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)



MAGNUM GEL HORMIGAS IGR PLUS

Product type 18

Imidacloprid and S-Methoprene as included in the Union list of approved active substances.

Case Number in R4BP: BC-XK019347-22

Evaluating Competent Authority: Spain

Date: January 2023

**Overview of applications**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **Ref MS** | **Case number/Asset number in the ref MS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | ES | BC-XK019347-22 | May 2015 | Initial assessment |
| NA-APP | ES | ES-0015195-0000  | August 2021 | First authorisation |
| NA-AAT | ES | ES-0015195-0000 | August 2021 | Amendment |
| NA-AAT | ES | ES-0015195-0000 | September 2021 | Amendment. Removal of Frech trade names.  |
| NA-ADC | ES | ES-0015195-0000 | December 2021 | Amendment.1. Addition Spanish trade names.
2. Replacement source Imidacloprod active substance.
 |
| NA-MIC | ES | BC-BF073371-57 / ES-0015195-0000 | September 2022 | Change in the pack size range.Addition, replacement or modification of a measuring or administration device: Plastic bait station capsule |
| NA-ADC | ES | BC-AD083796-40 ES-0015195-0000 | Enero 2023 | Addition Spanish trade name.  |

Table of Contents

[1 Conclusion 5](#_Toc66431375)

[2 ASSESSMENT REPORT 7](#_Toc66431376)

[2.1 Summary of the product assessment 7](#_Toc66431377)

[2.1.1 Administrative information 7](#_Toc66431378)

[2.1.1.1 Identifier of the product 7](#_Toc66431379)

[2.1.1.2 Authorisation holder 7](#_Toc66431380)

[2.1.1.3 Manufacturer of the product 7](#_Toc66431381)

[2.1.1.4 Manufacturers of the active substances 7](#_Toc66431382)

[2.1.2 Product compoition and formulation 8](#_Toc66431383)

[2.1.2.1 Identity of the active substance 8](#_Toc66431384)

[2.1.2.2 Candidate for sustitution 8](#_Toc66431385)

[2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product 9](#_Toc66431386)

[2.1.2.4 Information on technical equivalence 9](#_Toc66431387)

[2.1.2.5 Information on the substances of concern 10](#_Toc66431388)

[2.1.2.6 Type of formulation 10](#_Toc66431389)

[2.1.3 Hazard and precautionary statements. 10](#_Toc66431390)

[2.1.4 Authorised uses 10](#_Toc66431391)

[2.1.4.1 Use description 1 10](#_Toc66431392)

[2.1.4.2 Use description 2 (NOT RELEVANT FOR SPAIN) 12](#_Toc66431393)

[2.1.4.3 Use description 3. 13](#_Toc66431394)

[2.1.4.4 Use description 4. 15](#_Toc66431395)

[2.1.5 General directions for use 16](#_Toc66431396)

[2.1.5.1 Instructions for use 16](#_Toc66431397)

[2.1.5.2 Risk mitigation measures 16](#_Toc66431398)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 17](#_Toc66431399)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 17](#_Toc66431400)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 18](#_Toc66431401)

[2.1.6 Other information 18](#_Toc66431402)

[2.1.7 Packaging of the biocidal product 19](#_Toc66431403)

[2.1.8 Documentation 19](#_Toc66431404)

[2.1.8.1 Data submitted in relation to product application 19](#_Toc66431405)

[2.1.8.2 Access to documentation 19](#_Toc66431406)

[2.2 Assessment of the biocidal product 20](#_Toc66431407)

[2.2.1 Intended uses as applied for by the applicant 20](#_Toc66431408)

[2.2.2 Physical, chemical and technical properties 23](#_Toc66431409)

[2.2.3 Physical hazards and respective characteristics 33](#_Toc66431410)

[2.2.4 Methods for detection and identification 37](#_Toc66431411)

[2.2.5 Efficacy against target organisms 41](#_Toc66431412)

[2.2.5.1 Function and field of use 41](#_Toc66431413)

[2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 42](#_Toc66431414)

[2.2.5.3 Effects on target organisms, including unacceptable suffering 42](#_Toc66431415)

[2.2.5.4 Mode of action, including time delay 42](#_Toc66431416)

[2.2.5.5 Efficacy data 42](#_Toc66431417)

[2.2.5.6 Occurrence of resistance and resistance management 55](#_Toc66431418)

[2.2.5.7 Known limitations 56](#_Toc66431419)

[2.2.5.8 Evaluation of the label claims 57](#_Toc66431420)

[2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product 57](#_Toc66431421)

[2.2.6 Risk assessment for human health 57](#_Toc66431422)

[2.2.6.1 Assessment of effects on Human Health 57](#_Toc66431423)

[2.2.6.2 Exposure assessment 64](#_Toc66431424)

[2.2.6.3 Risk characterisation for human health 76](#_Toc66431425)

[2.2.7 Risk assessment for animal health 82](#_Toc66431426)

[2.2.8 Risk assessment for the environment 83](#_Toc66431427)

[2.2.8.1 Effects assessment on the environment 83](#_Toc66431428)

[2.2.8.2 Exposure assessment 85](#_Toc66431429)

[2.2.8.3 Risk characterisation 96](#_Toc66431430)

[2.2.9 Measures to protect man, animals and the environment 99](#_Toc66431431)

[2.2.10 Assessment of a combination of biocidal products 100](#_Toc66431432)

[2.2.11 Comparative assessment 100](#_Toc66431433)

[3 Annexes 103](#_Toc66431434)

[3.1 List of studies for the biocidal product 103](#_Toc66431435)

[3.2 Output tables from exposure assessment tools 107](#_Toc66431436)

[3.2.1 Exposure assessment 107](#_Toc66431437)

[3.2.1.1 Calculations for Scenario [1] 107](#_Toc66431438)

[3.2.1.2 Calculations for Scenario [2] 107](#_Toc66431439)

[3.2.1.3 Calculations for Scenario [3] 108](#_Toc66431440)

[3.2.1.4 Calculations for Scenario [4] 108](#_Toc66431441)

[3.2.1.5 Calculations for Scenario [7] 108](#_Toc66431442)

[3.3 New information on the active substance 109](#_Toc66431443)

[3.4 Residue behaviour 109](#_Toc66431444)

[3.5 Summaries of the efficacy studies (B.5.10.1-08) 110](#_Toc66431445)

# Conclusion

The assessment presented in this report has shown that the ready-to-use product, MAGNUM GEL HORMIGAS IGR PLUS, with the active substances Imidacloprid and S-methoprene, at levels of 0.01% and 0.08% w/w, respectively, may be authorised for use as a insecticide (product-type 18) to kill ants for trained professional, professional and general public.

The biocidal product MAGNUM GEL HORMIGAS IGR PLUS is a colourless practically odourless gel and given the nature of the formulation it is not considered explosive, oxidizing, highly flammable or auto-flammable.

Hence, there not be hazards associated with the physico-chemical properties of the product under normal conditions of use.

There are substances in the biocidal product classified as hazardous (Regulation No 1272/2008), but finally, these substances do not contribute to the product hazard classification with regard to physical chemical properties.

Validated analytical method are available for determining the concentration of Imidacloprid in the biocidal product. Validated analytical methods are also available for the determination of Imidacloprid in soil, water and air matrices. Other analytical methods are not required.

The product was shown to be efficacious against ants (*Lasius niger, and Linephitema humile*) indoors applied as gel/drop lines or traps and against *Linephitema humile* outdoors applied as trap (bait station) in residential areas and commercial buildings.

The product is a ready-to-use gel bait which may applied as drops deposited by a syringe/cartridge or by the placement of a bait station indoors and outdoors. It has been demonstrated that the product is efficacious against the intended target organisms (ants) in the proposed area for use (residential and commercial buildings). The product contains two active substances, Imidacloprid which produces acute intoxication of adult ants resulting in mortality and S-Methoprene, which produces an ovicidal effect resulting in infertility of the queen ants to control ants infestations. Even so, the product has not demonstrated minimal ovicidal efficacy and therefore this claim is not accepted.Please find more information on efficacy of the product in chapter 2.2.5

Human exposure takes place via dermal contamination through hands taking into account the quantities that could potentially enter into contact with operator’s or consumer’s hands during opening, sealing and disposal of the cartridge or syringe, respectively. No exposure to the product is expected by differents users during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63). Indirect exposure is expected for toddlers via dermal and hand to mouth contact after application of the product.

Primary and secondary exposure assessment performed with the application of gel in drops is the worst case with regard to human exposure and cover the risk derived from the use of bait stations.

Based on the risk assessment results, the use of MAGNUM GEL HORMIGAS IGR PLUS as an insecticide is considered safe for human health taking into account primary and secondary exposure to the biocidal product as a consequence of use.

Dietary exposure as result of use (*i.e.*, food contamination and livestock exposure) can be excluded. The product is formulated as a gel and applied directly on localized spots so surface contamination, e.g., due to splashes, is unlikely. Furthermore measurable residues in food or feed from the use of MAGNUM GEL HORMIGAS IGR PLUS are not expected and so it is the transference of biocide residues to food. Likewise no dietary exposure is expected when using the gel in bait stations. In addition the label must include restrictions and instructions of use to avoid food contamination and exposure of animals (livestock and companion animals).

The product is not classified with regard to human health according to the Regulation (EC) Nº 1272/2008.

The addition of the packaging and a bait station capsule (NA-MIC, BC-BF073371-57) have no impact on the conclusion of the physical-chemical properties, efficacy and risk assessment for human health of the product since the mode of use of the new plastic bait station capsule is the same as the already authorized bait station (the bait station is activated at the moment of use).

**Risk assessment for the environment**

ES CA concludes the product MAGNUM GEL HORMIGAS IGR PLUS poses no risk to the terrestrial or aquatic environmental compartments for indoor and outdoor uses, whether for bait-boxes or gel drops, taking into account the intended application rate and the uses recommendations.

Nevertheless, the product contains the active substance Imidacloprid known to be toxic to bees and therefore a risk for bees cannot be excluded. For these reasons, in Spain when used outdoors, the product can only be used in bait boxes.

The addition of the packaging and a bait station capsule (NA-MIC, BC-BF073371-57) have no impact on the conclusion of the risk assessment for environment. It is worth noting that according to the intended use of this biocidal product for non-professional users, only 9.6 g per year are needed (0.6 g/m2 \* 2 m2 \* 8 times/year) and taking into account the shelf life of this product, 4 years, package sizes greater than 45 g are not allowed in order to avoid a misuse and an exceed of waste since the greater package sizes would exceed the requirements for non-professional users by far.

**Comparative assessment**

The active substance imidacloprid has been identified as candidate for substitution thus, a Comparative Assessment Report has been performed.

The Spanish CA concludes that there is not an adequate chemical diversity for products to kill ants for indoor and outdoor uses by differents users because as at least three different active substances – mode of action combinations should remain available through authorised biocidal product for a given use (indoor and outdoor uses by differents users categories).

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| MAGNUM GEL HORMIGAS IGR PLUSEC GEL HORMIGAS IGRX GEL IGR HORMIGASNOPE ANT KILLER | Spain |
| MAGNUM GEL ANTS IGR | Italy |
| MIRMEX GEL |
| MAGNUM GEL ANTS IGR | Hungary |
| MAGNUM GEL ANTS IGR | Poland |
| MAGNUM GEL ANTS IGR | UK |
| MAGNUM GEL ANTS IGR PLUS | Bulgaria |
| MAGNUM GEL AMEISEN IGR | Austria |
| MAGNUM GEL AMEISEN IGR | Germany |
| MAGNUM GEL FOURMIS IGR | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Mylva S.A. |
| **Address** | Via Augusta, 4808006 Barcelona, Spain |
| **Authorisation number** | ES/APP(NA)-2021-18-00768 |
| **Date of the authorisation** | 05/08/2021 |
| **Expiry date of the authorisation** | 05/08/2026 |

#### Manufacturer of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | Mylva S.A. |
| **Address of manufacturer** | Via Augusta, 4808006 Barcelona, Spain |
| **Location of manufacturing sites** | C/ Sant Galderic 23, Poligon industrial ponent, 08395 Sant Pol de MarBarcelona, Spain |

#### Manufacturers of the active substances

|  |  |
| --- | --- |
| **Active substance** | **Imidacloprid** |
| **Name of manufacturer** | ADAMA AGRICULTURE ESPAÑA S.A. |
| **Address of manufacturer** | Príncipe de Vergara 110-5ª, 28002 Madrid Spain |
| **Location of manufacturing sites 1** | Adama Makhteshim Ltd. - Neot-Hovav Eco-Industrial Park 84100 Beer Sheva Israël |
| **Location of manufacturing sites 2** | Jiangsu Yangnong Chemicals Group Co. Ltd - 39 Wenfeng Road, 225009 Yangzhou (China) |

|  |  |
| --- | --- |
| **Active substance** | **S-Methoprene** |
| **Name of manufacturer** | Bábolna Bioenvironmental Centre Ltd. |
| **Address of manufacturer** | H-1107 Budapest, Szállás u. 6, Hungary |
| **Location of manufacturing sites** | H-1107 Budapest, Szállás u. 6, Hungary |

### Product compoition 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 constituents** |
| **ISO name** | imidacloprid | S-Methoprene |
| **IUPAC or EC name** | (2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine | Isopropyl(2E,4E,7S)-11-methoxy-3,7,11-trimethyldodeca-2,4-dienoate |
| **EC number** | 428-040-8 | Not available |
| **CAS number** | 138261-41-3 | 65733-16-6 |
| **Index number in Annex VI of CLP** | 612-252-00-4 | Not available |
| **Minimum purity / content** | 97,0% | 95,0 % |
| **Structural formula** |  |  |

####  Candidate for sustitution

The active substance imidacloprid fulfills the criteria for substitution under Article 10 of Regulation (EU) 528/2012, notably it meets two of the criteria for being PBT in accordance with the Annex XIII to Regulation (EC) No 1907/2006. An evaluation of comparative assessment has been carried out.

Biocidal product MAGNUM GEL HORMIGAS IGR PLUS contains an active substance, imidacloprid, which meets the criteria for substitution under Article 10 of the Biocidal Products Regulation (EU) No 528/2012. Imidacloprid is considered to be very persistent (vP) and toxic (T) but not bioaccumulative (B) and consequently meets two of the criteria for being PBT. Therefore, in line with Article 23 (1) of the Biocides Regulation the Spanish CA has conducted a comparative assessment for the product MAGNUM GEL HORMIGAS PLUS according to the “Technical Guidance Note on comparative assessment of biocidal products” as agreed upon by the member states on the 55th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 (document: CA-May15-Doc.4.3.a - Final - TNG on comparative assessment.doc).

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Imidacloprid | (2E)-1-[(6-chloropyridin-3-yl) methyl]-N-nitroimidazolidin-2-imine | Active substance | 138261-41-3 | 428-040-8 | 0.01 (tech.)0.0097 (pure) |
| S-Methoprene | Isopropyl(2E,4E,7S)-11-methoxy-3,7,11-trimethyldodeca-2,4-dienoate | Active substance | 65733-16-6 | Not available | 0.08 (tech.)0.076 (pure) |
| Co-formulants  | See Confidential Annex |

Details of the product composition and **information on the co-formulants are confidential** and are presented in the confidential part of the dossier.

#### Information on technical equivalence

The manufacturer of the active substances and the manufacturing site of the active substances used in the biocidal product are identical to the manufacturer of the active substances and the production site of the active substances included in Annex I of Directive 98/8/EC. Therefore no check for equivalence is necessary.

December 2021 – Replacemnet source of Imidacloprid: Bayer CropScience AG by ADAMA Agriculture España S.A.T.

ADAMA Agriculture España sources have been granted technically equivalent to the Annex I source by ECHA (Decision Nº TAP-D-1096667-13-00/F and decision Nº TAPD-1099666-08-00/F).

#### Information on the substances of concern

Three co-formulants present in the product carry toxicological hazard classification. However, their concentration in the product does not exceed the limit for classification of the mixture according to Regulation UE Nº 1272/2008 and they are not considered to be substances of concern.

Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| RB – Bait (ready for use) |

### Hazard and precautionary statements.

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

| **Classification** |
| --- |
| Hazard category | Aquatic chronic 2 |
| Hazard statement | H411: Toxic to aquatic life with long lasting effects |
|  |
| **Labelling** |
| Hazard pictogram | GHS09 |
| Signal words | None |
| Hazard statements | H411:Toxic to aquatic life with long lasting effects |
| Precautionary statements | P102: Keep out of reach of children.P103: Read carefully and follow all instructions.P273: Avoid release to the environment.P391: Collect spillage.*Trained professional:*P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations.*Professional and general public*:P501: Remove the content and / or its container as hazardous waste according to the regulations in force. |

### Authorised uses

#### Use description 1

**Table 1**. **Use # 1 – Gel bait applied as drops/lines – Indoors- trained professionals, professionals and general public (non professional users).**

|  |  |
| --- | --- |
| **Product Type** | PT18.  |
| **Where relevant, an exact description of the authorised use** | Insecticide against ants. |
| **Target organism (including development stage)** | Insecticide against the following target insects (adults): * Argentine ants (*Linepithema humile*),
* Black ants (*Lasius niger*).
 |
| **Field of use** | Indoors. Residential, industrial, public and commercial or institutional buildings. Apply the biocidal product in spot application behind furniture and engines.  |
| **Application method** | Spot application of a gel bait from a syringe/cartridge. Apply MAGNUM GEL HORMIGAS IGR PLUS as drops or lines (elongated drops) where ants are present. |
| **Application rates and frequency** | Dose: 0.2-0.6 g/m2 = 1-3 drops/m2(1 drop = 1 line of 3 cm length = 0.2 g of gel bait)Frequency of application: Inspect after 7 days the point of applications. If the bait has been consumed and infestation persists, reapply once.Frequency of treatment: Three months after the infestation’s end, treatment may be repeated. Maximum of 8 application per year.  |
| **Categories of users** | Trained professional userProfessional userGeneral Public (non-professional user) |
| **Pack sizes and packaging material** | *General public (non-professional users)*:LDPE syringe of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40 and 45 g of gel bait.*Professional users*:LDPE syringe of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 and 60 g of gel bait.*Trained professional user:* LDPE cartridge of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450 and 500 g of gel bait. LDPE syringe of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 and 60 g of gel bait. |

##### Use-specific instructions for use

|  |
| --- |
| Use only indoor.Apply the biocidal product in restricted area as spot application behind furniture and engines. It is recommended to wash the hands before using the bait, to avoid contamination with offensive odors such as tobacco, etc...No spraying or misting chemicals near the areas where MAGNUM GEL HORMIGAS IGR PLUS is applied, they can contaminate and make inappetent for ants.Do not apply on porous surfaces. In case where it is not possible apply the product on a plastic sheet Do not apply in areas recently treated with another insecticide. |

#####  Use-specific risk mitigation measures

|  |
| --- |
| Avoid contact with eyes and skin. |

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

|  |
| --- |
| See section 2.1.5.3 |

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

|  |
| --- |
| See section 2.1.5.4 |

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

|  |
| --- |
| See section 2.1.5.6 |

#### Use description 2 (NOT RELEVANT FOR SPAIN)

**Table 2**. **Use # 2 – Gel bait applied as drops/lines – Outdoors- trained professionals.**

|  |  |
| --- | --- |
| **Product Type** | PT18.  |
| **Where relevant, an exact description of the authorised use** | Insecticide against ants. |
| **Target organism (including development stage)** | Insecticide against the following target insects (adults): * Argentine ants (*Linepithema humile*).
 |
| **Field of use** | Outdoors on paved surfaces. |
| **Application method** | Spot application of a gel bait from a syringe/cartridge. Apply MAGNUM GEL HORMIGAS IGR PLUS as drops or lines (elongated drops) where ants are present. |
| **Application rates and frequency** | Dose: 0.2-0.6 g/m2 = 1-3 drops/m2(1 drop = 1 line of 3 cm length = 0.2 g of gel bait)Frequency of application: Inspect after 7 days the point of applications. If the bait has been consumed and infestation persists, reapply once.Frequency of treatment: Three months after the infestation’s end, treatment may be repeated. Maximum of 8 applications per year.  |
| **Categories of users** | Trained professional user |
| **Pack sizes and packaging material** | LDPE cartridge of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450 and 500 g of gel bait. LDPE syringe of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55 and 60 g of gel bait. |

##### Use-specific instructions for use

|  |
| --- |
| Apply only on paved surfaces.It is recommended to wash the hands before using the bait, to avoid contamination with offensive odors such as tobacco, etc...No spraying or misting chemicals near the areas where MAGNUM GEL HORMIGAS IGR PLUS is applied, they can contaminate and make inappetent for ants.Do not apply on porous surfaces. Apply on paved surfaces only. In case where it is not possible, apply the product on a plastic sheet Do not apply in areas recently treated with another insecticide. |

#####  Use-specific risk mitigation measures

|  |
| --- |
| Avoid contact with eyes and skin.Prevent the direct contact of bees and other pollinators with the product by covering, for example with a flowerpot or a tile (ensuring that the ants still get access to the bait. |

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

|  |
| --- |
| See section 2.1.5.3 |

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

|  |
| --- |
| See section 2.1.5.4 |

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

|  |
| --- |
| See section 2.1.5.6 |

#### Use description 3.

**Table 3. Use 3 – Gel bait applied as traps (bait stations)- Indoors - Trained professional, professional and general public (non-professional).**

|  |  |
| --- | --- |
| **Product Type** | PT18.  |
| **Where relevant, an exact description of the authorised use** | Insecticide against ants. |
| **Target organism (including development stage)** | Insecticide against the following target insects (adults): * Argentine ants (*Linepithema humile*),
* Black ants (*Lasius niger*).
 |
| **Field of use** | Indoors. Residential, industrial, public and commercial or institutional buildings. |
| **Application method** | Ready-to-use bait stations. |
| **Application rate and frequency** | Dose: 0.3-0.6 g/m2, depending on the infestation level, preferably divided in several bait stations for better efficacyFor example, place 2 to 3 bait stations (with 5-15 g of bait in all) per 25 m2Frequency of application: After seven days, inspect the application points and place a new bait station if the bait has been consumed and the infestation is not controlled yet.Frequency of treatment: Three months after the infestation’s end, treatment may be repeated. Maximum of 8 applications per year.  |
| **Categoryies of users** | General Public (non-professional user)ProfessionalTrained professional |
| **Pack sizes and packaging material** | *General public and professional users:*Plastic bait station/bait station capsule with 1, 2, 3, 4, 5 and 6 g of gel bait.*Trained professional user:* Plastic bait station/bait station capsule with 1, 2, 3, 4, 5, 6, 8, 10, 15, 20, 25, 30 and 60 g of gel bait. |

##### Use-specific instruction for use.

|  |
| --- |
| Gel bait in transparent traps (bait stations).Place the bait stations in areas (indoors) where ants are present near the ant trails or nests. Inspect frequently the point of applications and place a new bait station if the bait has been consumed and the infestation is not controlled yet. |

##### Use-specific mitigation measures.

|  |
| --- |
| The stations should not be manipulated after opening.Never introduce the fingers through the holes in the bait station.Remove bait stations at the end of the treatment. |

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

|  |
| --- |
| See section 2.1.5.3 |

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

|  |
| --- |
| See section 2.1.5.4 |

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

|  |
| --- |
| See section 2.1.5.5 |

####  Use description 4.

**Table 4. Use 4 – Gel bait applied as traps (bait stations)- Outdoors - Trained professional user.**

|  |  |
| --- | --- |
| **Product Type** | PT18.  |
| **Where relevant, an exact description of the authorised use** | Insecticide against *Linephitema humile*. (adults) |
| **Target organism (including development stage)** | * Argentine ants (*Linepithema humile*),
 |
| **Field of use** | Outdoors (around buildings, terraces…): near ant trails or nests on paved surfaces.  |
| **Application method** | Ready-to-use bait stations. |
| **Application rate(s) and frequency** | Dose: 0.2-0.6 g/m2, depending on the infestation level, preferably divided in several bait stations for better efficacy.For example, place 2 to 3 bait stations (with 5-15 g of bait in all) per 25 m2Frequency of application: After seven days, inspect the application points and place a new bait station if the bait has been consumed and the infestation is not controlled yet.Frequency of treatment: Three months after the infestation’s end, treatment may be repeated. Maximum of 8 applications per year.  |
| **Category of users** | Trained professional users |
| **Pack sizes and packaging material** | Plastic bait station/bait station capsule with 1, 2, 3, 4, 5, 6, 8, 10, 15, 20, 25 and 30 g of bait.  |

##### Use-specific instruction for use.

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| Gel bait in transparent traps (bait stations).Place the bait stations in areas (outdoors) where ants are present near the ant trails or nests. Place the bait stations only on paved surfaces and in places where are protected from rainfall events to avoid release of the product into the environment and in places to avoid exposure to direct sunlight. Outdoor use (terraces, patios, backyards or gardens), apply MAGNUM GEL HORMIGAS IGR PLUS places where it is more likely to find ants.Inspect frequently the point of applications and place a new bait station if the bait has been consumed and the infestation is not controlled yet. |

##### Use-specific mitigation measures.

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| The stations should not be manipulated after opening.Never introduce the fingers through the holes in the bait station.Remove bait stations at the end of the treatment.Put the bait stations only in places where they are protected from rainfall events to avoid release of the product into the environment. |

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

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| See section 2.1.5.3 |

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

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| See section 2.1.5.4 |

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

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| See section 2.1.5.5 |

### General directions for use

#### Instructions for use

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| Always read the label or leaflet before use and respect all the instructions provided.After extensive inspection to determine the infestation level (low or high), place the bait points where ants are detected.Remove alternative food source that may be in competition from near areas.The product has shown an efficacy of more than 90% mortality of adult ants within 15 days.This biocidal product contains imidacloprid which is dangerours to bees.  |

#### Risk mitigation measures

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| Keep away from heat, open flames and sparks.Do not mix with other chemicals.Do not use on wood or porous surfaces.Avoid contact with treated surfaces.This product should be used in alternation with other products not containing the same a.s. to avoid resistant populations.The product should be reapplied when finished only until the pest is controlled.Use products at recommended doses and intervals.Use only in areas inaccessible to children and animalsDo not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.Trained professional uses:* -Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc).
* -Do not apply the product in areas where resistance to the active substance (s) contained in this product is suspected or established.

Professional and non-professional uses:* Inform the registration holder if the treatment is ineffective.
 |

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

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| Basic First aid procedures: * IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
* IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor. Medical advice for doctors and sanitary staff:* Symptomatic and supportive treatment

**IF MEDICAL ADVICE IS NEEDED, KEEP THE LABEL OR CONTAINER HANDY AND CONSULT THE MEDICAL SERVICE FOR TOXICOLOGICAL INFORMATION****Telephone: (please include the telephone number of each country)**To include this telephone number on the label, you must notify the INTCF in accordance with the procedure established in Order JUS / 909/2017.**Emergency measures to protect the environment:**Environmental Precautions: Avoid contamination of drains, surface and groundwater as well as soil. |

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

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| Trained professionals:Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.Code the waste according to Decision 2014/955 / EU.Do not release to soil, ground, surface water or any kind of sewer.General public and professionals:Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.Do not release to soil, ground, surface water or any kind of sewer. |

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

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| The storage stability of this product in its original container is 4 years under normal conditions of storage.Protect from frost.Store in the original container tightly closed. Store in a dry , cool and well-ventilated place. It is recommended to store the product at a temperature preferably between 5ºC and 45ºC.Store away from light.Keep out of reach of children and non-target animals/pets. |

### Other information

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| According to national legislation, in Spain there are until three user categories: * Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
* Professional users (NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
* Non-professional users (NP): users who are not professionals and that apply the biocidal product is in his private life.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types.The product contains a bitter substance that makes it repulsive to people or pets.The applicant must ensure that the general public can understand the difference between species and the level of infestation for correct use of the dose. The drops should have 0.2 g of gel bait. The applicant should indicate in the label the size of a drop with 0.2 g of product.The number of bait stations should be indicated in the label depending on the amount of product included in the bait station. E.g. 0.2 g/m2 = 1 bait station with 5 g in a room of 25 m2.For trained professional only:The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development. |

### 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)** |
| Cartridge | 1, 2, 3, 4, 5, 6, 7, 8,9, 10, 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 125, 150, 175, 200,250,300,350, 400, 450 and 500 g | LDPE | Plastic | Trained Professional | Yes |
| Syringe | 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45 g | LDPE | Plastic | General public  | Yes |
| 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60 g | LDPE | Plastic | Trained professional and professional |
| Bait station / Bait station capsule | 1, 2, 3, 4, 5, 6 g | LDPE | Plastic | General publicProfessional | Yes |
| 1, 2, 3, 4, 5, 8, 10, 15, 20, 25, 30 g | LDPE | Plastic | Trained Professional |  |

### Documentation

#### Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the biocidal product described within this application.

The reference list (including updates) for the studies submitted in support of the BPD dossier has been included in Annex 3.1 whilst the reference list for the studies considered confidential has been included in the Confidential PAR.

#### Access to documentation

Mylva S.A. has submitted Letter of Access for the active ingredients Imidacloprid and S-Methoprene from ADAMA AGRICULTURE ESPAÑA S.A. and Babolna Bio respectively.

The applicant has provided the Physical, Chemical and Technical Properties of the biocidal product for supporting the Physical hazards and respective characteristics.

The applicant has provided the suitable analytical methods for identifying the active substances in the biocidal product.

The applicant has also provided the rest of analytical methods. This information is complementary to the included data in the Competent Authority Reports on the active substances Imidacloprid and S-Methoprene supported by Bayer SAS and Babolna Bioenvironmental Centre Ltd. respectively.

The applicant has provided laboratory and field trials against three species of ants to support the efficacy. The trials have been carried out with the product and the sponsor was MYLVA,S.A. so a letter of access to the studies and the composition certificated of product tested have not been necessary.

In relation to human health, two studies have been submitted by the applicant to address the acute oral and dermal toxicity. These studies were conducted with the product GEL CUCARACHAS MYLVA IMIDACLOPRID 2.15%. The data provided for these acute toxicity studies refer to a worst case.

On the other hand, the applicant has submitted a justification for non-submission data for acute inhalation toxicity, dermal and eye irritation, skin sensitisation and dermal absorption. Spanish-CA accepts these justifications.

## Assessment of the biocidal product

### Intended uses as applied for by the applicant

Table 2. Intended use # 1 – **Trained Professional Users**

|  |  |
| --- | --- |
| Product Type | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Imidacloprid 0.01 % and 0.08% S-Methoprene Gel is an indoor an outdoor gel bait insecticide against Monoronium Pharaonis, Linepithema Humile and Lasius Niger.Imidacloprid 0.01% and 0.08% S-methoprene Gel is designed for the controlled placement of bait in the following situations:-User: Trained professional, Non-trained professional and general public (Nonprofessional). |
| Target organism (including development stage) | Monomorium Pharaonis-Adults, Nymphs-Pharaoh AntLinepithema Humile-Adults, Nymphs-Argentine AntLasius Niger-Adults, Nymphs-Black Ant |
| Field of use | IndoorOutdoorOther |
| Application method | Bait application -Indoor use: Place spots or lines of gel or baitstation near ant trails, or where ants have been seen, in their nests, or in the areas where ants are detected.Places where it is more probable to find ants are: hollowwalls, kitchen, bathrooms, sinks, windowsills, ventilation grilles, garages, attics, etc.Outdoor use: Place gel inside their nests, or place gel or bait station next to ant trails and where ants are detected, avoiding sunlight sothat the gel does not dry. Places where it is more probable to find ants are: eaves, cornices, draining holes,where cables and pipes enter the building structure, trees, stumps, roots, wood roofs, fences, plant pots, etc.Place on windowsills and doorways to avoid ant entering houses or buildings.After some days, inspect application points and repeat treatment if necessary until total colony control isachieved. Get rid of other near sources of food that could compete with the bait. |
| Application rates and frequency | Cartridge and syringe : Apply spots or lines of Gel on infested areas. Use 1-3 lines perbait placement. / Bait station: 5g/25m2 - 0 -Check the baits and replace the consumed ones daily during treatment. |
| Category of users | Trained professional |
| Pack sizes and packaging material | Three packaging are of plastic material. Cartridge and syringe are provided with a security cap.Cartridge: -Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450 and 500 g.Syringe:-Size: 1, 2, 3, 4, 5, 6, 7, 8,9, 10,15, 20, 25, 30, 35, 40, 50 g.Bait station:-Size: 1, 2, 2.5, 3, 4, 5, 8, 10, 15, 20, 25, 30 g. |

Table 2. Intended use # 2 – **Non-Trained Professional Users**

|  |  |
| --- | --- |
| Product Type | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Imidacloprid 0.01 % and 0.08% S-Methoprene Gel is an indoor an outdoor gel bait insecticide against Monoronium Pharaonis, Linepithema Humile and Lasius Niger. Imidacloprid 0.01% and 0.08% S-methoprene Gel is designed for the controlled placement of bait in the following situations:-User: Trained professional, Non-trained professional and general public (Nonprofessional). |
| Target organism (including development stage) | Monomorium Pharaonis-Adults, Nymphs-Pharaoh AntLinepithema Humile-Adults, Nymphs-Argentine AntLasius Niger-Adults, Nymphs-Black Ant |
| Field of use | IndoorOutdoorOther |
| Application method | Bait application -Indoor use: Place spots or lines of gel or baitstation near ant trails, or where ants have been seen, in their nests, or in the areas where ants are detected.Places where it is more probable to find ants are: hollowwalls, kitchen , bathrooms, sinks, windowsills, ventilation grilles, garages, attics, etc.Outdoor use: Place gel inside their nests, or place gel or bait station next to ant trails and where ants are detected, avoiding sunlight sothat the gel does not dry. Placeswhere it is more probable to find ants are: eaves, cornices, draining holes,where cables and pipes enter the building structure, trees, stumps, roots, wood roofs, fences, plantpots, etc.Place on windowsills and doorways to avoid ant entering houses or buildings.After some days, inspect application points and repeat treatment if necessaryuntil total colony control isachieved. Get rid of other near sources of food that could compete with the bait. |
| Application rates and frequency | Cartridge and syringe : Apply spots or lines of Gel on infested areas. Use 1-3 lines perbait placement. / Bait station: 5g/25m2 - 0 -Check the baits and replace the consumed ones daily during treatment. |
| Category of user | Professional |
| Pack sizes and packaging material | Three packaging are of plastic material. Cartridge and syringe are provided with a security cap.Cartridge: -Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450 and 500 g.Syringe:-Size: 1, 2, 3, 4, 56, 7, 8, 9, 10,15, 20, 25, 30, 35, 40, 50 g.Bait station:-Size: 1, 2, 2.5, 3, 4, 5, 8, 10, 15, 20, 25, 30 g. |

Table 3. Intended use # 3 – **Non-Professional User (General Public)**

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Imidacloprid 0.01 % and 0.08% S-Methoprene Gel is an indoor an outdoor gel bait insecticide against Monoronium Pharaonis, Linepithema Humile and Lasius Niger.Imidacloprid 0.01% and 0.08% S-methoprene Gel is designed for the controlled placement of bait in the following situations:-User: Trained professional, Non-trained professional and general public (Nonprofessional). |
| Target organism (including development stage) | Monomorium Pharaonis-Adults, Nymphs-Pharaoh AntLinepithema Humile-Adults, Nymphs-Argentine AntLasius Niger-Adults, Nymphs-Black Ant |
| Field of use | IndoorOutdoorOther |
| Application method(s) | Bait application -Indoor use: Place spots or lines of gel or baitstation near ant trails, or where ants have been seen, in their nests, orin the areas where ants are detected.Places where it is more probable to find ants are: hollowwalls, kitchen , bathrooms, sinks, windowsills, ventilation grilles, garages, attics, etc.Outdoor use: Place gel inside their nests, or place gel or bait station next to ant trails and where ants are detected, avoiding sunlight so that the gel does not dry. Placeswhere it is more probable to find ants are: eaves, cornices, draining holes,where cables and pipes enter the building structure, trees, stumps, roots, wood roofs, fences, plantpots, etc. Place on windowsills and doorways to avoid ant entering houses or buildings.After some days, inspect application points and repeat treatment if necessaryuntil total colony control isachieved. Get rid of other near sources of food that could compete with the bait. |
| Application rate(s) and frequency | Cartridge and syringe : Apply spots or lines of Gel on infested areas. Use 1-3 lines per bait placement. / Bait station: 5g/25m2 - 0 -Check the baits and replace the consumed ones daily during treatment. |
| Category of user | General public (non-professional) |
| Pack sizes and packaging material | Three packaging are of plastic material. Cartridge and syringe are provided with a security cap.Cartridge: -Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450 and 500 g.Syringe:-Size: 1, 2, 3, 4, 5, 6, 7, 8, 9,,10,15, 20, 25, 30, 35, 40, 50 g.Bait station:-Size: 1, 2, 2.5, 3, 4, 5, 8, 10, 15, 20, 25, 30 g. |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | US EPA Product Properties Test Guidelines: OPPTS 830.6303 Physical State[EPA 712-C-96-020]. | 0.01% (Imidacloprid) 0.08% (S-methoprene)Batch J709 | Initially:GelAfter 14 days at 54ºC:Gel After 17, 24, 36 & 48 months at 25ºC:Gel. | Final Report AGQ E-15/0003 |
| Colour at 20 °C and 101.3 kPa | US EPA Product Properties Test Guidelines: OPPTS 830.6302 Color [EPA712-C-96-019]. | 0.01% (Imidacloprid) 0.08% (S-methoprene)Batch J709 | Initially:10Y8/6 – yellowish traslucentAfter 14 days at 54ºC:7.5YR5/10 - brownAfter 17, 24, 36 & 48 months at 25ºC:10Y8/6 – yellowish traslucent | Final Report AGQ E-15/0003 |
| Odour at 20 °C and 101.3 kPa | US EPA Product Properties Test Guidelines: OPPTS 830.6304 Odor [EPA712-C-96-021]. | 0.01% (Imidacloprid) 0.08% (S-methoprene)Batch J709 | Initially:OdourlessAfter 14 days at 54ºC:OdourlessAfter 17, 24, 36 & 48 months at 25ºC:Odourless. | Final AGQ E-15/0003 |
| Acidity / alkalinity | Standard Methods for drinking water and wastewater, ALPHA- AWWA-WPCF, Edition 17th.CIPAC MT 75“Determination of pH Values” Handbook F, p 205, 1995.Free acidity or alkalinity. MT 31. Collaborative International Pesticides Analytical Council Limited(CIPAC) handbook. Volume F. | 0.01% (Imidacloprid) 0.08% (S-methoprene)Batch J709 | Not required.  | Final Report AGQ E-15/0003 |
| Relative density / bulk density | European Union EEC Method A.3. Pycnometer method. Council Regulation (EC) No 440/2008, of 30 May 2008, laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration,Evaluation, Authorization and Restriction of Chemicals (REACH). | 0.01% (Imidacloprid) 0.08% (S-methoprene)Batch J709 | 1.3046 ±0.0003 g/mL | Final Report AGQ E-15/0003 |
| Storage stability test – **accelerated storage** | CIPAC Guideline MT46.3"Accelerated Storage Procedure" | 0.01% (Imidacloprid) 0.08% (S-methoprene)Batch J709 | No change in physical conditions, colour or odour of the product was observed.Also there was no change in the packaging. | Final Report AGQ E-15/0003 |
| Active Ingredient Content | HPLC-MS (analytical method has been successfully validated) |  | IMIDACLOPRIDInitially:**0.0098 ± 0.0004 % w/w**After storage at 54 °C for 14 days:**0.0093 ± 0.0004 % w/w**Diference: -5.10%S-METHOPRENEInitially:**0.0845 ± 0.0055 % w/w** After storage at 54 °C for 14 days:**0.0832 ± 0.0025 % w/w** Difference: -1.54% |  |
| Homogeneity of application |  |  | The application system in both the syringe and the application gun for the cartridge container allow a precise and homogeneous application of the product in the form of drops of the same size and weight |  |
| Appearance and stability of the package |  |  | There was no change in the packaging (LDPE) |  |
| pH | Standard for Analysis of Water and Wastewater, ALPHAAWWA-WPCF, Edition 17th.CIPAC MT 75.3 “Determination of pH Values” Handbook F, p 205, 1995. |  | Initially:pH = 6.62 ± 0.01After storage at 54 °C for 14 days:pH = 6.27 ± 0.01 |  |
| Storage stability test – **long term storage at ambient temperature** | Guidelines for Specifying the Shelf Life of Plant Protection Products (Technical Monograph number 17, 2nd edition) | 0.01% (Imidacloprid) 0.08% (S-methoprene)Batch J709 | The formulation is stable for 4 years stored at ambient temperature. | Final Report AGQ E-15/0003 |
| Active Ingredient Content | HPLC-MS (analytical method has been successfully validated) |  | IMIDACLOPRIDInitially:**0.0098 ± 0.0004 % w/w** After storage at 25 °C for 12 months:**0.0098 ± 0.0003 % w/w** Diference: 0.00%After storage at 25 °C for 24 months:**0.0095 ± 0.0002 % w/w** Diference: 3.06%After storage at 25 °C for 36 months:**0.0097 ± 0.0002 % w/w** Difference: 1.02%After storage at 25 °C for 48 months:**0.0096 ± 0.0002 % w/w** Difference: -2.04%S-METHOPRENEInitially:**0.0845 ± 0.0055 % w/w**After storage at 25 °C for 12 months:**0.0848 ± 0.0040 % w/w**Difference: +0.36%After storage at 25 °C for 24 months:**0.0846 ± 0.0011 % w/w**Difference: 0.12%After storage at 25 °C for 36 months:**0.0802 ± 0.0040 % w/w**Difference: -5.09%After storage at 25 °C for 48 months:**0.085 ± 0.0009 % w/w** Difference: 1.02% |  |
| Homogeneity of application |  |  | The application system in both the syringe and the application gun for the cartridge container allow a precise and homogeneous application of the product in the form of drops of the same size and weight |  |
| Appearance and stability of the package |  |  | There was no change in the packaging (LDPE) |  |
| pH | Standard for Analysis of Water and Wastewater, ALPHAAWWA-WPCF, Edition 17th.CIPAC MT 75.3 “Determination of pH Values” Handbook F, p 205, 1995. |  | Initially:pH = 6.62 ± 0.01After storage at 25 °C for 17 months:pH = 6.31 ± 0.02After storage at 25 °C for 24 months:pH = 6.39 ± 0.02After storage at 25 °C for 36 months:pH = 6.57 ± 0.02After storage at 25 °C for 48 months:pH = 6.12 ± 0.01 |  |
| Storage stability test – **low temperature stability test for liquids** |  |  | Not applicable |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not relevant. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The formulation is stable for 4 years stored at ambient temperature. | Final Report AGQ E-15/0003 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | The formulation is stable for 4 years stored at ambient temperature. | Final Report AGQ E-15/0003 |
| Wettability |  |  | Not relevant. Not applicable as the product is a GL. |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not relevant. Not applicable as the product is a GL. |  |
| Wet sieve analysis and dry sieve test |  |  | Not relevant. Not applicable as the product is a GL. |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not relevant. Not applicable as the product is a GL. |  |
| Disintegration time |  |  | Not relevant. Not applicable as the product is a GL. |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not relevant. Not applicable as the product is a GL. |  |
| Persistent foaming |  |  | Not relevant. Not applicable as the product is a GL. |  |
| Flowability/Pourability/Dustability |  |  | Not relevant. Not applicable as the product is a GL. |  |
| Burning rate — smoke generators |  |  | Not applicable |  |
| Burning completeness — smoke generators |  |  | Not applicable |  |
| Composition of smoke — smoke generators |  |  | Not applicable |  |
| Spraying pattern — aerosols |  |  | Not applicable |  |
| **Other technical characteristics** |  |  |  |  |
| Determination whether a material is liquid or solid | ASTM D 4359-90 | 0.01% (Imidacloprid) 0.08% (S-methoprene)Batch J709 | Biocidal product is a liquid. | Interim Report M PG007-14/05 |
| Physical compatibility |  |  | Not relevant. |  |
| Chemical compatibility |  |  | Not relevant. |  |
| Degree of dissolution and dilution stability |  |  | Not applicable |  |
| Surface tension | European Union EEC Method A.5. Ring Method – Council Regulation (EC) No 440/2008, of 30 May 2008, laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).Chemistry and Physics, CRC Handbook (75th Edition).“Surface Tension of Aqueous Solutions”. OECD Guideline for the testing of chemicals115. 27 July 1995. | 0.01% (Imidacloprid) 0.08% (S-methoprene)Batch J709 | 43.8 ± 0.4 mM/mTherefore the sample is classified as a surface-active material. | Final Report AGQ E-15/0003 |
| Viscosity | “Viscosity of liquids”. OECD Guideline for testing of chemicals 114. 12 May 1981. | 0.01% (Imidacloprid) 0.08% (S-methoprene)Batch J709 | Initially:86052 mPa.s at 20 oC and 4 rpm.67542 mpa.s at 20ºC and 6 rpm46515 mpa.s at 40 oC and 4 rpm35796 mPa.s at 40ºC and 6 rpmAfter 14 days at 54ºC:53233 mPa.s at 20 oC and 4 rpm.41673 mpa.s at 20ºC and 6 rpm30644 mpa.s at 40 oC and 4 rpm24565 mPa.s at 40ºC and 6 rpmAfter 17 months at 25ºC:100832 mPa.s at 20 oC and 4 rpm.80584 mpa.s at 20ºC and 6 rpm62771 mpa.s at 40 oC and 4 rpm56978 mPa.s at 40ºC and 6 rpmAfter 24 months at 25ºC:100878 mPa.s at 20 oC and 4 rpm.86996 mpa.s at 20ºC and 6 rpm68832 mpa.s at 40 oC and 4 rpm52967 mPa.s at 40ºC and 6 rpmAfter 36 months at 25ºC:71892 mPa.s at 20 oC and 4 rpm.58043 mpa.s at 20ºC and 6 rpm62776 mpa.s at 40 oC and 4 rpm40338 mPa.s at 40ºC and 6 rpmAfter 48 months at 25ºC:73518 mPa.s at 20 oC and 4 rpm.58133 mpa.s at 20ºC and 6 rpm61884 mpa.s at 40 oC and 4 rpm40227 mPa.s at 40ºC and 6 rpm | Final Report AGQ E-15/0003 |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| **NOTE:** The applicant has declared that the composition of all batches used in the dossier is the same as the composition to be marketed.Batch J709 - due to Mylva's long experience in design, development and manufacture of gel-based formulations, the stability of the product at room temperature for 4 years has been established by previous stability tests.**Appearance**Magnum Gel Hormigas IGR Plus is a colourless practically odourless gel.**Acidity / alkalinity**No acidity/alkalinity has been reported as pH of sample is within the range 4-10.**pH**pH of a 1% w/v dilution.**Relative density / bulk density**The relative density of the biocidal product at 20ºC was determined according to EU Method A.3 (relative density), CIPAC MT 3.3.2 and Calculation under GLP. The determined relative density is 1.3046 ± 0.0003. The key study is supported by weight of evidences data from internal quality control that was adquired under GLP conditions.**Storage stability test – accelerated storage**After the inspection, no change in physical conditions, colour or odour of the product was observed.The data obtained in the simulation study of stability through accelerated storage indicate that the variation of the active ingredients contents (Imidacloprid and S-Methoprene) on MAGNUM GEL HORMIGAS IGR PLUS product after 14 days in the oven at 54 ± 2ºC were -5.10% and 1.54% respectively according to the data at t=0 days and at t=14 days.These results are within the range indicated in the Study for both active ingredients, according to “Guidelines for Specifying the Shelf Life of Plant Protection Products. Technical Monograph n°17, 2nd Edition”.**Storage stability test – long term storage at ambient temperature**After the inspection, no change in physical conditions, colour or odour of the product was observed.The data obtained at t=0 days and t=48 months during the long term storage study indicate that the variation of the active ingredients contents (Imidacloprid and S‐Methoprene) on MAGNUM GEL HORMIGAS IGR PLUS product after 48 months in the incubator at 25 ± 2ºC was -2.04 % and 1.02% w/w, respectively.These results are within the range indicated in the Study for both active ingredients, according to “Guidelines for Specifying the Shelf Life of Plant Protection Products. Technical Monograph n°17, 2nd Edition”.**Storage stability test – low temperature stability test for liquids**The biocidal product is a Liquid. Therefore, if this study is not submitted the phrase ‘protect from frost’ must be included in the label.**Effects on content of the active substance and technical characteristics of the biocidal product - light**Not relevant. Product is stored away from light.**Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity & reactivity towards container material**Temperature and humidity were monitored throughout storage. The product had approximately the same appearance and the packing remains unchanged after the accelerated storage and long term storage.**Technical characteristics of the biocidal product**Not applicable as the product is a GL.**Other technical characteristics -** **determination whether a material is a liquid or a solid** According to the interpretation of results, the Biocidal Product behaves as a liquid since all the product came out immediately when the can was put upside down.**Physical and chemical compatibility with other products**The product is ready to use and it is not intended to be used in mixture with any other product.**Surface tension**Under the conditions of this method, a substance showing a surface tension lower than 60 mN/m should be regarded as being a surface-active material.The average value obtained for surface tension of an aqueous solution of the analysed sample (178 mg/L) at 20ºC is 43.8 ± 0.4 mN/m. Therefore the analysed sample is classified as a surface-active material.**Viscosity** The viscosity of the biocidal product was determined under GLP condicions according to EU methods.**Conclusions** Magnum Gel Hormigas IGR Plus is a colourless practically odourless gel. The product has a density of 1.3046 ± 0.0003 g/mL and a viscosity of >2·105 mPa.s at 20ºC and 40ºC.Accelerated storage stability study (14 days, 54ºC ± 2ºC) has been performed to demonstrate that the product “MAGNUM GEL HORMIGAS IGR PLUS " is likely to be stable for two years at ambient storage.However, a long-term storage stability study of 4 years and compatibility with the LDPE original container concludes that the test product is storage stable at 25 ± 2 ° C for at least 48 months.The phrase ‘protect from frost’ must be included in the label because the low temperature stability test has not been submitted by the applicant. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives |  |  | Not explosive properties |  |
| Flammable gases |  |  | Not applicable |  |
| Flammable aerosols |  |  | Not applicable |  |
| Oxidising gases |  |  | Not applicable |  |
| Gases under pressure |  |  | Not applicable |  |
| Flammable liquids | Commission Regulation (EC) No 440/2008, Method A9Commission Regulation (EU) No 545/2011, 2.3(UNE-EN-ISO 3679) | 0.01% w/w ImidaclopridBatch K931 | The flash point is > 75ºC. Not flammable | See PAR confidential |
| Flammable solids |  |  | Not applicable |  |
| Self-reactive substances and mixtures |  |  | Not self-reactive |  |
| Pyrophoric liquids |  |  | Not applicable |  |
| Pyrophoric solids |  |  | Not applicable |  |
| Self-heating substances and mixtures |  |  | Not applicable |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not applicable |  |
| Oxidising liquids |  |  | Not oxidising properties |  |
| Oxidising solids |  |  | Not applicable |  |
| Organic peroxides |  |  | Not applicable |  |
| Corrosive to metals | ASTM G 31 (equivalent to UN MTC C.1) |  | Not corrosive to metals | See confidential PAR |
| Auto-ignition temperatures of products (liquids and gases) |  |  | Not applicable |  |
| Relative self-ignition temperature for solids |  |  | Not applicable |  |
| Dust explosion hazard |  |  | Not applicable |  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| **NOTE:** The applicant has declared that the composition of all batches used in the dossier is the same as the composition to be marketed.Batch J709 - due to Mylva's long experience in design, development and manufacture of gel-based formulations, the stability of the product at room temperature for 4 years has been established by previous stability tests.**Explosiveness**The concentration of imidacloprid in the biocidal product is 0.01% and its contribution to the biocidal product explosiveness is anticipated to be very low.S-methoprene is not explosive and the co-formulants (water, the different sugars, glycerol) do not comprise any structural markers for explosive properties.In addition, the biocidal product is a water-based product (>30%).Hence, in spite of the presence of chemical groups in the molecule which are associated with explosive properties, there are no substances present in the biocidal product associated with explosive properties, or, the sole substance that might be associated to explosive properties shows a minimum effect, or, the explosive properties of the biocidal product are not foreseen.Furthermore, a read across can be established with other neonicotinoids (e.g. thiametoxam, acetamiprid, chlotianidin, thiacloprid) with similar oxygen balance and chemical groups indicators of explosive properties. These neonicotinoids have no explosive properties according to their ARs and CLH reports, therefore, it can be anticipated that the imidacloprid will not have explosive properties.Finally, even thought OECD 113 could be considered similar but not 100% equivalent to the study included in the section 20.3.3.3 of the UN MTC, the conclusions reached characterize the behaviour of the biocidal product. We can conclude form this study:* The biocidal product is stable at room temperature.
* The biocidal product is fully molten at 170ºC.
* Taking into account that the DSC of the b.p. presents a multistage decomposition above 200ºC with low enthalpies and Imidacloprid decomposes above 200ºC, it can be assumed that the imidacloprid does not contribute to the explosive properties of the biocidal product due to its low concentration and decomposition

**Flammability**The product MAGNUM GEL HORMIGAS IGR PLUS is not expected to be flammable. See confidential PAR for more information on set read across.**Self-reactive substances and mixtures**The classification procedure for self-reactive properties does not need to be applied for imidacloprid according to the AR and CLH reports.S-methoprene is not self-reactive according to its AR and CLH reports and the co-formulants (water, the different sugars, glycerol) do not comprise any structural markers for self-reactive properties.Hence, in spite of the presence of the chemical groups in the imidacloprid which are associated with self-reactive propertie, the self-reactive propertie of the biocidal product is not foreseen and no new data are necessary and the classification procedure does not need to be applied.**Pyrophoric solids**The study does not need to be conducted based on the experience/handling of the biocidal product..**Self-heating substances and mixtures**The study does not need to be conducted based on the experience/handling of the biocidal product.**Substances and mixtures which in contact with water emit flammable gases**The study does not need to be conducted because none of the components is expected to emit flammable gases when they are in contact with water.**Oxidising properties**According to the ARs and the CLH reports of both active substances, Imidacloprid and s-Methopren do not show oxidising properties and their concentration is less than 0.1 %.The other ingredients (water, the different sugars, glycerol) do not comprise any structural markers for oxidising properties and therefore testing is not necessary. Which means that they can be regarded as non-oxidising.Additionally the “Guidance on the Application of the CLP Criteria” states that:„An inert material by definition does not contribute to the oxidising capability of the oxidising substance. Hence, the mixture can never be classified into a more severe hazard category.“Therefore the mixture can be regarded as non-oxidising.**Organic peroxides**The study does not need to be conducted because none of the components does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual tests and criteria.**Corrosive to metals**It is not possible to waive an endpoint on physical hazards by the structure of the BP components, when one of the components (imidacloprid comprises chlorine) comprises a chemical group which indicates that the BP may corrode metals. Therefore, the test needs to be applied.After the immersion test, the sample presents pitting corrosion; reaching up to one depth of approximately 26 μm (<120 μm) of the base material. Furthermore, the data, photos and micrographs in the report clearly show that the product Magnum Gel Hormigas IGR Plus is not corrosive. **Auto-ignition temperature (liquids and gases)**The 0.01 % w/w Imidacloprid and 0.08 % w/w S-methoprene Gel formulation is not expected to be flammable.The test was omitted because the product MAGNUM GEL HORMIGAS IGR PLUS is not expected to have oxidizing and flammable properties. See confidential PAR for more information on set read across.**Conclusions** It is not considered as explosive and does not contain any ingredient which may indicate oxidizing properties on combustible material. It is not flammable and not corrosive to metals.Magnum Gel Hormigas IGR Plus is not considered to be potentially explosive or contain an oxidising or reducing agent. The preparation is not recommended for use with other products.The technical properties indicate that no particular problems are to be expected when it is handled, stored or applied as recommended. |

### Methods for detection and identification

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| **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 (%)1** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Imidacloprid* | LC-MS | 5 | 0.025-0.500 mg/Ly=2.887374E+08x + 9.360824E+06r2=0.9986n = 7 | Yes. No other peaks observed. | / | / | / | / | FINAL REPORT E- 15/0003 |
| *S-Methoprene* | LC-MS | 5 | 0,2-1,0 mg/Ly=1.04E+04x + 55.5r2=0.9992n = 6 | Yes. No other peaks observed. | / | / | / | / |
| *1 “Due to samples were simple solution of the preparation in a solvent, recovery is not required.” The metrological compatibility of nominal or declared and measured mass concentration values of both active substances has been fulfilled and therefore the reliability of the results was confirmed by several determinations within long term period* |

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| **Analytical methods for soil** |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Imidacloprid (soil)* | LC-MS/MS |  |  |  |  |  |  | 0.005 mg/kg | CAR (2011) |
| *Imidacloprid (soil)* | HPLC-UV RP-18 and CN column |  |  |  |  |  |  | 0.005 mg/kg | CAR (2011) |

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| **Analytical methods for air** |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Imidacloprid (air)* | HPLC-UV RP-18 column |  |  |  |  |  |  | 0.005 mg/m3 | CAR (2011) |
| *Imidacloprid (air)* | HPLC-UV CN column |  |  |  |  |  |  | 0.005 mg/m3 | CAR (2011) |

| **Analytical methods for water** |
| --- |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Imidacloprid (drinking and surface water)* | HPLC-UV RP-18 and CN column |  |  |  |  |  |  | 0.03 µg/L | CAR (2011) |
| *Imidacloprid (surface water)* | LC-MS/MS |  |  |  |  |  |  | 0.1 µg/L | CAR (2011) |
| *s-Methoprene in Drinking water* | GC-MS(m/z = 175, 191 and 219 m/z) | 0.1 μg/L (n=5) | r >0.9960.07 – 1.2 µg/L 8 point calibration | Retention time match between standard and sample for analyte. The method of analysis is considered to be highly specific (GC-MS with 3 ions > 100m/z used for identification) | 74 – 107 | 95 | 13.3 | 0.1 μg/L | CAR (2013) |
| 1.0 μg/L (n=5) | 97 – 110  | 105 | 5.15 |
| *s-Methoprene in Surface water* | GC-MS(m/z = 175, 191 and 219 m/z) | 0.1 μg/L (n=5) | r >0.9960.07 – 1.2 µg/L 8 point calibration | Retention time match between standard and sample for analyte. The method of analysis is considered to be highly specific (GC-MS with 3 ions > 100m/z used for identification) | 70 – 82 | 75 | 6.1 | 0.1 μg/L | CAR (2013) |
| 1.0 μg/L (n=5) | 77 – 110 | 96 | 17.3 |
| *s-Methoprene in Ground water* | *GC-MS**(m/z = 175, 191 and 219 m/z)* | 0.1 μg/L (n=5) | r >0.9960.07 – 1.2 µg/L 8 point calibration | Retention time match between standard and sample for analyte. The method of analysis is considered to be highly specific (GC-MS with 3 ions > 100m/z used for identification) | 74 – 96 | 82 | 10.6 | 0.1 μg/L | CAR (2013) |
| 1.0 μg/L (n=5) | 89 - 110 | 99 | 8.5 |

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| **Conclusion on the methods for detection and identificationof the product** |
| **NOTE:** The applicant has declared that the composition of all batches used in the dossier is the same as the composition to be marketed.Batch J709 - due to Mylva's long experience in design, development and manufacture of gel-based formulations, the stability of the product at room temperature for 4 years has been established by previous stability tests.**Analytical methods for the analysis of the product as such including the active substance**The method was validated according to the requirements guideline SANCO 3030/99 rev.4**Analytical methods for soil**It is proposed that the analytical methods for the determination of Imidacloprid and S-methoprene content in the preparation Magnum Gel Hormigas IGR Plus is also relevant to determinate the Imidacloprid and S-methoprene content in soil. No additional residues are formed in the product. Please refer to the letter of access granted by BAYER and Babolna Bio Ltd to MYLVA S.A. for the information regarding the active ingredients Imidacloprid and S-methoprene.**Analytical methods for air**It is proposed that the analytical methods for the determination of Imidacloprid and S-methoprene in air are not applicable according to the physicochemical properties of the biocidal product.**Analytical methods for water**It is proposed that the analytical methods for the determination of Imidacloprid and S-methoprene content in the preparation Magnum Gel Hormigas IGR Plus is also relevant to determinate the Imidacloprid and s-methoprene content in water. No additional residues are formed in the product. Please refer to the letter of access granted by BAYER and Babolna Bio Ltd to MYLVA S.A. for the information regarding the active ingredients Imidacloprid and S-methoprene.**Analytical methods for animal and human body fluids and tisues**It is proposed that the analytical methods for the determination of Imidacloprid and s-methoprene content in the preparation Magnum Gel Hormigas IGR Plus is also relevant to determinate the Imidacloprid and s-methoprene contenct in animal and human body fluids and tisues. No additional residues are formed in the product. Please refer to the letter of access granted by BAYER and Babolna Bio Ltd to MYLVA S.A. for the information regarding the active ingredients Imidacloprid and S-methoprene.**Analytical methods for monitoring of active substances and residues in food and feeding stuff**It is proposed that the analytical methods for the determination of Imidacloprid and s-methoprene in treated food or feeding stuffs are not applicable according to the intended use of the biocidal product.**Conclusions**Determination of the active substances Imidacloprid and S-methoprene has been performed by a HPLC-MS system. The method has been successfully validated and is considered acceptable.The applicant has submitted the Letter of Access granted by Bayer Environmental Science for information on Analytical methods for the Imidacloprid active substance and to the Letter of Access granted by Babolna Bioenvironmental Centre Ltd for information on Analytical methods for the S-methoprene active substance:IMIDACLOPRIDResidue analytical methods are available for determination of Imidacloprid in soil, air, drinking and surface water. The analytical method for the determination of residues in surface water is also validated for the metabolites guanidine, olefinic compound and urea compound. Validated confirmatory methods for soil, drinking and surface water were presented. An analytical method for the determination of residues in air using a column of different selectivity was presented. Although the method is not validated in the necessary extent, it is considered to be appropriate for confirmatory purposes. According to the residue definition and the intended uses for the Annex I inclusion no analytical methods for residues in body fluids and tissues, plants and animal matrices are necessary.S-METHOPRENEAnalytical methods for determination of S-methoprene in soil, food and foodstuffs were not submitted based on the specific use of the product. An acceptable method was supplied for analysis of residues of parent S-methoprene in surface, ground and drinking water to an LOQ of 0.1 µg/L. A method for residues in air is not required based on the results of the vapour pressure study (v.p. <0.01 Pa). Because the molecule does not classify as either toxic or very toxic, a method for residues in body fluids and tissues is not required.Finally, the available methods are considered acceptable and scientifically valid. |

### Efficacy against target organisms

#### Function and field of use

Main Group 03: Pest Control

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

MAGNUM GEL HORMIGAS IGR PLUS is presented as a ready-to use gel bait insecticide and packaged in a bait station, a syringe or a cartridge. It is intended to be used by trained professionals, professionals and non-professionals (general public).

The biocidal product MAGNUM GEL HORMIGAS IGR PLUS is a bait preparation used against ants’ infestations indoors and outdoors (e.g. terraces, patios, etc.) in houses and industrial/commercial buildings by spot application.

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

MAGNUM GEL HORMIGAS IGR PLUS is used against tropical and garden ants (*Linepithema humile and Lasius niger*).

The products, organisms or objects to be protected are stored products and food from private houses and commercial buildings.

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

MAGNUM GEL HORMIGAS IGR PLUS is formulated with two active substances (insecticides):

- Imidacloprid (adulticide)

It belongs to the chemical family of nitroguanidines (neonicotinoids). These act by binding to the insects’ neurons. This binding causes a disturbance in the transmission of nerve impulses which is lethal to the target insects.

- S-Methoprene (ovicide)

It belongs to the group of Insect Growth Regulators (IGR). It acts as a juvenile hormone analogue to disrupt the normal development of insects. It displays no immediate killing effect on the target organisms but disrupts metamorphosis. Therefore the maturation processes to the adult stage is impaired and individuals develop physical deformities and cannot mature to reproductive adults.

#### Mode of action, including time delay

Ants are attracted by some nutritional ingredients that are present in the formulation and spread the gel insecticide by moving and causing poisoning (by contact and ingestion) and the indirect death of the individuals who live in the colony, regardless their stage of development (pupae, adults). In field trials most ants were killed after 2 weeks of exposure to the gel bait (either by drops or by bait stations).

In addition queen ants will not be able to reproduce (production of eggs) as a consequence of the Insect Growth Regulator (S-Methoprene). These effects will be noticed after six weeks of exposure to the gel bait.

#### Efficacy data

**DROPS:**

| **Experimental data on the efficacy of the biocidal product against target organism(s)** |
| --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organisms** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Laboratory | Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait) | *Linepithema humile* | Laboratory bioassay:Mortality and palatability Gel bait applied as drops/lines on slide | Choice test arena. 4 replicates and control. N ≈ 320 workersArena 18 x 18 cmDose: 3 cm line (0.2 g) per replicate.Continuous exposure until day 44 | ≥ 95% average mortaility in 44 days (controls 11.4%). Palatable bait (fresh bait). | Test report: ES0018-13/23See confidential annex |
| *Monomorium pharaonis* | ≥ 95% average mortaility in 44 days (controls 33.8%).Low palatability (fresh bait). |
| *Lasius niger* | ≥ 95% average mortaility in 18 days (controls 19.3%).Palatable bait (fresh bait). |
| Insecticide | Indoors | Imidacloprid 0.01% w/w and s-Methoprene 0.08% w/w (gel bait) | *Lasius niger* | Simulated-useGel bait applied as spot treatment on Petri dishes (non-porous)1 drop= 1 line of 3 cm length=0.2g of gel bait.  | Simulated kitchen (6.25 m2) with AFS3 replicates per treatment and controln ≈ 800 workers and one queen.A total of 1.25 g of the product was applied. Dose rate: 0.2 g/m2. (1 drop/m2)No re-application.  | Av. population reduction 98.9% in 15 days. Control 4.9% | Test report ES0034-A/7See confidential annex |
| Insecticide | Outdoors | Imidacloprid 0.01% w/w.gel bait) | *Lasisu niger* | Field trial.Gel bait applied as spot treatment.1 drop= 1 line of 3 cm length=0.2g of gel bait | Site 4: open area, 5.5m2 Initial application: 1.1gInitial dose rate: 0.2g/m2 Day 6: re-aplication 1.1gTotal amount: 2.2 gAverage dose in 15 days: 0.2 g/m2.Site 5: open area, 4m2 Initial application: 0.8 gInitial dose rate: 0.2g/m2 Day 6: re-aplication 0.8 gDay 9: re-aplication 0.4gTotal amount: 2 gAverage dose in 15 days: 0.5 g/m2.Site 6: open area, 3m2 Initial application: 0.6 gInitial dose rate: 0.2g/m2 Day 6: re-aplication 0.6 gTotal amount: 1.2 gAverage dose in 15 days: 0.2 g/m2. | Average mortality: 97.1% after 15 days.0% in control*.* The population of the control colonies has remained stable. | Test report: 13/062Complementary study. |
| Insecticide | Outdoors | Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait) | *Linepithema humile* | Field trialGel bait in bait station or as spot treatment on non porous surfaces. .Reapplication when consumed. | Site 1: open area, 100.5m2 11 bait stations (5 g/trap).Ínitial application: 55g.Initial dose rate: 0.5g/m2 Day 2: 3 traps were cancelled and 2 traps were replaced. (10 g)Day 4: 2 traps were replaced. (10g)Day 10: 2 traps were replaced. (10 g)Total amount: 85 gAverage dose in 15 days: 1.18g/m2.Site 2: around building. 70.5 m2. Initial application: 14.1g. Initial dose rate:0.2g/m2. Day 2: re-application 2.3g. Day 4: re-application 2g. Day 10: re-application 2g.Total amount: 20.4g.Average dose in 15 days: 0.28g/m2Site 3: around building, 61 m2. Initial application:12.2gInitial dose rate:0.2g/m2 Day 2: re-application 3g. Day 4: re-application 3.5g. Day 10: re-application 1.5g.Total amount 20.2 g.Average dose in 15 days; 0.3g/m2Site 4: around building. 59 m2, Initial application:11.8gInitial dose rate:0.2g/m2 Day 2: re-application 2.5g. Day 4: re-application 3g. Day 10: re-application 2.Total amount 19.3 g.Average dose in 15 days: 0.3g/m2 | Average population reduction 98.7% after 15 days.The population of the control colonies has remained stable. | Test report:ES0032-4/12See confidential annex |
| Insecticide | Indoors  | *Monomorium pharaonis* | Simulated-useGel bait applied as spot treatment on petri dishes (non-pororus surfaces).1 drop= 1 line of 3 cm length=0.2g of gel bait.. | Simulated kitchen (3.24 m2) with AFS3 replicates per treatment and controlsn ≈ 900-1500 workers + 20 queensA total of 2 g of the product was applied. Dose rate: 0.6 g/m2. (3 drops/m2)No re-application.  | Average population reduction 99.1% after 15 days. Untreated control:25.4% |
| Insecticide | Laboratory | S-methoprene 0.08% w/w (gel bait) | *Linepithema humile* | Laboratory trail:Egg production. Gel bait as lines in slide. | Choice test (AFS) in arenas.Fresh bait. 3 replicates and 2 controlsn ≈ 100 workers + 1 gravid queen + eggs + larvaeArenas 18 x 18 x 12 cmDose 0.1 g (1 line of 2 cm per arena) Continuous exposure until 6 weeks. | Average reduction of no. of eggs 100% in 6 weeks The total population (larvae, eggs and pupae) of the controls have remained stable. | ES0046.A-3/19See confidential annex |
| Insecticide | Laboratory | Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait). 3 years of being manufactured and stored.  | *Lasius grandis* | LaboratorySimulated-use test:.Mortality and palatability. Gel bait applied as drops/lines on slide | Test ARENA 18x18x12 cm.Dose: 2cm line (0.1g)3 replicates and an untreated control.Continuous exposure until 11 days. | 100% mortality in 11 days. (control 4.4%)Palatable bait (aged bait).N=233-262 | Study ES0035-3/12See confidential annex |
| *Linephitema humile* | 100% mortality in 11 days. (control 6.5%)Palatable bait with aged bait.N=209-260 |
| *Monomorium pharaonis* | 100% mortality in 11 days.(control 8.5%)Palatable bait with aged bait.N=171-236 |
| Insecticide | Laboratory | Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait). 4 years of being manufactured and stored.  | *Lasius grandis* | LaboratorySimulated-use test:.Mortality and palatability. Gel bait applied as drops/lines on slide | Test ARENA 18x18x12 cm.Dose: 2cm line (0.1g)3 replicates and an untreated control.Continuous exposure until 11 days | 100% mortality in 11 days (control 3.29%)Palatable bait (aged bait).N=161-229 workers | Study ES0035-11/19See confidential annex. |
| *Linephitema humile* | 100% mortality in 11 days (control 7.37%)Palatable bait N=178-258 workers |
| *Monomorium pharaonis* | 100% mortality in 11 days. (control 8.86%)Palatable bait (aged bait).N=208-225 workers. |

**BAIT STATION:**

| **Experimental data on the efficacy of the biocidal product against target organism(s)** |
| --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organisms** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Laboratory | Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait) | *Linepithema humile* | Laboratory bioassay:Mortality and palatability.Gel bait in bait station. | Choice test in arenas. Three replicates were conducted for each treatment with black ant (*Lasius niger*) and argentine ant (*Linepithema humile* ).Four replicates were conducted for pharaoh ant (*Monomorium**pharaonis*).Each replicate consisting for one ant colony in one test arena.Arenas 28 x 15 cm (420 cm2)Dose rate: 1 bait station per arena (1g of product) Continuous exposure until day 35 | ≥ 95% average mortality in 14 days (control 14%). N:400 workers+ 3 queens.Palatable bait (fresh bait). | Study ES0039/02See confidential annex |
| *Monomorium pharaonis* | ≥95% average mortality in 35 days (control 9%).N:400 workers.Palatable bait (fresh bait). |
| *Lasius niger* | 100% moratilty in 13 days (control 7%).N:400 workers.Palatable bait (fresh bait). |
| Insecticide | Indoors / outdoors | Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait) | *Linepithema humile* | Field trialGel bait in bait station. Reapplication when consumed. | Site 1: indoors, 9 m2, 2 stations (1 g/trap), 0 bait station were replaced.Dose rate: 0,23g/m2Site 2: outdoors, 115m2, 3 stations (5 g/trap), one trap were replaced at 10 days. Dose rate:0.18g/m2Site 3:indoors, 15 m2 3 stations, 1 g/trap, 0 bait station were replaced.Dose rate: 0.2 g/m2 | Average population reduction 97.8% after 15 days-The population of the control colonies has remained stable. | Study: ES0036-7/13See confidential annex |
| *Monomorium pharaonis* | Simulated-use trialGel bait in bait station. No re-application.  | Simulated kitchen (6.25 m2) with AFS including proteins3 replicates and a control per organism.n ≈ 800 workers + 20 pharaoh queens.n≈ 800 workers +1 black ant queen.Dose rate: 0.32 g/m2. Total amount: 2 bait stations (1 g/station). | Av. population reduction 98.5% after 15 d.Untreated control 5.84% |
| *Lasius niger* | Av. population reduction 98.4% after 15 d.Untreated control 6.15% |
| Insecticide | outdoors | Imidacloprid 0.01% w/w (gel bait) | *Linephitem humile* | Field trialGel bait in bait station. Reapplication when consumed. | Site 1: outdoors, 120 m2, Initial aplication: 3 stations (5 g/trap), Initial dose: 0.125g/m2Day 9: 1bait station were replaced.Total amount: 20g (4 bait stations)Average dose in 15 days: 0,16 g/m2Site 2: outdoors, 129m2, Initial application:3 stations (5 g/trap), Initial dose: 0.11g/m2Day 9: 1bait station were replaced Total amount: 20g. (4 bait stations)Average dose in 15 days:0.15g/m2Site 3:outdoors 210 m2 Initial applications: 5 stations, (5 g/trap).Initial dose: 0.11g/m2Day 5: 2 bait station were replaced.Total amount: 35 g (7 bait stations)Average dose in 15 days: 0.16 g/m2 | Average population reduction 98.4% after 15 days-The population of the control colonies has remained stable. | Test report: ES0036-7/12 (2014)Complementary study |

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| **Conclusion on the efficacy of the product** |
| **EFFICACY AS ADULTICIDE**MAGNUM GEL HORMIGAS IGR PLUS has demonstrated sufficient efficacy in laboratorywith choice and field/simulated-use trials against three species of ants (*Monomorium pharaonis, Linepithema humile* and *Lasius niger*) living in houses, gardens and commercial buildings. The aplicant has submitted andsimulated use/ (semi) field trials with bait stations and drops/lines. The studies weres performed according to the TNsG for PT 18 and PT 19 (CA-Dec12-Doc.6.2.a-Final).The biocidal product is formulated as bait, containing attractive nutritional elements for ants. In case of baits, the Guidance indicates that intrinsic palatability of the formulated bait should be enough to prove acceptable toxicity in competition with the alternative food source. Palatability of the fresh bait containing MAGNUM GEL HORMIGAS PLUS was demonstrated for the three species; and it was particularly atractive for *L. niger* and *L. humile.***GEL BAIT BY DROPS/LINES**The Applicant submitted three laboratory trials and two simulated-use trials against *Lasius niger, Monomorium pharonis and Linepithema humile*. The application method is by drops/lines. 1. The simulated use study with fresh was conducted in a test arena (18 x 18 cm) with 4 replicates per treatment and 1 control replicate. A population of around 340 workers was tested in each replicate. The gel bait was applied onto an acetated sheet as 3cm line (1 drop=0.2g per replicate). An AFS (honey) was included to investigate the palatability of the product.

*Lasius niger*: The study proved the efficacy against this species. Average mortality was ≥ 95% in 18 days. The average mortality in controls was 19,3%, probably for additional stress. Even so, these high controls mean that the study cannot be validated for this species, but the applicant has also provided laboratory tests with bait aged at 3 (Study ES0035-3/12) and 4 years (Study ES0035-11/19) , which do allow to demonstrate the efficacy of the product in laboratory.*Monomorium pharaonis*:The study proved the efficacy against this species. Average mortality was ≥ 95% in 44 days. The average mortality in controls is very high was 33.8% average, but it is a normal thing when working with small colonies for this specie in laboratory tests that run for a long period. Even so, these high controls mean that the study cannot be validated for this species, but the applicant has also provided laboratory tests with bait aged at 3 (Study ES0035-3/12) and 4 years (Study ES0035-11/19) , which do allow to demonstrate the efficacy of the product in laboratory.*Linepithema humile*:The study proved the efficacy against this species. Average mortality was was ≥ 95% in 44 days. The average mortality in controls was 11.4%. There was a field trial against *Linepithema humile*, including one outdoor site with application by traps and three around building sites with spot application of the gel bait as droplets. The application rate was 0.2-0.6g/m2. The product was re-applied where the bait had been consumed after few days/weeks following the first application. If we only take into account the sites applied by droplets, the data show that there is an average reduction of more than 90% of the population in 15 days. Therefore the product demonstrated the efficacy under worst-case conditions in actual field sites.There were two simulated-use studies with spot application of the product as drops/lines. Trying to gain access to possible sites infested with *Lasius niger* and *Monomorium pharaonis* was a significant challenge and following almost one year in trying to find suitable and cooperatives sites the laboratory decided to conduct a simulated use test. The test systems were built up in a simulated kitchen of 3.24 m2 (*M. pharaonis*) and 6.25 m2 for (*L. niger*) in the presence of an AFS. There were 3 replicates per treatment and controls. The population included 800 worker balck ants and one queen and 900-1500 pharaoh workers plus 20 queens. *Lasius niger*: The study proved the efficacy against this species. In total, 1.25 g of bait was applied in Petri dishes, giving a tested dose of 0.2g/m2 were used. The study proved the efficacy against this species. Average population reduction was 98.9% after 15 days. The average mortality in controls was 4.9%. In addition, as a complementary study, a field test against *Lasius niger* is incorporated. The test has been carried out with the MAGNUM GEL HORMIGAS PLUS product.(Go to confindential PAR to see the composition and justification of the read across).The doses and exposure time of the bait is the same. The test shows that the product is effective when applied at a dose of 0.2-0.5 g/m2. Average mortality: 97.1% after 15 days. The population of the control colonies has remained stable.*Monomorium pharaonis*:The study proved the efficacy against this species. In total, 2.0 g of bait was applied in Petri dishes, giving a tested dose of 0.6 g/m2 were used. Average population reduction was 99.1% after 15 days. The average mortality in controls was 25.4%. As we mentioned before, is a normal thing when working with small colonies for this specie for a long period.No field trials have been provided against this species, therefore the data package is incomplete and cannot be authorized.**The eCA concludes that the product MAGNUM GEL HORMIGAS IGR PLUS is effective against *Lasius niger, and Linephitema humile* (adults) with the method of application by droplets on non-porous surfaces indoors. In relation to open areas, it has only been demonstrated against *Linephitema humile*. We think that it cannot be guaranteed that the general public will be able to distinguish this species. Therefore, only trained professional will be authorized to use outdoors against *Linephitema humile*.****BAIT STATIONS INCLUDING GEL BAIT INSIDE**In a simulated use, MAGNUM GEL HORMIGAS IGR PLUS demonstrated its efficacy as insecticide against three species of ants (adults) living in houses and other commercial buildings. The product was applied by placement of ready-to-use bait stations (1 g/station) inside the arenas (1 station/arena) in the presence of AFS. Arenas (28 x 15 cm) included a population of around 400 workers. 4 replicates per treatment and controls were set up. Palatability was demonstrated for the three species. *Lasius niger*: The study proved the efficacy against this species. Average mortality was 100% in 13 days. The average mortality in controls was 7%.*Monomorium pharaonis*:The study proved the efficacy against this species. Average mortality was 97% in 35 days. The average mortality in controls was 9%.*Linepithema humile*:The study proved the efficacy against this species. Average mortality was 99% in 14 days. The average mortality in controls was 14%. There was a field trial against *Linepithema humile*, including one outdoor and two indoor sites, and application of the gel bait by placement of bait stations. The initial application rate was 0.2 g/m2 (range 0.17-0.23 g/m2). The average population reduction was 97.8% after 15 days. In addition, as we have already discussed, there is another field study with *L. humile* including one site in an open area (outdoors). A preliminar assessment was made to estimate the infestation level. 5 stations containing 5 g of gel bait were placed at start. In total 11 bait stations were needed to control the infestation (i.e. 55 g). The average population reduction was 100% after 4 days. In addition, as a complementary study, a field test against *Linephitema humile* is incorporated. The test has been carried out with the MAGNUM GEL HORMIGAS PLUS product.(Go to confindential PAR to see the composition and justification of the read across).The doses and exposure time of the bait is the same. The test shows that the product is effective outdoors when applied at a dose of 0-2 g/m2. Average mortality: 98.4% after 15 days. The population of the control colonies has remained stable.Therefore the product demonstrated efficacy against this species under outdoor and indoor conditions.There were two simluated- studies against *Monomorium pharaonis* and *Lasius niger* with application of the product in bait stations.Tthe laboratory justification is the same as for droplet tests.The test systems were built up in a simulated kitchen of 3.24 m2 (*M. pharaonis*) and 6.25 m2 for (*L. niger*) in the presence of an AFS. There were 3 replicates per treatment and controls. The population included 800 worker black ants and 900-1500 pharaoh workers plus 20 queens. A total of 2 bait stations with 1 g/station were applied in each site, starting with 1 station. Therefore the dose was estimated as 0.32 g/m2. *Lasius niger*: The study proved the efficacy against this species. Average population reduction was 98.4% after 15 days. The average reduction in controls was 6.15%.No field trials have been provided against this species, but taking into account that a simulated-use trial with traps has been provided, and a field trial with droplets, (which is a worse case) we accept the data package to authorize this species with bait stations.*Monomorium pharaonis*:The study proved the efficacy against this species. Average population reduction was 98.5% after 15 days. The average reduction in controls was 5.8%.No field trials have been provided against this species, therefore the data package is incomplete and cannot be authorized.**The eCA concludes that the product MAGNUM GEL HORMIGAS IGR PLUS is effective against *Lasius niger, and Linephitema humile* (adults) with the method of application by placement of bait stations indoors. In relation to open areas, it has only been demonstrated against *Linephitema humile*. We think that it cannot be guaranteed that the general public will be able to distinguish this species. Therefore, only trained professional will be authorized to use outdoors against Linephitema humile. .****EFFICACY AS OVICIDE**MAGNUM GEL HORMIGAS IGR PLUS was also studied in a laboratory study (choice test) to test its effect as ovicide against *Linepithema humile*. The study tested the same formulation excluding the a.s. Imidacloprid, in the presence of AFS (agar, eggs, honey, vitamins, and minerals). In the trials the formulation containing S-Methoprene (0.08 %) was tested against a population of ca. 100 workers, 1 gravid queen, eggs, pupae and larvae for 6 weeks. 3 replicates and 2 controls (i.e. 0% S-Methoprene) were included. Observed parameters were the total number of laid eggs, larvae, pupae and total brood (sum of the former stages). The product was applied as a 2-cm line of gel bait (0.1 g) placed on a slide inside the arenas.The number of eggs produced in the controls increased from week 1 to week 2, but from week 4 there was a gradual reduction. After 6 weeks controls produced less eggs than at the beginning of the study, maybe showing the effect of captive breeding. In the treated arenas after 6 weeks of continuous treatment, 100% reduction of the number of eggs was achieved. There were still some other individuals (larvae and pupae) which are not affected by the product, since it acts only on the eggs laid by the queen. However it was clear that the formulation containing only S-Methoprene produced the inhibition of fertility of gravid queens compared to the controls.On the other hand, to achieve infertility in females, the product must be kept for at least 6 weeks in a continuous exposure that does not comply with the instructions for use, nor the mortality tests. Therefore **the product cannot be claimed as an ovicide.****Long period of storage:**The applicant has submitted 2 laboratory test with 3 and 4 years aged bait. The trials have been made with the garden ant *Lasius grandis*, instead of the usual *Lasius niger* ant. Both species are very similar in terms of feeding and behaviour, the factors that set one type of control or another. *Lasius niger* and *Lasius grandis* are monogynic, meaning they have one single queen per nest.They form big colonies with between 4.000 and 7.000 ants. Their diet is mainly based on sugary liquids obtained by grazing aphids. They also sometimes supply of proteins obtained by consuming the aphids themselves or other small arthropods. Being that similar, it can be assumed that the efficacy against *L.grandis* can be extrapolated to *L.niger*Both the three-year and four-year laboratory tests showed mortality for the three species of 100% in 11 days. Mortality of untreated controls are acceptable.The tests have been carried out with the application by droplets.Palatability tests with fresh bait on bait station and droplets, storage stability test with the worst packaging (syringes) and tests with aged bait have been provided. Taking into account that the bait product is the same for bait station and syringes, we can authorize a shel-life of the product to 4 years, both droplets and bait stations.**We accept the trials and consider that a shelf-life up to 4 years, in relation to the efficacy, can be authorized.** |

#### Occurrence of resistance and resistance management

No resistant strains have been shown in the efficacy laboratory/field trials conducted with ants. No other studies on the resistance of Imidacloprid and s-Methoprene were available to the applicant.

In the final CAR of Imidacloprid, the RMS was aware of the potential for the development of resistance against the a.s. and suggested to further address this issue at product authorisation stage. Imidacloprid belongs to a new class of insecticides, the neonicotinoids that has not been used, previously, for ant control in Europe.

Several literature studies were summarised in the CAR to show the resistance of target insects to neonicotinoids. However studies on specific resistance to Imidacloprid were not presented during the a.s. approval.

The resistance of target insects (ants) to Imidacloprid was searched for in the literature during the evaluation of MAGNUM GEL HORMIGAS IGR PLUS but no updated references and documentation was found about neonicotinoides insecticide resistance of ants. According to the TNsG (point.1.3.14), ant is an insect “*with one or few queens who lay eggs for a long period, and a biocide that kills the whole colony most of the time, so it is not to be expected that resistance will build up”*. In addition, ants are not considered a serious threat to public health or threat to crops, which could justify the lack of such research in this field of study. Even so, in the 70s, cases of resistance argentine ant were recorded against the actives substances *aldrin* and *diedrin*, currently not allowed, who acted on GABA channels. (Ettershank, G. (1975). In: Kerr 1977.)

Imidacloprid acts, in this case, as systemic insecticide. The mode of action is to be agonist nicotinic acetylcholine receptor (nAChR) competitive modulators. The substance causes a hyper-excitation of the central nervous system that causes the death of the individual. Imidacloprid is listed by IRAC (Insecticide Resistance Action Committee): *Group 4A. Neonicotinoide,* along with other actives substances such as *acetamiprid or thiamethoxam*.

Additionally the use pattern as gel bait ensures that most of the room surface is not treated thereby reducing the likelihood of contacting a sublethal deposit.

In conclusion the potential for resistance is high as a neonicotinoid but particular problems have not arisen for imidacloprid. Nevertheless, to minimise the chances of resistance developing in the future, it is advisable to avoid using products containing Imidacloprid exclusively and continuously as the sole agent for ant control. Therefore Imidacloprid containing products should be used as one component of an integrated pest management program which features products from alternative chemical classes.

The IRAC group (Insecticide Resistance Action Committee) provides guidelines on resistance management for neonicotinoids in agricultural settings. These also may be used for a resistance management strategy for biocidal products (insecticides used in urban environments).

The proposed resistance management strategy includes the following actions:

* The incorporation of a label warning: ‘this product should be used in alternation with other products not containing the same a.s. to avoid resistant populations’.
* The label warning included by the Applicant indicating that ‘the product should be reapplied when finished’ should be changed to the following: ‘the product should be reapplied only until the pest is controlled”.
* The incorporation of a label warning: ‘Use products at recommended doses and intervals’.

In the final CAR of s-Methoprene the eCA explained that data from published studies indicated that S-Methoprene is unlikely to induce resistance in Pharaoh ants. It should be noted that the representative product was an insecticide for the control of Paraoh ants.

The resistance of ants to s-Methoprene was also searched for in the literature during the evaluation of MAGNUM GEL HORMIGAS IGR PLUS but no references were found addressing this issue. In the literature S-methoprene was proven to be capable of inducing resistance in other organisms like flies and mosquitos, but in ants this phenomenon was not described so far. The proposed resistance management strategy is in principle also valid to manage possible resistance in ants.

#### Known limitations

These known limitations should be followed for the safe use of this biocidal product and therefore they should be incorporated in the product label:

* Do not use on food or utensils. May not be applied on surfaces where food is handled, prepared or served or consumed.
* Keep out of reach of children.
* Do not apply the operation in the presence of people and / or pets.
* Do not mix with other chemicals.
* Do not use on wood or porous surfaces.
* Avoid contact with treated surfaces.
* To avoid risks to man and the environment follow the instructions.

Please note that the above list is not exhaustive. Label claims to preclude food contamination and/or animal/livestock exposure are not definitely proposed.

#### Evaluation of the label claims

The label claims reflected the expected use of the products (insecticide) for the specific target organisms and the kind of use, but above all they must be supported by efficacy trials.

The product has proven effective for the following label claims.

- Insecticide for kill worker ants (*Linepithema humile* and *Lasius niger)*. The a.s. Imidacloprid produces kill of ants in 2 weeks. - Ready-to-use gel bait with application by droplets on non-porous surfaces (cartridge or syringe) indoors against the three species and all users.

- Ready-to-use gel bait with application of bait stations bait outdoors only against *Linephitema humile*, and for trained profesionar users.

- The fresh gel bait is palatable for ants.

- The 4 years aged bait is palatable for ants.

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

The applicant has indicated that the gel bait should not be applied in areas recently treated with another insecticide.

### Risk assessment for human health

The biocidal product Magnum Gel Hormigas IGR Plus is composed of the active substances Imidacloprid 0.01% w/w and S-Methoprene 0.08% w/w, combined with a number of co-formulants. Current classification is proposed in accordance with the provisions laid down in Regulation (EC) Nº 1272/2008. Proposed classification for Magnum Gel Hormigas IGR Plus based on the acute toxicity results performed with other formulated product Magnum Gel for human health effects has been included as part of this submission. Magnum Gel is composed of the active substance Imidacloprid 2.15% w/w combined with a number of co-formulants.

Two studies GLP compliant (2013) have been submitted by the applicant to address the acute oral and dermal toxicity. These studies were conducted with the product Magnum Gel Cucarachas which is a gel formulation containing Imidacloprid 2.15% (w/w) as active substance. The Spanish-CA accepts that the data generated for this product can be extrapolated to the product Magnum Gel Hormigas IGR Plus because the concentration of imidacloprid is higher and the rest of the co-formulants do not classify for these routes of toxicity. So, it is a worse case.

On the other hand, the applicant has submitted a justification for non-submission data for acute inhalation toxicity, dermal, skin and eye irritation, skin sensitisation and dermal absorption. Spanish-CA accepts these justifications.

See also DETAILED INFORMATION ABOUT COMPOSITION AND TOXICOLOGY OF THE BIOCIDAL PRODUCT in the confidential section. It must be noted that S-Methoprene is not classified for human health hazards.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Not skin corrosive. Not skin irritant |
| Justification for the value/conclusion | Based on the classification of Imidacloprid, S-Methoprene and the coformulants, and their respective content in the final formulation |
| Classification of the product according to CLP and DSD | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, **no classification is required** |

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| **Data waiving** |
| Information requirement | Skin Irritation  |
| Justification | Skin irritation toxicity studies for Magnum Gel Hormigas IGR Plus have not been performed.There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Thus the study does not need to be conducted.Therefore, Magnum Gel Hormigas IGR Plus can be considered as no irritant to skin and do not meet the criteria for classification as irritant or corrosive.It is therefore proposed that the preparation Magnum Gel Hormigas IGR Plus is not a skin irritant and is not classified. |

***Eye irritation***

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| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | Not an eye irritant |
| Justification for the value/conclusion | Based on the classification of Imidacloprid, S-Methoprene and the coformulants, and their respective content in the final formulation |
| Classification of the product according to CLP and DSD | The preparation Magnum Gel Hormigas IGR Plus is not classified as irritant to eyes. |

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| **Data waiving** |
| Information requirement | Eye irritation  |
| Justification | Eye irritation toxicity studies for MAGNUM Gel Hormigas IGR Plus have not been performed. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Thus this study does not need to be conducted. Therefore, Magnum Gel Hormigas IGR Plus can be considered as no irritant to eyes and do not meet the criteria for classification as irritant or corrosive. |

***Respiratory tract irritation***

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| **Conclusion used in the Risk Assessment – Respiratory tract irritation** |
| Justification for the conclusion | Based on the classification of Imidacloprid, S-Methoprene and the coformulants, and their respective content in the final formulation |
| Classification of the product according to CLP and DSD | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, **no classification is required** for respiratory tract irritation. |

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| **Data waiving** |
| Information requirement | Respiratory Tract Irritation  |
| Justification | No study on the respiratory tract irritation of the formulation Magnum Gel Hormigas IGR Plus has been performed.No data on respiratory tract irritation is submitted. Furthermore, this data is not required under Biocides Regulation. However, there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation). **no classification is required** for respiratory tract irritation. |

***Skin sensitization***

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| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | No skin sensitizer |
| Justification for the value/conclusion | Based on the classification of Imidacloprid, S-Methoprene and the coformulants, and their respective content in the final formulation |
| Classification of the product according to CLP and DSD | The preparation Magnum Gel Hormigas IGR Plus is not classified as skin sensitiser. |

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| **Data waiving** |
| Information requirement | Skin sensitisation  |
| Justification | Skin sensitisation studies for Magnum Gel Hormigas IGR Plus have not been performed. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Thus the study does not need to be conducted. **No classification is required** for skin sensitization. |

***Respiratory sensitization (ADS)***

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| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | Not respiratory sensitiser |
| Justification for the value/conclusion | Based on the classification of Imidacloprid, S-Methoprene and the coformulants, and their respective content in the final formulation. |
| Classification of the product according to CLP and DSD | The preparation Magnum Gel Hormigas IGR Plus is not classified as respiratory sensitiser. |

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| **Data waiving** |
| Information requirement | Respiratory sensitization  |
| Justification | No data on the respiratory sensitisation of the product Magnum Gel Hormigas IGR Plus has been submitted, because of its physical nature (gel) and the low vapour pressure of the components. Magnum Gel Hormigas IGR Plus is not expected to have respiratory sensitizing properties and none of the components of the mixture shows respiratory sensitisation effects. |

***Acute toxicity***

*Acute toxicity by oral route*

| **Summary table of animal studies on acute oral toxicity** |
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| **Method Guideline****GLP status, Reliability**  | **Species,Strain,Sex,No/group** | **Test substance****Dose levelsType of administration** *(gavage, in diet, other)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **ValueLD50** | **Remarks** *(e.g. major deviations)* | **Reference**  |
| OECD- 423 Method B1 bis Commission Regulation (EC) No. 440/2008 GLP YesReliability 1 | Wistar (RccHanTM: Wist) ratsFemale (nulliparous and non-pregnant) 8–12 weeks3 animals/group | Imidacloprid 2.15% gel (purity unknown)Oral (gavage)2000 mg/kg bodyweight 14 day post exposure period | No deathsNo signs of systemic toxicity No abnormalities at necropsy | >5000 mg/kg body weight | No analysis was conducted to determine the homogeneity, concentration or stability of the test item formulation.  | XxxxxxXxxxxxxxx |

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| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | LD50>5000mg/kg bw |
| Justification for the selected value | No toxicity effects at the maximum dose rate of 5000 mg/Kg bw |
| Classification of the product according to CLP and DSD | Imidacloprid 0.01% & S-Methoprene 0.08% gel formulation is not classified as Oral Acute Toxic, according the addition method of CLP Regulatory for mixtures, from components data, because the ATEmix > 2000. Gel formulation is not classified as harmful by the oral route  |

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| **Data waiving** |
| Information requirement | Acute oral toxicity  |
| Justification | Acute oral toxicity studies for product Magnum Gel Hormigas IGR Plus have not been performed. The data provided for acute toxicity studies refer to an Imidacloprid 2.15% Gel formulation.Magnum Gel Hormigas IGR Plus contains 0.01% (w/w) of the active substance Imidacloprid, 0.08% (w/w) of the active substance S-Methoprene and other co-formulants, The main component contributing to the toxicity of the formulation is the active substance Imidacloprid, which is in a lower concentration than that present in the test item (Imidacloprid 2.15% Gel formulation MAGNUM GEL CUCARACHAS). Therefore, the tests results can be extrapolated to the Imidacloprid 0.01% Gel formulation.It is therefore proposed that the product Magnum Gel Hormigas IGR Plus is not harmful by the oral route and will remain unclassified. |

*Acute toxicity by inhalation*

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| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | Not harmful by the inhalation route  |
| Justification for the selected value | Based on the classification of Imidacloprid, S-Methoprene and the coformulants and their respective content in the final formulation, as well as the physical nature of the formulation and the low vapour pressure of the components |
| Classification of the product according to CLP and DSD | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for inhalation acute toxicity  |

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| **Data waiving** |
| Information requirement | Acute inhalation toxicity  |
| Justification | Acute inhalation toxicity studies for Magnum Gel Hormigas IGR Plus have not been performed. Considering the physical nature of the formulation, the low volatility of the components and the mode of application, the product is applied in drops or by using bait station and therefore, no aerosol particles or droplets of an inhalable size are generated, it is considered unlikely that the preparation could represent a significant hazard by the inhalation route.It is therefore proposed that the product Magnum Gel Hormigas IGR Plus is not harmful by the inhalation route and will remain unclassified. |

*Acute toxicity by dermal route*

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| **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** *(nature, onset, duration, severity, reversibility)* | **LD50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| OECD No. 402 Method B3 Commission Regulation (EC) No. 440/2008 GLP YesReliability 1 | Wistar (RccHanTM: Wist) Rat 5 Males and 5 females (The females were nulliparous and non-pregnant)  | 2000 mg/kg Imidacloprid 2.15% gel undilutedSemiocclusive No vehicleApproximately 10% of the total body surface area 24 hours exposure  | Dark brown coloured staining of all males and one female Small superficial scattered scabs of two females. no signs of dermal irritation of the remaining animals No abnormalities at necropsy. no deaths no signs of systemic toxicity  | >2000 mg/Kg bw |  | Xxxxxxxxxxxxx |

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | LD50>2000mg/kg bw |
| Justification for the selected value | No toxicity effects at the maximum dose rate of 2000 mg/Kg bw |
| Classification of the product according to CLP and DSD | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for dermal acute toxicity. |

|  |
| --- |
| **Data waiving** |
| Information requirement | Acute dermal toxicity  |
| Justification | Acute dermal toxicity studies for product Magnum Gel Hormigas IGR Plus have not been performed. The data provided for acute toxicity studies refer to at Imidacloprid 2.15% Gel formulation.Magnum Gel Hormigas IGR Plus contains 0.01% (w/w) of the active substance Imidacloprid, 0.08% (w/w) of the active substance S-Methoprene and other co-formulantsThe main component contributing to the toxicity of the formulation is the active substance Imidacloprid, which is in a lower concentration than that present in the test item (MAGNUM GEL CUCARACHAS). Therefore, the tests results can be extrapolated to the Imidacloprid 0.01% Gel formulation MAGNUM GEL HORMIGAS PLUS.It is therefore proposed that the product Magnum Gel Cucarachas IGR Plus is not harmful by the dermal route and will remain unclassified. |

***Information on dermal absorption***

|  |
| --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Substance | Imidacloprid / S-Methoprene | Imidacloprid / S-Methoprene |
| Value(s)\* | 75% for primary exposure | 75% for secondary exposure |
| Justification for the selected value(s) | EFSA Journal 2012;10(4):26651 | EFSA Journal 2012;10(4):26651 |

1 *Guidance on Dermal Absorption, EFSA Journal 2012;10(4):2665 ‘In absence of data on the formulation into consideration, a default value of 75% should be used for products or in use dilutions containing ≤ 5% active substance’.*

|  |
| --- |
| **Data waiving** |
| Information requirement | Dermal absorption studies on Magnum Gel Hormigas IGR Plus formulation are not required. |
| Justification | Dermal absorption studies for the biocidal product Magnum Gel Hormigas IGR Plus have not been submitted.The relevant exposure route during application of the biocidal product Magnum Gel Hormigas IGR Plus is only dermal for the gel formulation applied as drops. No exposure is expected for the bait station application.According to EFSAguidance (2012) in absence of data on the formulation into consideration, a default value of 75% should be used for products or in use dilutions containing ≤5% active substance.Hence, in absence of data on the product Magnum Gel Hormigas IGR Plus, the use of default value of 75% dermal absorption for each active substance is believed to represent a sufficient conservative approach for human exposure and risk assessment. Given that comparison against AELs leads to acceptable exposure levels, no further studies are required for the biocidal product Magnum Gel Hormigas IGR Plus. |

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

The formulation contains 0.01% (w/w) of the active substance Imidacloprid, 0.08% (w/w) of the active substance S-Methoprene and other co-formulants, several of which are classified for human health hazards. However, the concentration of these substances in the preparation does not exceed the classification limits set in Regulation (EC) Nº 1272/2008 and the biocidal product is not classified on the basis of their presence in the preparation.

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

No data.

***Endocrine disruption***

**Assessment of the ED properties of the active substances:**

The biocidal product contains S-Methoprene and imidacloprid.

According to *List compilation exclusion or substitution criteria (Version. January 2019)*, imidacloprid and S-Methoprene there are no concern for endocrine disruption.

Also, the assessment report of S-Methoprene indicate: “*S-Methoprene is not included in the Commission staff working document on implementation of the EU Strategy for Endocrine Disrupters. Whilst s-Methoprene is a juvenile (insect) hormone analogue, there is no evidence of any endocrine disruption potential in the human health studies presented in the dossier*”

The Assessment of the ED properties of non-active substances (co-formulants), see in Confidential Annex.

None of the co-formulants has been identified in the previous database searches. Furthermore, none of the co-formulants has Repr. Tox. or STOT-RE classification that could be related to ED properties. Therefore, there is no evidence that the non-active substances present in this biocidal product have ED properties.

**Overall conclusion on the biocidal product regarding ED properties:**

There is no indication of concern regarding the ED properties of the substances used in the biocidal product MAGNUM GEL HORMIGAS IGR PLUS.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product  authorisation will be revised.

***Other***

No other additional tests relating to exposure of Imidacloprid or the formulated product Magnum Gel Hormigas IGR Plus, other than those outlined in previous data points are considered necessary due to the lack of risk of the different population groups that are exposed as a consequence of the intended uses.

Due to the intended use pattern of the product MAGNUM GEL HORMIGAS IGR PLUS it will not come into contact with food, foodstuffs or feeding stuffs.

#### Exposure assessment

Magnum Gel Hormigas IGR Plus is a ready-to-use product to be applied indoor and outdoor as gel drops and using bait stations by trained professionals, professionals and the general public to kill ants.

No exposure to the product is expected either by (trained-)professionals or the general public during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63: ‘the exposure due to the use of ant and cockroach bait stations is considered to be negligible. Accidents (swallowing, children who open bait stations) do not form a part of a standard assessment’).

Therefore, human exposure when using bait stations is not considered in this assessment. Primary and secondary exposure assessment performed with the application of gel in drops is the worst case with regard to human exposure and cover the risk derived from the use of bait stations.

The product contains the active substances Imidacloprid 0.01% w/w and 0.08% w/w S-methoprene along with other co-formulants.

There are no substances of concern.

The eCA considers the authorised dose should be 0.2-0.6 g/m2 using gel bait by bait stations and gel bait by drops/lines where 1 drop = 1 line of 3 cm = 0.2 g (200 mg), according to the efficacy section.

Relevant exposure routes to humans during MAGNUM GEL HORMIGAS IGR PLUS application are described in the following table:

**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**  |
| **Trained professional** | **Professional use** | **Non-professional use\*****(General public)** | **Trained professional** | **Professional use\*** | **Non-professional use\*. General public** | **Via food** |
| Inhalation1 | No | No | No | n.a. | No | No | No |
| Dermal | Yes | Yes | Yes | n.a. | No2 | Yes3 | No |
| Oral | No | No | No | n.a. | No | Yes3 | No4 |

**\*** *To Spanish CA, professional users are considered similar to non-professional users. Therefore, exposure assessment and risk characterisation are calculated in the same way for both users.*

*1 exposure via inhalation route is considered negligible due to the low vapour pressure of the active substances Imidacloprid (4E-10 Pa, 20ºC) and S-Methoprene (6.23E-4 Pa, 20ºC).*

*2 secondary exposure is only considered for toddlers via dermal and hand to mouth contact after application of gel.*

*3 for toddlers via dermal and hand to mouth contact after application of gel.*

*4 in the event that the product is applied e.g., in the food industry, livestock farming installations or in kitchens at private homes (professional and non-professional uses) the gel formulation applied either as targeted spot or bait stations precludes surface contamination (hence, dietary exposure). In addition, the label must include restrictions and instructions of use to avoid food contamination and exposure of animals (livestock and companion animals).*

***List of scenarios***

| **Summary table: scenarios** |
| --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure** **Description of scenario** | **Exposed group** |
| 1. | Application | Primary exposure: gel application using a cartridge/syringe | Trained professionals |
| 2. | Post application | Primary exposure: disposal of used cartridge/syringe | Trained Professionals |
| 3. | Application | Primary exposure: gel application using a cartridge/syringe | Professionals/ Non-professionals |
| 4. | Post application | Primary exposure: disposal of used cartridge/syringe | Professionals/ Non-professionals |
| 5. | Application | Primary exposure: gel application using bait stations\* | Trained professionals/ Professionals/ Non-professionals |
| 6. | Post application | Primary exposure: collection of used bait stations\* | Trained professionals/ Professionals/ Non-professionals |
| 7. | Post application | Secondary exposure: dermal and hand to mouth contact with gel | Bystander (toddler) |

\* *No exposure to the product is expected by users during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63: ‘the exposure due to the use of ant and cockroach bait stations is considered to be negligible. Accidents (swallowing, children who open bait stations) do not form a part of a standard assessment’). Therefore, human exposure to biocidal product when using bait stations is not considered in this assessment.* *Primary and secondary exposure assessment performed with the application of gel in drops is the worst case with regard to human exposure and cover the risk derived from the use of bait stations.*

***Industrial exposure***

The active substances Imidacloprid and S-Methoprene, and the biocidal product are produced in the EU. The exposure during the production of the active substances and the formulation of the biocidal product are not assessed by the CA under the requirements of the BPR. However, the CA assumes that the production is performed in conformity with national and European occupational safety and health regulations.

***Trained Professional exposure***

*Scenario [1] Application of Magnum Gel Hormigas IGR Plus by trained professional users*

| **Description of Scenario [1]** |
| --- |
| For trained professionals (pest control operators) exposure is estimated using the models and assumptions presented in the original CAR of Imidacloprid. The product is a ready-to use bait in cartridges/syringes for the controlled placement using a suitable gel applicator by trained professionals (pest control operators). The gel is applied as drops in inaccessible places as behind furnitures, etc. In the following, the application of gel using cartridge is considered for exposure assessment purposes (worst case).Chronic exposure is expected.According to Imidacloprid CAR the only relevant exposure route of the gel product to professional users is via dermal contamination through hands. Exposure estimations were performed taking into account the quantities that could potentially enter into contact with operator’s hands during opening and sealing the cartridge (5 opening and 5 sealing operations per day). The product remaining on the tip of the cartridge (or cartridge nozzle) will contaminate operator’s hand during removal or placing the cap before and after the application, respectively. Exposure during use of cartridges is estimated worst case compared to syringes.  |
|  | Parameters | Value |
| Tier 1 | Equivalence 0.5 cm gela | 33.3 mg product  |
| number of opening and sealing per dayb | 10 |
| content of active substance in product | 0.01% Imidacloprid0.08% S-Methoprene |
| Body weight adultc | 60 kg |
| Dermal absorptionabsorptiond | 75% |

*a According to the CAR a string of gel estimated to be 0.5 cm long is transferred to the hand during opening or sealing the cartridge. To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information (diameter of the nozzle lumen) is not available for the packaging of of MAGNUM GEL HORMIGAS PLUS. The CA uses the amount of product in a line of gel 0.5 cm length as indicated in CAR (aprox. 33.3 mg of product) to estimate the exposure of trained professionals via dermal route, taking into account that the applicant has noted that a drop of 3 cm diameter of Magnum Gel Hormigas IGR Plus equals aprox. 200 mg of product (see Annex 3.2)*

*b CAR.*

*c HEEG Opinion 17.*

*d EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665)*

**Calculations for Scenario [1]**

See calculations in Annex 3.2

| **Summary table: estimated systemic exposure to Imidacloprid from trained professional uses (mg/kg bw/d)** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario 1 | 1/none | - | 4.16E-04 | - | 4.16E-04 |
| **Summary table: estimated systemic exposure to S-Methoprene from trained professional uses (mg/kg bw/d)** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario 1 | 1/none | - | 3.33E-03 | - | 3.33E-03 |

**Further information and considerations on scenario [1]**

Not applicable.

*Scenario 2* *Disposal of used cartridges by trained professional users*

|  |
| --- |
| **Description of Scenario 2** |
| For trained professionals (pest control operators) exposure is estimated using the models and assumptions presented in the original CAR. In the following the disposal of used cartridge is considered for exposure assessment purposes.Chronic exposure is expected.Exposure takes place via dermal contamination through hands. Exposure estimation is performed taking into account the quantities that could potentially enter into contact with operator’s hands during disposal of used cartridges (1 operation a day). The product remaining on the tip of the cartridge (or cartridge nozzle) will contaminate operator’s hand during cartridge disposal. |
|  | Parameters | Value |
| Tier 1 | Equivalence 0.5 cm gela | 33.3 mg product  |
| number of disposed cartridges per dayb | 1 |
| content of active substance in product | 0.01% Imidacloprid0.08% S-Methoprene |
| Body weight adultc | 60 kg |
| Dermal absorptionabsorptiond | 75% |

*a According to the CAR a string of gel estimated to be 0.5 cm long is transferred to the hand during opening or sealing the cartridge. To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information (diameter of the nozzle lumen) is not available for the packaging of of MAGNUM GEL HORMIGAS PLUS. The CA uses the amount of product in a line of gel 0.5 cm length as indicated in CAR (aprox. 33.3 mg of product) to estimate the exposure of trained professionals via dermal route, taking into account that the applicant has noted that a drop of 3 cm diameter of Magnum Gel Hormigas IGR Plus equals aprox. 200 mg of product (see Annex 3.2)*

*b CAR.*

*c HEEG Opinion 17.*

*d EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665)*

**Calculations for Scenario 2**

See calculations in Annex 3.2

| **Summary table: estimated systemic exposure to Imidacloprid from trained professional uses (mg/kg bw/d)** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario 2 | 1/none | - | 4.16E-05 | - | 4.16E-05 |
| **Summary table: estimated systemic exposure to S-Methoprene from trained professional uses (mg/kg bw/d)** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario 2 | 1/none | - | 3.33E-04 | - | 3.33E-04 |

**Further information and considerations on scenario [2]**

Not applicable.

*Combined scenarios*

Total exposure of trained professionals during a working day is estimated by a combination

of scenarios 1 & 2.

| **Summary table: combined systemic exposure to Imidacloprid from trained professional uses (mg/kg bw/d)** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario 1 + 2 | 1/none | - | 4.58E-04 | - | 4.58E-04 |
| **Summary table: combined systemic exposure to S-Methoprene from trained professional uses (mg/kg bw/d)** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario 1 + 2 | 1/none | - | 3.66E-03 | - | 3.66E-03 |

***Professional exposure***

To Spanish CA, professional users are considered similar to general public (non-professional users). Therefore, exposure assessment and risk characterisation are calculated in the same way for both users. See calculations below.

***Non-professional (general public )exposure***

*Scenario [3] Application of Magnum Gel Hormigas IGR Plus in cartridges by professionals and the general public*

| **Description of Scenario [3]** |
| --- |
| The product is a ready-to use bait in cartridges/syringes for professionals and non-professional uses. The gel is applied as round spots in hidden places with difficult access such as behind furniture, etc. For both categories of users exposure is estimated using the models and assumptions presented in the original CAR of Imidacloprid adapted to consumer use according to expert judgment.In the following it is assumed as a worst case that a consumer applies the product every two weeks during 6 months per year (ants are expected during spring and summer). As a worst case, medium term exposure is expected.Exposure takes place via dermal contamination through hands. Exposure is estimated taking into account the quantities that could potentially enter into contact with consumer’s hands during opening and sealing the cartridge (1 opening and 1 sealing operations per application are assumed).  |
|  | Parameters | Value |
| Tier 1 | Equivalence 0.5 cm gela | 33.3 mg product  |
| number of opening and sealing per dayb | 2 |
| content of active substance in product | 0.01% Imidacloprid0.08% S-Methoprene |
| Dermal absorptionc | 75% |
| Body weight adultd | 60 kg |

*a According to the CAR a string of gel estimated to be 0.5 cm long is transferred to the hand during opening or sealing the cartridge. To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information (diameter of the nozzle lumen) is not available for the packaging of of MAGNUM GEL HORMIGAS PLUS. The CA uses the amount of product in a line of gel 0.5 cm length (as indicated in CAR (aprox. 33.3 mg of product) to estimate the exposure of professionals and non-professionlas via dermal route, taking into account that the applicant has noted that a drop of 3 cm diameter of Magnum Gel Hormigas IGR Plus equals aprox. 200 mg of product (see Annex 3.2)*

*b CAR, adapted for consumer use.*

*c EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665)*

*d HEEG Opinion 17.*

**Calculations for Scenario [3]**

See relevant calculations in Annex 3.2

| **Summary table: estimated systemic exposure to Imidacloprid from professional/non-professional uses (mg/kg bw/d)** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [3] | 1/none | - | 8.33E-05 | - | 8.33E-05 |
| **Summary table: estimated systemic exposure to S-Methoprene from professional/non-professional uses (mg/kg bw/d)** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [3] | 1/none | - | 6.66E-04 | - | 6.66E-04 |

**Further information and considerations on scenario [3]**

Not applicable

*Scenario [4]* *Disposal of used cartridges of Magnum Gel Hormigas IGR Plus by professional/non-professional users*

| **Description of Scenario [4]** |
| --- |
| For professional / non-professional users exposure is estimated using the models and assumptions presented in the original CAR of Imidacloprid adapted to consumer use according to expert judgment.In the following it is assumed as a worst case that a consumer discharges a used cartridge every two weeks during 6 months per year (cockroaches are expected during spring and summer). As a worst case, medium term exposure is expected.Exposure takes place via dermal contamination through hands. Exposure estimation is performed taking into account the quantities that could potentially enter into contact with consumer’s hands during disposal of used cartridge (1 operation per day of application is assumed). The CA assumes that one drop of gel enters in contact with consumer’s hand during disposal off used cartridge. |
|  | Parameters | Value |
| Tier 1 | Equivalence 0.5 cm gela | 33.3 mg product  |
| number of cartridges disposed off per event b | 1 |
| content of active substance in product | 0.01% Imidacloprid0.08% S-Methoprene |
| Dermal absorptionc | 75% |
| Body weight adultd | 60 kg |

*a Packaging specifications for cartridges do not include information on the diameter of the nozzle lumen. In a similar way as above, the CA uses the amount of product in a line of gel 0.5 cm length (as indicated in CAR) to estimate the exposure of the general public via dermal route (see Annex 3.2).*

*b CAR, adapted for consumer use.*

*c EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665)*

*d HEEG Opinion 17.*

**Calculations for Scenario [4]**

See calculations in Annex 3.2

| **Summary table: estimated systemic exposure to Imidacloprid from professional/non-professional uses (mg/kg bw/d)** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [4] | 1/none | - | 4,16E-05 | - | 4,16E-05 |
| **Summary table: estimated systemic exposure to S-Methoprene from professional/non-professional uses (mg/kg bw/d)** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [4] | 1/none | - | 3,33E-04 | - | 3,33E-04 |

*Combined scenarios*

Total exposure of professionals or consumers during the use of Magnum Gel Hormigas IGR Plus in cartridges is estimated by a combination of scenarios 3 & 4.

| **Summary table: combined systemic exposure to Imidacloprid from professional/non-professional uses (mg/kg bw/d)** |
| --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios [3 & 4] Tier 1 | - | 1,25E-04 | - | 1,25E-04 |
| **Summary table: combined systemic exposure to S-Methoprene from professional/non-professional uses (mg/kg bw/d)** |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios [3 & 4] Tier 1 | - | 9,99E-04 | - | 9,99E-04 |

*Scenario 5 & Scenario 6. Use and disposal of bait stations containing Magnum Gel Hormigas IGR Plus*

| **Description of Scenarios 5 & 6** |
| --- |
| No exposure to the product is expected by either professionals or the general public during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63: ‘the exposure due to the use of ant and cockroach bait stations is considered to be negligible. Accidents (swallowing, children who open bait stations) do not form a part of a standard assessment’).Therefore, human exposure when using bait stations is not considered in this assessment. Primary and secondary exposure assessment performed with the application of gel in drops/lines is the worst case with regard to human exposure and cover the risk derived from the use of bait stations |

***Indirect exposure of the general public***

Indirect exposure scenarios are described in the following

*Scenario [7]* *Toddler: dermal contact with Magnum Gel Hormigas IGR Plus and hand to mouth transfer after application*

| **Description of Scenario [7]** |
| --- |
| According to the definitions in HEEG Opinion 17, the population under consideration here are toddlers (1-2 years old) who can explore their environment and exhibit hand to mouth transfer of residues.Secondary exposure can be considered as occasional and of short-term (not continuous) and therefore the exposure is considered as acute.Considering that the product is applied in lines/drops in localized spots (there is not an uniform application on surfaces as paints, for example), the following scenario assumes that a toddler contacts certain amount of product in one event. Additionally to dermal absorption, hand to mouth transfer may take place: the hands form about 20% of the total uncovered skin. It is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact. This means that via hand-mouth contact 10% of the external dermal exposure is ingested (RIVM report 320005002 pp. 28). The ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth contact.Tier 1 assumes that the amount dislodged is 100%; 100% oral absorption and 75% dermal absorption are considered. |
|  | Parameters | Value |
| Tier 1 | Equivalence of 1 line of gel 5 cma | 333.3 mg product  |
| number of lines contacted per eventb | 1 |
| content of active substances in product | 0.01% Imidacloprid0.08% S-Methoprene |
| Dermal absorptionc | 75% |
| Dislodged amountb | 100% |
| Amount of product available for oral intaked | 10% of external dermal load |
| Oral absorptione | 100% Imidacloprid35% S-Methoprene |
| Body weight toddlerf | 10 kg |

*a The CA uses the amount of product in a line of gel 5 cm length as indicated in CAR (aprox. 333.3 mg of product) to estimate the exposure of general public via dermal route, taking into account that the applicant has noted that a drop of 3 cm diameter of Magnum Gel Hormigas IGR Plus equals aprox. 200 mg of product (see Annex 3.2).*

*b assumption*

*c EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665)*

*d ConsExpo Pest product fact sheet RIVM report 320005002 (Post Application; pp. 28)*

*e Assessment Reports for Imidacloprid and S-Methoprene*

*f HEEG Opinion 17*

**Calculations for Scenario [7]**

See calculations in Annex 3.2

| **Summary table: systemic indirect exposure to Imidacloprid from non-professional uses (mg/kg bw/d)** |
| --- |
| **Exposure scenario** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [7]  | - | 2,25E-03 | 3.33E-04 | 2,58E-03 |
| **Summary table: systemic indirect exposure to S-Methoprene from non-professional uses (mg/kg bw/d)** |
| **Exposure scenario** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios [7]  | - | 1,80E-02 | 9.33E-04 | 1,89E-02 |

**Further information and considerations on scenario [7]**

The Tier 1 estimation presented here is a worst case assumption where the dislodgeability is 100% and the effect of the bittering substance in the ingestion is not considered.

Considering the application pattern of Magnum Gel Hormigas IGR Plus as a gel application (drops/lines) in hidden places with difficult access, exposure may occur accidentally for toddler via dermal contact. Although toddlers can explore their environment and exhibit hand to mouth transfer of residues, it is reasonable to assume that the gel would not be ingested due to the presence of the bittering agent.

Exposure is considered as occasional and of short-term (not continuous).

*Combined scenarios*

Not applicable.

***Monitoring data***

Not applicable.

***Dietary exposure***

*Food contamination as result of use*

The biocidal product is a gel formulation applied directly on localized spots difficult to access. This precise formulation and mode of application prevents the contamination of surfaces (e.g., due to the formation of splashes); it is unlikely that there could be transference of residues to food. Likewise, food contamination is not expected when using the gel in bait stations.

In addition, the label must include restrictions or instructions of use, so that, food contamination is avoided when the product is applied e.g., in food industry, restaurants or kitchens at private homes (professional and non-professional uses).

*Conclusion*

Dietary risk does not have to be further considered.

The following label restrictions preclude food contamination:

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

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

| **Summary table of other (non-biocidal) uses of Imidacloprid** |
| --- |
|  | **Sector of use 1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant protection product | Not approved under Regulation Nº 1107/2009 3 | MRL 4 |
| 2. | Veterinary use | treatment of domestic pets to control fleas 5 | Withdrawal period n.a. 6 |
| **Summary table of other (non-biocidal) uses of S-Methoprene** |
|  | **Sector of use 1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant protection product | Not approved under Regulation Nº 1107/2009 7 | MRL 4 |
| 2. | Veterinary use | Antiparasitic products, insecticides and repellents, avermectins 8 | Withdrawal period n.a. 5 |
| *1 e.g. plant protection products, veterinary use, food or feed additives**2 e.g.: MRL: maximum residues levels**3**Commission Implementing Regulation (EU) No 2020/1643**4 Commission Regulation (EU) No 899/2012 of 21 September 2012: MRL set at the lower limit of analytical determination**5 EMEA/V/C/000076**6 n.a. not applicable**7 Commission Regulation (EC) No 2076/2002 of 20 November 2002.**8 EMEA/V/C/002700: Combined with other substances is used in cats with, or at risk from mixed infestations by cestodes, nematodes and ectoparasites.* |

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

The biocidal product is a gel formulation applied directly on localized spots difficult to access. This precise formulation prevents the formation of splashes making surface contamination unlikely. Likewise, surface contamination is not expected when using the gel in bait stations. In addition, the product should be placed in spots inaccessible to animals; hence, exposure of livestock to residues of the biocidal product is not expected.

In conclusion, the label must include restrictions or instructions of use to avoid exposure of animals or contamination of feedstuff in the event that the biocidal product is applied in animal husbandry by professional users and/or the general public.

**Conclusion**

Livestock exposure does not have to be further considered.

The following label restriction preclude livestock exposure:

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

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

Transference of residues of the biocidal product into foods as a result of trained professional uses is not expected due to the formulation as a gel that prevent surface contamination (*e.g.* splashes) and the application pattern in localized spots difficult to access.

In addition, the label must include the following restrictions/instructions of use to preclude food contamination.

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

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

Transference of residues of the biocidal product into foods as a result of uses by the professional and general public is not expected due to the formulation as a gel that prevent surface contamination (e.g*.* splashes) and the application pattern in localized spots difficult to access.

In addition, the label must include the following restrictions /instructions of use to preclude food contamination.

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

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

Imidacloprid, S-Methoprene and the biocidal product are produced in the EU. The exposure during the production of the active substances and the formulation of the biocidal product are not assessed by the rapporteur under the requirements of the BPR. However, the rapporteur assumes that the production is performed in conformity with national and European occupational safety and health regulations.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** |
| --- |
| **Scenario number** | **Exposed group****(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake****Imidacloprid****mg /kw bw/d** | **Estimated total uptake****S-Methoprene****mg /kw bw/d** |
| 1. Application | Trained professionals | Tier 1 /none | 4,16E-04 | 3,33E-03 |
| 1. Application | Trained professionals | Tier 2 /gloves | 4,16E-05 | 3,33E-04 |
| 2. Post-Application | Trained professionals | Tier 1 /none | 4,16E-05 | 3,33E-04 |
| 2. Post-Application | Trained professionals | Tier 2 /gloves | 4,16E-06 | 3,33E-05 |
| 3. Application | Professionals and Non-professionals | Tier 1 /none | 8,33E-05 | 6,66E-04 |
| 4. Post-application | Professionals and Non-professionals | Tier 1 /none | 4,16E-05 | 3,33E-04 |
| 7. Indirect | Bystanders (toddlers) | Tier 1 /none | 2,58E-03 | 1,89E-02 |

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL** mg/Kg bw [d] | **AF1** | **Correction for oral absorption** | **Value** mg/Kg bw [d] |
| AELshort-term | acute neurotoxic study in rats | 40 | 100 | - | 0.4 |
| AELmedium-term | rat multigeneration study | 20 | 100 | - | 0.2 |
| AELlong-term | two year chronic toxicity study in rats  | 6 | 100 | - | 0.06 |
| ARfD2 | - | - | - | - | - |
| ADI2 | - | - | - | - | - |

1 *EU agreed AEL values (please refer to the Assessment Report for Imidacloprid 2011)*

*2 An ARfD and an ADI have not been derived for Imidacloprid used in biocidal products (PT 18).*

**Reference values for S-Methoprene to be used in Risk Characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL** mg/Kg bw [d] | **AF1** | **Correction for oral absorption** | **Value** mg/Kg bw [d] |
| AELshort-term | rabbit developmental study | 100 | 100 | 35% | 0.35 |
| AELmedium-term | 90-day dog repeat oral dose study | 100 | 100 | 35% | 0.35 |
| AELlong-term | 2-year rat combined chronic and carcinogenicity study | 21.7 | 100 | 35% | 0.076 |
| ARfD2 | - | - | - | - | - |
| ADI2 | - | - | - | - | - |

1 *EU agreed AEL values (please refer to the Assessment Report for S-Methoprene, 2013); Systemic NOAEL is estimated considering oral absorption*

*2 An ARfD and an ADI have not been derived for S-Methoprene used in biocidal products (PT 18).*

**Maximum residue limits or equivalent**

No MRL for biocidal uses of the active substances Imidacloprid and S-Methoprene are set.

***Risk for trained professional users***

Trained professional users are expected to use the biocidal product on a daily basis. Hence exposure levels are compared to AELlong-term for risk assessment purposes.

The exposure assessment for trained professional under reasonable worst case assumptions (10 applications and 1 post-application/day), yields a potential dermal exposure leading to a systemic dose of 4.58E-04 and 3.66E-03 mg/kg/day for an unprotected operator (see combined systemic exposure to Imidacloprid and S-Methoprene, Tier 1, respectively, in tables below).

The comparison to the respective AELlong-term shows that the use of Magnum Gel Hormigas IGR Plus containing 0.01% Imidacloprid and S-Methoprene 0.08% does not cause health risk for trained professionals not wearing protective equipment, as indicated by the resulting values expressed as %AEL.

See Tables below.

**Systemic effects: exposure** **to Imidacloprid from trained professional uses**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Application/ Scenario 1 | 1 | 6 | 0.06 | 4,16E-04 | 0,69 | yes |
| Post application/ Scenario 2 | 1 | 6 | 0.06 | 4,16E-05 | 0,07 | yes |

**Systemic effects: exposure** **to S-Methoprene from trained professional uses**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Application/ Scenario 1 | 1 | 21.7 | 0.076 | 3,33E-03 | 4,38 | yes |
| Post application/ Scenario 2 | 1 | 21.7 | 0.076 | 3,33E-04 | 0,44 | yes |

**Combined scenarios: systemic exposure to Imidacloprid from trained professional uses**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL****(%)** | **Acceptable****(yes/no)** |
| Application/ Scenario 1 & Post application/ Scenario 2 | 1 | 6 | 0.06 | 4,58E-04 | 0,76 | Yes  |

**Combined scenarios: systemic exposure to S-Methoprene from trained professional uses**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL****(%)** | **Acceptable****(yes/no)** |
| Application/ Scenario 1 & Post application/ Scenario 2 | 1 | 21.7 | 0.076 | 3,66E-03 | 4,82 | yes |

**Local effects**

Not applicable

**Conclusion**

The long term exposure assessment to Imidacloprid and S-Methoprene for trained professional users under worst case assumptions do not raise concerns for human health for Tier 1 estimation.

The use of Magnum Gel Hormigas IGR Plus containing 0.01% Imidacloprid and 0.08% S-Methoprene, does not cause any health risk for pest control operators without gloves.

***Risk for professional and non-professional (general public ) users***

Professional and non-professional users are expected to use the biocidal product every two weeks during 6 months per year (ants are expected during spring and summer) as a worst case. Medium term exposure to the biocidal product is expected.

Hence, exposure estimates are compared to the relevant AELmedium-term for Imidacloprid and S-Methoprene for risk assessment purposes.

The exposure assessment for professional and non-professionals under reasonable worst case assumptions (2 applications and 1 post-application/day), yielded a potential dermal exposure leading to systemic doses of 1.25E-04 mg/kg bw/day and 9.99E-04 mg/kg bw/day (combined systemic exposure to Imidacloprid and S-Methoprene, respectively). The estimated uptake represents 0.06% of the proposed AELmedium-term of 0.2 mg/kg bw/day for Imidacloprid and 0.3% of the proposed AELmedium-term of 0.35 for S-Methoprene, respectively.

Even considering that there could be professionals using the product on a long-term basis, the comparison of the combined systemic exposures to the AELlong-term raise no concern as they uptake represent 0.21% and 1.31% of the AELlong-term for Imidacloprid and S-Methoprene respectively.

See Tables below.

**Systemic effects: exposure** **to Imidacloprid for professionals and the general public**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Application/ Scenario 3 | 1 | 20 | 0.2 | 8,33E-05 | 0,04 | Yes |
| Post application/ Scenario 4 | 1 | 20 | 0.2 | 4,16E-05 | 0,02 | yes |

**Combined scenarios: systemic exposure to Imidacloprid for professionals and the general public**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL****(%)** | **Acceptable****(yes/no)** |
| ProfessionalsApplication/ Scenario 3 & Post application/ Scenario 4 | 1 | 20 | 0.2 | 1,25E-04 | 0,06 | yes |
| Non-professionalsApplication/ Scenario 3 & Post application/ Scenario 4 | 1 | 6 | 0.06 | 1,25E-04 | 0.21 | yes |

**Systemic effects: exposure** **to S-Methoprene for professionals and the general public**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Application/ Scenario 3 | 1 | 35 | 0.35 | 6,66E-04 | 0,19 | yes |
| Post application/ Scenario 4 | 1 | 35 | 0.35 | 3,33E-04 | 0,10 | yes |

**Combined scenarios: systemic exposure to S-Methoprene for professionals and the general public**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL****(%)** | **Acceptable****(yes/no)** |
| Application/ Scenario 3 & Post application/ Scenario 4 | 1 | 35 | 0.35 | 9,99E-04 | 0,29 | yes |
| Application/ Scenario 3 & Post application/ Scenario 4 | 1 | 21,7 | 0.076 | 9,99E-04 | 1,31 | yes |

**Local effects**

Not applicable

**Conclusion**

The medium term exposure assessment to Imidacloprid and S-Methoprene for non-professional users under worst case assumptions do not raise concerns for human health. For professionals users both the medium and the long term exposure assessment to Imidacloprid and S-Methoprene under worst case assumptions do not raise concerns for human health.

No risk is envisaged for the use of Magnum Gel Hormigas IGR Plus by professional and non-professional users.

***Risk for the indirect exposure***

**Systemic effects: indirect exposure** **to Imidacloprid for toddlers**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw** | **AEL****mg/kg bw** | **Estimated uptake****mg/kg bw** | **%AEL** | **Acceptable****(yes/no)** |
| Dermal and hand to mouth contact for toddlers/ Scenario 7 | 1 | 40 | 0.4 | 2,58E-03 | 0.65 | Yes |

**Systemic effects: indirect exposure** **to S-Methoprene for toddlers**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw** | **AEL****mg/kg bw** | **Estimated uptake****mg/kg bw** | **%AEL** | **Acceptable****(yes/no)** |
| Dermal and hand to mouth contact for toddlers/ Scenario 7 | 1 | 35 | 0.35 | 1,89E-02 | 5.41 | Yes |

**Combined scenarios secondary exposure**

No combined exposure is foreseen.

**Local effects**

Not applicable.

**Conclusion**

The short term exposure assessment for toddlers under worst case assumptions leads to systemic doses of 1.47E-02 mg/kg bw and 2.92E-03 mg/kg during the indirect exposure via oral and dermal route after the application of biocidal product. The estimated uptake represents 0.73% of the proposed AELshort-term of 0.4 mg/kg bw for Imidacloprid and 4.19% of the proposed AELshort-term of 0.35 mg/kg bw for S-Methoprene, respectively.

Tier 1 assessment indicates an acceptable risk for the indirect exposure of toddlers.

Based on the risk assessment results, the use of Magnum Gel Hormigas IGR Plus as an insecticide is considered safe taking into account primary and secondary exposure to the biocidal product as a consequence of use.

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

The biocidal product is a gel formulation applied directly on localized spots difficult to access. This precise formulation prevents the formation of splashes making surface and food contamination unlikely. Likewise, food contamination is not expected when using the gel in bait stations.

In addition, the label must include restrictions or instructions of use so that food contamination is precluded in the event that the product is applied e.g., in the food industry, restaurants or in kitchens at private homes (Trained professional, professional and non-professional uses).

Following label restrictions preclude food contamination (Trained professional uses):

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

Following label restrictions preclude food contamination (Professional and non-professional uses):

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

No risk is envisaged for consumers via residues in food.

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

Cumulative risk assessment is performed according to Guidance on the BPR: Volume III, Assessment & Evaluation (Parts B+C), Version 2.1 – February 2017, (pp 261 & Appendix 4.7, pp 293).

**Preliminary step:**

Imidacloprid acts on several types of post-synaptic nicotinic acetylcholine receptors in the nervous system. In insects, these receptors are located only within the central nervous system. On the other hand, S-Methoprene is a juvenile hormone mimic (terpene) effective by contact and stomach action, which acts by mimicing the action of the juvenile hormone keeping the insect in an immature state.

Given their mode of action we can assume that there is no indication of synergy within both active substances.

A summary of systemic exposures for the scenarios assessed are shown in table below.

|  |
| --- |
| **Primary exposure Trained professional use** **as mg/kg bw/d** |
|  | **Imidacloprid** | **S-Methoprene** |
| Value of exposure (without PPE) | 4,58E-04 | 3,66E-03 |
| **Primary exposure general public /professional use as mg/kg bw/d** |
|  | **Imidacloprid** | **S-Methoprene** |
| Medium term value of exposure | 1,25E-04 | 9,99E-04 |
| Chronic value of exposure | 1,25E-04 | 9,99E-04 |
| **Secondary exposure Toddler as mg/kg bw** |
|  | **Imidacloprid** | **S-Methoprene** |
| Acute value of exposure | 2,58E-03 | 1,89E-02 |

**TIER 1 and TIER 2:**

Tier 1 is an intermediary step to verify risk acceptability for each active ingredient used in the product, as currently performed. It is followed by Tier 2, which involves assessing the combined exposure to the substances of the mixture/biocidal product.

For the toxicological section, primary exposure of trained professionals has been considered and exposure estimations were compared to the chronic AEL for each substance. Primary exposure of consumers/ professionals has been considered and exposure estimations were compared to the medium term AEL for each substance and also for professionals primary exposure was compared to the chronic AEL for each substance. Secondary exposure for toddlers was performed according to a short term scenario using acute AEL.

Results of Tier 1 assessments are shown in the following table.

|  |  |
| --- | --- |
| **Primary exposure: Trained professional, chronic exposure** |  |
| **Without PPE** | **Imidacloprid** | **S-Methoprene** | **conclusion** |
| Tier 1  | 0.76 %AEL | 4.82 %AEL | acceptable |
| Tier 2 | 0.0076 | 0.0482 | acceptable |
|  | HI = 0.0558 |
| **Primary exposure: consumer/ professional, medium term exposure** |
| **Without PPE** | **Imidacloprid** | **S-Methoprene** | **conclusion** |
| Tier 1 | 0.06 %AEL | 0.29 %AEL | acceptable |
| Tier 2 | 0.0006 | 0.0029 | acceptable |
|  | HI = 0.0035 |
| **Primary exposure: professional, chronic exposure** |
| **Without PPE** | **Imidacloprid** | **S-Methoprene** | **conclusion** |
| Tier 1 | 0.21 %AEL | 1.31 %AEL | acceptable |
| Tier 2 | 0.0021 | 0.0131 | acceptable |
|  | HI = 0.0152 |
| **Indirect exposure: toddler, acute exposure** |  |
|  | **Imidacloprid** | **S-Methoprene** | **conclusion** |
| Tier 1 | 0.65 %AEL | 5.41 %AEL | acceptable |
| Tier 2 | 0.0065 | 0.0541 | acceptable |
|  | HI = 0.0606 |

**Conclusion:**

*For trained professional use:*

TIER I: Risk assessment is acceptable for Imidacloprid in the product without PPE. For S-Methoprene in the product risk assessment is acceptable with and without PPE as well.

TIER 2: Mixture risk assessment is also acceptable in T2 without PPE.

*For professional and consumer use:*

TIER I: Risk assessment is acceptable for both active substances in the product without PPE.

TIER 2: Mixture risk assessment is acceptable in T2 without PPE.

*For the indirect exposure of toddlers:*

TIER I: Risk assessment is acceptable for both active substances in the product.

TIER 2: Mixture risk assessment is acceptable in T2.

### Risk assessment for animal health

Exposure of animals (either companion animals or livestock) to Imidacloprid and S-Methoprene is prevented due to the application pattern of the biocidal product in spots out of reach of animals and the type of formulation (gel) that prevents surface contamination.

In addition, the label must include restrictions and instructions of use to preclude exposure of animals.

The following label restriction must be included in all products to preclude the exposure of animals:

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

No risk is envisaged for animal health.

### Risk assessment for the environment

MAGNUM GEL HORMIGAS IGR PLUS is an indoor/outdoor gel insecticide to be applied via droplets or bait stations. It kills adults populations of argentine ants (Linepithema humile), and black ants (Lasius niger).

#### Effects assessment on the environment

|  |  |  |
| --- | --- | --- |
|  | Imidacloprid | S-Methoprene |
| PNECwater (mg/L) | 4.8E-06 | 1.9E-04 |
| PNECmicroorganisms STP (mg/L) |  61.3 | 6.85 |
| PNECsediment (mg/kg wwt) | 2.6E-05 | 3.8E-04 |
| PNECsoil (mg/kg wwt) | 1.58E-02 | 0.148 |
| PNECoral bird (mg/kg food) | 4.2 |  |
| PNECoral mammal (mg/kg food) | 8.33 | 43.60 |

\*according to the addendum from 2018 to the AR for S-methoprene

 No ecotoxilogical data are available to a set a PNEC value for birds for s-methoprene

The CAR addendum of S-Methoprene (June 2016) shows the presence of significant metabolites in water and sediment phases. However, the DT50 of S-Methoprene metabolites are lower than the S-Methoprene DT50. Therefore, S-Methoprene metabolites are not considered in the environmental risk assessment..

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

The biocidal product MAGNUM GEL HORMIGAS IGR PLUS contains 0.01% and 0.08% of imidacloprid and s-methoprene, respectively, as the ingredients to contribute to the classification regarding environmental properties. The current harmonised classification of imidacloprid is aquatic acute (H400) and aquatic chronic (H410) (1st ATP). The current harmonised classification of s-methoprene is aquatic acute (H400) and aquatic chronic 1 (410) (13th ATP), for S-metoprene the factors are given however no factor are given in the 1st ATP for imidacloprid, according to the most recent effect data, the following M factors are considered, M factor of 100 and M factor of 1000 for aquatic chronic and aquatic acute, respectively. The biocidal product MAGNUM GEL HORMIGAS IGR PLUS is classified as Aquatic Chronic Category 2 (H411). H411 for labelling purposes

***Further Ecotoxicological studies***

No new data is available.

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

No additional trials to assess risk to non-target organisms have been conducted

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

No additional studies on acceptance of ingestion of the biocidal product by non-target organisms have been performed.

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***Not relevant

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

Please refer to section Fate and distribution and distribution in exposed environmental compartments*.*

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

No new data is available.

***Leaching behaviour (ADS)***

No relevant.

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

No relevant.

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

No relevant.

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

No relevant.

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

No 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)***

No relevant.

***Assessment of Endocrine Disruption (ED)***

Assessment of the ED properties of the active substances:

The biocidal product contains imidacloprid and s-methoprene as active substances. The CAR of the active substance S-methoprene indicated: “S-Methoprene is not included in the Commission staff working document on implementation of the EU Strategy for Endocrine Disrupters. Whilst S-Methoprene is a juvenile (insect) hormone analogue, there is no evidence of any endocrine disruption potential in the human health or ecotoxicological studies presented in the dossier”. However nothing is comented in the CAR of the active substance Imidacloprid about its disruption properties.

Assessment of the ED properties of non-active substances (co-formulants):

The potential ED properties of co-formulants has been reviewing by consulting the following data bases:

* ECHA data for identification of ED and PBT, under REACH, BPR or CLP
* Identified as ED by United States EPA (https://comptox.epa.gov/dashboard/)
* Identified as ED by the United Nations Environment (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc\_report2.pdf?sequence=1&isAllowed=y and <https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y>)

During screening performance none of the co-formulant triggered an alert for ED property thus, ES CA considers that there is no concern regarding the ED properties of these co-formulants

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | *PT 18* |
| Assessed scenarios | Scenario 1: Outdoor use. Spot application around commercial buildings Scenario 2: Outdoor use. Terrace Scenario.Scenario 3: Indoor use spot treatment private houses.Scenario 4: Indoor use spot treatment private houses and large buildings.Scenario 5: Outdoor use bait station.Scenario 6: Indoor use bait station.. |
| ESD(s) used | Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses. |
| Approach | A consumption based approach has been used as a suitable protective measure at the local level. |
| Distribution in the environment | Guidance on the Biocidal Products RegulationVolume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0, October 2017 (alternative: based on measured data), Technical Agreements for BiocidesEnvironment (ENV). Version 2.1, December 2019. |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed |  |
| Remarks | None |

***Emission estimation***

MAGNUM GEL HORMIGAS IGR PLUS is a ready-to-use product to be applied indoors and outdoors as a gel or by using bait stations.

**Scenario [1]: outdoor use around the buildings.**

*Spot application around large buildings*

Input values for determining releases to STP in the course of spot application are summarised in the following table:

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario:outdoor use, indirect releases |
| Quantity of b.p. applied (Qbp) | 0.2 | g |  |
| Fraction of the active substance in the product (Fai) | 0.0001 | - |  |
| Quantity of a.s. applied (Qas) | 2x10-5 | g |  |
| Application rate of the b.p. (APPb.p.) | 3 | Spot/m |  |
| Perimeter treated with the product (PERIMETERTreated)  | 100 | m |  |
| Perimeter width (PERIMETERwidth) | 0.5 | m |  |
| Number applications per day (Nappl) | 1 | d-1 |  |
| Number of point per area (Nsites) | 300 | - |  |
| Fraction emitted to STP during outdoor gel application (Fspot,gel) | 0.9 | - |  |
| Number of larger buildings per STP | 300 |  |  |
| Simultaneity factor (Fsim) | 0.03 |  |  |

S-methoprene

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario:outdoor use, indirect releases |
| Quantity of b.p. applied (Qbp) | 0.2 | g |  |
| Fraction of the active substance in the product (Fai) | 0.0008 | - |  |
| Quantity of a.s. applied (Qas) | 1.6x10-4 | g |  |
| Application rate of the b.p. (APPb.p.) | 3 | Spot/m |  |
| Perimeter treated with the product (PERIMETERTreated)  | 100 | m |  |
| Perimeter width (PERIMETERwidth) | 0.5 | m |  |
| Number applications per day (Nappl) | 1 | d-1 |  |
| Number of point per area (Nsites) | 300 | - |  |
| Fraction emitted to STP during outdoor gel application (Fspot,gel) | 0.9 | - |  |
| Number of larger buildings per STP | 300 |  |  |
| Simultaneity factor (Fsim) | 0.03 |  |  |

According to TAB, Version 2.1, December 2019, for outdoor applications of insecticides around commercial buildings, a default perimeter of 100 m is proposed with a perimeter width of 0.5 m. Considering an application rate of 3 spot.m-1, this leads to 300 gel spots applied for each commercial building. The ESD PT 18 (2008) indicates that about 90% of the insecticidal products deposited to the treated spot can be released to the environment, either directly or through ultimate release after target insect death. Thus, the fraction emitted to soil is 90%. The simultaneity factor is considered as 0.03 for outdoor treatments. In addition, following the instructions agreed in the TAB, Version 2.1, December 2019, the following assumption is considered, number of larger buildings per STP is 300.

Calculations for Scenario [*1*]

Local direct emission rate to STP per treatment:

Espot, STP = Qb.p. x Fa.i. x Nsites x Nappl x Fspot,gel xPERIMETERTreated x PERIMETERwidth

Imidacloprid, Espot, STP = 0.00270 g.d-1

S-methoprene, Espot, STP = 0.0216 g.d-1

Simultaneous emission to waste water during outdoor use:

Elocal water, sim = Espot,STP x Nhouses x FSim

Imidacloprid, Elocalwater, sim = 0.0243 g.d-1

S-methoprene, Elocalwater, sim = 0.194 g.d-1

| **Resulting local emission to relevant environmental compartments** |
| --- |
| **Compartment STP** | **Local emission (Elocalwater, sim) [kg/d]** | **Remarks** |
| Imidacloprid | 2.43 E-05 |  |
| S-methoprene | 1.94 E-04 |  |

**Scenario [2]: outdoors use, terrace scenario.**

*Spot application on paved surfaces*

According to the TAB, Version 2.1, December 2019, in case of spot application on paved surfaces around domestic premises the terrace scenario should be used (no release to sewer/STP is assumed, only releases to soil compartment around a terrace)

According to the TAB, Version 2.1, terrace length in 6 m and the soil area exposed in 8.5 m2. The ESD PT 18 (2008) indicates that about 90% of the insecticidal products deposited to the treated spot can be released to the environment, either directly or through ultimate release after target insect death.

Input values for determining direct emissions to soil:

Imidacloprid

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario:outdoor use, terrace scenario |
| Quantity of b.p. applied (Qbp) | 0,2 | g/drop |   |
| Fraction of the active substance in the product (Fai) | 1,00E-04 |   |   |
| Quantity of a.s. applied (Qas) | 2,00E-05 |   |   |
| Terrace length | 6 | m |   |
| Perimeter treated with the product (PERIMETERTwidth)  | 0,5 | m |   |
| Number applications per day | 1 | - |   |
| Number of point per area | 3 | drops/m2 |   |
| Fraction emitted to soil during outdoor gel application (Fspot,gel) | 0,9 | - |   |
| Soil area exposed (Areaexposed) | 8,5 | m2 |   |
| Soil depht (Depthsoil) | 0,5 | m |   |
| RHOsoil | 1700 | kg/m3 |   |

S-methoprene

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario:outdoor use, terrace scenario |
| Quantity of b.p. applied (Qbp) | 0,2 | g/drop |   |
| Fraction of the active substance in the product (Fai) | 8,00E-04 |   |   |
| Quantity of a.s. applied (Qas) | 1,60E-04 |   |   |
| Terrace length | 6 | m |   |
| Perimeter treated with the product (PERIMETERTwidth)  | 0,5 | m |   |
| Number applications per day | 1 | - |   |
| Number of point per area | 3 | drops/m2 |   |
| Fraction emitted to soil during outdoor gel application (Fspot,gel) | 0,9 | - |   |
| Soil area exposed (Areaexposed) | 8,5 | m2 |   |
| Soil depht (Depthsoil) | 0,5 | m |   |
| RHOsoil | 1700 | kg/m3 |   |

Calculations for Scenario [*2*]

Espot, soil = Qb.p. x Fa.i. x Nsites x Nappl x Fspot,soil x Terracelength x PERIMETERTwidth

Imidacloprid, Espot, SOIL = 1.62 E-04E g.d-1

S-methoprene, Espot, SOIL = 1.30 E-03 g.d-1

Cspot, soil =( Espot, soil / (Areaexposed x Depthsoil x RHOsoil))\*103

| **Resulting local emission to relevant environmental compartments** |
| --- |
| **Compartment STP** | **Local emission (Cspot soil) [mg/Kg]** | **Remarks** |
| Imidacloprid | 2.24 E-05 |  |
| S-methoprene | 1.79 E-05 |  |

**Scenario [3]: indoor use, spot treatment, private houses.**

This scenario is cover for scenario 4

**Scenario [4]: indoor use, spot treatment, private houses and large buildings.**

*Indoor use spot treatment private houses and large buildings*

According to the TAB, Version 2.1, generic treatment areas has been agreed for the indoor use of insecticides for each specific pest. In the case of ants, spot treatment is an appropriate scenario for indoor use.

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario:spot treatment in a house and large buildings. |
| Application rate of biocidal product *[alternative: annual tonnage in the EU]* | 0.2 | *g/drop* | 3 drops/ m2 (each drop contains 0.2 g of product)  |
| Concentration of active substance in the product | 0.1 | *g/Kg* |  |
| Number applications per day | 1 | - |  |
| Number of point per area | 3 | - |  |
| Area treated with product (private houses) | 2 | m2 |  |
| Area treated with product (large buildings) | 9.3 | m2 |  |

S-methoprene

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario: spot treatment in a house and large buildings. |
| Application rate of biocidal product *[alternative: annual tonnage in the EU]* | 0.2 | *g/drop* | 3 drops/ m2 (each drop contains 0.2 g of product)  |
| Concentration of active substance in the product | 0.8 | *g/Kg* |  |
| Number applications per day | 1 | - |  |
| Number of point per area | 3 | - |  |
| Area treated with product (private houses) | 2 | m2 |  |
| Area treated with product (large buildings) | 9.3 | m2 |  |

Calculations for Scenario [*4*]

Emissions of imidacloprid and s-methoprene to the environment due to indoor use were assumed to only occur via the release from the treated surfaces to the sewer system and thus to the STP by wet cleaning. Therefore the exposed environmental compartments comprise STP, the adjacent surface water, sediment, soil and groundwater.

According to te applicant the worst scenario is 3 drops (with 0.2 g of product) per m2 in the a spot treatment followed by a wet cleaning event. The emissions from this application are calculated for both applications private houses and large buildings using a default value agreed in the TAB version 2.1 (2019). Hence, the default value used for a private house and large building are 2 and 9.3 m2, respectively.

**Table 2.2.9.2-1: Release of imidacloprid during application (ESD PT18, 2008)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Definition** | **Imidacloprid** | **s-methoprene** |
| **Private houses** | **Large buildings** | **Private houses** | **Large buildings** |
| Number of application per day | Nappl | 1 | 1 |
| Number of point per area | Npoint | 3 | 3 |
| Fraction emitted to treated surfaces during application | Fappl | 1 | 1 |
| Quantity of commercial product applied per point of gel [g/point] | Qprod, point | 0.2 | 0.2 |
| Fraction of active substance in the commercial product | Fai | 0.0001 | 0.0008 |
| Area treated with product [m2] | AREAtreated | 2 | 9.3 | 2 | 9.3 |
| **Emission rate to treated surface during application [g/d]** | **Eapplication, surface =** **Qprod, point x Npoint x Fai x AREAtreated x Fappl x Nappl** | **1.20 E-04** | **5.58E-04** | **9.6E-04** | **4.46E-03** |

**Cleaning**

Releases to wastewater during cleaning event depend on the efficiency of the cleaning. It is considered that the cleaning efficiency (FCE) for the use of the MAGNUM GEL HORMIGAS IGR PLUS is 25% since the application is perfomed in a surface

**Table 2.2.9.2-2: Release of imidacloprid during cleaning (ESD PT18, 2008)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Definition** | **imidacloprid** | **s-methoprene** |
| **Private houses** | **Large buildings** | **Private houses** | **Large buildings** |
| Emission to floor during application step [g/d] | Eapplication, floor | 0 | 0 | 0 | 0 |
| Emission to treated surfaces during application step | Eapplication, surface | 1.20 E-04 | 5.58E-04 | 9.6E-04 | 4.46E-03 |
| Fraction emitted to wastewater during cleaning step | Fww | 1 | 1 |
| Cleaning efficiency | FCE | 0.25 | 0.25 |
| **Emission rate to wastewater during cleaning step [g/d]** | **Elocalww =** **(Eapplication, floor + Eapplication, surface) x Fww x FCE** | **3.00E-05** | **1.40E-04** | **2.40E-04** | **1.12E-03** |

Emissions have been calculated for one house and one large building, according to the ESD these values have to be multiplied by the number of houses, 4000. The number of large buildings has been refined from 1000 to 300 TAB version 2.1 (2019).

According to the applicant the product is going to be used 3 to 11 times per year depending of the level of infestation (worst case according to the efficacy studies). As this frequency of use is not indicated in the ESD PT 18, we are going to use the frequency of 8 treatment per year therefore, the simultaneity factor is:

Fsimultaneity = ((32.15\*1.9)+(37.82\*0.54))/100 = 0.815%

Thus, total emissions in wastewater are (ESD PT18, 2008):

**Table 2.2.9.2-3: Total emissions in wastewater of imidacloprid during cleaning (ESD PT18, 2008)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Definition** | **imidacloprid** | **s-methoprene** |
| **Private houses** | **Large buildings** | **Private houses** | **Large buildings** |
| Emission from treated surface to wastewater during cleaning step [g/d] | Elocalww | 3.00E-05 | 1.40E-04 | 2.40E-04 | 1.12E-03 |
| Simultaneously treated houses per STP [-] | Nhouses | 4000 | 300 | 4000 | 300 |
| Simultaneity factor[-] | Fsimultaneity | 0.00815 | 0.00815 |
| **Emission to wastewater [g/d]** | **Elocalww = Elocalww x Nhouses x Fsimultaneity** | **9.78E-04** | **3.14E-04** | **7.82E-03** | **274E-03** |
| **Total emission to wastewater [kg/d]** | **Eww total = ∑(Eww)/1000** | **1.32E-06** | **1.06E-05** |

| **Resulting local emission to relevant environmental compartments** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP (imidacloprid)  | **1.32E-06** | Worst case private house + large buildings |
| STP (s-methoprene) | **1.06E-05** | Worst case private house + large buildings |

**Scenario [5]: outdoor use in bait station.**

As it is stated in section 2.1.4.4.1, in the specific instruction of use for traps outdoor, traps should be place only in paved surfaces and places where are protected from rainfall events to avoid release of the product into the environment so, no emissions to the environment are expected (TAB ENV 158, V. 2.1. December 2019).

**Scenario [6]\_ indoors use in bait station.**

According to the OCDE ESD PT 18 (2008) emission to the environment during the use of gels deployed in bait stations are negligible during the service life stage. Therefore, from the indoor use of the biocidal product MAGNUN GEL HORMIGAS IGR PLUS in bait stations, neither direct nor indirect emission to the aquatic or terrestrial compartments can be expected thus, an environmental exposure assessment for this use in not performed.

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

| **Identification of relevant receiving compartments based on the exposure pathway** |
| --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1  | yes | Yes | No | No | Yes | No | Yes | No |  |
| Scenario 2 | No | No | No | No | No | No | Yes | Yes |  |
| Scenarios 4  | Yes | Yes | No | No | Yes | No | Yes | Yes |  |
| Scenario 5  | No | No | No | No | No | No | No | No |  |
| Scenarios 6 | No | No | No | No | No | No | No | No |  |

|  |
| --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment Imidacloprid** |
| Input  | Value  | Unit | Remarks |
| Molecular weight | 255.7 |  |  |
| Melting point | 144 | °C |  |
| Boiling point | Descomposition | °C |  |
| Vapour pressure (at 20ºC) | <0.1 | Pa |  |
| Water solubility (at 20°C) | 613 | mg/l |  |
| Log Octanol/water partition coefficient | 0.57 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 230 | l/kg |  |
| Henry’s Law Constant (at 20 C)*[if measured data available]* | 1.7x10-10 | Pa/m3/mol |  |
| Biodegradability | No  |  |  |
| DT50 for hydrolysis in surface water | 2.75 years at 12ºC/pH 9 | d or hr (at 12ºC /pH)  |  |
| DT50 for photolysis in surface water | DT50 calculated: 1.4 -16 days(fall, winter) 0.5-1.6 days (spring, summer) 1.6 days (spring, summer) | d or hr |  |
| DT50 for degradation in soil | 135.1 days | d or hr (at 12ºC) | N=4 |
| DT50 for degradation in air | 2.54 | d or hr |  |
| BCF fish | 0.61 | L.kg-1 |  |
| BMF fish | 1 | - |  |
| BCF worm | 0.88 | L.kg-1 |  |

|  |
| --- |
| Calculated fate and distribution of Imidacloprid in the STP (EUSES model 2.1) |
| Compartment | Percentage [%] |
|  |
| Air | 0 |
| Water | 97.21 |
| Sludge | 2.79 |
| Degraded in STP | 0 |

|  |
| --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment S-methoprene** |
| Input  | Value  | Unit | Remarks |
| Molecular weight | 310.48 |  |  |
| Melting point |  | °C |  |
| Boiling point | 279.9 | °C |  |
| Vapour pressure (at 20ºC) | 0.623 mPa at 20oC | mPa |  |
| Water solubility (at 20°C) | 6.85 at 20ºC | mg/l |  |
| Log Octanol/water partition coefficient (log POW) (pH 7) | 6.34 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 876 | l/kg |  |
| Henry’s Law Constant (at 20 C)*[if measured data available]* | 0.0306 | Pa/m3/mol |  |
| Biodegradability | Inherently biodegradable, not fulfilling the criteria |  |  |
| Degradation in soil (DT50) (at 12°C) | 1.55 | days |  |
| DT50 for hydrolysis in surface water | *S-Methoprene technical was found to be hydrolytically stable at pH 4, 7 and 9* *(examined* *at25, 37 and 50°C). In strong acid solution (pH 1.2), hydrolysis is rapid with a half-life of 17 hours at 37°C.* | d or hr (at 12ºC /pH)  |  |
| BCF fish | 516 | L.kg-1 |  |
| BMF fish | 10 | - |  |
| BCF earthworms | 26253.98 | L.kg-1 |  |

|  |
| --- |
| Calculated fate and distribution of S-Methoprene in the STP (EUSES model 2.1) |
| Compartment | Percentage [%] |
|  |
| Air | 0.0345 |
| Water | 90.2 |
| Sludge | 9.8 |
| Degraded in STP | 0 |

***Calculated PEC values***

The concentrations in the different environmental compartments for the different scenarios are summarized in the following table:

|  |
| --- |
| **Summary table on calculated PEC values** |
|  |  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW** | **PECair** |
|  | [mg/L] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [µg/kg] | [μg/l] | [mg/m3] |
| Scenario 1: outdoor use around the buildings | Imidacloprid | 1.18x10-5 | 1.18x10-6 | 6.81x10-6 | - | - | 1.35x10-6 | 2.22 x10-4 | - |
| S-methoprene | 8.77x10-5 | 8.76x10-6 | 1.74x10-4 | - | - | 2.64x10-6 | 2.83x10-5 | - |
| Scenario 2;Outdoor use terraces.  | Imidacloprid | - | - | - | - | - | 2.24x10-5 | 5.37x10-3 | - |
| S-methoprene | - | - | - | - | - | 1.79x10-4 | 4.29x10-2 | - |
| Scenario 4: Indoor sue, spot treatment, private and large buildings | Imidacloprid | 6.41x10-7 | 6.41x10-8 | 3.71x10-7 |  |  | 7.31x10-8 | 1.25x10-5 | - |
| S-methoprene | 4.76x10-6 | 4.75x10-7 | 9.42x10-6 |  |  | 1.43x10-7 | 1.53x10-6 | - |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is the direct consumption of insecticide by birds or mammals. No primary poisoning as consequence of the application of MAGNUM GEL HORMIGAS IGR PLUS is envisaged. According to the ESD for PT 18 (OECD, 2008), a gel formulation is not a form that could be sufficiently appetent to bird and mammals. In addition, the biocidal product should be applied only in places inaccessible by pets so that primary exposure is unlikely. Furthermore, the product contains a bittering agent that should prevent the consumption of the product by animals up in the food chain (vertebrates).A risk assessment for non-target animals primary exposed to imidacloprid and S-methoprene is therefore not deemed reasonable.

Secondary poisoning

Mammals and birds may consume contaminated worms from the contaminated soil. The concentration of the active substance in earthworms is calculated according to the guidance for the biocidal product assessment (2015).

Imidacloprid has a low potential for bioaccumulation and as such there is no significant risk of secondary poisoning from this product. However, a risk assessment for secondary poisoning has been included for informational purposes. It is has a log Kow < 3 (log Kow = 0.57) and a BCF< 100 (BCF in earthworm = 0.88 L.kg-1).

The active substance S-Methoprene has a log Kow > 3 (log Kow = 6.34) and a BCF > 100 (BCF in fish = 516 L.kg-1, BMF = 1 and BCF in earthworm = 26253.9 L.kg-1). According to the scenario secondary poisoning may occur via the aquatic food chain and/or via the terrestrial food chain. The concentration of S-Methoprene in food (i.e. in fish and in earthworm) of fish-eating and worm-eating predators (mammals) has been calculated.

Sencondary poisoning has been calculated for the worst case, scenario 1.

In accordance with the equations of the Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0, 2017, PECoral,predator for both food chain were calculated as followed:

Imidacloprid

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter / variable** | **Symbol** | **Unit** | **Value** |
| ***Aquatic food chain:*** |
| Predicted environmental concentration during episode | PEClocal,water | [mg.l-1] | 1.18E-06 |
| Bioconcentration factor for fish on wet weight basis | BCFfish | [l.kg-1wet fish] | 0.61 |
| Biomagnification factor in fish | BMF | [-] | 1 |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet fish]** | **7.20E-07** |
| ***Terrestrial food chain :*** |  |  |  |
| log of partition coefficient n-octanol-water | Log Kow | [-] | 0.57 |
| Bioconcentration factor for earthworm on wet weight basis | BCFearthworm | [l.kg-1wet earthworm] | 0.88 |
| Concentration in porewater | Cporewater | [mg.l-1] | 2.22E-04 |
| Concentration in soil | Csoil | [mg.kg-1wwt] | 1.35E-06 |
| Fraction of gut loading in worm | Fgut | [kgdwt.kg-1wwt] | 0.1 |
| Conversion factor for soil concentration wet-dry weight soil | CONVsoil | [kgwwt.kg-1dwt] | 1.13 |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet earthworm]** | **3.12E-07** |

S-methoprene

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter / variable** | **Symbol** | **Unit** | **Value** |
| ***Aquatic food chain:*** |
| Predicted environmental concentration during episode | PEClocal,water | [mg.l-1] | 8.76E-06 |
| Bioconcentration factor for fish on wet weight basis | BCFfish | [l.kg-1wet fish] | 516 |
| Biomagnification factor in fish | BMF | [-] | 10 |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet fish]** | **4.52E-02** |
| ***Terrestrial food chain :*** |  |  |  |
| log of partition coefficient n-octanol-water | Log Kow | [-] | 6.34 |
| Bioconcentration factor for earthworm on wet weight basis | BCFearthworm | [l.kg-1wet earthworm] | 26263.9 |
| Concentration in porewater | Cporewater | [mg.l-1] | 2.83E-05 |
| Concentration in soil | Csoil | [mg.kg-1wwt] | 2.64E-06 |
| Fraction of gut loading in worm | Fgut | [kgdwt.kg-1wwt] | 0.1 |
| Conversion factor for soil concentration wet-dry weight soil | CONVsoil | [kgwwt.kg-1dwt] | 1.13 |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet earthworm]** | **6.68E-04** |

#### Risk characterisation

***Atmosphere***

Conclusion.

According to the TGD on Risk Assessment (ECB Part II, 2003) there is currently no appropriate guidance to calculate a PNECair. The physical-chemical properties of imidacloprid in the environment, such as vapour pressure 4×10-10 Pa) and molecular weight (255.7), allow that imidacloprid will not readily volatilize into the atmosphere at ambient temperature and pressure. According to the Atkinson method of calculation, the main route of degradation of imidacloprid in air is via the reaction with hydroxyl radicals. The OH-radical reaction rate constant was estimated to be 5×105 OH radicals per cm3. This result indicates that imidacloprid will quickly photodegrade in air via OH reactions with a half-life of 2.54 hours considering a global 24-hours mean OH-radical concentration.

In accordance with (CAR 2013), the vapour pressure (0.623 mPa at 20 ºC) and molecular weight (310.5) indicate that S-Methoprene will not readily volatilise into the atmosphere at ambient temperature and pressure. If atmospheric exposure did occur a very short half life would be expected given the propensity for S-Methoprene to undergo rapid photodegradation.

The product is a gel and excessive release or dispersal of imidacloprid and s-methoprene into the atmosphere is highly unlikely.

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

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  |  | **PEC/PNECSTP** |
| Scenario 1: , outdoor use around building. | Imidacloprid | 1.92 x10-7 |
| S-methoprene | 1.28 x10-5 |
| Scenario 4: , indoor use, spot treatment, large buildings and private houses. | Imidacloprid | 1.05x10-8 |
| S-methoprene | 6.95x10-7 |

Conclusion:*]*

As all the PEC/ PNEC values are less than 1, an acceptable level of risk for this compartment is predicted from these scenarios..

***Aquatic compartment***

|  |
| --- |
| Summary table on calculated PEC/PNEC values |
|  |  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECsea-water** | **PEC/PNECseased** |
| Scenario 1: outdoor use aroung buildings | Imidacloprid | 2.45X10-1 | 2.62X10-1 |  |  |
| S-methoprene | 4.61X10-2 | 4.57X10-1 |  |  |
| Scenario 4: , indoor use, spot treatment, private houses and large buildings. | Imidacloprid | 1.34X10-2 | 1.43X10-2 |  |  |
| S-methoprene | 2.50X10-3 | 2.48X10-2 |  |  |

Conclusion:

As all the PEC/ PNEC values are less than 1, an acceptable level of risk to the aquatic compartment is predicted from these scenarios.

***Terrestrial compartment***

|  |  |
| --- | --- |
|  | **Calculated PEC/PNEC values** |
|  |  | **PEC/PNECsoil** |
| Scenario 1: , outdoor use around buildings. | Imidacloprid | 8.60 x 10-5 |
| S-methoprene | 1.78 x 10-5 |
| Scenario 2: , outdoor use, terrace scenario. | Imidacloprid | 1.42 x 10-3 |
| S-methoprene | 1.21 x 10-3 |
| Scenario 4: , indoor use, spot treatment, private houses and large buildings | Imidacloprid | 4.63 x 10-6 |
| S-methoprene | 9.69 x 10-7 |

Conclusion:

As the PEC/PNEC values are less than 1, an acceptable level of risk to soil is predicted from these scenarios*.*

***Groundwater***

An acceptable level of risk to groundwater is predicted for this product.

***Primary and secondary poisoning***

Primary poisoning

Risk to bees:

Imidacloprid was shown to be highly toxic to bees both by oral and contact exposure with LD50 of 0.0037 µg per bee and 0.038 µg per bee, respectively (Imidacloprid IIA, 8.3.1.1/01(BAY 158/901384)). The product MAGNUM GEL HORMIGAS IGR PLUS contain a concentration of imidacloprid of 0.01% w/w, the quantity of product necessary to reach LD50 oral and the LD50 contact are 37 µg and 810 µg, respectively. The product is a ready to use gel bait with a high contain of sugar. MAGNUM GEL HORMIGAS IGR PLUS is applied by drops or lines (elongated drops) where ants are present, the application rate is 3 drops/ m2 (1 drop=0.2 g of gel bait). Therefore, the exposure of a honeybee to the product and its mortality after consuming the biocidal product, MAGNUM GEL HORMIGAS IGR PLUS cannot be excluded.

For these reasons, ES CA suggests that when used outdoors, the product must be used in bait boxes to protect from non-target organisms.

Secondary poisoning

Secondary poisoning has been calculated for the worst case, scenario 2. The results for this scenario are summarised in the following table.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Imidacloprid | S-methoprene |
| Aquatic | Birds | 1.71 x 10-7 | - |
|  | Mammals | 8.64 x 10-8 | 1.04 x 10-3 |
| Terrestrial | Birds | 7.44 x 10-8 | - |
|  | Mammals | 3.75 x 10-8 | 1.53 x 10-5 |

Conclusion:

The risks of secondary poisoning is acceptable for the use of this product.

**MYSTURE TOXICITY**

The result of mixture toxicity assessment of the product containing two active substances (imidacloprid an d S-Methoprene) is summarised in the following table.

|  |
| --- |
| Summary table on calculated ΣPEC/PNEC values |
|  | **ΣPEC/PNECSTP** | **ΣPEC/PNECwater** | **ΣPEC/PNECsed** | **ΣPEC/PNECsoil** | **ΣPECGW** |
| Scenario 1, outdoor use aroundo buildings. | 1.30x10-5 | 2.92x10-1 | 7.19x10-1 | 1.35x10-4 | 2.51x10-4 |
| Scenario 2, outdoor use, terrace scenario. | - | **-** | **-** | 5.26x10-4 | 9.66x10-3 |
| Scenario 4, indoor use, spot treatment, private houses and large buildings. | 7.05x10-7 | 1.59x10-2 | 3.91x10-2 | 5.60x10-6 | 1.36x10-5 |
| . | - | **-** | **-** | . | - |

**Conclusion:**

The risks related to the use of this product MAGNUM GEL HORMIGAS IGR PLUS is acceptable for all the environmental compartments.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| Overall conclusion on the risk assessment for the environment of the product is summarized in the table bellow:

|  |
| --- |
| Summary table for the risk assessment of this product. |
|  | PEC/PNECstp | PEC/PNECwater | PEC/PNECsed | PEC/PNECsoil | PEC/PNECGW |
| Scenario 1, outdoor use around the building | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable |
| Scenario 2, outdoor use, terrace scenario |  |  |  | Acceptable | Acceptable |
| Scenario 4, indoor use spot treatment | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable |
| . |  |  |  |  |  |

ES CA concludes the product MAGNUM GEL HORMIGAS IGR PLUS poses no risk to the terrestrial or aquatic environmental compartments for indoor and outdoor uses, whether for bait-boxes or gel drops, taking into account the intended application rate and the uses recommendations. Nevertheless, the product contains the active substance Imidacloprid known to be toxic to bees and therefore a risk for bees cannot be excluded. For these reasons, in Spain when used outdoors, the product can only be used in bait boxes.  |

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

Recommended methods and precautions concerning handling, use, storage, transport or fire.

Handling:

Avoid contact with eyes and skin.

Use: Protection of man and animals.

The biocidal product label must state the restrictions and instructions of use to preclude exposure of man and animals:

• The product should be applied in areas inaccessible to children and animals.

Trained professional uses:

• The product can not be applied on surfaces where food/feedingstuff is prepared, consumed or stored.

• The product will be applied in the food industry in absence of foodstuff except in storerooms where the product is kept properly packaged.

• Proper measures must be taken in order to ensure that food, equipment or any utensil handled in sites previously treated with the product do not contain residues of the active substance.

Professional /General public (Non-professional uses):

• Keep away from food/feedingstuff, eating utensils or food/feed contact surfaces.

Storage:

Store in the original container tightly closed. Store in a dry, cool and well-ventilated place. It is recommended to store the product at a temperature preferably between 5°C and 45°C.

Emergency measures to protect the environment:

* Environmental Precautions: Avoid contamination of drains, surface and groundwater as well as soil.

### Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

### Comparative assessment

**Comparative Assessment for the biocidal product “MAGNUM GEL HORMIGAS IGR PLUS”**

**Background**

The Spanish competent authority has been processing an application for a biocidal product, MAGNUM GEL HORMIGAS IGR PLUS which contains an active substance, imidacloprid, which meets the criteria for substitution under Article 10 of the Biocidal Products Regulation (EU) No 528/2012. Imidacloprid is considered to be very persistent (vP) and toxic (T) but not bioaccumulative (B) and consequently meets two of the criteria for being PBT. Therefore, in line with Article 23 (1) of the Biocides Regulation the Spanish CA has conducted a comparative assessment for the product MAGNUM GEL HORMIGAS IGR PLUS according to the “Technical Guidance Note on comparative assessment of biocidal products” as agreed upon by the member states on the 55th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 (document: CA-May15-Doc.4.3.a - Final - TNG on comparative assessment.doc).

**1.- Application administrative details:**

**Procedure**: NA

**Purpose:** Authorisation

**Case Number in R4BP**: -

**Evaluating Competent Authority:** ES CA

**Applicant:** Mylva, S.A..

**(Prospective) Authorisation holder**: Mylva, S.A.

**2.- Administrative information of the BP/BPF**

**Trade name**: MAGNUM GEL HORMIGAS IGR PLUS

**Product type**: 18 (insecticide)

**Active substance**: Imidacloprid (CAS number: 138261-41-3)

**3.- Intended uses for the relevant BP in the application**

According to the applicant MAGNUM GEL HORMIGAS PLUS is an insecticide (PT18) which contains the active substance imidacloprid. The product is to be used indoors and outdoors to kill ants.

Table 3.1 List of intended uses of the biocidal product:

|  |  |
| --- | --- |
| Product type | Insecticide (PT 18) |
| Where relevant, an exact description of the authorised use | This product can only be used to kill ants |
| Target organism (including, where relevant, development stage) | Pharaoh ants (*Monomorium pharonis*), Argentine ants (*Linepithema humile*), Black ants (*Lasius niger*). |
| Field(s) of use | Indoor and outdoor use |
| Application method(s) | Gel, ready to use product (directly or in bait station) |
| Category(ies) of users | All users |

**4.- Mapping of existing alternatives to the relevant BP**

**4.1.- Identified eligible alternative BPs**

The Spanish CA has used the information available to the ES CA on the 19th of June 2019 of the biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012. In Spain 90 products PT18 have been authorised. These products are based in twelve active substances but only four of these actives substances are used for the control of ants: indoxacarb, spinosad, fipronil and deltamethrin.

Espinosad and fipronil are themselves candidates for substitution, both substances are very persistent.

The product based on indoxacarb is to be used indoor and outdoor by professional users so; this product is not considered as eligible alternative BP. Only three products bases on the active substances, spinosad and deltamethrin are for all users to control ants.

**4.2.- Identified eligible non-chemical alternatives**

Not relevant in the screening phase.

**5.- Screening phase**

**5.1.- Description of the assessment of the adequate chemical diversity in authorised BPs to minimise the occurrence of resistance and conclusion.**

In accordance with Article 23(b) of the BPR, the eCA has to check first if the chemical diversity of the available ASs within the identified alternative BPs can be considered as adequate to minimise the occurrence of resistance in the target harmful organism(s). In the Technical Guidance Note on comparative assessment of biocidal products (document: CA-May15-Doc.4.3.a - Final - TNG on comparative assessment.doc) is proposed as a general rule, at least three different “active substances/ mode action” combination should remain available through authorised BPs for a given use in order to consider that the chemical diversity is adequate. This availability of ASs should be also looked at taking into account the different user categories, so that chemical diversity is adequate in BPs authorised both for professional and non-professional users. An inadequate chemical diversity for one user category could lead to resistance occurrence, which might spread afterwards across the target organism population.

The Spanish CA has checked whether the chemical diversity of the available active substances/ mode action within the identified alternative biocidal products can be considered adequate to minimise the occurrence of resistance in the target harmful organism (i.e. ants).

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

Based on the Assessment Report for active substance approval, imidacloprid shall be considered a candidate for substitution using the criteria in Article 10 (1). Imidacloprid is not considered as meeting the exclusion criteria according to Article 5 (1). Imidacloprid is considered to be very persistent (vP) and toxic (T) but not bioaccumulative (B) and therefore meets two of the criteria for being PBT.

**5.3.- Conclusion of the screening phase:**

Stop the comparative assessment. The Spanish CA concludes that there is not an adequate chemical diversity for products to kill ants for indoor and outdoor use by professional, non-professionals and trained professionals.

The comparative assessment is finalised at this stage. The product MAGNUM GEL HORMIGAS IGR PLUS is authorised for a period not exceeding 5 years in accordance with Article 23 (6).

# Annexes

## List of studies for the biocidal product

| **Section No.**  | **Author(s)**  | **Year** | **Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published**  |
| --- | --- | --- | --- |
| 2.1.2 | Anonymous  | 2015 | MSDS of MAGNUM GEL HORMIGAS IGR PLUS Sheet Facility: MYLVA S.A.; Vía Augusta, 48, 08006- BARCELONA, Spain. |
| 2.1.2 | Anonymous  | 2015 | MSDS of IMIDACLOPRID TC Sheet Facility: Bayer CropScience AG; Alfred-Nobel-Straße 50, 40789 Monheim am Rhein, Germany. |
| 2.1.2 | Anonymous  | 2017 | MSDS of S-(+)-Methoprene Sheet Facility: Bábolna Bioenvironmental Centre Ltd.; H-1107 Budapest, Szállás u. 6. Hungary. |
| 2.1.2 | Anonymous  | 2014 | MSDS of Co-formulant 1Sheet Facility: Emilio Peña, S.A.; Pol.Ind. Masía del juez; C/ Dels Llibrers, 19 – 46900; Torrente – Valencia – España |
| 2.1.2 | Anonymous  | 2018 | MSDS of Co-formulant 2 Sheet Facility: Johnson Matthey plc; Wheatfield Road, Edinburgh, EH11 2QA; Scotland |
| 2.1.2 | Anonymous  | 2014 | MSDS of Co-formulant 3Sheet Facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS -MADRID |
| 2.1.2 | Anonymous  | 2012 | MSDS of Co-formulant 4Sheet Facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS -MADRID |
| 2.1.2 | Anonymous  | 2016 | MSDS of Co-formulant 5Sheet Facility: SUCESORES DE JOSÉ ESCUDER, S.L.; Avda. Antoni Gaudí, 60 - 62 Pol. Ind. Rubí-Sud 08191; Rubí; Barcelona; Spain. |
| 2.1.2 | Anonymous  | 2014 | MSDS of Co-formulant 6Sheet Facility: Gadot Biochemical Industries Ltd; 117 Hahistadrut Ave; P.O.B 10636; Haifa Bay 26118; Israel |
| 2.1.2 | Anonymous  | 2015 | MSDS of Co-formulant 7Sheet Facility: SPI Pharma Inc.; Rockwood Office Park; 503 Carr Road; Wilmington, Delaware 19809 |
| 2.1.2 | Anonymous  | 2018 | MSDS of Co-formulant 8 Sheet Facility: SUCESORES DE JOSÉ ESCUDER, S.L.; Avda. Antoni Gaudí, 60 - 62 Pol. Ind. Rubí-Sud 08191; Rubí; Barcelona; Spain. |
| 2.1.2 | Anonymous  | 2018 | MSDS of Co-formulant 9Sheet Facility: Emilio Peña, S.A.; Pol.Ind. Masía del juez; C/ Dels Llibrers, 19 – 46900; Torrente – Valencia – España |
| 2.2.2 | Xxxxxxx xxxxxxx xx | 2015 | Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL HORMIGAS IGR PLUS (IMIDACLOPRID 0.01% W/W AND S-METHOPRENE 0.08% W/W) Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain.Study code: E-15/0002 at July 2015GLP compliance → YesData protection claimed → Yes |
| 2.2.2 / 2.2.4 | Xxxxxxx xxxxxxx xx | 2017 | Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL HORMIGAS IGR PLUS (IMIDACLOPRID 0.01% W/W AND S-METHOPRENE 0.08% W/W) Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain.Study code: E-15/0003 at March 2017GLP compliance → YesData protection claimed → Yes |
| 2.2.2 / 2.2.4 | Xxxxxxx xxxxxxx xx | 2017 | Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL HORMIGAS IGR PLUS (IMIDACLOPRID 0.01% W/W AND S-METHOPRENE 0.08% W/W) Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain.Study code: E-15/0003 at August 2017GLP compliance → YesData protection claimed → Yes |
| 2.2.2 / 2.2.4 | Xxxxxxx xxxxxxx xx | 2018 | Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL HORMIGAS IGR PLUS (IMIDACLOPRID 0.01% W/W AND S-METHOPRENE 0.08% W/W) Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain.Study code: E-15/0003 at August 2018GLP compliance → YesData protection claimed → Yes |
| 2.2.2 / 2.2.4 | Xxxxxxx xxxxxxx xx | 2020 | Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL HORMIGAS IGR PLUS (IMIDACLOPRID 0.01% W/W AND S-METHOPRENE 0.08% W/W) Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain.Study code: E-15/0003 at January 2020GLP compliance → YesData protection claimed → Yes |
| 2.2.2 | Xxxxxxxx xx xxxxx xx | 2015 | Title: Determination of whether the bait samples Magnum Gel Cucarachas IGR Plus 2.15 % and Magnum Gel Hormigas IGR Plus 0’01 % are a solid or a liquid. Test Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain.Study code: PG007-14/05GLPData protection claimed → Yes |
| 2.2.3 | Xxxxxxxx xx xxxxx xx | 2021 | Title: Determination of DSC of Magnum Gel Cucarachas IGR Plus. Test Facility: Laboratory of Magnetic and Thermal Measurements (LMT), Universidad de Barcelona, Edifici Cn Campus de la UAB 08193 Bellaterra (Cerdanyola del Vallès) Barcelona. SpainTel.: 34 - 93 581 34 74 / 34 93 581 16 57 - Fax: 34 - 93 581 21 55LMT@uab.es<http://sct.uab.cat/lmt/>Study code: 210603Non-GLPData protection claimed → Yes |
| 2.2.3 | Xxxxxxxx xx xxxxx xx | 2021 | Title: IMMERSION CORROSION TESTING S/ASTM-G 31.REF.: MAGNUM ANT GEL IGR PLUS BATCH: P649 F. EXPIRY DATE: 06-2023Test Facility: metal test – laboratorio de ensayos y verificacion 3D. Pol. Ind. Del Circuit C/ Mass Moreneta, esq. Can Cabanyes, 08160, Montmeló, Barcelona.Tel.: +34 - 93 564 54 53 - Fax: +34 - 93 564 50 73Study code: E-01430.00001Non-GLPData protection claimed → Yes |
| 2.2.5 | Xxxxx xx  | 2016  | Title: Laboratory bioassay to determine the efficacy of Magnum Gel/Ecogel hormigas IGR Plus (Bait station) against *Linepithema humile*, *Monomorium pharaonis* and *Lasius niger.*Test facility: Mylva S.A. Report no. ES0039/02Data protection claimed → Yes |
| 2.2.5 | Xxxxxxxx xx  | 2015  | Title: Laboratory bioassay to determine the efficacy of Magnum Gel Hormigas IGR Plus against *Linepithema humile*, *Monomorium pharaonis* and *Lasius niger.*Test facility: Mylva S.A.Report no. ES0018-13/23Data protection claimed → Yes |
| 2.2.5 | Xxxxxxxx xx  | 2016  | Title: Field trial to determine the efficacy of Magnum Gel / Ecogel Hormigas IGR Plus (BaitStation) against *Linepithema humile*, *Monomorium pharaonis* and *Lasius niger*Test facility: Mylva S.A.Report no. ES0036-7/13Data protection claimed → Yes |
| 2.2.5 | Xxxxxxxx xx | 2016  | Title: Semi-field trial to determine the efficacy of Magnum Gel / Ecogel Hormigas IGR Plus against *Lasius niger*Test facility: Mylva S.A.Report no. ES0034-A/7Data protection claimed → Yes |
| 2.2.5 | Xxxxxxxx xx | 2015  | Title: Field trial to determine the efficacy of Magnum Gel Hormigas IGR Plus against *Linepithema humile* , *Monomorium pharaonis* and *Lasius niger*Test facility: Mylva S.A.Report no. ES0032-4/12Data protection claimed → Yes |
| 2.2.5 | Xxxxxx xx | 2019  | Title: Laboratory bioassay to determine the the effect of 0.08% S-methoprene against Argentine ant, *Linepithema humile*.Test facility: Mylva S.A.Report no. ES0046.A-3/19Data protection claimed → Yes |
| 2.2.5. | XXXXXXXX | 2018 | Title: Laboratory bioassay to determine the efficacy of Magnum Gel Hormigas IGR Plus against *Linepithema humile, Monomorium pharaonis and Lasius grandis*. (·3 years)Test facility: Mylva S.A.Report no. ES0035-3/12Data protection claimed → Yes |
| 2.2.5. | XXXXXXX | 2019 | Title: Laboratory bioassay to determine the efficacy of Magnum Gel Hormigas IGR Plus against *Linepithema humile, Monomorium pharaonis and Lasius grandis*. (4 years)Test facility: Mylva S.A.Report no. ES0035-11/19Data protection claimed → Yes |
| 2.2.6 | Mylva Regulatory Affairs | 2015 | Acute Toxicity of the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUSTest Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain.Toxicity Report: ATR004.1-08/15 |
| 2.2.6 | Xxxxxx xx | 2015 | Risk Characterisation of the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUSTest Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain.Report code: RC002.2-08/15 |
| 2.2.6 | Mylva Regulatory Affairs | 2017 | Risk Characterisation of the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUSTest Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain.Report code: RC002.2-09/17 |
| 2.2.6 | Mylva Regulatory Affairs | 2018 | Risk Characterisation of the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUSTest Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain.Report code: RC002.2-10/18 |
| 2.2.6 | Xxxxxx xx | 2015 | Effects and Exposure Assessment for the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUSTest Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain.Report code: EA002.1-08/15 |
| 2.2.6 | Mylva Regulatory Affairs | 2017 | Effects and Exposure Assessment for the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUSTest Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain.Report code: EA002.1-09/17 |
| 2.2.6 | Mylva Regulatory Affairs | 2018 | Effects and Exposure Assessment for the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUSTest Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain.Report code: EA002.1-10/2018 |
|  | ECHA | 2011 (revised version: July 2015) | Competent Authority Report and Assessment Report of IMIDACLOPRID. |
|  | ECHA | 2013 | Competent Authority Report and Assessment Report of S-METHOPRENE. |
|  | Official Journal of the European Union | 2011 | COMMISSION DIRECTIVE 2011/69/EU |
|  | Official Journal of the European Union | 2014 | COMMISSION IMPLEMENTING REGULATION (EU) No 91/2014 |

## Output tables from exposure assessment tools

### Exposure assessment

#### Calculations for Scenario [1]

Exposure is estimated using the following calculations:

*Exposure = (Number of events \* quantity of product per event \* Fraction of active substance/Kg bw/person) \* dermal absorption*

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameters** | **Imidacloprid** | **S-Methoprene** | **Units**  |
| Chronic exposure  | 33,30 | 33,30 | mg |
| number of opening and sealing per day | 10 | 10 |  |
| content of active substance in product | 0,0001 | 0,0008 | mg/kg |
| Dermal absorption | 75% | 75% | % |
| Body weight adult | 60 | 60 | kg |
| potential exposure a.s. | 3,33E-02 | 0,2664 | mg |
| aborbed dermal dose a.s. | 2,50E-02 | 0,1998 | mg |
| **actual exposure**  | **4,16E-04** | **3,33E-03** | **mg/kg bw/d** |

#### Calculations for Scenario [2]

Exposure is estimated using the following calculations:

*Exposure = (Number of events \* quantity of product per event \* Fraction of active substance/Kg bw/person) \* dermal absorption*

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameters** | **Imidacloprid** | **S-Methoprene** | **Units**  |
| Post-application | 33,30 | 33,30 | mg |
| number of opening and sealing per day | 1 | 1 |  |
| content of active substance in product | 0,0001 | 0,0008 | mg/kg |
| Dermal absorption | 75% | 75% | % |
| Body weight adult  | 60 | 60 | kg |
| potential exposure a.s. | 3,33E-03 | 2,66E-02 | mg |
| aborbed dermal dose a.s. | 2,50E-03 | 2,00E-02 | mg |
| **actual exposure mg/kg bw/d** | **4,16E-05** | **3,33E-04** | **mg/kg bw/d** |

#### Calculations for Scenario [3]

Exposure is estimated using the following calculations:

*Exposure = (Number of events \* quantity of product per event \* Fraction of active substance/Kg bw/person) \* dermal absorption*

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameters** | **Imidacloprid** | **S-Methoprene** | **Units**  |
| Amount b.p. (worst case) | 33,30 | 33,30 | mg |
| number of opening and sealing per day | 2 | 2 | -- |
| content of active substance in product | 0,0001 | 0,0008 | mg/kg |
| Dermal absorption | 75% | 75% | % |
| Body weight adult  | 60 | 60 | kg |
| potential exposure a.s. | 6,66E-03 | 5,33E-02 | mg |
| absorbed dermal dose a.s. | 5,00E-03 | 4,00E-02 | mg |
| **actual exposure**  | **8,33E-05** | **6,66E-04** | **mg/kg bw/d** |

#### Calculations for Scenario [4]

See section 3.2.1.2

#### Calculations for Scenario [7]

Exposure is estimated using the following calculations:

* *External dermal load (EDL) = Quantity of product in 1 line 3 cm length \* dislodgeable residue \* fraction of a.s. in the product*
* Estimated dermal uptake = (EDL \* dermal absorption)/Kg bw
* Estimated oral uptake = (EDL \* 10% \* oral absortion) / body weight.
* Estimated total uptake = estimated dermal uptake + estimated oral uptake

|  |  |  |  |
| --- | --- | --- | --- |
| **Parametres** | **S-Methoprene** | **Imidacloprid** | **Units** |
| bw toddler | 10 | 10 | kg |
| amount b.p. (worst case) | 333.3 | 333.3 | mg |
| Oral absorption | 35% | 100% | % |
| DA | 75% | 75% | % |
| content as | 0,08% | 0,01% | % |
| potential exp | 0,27 | 3,33E-02 | mg as |
| absorbed dermal dose | 0,20 | 2,50E-02 | mg as |
| actual exp dermal toddler | 2,00E-02 | 2,50E-03 | mg/kg bw |
| 90% external dermal load | 1,80E-02 | 2,25E-03 | mg/kg bw |
| actual exp oral tod (10% external dermal ingested) | 9.33E-04 | 3.33E-4 | mg/kg bw |
| **combined exposure toddler** | 1,89E-02 | 2,58E-03 | **mg/kg bw** |

## New information on the active substance

New information on the active substance has not been submitted.

## Residue behaviour

MAGNUM GEL HORMIGAS PLUS provides efficacy to kill ants (Product Type 18).

Active substance(s): Imidacloprid 0.01% w/w and S-Methoprene 0.08%.

Formulation of biocidal product: ready-to-use gel bait

MAGNUM GEL HORMIGAS IGR PLUS is supplied as ready to use gel intended for use by professional and non-professional users to kill ants: Argentine ant (*Linepithema humile*), and Black ant (*Lasius niger*).

The biocidal product is manually applied by using a cartridge/syringe in drops or lines (up to three lines of bait per site). Ready for use bait stations are manually placed in areas where ants are known to travel. The bait is placed at the appropriate spots where the ants may be present and close to the ants’ nests.

The biocidal product is a gel formulation applied directly on localized spots difficult to access. This precise formulation prevents the formation of splashes making surface contamination unlikely. Likewise, surface contamination is not expected when using the gel in bait stations. Also, the product should be placed in spots inaccessible to children and animals.

In addition the biocidal product label must state the restrictions and instructions of use to preclude dietary exposure.

The following label restrictions preclude food contamination (trained professional uses):

* + The product can not be applied on surfaces where food is prepared, consumed or stored.
	+ The product will be applied in the food industry in absence of foodstuff except in storerooms where the stored products are kept properly packaged.
	+ Proper measures must be taken in order to ensure that food, equipment or any utensil handled in sites previously treated with the product do not contain residues of the active substance.

The following label restrictions preclude food contamination (professional/non-professional uses):

* + Do not apply on surfaces or utensils that can be in contact with foodstuff. The following label restrictions preclude the exposure of animals:
	+ The treatment must be restricted to areas out of reach of animals
	+ The product can not be applied on surfaces where feed is prepared, consumed or stored.
	+ Do not apply on surfaces or utensils that can be in contact with feedingstuff. It is concluded that dietary exposure i.e., food contamination and exposure of livestock to residues of the biocidal product is not expected.

## Summaries of the efficacy studies (B.5.10.1-08)

Please, see efficacy data table.