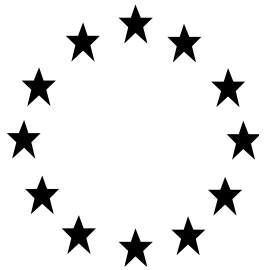
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



MAGNUM GEL CUCARACHAS

Product type 18

IMIDACLOPRID

Case Number in R4BP: BC-KN010529-32

Evaluating Competent Authority: SPAIN

April 2020

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# 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-KN010529-32 | June 2013 | Initial assessment |
| NA-APP | ES | ES-0008960-0000 | August 2017 | First authorisation |
| NA-AAT | ES | ES-0008960-0000 | February 2018 | Amendment |
| NA-AAT | ES | ES-0008960-0000 | January 2019 | Amendment |
| NA-AAT | ES | ES-0008960-0000 | May 2019 | Amendment |
| NA-MIC | ES | BC-CB048371-65 | January 2020 | Extension of shelf-life. |
| NA-AAT | ES | | April 2020 | Amendment |

The new information is found in section 3.7. Addendum and 3.8. Confidential annex.

# 1 CONCLUSION

The assessment presented in this report has shown that the ready-to-use product, MAGNUM GEL CUCARACHAS, with the active substance imidacloprid, at a level of 2.15% w/w, may be authorised for use as an insecticide (product-type 18) for the control against cockroaches. Please, note that this Assessment Report includes the uses requested by the applicant, as information for the concerned member states.

The biocidal product is a gel solid practically odourless. The formulation exhibited stability under accelerated storage and storage for 3 years at room temperature. The formulation does not have a corrosive effect and it does not react with the packing material. The formulation is not considered flammable. It is predicted to be neither explosive nor oxidizing. Even so, there may not be hazards associated with the physic-chemical properties of the product under normal conditions of use.

A validated analytical method is 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.

MAGNUM GEL CUCARACHAS has demonstrated sufficient efficacy in laboratory choice tests and field trials against three species of cockroaches (*Blatta orientalis, Blattella germanica* and *Periplaneta americana*) living in houses and commercial buildings with the method of application by droplets and bait stations. The applicant has not provided trials with the aged bait at the maximum storage period demonstrated.

No substances of concern has been identified for human health. The risk assessment has been carried out the active substance imidacloprid. The biocidal product is not classified for human health.

MAGNUM GEL CUCARACHAS is a ready-to-use product to be applied indoor as gel drops/lines and using bait stations. 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 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 CUCARACHAS 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.

Exposure of consumers via residues in food as result of product uses is not expected due to the application method and the physical properties of product. Moreover, some label restrictions to avoid this contamination have been included. See point 2.2.6.3 *Risk for consumers via residues in food.*

For the same reasons, neither is expected exposure of animals (companion animals, livestock) and some labels restrictions to avoid this exposure have been also included. See point 2.2.7. *Risk assessment for animal health*

Regarding environment, since no substance of concern has been identified the risk assessment of this product has been based only on the active substance Imidacloprid. The risk assessment for the product has been carried out for the intended use(s) proposed by the applicant. Based on the risk assessment (chapter 2.2.8), the intended uses proposed in chapter 2.1.10 following the direction for use and risk mitigation measures do not cause any unacceptable risk for the environment.

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 control cockroaches for indoor use by different 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 use by different users categories.).

# 2 ASSESSMENT REPORT

## 2.1 Summary of the product assessment

### 2.1.1 Administrative information

#### 2.1.1.1. Identifier of the product

| **Identifier** | **Country (if relevant)** |
|---|---|
| MAGNUM GEL CUCARACHAS | SPAIN |

#### 2.1.1.2. Authorisation holder

| | | |
|---|---|---|
| **Name and address of the authorisation holder** | **Name** | MYLVA S.A. |
| | **Address** | Via Augusta, 48<br>08006 Barcelona<br>Telephone: +34 934 153226<br>Fax: +34 934156344<br>E-mail: mylva@mylva.eu |
| **Authorisation number** | ES/NA-APP-2017-18-00449 | |
| **Date of the authorisation** | | |
| **Expiry date of the authorisation** | 5 years since the date of the authorisation. | |

#### 2.1.1.3. Manufacturer of the products

| | |
|---|---|
| **Name of manufacturer** | MYLVA, S.A. |
| **Address of manufacturer** | Via Augusta, 48<br>08006 Barcelona<br>Telephone: +34 934 153226<br>Fax: +34 934156344<br>E-mail: mylva@mylva.eu |
| **Location of manufacturing sites** | C/ Sant Galderic, 23 Polígono Industrial Ponent, Sant Pol de Mar<br>08395 Barcelona |

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

| | |
|---|---|
| **Active substance** | Imidacloprid |
| **Name of manufacturer** | Bayer CropScience AG |
| **Address of manufacturer** | Industiral Operations<br>Alfred Nobel-Strasse 50<br>D-40789 Monheim am Rhein (Germany) |
| **Location of manufacturing sites** | D-41538 Dormagen (Germany) |

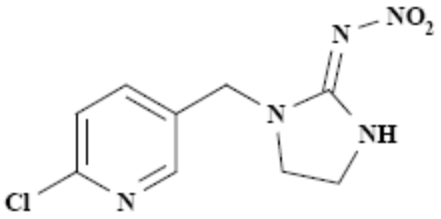
### 2.1.2 Product composition and formulation

NB: the full composition of the product has been 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

### 2.1.3 Identity of the active substance

| **Main constituent** | |
|---|---|
| **ISO name** | Imidacloprid |
| **IUPAC or EC name** | (2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine |
| **EC number** | 428-040-8 |
| **CAS number** | 138261-41-3 |
| **Index number in Annex VI of CLP** | 612-252-00-4 |
| **Minimum purity / content** | 970 g/kg (97% w/w) |
| **Structural formula** |  |

### 2.1.4 Candidate for substitution

Biocidal product MAGNUM GEL CUCARACHAS 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 CUCARACHAS according to the "Technical Guidance Note on comparative assessment of biocidal products" as agreed upon by the member states on the 55$^{th}$ 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).

MAGNUM GEL CUCARACHAS is an insecticide (PT 18) to be used indoor by different users to control cockroaches (German cockroaches [*Blattella germanica*], Oriental cockroaches [*Blatta orientalis*], American cockroaches [*Periplaneta americana*], and *Supella longipalpa*). The product has been only compared with alternative products

authorised in Spain as the searchable SPCs and a corresponding search tool in the Register for Biocidal Products (R4BP) is currently not available. The Spanish CA has used the information available to the ES CA on the 30th of January 2016 of the biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012. In Spain seven products PT18 have been authorised. These products are based in four active substances but only three of these actives substances are used for the control of cockroaches: Indoxacarb, nitrogen and abamectin. The biocidal product containing nitrogen is for professional users to be used in closed environment such as sealed fumigation chambers so, this product is not considered as eligible alternative BP and therefore is not include in the comparative assessment. The BP containing indoxacarb is for professional users to be use indoor and outdoor. Products based on abamectin (two products) are to be used indoor by non-professionals. The active substance abamectin also fulfils the substitution criteria, but it is considered to persistent (P) while imidacloprid is considered very persistent. Neither of the BPs mentioned above control all the species of cockroaches controlled by MAGNUM GEL CUCARACHAS. On the other hand, no eligible non-chemical alternatives were identified on the screening phase.

As a general rule at least three different active substances – mode of action combinations should remain available through authorised biocidal product for a given use (indoor/outdoors use by different 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. cockroaches). The Spanish CA concludes that there is not an adequate chemical diversity for products to control cockroaches for indoor use by different users categories. Therefore, the comparative assessment is finalised at the screening phase. The product MAGNUM GEL CUCARACHAS is authorised for a period not exceeding 5 years in accordance with Article 23 (6).

### 2.1.5 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 | 2.15 |
| - | - | Non-active substance | - | - | - |

### 2.1.6 Information on technical equivalence

The manufacturer and the manufacturing site of the active substance used in the biocidal product are identical to the manufacturer and the manufacturing site of the

active substance approved under Regulation (EU) Nº 528/2012. Therefore no check for equivalence is necessary.

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

MAGNUM GEL CUCARACHAS contains 1,2-Benzisothiazol-3(2H)-one and 2-octyl-1,2-thiazol-3-one as preservatives which are currently under evaluation as a biocidal active substances but toxicological reference values have not been agreed on. Furthermore, their concentration in the biocidal product is below concentration limits for classification as a sensitizers. Therefore, according to the Substances of Concern Guidance, these substances are currently not identified as substances of concern.

Regarding environmental aspects, the biocidal product contains four compounds different from the active substance (imidacloprid) classified as dangerous for the environment. The bittering agent (denatonium benzoate), should not be considered a substance of concern due to the low percentage in which it is present in the biocidal product. Polyoxyethilene tridecyl ether, classified as A1, but due to the low percentage in which it is present in the product should not be considered a substance of concern. The product also contains two preservatives currently in the review program of active substances (2-octyl-2H-isothiazol-3-one (OIT) and 1,2-benzisothiazol-3(2H)-one (BIT)). The data related to these preservatives shall be taken into account in the evaluation after their approvals at European level, at product's renewal stage.

Therefore environmental effects of the product can be extrapolated from the environmental effect studies on imidacloprid.

### 2.1.8 Type of formulation

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

### 2.1.9 Hazard and precautionary statements

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

| **Classification** | |
|---|---|
| Hazard category | Aquatic Acute 1, Aquatic Chronic 1 |
| Hazard statement | H400: Very toxic to aquatic life.<br>H410: Very toxic to aquatic life with long lasting effects. |
| | |
| **Labelling** | |
| Hazard pictograms |  <br>GHS09 |
| Signal words | Warning |

| | |
|---|---|
| Hazard statements | H410 Very toxic to aquatic life with long lasting effects<br>EUH208 Contains 1,2-Benzisothiazol-3(2H)-one and 2-octyl-1,2-thiazol-3-one. May produce an allergic reaction. |
| Precautionary statements | P102 Keep out of reach of children.<br>P103 Read label before use.<br>P273 Avoid release to the environment.<br>P391 Collect spillage.<br>P501 Dispose of contents/containers in accordance with local regulations. |
| | |

## 2.1.10 Authorised uses

2.1.10.1. Use description. Table 1

Table 1. Use 1 – Indoor, crack and crevices, gel bait applied as drops - general public (non-professional)

| | |
|---|---|
| **Product Type** | PT18. |
| **Where relevant, an exact description of the authorised use** | Insecticide against cockroaches. |
| **Target organism (including development stage)** | Insecticide against the following target insects (adults)<br>German cockroaches (*Blattella germanica*),<br>Oriental cockroaches (*Blatta orientalis*)<br>American cockroaches (*Periplaneta Americana*) |
| **Field of use** | Indoors, crack and crevices. |
| **Application method** | Open application of a gel bait applied as a drops from a syringe/cartridge. |
| **Application rate and frequency** | Dose: depends on the level of infestations and species of cockroaches. (1 drop = 0'04 g).<br>German cockroaches (*Blattella germanica*): 0'12-0'16 g/$m^2$ (3-4 drops/$m^2$).<br>Oriental cockroaches (*Blatta orientalis*): 0'16-0'24g/$m^2$ (4-6 drops/$m^2$)<br>American cockroaches (*Periplaneta Americana*): 0'16g/$m^2$ - 0'24 g/$m^2$(4-6 drops/$m^2$)<br><br>Frequency of application: 1 application in 4 weeks. Reapply only once more if the infestation persists. Do not apply more than 12 drops per house per application.<br><br>Frequency of treatment: Three months after the infestation's end, treatment may be repeated |
| **Category of users** | General Public (non-professional) |

| | |
|---|---|
| **Pack sizes and packaging material** | LDPE plastic syringes of 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10g |

2.1.10.1.1 Use-specific instructions for use.

| |
|---|
| Apply the biocidal product only in crack and crevices, behind furniture and engines. The product can not be used on surfaces. |
| Do not mix with other chemicals or in areas recently treated with another insecticide. |
| Do not use on wood or porous surfaces. |
| Avoid contact with treated surfaces. |
| Do not expose bait drops to sunlight or heat source (i.e. radiator). |

2.1.10.1.2 Use-specific risk mitigation measures

| |
|---|
| Avoid contact with eyes and skin. |
| The product should not be applied in a zone accessible to children. |
| The treatment must be restricted to areas out of reach of animals. |
| Do not apply on surfaces or utensils which can be in contact with feed/foodstuff. |
| Use only in concealed areas difficult to access and kept away from water. |

2.1.10.1.3 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 2.1.11.3 |

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

| |
|---|
| See section 2.1.11.4. |

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

| |
|---|
| See section 2.1.11.5. |

2.1.10.2. Use description. Table 2

Table 2. Use # 2 – Indoor, crack and crevices.- gel bait applied as drops – professional user.

| | |
|---|---|
| **Product Type** | PT18. |
| **Where relevant, an exact description of the authorised use** | Insecticide against cockroaches. |
| **Target organism (including development stage)** | Insecticide against the following target insects (adults)<br>German cockroaches (*Blattella germanica*),<br>Oriental cockroaches (*Blatta orientalis*)<br>American cockroaches (*Periplaneta Americana*) |
| **Field of use** | Indoors, crack and crevices. |

| | |
|---|---|
| **Application method** | Open application of a gel bait applied as a drops from a syringe/cartridge. |
| **Application rate and frequency** | Dose: depends on the level of infestations and species of cockroaches. (1 drop = 0'04 g).<br>German cockroaches (*Blattella germanica*): 0'12-0'16 g/$m^2$ (3-4 drops/$m^2$).<br>Oriental cockroaches (*Blatta orientalis*): 0'16-0'24g/$m^2$ (4-6 drops/$m^2$)<br>American cockroaches (*Periplaneta Americana*): 0'16g/$m^2$ - 0'24 g/$m^2$(4-6 drops/$m^2$)<br><br>Frequency of application: 1 application in 4 weeks. Reapply only once more if the infestation persists. Do not apply more than 12 drops per house per application.<br><br>Frequency of treatment: Three months after the infestation's end, treatment may be repeated |
| **Category(ies) of users** | Professional. |
| **Pack sizes and packaging material** | LDPE plastic syringes of 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10g |

2.1.10.2.1 Use-specific instructions for use.

Apply the biocidal product only in crack and crevices, behind furniture and engines. The product can not be used on surfaces.

Do not mix with other chemicals or in areas recently treated with another insecticide.

Do not use on wood or porous surfaces.

Avoid contact with treated surfaces.

Do not expose bait drops to sunlight or heat source (i.e. radiator).

2.1.10.2.2 Use-specific risk mitigation measures

Avoid contact with eyes and skin.

The product should not be applied in a zone accessible to children

The treatment must be restricted to areas out of reach of animals.

Do not apply on surfaces or utensils which can be in contact with feed/foodstuff.

Use only in concealed areas difficult to access and kept away from water.

2.1.10.2.3 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 2.1.11.3

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

See section 2.1.11.4.

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

| |
|---|
| See section 2.1.11.5. |

2.1.10.3. Use description. Table 3

Table 3. Use # 3 – Indoor, crack and crevices, gel bait applied as drops – trained professional user.

| | |
|---|---|
| **Product Type** | PT18. |
| **Where relevant, an exact description of the authorised use** | Insecticide against cockroaches. |
| **Target organism (including development stage)** | Insecticide against the following target insects (adults)<br>German cockroaches (*Blattella germanica*),<br>Oriental cockroaches (*Blatta orientalis*)<br>American cockroaches (*Periplaneta Americana*) |
| **Field of use** | Indoors, crack and crevices. |
| **Application method** | Open application of a gel bait applied as a drops from a syringe/cartridge. |
| **Application rate and frequency** | Dose: depends on the level of infestations and species of cockroaches. (1 drop = 0'04 g).<br>German cockroaches (*Blattella germanica*): 0'12-0'16 g/$m^2$ (3-4 drops/$m^2$).<br>Oriental cockroaches (*Blatta orientalis*): 0'16-0'24g/$m^2$ (4-6 drops/$m^2$)<br>American cockroaches (*Periplaneta Americana*): 0'16g/$m^2$ - 0'24 g/$m^2$(4-6 drops/$m^2$)<br><br>Frequency of application: 1 application in 4 weeks. Reapply only once more if the infestation persists. Do not apply more than 12 drops per house per application.<br><br>Frequency of treatment: Three months after the infestation's end, treatment may be repeated. |
| **Category of user** | Trained Professional user. |
| **Pack sizes and packaging material** | LDPE plastic syringes of 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10g<br>LDPE plastic cartridge of 15, 20, 30, 35, 40 y 50 g. |

2.1.10.3.1 Use-specific instructions for use.

| |
|---|
| Apply the biocidal product only in crack and crevices, behind furniture and engines. The product can not be used on surfaces.<br>Do not mix with other chemicals or in areas recently treated with another insecticide. |

Do not use on wood or porous surfaces.

Avoid contact with treated surfaces.

Do not expose bait drops to sunlight or heat source (i.e. radiator).

2.1.10.3.2 Use-specific risk mitigation measures

Wear appropriate gloves during application.

Avoid contact with eyes and skin.

The product should not be applied in a zone accessible to children.

The treatment must be restricted to areas out of reach of animals.

The product can not be applied on surfaces where feed/foodingstuff is prepared, served, 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 substanceUse only in concealed areas difficult to access and kept away from water.

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.)

Check the efficacy of the product on site: if need be, cause of reduced efficacy must be investigated to ensure that there is no resistance or t identify potential resistance.

Do not use the product in areas where resistance is suspected or established.

Inform the authorisation holder if the treatment is ineffective.

2.1.10.3.3 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 2.1.11.3

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

See section 2.1.11.4.

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

See section 2.1.11.5.

2.1.10.4. Use description. Table 4.

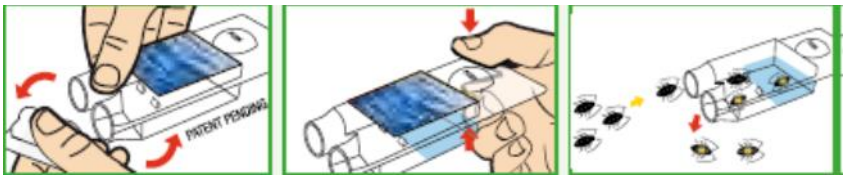
Table 4. Use # 4 – Indoor - Gel bait applied as bait stations – general public (non-professional)

| | |
|---|---|
| **Product Type** | PT18. |
| **Where relevant, an exact description of the authorised use** | Insecticide against cockroaches |
| **Target organism (including development stage)** | Insecticide against the following target insects (adults)<br>German cockroaches (*Blattella germanica*),<br>Oriental cockroaches (*Blatta orientalis*)<br>American cockroaches (*Periplaneta Americana*) |
| **Field of use** | Indoors. |
| **Application method** | Ready-to-use bait stations. |
| **Application rates and frequency.** | Application rate is: 0.2-0.4 g/$m^2$, depending on the infestation level, divided in several bait stations.<br><br>For example, with a bait station containing 2.5 g, the dose is:<br>- 2 bait stations per room for *low* infestations (ca. 5 g/22 $m^2$)<br>- 4 bait stations per room for *high* infestations (ca. 10 g/22 $m^2$)<br><br>Frequency of application: After about 4 weeks, bait stations should be replaced with fresh ones if the infestation persists.<br><br>Frequency of treatment: Three months after the infestation's end, treatment may be repeated. |
| **Category of user** | General Public (non-professional user) |
| **Pack sizes and packaging material** | Plastic bait station with 1, 1.2, 1.5, 2, 2.5 g of gel bait. |

2.1.10.4.1 Use-specific instructions for use

Apply this product in dark and wet places: under the sink, behind the toilet, near the drain.

Gel bait in bait stations.




1. Open the bait station: cut the end of the plastic box on the pre-cut line.

2. Activate the bait station: completely push the capsule until the gel has been deposited in the central compartment. Do not separate the capsule after activation.

3. Place the activated bait station at recommended places.

2.1.10.4.2 Use-specific risk mitigation measures

The stations should not be opened or handled.

Never introduce the fingers through the holes in the bait station.

| |
|---|
| At the end of the treatment campaign, collect bait boxes for disposal. |

2.1.10.4.3 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 2.1.11.3. |

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

| |
|---|
| See section 2.1.11.4. |

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

| |
|---|
| See section 2.1.11.5. |

2.1.10.5. Use description. Table 5.

Table 5. Use # 5 – Indoor - Gel bait applied as bait stations – professional user.

| | |
|---|---|
| **Product Type** | PT18. |
| **Where relevant, an exact description of the authorised use** | Insecticide against cockroaches |
| **Target organism (including development stage)** | Insecticide against the following target insects (adults)<br>German cockroaches (*Blattella germanica*),<br>Oriental cockroaches (*Blatta orientalis*)<br>American cockroaches (*Periplaneta Americana*) |
| **Field of use** | Indoors. |
| **Application method(s)** | Ready-to-use bait stations. |
| **Application rates and frequency** | Application rate is: 0.2-0.4 g/m2, depending on the infestation level, divided in several bait stations.<br>For example, with a bait station containing 2.5 g, the dose is:<br>- 2 bait stations per room for low infestations (ca. 5 g/22 m2)<br>- 4 bait stations per room for high infestations (ca. 10 g/22 m2)<br><br>Frequency of application: After about 4 weeks, bait stations should be replaced with fresh ones if the infestation persists.<br><br>Frequency of treatment: Three months after the infestation's end, treatment may be repeated. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Plastic bait station with 1, 1.2, 1.5, 2, 2.5 g of gel bait. |

2.1.10.5.1 Use-specific instructions for use

Apply this product in dark and wet places: under the sink, behind the toilet, near the drain.

Gel bait in bait stations.


1. Open the bait station: cut the end of the plastic box on the pre-cut line.

2. Activate the bait station: completely push the capsule until the gel has been deposited in the central compartment. Do not separate the capsule after activation.

3. Place the activated bait station at recommended places.

2.1.10.5.2 Use-specific risk mitigation measures

The stations should not be opened or handled.

Never introduce the fingers through the holes in the bait station.

At the end of the treatment campaign, collect bait boxes for disposal.

2.1.10.5.3 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 2.1.11.3.

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

See section 2.1.11.4.

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

See section 2.1.11.5.

2.1.10.6. Use description. Table 6.

Table 6. Use # 6 – Indoor - Gel bait applied as bait stations – trained professional user.

| | |
|---|---|
| **Product Type** | PT18. |
| **Where relevant, an exact description of the authorised use** | Insecticide against cockroaches |
| **Target organism (including development stage)** | Insecticide against the following target insects (adults)<br>German cockroaches (*Blattella germanica*),<br>Oriental cockroaches (*Blatta orientalis*)<br>American cockroaches (*Periplaneta Americana*) |
| **Field of use** | Indoors. |

| | |
|---|---|
| **Application method** | Ready-to-use bait stations. |
| **Application rates and frequency** | Application rate is: 0.2-0.4 g/m2, depending on the infestation level, divided in several bait stations.<br>For example, with a bait station containing 2.5 g, the dose is:<br>- 2 bait stations per room for low infestations (ca. 5 g/22 m2)<br>- 4 bait stations per room for high infestations (ca. 10 g/22 m2)<br>The application rate is:<br>- 2 bait stations per room for low infestations (ca. 5 g/22 m2)<br>- 4 bait stations per room for high infestations (ca. 10 g/22 m2)<br>Frequency of application: After about 4 weeks, bait stations should be replaced with fresh ones if the infestation persists.<br><br>Frequency of treatment: Three months after the infestation's end, treatment may be repeated. |
| **Category of user** | Trained professional |
| **Pack sizes and packaging material** | Plastic bait station with 1, 1.2, 1.5, 2, 2.5 g of gel bait. |

2.1.10.6.1 Use-specific instructions for use

Apply this product in dark and wet places: under the sink, behind the toilet, near the drain.

Gel bait in bait stations.


1. Open the bait station: cut the end of the bait station on the pre-cut line.

2. Activate the bait station: completely push the capsule until the gel has been deposited in the central compartment. Do not separate the capsule after activation.

3. Place the activated bait station at recommended places.

2.1.10.6.2 Use-specific risk mitigation measures

The stations should not be opened or handled.

Never introduce the fingers through the holes in the bait station.

At the end of the treatment campaign, collect bait boxes for disposal.

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.)

Check the efficacy of the product on site: if need be, cause of reduced efficacy must be

investigated to ensure that there is no resistance or t identify potential resistance.

Do not use the product in areas where resistance is suspected or established.

Inform the authorisation holder if the treatment is ineffective.

2.1.10.6.3 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 2.1.11.3.

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

See section 2.1.11.4.

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

See section 2.1.11.5.

## 2.1.11 General directions for use

### 2.1.11.1. Instructions for use

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

Make an inspection before applying the product to check the level of infestation and affected areas.

Use only indoor.

### 2.1.11.2. Risk mitigation measures

This product should be used in alternation with other products not containing the same a.s. to avoid resistant populations.

Baits should not be placed where food, feeding stuffs or drinking water could be contaminated.

The product should be reapplied when finished only until the pest is controlled.

Use products at recommended doses and intervals.

To optimise the treatment efficacy, respect good hygiene practices: remove or prevent access to all source of food. The bait must be the main source of food available for the cockroaches.

To optimise the efficacy, check the bait once a week and replace/replenish bait if they are damaged or soiled.

Product must be securely applied in a way so as to minimize the risk of consumption by other animals or children.

Do not throw the product on the ground, into a water course, into the sink or down the drain.

Avoid release to the environment (P273).

Use only in concealed areas difficult to access and kept away from water.

At the end of the treatment campaign, collect bait boxes for disposal.

Dispose of unused product, its packaging and all other waste (i.d. dead insects) in accordance with local regulations.

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

**Basic First aid procedures:**

- If contact in eyes, rinse with plenty of water for at least 15 minutes. Do NOT forget to remove the contact lenses
- If contact on skin, wash with soap and plenty of water, without rubbing
- If necessary take person to a hospital and show the label or packaging when possible. Do not leave poisoned person alone.

**Medical advice for doctors and sanitary staff**

- Symptomatic and supportive treatment

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

**Emergency measures to protect the environment:**

Precautions: Prevent product from entering the environment (surface and ground water), sewerage, drainage, etc. with the construction of protective barriers and closing drains.
Communicate to the relevant authorities or tipping leaks into waterways, drains, sewers...
Methods and materials for containment and cleaning: Absorb spill on inert material (sand, kaolin ...), collect and place in containers for later properly identified as a hazardous waste management.

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

Dispose of contents/containers in accordance with local regulations (P501).

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

The storage stability of this product in its original container is 4 years under normal condition of storage.

Store in the original container.

Keep containers tightly closed 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.

### 2.1.12 Other information

Definitions:
Trained professional: pest control operators, having received specific training in insects control according to the national legislation in force.

Professional: User applying biocidal products in the workplace. This user has some knowledge and skills in the handling of chemicals, and is able to correctly use personal protective equipment (PPE) if necessary.

General public (non-professional user): Users who are not professionals and who apply the product in the context of their private life.

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.

### 2.1.13 Packaging of the biocidal product

| Type of packaging | Size/volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, non-professional) | Compatibility of the product with the proposed packaging materials (Yes/No) |
|---|---|---|---|---|---|
| Syringe | 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10g | LDPE | Plastic | General public<br>Professional<br>Trained professional | Yes |
| Cartridge | 15, 20, 30, 35, 40 y 50 g | LDPE | Plastic | Trained professional | Yes |
| Bait station | 1, 1'2, 1'5, 2 and 2'5 g. | PET | Plastic | General public<br>Professional<br>Trained professional | Yes |

### 2.1.14 Documentation

### 2.1.15 Data submitted in relation to product application

See list of studies for the biocidal product in annex 3.1.

### 2.1.16 Access to documentation.

Letter of access from Bayer Environmental Science SAS to protected data of imidacloprid to support the application of MAGNUM GEL CUCARACHAS of MYLVA, SA. Bayer Environmental Science SAS has granted access to relevant data related only to the imidacloprid active substance and not the Docs B data/product.

[redacted].

[redacted].

[redacted].

[redacted].

[redacted].

## 2.2 Assessment of the biocidal product

### 2.2.1 Intended uses as applied for by the applicant.

**Table 1**. Intended use 1 - Insecticide gel bait by drops - Indoors - Trained professional, professional and general public (non-professional)

| | |
|---|---|
| **Product Type(s)** | PT18 |
| **Where relevant, an exact description of the authorised use** | Insecticide against cockroaches |
| **Target organism (including development stage)** | The insecticide is for controlling the following target insects (nymphs and adults):<br>- German cockroach *(Blattella germanica)*<br>- Oriental cockroach *(Periplaneta americana)*<br>- American cockroach (*Blatta orientalis*) |
| **Field of use** | Indoor |
| **Application method(s)** | Application via droplets by using a syringe and a cartridge. |
| **Application rate(s) and** | 1-4 gel drops/m2 against *Blattella germanica* and 2-6 gel |

| | |
|---|---|
| **frequency** | drops/m2 against *Blatta orientalis* and *Periplaneta americana* |
| **Category(ies) of user(s)** | Trained professional<br>Professional<br>Non-professional user (general public) |
| **Pack sizes and packaging material** | Plastic syringes of 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10g.<br>Plastic cartridge of 15, 20, 30, 35, 40 y 50 g. |

**Table 2**. Intended use 2 - Insecticide gel bait in bait stations – Indoors - Trained professional, professional and general public (non-professional)

| | |
|---|---|
| **Product Type** | 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide to control cockroaches. |
| **Target organism (including development stage)** | The insecticide is for controlling the following target insects (nymphs and adults):<br>- German cockroach *(Blattella germanica)*<br>- Oriental cockroach *(Periplaneta americana)*<br>- American cockroach (*Blatta orientalis*) |
| **Field of use** | Residential and commercial buildings. Indoors |
| **Application method(s)** | Ready-to-use bait stations |
| **Application rate(s) and frequency** | The recommended application rate is:<br><br>- 2 bait stations per room for *low* infestations (ca. 5 g/22 $m^2$)<br>- 4 bait stations per room for *high* infestations (ca. 10 g/22 $m^2$)<br><br>After about 4 weeks, bait stations should be replenished with fresh ones if the infestation persists.<br><br>Three months after the infestation's end, treatment may be repeated. |
| **Category(ies) of users** | Trained professional.<br>Professional.<br>General public (non-professional) |
| **Pack sizes and packaging material** | Plastic bait station with 1, 1.2, 1.5, 2, 2.5 g of gel bait. |

### 2.2.2 Physical, chemical and technical properties

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Physical state and nature at 20 °C and 101.3 kPa | PA-U10-METDESCR (visual method) | | | [redacted] |
| Plastic cartridge | | 2.15% w/w Imidacloprid Batch E200 | Initially: Gel<br>After 14 days at 54°C ± 2°C: Gel<br>After 3 months at 25ºC±2ºC: Gel<br>After 1 year at 25ºC±2ºC: Gel<br>After 2 years at 25ºC±2ºC: Gel<br>After 3 years and 4 months at 25ºC±2ºC: Gel | |
| Plastic syringe | | 2.15% w/w Imidacloprid Batch E240 | Initially: Gel<br>After 14 days at 54°C ± 2°C: Gel<br>After 3 months at 25ºC±2ºC: Gel<br>After 1 year at 25ºC±2ºC: Gel<br>After 2 years at 25ºC±2ºC: Gel<br>After 3 years and 4 months at 25ºC±2ºC: not available | |
| Bait station | | 2.15% w/w Imidacloprid Batch E200 | Initially: Gel<br>After 14 days at 54°C ± 2°C: Gel | [redacted] |
| Colour at 20 °C and 101.3 kPa | PA-U10-METDESCR (visual method) | | | [redacted] |
| Plastic cartridge | | 2.15% w/w Imidacloprid Batch E200 | Initially: Brown<br>After 14 days at 54°C ± 2°C: Dark brown (small modification of colour)<br>After 3 months at 25ºC±2ºC: brown<br>After 1 year at 25ºC±2ºC: Dark brown<br>After 2 years at 25ºC±2ºC: brown<br>After 3 years and 4 months at 25ºC±2ºC: dark brown | |
| Plastic syringe | | 2.15% w/w Imidacloprid Batch E240 | Initially: Brown<br>After 14 days at 54°C ± 2°C: Dark | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Bait station | | 2.15% w/w Imidacloprid Batch E200 | brown (small modification of colour)<br>After 3 months at 25ºC±2ºC: brown<br>After 1 year at 25ºC±2ºC: Dark brown<br>After 2 years at 25ºC±2ºC: brown<br>After 3 years and 4 months at 25ºC±2ºC: not available<br>Initially: Black<br>After 14 days at 54°C ± 2°C: Black | [redacted] |
| Odour at 20 °C and 101.3 kPa | PA-U10-METDESCR (visual method) | | | [redacted] |
| Plastic cartridge | | 2.15% w/w Imidacloprid Batch E200 | Initially: Practically odourless<br>After 14 days at 54°C ± 2°C: Practically odourless<br>After 3 months at 25ºC±2ºC: Practically odourless<br>After 1 year at 25ºC±2ºC: Practically odourless<br>After 2 years at 25ºC±2ºC: Practically odourless<br>After 3 years and 4 months at 25ºC±2ºC: Practically odourless | |
| Plastic syringe | | 2.15% w/w Imidacloprid Batch E240 | Initially: Practically odourless<br>After 14 days at 54°C ± 2°C: Practically odourless<br>After 3 months at 25ºC±2ºC: Practically odourless<br>After 1 year at 25ºC±2ºC: Practically odourless<br>After 2 years at 25ºC±2ºC: | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Bait station | | 2.15% w/w Imidacloprid Batch E200 | Practically odourless<br>After 3 years and 4 months at 25ºC±2ºC: Not available<br>Initially: Practically odourless<br>After 14 days at 54°C ± 2°C: Practically odourless | [redacted] |
| Acidity/Alkalinity | | | | [redacted] |
| Plastic cartridge | CIPAC MT 191 | 2.15% w/w Imidacloprid Batch E200. | Initially:<br>0.126 % as NaOH<br>After 14 days at 54°C ± 2°C: Not available<br>After 3 months at 25ºC±2ºC: Not available<br>After 1 year at 25ºC±2ºC: Not available<br>After 2 years at 25ºC±2ºC: Not available<br>After 3 years and 4 months at 25ºC±2ºC: Not available | |
| | CIPAC MT 75.3 | 2.15% w/w Imidacloprid Batch E200 | Initially:<br>pH=5.73 at 19ºC<br>After 14 days at 54°C ± 2°C: pH=5.23 at 19ºC<br>After 3 months at 25ºC±2ºC: pH=5.61 at 26ºC<br>After 1 year at 25ºC±2ºC: pH=5.38 at 21ºC<br>After 2 years at 25ºC±2ºC: pH=5.22 at 22ºC<br>After 3 years and 4 months at 25ºC±2ºC: pH=5.02 at 22ºC | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Plastic syringe | Not available | 2.15% w/w Imidacloprid Batch E240 | Not available | |
| Bait station | Not available | Not available | Not available | |
| Relative density/bulk density | | | | [redacted] |
| Plastic cartridge | CIPAC MT 3.3.2 | 2.15% w/w Imidacloprid Batch E200. | Initially:<br>Density at 20±0.5ºC: 1.2553 g/mL<br>After 14 days at 54°C ± 2°C: Not available<br>After 3 months at 25ºC±2ºC: Not available<br>After 1 year at 25ºC±2ºC: Not available<br>After 2 years at 25ºC±2ºC: Not available<br>After 3 years and 4 months at 25ºC±2ºC: Not available | |
| | Calculation | 2.15% w/w Imidacloprid Batch E200. | Initially:<br>$D_{4^{\circ}C}^{20^{\circ}C}$ (relative density) = 1.2553 | |
| Plastic syringe | Not available | 2.15% w/w Imidacloprid Batch E240 | Not available | |
| Bait station | Not available | Not available | Not available | |
| Storage stability test – **accelerated storage (14 days at 54ºC)** | CIPAC MT 46.3.1 | | | [redacted] |
| Imidacloprid content<br><br>Plastic cartridge | HPLC method | 2.15% w/w Imidacloprid Batch E200 | The formulation is stable under the test conditions.<br>Initially:<br>**2.020 ± 0.092% w/w**<br>**or** | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Plastic syringe | | 2.15% w/w Imidacloprid Batch E240 | **20.20 ± 0.92g/kg**<br>After 14 days at 54°C ± 2°C:<br>**1.953 ± 0.109% w/w**<br>**or**<br>**19.53 ± 1.09 g/kg**<br>Difference : -3.3%<br>Initially:<br>**2.215 ± 0.064% w/w**<br>**or**<br>**22.15 ± 0.64g/kg**<br>After 14 days at 54°C ± 2°C:<br>**2.211 ± 0.047% w/w**<br>**or**<br>**22.11 ± 0.47 g/kg**<br>Difference : -0.2% | |
| Bait station | | Not available | Not available | |
| Homogeneity of application | PA-U10-METAPPLGEL | | No significant different | |
| Plastic cartridge | | 2.15% w/w Imidacloprid Batch E200 | Initially: Amount of product deposited in form of spots of 5 mm diameter (n = 9)<br>**47.1 mg**<br>After 14 days at 54°C ± 2°C: Amount of product deposited in form of spots of 5 mm diameter (n = 9)<br>**39.6 mg** | |
| Plastic syringe | | 2.15% w/w Imidacloprid Batch E240 | Initially: Amount of product deposited in form of spots of 5 mm diameter (n = 9)<br>**39.6 mg**<br>After 14 days at 54°C ± 2°C: Amount of product deposited in form of spots of 5 mm diameter (n = 9) | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | **39.0 mg** | |
| Bait station<br>Appearance and stability of the package | Not available<br>PA-U10-METDESCR (visual method) | Not available | Not available | |
| Plastic cartridge | | 2.15% w/w Imidacloprid<br>Batch E200 | Initially:<br>**Outside aspect:**<br>plastic cartridge (for gun applicator) supplier with applicator tip.<br>Capacity: 30 g<br>Closing: with a white plastic screw end-piece<br>intact cartridge<br>No observable sign of test item contamination on the outer surface.<br>No leak during shaking or turning.<br>No noticeable odour before opening.<br>**Inside aspect:**<br>No deformation and no observable alteration of package material by the test item.<br>After 14 days at 54°C ± 2°C:<br>No modification of appearance or significant pack weight change | |
| Plastic syringe | | 2.15% w/w Imidacloprid<br>Batch E240 | Initially:<br>**Outside aspect:**<br>plastic syringe with applicator tip and a plastic plunger<br>Capacity: 5 g<br>Closing: with a clap clip to protect the applicator tip<br>Colour: syringe: opaque white, plunger: red; clap clip: red intact | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Bait station | | 2.15% w/w Imidacloprid<br>Batch E200 | syringe<br>No observable sign of test item contamination on the outer surface.<br>No leak during shaking or turning before and after opening.<br>No noticeable odour before opening.<br>**Inside aspect:**<br>No deformation and no observable alteration of package material by the test item.<br><u>After 14 days at 54°C ± 2°C:</u><br>No modification of appearance or significant pack weight change<br><u>Initially:</u><br>**Outside aspect:**<br>plastic trap<br>Capacity: 2.5 g<br>Colour: black<br>No observable sign of test item contamination on the outer surface.<br>No leak during shaking or turning.<br>No noticeable odour before opening.<br>**Inside aspect:**<br>No deformation and no observable alteration of package material by the test item.<br><u>After 14 days at 54°C ± 2°C:</u><br>**Outside aspect:**<br>No observable sign of test item contamination on the outer surface.<br>No leak during shaking or turning.<br>No noticeable odour before opening.<br>**Inside aspect:**<br>No deformation and no observable | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | alteration of package material by the test Item.<br>No modification of appearance or significant pack weight change. | |
| pH | See Acidity/Alkalinity point | See Acidity/Alkalinity point | See Acidity/Alkalinity point | |
| Storage stability test – **long term storage at ambient temperature** | | | | |
| 3 Years storage stability (25ºC)<br>Active Ingredient Content | CropLife nº 17<br>HPLC method | | Ongoing study. Interim results after 3 years and 4 months storage: | [redacted] |
| Plastic cartridge | | 2.15% w/w Imidacloprid Batch E200 | After 3 months at 25ºC±2ºC:<br>**2.038± 0.067 % w/w or 20.38±0.67 g/kg**<br>Difference: +0.9%<br>After 1 year at 25ºC±2ºC:<br>**1.987± 0.045 % w/w or 19.87±0.45g/kg**<br>Difference: -1.6%<br>After 2 years at 25ºC±2ºC:<br>**2.010 ± 0.252 % w/w or 20.10 ± 2.52g/kg**<br>Difference: -0.5%<br>After 3 years and 4 months at 25ºC±2ºC:<br>**1.993± 0.249 % w/w or 19.93±2.49g/kg**<br>Difference: -1.3% | |
| Plastic syringe | | 2.15% w/w Imidacloprid Batch E240 | After 3 months at 25ºC±2ºC:<br>**2.235± 0.058 % w/w or** | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | **22.35±0.58 g/kg**<br>Difference: +0.9%<br>After 1 year at 25ºC±2ºC:<br>**2.224± 0.025 % w/w or**<br>**22.24±0.25g/kg**<br>Difference: +0.4%<br>After 2 years at 25ºC±2ºC:<br>**2.284 ± 0.132 % w/w or**<br>**22.84±1.32g/kg**<br>Difference: +3.0%<br>After 3 years and 4 months at 25ºC±2ºC:<br>Not available | |
| Bait station | Not available | Not available | Not available | |
| Homogeneity of application | PA-U10-METAPPLGEL | | | |
| Plastic cartridge | | 2.15% w/w Imidacloprid Batch E200 | After 3 months at 25ºC±2ºC:<br>Amount of product deposited in form of spots of 5 mm diameter (n=9)<br>**42.6 mg**<br>After 1 year at 25ºC±2ºC:<br>Amount of product deposited in form of spots of 5 mm diameter (n=9)<br>**51.1 mg**<br>After 2 years at 25ºC±2ºC:<br>Amount of product deposited in form of spots of 5 mm diameter (n=9)<br>**51.8 mg**<br>After 3 year and 4 months at 25ºC±2ºC:<br>Not available | |
| Plastic syringe | | 2.15% w/w Imidacloprid Batch E240 | After 3 months at 25ºC±2ºC:<br>Amount of product deposited in form | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | of spots of 5 mm diameter (n=9)<br>**35.7 mg**<br>After 1 year at 25ºC±2ºC:<br>Amount of product deposited in form of spots of 5 mm diameter (n=9)<br>**41.9 mg**<br>After 2 years at 25ºC±2ºC:<br>Amount of product deposited in form of spots of 5 mm diameter (n=9)<br>**43.8 mg**<br>After 3 year and 4 months at 25ºC±2ºC:<br>Not available | |
| Bait station | Not available | Not available | Not available | |
| Appearance and stability of the package | PAU-U10-METDESCR (visual method) | | | |
| Plastic cartridge | | 2.15% w/w Imidacloprid Batch E200 | After 3 months at 25ºC±2ºC:<br>No modification of appearance or pack weight change<br>After 1 year at 25ºC±2ºC:<br>No modification of appearance or significant pack weight change<br>After 2 year at 25ºC±2ºC:<br>No modification of appearance or significant pack weight change<br>After 3 years and 4 months at 25ºC±2ºC: No modification of appearance or significant pack weight change | |
| Plastic syringe | | 2.15% w/w Imidacloprid Batch E240 | After 3 months at 25ºC±2ºC:<br>No modification of appearance or pack weight change | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Bait station<br>pH | Not available<br>See Acidity/Alkalinity point | Not available<br>See Acidity/Alkalinity point | After 1 year at 25ºC±2ºC:<br>No modification of appearance or pack weight change<br>After 2 year at 25ºC±2ºC:<br>No modification of appearance or significant pack weight change<br>After 3 years and 4 months at 25ºC±2ºC: Not available<br>Not available<br>See Acidity/Alkalinity point | |
| Storage stability test – **low temperature stability test for liquids** | CIPAC Method MT 39.3<br>Commission Regulation (EU) No 545/2011, 2.7.3 | | | |
| 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** | | | Stability test: no modification in container material | |
| Effects on content of the active | | | Stability test: no modification in container material | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| substance and technical characteristics of the biocidal product - **reactivity towards container material** | | | | |
| 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 | |
| Persistence of 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 | | | | |
| Burning completeness — smoke generators | | | | |
| Composition of | | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| smoke — smoke generators | | | | |
| Spraying pattern — aerosols | | | | |
| **Other technical characteristics**<br>Determination whether a material is liquid or solid | ASTM D 4359-90 | 2.15% w/w Imidacloprid Batch E200 | Biocidal product is a solid. | [redacted] |
| Compatibility with other products | | | Not relevant. The produt is ready to use and it is not intended to be used in mixture with any other products | |
| Degree of dissolution and dilution stability | | | | |
| Surface tension | OECD 92/69/EWG EEC A.5. | | Not relevant. Product is a GL. Data requirement for liquid preparations containing aliphatic, aromatic or alicyclic hydrocarbons at greater than 10%. | |
| Viscosity | CIPAC MT 192 (equivalent to OECD 114) | | No Newtonian flow behaviour. Dependent on the shear rate applied to the sample. | [redacted] |
| Plastic cartridge | | 2.15% w/w Imidacloprid Batch E200 | <u>At 20 ± 0.5°C:</u><br>Initially:<br>**372398 mPa.s to 55112 mPa.s**<br>[0.977 – 19.76 $s^{-1}$]<br>After 14 days at 54°C ± 2°C:<br>**352958 mPa.s to 79120 mPa.s**<br>[0.977 – 10.32 $s^{-1}$]<br>After 3 months at 25ºC±2ºC:<br>**278235 mPa.s to 39100 mPa.s**<br>[0.977 – 10.32 $s^{-1}$]<br>After 1 year at 25ºC± 2°C: Not | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | carried out because the product is considered as a solid.<br><br><u>At 40 ± 0.5°C</u>**<u>:</u>**<br>Initially:<br>**139118 mPa.s to 27715 mPa.s**<br>Dependent on the shear rate applied to the sample<br>[0.977 – 10.32 $s^{-1}$]<br>After 14 days at 54°C ± 2°C:<br>**133650 mPa.s to 27888 mPa.s**<br>[0.977 – 10.32 $s^{-1}$]<br>After 3 months at 25ºC±2ºC:<br>**140333 mPa.s to 27715 mPa.s**<br>[0.977 – 10.32 $s^{-1}$]<br>After 1 year at 25ºC± 2°C: Not carried out because the product is considered as a solid.<br><u>After 3 years and 4 months at 25ºC±2ºC:</u> Not available | |
| Plastic syringe | Not available | Not available | Not available | |
| Bait station | Not available | Not available | Not available | |

**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 than the composition to be marketed.
This section is submitted for the GEL formulation. According to the FAO Manual, GL (emulsifiable gel → a gelatinized formulation to be applied as an emulsion in water) ≈ EW (emulsion, oil in water → a fluid, heterogeneous formulation consisting of a solution of pesticide in an organic liquid dispersed as fine globules in a continuous water phase).

**Appearance**
Brown gel practically odourless.

**Relative density**
The applicant applied "CIPAC method MT 3.3.2" (density bottle method) method for the determination of the relative density. This method is equivalent to EEC method A.3 published in the Commission Regulation (EC) Nº. 440/2008. The applicant's version is adopted.

**Bulk density**
The non submission of data is justified as biocidal product is a liquid.

**Storage stability**
According to the Guidance, the applicant has set the plastic cartridge as worst case packaging. Therefore, the plastic cartridge results can be extrapolated to different packaging types.

**Technical characteristics**
Not applicable as the product is a GL.
According to the CAR, the only technical characteristic appropriate for assessment for Imidacloprid gel formulations, based on its formulation type and use pattern (RTU without dilution) is viscosity.

**Other technical characteristics -** determination whether a material is a liquid or a solid
According to the interpretation of results, the Biocidal Product can be considered as a solid since the specimen did not flow during the test..
On the other hand, according to the CAR, the only technical characteristic appropriate for assessment for Imidacloprid 2.15% Gel, based on its formulation type and use pattern (RTU without dilution) is viscosity.
Finally, we think that is easier to follow the CAR indications and the applicant should analyse the surface tension and the viscosity of the product to avoid issues in setting of the technical properties of the formulation.

**Surface tension**
The product is on the form of a gel solid (confirmed by the ASTM 4359-90 method) and it is is not technically feasible (and not necessary) to measure the surface tension of the neat product because it is not possible to obtain a perfectly flat surface, a necessary condition to be able to measure the surface tension and because the

Wilhelmy plate or the Du Noùy ring used in EEC. A.5 method, do not penetrate the surface of the gel.
The justification for non-submission of data is accepted.

**Viscosity**
According to the technical characteristics comment, we agreed to stop the viscosity study because the results seemed stable.
Magnum Gel Cucarachas is a product gel which is closer to be a solid than to be a liquid and in consequence, the measurement of dynamic viscosity is more difficult than in other product.
Because of that at certain speed, a vacuum appears in the product and at that points correct measurement becomes impossible.
Is for that reason that in the report has been stated the sentence: "Remark: unstable and not reproducible measurement above the speed 9 (59.1 rpm)".
Also, we would like to comment that under the European Regulation two different shear rates measurements of viscosity are required and in our case we have performed more than two even if the one at 19.76 $s^{-1}$ has not been possible in some cases.

**Conclusions**
The biocidal product [redacted] is based in the active substance Imidacloprid.
Imidacloprid 2.15% Gel is a brown gel practically odourless.
Determination of acidity/alkalinity resulted in a 0.126% as NaOH and a pH of 5.72 at 19ºC.
The product has a density of 1.25 g/mL and the viscosity is dependent on the shear rate applied to the sample (e.g. 372398 mPa.s to 55112 mPa.s at 20ºC [0.977 – 19.76 $s^{-1}$]).
The data submitted in the storage stability study shows a storage stability of 3 years and 4 months. The applicant has not provided trials with the aged bait at the maximum storage period demonstrated, so the shelf-life of the product on normal conditions of storage is 2 years.
The preparation is not recommended for use with other products.

## 2.2.3 Physical hazards and respective characteristics

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Explosive Properties | Commission Regulation (EC) No 440/2008, Method A14 Commission Regulation (EU) No 545/2011, 2.2 | 2.15% w/w Imidacloprid | The test was omitted. Imidacloprid 2.15% Gel is not explosive in the sense of EC Guideline A14 | |
| Oxidising Properties | Commission Regulation (EC) No 440/2008, Method A21 Commission Regulation (EC) No 545/2011, 2.2 | 2.15% w/w Imidacloprid | The test was omitted. Imidacloprid 2.15% Gel is not expected to have oxidizing properties. | |
| Flash point | Commission Regulation (EC) No | 2.15% w/w Imidacloprid | The sample does not ignite | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | 440/2008, Method A9 Commission Regulation (EU) No 545/2011, 2.3 (UNE-EN-ISO 3679) | Batch K890 | below 75ºC. | |
| Auto-ignition | Commission Regulation (EC) No 440/2008, Method A15 Commission Regulation (EU) No 545/2011, 2.3 | | No data | |
| Other indications of flammability | | | The 2.15% Gel formulation is not expected to be flammable | |

**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 than the composition to be marketed.

Explosive and Oxidizing properties
The non performance of a test for explosive and oxidizing properties is acceptable as none of the components of the formulation are classified as explosive. The justification for non-submission of data is accepted.

Flash-point and other indications of flammability or spontaneous ignition
The applicant applied "UNE-EN-ISO 3679" (closed glass method) method for the determination of the flash point. This method is equivalent to EEC method A.9 published in the Commission Regulation (EC) Nº. 440/2008. The applicant's version is adopted.

Conclusions
The Biocidal Product is not considered to be potentially explosive or contain an oxidising or reducing agent. It is not flammable.
The technical properties indicate that no particular problems are to be expected when it is handled, stored or applied as recommended.

### 2.2.4 Methods for detection and identification

| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| Imidacloprid(a.s.) | HPLC-DAD | 1.068 – 3.195 % w/w<br>n = (3 x 2) | 301.4-1497.0 µg/mL<br>y = 10.0448x + 389.2224<br>R > 0.9979<br>n = (3 x 2) | Specific | 99.6 - 102.5 | 100.9 | 1.8 % | 1.068 % w/w | [redacted] |

| **Analytical methods for monitoring** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **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 | | |
| No applicable | | | | | | | | | |

| **Analytical methods for soil** | | | |
|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Parent compound (soil) | LC-MS/MS | 0.005 mg/kg | CAR (2011) |
| Parent compound (soil) | HPLC-UV RP-18 and CN column | 0.005 mg/kg | CAR (2011) |

| **Analytical methods for air** | | | |
|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Limit of quantification (LOQ) or other limits** | **Reference** |

| | | | |
|---|---|---|---|
| Parent compound (air) | HPLC-UV RP-18 column | 0.005 mg/m$^3$ | CAR (2011) |
| Parent compound (air) | HPLC-UV CN column | 0.005 mg/m$^3$ | CAR (2011) |

| **Analytical methods for water** | | | |
|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Parent compound (drinking and surface water) | HPLC-UV RP-18 and CN column | 0.03 µg/L | CAR (2011) |
| Parent compound (surface water) | LC-MS/MS | 0.1 µg/L | CAR (2011) |

| **Analytical methods for animal and human body fluids and tisues** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **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 | | |
| Not required since not classified as toxic or highly toxic | | | | | | | | | CAR (2011) |

| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **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 | | |
| No relevant residues expected | | | | | | | | | CAR (2011) |

| **Conclusion on the methods for detection and identificationof the product** |
|---|
| A validated analytical method is available for determining the concentration of Imidacloprid in the biocidal product. |

The applicant has showed that they have access rights to the analytical methods studies contained in the CAR. The LoA has been submitted. Therefore, validated analytical methods are also available for the determination of Imidacloprid in soil, water and air matrices. Other analytical methods are not required.

## 2.2.5 Efficacy against target organisms

### 2.2.5.1. Function and field of use

Main Group 03: Pest Control

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

MAGNUM GEL CUCARACHAS is presented as a ready-to use gel bait insecticide and packaged in a bait station, a syringe or a cartridge. It is used by trained professionals, professionals and general public (Non-professional)

The biocidal product MAGNUM GEL CUCARACHAS is a bait preparation used against cockroaches´s infestations in houses and industrial/commercial buildings.

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

MAGNUM GEL CUCARACHAS is used against small ang big cockroaches (*Blattella germanica*, *Blatta orientalis* and *Periplaneta americana*).
The products, organisms or objects to be protected are stored products and food from private houses and commercial buildings.

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

The a.s. Imidacloprid 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.

### 2.2.5.4. Mode of action, including time delay

Cockroaches 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 (larvae, adults).

### 2.2.5.5. Efficacy data

DROPS

| Experimental data on the efficacy of the biocidal product against target organism(s) | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Function** | **Test substance** | **Field of use envisaged** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| *Insecticide* | [redacted] | *Laboratory* | *Blatta orientalis* | *Laboratory bioassay: Mortality and palatability. (gel bait by drops) According to TNsG 18-19* | *Choice test arena. Test arena: 0.24m²<br>3 replicates and control* | *Average mortality of 95% on 8 days.<br>Acumulative percent mortality of control: 3.1% on 10 days.<br>Palatable bait (fresh bait)<br>Dose: 0'24 g/m²<br>N:70* | [redacted] III-B.5.10.1. |
| | | | *Blattella germanica* | | | *Average mortality of 95% on 8 days.<br>Acumulative percent mortality of control: 2.9% on 10 days.<br>Palatable bait (fresh bait)<br>Dose: 0'16g/m²<br>N: 80 (adult and nymphs)* | |
| | | | *Periplaneta americana* | | | *Average mortality of 95% on 16 days.<br>Acumulative percent mortality of control: 0.6% on 10 days Palatable bait (fresh bait)<br>Dose: 0'24 g/m²<br>N: 60 (adults and nymphs)* | |
| | | *Indoors* | *Blatta orientalis* | *Field trial: (gel bait by drops) According to* | *3 replicates and control<br>Average area: 92.59m²<br>Dose: 0'16-0'23 g/m²<br>Frequency of application:1 application in 4 weeks.* | *Average mortality of 90.0% (±3.6.) on 5/6 weeks.* | [redacted] III-B.5.10.2. |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | *Blattella germanica* | *TNsG 18-19* | *3 replicates and control*<br>*Average area: 71.4m²*<br>*Dose: 0'08-0'19g/m²*<br>*Frequency of application: 1application in 4 weeks* | *Average mortality of 92.0% (±3.1.) on 5/6 weeks* | |
| | | | *Periplaneta americana* | | *3 replicates and control*<br>*Average area: 37.84 m²*<br>*Dose: 0'08-0'15g/m²*<br>*Frequency of application: 1application in 4 weeks.* | *Average mortality of 95.4% (±4.6.) on 3 weeks.*<br>*(Explanatory note: trials have been done with few cockroaches. Low infestation)* | |

BAIT STATIONS

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Function** | **Test substance** | **Field of use envisaged** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| *Insecticide* | [redacted] | *Laboratory* | *Blatta orientalis* | *Laboratory bioassay:*<br>*Mortality and palatability. (gel bait in bait stations)*<br>*According to TNsG 18-19* | *Choice test arena. 3 replicates and control.*<br>*Test Arena: 0.24 m²* | *95% killed at 9days. Acumulative percent mortality of control: 3.3% on 13 days. Palatable bait (only fresh)*<br>*Dose: 1 station.(2.5g product)*<br>*N=70* | [redacted] III-B.5.10.3 |
| | | | *Blattella germanica* | | | *95% killed at 9 days. Acumulative percent average mortality of control: 2.9% on 13 days. Palatable bait (only fresh)*<br>*Dose: 1 station.(2.5g* | |
| | | | *Periplaneta americana* | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | | *product)*<br>*N=80* | |
| | | | | | | *95% killed at 17 days*<br>*Acumulative percent average mortality of control: 2.2% on 13 days.*<br>*Palatable bait (only fresh)*<br>*Dose: 1 station.(2.5g product)*<br>*N=60* | |
| | | *Indoors* | *Blatta orientalis* | *Field trial:*<br>*(gel bait in bait stations)*<br>*According to TNsG*<br>*18-19* | *2 stations (2.5 g/station) per site.*<br>*Low infestation.*<br>*3 replicates*<br>*Average area: 26.85 $m^2$* | *100% mortality after 3 and5 weeks.* | [redacted]<br>III-B.5.10.4 |
| | | | *Blattella germanica* | | *2 stations (2.5 g/station) per site*<br>*Low infestation*<br>*3 replicates*<br>*Average area: 10.19$m^2$* | | |
| | | | *Periplaneta americana* | | *2 stations (2.5 g/station) per site.*<br>*Low infestation*<br>*3 replicates.*<br>*Average area: 19.39 $m^2$* | | |

**Conclusion on the efficacy of the product**

MAGNUM GEL CUCARACHAS has demonstrated sufficient efficacy in laboratory choice tests and field trials against three species of cockroaches (*Blatta orientalis, Blattella germanica* and *Periplaneta americana*) living in houses and commercial buildings.

The Applicant has submitted laboratory and field trials with the product included in bait stations and applied asdrops (deposited by syringe or cartridge). The studies were 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 the cockroaches. 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 CUCARACHAS was demonstrated for the three species.

The applicant has not provided trials with the aged bait at the maximum storage period demonstrated.

**GEL BAIT BY DROPS.**

The applicant has submitted a laboratory trial and a field trial against three species: *Blattella germanica, Blatta orientalis and Periplaneta americana*. The application method is by drops.

The laboratory study is in a test arena (III-B.5.10.1). 1-6 drops (1 drop = 0'04 g) per replicate (depends on the species). An standard food were supplied to investigate the palatability. 3 replicates and 1 control to validated the test for each specie, gender and stage.

*Blattella germanica*:

The study prove the efficacy against *Blattella germanica*. Average mortaility is 100% in 7, 9 and 10 days, depending if they are respectively males, females or nymphs.

*Blatta orientalis*:

The study prove the efficacy against *Blatta orientalis*. Average mortaility is 100% in 9, 10 and 13 days, depending if they are respectively males, females or nymphs.

*Periplaneta americana*:

The study prove the efficacy against *Periplaneta americana*. Average mortaility is 100% in 16, 16 and 21 days, depending if they are respectively males, females or nymphs.

It has developed a field test (III.B.5.10.2) for species *Blattella germanica, Blatta orientalis* and *Periplaneta americana*, indoors with droplets. 3 replicates for each specie.

*Blattella germanica*:

Doses ranging from 0.08 to 0.19 have been used depending on the degree of infestation. On the fourth week the baits have been inspected and it has replenised a small amount. The mean total dose of the three replicates during treatment was 0.15 $g/m^2$. A mortality of 92% has been achieved in week 5/6.

*Blatta orientalis*:

Doses ranging from 0.16 to 0.23 have been used depending on the degree of infestation. On the fourth week the baits have been inspected and it has replenised a small amount. The mean total dose of the three replicates during treatment was 0.19 g/m$^2$. A mortality of 90% has been achieved in week 5/6.

*Periplaneta Americana*:
Doses ranging from 0.08 to 0.15 have been used. Over four weeks small amounts of bait have been filled. The mean total dose of the three replicates during treatment was 0.15 g/m$^2$. A mortality of 95,4% has been achieved in week 3. The trial has been done with a low infestation and the dose rate had adjusted to drops size and more realistic conditions, so the dose rate is 0.16-0.14g/m$^2$

**We can conclude that the product MAGNUM GEL CUCARACHAS is effective against cockroaches with the method of application by droplets, indoors.**
**The product was applied at the recommended application rate of 0.12-0.16 g/m$^2$ for small species and 0.16-0.24 g/m$^2$ for large species.**

**GEL BAIT BY BAIT STATIONS**
In a laboratory study (III-B.5.10.3), MAGNUM GEL CUCARACHAS demonstrated its efficacy as insecticide against three species of cockroaches (nymphs and adults) living in houses and other commercial buildings. The product was applied by the placement of ready-to-use bait stations (2.5 g each) inside the arenas (1 station/arena) in the presence of alternative food source. 95% mortality was achieved after 9 to 17 days. Palatability was also demonstrated for the three species.

In a field trial (III-B.5.10.4), MAGNUM GEL CUCARACHAS also demonstrated efficacy when applied indoors as bait stations. The recommended dose rates are 0.23-0.45 g bait/m$^2$, according to the Applicant. In the trials, the dose rate of 2 bait stations/site was used (2.5 g each station) because the infestation level was low (less than 15-20 cockroaches per day). Since the size of sites was different in every trial (from 6.6 to 41.3 m$^2$), the application doses were equivalent to ca. 0.1–0.7 g/ m$^2$. 100% cockroaches were killed after 2-3 weeks.

**We can conclude that the product MAGNUM GEL CUCARACHAS is effective against cockroaches with the method of application by bait stations, indoors. The product was applied at the recommended application rate of 2 to 4 bait station per room, depending on the infestation levels.**

### 2.2.5.6. Occurrence of resistance and resistance management

No resistant strains have been shown in the efficacy laboratory/field trials conducted with cockroaches. No other studies on the resistance of Imidacloprid 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 cockroach control in Europe.

Neonicotinoids have a different mode of action to other classes of insecticide such as pyrethroids and organophosphates.

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 by the RMS (DE) during the a.s. approval.

The resistance of target insects (cockroaches) to Imidacloprid was also searched for in the literature during the evaluation of MAGNUM GEL CUCARACHAS. There were several studies investigating resistance of other target insects (e.g. beettles, flies, grasshoppers) to Imidacloprid. However, studies on resistance to Imidacloprid of cockroaches were scarce. Chai & Lee 2010 concluded that no resistance to Imidacloprid or very low levels (0.8-3.8x) were found in German cockroaches from Singapur. In a recent review, Bass et al. 2015 did not report resistance of cockroaches to Imidacloprid. In conclusion, the potential for resistance is high as a neonicotinoid but particular problems have not arisen.

Additionally the use pattern as gel bait ensures that most of the room surface is not treated thereby reducing the likelihood of contacting a sub lethal deposit. Given the a.s. is incorporated into a palatable bait, cockroaches readily consume a lethal dose from a single meal.

Nevertheless, to minimise the chances of resistance developing in the future, it is advisable to avoid using product containing Imidacloprid exclusively and continuously as the sole agent for cockroach 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 when finished only until the pest is controlled’
- The incorporation of a label warning: ‘Use products at recommended doses and intervals’.

For trained professional only:

- 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.)

- Check the efficacy of the product on site: if need be, cause of reduced efficacy must be investigated to ensure that there is no resistance or t identify potential resistance.
- Do not use the product in areas where resistance is suspected or established.
- Inform the authorisation holder if the treatment is ineffective.

#### 2.2.5.7. 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:

- The product contains a bitter substance that makes it repulsive to people or pets. Do not use on food or utensils. May not be applied on surfaces where food is handled, prepared or served or consumed.
- Avoid contact of children with treated surfaces.
- Do not perform 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.

#### 2.2.5.8. 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 applicant have not supported residual efficacy trials and palatability tests with aged bait.

The product has proven effective for the following label claims.

- Insecticide for cockroaches control (*Blatta orientalis, Blattella germanica, Periplaneta Americana)*.
- Ready-to-use gel bait indoors by droplets on non-porous surfaces (cartrige or syringe) and included in bait stations.

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

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

### 2.2.6 Risk assessment for human health

MAGNUM GEL CUCARACHAS is a gel containing 2.15 % imidacloprid.

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 [redacted]. The applicant has declared that the product

MAGNUM GEL CUCARACHAS is identical to [redacted], so data generated for this product can be referred to the product MAGNUM GEL CUCARACHAS.

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.

#### 2.2.6.1. Assessment of effects on Human Health

### *Skin corrosion and irritation*

| **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 the Imidacloprid and the coformulants and, their respective content in the final formulation |
| Classification of the product according to CLP. | MAGNUM GEL CUCARACHAS is not classified as corrosive or irritant to skin. |

| **Data waiving** | |
|---|---|
| Information requirement | Skin corrosion and irritation study |
| Justification | 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. So this study does not need to be conducted.<br>In addition, we consider appropriate to refer to the results found in an acute toxicity study performed with the formulation 2.15% Imidacloprid. This study does not indicate any skin irritation up to the limit dose level of 2,000mg/kg bw. |

### *Eye irritation*

| **Conclusion used in Risk Assessment – Eye irritation** | |
|---|---|
| Value/conclusion | Not eyes irritant |
| Justification for the value/conclusion | Based on the classification of the Imidacloprid and the coformulants and, their respective content in the final formulation |
| Classification of the product according to CLP. | MAGNUM GEL CUCARACHAS is not classified as irritant to eyes. |

| **Data waiving** | |
|---|---|
| Information requirement | Eye irritation study |
| Justification | 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. So this study does not need to be conducted. |

### *Respiratory tract irritation*

| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
|---|---|
| Justification for the conclusion | Based on the classification of the Imidacloprid and the coformulants and, their respective content in the final formulation |
| Classification of the product according to CLP | MAGNUM GEL CUCARACHAS is not classified as "specific target organ toxicity - single exposure, Category 3 H335 |

| **Data waiving** | |
|---|---|
| Information requirement | Respiratory tract irritation data |
| Justification | 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). |

### *Skin sensitization*

| **Conclusion used in Risk Assessment – Skin sensitisation** | |
|---|---|
| Value/conclusion | Not skin sensitizer |
| Justification for the value/conclusion | Based on the classification of the Imidacloprid and the coformulants and, their respective content in the final formulation |
| Classification of the product according to CLP. | MAGNUM GEL CUCARACHAS is not classified as skin sensitizer. Nevertheless, the following statement should be included:<br>EUH208 Contains 1,2-Benzisothiazol-3(2H)-one and 2-octyl-1,2-thiazol-3-one. May produce an allergic reaction. |

| **Data waiving** | |
|---|---|
| Information requirement | Skin sensitisation study |
| Justification | 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. So this study does not need to be conducted. |

### *Respiratory sensitization (ADS)*

| **Conclusion used in Risk Assessment – Respiratory sensitisation** |
|---|

| | |
|---|---|
| Value/conclusion | Not respiratory sensitizer. |
| Justification for the value/conclusion | Based on the classification of the Imidacloprid and the coformulants and, their respective content in the final formulation. |
| Classification of the product according to CLP and DSD | MAGNUM GEL CUCARACHAS is not classified as respiratory sensitizer. |

| **Data waiving** | |
|---|---|
| Information requirement | Respiratory sensitisation data |
| Justification | No data on the respiratory sensitisation of the product MAGNUM GEL CUCARACHAS has been submitted, because of its physical nature (gel) and the low vapour pressure of the components. MAGNUM GEL CUCARACHAS 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** | | | | | | |
|---|---|---|---|---|---|---|
| **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)* | **Value LD50** | **Remarks** *(e.g. major* deviations*)* | **Reference** |
| OECD TG 423 and EU B1.tris /GLP/1 | Rat, Whistar RccHanTM: WIST Female 3 animals at 2000 mg/Kg bw and 3 animals at 2000 mg/Kg bw | [redacted] 2000mg/Kg bw by gavage | There were no deaths. No signs of systemic toxicity were noted during the observation period. All animals showed expected gains in body weight over the observation period. No abnormalities were noted at necropsy. | $DL_{50}$>5000mg/kg bw | None | [redacted] |

No human data on acute oral toxicity is available

| **Value used in the Risk Assessment – Acute oral toxicity** | |
|---|---|
| Value | $DL_{50}$>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. | Not classified |

*Acute toxicity by inhalation*

| **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 the Imidacloprid and the coformulants and, their respective content in the final formulation, as well as the low vapour pressure of the components and te physical state of the product. |
| Classification of the product according to CLP | Not classified. |

| **Data waiving** | |
|---|---|
| Information requirement | Not required |
| Justification | Taking into account the nature of the active substance, Imidacloprid, present in the formulation MAGNUM GEL CUCARACHAS, the physical state of the formulation itself and the likely routes of human exposure, inhalation route is not considered of concern.<br>Exposure of humans via inhalation is not likely taking into account:<br>-The low vapour pressure of the active substance imidacloprid.<br>-The physical state of the product, formulated as a gel, and its viscosity that exclude that the product particles can access the pulmonary system and that,<br>-The product is applied in drops or by using bait station and therefore, no aerosol particles or dopltes of an inhalable size are generated. |

*Acute toxicity by dermal route*

| **Summary table of animal studies on acute dermal toxicity** |
|---|

| **Method, Guideline, GLP status, Reliability** | **Species, strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LD50** | **Remarks** *(e.g. major deviations)* | **Reference** |
|---|---|---|---|---|---|---|
| OECD TG 402 and EU B.3 / GLP/ 1 | Rat, Whistar RccHanTM: WIST Male and female 5 animals per sex and dose | [redacted] No vehicle. Single dose 2000 mg/Kg bw moistened with distilled water Semiocclusive coverage. 10% of the total body surface. | There were no deaths. No signs of systemic toxicity were noted during the observation period. All animals showed expected gains in body weight over the observation period. Dark brown coloured staining was noted at the test sites of all males and one female during the study. Small superficial scattered scabs were noted at the test sites of two females. The were no signs of dermal irritation noted at the test sites of the remaining animals. No abnormalities were noted at necropsy. | $DL_{50}$>2000 mg/kg bw | | [redacted] |

No human data on acute dermal toxicity is available

| **Value used in the Risk Assessment – Acute dermal toxicity** | |
|---|---|
| Value | $DL_{50}$>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 | Not classified |

### *Information on dermal absorption*

| **Value(s) used in the Risk Assessment – Dermal absorption** | |
|---|---|
| Substance | Imidacloprid |
| Value(s)* | 75% |
| Justification for the selected value(s) | As there are no data on the formulation, according to the EFSA guidance on dermal absorption (EFSA Journal, 2012;10(4):2665), a default value of 75% should be used for products or in use dilutions containing ≤ 5% active substance. |

| **Data waiving** | |
|---|---|
| Information requirement | Not required |
| Justification | There is no experimental data available on the dermal absorption of MAGNUM GEL CUCARACHAS since no study has been conducted thus far. As a result, risk assessment calculations for human exposure have been made according to the EFSA guidance on dermal absorption (EFSA Journal, 2012;10(4):2665) using a default value of 75% dermal absorption for this product (products or in use dilutions containing ≤ 5% active substance). |

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

The formulation contains 2.15% (w/w) of the active substance Imidacloprid and other co-formulants, several of which are classified for human toxicity. 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*

Not applicable.

### *Other*

No other additional tests relating to exposure of Imidacloprid or the formulated product Imidacloprid 2.15% Gel, 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 CUCARACHAS it will not come into contact with food, foodstuffs or feeding stuffs.

### 2.2.6.2. Exposure assessment

MAGNUM GEL CUCARACHAS is a ready-to-use product to be applied indoors as gel drops or using bait stations. No exposure to the product is expected either by trained professionals, professionals or 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 covers the risk derived from the use of bait stations.

There are no substances of concern.

Relevant exposure routes to humans during gel application of MAGNUM GEL CUCARACHAS 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: application by gel drops, relevant paths of human exposure** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| | **Trained professional use** | **Professional use** | **Non-professional use*** **(General public)** | **Trained professional use** | **Professional use** | **Non-professional use*** **(General public)** | **Via food** |
| Inhalation[1] | No | No | No | n.a. | No | No | No |
| Dermal | Yes | Yes | Yes | n.a. | No[2] | Yes[3] | No |
| Oral | No | No | No | n.a | No | Yes[3] | No[4] |

** 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 substance (9E-10 Pa, 25ºC).*

*[2] secondary exposure of professionals after application of gel is not expected (as indicated in the CAR); neither is secondary exposure of consumers after application.*

*[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).*

**Industrial use:** Imidacloprid and the biocidal product are produced in the EU. The exposure during the production of the active substance 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.

### *List of scenarios*

| Summary table: scenarios | | | |
|---|---|---|---|
| **Scenario number** | **Scenario** | **Primary or secondary exposure**<br>**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 | Non-professionals/ Professionals |
| 4. | Post application | Primary exposure: disposal of used cartridge/syringe | Non-professionals/ 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 | Bystanders (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***

Imidacloprid and the biocidal product are produced in the EU. The exposure during the production of the active substance 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.

## ***Trained Professional exposure***

*Scenario 1 Application of MAGNUM GEL CUCARACHAS by trained professional users*

| **Description of Scenario 1** | | |
|---|---|---|
| The product is a ready-to use bait in cartridges/syringes for controlled placement using a suitable gel applicator. The gel is applied as round spots or thin lines close to ant harborages, foraging and feeding areas such as corners and cracks and crevices for indoor and outdoor control of cockroaches.<br>For trained professionals (pest control operators), exposure is estimated using the models and assumptions presented in the original CAR.<br>Chronic exposure is expected.<br>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 opening and sealing the cartridge (5 opening and 5 sealing operations per day).<br>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.<br>Exposure during use of cartridges is estimated worst case compared to syringes. | | |
| | Parameters | Value |
| Tier 1 | Equivalence 0.5 cm gel [a] | 47.1 mg product |
| | number of opening and sealing per day[b] | 10 |
| | content of active substance in product | 2.15% |
| | Dermal absorption[c] | 75% |
| | Body weight adult[d] | 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 CUCARACHAS. The CA uses the amount of product in a 0.5cm diameter drop of*

*MAGNUM GEL CUCARACHAS, as indicated in Section 2.2.2, storage stability study: aprox. 47.1 mg of product, to estimate the exposure of professionals via dermal route (see Annex 3.2)*

[b] *CAR.*

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

[d] *HEEG Opinion 17.*

**Calculations for Scenario 1**

See relevant calculations in Annex 3.2

| **Summary table: estimated exposure 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 | - | 0,12658125 | - | 0,12658125 |

**Further information and considerations on scenario 1**

Not applicable

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

| **Description of Scenario 2** | | |
|---|---|---|
| For pest control operators (trained professionals), exposure is estimated using the models and assumptions presented in the original CAR.<br>Chronic exposure is expected.<br>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 gel [a] | 47.1 mg product |
| | number of disposed cartridges per day [b] | 1 |
| | content of active substance in product | 2.15% |
| | Dermal absorption[c] | 75 % |
| | Body weight adult[d] | 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 MAGNUM GEL CUCARACHAS. The CA uses the amount of product in a 0.5cm diameter drop of MAGNUM GEL CUCARACHAS, as indicated in Section 2.2.2, storage stability study: aprox. 39 mg of product, to estimate the exposure of professionals via dermal route (see Annex 3.2)*

*b CAR.*

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

*d HEEG Opinion 17.*

**Calculations for Scenario 2**

See calculations in Annex 3.2

| **Summary table: estimated exposure 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 | - | 0,01265813 | - | 0,01265813 |

*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 from trained professional uses (mg/kg bw/d)** | | | | |
|---|---|---|---|---|
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios [1 & 2] /Tier 1 | - | 0,13923938 | - | 0,13923938 |

## ***Professionals 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.**

## ***General Public (non-professional) exposure***

*Scenario 3 Application of MAGNUM GEL CUCARACHAS by professionals and general public*

**Description of Scenario 3**

The product is a ready-to use bait in syringes/cartridges for use by professionals and general public. The gel is applied as round spots or thin lines close to ant harborages, foraging and feeding areas such as corners and cracks and crevices for indoor and outdoor control of cockroaches.

Assuming that general public and professionals use either cartridges or syringes, exposure for this category of users is estimated using the models and assumptions presented for general public adapted to these users according to expert judgment.

In the following it is assumed as a worst case that a professional or consumer applies the product every two weeks during 6 months per year. 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 users 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 gel [a] | 47.1 mg product |
| | number of opening and sealing per day[b] | 2 |
| | content of active substance in product | 2.15% |
| | Dermal absorption[c] | 75 % |
| | Body weight adult[d] | 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 MAGNUM GEL CUCARACHAS. The CA uses the amount of product in a 0.5cm diameter drop of MAGNUM GEL CUCARACHAS, as indicated in Section 2.2.2, storage stability study: aprox. 39 mg of product, to estimate the exposure of professionals via dermal route (see Annex 3.2)*

[b] *CAR, adapted for consumer use.*

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

[d] *HEEG Opinion 17.*

**Calculations for Scenario 3**

See calculations in Annex 3.2

**Summary table: systemic exposure from professional and 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 | - | 0,02531625 | - | 0,02531625 |

**Further information and considerations on scenario 3**

None

*Scenario 4 Disposal of used cartridge of MAGNUM GEL CUCARACHAS by professional and non-professional users (the general public)*

| **Description of Scenario 4** |
|---|
| For general public and professionals, exposure is estimated using the models and assumptions presented in the original CAR adapted to theser users according to expert judgment.<br>In the following, it is assumed as a worst case that a professional or consumer discharges an used cartridge every two weeks during 6 months per year. As a worst case, medium term exposure is expected.<br>Exposure takes place via dermal contamination through hands. Exposure estimation is performed taking into account the quantities that could potentially enter into contact with professional or consumer's hands during disposal of used cartridge (1 operation per application is assumed). |

| | Parameters | Value |
|---|---|---|
| Tier 1 | Equivalence 0.5 cm gel [a] | 47.1 mg product |
| | number of cartridge disposed off per event [b] | 1 |
| | content of active substance in product | 2.15% |
| | Dermal absorption [c] | 75 % |
| | Body weight adult [d] | 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 0.5cm diameter drop of MAGNUM GEL CUCARACHAS, as indicated in Section 2.2.2, storage stability study: aprox. 39 mg of product, to estimate the exposure of professionals via dermal route (see Annex 3.2)*

[b] *CAR, adapted for consumer use.*

[c] *'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: systemic exposure from professional or 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 | - | 0,012658125 | - | 0,012658125 |

**Further information and considerations on scenario 4**

None

*Combined scenarios*

Total exposure of professionals or consumers during the use of MAGNUM GEL CUCARACHAS in cartridges is estimated by a combination of scenarios 3 & 4.

| **Summary table: combined systemic exposure from professional and 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 | - | 0,037974375 | - | 0,037974375 |

*Scenario 5 & Scenario 6. Use and disposal of bait stations containing MAGNUM GEL CUCARACHAS*

| **Description of Scenarios 5 & 6** |
|---|
| No exposure to the product is expected by 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').<br><br>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 CUCARACHAS 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.<br>Secondary exposure can be considered as occasional and of short-term (not continuous) and therefore the exposure is considered as acute.<br>Considering that the product is applied in drops on localized spots (there is not an uniform application on surfaces as paints, for example), the following scenario assumes that a toddler contacts one DROP of product in one event. Additionally to dermal absorption, hand to mouth transfer may take place: it is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact (Crack & Crevice Use – Post Application; RIVM report 320005002 pp. 28); consequently 50% of external dermal load is absorbed via dermal route.<br>Tier 1 assumes 100% dislodgeability, 100% oral absorption and 75% dermal absorption. | | |
| | Parameters | Value |
| Tier 1 | One drop of gel 5 mm diameter[a] | 47.1 mg product |
| | number of drops contacted per event [b] | 1 |
| | content of active substance in product | 0.01% |
| | Dermal absorption [c] | 75% |
| | Dislodged amount [b] | 100% |
| | Amount of product available for oral intake[d] | 50% of external dermal load |
| | Oral absorption | 100% |
| | Body weight toddler[e] | 10 kg |

[a] *Section 2.2.2, storage stability study: a drop of 0.5 cm diameter of MAGNUM GEL CUCARACHAS from a cartridge equals aprox. 39.6 mg of product (see Annex 3.2).*

[b] *assumption*

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

[d] *ConsExpo Pest product fact sheet RIVM report 320005002 (Crack & Crevice Use – Post Application; pp. 28)*

[e] *HEEG Opinion 17.*

**Calculations for Scenario 7**

See calculations in Annex 3.2

| **Summary table: systemic indirect exposure as result of use (mg/ kw bw)** | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [7] | 1/none | - | 0,07594875 | 0,0506325 | 0,12658125 |

**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 CUCARACHAS as a gel application (drops) in hidden places with difficult access such as crack and crevice, 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:

- The product can not be applied on surfaces where foodstuff 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.
- . Do not apply on surfaces or utensils which can be in contact with feed/foodstuff.

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

| **Summary table of other (non-biocidal) uses** | | | |
|---|---|---|---|
| | **Sector of use[1]** | **Intended use** | **Reference value(s) [2]** |
| 1. | Plant protection product | Seed, soil, trunk and foliar treatments | MRL[2] |
| 2. | Veterinary use | treatment of domestic pets to control fleas | Withdrawal period n.a.[3] |

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

[2] *COMMISSION REGULATION (EU) No 491/2014 No agreement on the residue definition during peer review (EFSA Scientific Report (2008) 148, 1-120, Conclusion on the peer review of Imidacloprid)*

[3] *Product number: EMEA/V/C/000076; n.a. not applicable*

MRL: Maximum Residue Level

*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 restrictions preclude livestock exposure:

- The treatment must be restricted to areas out of reach of animals

- The product can not be applied on surfaces where feedingstuff is prepared, consumed or stored.
- Keep away from feedingstuff or feed contact surfaces.

*Estimating transfer of biocidal active substances into foods as a result of trained professional 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.

- The product can not be applied on surfaces where foodstuff 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.

*Estimating transfer of biocidal active substances into foods as a result of use by the professional and general public*

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.

- Keep away from foodstuff, eating utensils or food contact surfaces.

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

Imidacloprid and the biocidal product are produced in the EU. The exposure during the production of the active substance 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 mg/kw bw/d |
|---|---|---|---|
| 1. Application | Trained professionals | Tier 1 /none | 0,12658125 |
| 2. Post-Application | Trained professionals | Tier 1 /none | 0,01265813 |
| 3. Application | Professionals and Non-professionals | Tier 1 /none | 0,02531625 |
| 4. Post-application | Professionals and Non-professionals | Tier 1 /none | 0,012658125 |
| 7. Indirect | Bystanders (toddlers) | Tier 1 /none | 0,088606875 |

### 2.2.6.3. Risk characterisation for human health

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

| Reference | Study | NOAEL (LOAEL) | AF[1] | Correction for oral absorption | Value |
|---|---|---|---|---|---|
| $AEL_{short-term}$ | Rat, acute neurotoxicity, supported by dog, 28-d (acute effects) | 40 mg/kg bw/d | 100 | 100 | 0.4 mg/kg bw/d |
| $AEL_{medium-term}$ | Rat, 2-gen., supported by dog, 90-d and rabbit, developmental | 20 mg/kg bw/d | 100 | 100 | 0.2 mg/kg bw/d |
| $AEL_{long-term}$ | Rat, 2-yr | 6 mg/kg bw/d | 100 | 100 | 0.06 mg/kg bw/d |
| ARfD[2] | No value in CAR | | | | |
| ADI[2] | No value in CAR | | | | |

[1] safety factor of 100 was applied taking into account a factor for inter and intraspecies differences (10 x 10).
[2] *An ARfD and an ADI have not been derived for Imidacloprid used in biocidal products (PT 18). However it should be noted that these values have been set analogously to the acute and long-term AELs above by the WHO JMPR in 2001 and have been confirmed by the RMS during the preparation of the Draft Assessment Report for inclusion of Imidacloprid in Annex I of Dir 91/414/EEC.*

**Specific reference value for groundwater**

No applicable

***Maximum residue limits or equivalent***

Residue definition: Imidacloprid.

MRL values: see Commission Regulation (EU) No 491/2014.

See also Regulation (EU) No 485/2013: restriction of the uses of clothianidin, thiamethoxam and imidacloprid, to provide for specific risk mitigation measures for the protection of bees.

***Risk for trained-professional users***

Trained professional users are expected to use the biocidal product on a daily basis for 230 working days every year along their working lifes.

Then, exposure has been compared with the relevant Long Term Acceptable Exposure Level ($AEL_{long\ term}$) dividing the relevant NOAEL by an assessment factor of 100 used to account for interspecies and intraspecies derived in the Assessment Report for Imidacloprid, 2011.

**$AEL_{long\text{-}term}$ = 0.06 mg/Kg bw/day**, based on a NOAEL of 6 mg/Kg bw/day from 2-year chronic toxicity in rats**.**

The exposure assessment for trained professional under reasonable worst case assumptions (10 applications and 1 post-application/day), yielded a potential dermal exposure leading to a systemic dose of 0,13923938 mg/kg/day for an unprotected operator. Comparison to the $AEL_{long\ term}$ of 0,06mg/kg /day shows that the use of MAGNUM GEL CUCARACHAS containing 2.15 % IMIDACLOPRID cause health risk for trained professionals not wearing appropriate PPE (gloves), as indicated by the resulting in a %AEL of 232. See Tables below.

Since trained professionals wear protective gloves by default during pest control operations, a refined assessment is conducted. The resulting %AEL of 23,3 indicates that the use of MAGNUM GEL CUCARACHAS containing 2.15 % IMIDACLOPRID does not cause any risk for pest control operators if gloves are worn. See Tables below.

**Systemic effects**

| **Task/ Scenario** | **Tier** | **Systemic NOAEL mg/kg bw/d** | **AEL mg/kg bw/d** | **Estimated uptake mg/kg bw/d** | **%AEL** | **Acceptable (yes/no)** |
|---|---|---|---|---|---|---|
| Application/ Scenario 1 | 1 | 6 | 0.06 | 0,12658125 | 210,96875 | NO |
| Post application/ Scenario 2 | 1 | 6 | 0.06 | 0,01265813 | 21,096875 | YES |

**Combined scenarios**

| **Scenarios combined** | **Tier** | **Systemic NOAEL mg/kg bw/d** | **AEL mg/kg bw/d** | **Estimated uptake mg/kg bw/d** | **%AEL** | **Acceptable (yes/no)** |
|---|---|---|---|---|---|---|
| Application/ Scenario 1 & Post | 1 | 6 | 0.06 | 0,13923938 | 232,06562 | NO |

| | | | | | | |
|---|---|---|---|---|---|---|
| application/ Scenario 2 | | | | | | |
| Application/ Scenario 1 & Post application/ Scenario 2 | 2<br>With gloves | 6 | 0.06 | 0,01392393 | 23,206562 | YES |

**Local effects**

Not applicable

**Conclusion**

The chronic exposure assessment for trained-professional users under worst case assumptions yields a potential dermal exposure leading to systemic doses of 0,13923938 mg/kg bw/day during the application and postapplication processes combined, (Tier 1). This estimated uptake represents 232% of the proposed AEL of 0.06 mg/kg bw/day.

Taking into account trained professionals wear protective gloves by default during pest control operations, a refined assessment is conducted resulting in a 23,3% of AEL.

Tier 1 assessment indicates an unacceptable risk for trained-professional users.

Tier 2 assessment indicates an acceptable risk for trained-professional users.

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

Professional and non-professional users are expected to use the biocidal product on a basis for up to six times a year.
Then, exposure has been compared with the relevant Medium Term Acceptable Exposure Level ($AEL_{medium\ term}$) dividing the relevant NOAEL by an assessment factor of 100 used to account for interspecies and intraspecies derived in the Assessment Report for Imidacloprid, 2011.
**$AEL_{medium\text{-}term}$ = 0.2 mg/Kg bw/day.**

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 a systemic dose of 0,037974 mg/kg/day. Comparison to the $AEL_{medium\ term}$ of 0,2mg/kg /day shows that the use of MAGNUM GEL CUCARACHAS containing 2.15 % IMIDACLOPRID do not cause health risk for professionals nor for non-professionals as indicated by the resulting in a %AEL of 19. See Tables below.

Even considering that some professionals could make a repeated and long-term use of product, an $AEL_{long\ term}$ of 0.06 mg/kg bw/d could be used. In this case, the estimated uptake would represent 63% which would indicates an acceptable risk also for this use. Tier 1 assessment indicates an acceptable risk for professional and non-professional users.

See Tables below.

**Systemic effects combined exposure 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 | %AEL | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| Application / Scenario 3 | 1 | 20 | 0.2 | 0,0253162 | 12,658125 | Yes |
| post application/ Scenario 4 | 1 | 20 | 0.2 | 0,0126581 | 6,3290625 | Yes |

**Combined scenarios**

| Scenarios combined | Tier | Systemic NOAEL mg/kg bw/d | AEL mg/kg bw/d | Estimated uptake mg/kg bw/d | %AEL | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| Application/ Post application Scenario 3 & 4 | 1 | 20 | 0.2 | 0,0379744 | 18,987187 | Yes |
| Application/ Post application Scenario 3 & 4 $AEL_{long-term}$ | 1 | 6 | 0.06 | 0,0379744 | 63,290625 | Yes |

**Local effects**

Not applicable

**Conclusion**

No risk is envisaged for the use of MAGNUM GEL CUCARACHAS by professional and non-professional users.

***Risk for the indirect exposure***

**Systemic effects combined indirect exposure for toddlers**

| Task/ Scenario | Tier | Systemic NOAEL mg/kg bw | AEL mg/kg bw | Estimated uptake mg/kg bw/d | %AEL | Acceptable (yes/no) |
|---|---|---|---|---|---|---|
| Dermal and hand to mouth contact for toddlers/ Scenario 7 | 1 | 40 | 0.4 | 0.12658 | 31.65 | 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 0. 12658mg/kg bw during the indirect exposure via oral and dermal route after the application of biocidal product, (Tier 1). The estimated uptake represents 31.65% of the proposed AEL of 0.4 mg/kg bw.

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

Based on the risk assessment results, the use of MAGNUM GEL CUCARACHAS 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):

- 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 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.

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

- Keep away from foodstuff, eating utensils or food contact surfaces.

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***

Not applicable

## 2.2.7 Risk assessment for animal health

Exposure of animals (either companion animals or livestock) to Imidacloprid 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 restrictions preclude the exposure of animals:

- The treatment must be restricted to areas out of reach of animals

The following label restrictions preclude the exposure of animals (Trained professional uses):

- The product can not be applied on surfaces where feed is prepared, consumed or stored.

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

- Keep away from feedingstuff or feed contact surfaces.

No risk is envisaged for animal health.

### 2.2.8 Risk assessment for the environment

MAGNUM GEL CUCARACHAS is formulated as gel insecticide and applies via droplets by using a cartridge/syringe or bait stations for indoors use. It is against German cockroaches (*Blattella germanica*), Oriental cockroaches (*Blatta orientalis*), and American cockroaches (*Periplaneta americana*).

MAGNUM GEL CUCARACHAS is a gel containing 2.15% of the active substance imidacloprid combined with a number of co-formulants. The Annex I assessment of this active substance, imidacloprid, was supported by two active formulations [redacted] and [redacted], contained 0.5 and 2.15% of the active substance, respectively. The biocidal product [redacted], is a gel; it is a ready-to-use bait for indoor use. The product [redacted], is a ready-to-use granular bait. It is a bait for 'indoor use in rural hygiene situations', which is 'for use in animal houses and/or other agricultural buildings', leading to 'rapid knockdown and mortality of insect'. MAGNUM GEL CUCARACHAS is the same type of formulation as GL2.15, both are gel, and they have the same concentration of the active substance, imidacloprid, although they have different co-formulants. The co-formulants, in the product, are not at concentrations enough to be triggered as substances of concern, so, the risk assessment arising from the product can be adequately determined based on the assessment of the active substance, imidacloprid. Both products [redacted] and MAGNUM GEL CUCARACHAS are for indoor use. The applicant has calculated the exposure level in each environmental compartment and compared this to the most sensitive PNEC value. The applicant, as it is stated in the imidacloprid CAR, has used the last version of ESD PT18 and the Manual Technical Agreements (MOTA).

The applicant has a letter of access to all data presented by Bayer Environmental Science that supported the original Annex I listing of imidacloprid. No new data have been submitted in support of this application. The environmental exposure assessment has been carried out on the basis of the updated emission scenario for PT18, the Emission Scenario Document for Insecticides, Acaricides and Products to control other Arthropods (PT18) for household and professional uses (July 2008), and the Manual Technical Agreements (MOTA), as it is indicated in the Annex I assessment.

A full presentation of the environmental risk assessment to assess this product application can be found in Annex 3.7.

#### 2.2.8.1. Effects assessment on the environment

All the studies supporting environmental fate and toxicity properties of the product MAGNUM GEL CUCARACHAS are based on the active substance imidacloprid as reported in the CAR document. In addition, no substances of concern regarding the environment are contained in the biocidal product in such quantity as to lead to classification and therefore this assessment is based only on the properties of the active substance imidacloprid as reported in the CAR, as well as specific characteristics related with product application.

The following PNEC values were derived in the Assessment Report of imidacloprid less the $PNEC_{water}$ which has been reviewed:

**$PNEC_{water}$ =** This PNEC has been change from 0.174 µg/l $PNEC_{water}$ to **4.8 ng/L** from the paper by Roessink *et al*. 2013 assuming a factor of 5. This new value has been taken instead of the CAR's value. This new value was adopted by Member States following discussion at TM-IV-2013 (Environmental session) and the Biocides meeting CG-2. This PNEC was discussed and agreed at the BPC-WG ENV IV in September 2014.

**$PNEC_{microorganisms}$ (STP) = 100 mg/l.** According to the TGD on Risk Assessment (ECB Part II, 2003), the PNEC for microorganisms in a STP is derived by dividing the NOEC from a respiration inhibition test (OECD 209) by a factor of 10 or by dividing the $EC_{50}$ by a factor of 100. The lowest value should be chosen for PNEC derivation. The NOEC and $EC_{50}$ values of imidacloprid were determined to be 10000 mg/l (Document IIA 4.2.1).

**$PNEC_{sediment}$ =** 0.95 µg/$kg_{wwt}$ According with the Assessment Report for the substance imidacloprid, $PNEC_{sed}$ was derived using equilibrium partitioning method according with the TGD (2003). However the newly derived $PNEC_{water}$ also influences the assessment for the sediment compartment, as the $PNEC_{sediment}$ is derived from the $PNEC_{water}$ using equilibrium partitioning method. Using a $K_{susp\text{-}water}$ of 6.3 and a $RHO_{susp}$ of 1150 kg/$m^3$ results in a $PNEC_{sediment}$ of **26 ng/kg ww.**

**$PNEC_{soil}$ = 0.01575 mg/$kg_{wwt}$** Toxicity tests on organisms present in the soil such as earthworms, collembolans, mites, etc. were assessed and accepted in the Assessment Report for the active substance imidacloprid. $PNEC_{soil}$ value was derived from the available data applying an assessment factor of 10.

**$PNEC_{secondary\ poisoning}$:**

**$PNEC_{oral\ mammal}$: 8.3 mg/kg food**

**$PNEC_{oral\ bird}$: 4.2 mg/kg food**

### *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 CUCARACHAS contains 2.15% of imidacloprid as the only ingredient to contribute to the classification regarding environmental properties. Imidacloprid is classified as aquatic acute (H400) with M factor of 100 and aquatic chronic (H410) with an M factor of 1000. The concentration of the active substance in the product leads to classification according to M factor multiplication as set out in the Regulation EC 1272/2008. The biocidal product MAGNUM GEL CUCARACHAS is classified as Aquatic Acute (H400), Aquatic Chronic Category 1 (H410). H410 for labelling purposes.

### *Further Ecotoxicological studies*

No further data are available. Ecotoxicological data have been extrapolated from the active substance as reported in the CAR.

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

No further data are available. Ecotoxicological data have been extrapolated from the active substance as reported in the CAR.

### *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. The biocidal product MAGNUM GEL CUCARACHAS is an insecticide to be used indoors and therefore this study is not required.

### *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*

MAGNUM GEL CUCARACHAS is applied indoors in inaccessible places: cracks, crevices, behind furniture, etc., where cockroaches may be present; in dark and wet places: under the sink, behind the toilet, near the drain; in high temperature places: behind

the engines, refrigerators, washing machines, dishwashers; and in places with food waste or organic materials: under or behind kitchen cupboards, near the dustbin, in the storeroom, in the cellars, in the courtyards. Two different applications patterns are requested for this product: it may be applied as gel drops directly to the target surface or it can be used as a ready-to-use bait stations. According to these uses and applications patterns requested by the applicant an environmental risk assessment has been carried out.

The biocidal product is not considered to contain any additional substances at concentrations high enough to be triggered as substance of concern for the environment. Therefore it has not been needed a risk assessment of substances of concern. The risk assessment arising from the product can be adequately determined based on the assessment of the active substance alone.

Exposure to the receiving environmental compartments such as soil, water and air depends on the physical-chemical properties of the active substance as well as its formulation type, mode of application, use and disposal.

Different release pathways are envisaged depending on the mode of application of the product according to the *Emission Scenario Document for Insecticides, Acaricides and Products to Control other Arthropods for Household and Professional Users* (*OECD Series of Emission Scenario Documents No.18*) and the *Guidance on the Biocidal Products Regulations, Vol. IV Environment – Part B Risk Assessment* (Version 1.0, April 2015).

According to the Exposure Scenario Document and the Guidance on Risk Assessment of Biocidal products, indoor application may result in indirect environmental exposure via the sewage system (i.e. during a cleaning operation following treatment). This poses a risk of the product entering sewage treatment plants (STPs) and subsequently being released via effluent into surface water, soil after sludge application and subsequently ground water. Different organisms dwelling in affected compartments can also be affected transferring the chemical up through the trophic chain to top predators.

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

No new environmental fate & behaviour or leaching data on imidacloprid or product specific data are available as they have not been considered necessary. All agreed endpoints have been taken from the PT 18 CAR for imidacloprid.

### *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.

#### 2.2.8.2. Exposure assessment

**General information**

| | |
|---|---|
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: Indoor use, spot application in crack and crevice application in private houses.<br>Scenario 2: Indoor use, spot application in crack and crevice application in private houses and large buildings.<br>Scenario 3: Indoor use, spot application, surface treatment in private houses.<br>Scenario 4: Indoor use, spot application, surface treatment in private houses and large buildings.<br>Scenario 5: indoor use in ready-to-use bait stations. |
| 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 | Calculated based on TGD 2003 (alternative: based on measured data) |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Imidacloprid 2.15% Gel is produced in small batches in closed systems with appropriate control measurements in place to exclude release of the active substance to the environment during formulation of the product (the substance is manufactured outside the EU). In addition to this according to the Technical Notes for Guidance on Human Exposure to Biocidal Products (June 2007) processes including the manufacturing of the active substance and the biocidal product are regulated under various other Directives. It is therefore considered acceptable that the exposure during the production/formulation of the insecticide imidacloprid is not considered here. |
| Remarks | None |

## *Emission estimation*

### Scenario [1]

This scenario is covered by scenario 2 thus, emissions from this scenario has not been calculated.

### Scenario [2]

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: crack and crevice application in a house and large buildings. | | | |
| Application rate of biocidal product | 0.04 | g/droplet | The worst scenario is 6 drops/$m^2$ (each drop contains 0.04 g of product) |
| Concentration of active substance in the product | 21.5 | g/Kg | |
| Number applications per day | 1 | - | |
| Number of point per area | 6 | Droplet/ $m^2$ | |
| Area treated with product (private houses) | 2 | $m^2$ | |
| Area treated with product (large buildings) | 9.3 | $m^2$ | |

Calculations for Scenario [*2*]

Emissions of imidacloprid 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 the applicant the worst scenario is 6 drops (with 0.04 g of product) per $m^2$ in crack and crevice 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 MOTA (2011). Hence, the default value used for a private house and a large building is 2 and 9.3 $m^2$, respectively.

**Table 2.8.1-1: Release of imidacloprid during application (ESD PT18, 2008)**

| **Parameter** | **Definition** | **Value** | |
|---|---|---|---|
| | | **Private houses** | **Large buildings** |
| Number of application per day | $N_{appl}$ | 1 | |

| | | | |
|---|---|---|---|
| Number of point per area | $N_{point}$ | 6 | |
| Fraction emitted to treated surfaces during application | $F_{appl}$ | 1 | |
| Quantity of commercial product applied per point of gel [g/point] | $Q_{prod, point}$ | 0.04 | |
| Fraction of active substance in the commercial product | $F_{ai}$ | 0.0215 | |
| Area treated with product [m2] | $AREA_{treated}$ | 2 | 9.3 |
| **Emission rate to treated surface during application [g/d]** | $\mathbf{E_{application, surface} = Q_{prod, point} \times N_{point} \times F_{ai} \times AREA_{treated} \times F_{appl} \times N_{appl}}$ | **1.03E-02** | **4.80E-02** |

**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 CUCARACHAS represents a maximum exposure to cleaning of 3% for household and large buildings according to the CEFIC Insecticides Working Group, considering that this type of product is applied in areas difficult to access and not subject to cleaning (ESD PT18, 2008).

**Table 2.8.1-2: Release of imidacloprid during cleaning (ESD PT18, 2008)**

| **Parameter** | **Definition** | **Value** | |
|---|---|---|---|
| | | **Private houses** | **Large buildings** |
| Emission to floor during application step [g/d] | $E_{application, floor}$ | 0 | 0 |
| Emission to treated surfaces during application step | $E_{application, surface}$ | 0.0103 | 0.0480 |
| Fraction emitted to wastewater during cleaning step | $F_{ww}$ | 1 | |
| Cleaning efficiency | $F_{CE}$ | 0.03 | |
| **Emission rate to wastewater during cleaning step [g/d]** | $\mathbf{Elocal_{ww} = (E_{application, floor} + E_{application, surface}) \times F_{ww} \times F_{CE}}$ | **3.10E-04** | **1.44E-03** |

Emissions have been calculated for one private house and one large building, according to the ESD these values have to be multiplied by the number of houses, 4000, and large buildings, 1000. The number of large buildings has been refined from 1000 to 300 (TMI 2010)

According to the applicant the product is going to be used 3 to 6 times per year depending of the level of infestation. Therefore, the product application frequency is 3-11 times per year. With this application rate, the simultaneity factor is:

$F_{simultaneity}$ = ((32.15*1.9)+(37.82*0.54))/100 = 0.815

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

**Table 2.8.1-3: Total emissions in wastewater of imidacloprid during cleaning (ESD PT18, 2008)**

| **Parameter** | **Definition** | **Value** | |
|---|---|---|---|
| | | **Private houses** | **Large buildings** |
| Emission from treated surface to wastewater during cleaning step [g/d] | $Elocal_{ww}$ | 3.10E-04 | 1.44E-03 |
| Simultaneously treated houses per STP [-] | $N_{houses}$ | 4000 | 300 |
| Simultaneity factor[-] | $F_{simultaneity}$* | 0.00815 | |
| **Emission to wastewater [g/d]** | **$Elocal_{ww}$ = $Elocal_{ww}$ x $N_{houses}$ x $F_{simultaneity}$** | **1.01E-02** | **3.52E-03** |
| **Total emission to wastewater [kg/d]** | **$E_{ww\ total}$ = Σ($E_{ww}$)/1000** | **1.36E-05** | |

*This value is calculated in percentage (%)

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| STP | **1.36E-05** | Worst case private house + large buildings |

**Scenario [3]**

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: surface treatment application in a house. | | | |
| Application rate of biocidal product | 0.04 | g/m² | The worst scenario is 6 drops per $m^2$ (each drop contains 0.04 g of product) |
| Concentration of active substance in the product | 21.5 | g/Kg | |

| | | | |
|---|---|---|---|
| Number applications per day | 1 | - | |
| Number of point per area | 6 | - | |
| Area treated with product (private houses) | 38.5 | $m^2$ | |

Calculations for Scenario [*3*]

Emissions of imidacloprid 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 the applicant the worst scenario is 6 drops (with 0.04 g of product) per $m^2$ in crack and crevice followed by a wet cleaning event. The emissions from this application is calculated for private houses. According to TMI 2010, a surface area of a standard house of 130 $m^2$ is considered as default for general treatment. A wet cleaning zone leading to a release to the STP of 38.5 $m^2$ will be used. Hence, the default value used for a private house is 38.5 $m^2$.

**Table 2.8.1-4: Release of imidacloprid during application (ESD PT18, 2008)**

| **Parameter** | **Definition** | **Value** |
|---|---|---|
| | | **Private houses** |
| Number of application per day | $N_{appl}$ | 1 |
| Number of point per area | $N_{point}$ | 6 |
| Fraction emitted to treated surfaces during application | $F_{appl}$ | 1 |
| Quantity of commercial product applied per point of gel [g/point] | $Q_{prod,\ point}$ | 0.04 |
| Fraction of active substance in the commercial product | $F_{ai}$ | 0.0215 |
| Area treated with product [m2] | $AREA_{treated}$ | 38.5 |
| **Emission rate to treated surface during application [g/d]** | $\mathbf{E_{application,\ surface} = Q_{prod,\ point} \times N_{point} \times F_{ai} \times AREA_{treated} \times F_{appl} \times N_{appl}}$ | **1.99E-01** |

**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

CUCARACHAS represents a maximum exposure to cleaning of 25% for household and large buildings according to the CEFIC Insecticides Working Group, considering that this type of product for surface treatment (Table 3.3.-8, ESD PT18, 2008).

**Table 2.8.1-5: Release of imidacloprid during cleaning (ESD PT18, 2008)**

| Parameter | Definition | Value |
|---|---|---|
| | | Private houses |
| Emission to floor during application step [g/d] | $E_{application, floor}$ | 0 |
| Emission to treated surfaces during application step | $E_{application, surface}$ | 0.199 |
| Fraction emitted to wastewater during cleaning step | $F_{ww}$ | 1 |
| Cleaning efficiency | $F_{CE}$ | 0.25 |
| **Emission rate to wastewater during cleaning step [g/d]** | **$Elocal_{ww}$ = ($E_{application, floor}$ + $E_{application, surface}$) x $F_{ww}$ x $F_{CE}$** | **4.97E-02** |

Emissions have been calculated for one house, according to the ESD these values have to be multiplied by the number of houses, 4000.

According to the applicant the product is going to be used 3 to 6 times per year depending of the level of infestation. Therefore, the product application frequency is 3-11 times per year. With this application rate, the simultaneity factor is:

$F_{simultaneity}$ = ((32.15*1.9)+(37.82*0.54))/100 = 0.815

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

**Table 2.8.1-6: Total emissions in wastewater of imidacloprid during cleaning (ESD PT18, 2008)**

| Parameter | Definition | Value |
|---|---|---|
| | | Private houses |
| Emission from treated surface to wastewater during cleaning step [g/d] | $Elocal_{ww}$ | 4.97E-02 |
| Simultaneously treated houses per STP [-] | $N_{houses}$ | 4000 |
| Simultaneity factor[-] | $F_{simultaneity}$* | 0.00815 |
| **Emission to wastewater [g/d]** | **$Elocal_{ww}$ = $Elocal_{ww}$ x $N_{houses}$ x $F_{simultaneity}$** | **16.2** |

| | | |
|---|---|---|
| **Total emission to wastewater [kg/d]** | **$E_{ww\ total}$ = $\Sigma(E_{ww})/1000$** | **1.62E-03** |

* This value is calculated in percentage (%).

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| STP | **1.62E-03** | |

**Scenario [4]**

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: surface application in private houses and large buildings. | | | |
| Application rate of biocidal product *[alternative: annual tonnage in the EU]* | 0.04 | g/droplet | The worst scenario is 6 drops per $m^2$ (each drop contains 0.04 g of product) |
| Concentration of active substance in the product | 21.5 | g/Kg | |
| Number applications per day | 1 | - | |
| Number of point per area | 6 | droplet/ $m^2$ | |
| Area treated with product (large buildings) | 609 | $m^2$ | |
| Area treated with product (private houses) | 38.5 | $m^2$ | |

Calculations for Scenario [*4*]

Emissions of imidacloprid 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 the applicant the worst scenario is 6 drops (with 0.04 g of product each drop) per $m^2$ in surface 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 values of 38.5 and 609 $m^2$, respectively.

**Table 2.8.1-7: Release of imidacloprid during application (ESD PT18, 2008)**

| **Parameter** | **Definition** | **Value** |
|---|---|---|

| | | Private houses | Large buildings |
|---|---|---|---|
| Number of application per day | $N_{appl}$ | 1 | |
| Number of point per area | $N_{point}$ | 6 | |
| Fraction emitted to treated surfaces during application | $F_{appl}$ | 1 | |
| Quantity of commercial product applied per point of gel [g/point] | $Q_{prod, point}$ | 0.04 | |
| Fraction of active substance in the commercial product | $F_{ai}$ | 0.0215 | |
| Area treated with product [m2] | $AREA_{treated}$ | 38.5 | 609 |
| **Emission rate to treated surface during application [g/d]** | **$E_{application, surface} = Q_{prod, point} \times N_{point} \times F_{ai} \times AREA_{treated} \times F_{appl} \times N_{appl}$** | **1.99E-01** | **3.14E-00** |

**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 CUCARACHAS represents a maximum exposure to cleaning of 25% for household and large buildings according to the CEFIC Insecticides Working Group, considering that this type of product is applied in surfaces (Table 3.3.-8,ESD PT18, 2008).

**Table 2.8.1-8: Release of imidacloprid during cleaning (ESD PT18, 2008)**

| **Parameter** | **Definition** | **Value** | |
|---|---|---|---|
| | | **Private houses** | **Large buildings** |
| Emission to floor during application step [g/d] | $E_{application, floor}$ | 0 | 0 |
| Emission to treated surfaces during application step | $E_{application, surface}$ | 0.199 | 3.14 |
| Fraction emitted to wastewater during cleaning step | $F_{ww}$ | 1 | |
| Cleaning efficiency | $F_{CE}$ | 0.25 | |
| **Emission rate to wastewater during cleaning step [g/d]** | **$Elocal_{ww} = (E_{application, floor} + E_{application, surface}) \times F_{ww} \times F_{CE}$** | **4.97E-02** | **7.86E-01** |

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, and large buildings, 1000. The number of large buildings has been refined from 1000 to 300 (TMI 2010)

According to the applicant the product is going to be used 3 to 6 times per year depending to the level of infestation. Therefore, the product application frequency is 3-11 times per year. With this application rate, the simultaneity factor is:

$F_{simultaneity}$ = ((32.15*1.9)+(37.82*0.54))/100 = 0.815

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

**Table 2.8.1-9: Total emissions in wastewater of imidacloprid during cleaning (ESD PT18, 2008)**

| **Parameter** | **Definition** | **Value** | |
|---|---|---|---|
| | | **Private houses** | **Large buildings** |
| Emission from treated surface to wastewater during cleaning step [g/d] | $Elocal_{ww}$ | 4.97E-02 | 7.86E-01 |
| Simultaneously treated houses per STP [-] | $N_{houses}$ | 4000 | 300 |
| Simultaneity factor[-] | $F_{simultaneity}$* | 0.00815 | |
| **Emission to wastewater [g/d]** | **$Elocal_{ww}$ = $Elocal_{ww}$ x $N_{houses}$ x $F_{simultaneity}$** | **1.62E01** | **1.92E01** |
| **Total emission to wastewater [kg/d]** | **$E_{ww\ total}$ = $\Sigma(E_{ww})/1000$** | **3.54E-02** | |

* This value is calculated in percentage (%)

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| STP | **3.54E-03** | Private house + large buildings |

**Scenario [5]**

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 CUCARACHAS 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, 2, 3 and 4 | Yes | Yes | No | No | Yes | No | Yes | Yes | |

| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
|---|---|---|---|
| Input | Value | Unit | Remarks |
| Molecular weight | 255.7 | | |
| Melting point | 144 | °C | |
| Boiling point | Descomposition | °C | |
| Vapour pressure (at XC) | <0.1 | Pa | |
| Water solubility (at X°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 X C)*[if measured data available]* | $1.7x10^{-10}$ | Pa/m3/mol | |
| Biodegradability | No | | |
| $DT_{50}$ for hydrolysis in surface water | 2.75 years at 12 ºC/ pH 9 | d or hr (at 12ºC /pH) | |
| $DT_{50}$ for photolysis in surface water | DT50 calculated : 1.4 - 16 days (fall, winter) 0.5-1.6 days (spring, summer) | d | |
| $DT_{50}$ for degradation in soil | 295 days | d (at 12ºC) | n=4 |
| $DT_{50}$ for degradation in air | 2.54 | hr | |

| **Calculated fate and distribution in the STP** | | |
|---|---|---|
| Compartment | Percentage [%] | Remarks |
| | Scenario 1, 2, 3 and 4 | |
| Air | $3.72 \times 10^{-10}$ | |
| Water | 97.2 | |
| Sludge | 2.79 | |
| Degraded in STP | 0 | |

### *Calculated PEC values*

| Summary table on calculated PEC values[1] | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{water}$** | **$PEC_{sed}$** | **$PEC_{seawater}$** | **$PEC_{sased}$** | **$PEC_{soil}$** | **$PEC_{GW}$** | **$PEC_{air}$** |
| | [mg/L] | [mg/l] | [$mg/kg_{wwt}$] | [mg/l] | [$mg/kg_{wwt}$] | [$mg/m^3$] | [µg/l] | [$mg/m^3$] |
| Scenario 2 | $6.81 \times 10^{-6}$ | $6.61 \times 10^{-7}$ | $3.82x10^{-6}$ | | | $5.79x10^{-7}$ | $1.38x10^{-4}$ | |
| Scenario 3 | $7.87 \times 10^{-5}$ | $7.87 \times 10^{-4}$ | $4.55x10^{-3}$ | | | $1.719x10^{-3}$ | $0.16x10^{-1}$ | |
| Scenario 4 | $1.77 \times 10^{-3}$ | $1.72 \times 10^{-4}$ | $9.95x10^{-4}$ | | | $1.50x10^{-4-3}$ | $3.60x10^{-2}$ | |

PEC calculations for all scenarios are in Annex 3.3

### *Primary and secondary poisoning*

Primary poisoning

The product is a gel applied indoors in crack and crevices and therefore primary poisoning caused by product ingestion by animals is unlikely.

Secondary poisoning

| Summary table on calculated $PEC_{oral\ predator}$ values[1] | | |
|---|---|---|
| | **$PEC_{oral\ predator}$** earthworm | **$PEC_{oral\ predator}$** fish |
| | [mg/ kg diet] | [mg/ kg diet] |
| Scenario 2 | 1.62E-09 | 7.67E-07 |
| Scenario 3 | 7.49E-05 | 8.7E-07 |
| Scenario 4 | 2.68E-06 | 2.31E-04 |
| [1] Calculated using EUSES 2.1.2 software | | |

#### 2.2.8.3. Risk characterisation

### *Atmosphere*

Conclusion: According to the TGD on Risk Assessment (ECB Part II, 2003) there is currently no appropriate guidance to calculate a $PNEC_{air}$. The physical-chemical properties of imidacloprid in the environment, such as vapour pressure $4 \times 10^{-10}$ 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 $5 \times 10^5$ OH

radicals per $cm^3$. 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. Imidacloprid is to be used indoors as a gel and excessive release or dispersal of imidacloprid into the atmosphere is highly unlikely.

### *Sewage treatment plant (STP)*

| Summary table on calculated PEC/PNEC values | |
|---|---|
| | **$PEC/PNEC_{STP}$** |
| Scenario 2 | $6.81x10^{-8}$ |
| Scenario 3 | $8.1x10^{-6}$ |
| Scenario 4 | $1.77x10^{-5}$ |

Conclusion:
All the PEC/ PNEC values are less than 1, an acceptable level of risk to STP is predicted from all the scenarios assessed.

### *Aquatic compartment*

| Summary table on calculated PEC/PNEC values | | | | |
|---|---|---|---|---|
| | **$PEC/PNEC_{water}$** | **$PEC/PNEC_{sed}$** | **$PEC/PNEC_{seawater}$** | **$PEC/PNEC_{seased}$** |
| Scenario 2 | $1.38 \times 10^{-1}$ | $1.47 \times 10^{-1}$ | | |
| Scenario 3 | $1.64 \times 10^{+1}$ | $1.75 \times 10^{+1}$ | | |
| Scenario 4 | $3.58 \times 10^{+1}$ | $3.83 \times 10^{+1}$ | | |

Conclusion:
Only scenario 2 has shown an acceptable level of risk to the aquatic. Unacceptable risk for the aquatic compartment has been detected for scenarios 3 and 4.

### *Terrestrial compartment*

| Calculated PEC/PNEC values | |
|---|---|
| | **$PEC/PNEC_{soil}$** |
| Scenario 2 | $3.68 \times 10^{-5}$ |
| Scenario 3 | $4.38 \times 10^{-3}$ |
| Scenario 4 | $9.56 \times 10^{-3}$ |

Conclusion:
All PEC/ PNEC values are less than 1, an acceptable level of risk to soil is predicted from all scenarios assessed.

## *Groundwater*

No risk has been found for this compartment

## *Primary and secondary poisoning*

Primary poisoning

No primary poisoning as consequence of the application of MAGNUM GEL CUCARACHAS is envisaged. The product is a gel formulation and only indoor use is recommended so possibility to be ingested by animals (mammals or birds) is highly unlikely if proper handling and storage recommendations are followed. In addition the product contains a bittering agent that should prevent the consumption of the product by animals up in the food chain (vertebrates).

Secondary poisoning

| **Summary table on secondary poisoning** | | | | |
|---|---|---|---|---|
| | **$PNEC_{oral\ predator}$** Bird [mg/ kg diet] | **$PNEC_{oral\ predator}$** Mammal [mg/ kg diet] | **PEC/PNEC bird** | **PEC/PNEC mammal** |
| Scenario 2- earthworm | 4.2 | 8.33 | 0.38E-09 | 0.19 E-09 |
| Scenario 2- fish | 4.2 | 8.33 | 1.82E-07 | 0.91E-07 |
| Scenario 3- earthworm | 4.2 | 8.33 | 1.78E-05 | 0.17E-05 |
| Scenario 3- fish | 4.2 | 8.33 | 2.78E-07 | 1.04E-07 |
| Scenario 4- earthworm | 4.2 | 8.33 | 0.64E-06 | 0.32E-06 |
| Scenario 4- fish | 4.2 | 8.33 | 0.55E-04 | 0.27E-04 |

Refers to total emissions i.e. domestic or private house + large buildings summed

Conclusion:
All the PEC/ PNEC values are less than 1, an acceptable level of risk from the consumption of contaminated earthworms or fish contaminated with imidacloprid is predicted from all scenarios assessed.

## *Mixture toxicity*

As this product contains three biocidal substances (imidacloprid, 2-Octyl-2H-isothiazol-one (OTI) and 1,2-benzisothiazol-3(2H)-one (BIT)) and two other "Substances of Concern", it is possible that an assessment of mixture toxicity should be necessary to determine the overall toxicity of this product.

*Screening step*

This product contains the active substance, imidacloprid which produce the biocidal activity in the product, and two preservatives which are both currently in the review program of active substances (2-octyl-2H-isothiazol-3-one (OIT) and 1,2-benzisothiazol-3(2H)-one (BIT)). The product also contain 2 compounds which have the potential to classify as "Substances of Concern": denatonium benzoate and Polyoxyethilene ether. In relation to denatonium benzoate is classified as C3 and Polyoxyethilene ether as C1.

The data related to those preservatives (OIT and BIT) is no available at the moment but it shall be taken into account in the evaluation after their approvals at European level, at product's renewal stage. However, both preservatives are present at low levels in the formulation with a very low contribution in the overall toxicity of the product.

Although both SOCs, denatonium benzoate and Polyoxyethilene ether, could be considered in the assessment, the overall contribution to the risk of the formulation can be considered negligible. Both are present at low levels in the formulation and are significantly less toxic than the PT 18 active substance imidacloprid.

| **Overall conclusion on the risk assessment for the environment of the product** |
|---|
| Based upon the calculated PEC/PNEC ratios, it should be noted that acceptable risks are predicted to all environmental compartments for the use of MAGNUN GEL CUCARACHAS in crack and crevice. For other places where cockroaches can appear (under sink, behind toilet, near the drain…) a surface treatment has been evaluated to investigate the risk to the environment. For this scenario, an unacceptable risk has been found for the aquatic compartment (surface water and sediment) and ground water via sludge application.<br><br>According to the environmental assessment, ESCA concludes that this product can only be used as gel drops directly apply to the target surface in hidden areas or places with difficult access (crack and crevice), for the rest of the areas (under the sink, behind toilets, near the drain…) the product can only be used as ready-to-use bait stations. |

## 2.2.9 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:

- Avoid contact of children with treated surfaces.
- Product must be securely applied in a way so as to minimize the risk of consumption by other animals or children.
- The use of ready to use bait stations is in itself a risk mitigation measure. But the stations should not be open or handle.
- Never introduce the fingers through the holes in the bait station. In any case,

the bait station has built-in block inside to prevent you´re thefingers from touching, the insecticide gel.

- 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.
- The product contains a bitter substance that makes it repulsive to people or pets.

Trained professional uses:

- The product can not be applied on surfaces where feed or feedingstuff is prepared, served, 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.

Professional and non-professional uses:

- Keep away from feed or foodstuff, eating utensils or food 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:
Precautions: Prevent product from entering the environment (surface and ground water), sewerage, drainage, etc. with the construction of protective barriers and closing drains.
Communicate to the relevant authorities or tipping leaks into waterways, drains, sewers...
Methods and materials for containment and cleaning: Absorb spill on inert material (sand, kaolin ...), collect and place in containers for later properly identified as a hazardous waste management.

## 2.2.10 Assessment of a combination of biocidal products

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

## 2.2.11 Comparative assessment

**Background**

The Spanish competent authority has been processing an application for a biocidal product, MAGNUM GEL CUCARACHAS 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

CUCARACHAS 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:** BC-KN010529-32

**Evaluating Competent Authority:** ES-CA

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

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

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

**Trade name(s):** MAGNUM GEL CUCARACHAS

**Product type(s):** 18 (insecticide)

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

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

According to the applicant MAGNUM GEL CUCARACHAS is an insecticide (PT18) which contains the active substance imidacloprid. The product is to be used indoors at private houses or large buildings to control cockroaches.

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 control cockroaches |
| Target organism (including, where relevant, development stage) | German cockroaches (*Blattella germanica*), Oriental cockroaches (*Blatta orientalis*), American cockroaches (*Periplaneta americana*). |
| Field(s) of use | Indoor use |
| Application method(s) | Gel, ready to use product or into bait stations |
| Category(ies) of users | All users |

MAGNUM GEL is a ready to used product and it could be applied openly (in form of small drops) or in bait station indoors.

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

### 4.1.- Identified eligible alternative BPs

The product MAGNUM GEL CUCARACHAS has been only compared with alternative products authorised in Spain as the searchable SPCs and a corresponding search tool in the Register for Biocidal Products (R4BP) is currently not available. The Spanish CA has used the information available to the ES CA on the 10th of January 2017 of the biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012.

In Spain 25 products PT18 have been authorised. These products are based in ten active substances but only four of these actives substances are used for the control of cockroaches: Indoxacarb, nitrogen, abamectin and fipronil.

Abamectin and fipronil are themselves candidates for substitution. Abamectin is only persistent while fipronil and imidacloprid are very persistent.

In Spain products based on nitrogen and indoxacarb are only allowed for use by trained professionals so these products have been excluded. The product base in fipronil is allowed for professional user, so only products based on abamectin (two products) could be considered as eligible alternative. Products with abamectin are to be used indoor by non-professionals but they only control two of the three species of cockroaches controlled by MAGNUM GEL CUCARACHAS. Products identified as alternatives (only relevant uses are presented):

| Trade name | Field of use | Category of user | Target |
|---|---|---|---|
| **Product 1.** | Indoor | Non professional | German cockroaches (*Blattella germanica*), American cockroaches (*Periplaneta americana*). |
| **Product 2.** | Indoor | Non professional | German cockroaches (*Blattella germanica*) American cockroaches (*Periplaneta americana*). |

### 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. 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. cockroaches).

*Active substance/ mode of action combination*
Active substance presents in the product MAGNUM GEL CUCARACHAS and the two alternatives biocidal products:

Imidacloprid: it is a neonicotinoid insecticide which acts on the target organisms by contact and upon ingestion. It has residual activity. Like other neonicotinoids and nicotine, it acts on the insect central nervous system as an agonist of the postsynaptic nicotinic acetylcholine receptors (nAChRs).

Abamectin: it act interfering with the inhibitory neurotransmitter GABA by altering the gating mechanism and permeation of chloride ions at the neuromuscular junction, causing paralysis.

**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 control cockroaches for indoor use because as at least three different active substances – mode of action combinations should remain available through authorised biocidal product for a given use.

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

# 3 ANNEXES

## 3.1 List of studies for the biocidal product

See confidential PAR.

## 3.2 Output tables from exposure assessment tools

| Summary table: application by gel drops, relevant paths of human exposure | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| | **Trained professional use** | **Professional use** | **Non-professional use* (General public)** | **Trained professional use** | **Professional use** | **Non-professional use* (General public)** | **Via food** |
| Inhalation[1] | No | No | No | n.a. | No | No | No |
| Dermal | Yes | Yes | Yes | n.a. | No[2] | Yes[3] | No |
| Oral | No | No | No | n.a | No | Yes[3] | No[4] |

** ITo 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 substance (9E-10 Pa, 25ºC).*

*[2] secondary exposure of professionals after application of gel is not expected (as indicated in the CAR); neither is secondary exposure of consumers after application.*

*[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**<br>**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 | Non professionals/ Professionals |
| 4. | Post application | Primary exposure: disposal of used cartridge/syringe | Non professionals/ 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* | Professionals/ Professionals/ Non professionals |
| 7. | Post application | Secondary exposure: dermal and hand to mouth contact with gel | Bystanders (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.*

***Trained Professional exposure***

*Scenario 1 Application of MAGNUM GEL CUCARACHAS by trained professional users*

| | Parameters | Value |
|---|---|---|
| Tier 1 | Equivalence 0.5 cm gel [a] | 47.1 mg product |
| | number of opening and sealing per day[b] | 10 |
| | content of active substance in product | 2.15% |
| | Dermal absorption[c] | 75% |
| | Body weight adult[d] | 60 kg |

*[a] According to the CAR a drop of gel estimated to be 0.5 cm diameter 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 CUCARACHAS. The CA uses the amount of product in a 0.5cm diameter drop of MAGNUM GEL CUCARACHAS, as indicated in Section 2.2.2, storage stability study: aprox. 47.1 mg of product, to estimate the exposure of professionals via dermal route (see Annex 3.2)*

*[b] CAR.*

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

*[d] HEEG Opinion 17.*

**Calculations for Scenario 1**

Taking into account 5 times opening and 5 times sealing operations per day, the corresponding potential dermal exposure to Imidacloprid is calculated as shown below:

Absorbed dermal dose = (Number of events * quantity of product per event * Fraction of active substance* dermal absorption) /Kg bw

Estimated dermal uptake = [10 * 47.1 mg * 2.15% * 75%]/ 60 kg

| Scenario 1: application of MAGNUM GEL CUCARACHAS by professionals | | Estimated Internal Exposure as [mg /kg bw/d] | | | |
|---|---|---|---|---|---|
| | | Oral uptake | Inhalation uptake | Dermal uptake | Total uptake |
| **Tier 1** | **(no PPE)** | - | - | 0,12658125 | 0,12658125 |

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

| | Parameters | Value |
|---|---|---|
| Tier 1 | Equivalence 0.5 cm gel [a] | 47.1 mg product |
| | number of disposed cartridges per day [b] | 1 |
| | content of active substance in product | 2.15% |
| | Dermal absorption[c] | 75% |
| | Body weight adult[d] | 60 kg |

[a] *According to the CAR a drop of gel estimated to be 0.5 cm diameter 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 MAGNUM GEL CUCARACHAS. The CA uses the amount of product in a 0.5cm diameter drop of MAGNUM GEL CUCARACHAS, as indicated in Section 2.2.2, storage stability study: aprox. 47.1 mg of product, to estimate the exposure of professionals via dermal route*

[b] *CAR.*

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

[d] *HEEG Opinion 17.*

**Calculations for Scenario 2**

Taking into account 1 operation per day the corresponding potential hand exposure to Imidacloprid is calculated as shown below:

Absorbed dermal dose = (Number of events * quantity of product per event * Fraction of active substance* dermal absorption) /Kg bw

Estimated dermal uptake = [1 * 47.1 mg * 2.15% * 75%]/ 60 kg

| Scenario 2: post application of MAGNUM GEL CUCARACHAS by professionals | | Estimated Internal Exposure as [mg /kg bw/d] | | | |
|---|---|---|---|---|---|
| | | Oral uptake | Inhalation uptake | Dermal uptake | Total uptake |
| **Tier 1** | **(no PPE)** | - | - | 0,01265813 | 0,01265813 |

*Combined scenarios*

Total systemic exposure of a professional in a working day is estimated by a combination of scenarios 1 & 2. Chronic exposure is considered.

| Summary table: combined systemic exposure from professional uses (mg/kg bw/d) | | | | |
|---|---|---|---|---|
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios [1 & 2] Tier 1 | - | 0,13923938 | - | 0,13923938 |

***Professional and Non-professional exposure***

*Scenario 3 Application of MAGNUM GEL CUCARACHAS by professional and non-professional users (the general public)*

| | Parameters | Value |
|---|---|---|
| Tier 1 | Equivalence 0.5 cm gel [a] | 47.1 mg product |
| | number of opening and sealing per day[b] | 2 |
| | content of active substance in product | 2.15% |
| | Dermal absorption[c] | 75 % |
| | Body weight adult[d] | 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 MAGNUM GEL CUCARACHAS. The CA uses the amount of product in a 0.5cm diameter drop of MAGNUM GEL CUCARACHAS, as indicated in Section 2.2.2, storage stability study: aprox. 39 mg of product, to estimate the exposure of professionals via dermal route*

[b] *CAR, adapted for consumer use.*

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

[d] *HEEG Opinion 17.*

**Calculations for Scenario 3**

Taking into account 1 opening and 1 sealing of cartridge per day of application, the corresponding potential hand exposure to Imidacloprid is calculated as shown below:

Absorbed dermal dose = (Number of events * quantity of product per event * Fraction of active substance* dermal absorption) /Kg bw

Estimated dermal uptake = [2 * 47.1 mg * 2015% * 75%]/ 60 kg

| **Scenario 3: application of MAGNUM GEL CUCARACHAS by non-professionals** | | **Estimated Internal Exposure as [mg /kg bw/d]** | | | |
|---|---|---|---|---|---|
| | | **Oral uptake** | **Inhalation uptake** | **Dermal uptake** | **Total uptake** |
| **Tier 1** | **(no PPE)** | - | - | 0,02531625 | 0,02531625 |

*Scenario 4 Disposal of used cartridge of MAGNUM GEL CUCARACHAS by professional and non-professional users (the general public)*

| | Parameters | Value |
|---|---|---|
| Tier 1 | Equivalence 0.5 cm gel [a] | 47.1 mg product |
| | number of cartridge disposed off per event [b] | 1 |
| | content of active substance in product | 2.15% |
| | Dermal absorption [c] | 75 % |
| | Body weight adult [d] | 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 0.5cm diameter drop of MAGNUM GEL CUCARACHAS, as indicated in Section 2.2.2, storage stability study: aprox. 39 mg of product, to estimate the exposure of professionals via dermal route*

[b] *CAR, adapted for consumer use.*

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

[d] *HEEG Opinion 17.*

**Calculations for Scenario 4**

Taking into account 1 cartridge disposed per day of application, the corresponding potential hand exposure to Imidacloprid is calculated as shown below:

Absorbed dermal dose = (Number of events * quantity of product per event * Fraction of active substance* dermal absorption) /Kg bw.

Estimated dermal uptake = [1* 47.1 mg * 2.15% * 75%]/ 60 kg

| **Scenario 4: application of MAGNUM GEL CUCARACHAS by non-professionals** | | **Estimated Internal Exposure as [mg /kg bw/d]** | | | |
|---|---|---|---|---|---|
| | | **Oral uptake** | **Inhalation uptake** | **Dermal uptake** | **Total uptake** |
| **Tier 1** | **(no PPE)** | - | - | 0,012658125 | 0,012658125 |

*Combined scenarios*

Total systemic exposure of consumer or professional during the use of biocidal product is estimated by a combination of scenarios 3 & 4. Medium term exposure is considered (exposure is assumed every two weeks during six months).

| **Summary table: combined systemic exposure from 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 | - | 0,037974375 | - | 0,037974375 |

***Indirect Exposure of the general public***

Indirect exposure scenarios are described in the following.

*Scenario 7: Toddler: Accidental contact with gel, dermal exposure and hand to mouth transfer*

Considering the application pattern of MAGNUM GEL CUCARACHAS as a gel application in localized spots (drops/lines) in hidden places with difficult access such as crack and crevice,behind furniture, etc., exposure may occur accidentally for toddler via dermal contact.

In HEEG Opinion 17, 'children' are defined as individuals 6-11 years old, and 'infants' are individuals 6 to 12 month old. Whereas infants cannot walk or crawl extensively away from the place they are put to explore their environment, 'toddler' (in the age range 1 to <2 years old) can crawl/walk away from the place they are put and move to explore their environment, in addition toddlers can exhibit hand to mouth transfer of residues.

Hence, it is considered that toddlers are the most vulnerable population with regard to secondary exposure as results of use of the biocidal product.

The scenarios that may be considered to represent worst cases for all of the exposure routes are dermal (skin contact with residues) and oral (transference of residues via hand to mouth contact).

Although it is reasonable to assume that toddlers would not ingest the gel due to the presence of the bittering agent, exposure after ingestion via hand to mouth contact is estimated.

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 drops in localized spots (there is not an uniform application on surfaces as paints, for example), in the following scenario it is assumed that a toddler contacts 1 drop 0.5 cm diameter in one event. Additionally to dermal absorption, hand to mouth transfer may take place: it is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact (Crack & Crevice Use – Post Application; RIVM report 320005002 pp. 28); consequently 50% of external dermal load is absorbed via dermal route.

Tier 1 assumes 100% dislodgeability; 100% oral absorption and 75% dermal absorption.

| | Parameters | Value |
|---|---|---|
| Tier 1 | One drop of gel 5 mm diameter[a] | 47.1 mg product |
| | number of drops contacted per event [b] | 1 |
| | content of active substance in product | 0.01% |
| | Dermal absorption [c] | 75% |
| | Dislodged amount [b] | 100% |

| | | |
|---|---|---|
| | Amount of product available for oral intake[d] | 50% of external dermal load |
| | Oral absorption | 100% |
| | Body weight toddler[e] | 10 kg |

[a] *Section 2.2.2, storage stability study: a drop of 0.5 cm diameter of MAGNUM GEL CUCARACHAS from a cartridge equals aprox. 39.6 mg of product .*

[b] *assumption*

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

[d] *ConsExpo Pest product fact sheet RIVM report 320005002 (Crack & Crevice Use – Post Application; pp. 28)*

[e] *HEEG Opinion 17.*

**Calculations for Scenario 7**

Exposure is estimated using the following calculations:

*External dermal load (EDL) = Quantity of product in 1 drop 0.5 cm diameter * dislodgeable residue * fraction of a.s. in the product*

EDL = 47.1 mg * 100% * 2.15% = 1.01 mg active substance

Absorbed dermal dose = [EDL * dermal absorption]/ body weight

*Estimated dermal uptake = (1.01 mg * 75%)/ 10 kg=0.076mg a.s./kg/d*

Absorbed oral dose = [EDL * 50% * oral absorption] / body weight

*Estimated oral uptake = [1.01 * 50% * 100%] / 10 kg=0.05mg a.s./kg/d*

*Estimated total uptake = Estimated dermal uptake + Estimated oral uptake*

| **Summary table: systemic indirect exposure from non-professional uses** | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** *mg a.s./kg/d* | **Estimated oral uptake** *mg a.s./kg/d* | **Estimated total uptake** *mg a.s./kg/d* |
| Scenario [7] dermal and hand to mouth contact with gel/ Toddler | 1/none | - | 0.076 | 0.05 | 0.126 |

## 3.3 Environmental risk assessment (PEC Calculations)

### 3.3.1 Estimation of Predicted Environmental Concentrations for the aquatic compartment

According to the intended use of MAGNUM GEL, indirect emission to surface water and sediment via outputof the effluent from STP occurs. The predicted environmental concentrations for STP, surface water and sediment are estimated as follows:

PECSTP (=Clocalinf) and Clocaleff according to equation 32, 33 and 39, chapter 2.3.7.1, EU TGD
(2003),

Calculation of the STP influent concentration (EC, 2003, Equation 32)

| **Parameter** | | **Value** | |
|---|---|---|---|
| | | **Private houses** | **Large buildings** |
| Local emission rate to wastewater [g/day] | $E_{ww}$ | 1,01E-02 | 3,52E-03 |
| Cumulative local emission rate to wastewater [kg/d] | $E_{ww\ total}=\Sigma(Eww)/1000$ | 1,36E-05 | |
| Capacity of the STP [eq] | $CAPACITY_{STP}$ | 10000 | |
| Sewage flow per inhabitant [L/d/eq] | $WASTEW_{inhab}$ | 200 | |
| Effluent discharge rate [L/d] | $EFFLUENT_{STP} = CAPACITY_{STP}$ X $WASTES_{inhab}$ | 2000000 | |
| **Concentraton in untreated wastewater [mg/L]** | $Clocal_{inf}=\frac{E_{ww\ total}\ x\ 106}{EFLUENT_{STP}}$ | 6,81E-06 | |
| **Concentration in untreated wastewater [µg/L]** | **µg/L = mg/L x 1000** | 6,81E-03 | |

Calculation of the STP effluent concentration (EC, 2003, Equation 33)

| **Parameter** | **Definition** | **Value** |
|---|---|---|
| Concentration in untreated wastewater [µg/L] | $Clocal_{inf}$ | 6,81E-03 |
| Fraction of emission directed to water by STP [-] | $F_{STP}$ | 0,972 |
| **Concentration of substance in the STP effluent [µg/L]** | **$Clocal_{eff}$= Clocalinf x Fstpwater** | 6,62E-03 |

Calculation of PEC STP (EC, 2003, Equation 39)

PEC STP (mg/L) =$Clocal_{inf}$ 6,81E-06

**PEClocalsurfacewater** according to equation 45, EU TGD (2003),

| **Parameter** | **Definition** | **Value** |
|---|---|---|
| Concentreation of a.i. in the STP effluent [µg/L] | $Clocal_{eff}$ | 6,62E-03 |
| Solids-water partitioning coefficient of suspended matter [L/kg] | $Kp_{susp}$ | 23 |

| | | |
|---|---|---|
| Concentration of suspended matter in the river [mg/L] | $SUSP_{water}$ | 15 |
| Dilution factor [-] | DILUTION | 10 |
| **Local concentration in surface water during emission episode [µg/L]** | $Clocal_{water}$ = $Clocal_{eff}/((1+Kp_{susp}$ x $SUSP_{water}$ x $10^{-6}$) x DILUTION) | 6,61E-04 |

**PEClocalsediment** according to equation 50, EU TGD (2003).

| **Parameter** | **Definition** | **Value** |
|---|---|---|
| Concentrations in surface water duting emission episode [µg/L] | $PEC_{SW}$ | 6,61E-04 |
| Suspended matter-water partitioning coefficient [$m^3/m^3$] | $K_{susp\text{-}water}$ | 6,65 |
| Bulk density of suspended mater [$kg/m^3$] | $RHO_{susp}$ | 1150 |
| PEC in sediment [mg/kg] | $PEC_{SED} = \frac{Kp_{susp\_water}}{RHO_{susp}} x\ PECSW$ | 3,82E-06 |

### 3.3.2 Estimation of Predicted Environmental Concentrations for the terrestrial compartment

The application of sludge from the STP onto agricultural and grassland soil provokes an indirect
emission to soil, as well as the leaching of a.s. through soil following sludge application causes indirect emission to groundwater. The PECsoil is estimated according to equations 66 and 55 EU TGD
(2003).

**$PEClocal_{agr.soil}$ = $Clocal_{agr.soil}$ = (1/kT) x $C_{agr.soil\ 10}$ (0) x (1 - $e^{-kT}$) (66)(55)**

| **INPUTS** | | **Value** | **Unit** |
|---|---|---|---|
| Averaging time | T | 180 | d |
| First order rate constant for removal from top soil | k | 0,00268768 | $d^{-1}$ |
| Initial concentration after 10 years | $C_{agr.soil\ 10}$ (0) | 1,2585E-06 | $mg.kg^{-1}$ |

| | | | |
|---|---|---|---|
| **$PEClocal_{agr.soil}$=** | **$Clocal_{agr.soil}$** | 9,9773E-07 | $mg.kg^{-1}$ |

The estimation of the local PECs for groundwater. The PECgroundwater is calculated according to equations 68 and 67, EU TGD (2003)

**Groundwater:** **$PECloca l_{grw}$ = $PECloca l_{agr.soil,\ porewater}$ = ($PECloca l_{agr.soil}$ x $RHO_{soil}$) / ($K_{soil-water}$ x 1000)**

| INPUTS | | Value | Unit |
|---|---|---|---|
| Predicted environmental conc. in soil | $PECloca l_{agr.soil}$ | 9,97729E-07 | $mg.kg^{-1}$ |
| Soil-water partitioning coefficient | $K_{soil-water}$ | 7,1 | $m^3.m^{-3}$ |
| Bulk density of wet soil | $RHO_{soil}$ | 1700 | $kg.m^{-3}$ |

| | | | |
|---|---|---|---|
| **$PECloca l_{grw,skin}$ =** | **$PECloca l_{agr.soil,\ porewater,skin}$** | 2,38893E-07 | $mg.L^{-1}$ |

PEC calculations details for scenario 3:

STP

**$EFFLUENT_{STP}$ = $CAPACITY_{STP}$ x $WASTEW_{inhab}$** **(34)**

| | | | |
|---|---|---|---|
| Capacity of STP | 10000 | eq | D |
| Sewage flow per inhabitant | 200 | $l.d^{-1}.eq^{-1}$ | D |

**$PEC_{STP}$ = $Cloca l_{inf}$ (Intermittent release) = $Eloca l_{water}$ x $10^6$ / $EFFLUENT_{STP}$** **(32)**

| INPUTS | | Value | Unit | Origin |
|---|---|---|---|---|
| Local emission rate to wastewater | $Eloca l_{water}$ | 1,62E-03 | $kg.d^{-1}$ | D |
| Effluent discharge rate of STP (34) | $EFFLUENT_{STP}$ | 2000000 | $l.d^{-1}$ | eq. (34) |

| | | | | |
|---|---|---|---|---|
| **$PEC_{STP}$=** | **$Cloca l_{inf}$** | 8,10E-04 | $mg.L^{-1}$ | O |

**$PEC_{STP}$ = $Cloca l_{eff}$ (Continuous release) = $Cloca l_{inf}$ x $Fstp_{water}$** **(33)**

| INPUTS | | Value | Unit | Origin |
|---|---|---|---|---|
| Concentration in untreated wastewater | $Cloca l_{inf}$ | 0,00081 | $mg.L^{-1}$ | eq. (32) |
| Fraction of emission directed to water by STP | $Fstp_{water}$ | 0,972 | - | EUSES |

| | | | |
|---|---|---|---|
| **$Cloca l_{eff}$** | 7,87E-04 | $mg.L^{-1}$ | O |

Surface water

$$K_{p,susp} = Foc_{susp} \times K_{oc} \quad \textbf{(23)}$$

| | | | | |
|---|---|---|---|---|
| Weight fraction organic carbon in suspended solid | **$Foc_{susp}$** | 0,1 | $kg.kg^{-1}$ | Table 5 ECHA |
| Part.coef. Carbon-water | **$K_{oc}$** | 230 | $l.kg^{-1}$ | S |
| solids-water partitioning coefficient of suspended matter | **$K_{p,susp}$** | 23 | $l.kg^{-1}$ | O |

**$PEClocal_{water} = Clocal_{water} = Clocal_{eff} / [(1 + kp_{susp} \times SUSP_{water} \times 10^{-6}) \times DILUTION]$** **(45)**

| **INPUTS** | | **Value** | **Unit** | **Origin** |
|---|---|---|---|---|
| Concentration of the substance in the STP effluent | $Clocal_{eff}$ | 7,87E-04 | $mg.L^{-1}$ | eq. (33) |
| solids-water partitioning coefficient of suspended matter | $K_{p,susp}$ | 23 | $l.kg^{-1}$ | eq. (23) |
| Concentration of suspended matter in the river | SUSPwater | 15 | $mg.L^{-1}$ | D |
| Dilution factor | DILUTION | 10 | - | D |

| | | | | |
|---|---|---|---|---|
| **$PEClocal_{water}$=** | **$Clocal_{water}$** | 7,87E-05 | $mg.L^{-1}$ | O |

Sediment

Ksusp-water = Fwatersusp + [Fsolidsusp x (Kpsusp / 1000) x RHOsolid] **(24)**

| | | | | |
|---|---|---|---|---|
| Volume Fraction water in susp.matter | **$Fwater_{susp}$** | 0,9 | $m^3.m^{-3}$ | Table 5 ECHA |
| Volume Fraction solids in susp.matter | **$Fsolid_{susp}$** | 0,1 | $m^3.m^{-3}$ | Table 5 ECHA |
| solids-water part. Coef. of susp | **$Kp_{susp}$** | 23 | $l.kg^{-1}$ | eq. (23) |
| Density of the solid phase | **RHOsolid** | 2500 | $kg.m^{-3}$ | Table 5 ECHA |
| Suspended matter-water partitioning coefficient | **$K_{susp-water}$** | 6,65 | $m^3.m^{-3}$ | eq. (24) |

**$PEClocal_{sed} = (K_{susp-water} / RHO_{susp}) \times PEClocal_{water} \times 1000$** **(50)**

| **INPUTS** | **Value** | **Unit** | **Origin** |
|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Concentration in surface water during emission episode | **$PECloca l_{water,skin}$** | 7,87E-05 | $mg.L^{-1}$ | eq. (45) |
| Suspended matter-water partitioning coefficient | **$K_{susp-water}$** | 6,65 | $m^3.m^{-3}$ | eq. (24) |
| Bulk density of suspended matter | **$RHO_{susp}$** | 1150 | $kg.m^{-3}$ | eq. (18) |

| | | | |
|---|---|---|---|
| **$PECloca l_{sed}$=** | 4,55E-04 | $mg.kg^{-1}$ | O |

Terrestrial compartment

**Agric. Soil:** **$PECloca l_{agr.soil} = Cloca l_{agr.soil} = (1/kT) \times C_{agr.soil\ 10}(0) \times (1 - e^{-kT})$** **(66)(55)**

| **INPUTS** | | **Value** | **Unit** | **Origin** |
|---|---|---|---|---|
| Averaging time | T | 180 | d | Table 11 |
| First order rate constant for removal from top soil | k | 0,0054 | $d^{-1}$ | eq. (56) |
| Initial concentration after 10 years | $C_{agr.soil\ 10}(0)$ | 0,00010 | $mg.kg^{-1}$ | eq. (63) |
| | | | | |

| | | | | |
|---|---|---|---|---|
| **$PECloca l_{agr.soil}$=** | **$Cloca l_{agr.soil}$** | 6,89E-05 | $mg.kg^{-1}$ | O |

Ground water

**$PECloca l_{grw} = PECloca l_{agr.soil,\ porewater} = (PECloca l_{agr.soil} \times RHO_{soil}) / (K_{soil-water} \times 1000)$** **(68)(67)**

| **INPUTS** | | **Value** | **Unit** | **Origin** |
|---|---|---|---|---|
| Predicted environmental conc. in soil | $PECloca l_{agr.soil}$ | 6,89E-05 | $mg.kg^{-1}$ | eq. (66)(55) |
| | | | | |
| Soil-water partitioning coefficient | $K_{soil-water}$ | 7,1 | $m^3.m^{-3}$ | eq. (24) |
| Bulk density of wet soil | $RHO_{soil}$ | 1700 | $kg.m^{-3}$ | eq. (18) |

| | | | | |
|---|---|---|---|---|
| **$PECloca l_{grw}$ =** | **$PECloca l_{agr.soil,\ porewater,skin}$** | 1,650E-05 | $mg.L^{-1}$ | O |

PEC calculations details for scenario 4:

STP

**$EFFLUENT_{STP} = CAPACITY_{STP} \times WASTEW_{inhab}$** **(34)**

| | | | |
|---|---|---|---|
| Capacity of STP | 10000 | eq | D |
| Sewage flow per inhabitant | 200 | $l.d^{-1}.eq^{-1}$ | D |

**$PEC_{STP}$ = $Clocal_{inf}$ (Intermittent release) = $Elocal_{water}$ x $10^6$ / $EFFLUENT_{STP}$** **(32)**

| INPUTS | | Value | Unit | Origin |
|---|---|---|---|---|
| Local emission rate to wastewater | $Elocal_{water}$ | 3,54E-03 | $kg.d^{-1}$ | D |
| Effluent discharge rate of STP (34) | $EFFLUENT_{STP}$ | 2000000 | $l.d^{-1}$ | eq. (34) |
| **$PEC_{STP}$=** | **$Clocal_{inf}$** | 1,77E-03 | $mg.L^{-1}$ | O |

**$PEC_{STP}$ = $Clocal_{eff}$ (Continuous release) = $Clocal_{inf}$ x $Fstp_{water}$** **(33)**

| INPUTS | | Value | Unit | Origin |
|---|---|---|---|---|
| Concentration in untreated wastewater | $Clocal_{inf}$ | 0,00177 | $mg.L^{-1}$ | eq. (32) |
| Fraction of emission directed to water by STP | $Fstp_{water}$ | 0,972 | - | EUSES |
| **$Clocal_{eff}$** | | 1,72E-03 | $mg.L^{-1}$ | O |

Surface water

**$K_{p,susp}$ = $Foc_{susp}$ x $K_{oc}$** **(23)**

| | | | | |
|---|---|---|---|---|
| Weight fraction organic carbon in suspended solid | **$Foc_{susp}$** | 0,1 | $kg.kg^{-1}$ | Table 5 ECHA |
| Part.coef. Carbon-water | **$K_{oc}$** | 230 | $l.kg^{-1}$ | S |
| solids-water partitioning coefficient of suspended matter | **$K_{p,susp}$** | 23 | $l.kg^{-1}$ | O |

**$PEClocal_{water}$ = $Clocal_{water}$ = $Clocal_{eff}$ / [(1 + $kp_{susp}$ x $SUSP_{water}$ x $10^{-6}$) x DILUTION]** **(45)**

| INPUTS | | Value | Unit | Origin |
|---|---|---|---|---|
| Concentration of the substance in the STP effluent | $Clocal_{eff}$ | 1,72E-03 | $mg.L^{-1}$ | eq. (33) |
| solids-water partitioning coefficient of suspended matter | $K_{p,susp}$ | 23 | $l.kg^{-1}$ | eq. (23) |
| Concentration of suspended matter in the river | SUSPwater | 15 | $mg.L^{-1}$ | D |
| Dilution factor | DILUTION | 10 | - | D |

| | | | | |
|---|---|---|---|---|
| **$PECloca l_{water}$=** | **$Cloca l_{water}$** | 1,72E-04 | $mg.L^{-1}$ | O |

Sediment

Ksusp-water = Fwatersusp + [Fsolidsusp x (Kpsusp / 1000) x RHOsolid] **(24)**

| | | | | |
|---|---|---|---|---|
| Volume Fraction water in susp.matter | **$Fwater_{susp}$** | 0,9 | $m^3.m^{-3}$ | Table 5 ECHA |
| Volume Fraction solids in susp.matter | **$Fsolid_{susp}$** | 0,1 | $m^3.m^{-3}$ | Table 5 ECHA |
| solids-water part. Coef. of susp | **$Kp_{susp}$** | 23 | $l.kg^{-1}$ | eq. (23) |
| Density of the solid phase | **RHOsolid** | 2500 | $kg.m^{-3}$ | Table 5 ECHA |
| Suspended matter-water partitioning coefficient | **$K_{susp\text{-}water}$** | 6,65 | $m^3.m^{-3}$ | eq. (24) |

**$PECloca l_{sed} = (K_{susp\text{-}water} / RHO_{susp}) \times PECloca l_{water} \times 1000$** **(50)**

| **INPUTS** | | **Value** | **Unit** | **Origin** |
|---|---|---|---|---|
| Concentration in surface water during emission episode | **$PECloca l_{water,\ skin}$** | 0,00017 | $mg.L^{-1}$ | eq. (45) |
| Suspended matter-water partitioning coefficient | **$K_{susp\text{-}water}$** | 6,65 | $m^3.m^{-3}$ | eq. (24) |
| Bulk density of suspended matter | **$RHO_{susp}$** | 1150 | $kg.m^{-3}$ | eq. (18) |

| | | | |
|---|---|---|---|
| **$PECloca l_{sed}$=** | 9,95E-04 | $mg.kg^{-1}$ | O |

Terrestrial compartment

**$PECloca l_{agr.soil} = Cloca l_{agr.soil} = (1/kT) \times C_{agr.soil\ 10}(0) \times (1 - e^{-kT})$** **(66)(55)**

| **INPUTS** | | **Value** | **Unit** | **Origin** |
|---|---|---|---|---|
| Averaging time | T | 180 | d | Table 11 |
| First order rate constant for removal from top soil | k | 0,0054 | $d^{-1}$ | eq. (56) |
| Initial concentration after 10 years | $C_{agr.soil\ 10}(0)$ | 0,00023 | $mg.kg^{-1}$ | eq. (63) |
| | | | | |

| | | | | |
|---|---|---|---|---|
| **$PECloca l_{agr.soil}$=** | **$Cloca l_{agr.soil}$** | 0,00015 | $mg.kg^{-1}$ | O |

Ground water

**$PECloca l_{grw} = PECloca l_{agr.soil,\ porewater} = (PECloca l_{agr.soil} \times RHO_{soil}) / (K_{soil\text{-}water} \times 1000)$** **(68)(67)**

| **INPUTS** | | **Value** | **Unit** | **Origin** |
|---|---|---|---|---|
| Predicted environmental conc. in soil | $PECloca l_{agr.soil}$ | 0,000150628 | $mg.kg^{-1}$ | eq. (66)(55) |
| | | | | |
| Soil-water partitioning coefficient | $K_{soil\text{-}water}$ | 7,1 | $m^3.m^{-3}$ | eq. (24) |
| Bulk density of wet soil | $RHO_{soil}$ | 1700 | $kg.m^{-3}$ | eq. (18) |

| | | | | |
|---|---|---|---|---|
| **$PECloca l_{grw}$ =** | **$PECloca l_{agr.soil}$ , porewater,skin** | 3,60658E-05 | $mg.L^{-1}$ | O |

## 3.4 New information on the active substance

No applicable.

## 3.5 Residue behaviour

Not relevant. MAGNUM GEL CUCARACHAS is not intended to be used in livestock facilities or in conditions that may lead to contamination of food/feestuff

## 3.6 Summaries of the efficacy studies (B.5.10.1-4)

Summaries of efficacy studies are provided in tabular form in 2.2.5.5.

## 3.7 Addendum (November 2019)

Data for storage stability of 4 years has been submitted to change the currently authorised shelf life of 2 years to 4 years. In addition, the applicant has provided an efficacy trial with bait aged to 4 years.

After the evaluation of both tests, the request is accepted and the relevant documents have been modified. Data are acceptable and therefore a shelf life of 4 years can be granted.

This information will be updated in section 5.5. of the SPC with the sentence:

The storage satability if this product in its original packaging is 4 years under normal storage conditions.

The following added information will be taken into account in each of its corresponding sections.

2.2.2. Physiscal, chemical and technical properties:

| | | | |
|---|---|---|---|
| 4 Years storage stability (ambient temperature) | | [redacted] Batch: 110310 | The formulation is stable for 4 years stored at ambient temperature. |
| Active Ingredient Content | HPLC | | Initially: **2.020± 0,092 % w/w (not justified)** After 4 years at ambient temperature: **1.932±0.215% w/w** **Difference: -4,4%** |
| Homogeneity of application | PA-U10- METAPPLGEL | | Amount of product deposited in form of spots of 5 mm diameter (n = 9) **47.1 mg**<br>Amount of product deposited in form of spots of 5 mm diameter (n = 9) **49.3 mg** **No significant difference** |
| Appearance and stability of the package | PA-U10- METDESCR (visual method) | | Physical state : gel Colour : brown **Odour : practically odourless**<br>Physical state : gel Colour : dark brown Odour : practically odourless **No modification of appearance except a small modification of colour.** |
| pH of the test item | CIPAC MT 75.3<br>CIPAC MT 192 (equivalent to | | nitially: **5.73** After 4 years at ambient temperature: **4.95** |

| | | | |
|---|---|---|---|
| | OECD 114) | | |
| Viscosity of liquid by rotational viscometry Temperature : 20°C ± 0.5°C | CIPAC MT 192 (equivalent to OECD 114) | | Initially:<br>**No Newtonian flow behaviour 372398 mPa.s to 55112 mPa.s** Dependent on the shear rate applied to the sample [0.977 – 19.76 s1 ]<br><br>After 4 years at ambient temperature:<br>**No Newtonian flow behaviour 292815 mPa.s to 41170 mPa.s** Dependent on the shear rate applied to the sample [0.977 – 10.32 s1 ] |
| Temperature : 40°C ± 0.5°C | | | Initially:<br>**139118 mPa.s to 27715 mPa.s** Dependent on the shear rate applied to the sample [0.977 – 10.32 s1 ]<br>After 4 years at ambient temperature:<br>**148230 mPa.s to 28175 mPa.s** Dependent on the shear rate applied to the sample [0.977 – 10.32 s1 ] |
| Appearance and stability of the package | PA-U10-METDESCR (visual method) | | Initially:<br>**Outside aspect**: plastic cartridge (for gun applicator) supplied with applicator tip. Capacity: 30 g Colour: transparent white closing: with a white plastic screw end-piece intact cartridge no observable sign of test item contamination on the outer surface. no leak during shaking or turning before and after opening. no |

| | | | |
|---|---|---|---|
| | | | noticeable odour before opening. **Inside aspect**: no deformation and no observable alteration of package material by the test item.<br><br><u>After 4 years at ambient temperature:</u><br>**Outside aspect:** plastic cartridge (for gun applicator) supplied with applicator tip. Capacity: 30 g Colour: transparent white closing: with a white plastic screw end-piece intact cartridge no observable sign of test item contamination on the outer surface. no leak during shaking or turning before and after opening. no noticeable odour before opening.<br><br>**Inside aspect:** no deformation and no observable alteration of package material by the test item.<br><br>**No modification of appearance or significant pack weight change** |

| **Conclusion on the physical, chemical and technical properties of the product** |
|---|
| At the time of first authoristation the long term stability study was still on-going, only interim results until 3 years stability were available. Data for storage stability of 4 years has been submitted to change the currently authorised shelf life of 2 years to 4 years. Data are acceptable and therefore a shelf life of 4 years can be granted. |

2.2.5.5. Efficacy data:

DROPS:

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Function** | **Test** | **Field of** | **Test organisms** | **Test method** | **Test system /** | **Test** | **Reference** |

| | **substance** | **use envisaged** | | | **concentrations applied / exposure time** | **results: effects** | |
|---|---|---|---|---|---|---|---|
| *Insecticide* | [redacted] | *Laboratory* | *Blatta orientalis* | *Laboratory bioassay with aged bait.(4 years)*<br>*Mortality and palatability.*<br>*According to TNsG 18-19* | *Choice test arena. 2 replicates and control.*<br>*High and low dose.* | *Dose: 0.16 mg/m²*<br>*Dose: 0.24 mg/m²*<br>*Palatable bait.*<br>*Mean acumulative mortality: >95% in 14 days.*<br>*Control: 5.83%* | [redacted]<br>III-B.5.10.5 (a) |
| | | | *Blattella germanica* | | | *Dose: 0.12 mg/m²*<br>*Dose: 0.16 mg/m²*<br>*Palatable bait.*<br>*Mean acumulative mortality: >95% in 14 days.*<br>*Control: 3.75%* | |
| | | | *Periplaneta Americana.* | | | *Dose: 0.16 mg/m²*<br>*Dose: 0.24 mg/m²*<br>*Palatable bait.*<br>*Mean acumulative mortality: >95% in 14 days.*<br>*Control: 2.5%* | |
| | [redacted] | *Laboratory* | *Blatta orientalis* | *Laboratory bioassay with aged bait.(4 years)*<br>*Mortality and palatability.*<br>*According to TNsG 18-19* | *Choice test arena. 2 replicates and control.*<br>*Low dose.* | *Dose: 0.16 mg/m²*<br>*Palatable bait.*<br>*Mean acumulative mortality: >95% in 14 days.*<br>*Control: 4.17%* | [redacted]<br>III-B.5.10.5 Amendment of the study |
| | | | *Blattella germanica* | | | *Dose: 0.12mg/m²*<br>*Palatable bait.*<br>*Mean acumulative mortality: >95% in 10 days.* | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | *Blatta orientalis* | | | *Control: 2.50%*<br>*Dose: 0.16mg/m²*<br>*Palatable bait.*<br>*Mean acumulative mortality: >95% in 14 days.*<br>*Control: 1.67%* | |

**Conclusion on the efficacy of the product**

The applicant has submitted a laboratory test and subsequently incorporated a modification of the study itself. We consider this amendment to be, in fact, another test. Both are carried out under the same protocol. The difference between them it is that the fisrt part is done with a replice with high dose, and the other replice with low dose, according to the claim. The second essay is done only with low doses.

Althought we do not think that two replice per essay is very appropiated, we consider that the contribution of both, aleborated with the same protocol, gives reliability to the data where it is clearly demostrated that the product is still deadly and palatable with 4 year-old-bait, therefore we accept the trials.

Annexes:
3.1 List of studies for the biocidal product.

See confidential PAR

## 3.8 Confidential annex

See confidential PAR