN SENSITISATION POTENTIAL IN THE MOUSE USING THE LOCAL LYMPH NODE ASSAY (LLNA:BrdU) | Yes | XXX |
| XXX | XXX | EVALUATION OF ACUTE ORAL TOXICITY IN RATS – ACUTE TOXIC CLASS METHOD | Yes | XXX |
| XXX | XXX | ACUTE INHALATION TOXICITY STUDY OF ADDICT GEL FOURMIS IN RATS | Yes | XXX |
| XXX | XXX | EVALUATION OF ACUTE DERMAL TOXICITY IN RATS | Yes | XXX |

## Output tables from exposure assessment tools

## New information on the active substance

## Residue behaviour

## Summaries of the efficacy studies (B.5.10.1-xx)[[5]](#footnote-6)

## Confidential annex

## Other

1. Non-active substance(s), of which knowledge is essential for proper use of the product. In the SPC in the application the applicant shall indicate also the exact function (e.g. solvent, deterrent, preservative, pigment, etc.). In the SPC which will be disseminated this information will not be provided but limited to the name of non-active substance. [↑](#footnote-ref-2)
2. Efficacy trials method for bait insecticide products intended to control ants [↑](#footnote-ref-3)
3. ECHA Occupational Exposure limits (OELs) : <https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.003.461>; <https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.004.240> [↑](#footnote-ref-4)
4. 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-5)
5. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-6)