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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

MAGNUM GEL HORMIGAS PLUS

Product type 18

IMIDACLOPRID

Case Number in R4BP:·BC-BU010803-35

Evaluating Competent Authority: SPAIN

December 2019

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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-BU010803-35	June 2013	Initial assessment
NA-APP	ES	ES-0009293-0000	August 2017	First authorisation
NA-APP	ES	ES-0009293-0000	May 2019	Amendment
NA-AAT	ES	BC-BF055975-39	December 2019	Amendment

1 CONCLUSION

The assessment presented in this report has shown that the ready-to-use product, MAGNUM GEL HORMIGAS PLUS, with the active substance imidacloprid, at a level of 0.01% w/w, may be authorised for use as a insecticide (product-type 18) against ants.

MAGNUM GEL HORMIGAS PLUS is an insecticide product against garden ants (*Lasius niger*) and tropical ants (*Linephitema humile and Monomorium pharonis*). It is to be used indoors and outdoors by trained professional, professional and general public (non-professional). It is a ready to used bait to be applied as gel drop/lines or as bait stations.

The biocidal product MAGNUM GEL HORMIGAS PLUS contains 0.01 %w/w imidacloprid and given the nature of the formulation it is not considered explosive, oxidizing, highly flammable or auto-flammable. Therefore, there not be hazards associated with the physico-chemical properties of the product under normal conditions of use.

There are not substances of concern in the biocidal product but there are some substances different to the active substance that do not contribute to the product hazard classification with regard to physical chemical properties according to hazardous (Regulation (EC) No 1272/2008).

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.

The product was shown to be efficacious against the intended target organisms (garden ants and tropical ants) in the proposed area for use (indoors and outdoors in residential areas and commercial buildings). Please find more information on efficacy of the product in chapter 2.2.5.

No efficacy trials have been provided with aged bait. According to the e-consultation on 13 october 2016 with regard to the shelf-life and palatability tests provided, the authorization will **be conditioned to submit a laboratory choice test with 3 years aged bait**.

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

MAGNUM GEL HORMIGAS PLUS is a ready-to-use product to be applied indoor and outdoor as gel drops/lines or as trap. Human Exposure takes place via dermal contamination through hands taking into account the quantities that could potentially enter into contact with operator’s or consumer’s hands during opening, sealing and disposal of the cartridge or syringe. No exposure to the product is expected by either trained-professionals, professionals or the general public during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63). Indirect exposure is expected for toddlers via dermal and hand to mouth contact after application of the product.

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

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

Dietary exposure as result of use (*i.e.*, food contamination and livestock exposure) can be excluded. The product is formulated as a gel and applied directly on localized spots so surface contamination, e.g., due to splashes, is unlikely. Likewise no dietary exposure is expected when using the gel in bait stations. In addition the label must include restrictions and instructions of use to avoid food contamination and exposure of animals (livestock and companion animals).

Risk assessment for the environment

The risk assement of this product has been based on the active substance Imidacloprid as the substances of concern regarding the enviroment are not contained in the product in such quantity as to lead to classification.

The intended uses proposed for this product cause any unacceptable risk for the environment.

Comparative assessment

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

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

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 HORMIGAS PLUS	Spain.

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	MYLVA, S.A.
	Address	Via Augusta, 48 08006 Barcelona (España) Telefono: +34 934153226 Fax: +34 934156344 E-mail: mylva@mylva.eu
Authorisation number	ES/NA-APP-2017-18-00448	
Date of the authorisation		
Expiry date of the authorisation	5 years since the date of the authorisation	

2.1.1.3 Manufacturer of the product.

Name of manufacturer	MYLVA, S.A.
Address of manufacturer	Via Augusta, 48 08006 Barcelona (España) Telefono: +34 934153226 Fax: +34 934156344 E-mail: mylva@mylva.eu
Location of manufacturing sites	C/ Sant Galderic, 23 Polígono Industrial Ponent Sant Pol de Mar 08395- Barcelona (España)

2.1.1.4 Manufacturer of the active substance.

Active substance	Imidacloprid
Name of manufacturer	Bayer CropScience AG
Address of manufacturer	Industiral Operations Alfred Nobel-Strasse 50 D-40789 Monheim am Rhein (Germany)

Location of manufacturing sites	Alte Heerstr. D-41538 Dormagen (Germany)

2.1.2 Product composition and formulation

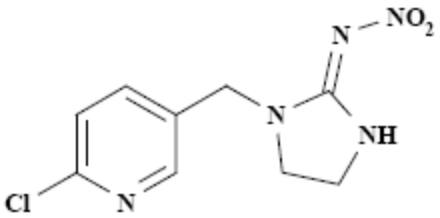
The biocidal product contains 0.01 % w/w of the active substance Imidacloprid. The composition of the biocidal product and the identity of its ingredients are confidential. This information is provided in the confidential part of this document.

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 ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
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	97% w/w
Structural formula	

2.1.2.2 Candidate(s) for substitution

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

Biocidal product MAGNUM GEL HORMIGAS PLUS contains an active substance, imidacloprid, which meets the criteria for substitution under Article 10 of the Biocidal Products Regulation (EU) No 528/2012. Imidacloprid is considered to be very persistent (vP) and toxic (T) but not bioaccumulative (B) and consequently meets two of the criteria for being PBT. Therefore, in line with Article 23 (1) of the Biocides Regulation the Spanish

CA has conducted a comparative assessment for the product MAGNUM GEL HORMIGAS PLUS according to the "Technical Guidance Note on comparative assessment of biocidal products" as agreed upon by the member states on the 55th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 (document: CA-May15-Doc.4.3.a - Final - TNG on comparative assessment.doc). MAGNUM GEL HORMIGAS PLUS is an indoor/outdoor gel insecticide to be applied via droplets by using a cartridge/syringe or bait stations. It has an effective control against populations of pharaoh ants (*Monomorium pharaonis*), argentine ants (*Linepithema humile*), and black ants (*Lasius niger*). 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 10th of January 2017 of the biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012. In Spain 26 products PT18 have been authorised. These products are based in four active substances but only four of these active substances are use for the control of ants: Indoxacarb, spinosad, fipronil and deltamethrin. The biocidal product containing indoxacar is for professional users so, this product is not considered as eligible alternative BP and therefore is not included in the comparative assessment. Neither of the BPs mentioned above control all the species of ants controlled by MAGNUM GEL HORMIGAS PLUS. On the other hand, no eligible non-chemical alternatives were identified in 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 use by non professionals; outdoor use by professionals). 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 ants for indoor use by different users. Therefore, the comparative assessment is finalised at the screening phase. The product MAGNUM GEL HORMIGAS PLUS is authorised for a period not exceeding 5 years in accordance with Article 23 (6).

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product.

Common name	IUPAC name	Function	CAS number	EC number	Content (w/w%)
Imidacloprid	(2E)-1-[(6-chloropyridin-3-yl) methyl]-N-nitroimidazolidin-2-imine	Active substance	138261-41-3	428-040-8	0.01

Non active substances	See Annexes, 3.6 Confidential Annex

2.1.2.4 Information on technical equivalence

The manufacturer of the active substance and the manufacturing site of the active substance used in the biocidal product are identical to the manufacturer of the active substance and the production site of the active substance approved according to BPR. Therefore no check for equivalence is necessary.

2.1.2.5 Information on the substances of concern

Please see the confidential annex for further details.

The biocidal product contains one 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.

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

2.1.2.6 Type of formulation

Gel bait (Ready to use) (RB)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Chronic 2
Hazard statement	H411 Toxic to aquatic life with long lasting effects
Labelling	
Hazard pictograms	 GHS09
Signal words	-----
Hazard statements	H411 Toxic to aquatic life with long lasting effects.

Precautionary statements	P102 Keep out of reach of children. P103 Read label before use. P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of contents/containers in accordance with local regulations.

2.1.4 Authorised uses

2.1.4.1 Use description. Table 1.

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

Product Type	PT 18
Where relevant, an exact description of the authorised use	Insecticide.
Target organism (including development stage)	The insecticide against following target insects (adults): - Pharaoh ants (*Monomorium pharaonis*), - Argentine ants (*Linepithema humile*), - Black ants (*Lasius niger*).
Field of use	Indoors. Residential, industrial, public and commercial or institutionals buildings. Outdoors. Around buildings, terraces and private gardens.
Application methods	Open application of a gel bait from a syringe/cartridge. Apply MAGNUM GEL HORMIGAS PLUS by drops or lines (elongated drops) where ants are present such as near ant trails or near their nests
Application rates and frequency	Dose: 0.2g/m^2 (1 drop = 1 line of 3 cm length = 0.2 g of gel bait) Frequency of application: After seven days, inspect the application points and re-applied if the bait has been consumed. Frequency of treatment: Three months after the infestation's end, treatment may be repeated.
Categories of users	Trained professional user Professional user General Public (non-professional user)
Pack sizes and packaging material	LDPE cartridge of 15, 20, 25, 30, 35, 40 and 50g of gel bait LDPE syringe of 1, 2, 3,4,5,6,7,8,9 and 10g of gel bait.

2.1.4.1.1 Use-specific instructions for use

It is recommended to wash the hands before using the bait, to avoid contamination with offensive odors such as tobacco, etc...
No spraying or misting chemicals near the areas where MAGNUM GEL HORMIGAS PLUS is applied, they can contaminate and make inappetent for ants.
Do not use on woods or porous surfaces. Apply the product in a non-porous support in case of not finding an adecuate place. e.g. plastic sheet.
Apply MAGNUM GEL HORMIGAS PLUS, as drops or lines near ant trails, in areas where ants are present such as in cracks and crevices of areas where their presence is detected.
Inspect frequently the point of applications.
Outdoors, when the ambient conditions affect the product, (rain, strongly sun exposure, dirtiness…) should be re-applied.
The product has shown an efficacy more than 90% mortality within 15 days.

2.1.4.1.2 Use-specific risk mitigation measures

Avoid contact with eyes and skin.
Avoid contact of children or animals with the treated surface.
Apply on areas not subject to frequent cleaning.

2.1.4.1.3 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 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

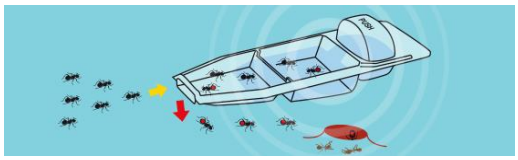
2.1.4.2 Use description. Table 2.

Table 2. Use 2–Insecticide. Gel bait applied as traps (bait station)-indoors/outdoors - Trained professional, professional and general public (non-professional).

Product Type	PT 18
Where relevant, an exact description of the authorised use	Insecticide.
Target organism (including development stage)	The insecticide is for the control of the following target insects (adults): - Argentine ants (*Linepithema humile*) -
Field of use	Indoors. Residential, industrial, public and commercial or institutionals buildings. Outdoors. Around buildings, terraces and private gardens.
Application method	Ready-to-use bait stations.
Application rates and frequency	Dose: 0.4 - 0.9 g/m^2, depending on the infestation level, divided in several bait stations for better efficacy. For example, place 2 to 4 stations with 5 grams of bait per 22 m^2 Frequency of application: After seven days, inspect the application points and place a new bait station if the bait has been consumed and the infestation is not controlled yet. Frequency of treatment: Three months after the infestation's end, treatment may be repeated.
Categories of users	Trained professional users Professional users General public (non-professional users)
Pack sizes and packaging material	Plastic traps of 1, 2, 3, 4, 5 and 6grams of gel bait

2.1.4.2.1 Use-specific instruction for use.

Gel bait in transparent traps (bait stations).



Open the trap: cut the end of the trap on the precut line where they will spend the ants.

Activate the trap:completely push the capsule until the gel has been deposited in the central compartment.

When used outdoors, places exposed to direct sunlight or rainfall should be avoided.

2.1.4.2.2 Use-specific risk mitigation measures.

The stations should not be handled after opening. Never introduce the fingers through the holes in the bait station. Remove bait stations at the end of the treatment (after 1 to 3 months).

2.1.4.2.3 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 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

MAGNUM GEL HORMIGAS PLUS is an insecticide formulated as gel bait against tropical ants and garden ants (*Monomorium pharaonis*, *Linepithema humile* and *Lasius niger*) to be used indoors and outdoors private and commercial buildings. It may be applied by using cartridges/syringes to control the three ants' species. It may also be applied by placing bait stations to control *Linepithema humile*.. After extensive inspection to determine the infestation level (low or high), place the bait points where ants are detected. Always read the label or leaflet before use and respect all the instructions provided. Remove alternative food source that may be in competition from near areas. Apply MAGNUM GEL HORMIGAS PLUS in areas where ants are present such as within their nests, near ant trails, or in cracks and crevices of areas where their presence is detected. Outdoors use (terraces, patios, backyards or gardens), apply MAGNUM GEL HORMIGAS PLUS places where it is more likely to find ants: eaves, cornices, where wires and pipes enter the structure of the building…

2.1.5.2 Risk mitigation measures

Do not apply the product (gel and bait station) in areas recently treated with another insecticide.

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 only until the pest is controlled.

Use products at recommended doses and intervals.

Follow the instructions to avoid risks to the environment.When used around buildings, do not apply near drains. If the treated zone is connected to rainwater collection or sewer, use only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.

Product must be securely applied to minimize the risk of consumption by 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).

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Trained professional use:

-The product cannot 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.

General public (non-professional)/ professional use:

-Do not apply on surfaces or utensils that can be in contact with feed/foodstuff

2.1.5.3 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:
Environmental Precautions: Avoid contamination of drains, surface and groundwater as well as soil.
Methods for cleaning up: Recover the product from the affected area witha wet disposable tisuue and dispose of with domestic waste. . In case of spillage on water, avoid spreading by using appropriate barrier devices. The recovered product must be disposed according with local law. Contact with the competent authorities if the situation cannot be controlled.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents/containers in accordance with local regulations (P501).
Dispose unused product, its packaging and all other waste (i.e. dead insects) in accordance with local regulations.
At the end of the treatment campaing, collect bait boxes for disposal.

2.1.5.5 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 3 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.

2.1.6 Other information

Definitions:

Trained professional: pest control operators, having received specific training in insecticide 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.

For tranied profesional only:
The users should inform if the treatment is ineffective and report straightforward to the resgistration holder any alarming signals wich could be assumed to be resistance development.

2.1.7 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, 10 gr	LDPE	Plastic	General public Professional Trained professional	Yes
Cartridge	15, 20, 25, 30, 35, 40, 50 g	LDPE	Plastic	General public Professional Trained professional	Yes
Bait station	1, 2, 3, 4, 5 y 6 gr	PET/PE	Plastic	General public Professional Trained professional.	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

See the confidential annex.

2.1.8.2 Access to documentation

The applicant has submitted the following letters of access:

- -a letter of access from Bayer Environmental Science (notifier and having on all the data included in the dossier for Imidacloprid presented by Bayer Environmental Science) to all the documents about the active substance associated to the Annex I listing.

[redacted]

[redacted]

[redacted]

2.2 Assessment of the biocidal product.

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

Table 1. Use 1 – Insecticide. Gel bait in a cartridge/syringe/bait station. Trained-Professional users

Product Type(s)	PT 18
Where relevant, an exact description of the authorised use	Insecticide to control ants
Target organism (including development stage)	The insecticide is for controlling the following target insects (adults, larvae): Pharaoh ants (*Monomorium pharaonis*), Argentine ants (*Linepithema humile*), Black ants (*Lasius niger*).
Field of use	Residential and commercial buildings. Indoors/outdoors.
Application method(s)	Cartridge: to be applied as drops or lines (elongated drops) Syringe: to be applied as drops or lines(elongated drops) Bait station: to be applied by placing bait stations.
Application rate(s) and frequency	Cartridge: apply 1 to 3 drops or lines per square meter (equivalent of 0.2-0.6 g/ m^2). (1 drop = 1 line of 3 cm length = 0.2 g of gel bait) Syringe: apply 1 to 3 drops or lines of 3 cm length per square meter (equivalent to 0.2-0.6 g/ m^2). Bait station: place 2 to 4 bait stations per room (for a station with 5g of gel and a standard room of 22 m^2, dose is equivalent to 0.4-0.9 g/m^2) Frequency: Start applying drops/lines at recommended dose. After several days, inspect the application points and if necessary repeat the application at recommended dose to get full control of the swarm.

	Three months after the infestation's end, treatment may be repeated.
Category(ies) of user(s)	Trained-Professional use
Pack sizes and packaging material	Plastic cartridge with 15, 20, 25, 30, 35, 40 and 50g of gel bait. Plastic Syringe with 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10g of gel bait. Plastic bait stations with 1, 2, 3,4, 5 and 6g of gel bait.

Table 2. Use 2 – Insecticide. Gel bait in a cartridge/syringe/bait station. General public (non-professional users)

Product Type	PT 18
Where relevant, an exact description of the authorised use	Insecticide to control ants
Target organism (including development stage)	The insecticide is for controlling the following target insects(adults): Pharaoh ants (*Monomorium pharaonis*) Argentine ants (*Linepithema humile*) Black ants (*Lasius niger*).
Field of use	Residential and commercial buildings. Indoors/outdoors.
Application method(s)	Cartridge: to be applied as drops or lines (elongated drops) Syringe: to be applied as drops or lines (elongated drops) Bait station: to be applied by placing bait stations.
Application rate(s) and frequency	Cartridge: apply 1 to 3 drops or lines per square meter (equivalent of 0.2-0.6 g/ m^2). (1 drop = 1 line of 3 cm length = 0.2 g of gel bait) Syringe: apply 1 to 3 drops or lines of 3 cm length per square meter (equivalent to 0.2-0.6 g/ m^2). Bait station: place 2 to 4 bait stations per room (for a station with 5g of gel and a standard room of 22 m^2, dose is equivalent to 0.4-0.9 g/m^2) Frequency: Start applying drops/lines or placing bait stations at recommended dose. After several days, inspect the application points and if necessary repeat treatment at recommended dose to get full control of the swarm. Three months after the infestation's end, treatment may be repeated.
Category(ies) of users	Professional user

	Non-professional use
Pack sizes and packaging material	Plastic cartridge with 15, 20, 25, 30, 35, 40 and 50g of gel bait. Plastic syringe with 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10g of gel bait. Plastic bait stations with 1, 2, 3, 4, 5 and 6g 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 cartridges		0.01% w/w Imidacloprid Batch E210	Initially: Gel After 14 days at 54°C ± 2°C: Gel After 3 months at 25ºC±2ºC: Gel After 1 year at 25ºC±2ºC: Gel After 2 years at 25ºC±2ºC: Gel After 3 years and 4 months at 25ºC±2ºC: Gel	
Plastic syringes		0.01% w/w Imidacloprid Batch E239	Initially: Gel After 14 days at 54°C ± 2°C: Gel After 3 months at 25ºC±2ºC: Gel After 1 year at 25ºC±2ºC: Gel After 2 years at 25ºC±2ºC: Gel	
Bait station		0.01% w/w Imidacloprid Batch E210	Initially: Gel 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		0.01% w/w Imidacloprid Batch E210	Initially: Colourless After 14 days at 54°C ± 2°C: translucent yellow After 3 months at 25ºC±2ºC: Colourless After 1 year at 25ºC±2ºC: Colourless and translucent yellow After 2 years at 25ºC±2ºC: Colourless and	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
			translucent yellow After 3 years and 4 months at 25ºC±2ºC: translucent yellow	
Plastic syringe		0.01% w/w Imidacloprid Batch E239	Initially: Colourless After 14 days at 54°C ± 2°C: Colourless After 3 months at 25ºC±2ºC: Colourless After 1 year at 25ºC±2ºC: Colourless After 2 years at 25ºC±2ºC: Colourless	
Bait station		0.01% w/w Imidacloprid Batch E210	Initially: transparent After 14 days at 54°C ± 2°C: transparent	[redacted]
Odour at 20 °C and 101.3 kPa	PA-U10-METDESCR (visual method)			[redacted]
Plastic cartridge		0.01% w/w Imidacloprid Batch E210	Initially: Practically odourless After 14 days at 54°C ± 2°C: Practically odourless After 3 months at 25ºC±2ºC: Practically odourless After 1 year at 25ºC±2ºC: Practically odourless After 2 years at 25ºC±2ºC: Practically odourless After 3 years and 4 months at 25ºC±2ºC: Practically odourless	
Plastic syringe		0.01% w/w Imidacloprid Batch E239	Initially: Practically odourless After 14 days at 54°C ± 2°C: Practically odourless After 3 months at 25ºC±2ºC: Practically odourless After 1 year at 25ºC±2ºC: Practically odourless	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
			After 2 years at 25ºC±2ºC: Practically odourless	
Bait station		0.01% w/w Imidacloprid Batch E210	Initially: Practically odourless After 14 days at 54°C ± 2°C: Practically odourless	[redacted]
Acidity/Alkalinity				[redacted]
Plastic cartridge	CIPAC MT 191	0.01% w/w Imidacloprid Batch E210	Not necessary 4<pH<10	
	CIPAC MT 75.3	0.01% w/w Imidacloprid Batch E210	Initially: pH=6.84 at 22ºC After 14 days at 54°C ± 2°C: pH=6.31 at 24ºC After 3 months at 25ºC±2ºC: pH=6.64 at 24ºC After 1 year at 25ºC±2ºC: pH=6.85 at 20ºC After 2 years at 25ºC±2ºC: pH=6.39 at 20ºC (yellow product) pH=5.90 at 21ºC (colourless product) After 3 years and 4 months at 25ºC±2ºC: pH=6.13 at 20ºC	[redacted]
Plastic syringe	Not available	0.01% w/w Imidacloprid Batch E239	Not necessary 4<pH<10	
Bait station	Not available	Batch E239 Not available	Not necessary 4<pH<10	
Relative density/bulk density				[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
Plastic cartridge	CIPAC MT 3.3.2	0.01% w/w Imidacloprid Batch E210	Initially: Density at 20±0.5ºC: 1.3167 g/mL After 14 days at 54°C ± 2°C: Not available After 3 months at 25ºC±2ºC: Not available After 1 year at 25ºC±2ºC: Not available After 2 year at 25ºC±2ºC: Not available	
	Calculation	0.01% w/w Imidacloprid Batch E210	Initially: $D_{4^{\circ}C}^{20^{\circ}C}$ (relative density) = 1.3167 After 14 days at 54°C ± 2°C: Not available After 3 months at 25ºC±2ºC: Not available After 1 year at 25ºC±2ºC: Not available After 2 year at 25ºC±2ºC: Not available	
Plastic syringe	Not available	0.01% w/w Imidacloprid Batch E239	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]
	HPLC method		The formulation is stable under the test conditions.	
Plastic cartridge		0.01% w/w Imidacloprid Batch E210	Initially: **0.0100 ± 0.0006% w/w** **or** **0.100 ± 0.006 g/kg** After 14 days at 54°C ± 2°C:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
			0.0096 ± 0.0001% w/w **or** **0.096 ± 0.001 g/kg** Difference : -4.0%	
Plastic syringe		0.01% w/w Imidacloprid Batch E239	Initially: **0.0098 ± 0.0001% w/w** **or** **0.098 ± 0.001 g/kg** After 14 days at 54°C ± 2°C: **0.0094 ± 0.0000 % w/w** **or** **0.094 ± 0.000 g/kg** Difference : -4.1%	
Bait station	Not available	Not available	Not available	
Homogeneity of application	PA-U10-METAPPLGEL		No significant different	
Plastic cartridge		0.01% w/w Imidacloprid Batch E210	Initially: Amount of product deposited to trace a line of 5 cm (n = 9) **179.9 mg** After 14 days at 54°C ± 2°C: Amount of product deposited to trace a line of 5 cm (n = 9) **178.8 mg**	
Plastic syringe		0.01% w/w	Initially: Amount of product deposited to trace a line	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
		Imidacloprid Batch E239	of 5 cm (n = 9) **172.1 mg** After 14 days at 54°C ± 2°C: Amount of product deposited to trace a line of 5 cm (n = 9) **178.5 mg**	
Bait station	Not available	Not available	Not available	
Appearance and stability of the package	PA-U10-METDESCR (visual method)			
Plastic cartridge		0.01% w/w Imidacloprid Batch E210	Initially: **Outside aspect:** plastic cartridge (for gun applicator) supplier with applicator tip. Capacity: 30 g 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. No noticeable odour before opening. **Inside aspect:** No deformation and no observable alteration of package material by the test item. After 14 days at 54°C ± 2°C: No modification of appearance or significant pack	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
			weight change	
Plastic syringe		0.01% w/w Imidacloprid Batch E239	Initially: **Outside aspect:** plastic syringe with applicator tip and a plastic plunger Capacity: 5 g Closing: with a clap clip to protect the applicator tip Colour: syringe: opaque white, plunger: green; clap clip: yellow intact syringe 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. After 14 days at 54°C ± 2°C: No modification of appearance or significant pack weight change	
Bait station		0.01% w/w Imidacloprid Batch E210	Initially: **Outside aspect:** plastic trap Capacity: 5 g Colour: transparent No observable sign of test item contamination on	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
			the outer surface. No leak during shaking or turning. No noticeable odour before opening. **Inside aspect:** No deformation and no observable alteration of package material by the test item. After 14 days at 54°C ± 2°C: **Outside aspect:** No observable sign of test item contamination on the outer surface. No leak during shaking or turning. No noticeable odour before opening. **Inside aspect:** No deformation and no observable alteration of package material by the test Item. 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	CropLife nº 17		Interim results until 3 years and 4 months:	[redacted]
3 Years storage stability (25ºC)	CropLife nº 17			[redacted]
Active Ingredient Content	HPLC method			
Plastic cartridge		0.01% w/w	After 3 months at 25ºC±2ºC:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
		Imidacloprid Batch E210	**0.0099± 0.0001 % w/w or 0.099±0.001 g/kg** Difference: -1.0% After 1 year at 25ºC±2ºC: **0.0098± 0.0001 % w/w or 0.098±0.001g/kg** Difference: -2.0% After 2 years at 25ºC±2ºC: **0.0096± 0.0001 % w/w or 0.096±0.001g/kg** Difference: -4.0% After 3 years and 4 months at 25ºC±2ºC: **0.0092± 0.0000 % w/w or 0.092±0.000g/kg** Difference: -8.0%	
Plastic syringe		0.01% w/w Imidacloprid Batch E239	After 3 months at 25ºC±2ºC: **0.0099± 0.0000 % w/w or 0.099±0.000 g/kg** Difference: +1.0% After 1 year at 25ºC±2ºC: **0.0098± 0.0000 % w/w or 0.098±0.000g/kg** Difference: 0.0% After 2 years at 25ºC±2ºC: **0.0097± 0.0000 % w/w or 0.097±0.000g/kg** Difference: -1.0% After 3 years and 4 months at 25ºC±2ºC: Not available yet	
Bait station	Not available	Not available	Not available	
Homogeneity of application	PA-U10-METAPPLGEL			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
Plastic cartridge		0.01% w/w Imidacloprid Batch E210	After 3 months at 25ºC±2ºC: Amount of product deposited to trace a line of 5 cm (n=9) **195.1 mg** After 1 year at 25ºC±2ºC: Amount of product deposited in form of spots of 5 mm diameter (n=9) **175.9 mg** After 2 year at 25ºC±2ºC: Amount of product deposited in form of spots of 5 mm diameter (n=9) **178.2 mg** After 3 years and 4 months at 25ºC±2ºC: Not available	
Plastic syringe		0.01% w/w Imidacloprid Batch E239	After 3 months at 25ºC±2ºC: Amount of product deposited to trace a line of 5 cm (n=9) **177.0 mg** After 1 year at 25ºC±2ºC: Amount of product deposited in form of spots of 5 mm diameter (n=9) **161.1 mg** After 2 year at 25ºC±2ºC: Amount of product deposited in form of spots of 5 mm diameter (n=9) **166.1 mg** After 3 years and 4 months at 25ºC±2ºC:	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
			Not available	
Bait station	Not available	Not available	Not available	
Appearance and stability of the package	PAU-U10-METDESCR (visual method)			
Plastic cartridge		0.01% w/w Imidacloprid Batch E210	After 3 months at 25ºC±2ºC: No modification of appearance or significant pack weight change After 1 year at 25ºC±2ºC: No modification of appearance or significant pack weight change After 2 year at 25ºC±2ºC: No modification of appearance or significant pack weight change After 3 years and 4 months at 25ºC±2ºC: No modification of appearance or significant pack weight change	
Plastic syringe		0.01% w/w Imidacloprid Batch E239	After 3 months at 25ºC±2ºC: No modification of appearance or significant pack weight change After 1 year at 25ºC±2ºC: No modification of appearance or significant pack weight change After 2 year at 25ºC±2ºC: No modification of appearance or significant pack weight change	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
			After 3 years and 4 months at 25ºC±2ºC: Not available	
Bait station	Not available	Not available	Not available	
pH	CIPAC MT 75.3	Batch E210	pH= 6,13	
Storage stability test – **low temperature stability test for liquids**	CIPAC Method MT 39.3 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**				
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
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 smoke — smoke generators				
Spraying pattern — aerosols				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
Dehydration	CQ0008.A	0.01% w/w Imidacloprid Batch K945/K888	The product Magnum Gel Ants remains humid and palatable for a 15 day period, even when stored in the most hostile conditions (45ºC and 20-30% relative humidity). The appearance of the applied product at the end of the test is humid and brilliant as well.	[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	PA-U10-METTENS equivalent to EEC A.5 and to OECD Tet Guideline 115			[redacted]
Plastic cartridge		0.01% w/w Imidacloprid Batch E210	At 25ºC± 0.5°C: **53.1 mN/m. The test item is surface active**	
Plastic syringe	Not available	Not available	Not available	
Bait station	Not available	Not available	Not available	
Viscosity	CIPAC MT 192 (equivalent to OECD 114)		No Newtonian flow behaviour. Dependent on the shear rate applied to the sample.	[redacted]
Plastic cartridge		0.01% w/w Imidacloprid	<u>At 20 ± 0.5°C:</u> <u>Initially:</u>	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
		Batch E210	3773 mPa.s to 18075 mPa.s [43.3 – 1.594 s-1] After 14 days at 54°C ± 2°C: 2451 mPa.s to 13406 mPa.s [76.0 – 1.594 s-1] 2979 mPa.s to 13046 mPa.s [43.3 – 1.594 s-1] After 3 months at 25ºC±2ºC: 3069 mPa.s to 16040 mPa.s [57.0 – 1.594 s-1] After 1 year at 25ºC±2ºC: 3253 mPa.s to 17476 mPa.s [57.0 – 1.594 s-1] After 2 years at 25ºC±2ºC: 3189 mPa.s to 16878 mPa.s [57.0 – 1.594 s-1] After 3 years and 4 months at 25ºC±2ºC: Not available yet At 40 ± 0.5°C: Initially: 1202 mPa.s to 9636 mPa.s [100.3 – 1.594 s-1] After 14 days at 54°C ± 2°C: 1033 mPa.s to 7781 mPa.s	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*
			[100.3 – 1.594 s-1] After 3 months at 25ºC±2ºC: 1202 mPa.s to 9576 mPa.s [100.3 – 1.594 s-1] After 1 year at 25ºC±2ºC: 1187 mPa.s to 9636 mPa.s [100.3 – 1.594 s-1] After 2 years at 25ºC±2ºC: 1358 mPa.s to 10773 mPa.s [100.3 – 1.594 s-1] After 3 years and 4 months at 25ºC±2ºC: Not available yet	
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.

Appearance
Colourless 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.

Dehydratation

A laboratory test was performed to determine the dehydration of [redacted] after 15 days of storage at different conditions. When stored in room conditions (25ºC and 40-60% relative humidity) the product lost on average 19.6% of its weight. When stored in an insectarium (23-25ºC and 42-47% relative humidity) the product lost on average 22.4%. When stored in an oven at 45ºC and 20-30% relative humidity, it lost 32.8% of its weight.

Conclusions

Imidacloprid 0.01% Gel is a colourless gel practically odourless. Determination of acidity/alkalinity resulted in a 0.029% as NaOH and a pH of 6.84. The product has a density of 1.32 g/mL and a viscosity of 18075 - 3773 mP a.s at 20ºC. The data submitted in the storage stability study shows a storage stability of 3 years and 4 months.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference*

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	0.01% w/w Imidacloprid	The test was omitted. Imidacloprid 0.01% 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	0.01% w/w Imidacloprid	The test was omitted. Imidacloprid 0.01% Gel is not expected to have oxidizing properties.	
Flash point	Commission Regulation (EC) No 440/2008, Method A9 Commission Regulation (EU) No 545/2011, 2.3 (UNE-EN-ISO 3679)	0.01% w/w Imidacloprid Batch K931	The flash point is > 75ºC but it was not technically possible to determined it because condensation appear and the flame goes out.	[redacted]
Auto-ignition	Commission Regulation (EC) No 440/2008, Method A15 Commission Regulation (EU) No 545/2011, 2.3			
Other indications of flammability			Not 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.

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 justification for non-submission of data is accepted, therefore MAGNUM GEL HORMIGAS PLUS is not considered to be potentially explosive or contain an oxidising or reducing agent. The preparation is not recommended for use with other products.

The technical properties indicate that no particular problems are to be expected when it is handled, stored or applied as recommended.

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	0.0049 – 0.0131 % w/w n = (3 x 2)	3.1 to 22.9 µg/mL r^2 = 1.0000 n = (3 x 2)	Specific	102.0-99.6	100.7	1.16 %	3.1 µg/mL	[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 HORMIGAS PLUS is presented as a ready-to use gel bait insecticide and packaged in a trap, a syringe or a cartridge. It is used by trained professionals, professionals and general public (Non professional).

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

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

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

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

Ants are attracted by some nutritional ingredients that are present in the formulation and spread the gel insecticide by moving and contaminate their peers, causing poisoning (by contact and ingestion).

2.2.5.5 Efficacy data

GEL DROPS/LINES

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Test substance**	**Field of use envisaged**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	*Imidacloprid 0'01%. (gel bait)*	*Laboratory*	*Lasius niger*	*Laboratory bioassay: Mortality and palatability. (gel bait by drops) According to TNsG 18-19*	*Choice test arena. 4 replicates and control The bait was applied into an acetated sheet a 3cm line (1 drop) =0'2g per replicate. Arenas (17 x 11.5 x 5cm) for M. pharaonis. Arenas (30 x 20x x21 cm) for L. niger an L. humile.*	*Average mortality of 100% in 28 days. (15.1% in control) Palatable bait. (fresh bait) N: 223-326 worker ants*	[redacted] III-B.5.10.1
			Monomorium pharonis			*Average mortality of 95% in 48 days. (37.5% in control) Non palatable bait. (fresh bait) N: 620 worker, larvae and queen ants*	
			Linephitema humile			*Average mortality of 92% in 49 days. (16% in control) Palatable bait. (fresh bait). N=228*	[redacted] III-B.5.10-1b
		Outdoors	*Lasius niger*	*Field trial: (gel bait by drops) According to TNsG 18-19*	*3 replicates and control Dose: 0'2g/m^2. Frequency application: 2 application in 15 days (day 7)*	*Average mortality: 97,1% in 2 weeks.(15 days) (0% in control) Area of the three treatment sites: 5.5m^2, 4m^2 and 3m^2.*	[redacted] III-B.5.10.2
		Indoors	*Monomorium pharonis*	*Semi-field trial. (gel bait by drops/lines) According to TNsG 18-19*	*3 replicates and control Dose: 0,2g/m^2 Area test arena:3,24m^2 Frequency: 1 application in 15 days*	*Average mortality: 98% in 2 weeks.(15 days) (25.75% in control) N: 1163 worker ants.*	
		Outdoors	*Linephitema humile*	*Field trial (gel bait by drops/lines) According to TNsG*	*3 replicates Dose: 0,2g/m2 Frequency: 2/4*	*Average mortality: 96% in 2 weeks.(15 days) Area of the three treatment*	

				18-19	*applications in 15 days*	*sites: 27m^2, 72.5m^2 and 72.5m^2*	

BAIT STATIONS

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Test substance**	**Field of use envisaged**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	*Imidaclopri d 0'01%. (gel bait)*	*Laboratory*	*Monomorium pharaonis*	*Laboratory bioassay: Mortality and palatability.(traps) According to TNsG 18-19*	*Choice test arena(traps) 4 replicates and control Dose 5 g (1 trap per arena) Exposure time 44 d (M. pharaonis), 49 d (L. humile) and 18 d (L. niger) Arenas 18 x 18 cm (324 cm^2)*	*Average mortality of 95% in 44 days. (20.8% in controls). N:335 workers. Palatable bait. (fresh bait).*	[redacted] III-B.5.10.3
			Linepithema humile			*Average mortality of 98% in 49 days. (14.8% in controls) N:335 workers. Palatable bait. (fresh bait).*	
			Lasius niger			*Average mortality of 99% in 18 days. (10.5% in controls) N:335 workers. Palatable bait. (fresh bait).*	
		Indoors	*Monomorium pharaonis*,	*Semi-field trial (traps) According to TNsG 18-19*	*Dose: 2 stations/site Controls included. Exposure time 15 d Arenas 6.25 m^2 N: 500-1500 workers + 20 queens*	*Average mortality: 96,6% in 2 weeks.(15 days) (15.3% in controls) N:980-1200 workers and 20 queens*	[redacted] III-B.5.10.4
			Lasius niger		*Dose: 2 stations/site (5g/3,1m^2)*	*Average mortality: 98% in 2 weeks.(15 days)*	

						(11.1% in controls) *N:1049-1431 workers and 20 queens*	
		Outdoors	*Linepithema humile*	*Field trial (traps)* *According to TNsG 18-19*	*Dose: 4-7 stations/site (5g/40m^2)* *Exposure time 15 d* *Site 1, 120 m^2; site 2, 129 m^2, site 3, 210 m^2.*	*Average mortality: 97,3% in 2 weeks.(15 days)*	

Conclusion on the efficacy of the product

MAGNUM GEL HORMIGAS PLUS has demonstrated sufficient efficacy in laboratory choice tests and field trials against three species of ants (*Monomorium pharaonis, Linepithema humile* and *Lasius niger*) living in houses, gardens and commercial buildings.

The aplicant has submitted laboratory and field trials with traps and drops/lines. The studies weres performed according to the TNsG for PT 18 and PT 19 (CA-Dec12-Doc.6.2.a-Final).

The biocidal product is formulated as bait, containing attractive nutritional elements for the ants. In case of baits, the Guidance indicates that intrinsic palatability of the formulated bait should be enough to prove acceptable toxicity in competition with the alternative food source. Palatability of the fresh bait containing MAGNUM GEL HORMIGAS PLUS was demonstrated for the three species; and it was particularly atractive for *L. niger* and *L. humile.*

GEL BAIT BY DROPS/LINES

The applicant has submitted a laboratory trial and a field/semi-field trial against three species: *Lasius niger, Monomorium pharonis and Linepithema humile*. The application method is by drops/lines.

The laboratory study is in a test arena (III-B.5.10.1 and III-B.5.10.1b). The bait was applied into an acetated sheet a 3cm line (1 drop)=0,2g per replicate. An standard food were supplied to investigate the palatability. 4 replicates and 1 control to validated the test for each specie.

Lasius niger:

The study prove the efficacy against *Lasius niger*. Average mortaility is 100% in 28 days.

The control 1 had a mortality more than 20%, probably for an additional stress. The average mortality for the controls has been 15%, but we have considered remove the replicate 1. In fact, mortality of all replicates has been 100%.

Monomorium pharaonis:

The efficacy against this specie meets requirements the TNsG. Average mortality is 95% in 48 days. The control mortality is very high, 35.7% average, but it is a normal thing when working with small colonies for this specie in laboratory tests that run for a long period.

Linepithema humile:

The efficacy against this specie fulfils the requirements according to TNsG. Average mortality is 92% in 49 days. The control mortality is 16% average. We consider acceptable this percentage of mortality.

It has developed a field test (III-B.5.10.2) for species *Lasius niger* and L*inephitema humile* outdoors with droplets and an indoor simulated-use test against *Monomorium pharaonis*, since the applicant has argued that has not found an infested area with this specie.

The bait was applied into a plastic sheet or non-porous surface with a dose of 0,2g/m^2. 3 replicates.

Lasius niger:

The efficacy trial demonstrates with a dose of 0,2g/m^2 and one application every 7 days, that the product reaches a mortality of more than 95% in 15 days.

Monomorium pharonis:

The semi-field was elaborated in a room of 3,24m2. The efficacy trial demonstrates with a dose of 0,2g/m2 and one single application, that the product reaches a mortality of more than 90% in 15 days.

Linephitema humile:

The efficacy trial demonstrates with a dose of 0,2g/m^2 and one application every 2/4 days (depends on the infestation level), that the product reaches a mortality of more than 90% in 15 days.

We can conclude that the product MAGNUM GEL HORMIGAS PLUS is effective against garden and tropical ants with the method of application by droplets on non-porous surfaces.

GEL BAIT BY BAIT STATION.

The product has demonstrated sufficient efficacy when it is applied in bait stations at a dose rate of 2 bait stations/site (5 g/station; 1 standard room = 22 m^2). Re-application of fresh bait stations was needed (up to 7 stations per site). This was equivalent to 0.4-0.9 g/m^2. In the field trial with bait stations, ants were killed (>95%) after 15 days.

In a laboratory bioassay (IIIB.5.10.3) [redacted] Three species of ants were tested for efficacy evaluation in terms of knockdown and mortality, i.e. *Linepithema humile, Monomorium pharaonis* and *Lasius niger.*

One bait station with 5g of gel bait was assessed (5 g/arena). Four replicates and one control were included in the test. Mixed age worker ant colonies were placed into test arenas with food for 7 days before the trial to acclimatise and without food for 4 days of starvation period. Palatability was tested the first day of the trial. The efficacy tests lasted 18, 44 and 49 days for the black, pharaoh and argentine ants, respectively.

Palatability of the bait was demonstrated for the three species. Exposure to the bait resulted in >99% mortality after 18 days for black ants, >95 % mortality of pharaoh ants after 44 days, 98% mortality for argentine ants after 49 days. Therefore the criteria for products intended for use as baits (i.e. at least 95% of test insects killed at a given time point) were fulfilled for the three species.

A field trial (III-B.5.10.4) was also conducted to determine the efficacy [redacted] against the same three ants' species, in terms of population control. For pharaoh and black ants, however, a semi-field trial was conducted due to the difficulties in obtaining access to suitable infestations in the field. The semi-field systems consisted of simulated kitchenettes of 6.25 m^2 containing harborages, scatttered food and water sourcesThree replicates of the treatment and controls were used. The infestation level was high in sites with Argentine ants, and medium in simulated sites with black and pharaoh ants.

Bait boxes containing 5g of product were used in the trials. The following number of

stations was used during the trial until complete mortality was achieved:

- Argentine ants: 4 to 7 bait stations per site (120, 129 and 210 m^2)
- Pharaoh and black ants: 2 bait stations per site (6.25 m^2)

The number of stations used in the argentine ants' trials was apparently higher than the recommended dose however the size of the field sites was also higher than a standard room of 22 m^2 and thus the resulting dose rate was ca.5 g/40 m^2, which is a worst-case in terms of efficacy. In site 1 and 2 there were 3 bait stations; 1 was replenished. In site 3, there were 5 stations; 2 were replenished. The stations were replenished when the bait was either consumed by the ants or dehydrated due to the exposure to weather. Even if the bait was replenished the exposure dose was always kept at the recommended dose range (i.e. ca. 0.15 g/ m^2). Therefore the doses recommended for Argentine ants were covered by the efficacy studies.

In the semi-field trials the dose of 2 stations/site was tested. The Applicant encourages the use of several baiting points to enhance efficacy independently of the amount of product used. Each station contained 5 grams of formulated product. In this case, the stations were not replenished as it was not needed. The station size of 5 grams was included in the test because it was the only one available in the market. Since it is essential to use the same bait stations as included in the authorisation, it was judged acceptable. The dose was 1.6 g/m^2, which is higher than the theoretical rate. However it does not mean that all bait was ingested by the ants. The tests showed that the product is palatable, the stations are accesible to ants and efficacy to control ants is acceptable. However the doses tested in the studies are not the doses recommended by the Applicant, particularly the lower dose which is considered the worst case in terms of efficacy. Therefore the eCA cannot conclude the use of the product in bait stations for Pharaoh and black ants is covered by the efficacy results.

The results showed that the application of the bait boxes was effective against black, argentine and pharaoh ants, resulting in 98%, 97.3% and 96.6% reduction in ant populations, respectively, after 15 days of experimental period. The test followed the TNsG on Product evaluation PT18 and PT19. The criterion for a sufficient level of efficacy for a product intended to be used as bait in field tests against ants was fulfilled, i.e. the population reduction > 90% relative to untreated sites or pre-treatment levels after a period of exposure of 2-4 weeks. However, as indicated above, the doses tested for Pharaoh and black ants do not represent the efficacious doses as recommended by the Applicant.

We can conclude that the product MAGNUM GEL HORMIGAS PLUS is effective against Argentine ants(*Linepithema humile*) with the method of application by bait stations.

2.2.5.6 Occurrence of resistance and resistance management

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

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

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

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

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

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

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

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

The proposed resistance management strategy includes the following actions:

- The incorporation of a label warning: 'this product should be used in alternation with other products not containing the same a.s. to avoid resistant populations'.
- The label warning included by the Applicant indicating that 'the product should be reapplied when finished' should be changed to the following: 'the product should be reapplied only until the pest is controlled".

- The incorporation of a label warning: 'Use products at recommended doses and intervals'

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.

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

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 tests provided do not demonstrate a total destruction of the colony, therefore, that claim is not accepted. Likewise, residual efficacy trials and palatability tests with aged bait are not supported.

The product has proven effective for the following label claims.

- Insecticide product against garden ants (*Lasius niger*) and tropical ants (*Linephitema humile* and *Monomorium pharonis*). Kill ants (garden and tropical ants)'.
- Ready-to-use bait outdoors and indoors by droplets on non-porous surfaces (cartrige or syringe) for Linephitema humile, *Monomorium pharonis* and *Lasius niger* and included in bait stations only for *Linephitema humile*..

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal products.

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

The biocidal product MAGNUM GEL HORMIGAS PLUS is composed of the active substance Imidacloprid(0.01% w/w), combined with a number of co-formulants. Current classification is proposed in accordance with the provisions laid down in Regulation (EC) Nº 1272/2008.

[redacted]

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	The biocidal product MAGNUM GEL HORMIGAS PLUS is not classified.

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. The formulation contains 0.01% (w/w) of the active substance Imidacloprid and other co-formulants, two of which are classified for skin corrosion and irritation. However, the concentration of these co-formulants in the preparation is well below the classification limits set in Regulation (EC) Nº 1272/2008 and the biocidal product does not meet the criteria for classification as irritant or corrosive on the basis of their presence in the preparation.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not an eye 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	The biocidal product MAGNUM GEL HORMIGAS PLUS 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. The formulation contains 0.01% (w/w) of the active substance Imidacloprid and other co-formulants, three of which are classified for eye irritation. However, the concentration of these co-formulants in the preparation is well below the classification limits set in Regulation (EC) Nº 1272/2008 and the biocidal product does not meet the criteria for classification as eye irritant on the basis of their presence in the preparation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Not a respiratory tract irritant
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Respiratory tract irritation.
Justification	There are valid data available on each of the components in the the product MAGNUM GEL HORMIGAS PLUS 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. None of the components present in the formulation is irritant to respiratory tract.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	No a 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	Not classified as skin sensitizer.

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. The formulation contains 0.01% (w/w) of the active substance Imidacloprid and other co-formulants, none of which are classified for skin sensitisation. The biocidal product can be considered as no skin sensitisant according to Regulation (EC) Nº 1272/2008.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitiser
Justification for the value/conclusion	No data on the respiratory sensitisation of the product MAGNUM GEL HORMIGAS PLUS has been submitted, because of its physical nature (gel) and the low vapour pressure of the components. Additionally, the formulation is not classified as sensitiser to skin.
Classification of the product according to CLP	Not classified as respiratory sensitizer.

Data waiving	
Information requirement	Respiratory sensitisation.
Justification	MAGNUM GEL HORMIGAS PLUS has not skin 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- 423 Method B1 bis Commission Regulation (EC) No. 440/2008 GLP Yes Reliability 1	Wistar (RccHanTM: Wist) rats Female (nulliparous and non-pregnant) 8 – 12 weeks 3 animals/group	Imidacloprid 2.15% gel (purity unknown) Oral (gavage) 2000 mg/kg bodyweight	No deaths No signs of systemic toxicity No abnormalities at necropsy	>5000 mg/kg body weight	No analysis was conducted to determine the homogeneity, concentration or stability of the test item formulation.	IIIB 6.1.1 [redacted]

No human data 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

Data waiving	
Information requirement	Acute oral toxicity studies
Justification	[redacted] MAGNUM GEL HORMIGAS PLUS contains 0.01% (w/w) of the active substance Imidacloprid and other co-formulants, one of which is classified for acute oral toxicity. However, the concentration of this co-formulant in

	the preparation is well below the classification limit set in Regulation (EC) Nº 1272/2008 and the biocidal product does not meet the criteria for classification as toxic by the oral route on the basis of its presence in the preparation. [redacted] It is therefore proposed that the product MAGNUM GEL HORMIGAS PLUS is not harmful by the oral route and will remain unclassified.

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	Acute inhalation toxicity studies
Justification	[redacted] Exposure of humans via inhalation is not likely taking into account: -The low vapour pressure of the active substance imidacloprid. -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, -The product is applied in drops or by using bait station and therefore, no aerosol particles or dopltes of an inhalable size are generated. The formulation contains 0.01% (w/w) of the active substance Imidacloprid and other co-formulants, none of which are classified for

	acute inhalation toxicity. The biocidal product can be considered as no toxic by the inhalation route according to Regulation (EC) Nº 1272/2008.

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 No. 402 Method B3 Commission Regulation (EC) No. 440/2008 GLP Yes Reliability 1	Wistar (RccHanTM: Wist) Rat 5 Males and 5 females (The females were nulliparous and non-pregnant)	2000 mg/kg Imidacloprid 2.15% gel undiluted Semiocclusive No vehicle Approximately 10% of the total body surface area 24 hours exposure	Dark brown coloured staining of all males and one female Small superficial scattered scabs of two females. No signs of dermal irritation of the remaining animals No abnormalities at necropsy. No deaths No signs of systemic toxicity	>2000 mg/Kg bw		IIIB 6.1.2 [redacted]

Value used in the Risk Assessment – Acute dermal toxicity	
Value	>2000 mg/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	Not classified.

Data waiving	
Information requirement	Acute dermal toxicity studies
Justification	Acute dermal toxicity studies for the product MAGNUM GEL HORMIGAS PLUS have not been performed. [redacted]

	[redacted] The main component contributing to the toxicity of the formulation is the active substance Imidacloprid, [redacted]. [redacted] It is therefore proposed that the product MAGNUM GEL HORMIGAS PLUS is not harmful by the dermal route and will remain unclassified.

Information on dermal absorption

According to the risk and exposure assessment for human health, the use of protective clothing (gloves) is not required for neither trained professional nor professional / non-professional users considering the following values for dermal absorption.

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Imidacloprid	Imidacloprid.
Value(s)*	75% for primary exposure	75% for secondary exposure
Justification for the selected value(s)	Guidance on Dermal Absorption[a] EFSA Journal 2012;10(4):2665	Guidance on Dermal Absorption[a], EFSA Journal 2012;10(4):2665

* No dermal absorption study on MAGNUM GEL HORMIGAS PLUS is submitted.

[a] In absence of data on the formulation into consideration, a default value of 75% should be used for products or in use dilutions containing ≤ 5% active substance.

Data waiving	
Information requirement	Dermal absorption studies on Imidacloprid 0.01% Gel formulation
Justification	A dermal absorption value of 8% was used for the formulation containing 2.15% Imidacloprid for exposure and risk assessment for Annex I inclusion of active substance extrapolating from a comparative in vitro dermal absorption study performed with an oil-based formulation (and aqueous dilutions thereof) of Imidacloprid in rat and human skin. [Please refer to the letter of access granted by BAYER to MYLVA S.A. based in the information reported in the Assessment Report for Imidacloprid (18th February 2011)]. According to EFSA guidance pp. 18, data generated with the active substance should only be used when the formulation under evaluation is very closely related to the vehicle used in the study with the active substance, in terms of solvent, surfactant content, skin irritancy and active substance content. This equivalence has not been demonstrated, hence the use of a dermal absorption value of 8% is not supported. In absence of data on the product MAGNUM GEL HORMIGAS PLUS, the use

	of default value of 75% following EFSA guidelines on dermal absorption, is believed to represent a sufficient conservative approach for human exposure.

Available toxicological data relating to non active substances (i.e. substances of concern)

The formulation contains 0.01% (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 0.01% 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.

2.2.6.2 Exposure assessment

MAGNUM GEL HORMIGAS PLUS is a ready-to-use product to be applied indoor and outdoor as gel drops and using traps. No exposure to the product is expected either by trained professionals, professionals or the general public during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63: 'the exposure due to the use of ant and cockroach bait stations is considered to be negligible. Accidents (swallowing, children who open bait stations) do not form a part of a standard assessment').

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

There are no substances of concern.

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

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

Summary table: relevant paths of human exposure		
Exposure	**Primary (direct) exposure**	**Secondary (indirect) exposure**

path	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).

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** **Description of scenario**	**Exposed group**
1.	Application	Primary exposure: gel application using a cartridge	Trained professionals
2.	Post application	Primary exposure: disposal of used cartridge	Trained professionals
3.	Application	Primary exposure: gel application using a cartridge/syringe	Professionals/ Non professionals
4.	Post application	Primary exposure: disposal of used cartridge/syringe	Professionals/ Non professionals
5.	Application	Primary exposure: gel application using bait stations*	All users
6.	Post application	Primary exposure: collection of used bait stations*	All users
7.	Post application	Secondary exposure: dermal and hand to mouth contact with gel	Bystanders (toddler)

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

For trained professionals (pest control operators), exposure is estimated using the models and assumptions presented in the original CAR.

Chronic exposure is expected.

Exposure takes place via dermal contamination through hands. Exposure estimation is performed taking into account the quantities that could potentially enter into contact with operator's hands during opening and sealing the cartridge (5 opening and 5 sealing operations per day).

The product remaining on the tip of the cartridge (or cartridge nozzle) will contaminate operator's hand during removal or placing the cap before and after the application, respectively.

Exposure during use of cartridges is estimated worst case compared to syringes.

	Parameters	Value
Tier 1	Equivalence 0.5 cm gel [a]	18 mg product
	number of opening and sealing per day[b]	10
	content of active substance in product	0.01%
	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 HORMIGAS PLUS. The CA uses the amount of product in a line of gel 0.5 cm length (as indicated in Section 2.2.2, storage stability study: a line of 5 cm length of MAGNUM GEL HORMIGAS PLUS from a cartridge equals aprox. 180 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 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	-	2.25E-04	-	2.25E-04

Further information and considerations on scenario [n]

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. Chronic exposure is expected. Exposure takes place via dermal contamination through hands. Exposure estimation is performed taking into account the quantities that could potentially enter into contact with operator's hands during disposal of used cartridges (1 operation a day). The product remaining on the tip of the cartridge (or cartridge nozzle) will contaminate operator's hand during cartridge disposal.		
	Parameters	Value
Tier 1	Equivalence 0.5 cm gel [a]	18 mg product
	number of disposed cartridges per day [b]	1
	content of active substance in product	0.01%
	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 HORMIGAS PLUS. The CA uses the amount of product in a line of gel 0.5 cm length (as indicated in Section 2.2.2, storage stability study: a line of 5 cm length of MAGNUM GEL HORMIGAS PLUS from a cartridge equals aprox. 180 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 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	-	2.25E-05	-	2.25E-05

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 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	-	2.48E-04	-	2.48E-04

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 HORMIGAS PLUS 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 ants. Assuming that professionals and general public use either cartridges or syringes, exposure for this category of users is estimated using the models and assumptions presented for professionals 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 (ants are expected during spring and summer). As a worst case, medium term exposure is expected. Exposure takes place via dermal contamination through hands. Exposure 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]	18 mg product
	number of opening and sealing per day[b]	2

	content of active substance in product	0.01%
	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 HORMIGAS PLUS. The CA uses the amount of product in a line of gel 0.5 cm length (as indicated in Section 2.2.2, storage stability study: a line of 5 cm length of MAGNUM GEL HORMIGAS PLUS from a cartridge equals aprox. 180 mg of product) to estimate the exposure of the general public 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 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	-	4.50E-5	-	4.50E-5

Further information and considerations on scenario [3]
None.

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

Description of Scenario 4		
For professionals and general public, exposure is estimated using the models and assumptions presented in the original CAR adapted to theser users according to expert judgment. 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 (ants are expected during spring and summer). As a worst case, medium term exposure is expected. Exposure takes place via dermal contamination through hands. Exposure 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]	18 mg product
	number of cartridge disposed off per event [b]	1
	content of active substance in product	0.01%
	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 line of gel 0.5 cm length (as indicated in Section 2.2.2 storage stability study: a line of 5 cm length of MAGNUM GEL HORMIGAS PLUS from a cartridge equals aprox. 180 mg of product) to estimate the exposure of the general public 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	-	2.25E-5	-	2.25E-5

Further information and considerations on scenario 4

None

Combined scenarios

Total exposure of professionals or consumers during the use of MAGNUM GEL HORMIGAS PLUS 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	-	6.75E-5	-	6.75E-5

Scenario 5 & Scenario 6 Use and disposal of bait stations containing MAGNUM GEL HORMIGAS PLUS

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

Indirect exposure of the general public

Indirect exposure scenarios are described in the following.

Scenario 7 Toddler: dermal contact with MAGNUM GEL HORMIGAS PLUS and hand to mouth transfer after application

Description of Scenario 7
According to the definitions in HEEG Opinion 17, the population under consideration here are toddlers (1-2 years old) who can explore their environment and exhibit hand to mouth transfer of residues. Secondary exposure can be considered as occasional and of short-term (not continuous) and therefore the exposure is considered as acute. Considering that the product is applied in lines/drops on localized spots (there is not an uniform application on surfaces as paints, for example), the following scenario assumes that a toddler contacts one line 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. Tier 1 assumes 100% dislodgeability, 100% oral absorption and 75% dermal absorption.

	Parameters	Value
Tier 1	Equivalence of 1 line of gel 5 cm [a]	180 mg product
	number of lines 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 line of 5 cm length of MAGNUM GEL HORMIGAS PLUS from a cartridge equals aprox. 180 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	-	1.35E-03	9.0E-04	2.25E-03

Further information and considerations on scenario 7
The Tier 1 estimation presented here is a worst case assumption where the dislodgeability is 100% and the effect of the bittering substance in the ingestion is not considered.

Considering the application pattern of MAGNUM GEL HORMIGAS PLUS as a gel application (drops/lines) 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 precluded in the event that the product is applied e.g., in the food industry, restaurants or in 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 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 that 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 values [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*

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.
- Do not apply on surfaces or utensils that can be in contact with feedingstuff.

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

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 general public.

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

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

- Do not apply on surfaces or utensils that can be in contact with foodstuff.

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**
1.	Trained-Professional	Tier 1 /none	2.25E-04 mg/kw bw/ d
2.	Trained-Professional	Tier 1 /none	2.25E-05 mg/kw bw/ d
3.	Professional and Non professional	Tier 1 /none	4.5E-05 mg/kw bw/ d
4.	Professional and Non professional	Tier 1 /none	2.25E-05 mg/kw bw/ d
7.	Bystanders (toddler)	Tier 1 /none	2.25E-03 mg/kw bw

2.2.7 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL**	**AF[1]**	**Correction for oral absorption**	**Value**
AELshort-term	acute neurotoxic study in rats	40 mg/Kg bw	100	-	0.4 mg/Kg bw
AELmedium-term	rat multigeneration study	20 mg/Kg bw/day	100	-	0.2 mg/Kg bw/day
AELlong-term	two year chronic toxicity study in rats	6 mg/Kg bw/day	100	-	0.06 mg/Kg bw/day
ARfD[2]	-	-	-	-	-
ADI[2]	-	-	-	-	-

[1] *EU agreed AEL values (please refer to the Assessment Report for Imidacloprid 18th February 2011):*

For acute, medium-term, and long-term exposure to Imidacloprid, the following systemic Acceptable Exposure Levels (AEL) were derived:

an AEL acute = 0.4 mg/kg bw/d, based on the NOAEL of ca. 40 mg/kg bw from the acute neurotoxicity study in rats and supported by the results from the 28-d oral toxicity study in dogs,

an AEL medium-term = 0.2 mg/kg bw/d, based on the overall NOAEL of ca. 20 mg/kg bw/d established for the rat multigeneration study and supported by the dog 90-d and rabbit developmental studies,

an AEL long-term = 0.06 mg/kg bw/d, based on the NOAEL of ca. 6 mg/kg bw/d obtained in the 2-yr study in rats.

In all cases, standard assessment factors of 100 were applied.

[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

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

Systemic effects combined exposure for professionals.

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Application / Scenario 1	1	6	0.06	2.25E-04	0.38	yes
Post application /Scenario 2	1	6	0.06	2.25E-05	0.04	yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application/ Scenario 1 & Post application/ Scenario 2	1	6	0.06	2.48E-04	0.41	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 2.48E-04 mg/kg bw/day during the application and postapplication processes combined, (Tier 1). The estimated uptake represents 0.4% of the proposed AEL of 0.06 mg/kg bw/day.

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

No risk is envisaged for the use of MAGNUM GEL HORMIGAS PLUS by trained-professional users when no PPE is considered.

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

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	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application / Scenario 3	1	20	0.2	4.50E-05	0.02	Yes
post application/ Scenario 4	1	20	0.2	2.25E-05	0.01	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application/ Post application Scenario 3 & 4	1	20	0.2	6.75E-05	0.03	yes

Local effects
Not applicable.

Conclusion
Exposure assessment for professional and non-professional users under worst case assumptions yields a potential dermal exposure leading to systemic doses of 6.75E-05 mg/kg bw/day during the application and postapplication processes combined, (Tier 1). The estimated uptake represents 0.03% of the proposed $AEL_{medium\text{-}term}$ of 0.2 mg/kg bw/day.
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 0.11% which would indicates an acceptable risk also for this use.Tier 1 assessment indicates an acceptable risk for professional and non-professional users.

No risk is envisaged for the use of MAGNUM GEL HORMIGAS PLUS 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	Estimated uptake/ AEL (%)	Acceptable (yes/no)

Dermal and hand to mouth contact for toddlers/ Scenario 7	1	40	0.4	2.25E-03	0.56	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 2.25E-03 mg/kg bw during the indirect exposure via oral and dermal route after the application of biocidal product, (Tier 1). The estimated uptake represents 0.6% 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 HORMIGAS PLUS as an insecticide is considered safe when 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 (professional and non-professional uses).

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

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

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

- Do not apply on surfaces or utensils that can be in contact with foodstuff
-

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.

2.2.8 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 feed contamination (professional/ non-professional uses):

- Do not apply on surfaces or utensils that can be in contact with feedingstuff

No risk is envisaged for animal health

2.2.9 Risk assessment for the environment

MAGNUM GEL HORMIGAS PLUS is an indoor/outdoor gel insecticide to be applied via droplets by using a cartridge/syringe or bait stations. It has an effective control against populations of pharaoh ants (*Monomorium pharaonis*), argentine ants (*Linepithema humile*), and black ants (*Lasius niger*).

MAGNUM GEL HORMIGAS PLUS is a gel contained 0.01% 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 GR0.5 and GL2.15, contained 0.5 and 2.15% of the active substance, respectively. The biocidal product (GL2.15) is a gel, it is a ready-to-use bait for indoor use. The product (GR 0.5) is a ready-to-use granular bait. It is a bait for '*indoor use in rural hygiene situations*' that is '*for use in animal houses and/ or other agricultural buildings*', leading to '*rapid knockdown and mortality of insect*'. GL2.15 is the same type of formulation, gel, as MAGNUM GEL HORMIGAS PLUS but with higher quantity of the active substance. GL2.15 is for indoor use while MAGNUM GEL HORMIGAS PLUS is to be used indoor and outdoor. 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 PT 18 and the Manual Technical Agreements (MOTA). ES CA

considers that the indoor use is within the Annex I level assessment while the new use proposed by the applicant must be evaluated.

The applicant has a letter of access to all data presented by Bayer Environmental Science that supported the original Annex I listing of imidacloprid. At Annex I level Bayer Environmental Science was able to demonstrate the safe use of GL2.15 the scenario for indoor application. ES CA agrees with applicant that the environmental risk assessment derived from the indoor use of gel application in drops cover the risk derived from the use of bait stations. The environmental exposure assessment has been carried out on the basis of the updated emission scenario for PT18 and the Manual Technical Agreements (MOTA), as it is indicated in the Annex I assessment.

The applicant proposes an additional use that has not been supported by the imidacloprid Annex I assessment, outdoor use. For this new use a risk characterization assessment has been performed.

2.2.9.1 Effects assessment on the environment

All the studies supporting environmental fate and toxicity properties of the product MAGNUM GEL HORMIGAS PLUS 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.

$PNEC_{sediment}$ = 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}**.

$PNEC_{microorganisms}$ (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).

$PNEC_{soil}$ = 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.

$PNEC_{secondary\ poisoning}$:

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

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

Effect on honeybees

The **¡Error! No se encuentra el origen de la referencia.** summarises the data available or the active substance imidacloprid:

Toxicity to honeybees

Organisms	Duration	Test substance	Ecotoxicolgical endpoint	Report No.
Honey bee	Acute, 48 h	Imidacloprid a.s.	LD_{50} oral 0.0037 µg/ bee	Imidacloprid IIA, 8.3.1.1/01 (BAY 158/901384)
			LD_{50} contact 0.081 µg/ bee	

The biocidal product MAGNUM GEL HORMIGAS PLUS contains 0.01% of imidacloprid as the only ingredient to contribute to the classification regarding environmental properties. The current harmonised classification of imidacloprid is aquatic acute (H400) and aquatic chronic (H410) (1^{st} ATP). As no factor are given in the 1^{st} ATP, according to the most recent effect data, the following M factors are considered, M factor of 100 and M factor of 1000 for aquatic acute and aquatic chronic, respectively. The biocidal product MAGNUM GEL HORMIGAS PLUS is classified as Aquatic Chronic Category 2 (H411). H411 for labelling purposes.

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

The biocidal product MAGNUM GEL HORMIGAS PLUS contains 0.01% of imidacloprid as the only ingredient to contribute to the classification regarding environmental properties. The current harmonised classification of imidacloprid is aquatic acute (H400) and aquatic chronic (H410) (1^{st} ATP). As no factor are given in the 1^{st} ATP, according to the most recent effect data, the following M factors are considered, M factor of 100 and M factor of 1000 for aquatic chronic and aquatic acute, respectively. The biocidal product MAGNUM GEL HORMIGAS PLUS is classified as Aquatic Chronic Category 2 (H411). H411 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.

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.

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 HORMIGAS PLUS is applied indoors in inaccessible places: cracks and crevices and in foraging trails. 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.

2.2.9.2 Exposure assessment

General information

Assessed PT	*PT 18*
Assessed scenarios	Scenario 1: Outdoor direct release. Scenario 2: Outdoor use indirect releases. Scenario 3: Indoor use crack and crevices private houses. Scenario 4: Indoor use crack and crevices private houses and large buildings. Scenario 5: Indoor use surface treatment private houses. Scenario 6: Indoor use surface treatment private houses and large buildings. Scenario 7: Outdoor use bait station. Scenario 8: Indoor use bait station.

ESD(s) used	Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses.
Approach	A consumption based approach has been used as a suitable protective measure at the local level.
Distribution in the environment	Calculated based on TGD 2003 (alternative: based on measured data)
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Imidacloprid 0.01% 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

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

Scenarios [1 and 2]

As it is stated by the applicant, the application of the gel in drops can be considered a worst case and the risk derived from this application method cover the risk derived from the use of bait stations (scenario 7) thus, the risk assessment of the bait stations outdoor has not been performed.

The application of the gel in drops can be described as spot application. Environmental exposure may arise following flooding from a rain event. These emissions may enter directly into the surrounding soil of the application spot or will be released to a STP system with subsequent indirect release to the environmental compartments surface water, sediment, soil (via sludge application) and groundwater. It is presumed, that outdoor areas of private houses are not connected to an STP system. Therefore, release to STP is only considered for the use of MAGNUM GEL HORMIGAS PLUS around commercial buildings. Moreover, a release and exposure estimation for mixing and loading steps is unnecessary as the biocidal product is a ready to use product. The release to the environment is assessed by the emission scenario described in chapter 3.3.2 and 4.4.5 of OECD ESD No. 18 (2008).

Scenario [1]

Estimation of direct release to soil

The input values for determining direct releases to soil in the course of spot application as well as the calculated emission rates are summarized in the following table. For outdoor gel application of the biocidal product, a typical application rate of 1 drop per m is envisaged, each drop containing 0.2 g of the biocidal product. According to ESD PT18 No. 18 (2008) for outdoor applications of insecticides around commercial buildings, a default perimeter width of 0.5 m is proposed. Considering an application rate of 1 gel drop per m perimeter, this leads to an area of 0.5 m² (1m x 0.5m) which is exposed directly to each application spot. For direct exposure estimation, an application frequency of 1 application per day is considered as worst case assumption. The ESD PT 18 (2008) indicates that about 90% of the insecticidal products deposits to the treated spot can be released to the environment, either directly or through ultimate release after target inset death. Thus, the fraction emitted to soil is 90%

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: outdoor use, direct release			
Quantity of b.p. applied (Q_{bp})	0.2	g	
Fraction of the active substance in the product (F_{ai})	0.0001		
Quantity of a.s. applied (Q_{as})	$2x10^{-5}$		
Number applications per day	1	-	
Number of point per area	1	-	
Fraction emitted to soil during outdoor gel application ($F_{spot,gel}$)	0.9	m^2	

Calculations for Scenario [*1*]

According to the ESD PT18, the equation for local releases to soil during spot application would be:

$E_{spot,\ soil}$ = Qb.p. x Fa.i. x N_{sites} x N_{appl} x $F_{spot,soil}$ = 1.8 x 10^{-5} g

The application of the b.p. in a typical scenario results in a direct release of 1.8 x 10^{-5} g imidacloprid per 0.5 m² of soil

Scenario [2]

Estimation of indirect release: through sewage treatment plants

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

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: outdoor use, indirect releases			

Quantity of b.p. applied (Q_{bp})	0.2	g	
Fraction of the active substance in the product (F_{ai})	0.0001	-	
Quantity of a.s. applied (Q_{as})	$2x10^{-5}$	g	
Application rate of the b.p. ($APP_{b.p.}$)	1	Spot/m	
Perimeter treated with the product ($PERIMETER_{Treated}$)	250	m	
Number applications per day	1	d^{-1}	
Number of point per area	250	-	
Fraction emitted to STP during outdoor gel application ($F_{spot,gel}$)	0.9	-	
Number of houses connected to SPT (N_{houses})	300		
Simultaneity factor (F_{sim})	0.03		

According to ESD PT18 (2008) for outdoor applications of insecticides around commercial buildings, a default perimeter of 250 m is proposed with a perimeter width of 0.5 m. Considering an application rate of 1 spot.m^{-1}, this leads to 250 gel spots applied for each commercial building. The ESD PT 18 (2008) indicates that about 90% of the insecticidal products deposited to the treated spot can be released to the environment, either directly or through ultimate release after target insect death. Thus, the fraction emitted to soil is 90%. The simultaneity factor is considered as 0.03 for outdoor treatments. In addition, following the instructions agreed in the Manual of Technical Agreements, Version 5; 2013, the following assumption is considered, number of larger buildings per STP is 300.

Calculations for Scenario [*2*]

Local direct emission rate to STP per treatment

$E_{spot,\ STP} = Q_{b.p.} \times F_{a.i.} \times N_{sites} \times N_{appl} \times F_{spot,gel}$

$E_{spot,\ STP} = 4.50 \times 10^{-3}\ g.d^{-1}$

Simultaneous emission to waste water during outdoor use:

$Elocal_{water,\ sim} = E_{spot,STP} \times N_{houses} \times F_{Sim}$

$Elocal_{water,\ sim} = 4.05x10^{-2}\ g.d^{-1}$

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{water,\ sim}$) [kg/d]**	**Remarks**
STP	$4.05x10^{-5}$	

Scenario [3]

This scenario is covered by scenario 4

Scenario [4]

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 *[alternative: annual tonnage in the EU]*	0.2	*g/m²*	1 drops/ m^2 (each drop contains 0.2 g of product)
Concentration of active substance in the product	0.1	*g/Kg*	
Number applications per day	1	-	
Number of point per area	1	-	
Area treated with product (private houses)	2	m^2	
Area treated with product (large buildings)	9.3	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) 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 large building is 2 and 9.3 m^2, respectively.

Table 2.2.9.2-1: 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}	1	
Fraction emitted to treated surfaces during application	F_{appl}	1	
Quantity of commercial product applied per point of	$Q_{prod,\ point}$	0.2	

gel [g/point]			
Fraction of active substance in the commercial product	F_{ai}	0.0001	
Area treated with product [m^2]	$AREA_{treated}$	2	9.3
Emission rate to treated surface during application [g/d]	**$E_{application, surface} = Q_{prod, point} \times N_{point} \times F_{ai} \times AREA_{treated} \times F_{appl} \times N_{appl}$**	**4.00E-05**	**1.86E-04**

Cleaning

Releases to wastewater during cleaning event depend on the efficiency of the cleaning. It is considered that the cleaning efficiency (FCE) for the use of the MAGNUM GEL HORMIGAS PLUS 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 2.2.9.2-2: 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	$E_{application, surface}$	4.00E-05	1.86E-04
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]	**$Elocal_{ww} = (E_{application, floor} + E_{application, surface}) \times F_{ww} \times F_{CE}$**	**1.20E-06**	**5.58E-06**

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 8 to 16 times per year depending of the level of infestation (worst case according to the efficacy studies). As this frequency of use is not indicated in the ESD PT 18, we are going to use the frequency of 1 treatment a week therefore, the simultaneity factor is:

$F_{simultaneity}$ = ((9.51*14.3)+ (17.74*3.22)+(32.15*1.9)+(37.82*0.54))/100 = 2.74%

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

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

Parameter	Definition	Value	
		Private houses	Large buildings
Emission from treated surface to wastewater during cleaning step [g/d]	$Elocal_{ww}$	1.2E-06	5.58E-06
Simultaneously treated houses per STP [-]	N_{houses}	4000	300
Simultaneity factor[-]	$F_{simultaneity}$	0.0274	
Emission to wastewater [g/d]	**$Elocal_{ww}$ = $Elocal_{ww}$ x N_{houses} x $F_{simultaneity}$**	**1.32E-04**	**4.59E-05**
Total emission to wastewater [kg/d]	**$E_{ww\ total}$ = $\Sigma(E_{ww})/1000$**	**1.77E-07**	

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	**1.77E-07**	Worst case private house + large buildings

Scenario [5]

This scenario has not been calculated since the assessment of scenario 6 covers this use.

Scenario [6]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: surface application in a house and large buildings.			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	0.2	g/m²	1 drops/ m^2 (each drop contains 0.2 g of product)
Concentration of active substance in the product	0.1	g/Kg	
Number applications per day	1	-	
Number of point per area	1	-	
Area treated with product (private houses)	38.5	m^2	

Area treated with product (large buildings)	609	m^2	

Calculations for Scenario [*6*]

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 treated surfaces 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 large building is 38.5 and 609 m^2, respectively.

Table 2.2.9.2-4: 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}	1	
Fraction emitted to treated surfaces during application	F_{appl}	1	
Quantity of commercial product applied per point of gel [g/point]	$Q_{prod,\ point}$	0.2	
Fraction of active substance in the commercial product	F_{ai}	0.0001	
Area treated with product [m2]	$AREA_{treated}$	38.5	609
Emission rate to treated surface during application [g/d]	$\mathbf{E_{application,\ surface} = Q_{prod,\ point} \times N_{point} \times F_{ai} \times AREA_{treated} \times F_{appl} \times N_{appl}}$	**7.70E-04**	**1.22E-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 HORMIGAS PLUS represents a maximum exposition 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 areas difficult to access and not subject to cleaning (ESD PT18, 2008).

Table 2.2.9.2-5: 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	$E_{application, surface}$	7.70E-04	1.22E-02
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}**	**1.93E-04**	**3.05E-03**

Emissions have been calculated for one house and one large building, according to the ESD these values have to be multiplied by the number of houses, 4000, 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 8 to 16 times per year depending of the level of infestation (worst case according to the efficacy studies). As this frequency of use is not indicated in the ESD PT 18, we are going to use the frequency of 1 treatment a week therefore, the simultaneity factor is:

$F_{simultaneity}$ = ((9.51*14.3)+ (17.74*3.22)+(32.15*1.9)+(37.82*0.54))/100 = 2.74%

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

Table 2.2.9.2-6: 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]	$Elocal_{ww}$	1.93E-04	3.05E-03
Simultaneously treated houses per STP [-]	N_{houses}	4000	300
Simultaneity factor[-]	$F_{simultaneity}$	0.0274	
Emission to wastewater [g/d]	**$Elocal_{ww}$ = $Elocal_{ww}$ x N_{houses} x $F_{simultaneity}$**	**2.11E-02**	**2.50E-02**

Total emission to wastewater [kg/d]	**$E_{ww\ total}$ = $\Sigma(E_{ww})/1000$**	**4.61E-05**

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	**4.61E-05**	Worst case private house + large buildings

Scenario [7]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: outdoor use, direct release			
Amount of product used at each refilling in the control operation for each bait box (Qprod)	0.2	g	
Fraction of the active substance in the product (F_{ai})	0.0001		
Number of application sites (Nsites)	4		
Number applications (Nappl)	1		
Fraction emitted to soil during outdoor gel application ($F_{spot,gel}$)	0.2	m^2	

Calculations for Scenario [*7*]

According to the ESD PT18, the equation for local releases to soil during spot application would be:

$E_{spot,\ soil}$ = Qb.p. x Fa.i. x N_{sites} x N_{appl} x $F_{spot,soil}$ = 1.6 x 10^{-5} g

The application of the b.p. in a typical scenario results in a direct release of 1.6 x 10^{-5} g imidacloprid

Since the Espot soil is lower than the value obtained in scenario 1, we conclude that this scenario is covered by scenario 1 and no more calculations are needed.

Scenario [8]

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

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway

	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	No	No	No	No	No	No	Yes	Yes	
Scenario 2	Yes	Yes	No	No	Yes	No	Yes	Yes	
Scenarios 3-6	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	Decomposition	°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)	$1.7x10^{-10}$	$Pa/m^3/mol$	
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) 0.2 - 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 [%] Scenario 1 y 2	Remarks
Air	3.72×10^{-10}	
Water	97.2	
Sludge	2.79	
Degraded in STP	0	

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[µg/kg]	[µg/l]	[mg/m^3]

			]					
Scenario 1	-	-	-	-	-	$4.23x10^{-2}$	$1.01x10^{-2}$	-
Scenario 2	$2.025x10^{-5}$	$1.96x10^{-6}$	$1.137x10^{-5}$	-	-	$5.46x10^{-4}$	$1.30x10^{-4}$	-
Scenario 4	$8.87x10^{-8}$	$8.62x10^{-9}$	$4.98x10^{-8}$			$7.54x10^{-9}$	$1.8x10^{-6}$	
Scenario 6	$2.31x10^{-5}$	$2.24x10^{-6}$	$1.30x10^{-5}$			$3.38x10^{-6}$	$8.09x10^{-4}$	
Snario 7	This scenario is cover by scenario 1							

Primary and secondary poisoning

Primary poisoning
Primary poisoning of non-target animals is excluded according to the design of the b.p

Secondary poisoning
Due to the low bioaccumulation potential of imidacloprid the assessment of secondary poisoning according to the EU TGD (2003), chapter 3.8.3 is not required. However, secondary poisoning due to the potential exposure of vertebrates (i.e. birds or mammals) consuming contaminated insects or taking their food has been performed.

An assessment of secondary poisoning of herbivorous species was carried out using the equation:

ETE = (FIR/bw) x RUD x Tappl x AV x PT x PD x 10-4

Where:
ETE = Estimated daily uptake (PECoral)
FIR = Food intake rate of indicator species
bw = Body weight of species
RUD = Residue value per unit dose
Tappl = Application rate of active substance
AV = Avoidance factor of contaminated food
PT = Proportion of diet obtained in treated area
PD = Proportion of food type in the diet of species of concern

The food intake rates for indicator species (FIR) are defined in the PT18 ESD, along with the body weights of indicator species (bw) and the residue value per unit dose (RUD). The application rate of the active substance (Tappl) in kg/m2 has been derived as a worst case value from the outdoor emission assessment. In the outdoor scenario it is calculated that there is a 1.8 x10-8 kg a.i. emission to a 0.5 m2 area of soil. Hence, here it is considered that there the application rate of the active substance is 3.6 x10-8 kg/m2. Once again,

worst case values are used for the avoidance factor (AV), the proporation of diet obtained in the area (PT) and the proportion of food type in the animals diet (PD). The ETE values for assessment of secondary poisoning via consumption of contaminated insects (acute and short term) for selected indicator species are presented below.

Expected daily uptake (ETE) of imidacloprid for selected indicator species following application of Imidasect Ants around private houses and commercial buildings

Species		**ETE insect [µg.(kg.d)-1]**	
		Acute	**Short**
Pipistrelle	Pipistrellus pipistrellus	$1.71*10^{-11}$	$6.24*10^{-12}$
Shrew	Sorex araneus	$1.58*10^{-11}$	$5.78*10^{-12}$
Hedgehog	Erinaceus europaeus	$4.53*10^{-12}$	$1.65*10^{-12}$
Badger	Meles meles	$4.53*10^{-12}$	$1.65*10^{-12}$
Tree sparrow	Passer domesticus	$9.73*10^{-11}$	$5.42*10^{-11}$
Blackbird	Turdus merula	$1.87*10^{-11}$	$1.04*10^{-11}$
Black-billed Magpie	Pica pica	$1.108*10^{-11}$	$4.03*10^{-12}$

2.2.9.3 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 4×10^{-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 5×10^{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 1	
Scenario 2	$2.025x10^{-7}$
Scenario 4	$8.87x10^{-10}$
Scenario 6	$2.24x10^{-7}$

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

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Scenario 1				
Scenario 2	0.41	0.44		
Scenario 4	$1.80X10^{-3}$	$1.92X10^{-3}$		
Scenario 6	0.46	0.5		

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

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	2.68×10^{-3}
Scenario 2	3.42×10^{-5}
Scenario 3	8.12×10^{-7}
Scenario 4	4.79×10^{-7}

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

Groundwater

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

Primary and secondary poisoning

Primary poisoning

Effects on honey bees

Imidacloprid was shown to be highly toxic to bees both by oral and contact exposure with LD_{50} of 0.0037 µg per bee and 0.038 µg per bee, respectively (Imidacloprid IIA, 8.3.1.1/01(BAY 158/901384)). The product MAGNUM GEL HORMIGAS PLUS contain a concentration of imidacloprid of 0.01% w/w, the quantity of product necessary to reach LD_{50} oral and the LD_{50} contact are 37 µg and 810 µg, respectively. The product is a ready to use gel bait with a high contain of sugar. MAGNUM GEL HORMIGAS is applied by drops or lines (elongated drops) where ants are present, the application rate is 1 drop/m^2 (1 drop=1 line of 3 cm lenght=0.2 g of gel bait).

Although the exposure of a honeybee to the product and its mortality after consuming the biocidal product, MAGNUM GEL HORMIGAS PLUS, cannot be excluded, we consider that doe to the high viscosity of the product, higher than 3000 mPa.s, bees would not be able to take the gel up. So, there is no risk when the product is applied in drops.

Secondary poisoning

	PEC (mg/kg)	**$PNEC_{oral\ predator}$** [mg/ kg feed]	**PEC/PNEC**
birds feeding on insects (acute)	1.108×10^{-14}	4.2	$0.26x10^{-14}$
birds feeding on insects (short-term)	4.03×10^{-14}	4.2	$0.95x10^{-14}$
mammals feeding on insects (acute)	1.58×10^{-14}	8.33	$0.18x10^{-14}$
mammals feeding on insects (acute)	5.78×10^{-15}	8.33	$0.69x10^{-15}$

Conclusion:
As the PEC/PNEC values are less than 1, an acceptable level of risk from the consumption of contaminated insects.

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 following proposed indoor and outdoor uses of this product.

PEC/PNEC ratios has been calculated for the intended use propose for the applicant.

Hence the authorisation of the product can be granted from an environmental fate and behaviour perspective.

2.2.10 Measures to protect man, animals and the environment

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

Handling:
Avoid contact with eyes and skin.

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

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

Trained professional uses:

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

Professional /General public (Non-professional uses):

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

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

Emergency measures to protect the environment:

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

Methods for cleaning up: Recover the product from the affected area with a wet disposable tissue and dispose of with domestic waste. . In case of spillage on water, avoid spreading by using appropriate barrier devices. The recovered product must be disposed according with local law. Contact with the competent authorities if the situation cannot be controlled.

2.2.11 Assessment of a combination of biocidal products

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

2.2.12 Comparative assessment

Comparative Assessment for the biocidal product "MAGNUM GEL HORMIGAS PLUS"
Background
The Spanish competent authority has been processing an application for a biocidal product, MAGNUM GEL HORMIGAS PLUS which contains an active substance, imidacloprid,

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

1.- Application administrative details:

Procedure: NA

Purpose: Authorisation

Case Number in R4BP: BC-BU010803-35

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 HORMIGAS PLUS

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

Table 3.1 List of intended uses of the biocidal product:

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

4.- Mapping of existing alternatives to the relevant BP

4.1.- Identified eligible alternative BPs

The product MAGNUM GEL HORMIGAS PLUS 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 26 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 ants: indoxacarb, spinosad, fipronil and deltamethrin.

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

The product based on indoxacarb is to be used indoor and outdoor by professional users so; this product is not considered as eligible alternative BP. Although the rest of the products banes on the others active substances, spinosad, fipronil and deltamethrin are for all users, any of them control all the species controlled by MAGNUM GEL HORMIGAS PLUS. So, there is no an alternative product for MAGNUM GEL HORMIGAS PLUS.

4.2.- Identified eligible non-chemical alternatives

Not relevant in the screening phase.

5.- Screening phase

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

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

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

Active substance/ mode of action combination

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).

Indoxacarb: upon ingestion by the insect, the indoxacarb is rapidly metabolized by the insect. The metabolized insecticide binds to the sodium channels within the insect, thus blocking sodium movement into the cell resulting in mild convulsions, paralysis and ultimately death. It belongs to class of pyrazoline like insecticide.

Spinosad: it is an insecticide that kills susceptible species by causing rapid excitation of the insect nervous system.

Fipronil: it is an insecticide acting both by contact and ingestion on the nervous system, blocking the GABA regulated chloride channel at very low doses. Its use causes uncontrolled nervous system activity and death of the exposed arthropods.

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 ants for indoor and outdoor use by non-professionals. This BP, MAGNUM GEL HORMIGAS PLUS, is the first product to be authorised for indoor and outdoor use by non-professionals to control ants in Spain. Even considering the product containing indoxacarb as alternative, the chemical diversity would be no adequate.

The comparative assessment is finalised at this stage. The product MAGNUM GEL HORMIGAS PLUS 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

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]

** 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** **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 either professionals or the general public during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63: 'the exposure due to the use of ant and cockroach bait stations is considered to be negligible. Accidents (swallowing, children who open bait stations) do not form a part of a standard assessment'). Therefore, human exposure 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 HORMIGAS PLUS by trained professional users

	Parameters	Value
Tier 1	Equivalence 0.5 cm gel [a]	18 mg product
	number of opening and sealing per day[b]	10
	content of active substance in product	0.01%
	Dermal absorption[c]	75 %
	Body weight adult[d]	60 kg

[a] Section 2.2.2, storage stability study: a line of 5 cm length of MAGNUM GEL HORMIGAS PLUS from a cartridge equals aprox. 180 mg of product.

[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 * 18 mg * 0.01% * 75%]/ 60 kg

Scenario 1: application of MAGNUM GEL HORMIGAS PLUS by professionals		Estimated Internal Exposure as [mg /kg bw/d]			
		Oral uptake	Inhalation uptake	Dermal uptake	Total uptake
Tier 1	**(no PPE)**	-	-	2.25E-04	2.25E-04

Scenario 2 Disposal of used cartridges by trained professional users

	Parameters	Value
Tier 1	Equivalence 0.5 cm gel [a]	18 mg product
	number of disposed cartridges per day [b]	1
	content of active substance in product	0.01%
	Dermal absorption[c]	75%
	Body weight adult[d]	60 kg

[a] *Section 2.2.2, storage stability study: a line of 5 cm length of MAGNUM GEL HORMIGAS PLUS from a cartridge equals aprox. 180 mg of product.*

[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 * 18 mg * 0.01% * 75%]/ 60 kg

Scenario 2: post application of MAGNUM GEL HORMIGAS PLUS by professionals		Estimated Internal Exposure as [mg /kg bw/d]			
		Oral uptake	Inhalation uptake	Dermal uptake	Total uptake
Tier 1	**(no PPE)**	-	-	2.25E-05	2.25E-05

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	-	2.48E-04	-	2.48E-04

Professional and Non-professional exposure

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

	Parameters	Value
Tier 1	Equivalence 0.5 cm gel [a]	18 mg product
	number of opening and sealing per day[b]	2
	content of active substance in product	0.01%
	Dermal absorption[c]	75 %
	Body weight adult[d]	60 kg

[a] *Section 2.2.2, storage stability study: a line of 5 cm length of MAGNUM GEL HORMIGAS PLUS from a syringe equals aprox. 180 mg of product.*

[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 * 18 mg * 0.01% * 75%]/ 60 kg

Scenario 3: application of MAGNUM GEL HORMIGAS PLUS by non-professionals		Estimated Internal Exposure as [mg /kg bw/d]			
		Oral uptake	Inhalation uptake	Dermal uptake	Total uptake
Tier 1	**(no PPE)**	-	-	4.50E-5	4.50E-5

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

	Parameters	Value
Tier 1	Equivalence 0.5 cm gel [a]	18 mg product

	number of syringe disposed of per event [b]	1
	content of active substance in product	0.01%
	Dermal absorption [c]	75 %
	Body weight adult [d]	60 kg

[a] *Section 2.2.2, storage stability study: a line of 5 cm length of MAGNUM GEL HORMIGAS PLUS from a syringe equals aprox. 180 mg of product.*

[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* 18 mg * 0.01% * 75%]/ 60 kg

Scenario 4: application of MAGNUM GEL HORMIGAS PLUS by non-professionals		**Estimated Internal Exposure as [mg /kg bw/d]**			
		Oral uptake	**Inhalation uptake**	**Dermal uptake**	**Total uptake**
Tier 1	**(no PPE)**	-	-	2.25E-5	2.25E-5

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	-	6.75E-5	-	6.75E-5

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 HORMIGAS PLUS 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 line 5 cm length 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	Equivalence of 5 cm length line of gel [a]	180 mg product
	number of lines contacted per event [b]	1
	Dislodged amount [b]	100%
	content of active substance in product	0.01%
	Dermal absorption [c]	75 %
	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 line of 5 cm length of MAGNUM GEL HORMIGAS PLUS from a syringe equals aprox. 180 mg of product*

[b] *worst case 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 line 5 cm length * dislodgeable residue * fraction of a.s. in the product*

EDL = 180 mg * 100% * 0.01% = 0.018 mg active substance

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

*Estimated dermal uptake = (0.018 mg * 75%)/ 10 kg*

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

*Estimated oral uptake = [0.018 * 50% * 100%] / 10 kg*

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**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [7] dermal and hand to mouth contact with gel/ Toddler	1/none	-	1.35E-03	9.0E-04	2.25E-03

DETAILS OF PEC CALCULATIONS

Calculations for Scenario 1

Soil

INPUTS		**Value**	**Unit**	**Origin**
Local direct emission rate of active substance to soil	$E_{spot,soil}$	0.000018	g	D
Area directly exposed to insecticide - Single point of release	$AREA_{exposed}$	0,5	m²	S
Depth of exposed soil	$DEPTH_{soil}$	0.5	m	D
Density of exposed soil RHO	RHO_{soil}	1,700	$kg.m^{-3}$	D

$PECloca l_{SOIL}$ = $C_{SPOT,SOIL}$ = $E_{spot,soil}$ **/ (**$AREA_{exposed}$ **x** $DEPTH_{soil}$ **x** RHO_{soil} **10^{-3})**

PEC_{SOIL}=	**$Clocal_{inf}$**	0,0000423	mg. kg^{-1}	O

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

INPUTS		Value	Unit	Origin
Predicted environmental conc. in soil	$PEClocal._{soil}$	0,0000423	$mg.kg^{-1}$	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)

$PEClocal_{grw}$ =	**$PEClocal_{agr.soil,\ porewater}$**	1,012E-05	$mg.L^{-1}$	O

Calculations for Scenario 2

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

INPUTS		Value	Unit	Origin
Local emission rate to wastewater	$Elocal_{water}$	0,0000405	$kg.d^{-1}$	D
Effluent discharge rate of STP (34)	$EFFLUENT_{STP}$	2000000	$l.d^{-1}$	eq. (34)

PEC_{STP}=	**$Clocal_{inf}$**	0,00002025	$mg.L^{-1}$	O

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

INPUTS		Value	Unit	Origin
Concentration in untreated wastewater	$Clocal_{inf}$	0,00002025	$mg.L^{-1}$	eq. (32)
Fraction of emission directed to water by STP	$Fstp_{water}$	0,972	-	EUSES

$Clocal_{eff}$	0,000019683	$mg.L^{-1}$	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

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

INPUTS		**Value**	**Unit**	**Origin**
Concentration of the substance in the STP effluent	$Clocal_{eff}$	1,97E-05	$mg.L^{-1}$	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

$PEClocal_{water}$=	**$Clocal_{water}$**	1,967E-06	$mg.L^{-1}$	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)

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

INPUTS		**Value**	**Unit**	**Origin**
Concentration in surface water during emission episode	**$PEClocal_{water,skin}$**	1,96762E-06	$mg.L^{-1}$	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)

$PECloca l_{sed}$=	1,1378E-05	mg. kg^{-1}	O

Soil

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

(despreciamos emisiones al aire)

INPUTS		**Value**	**Unit**	**Origin**
Averaging time	T	180	d	Table 11
First order rate constant for removal from top soil	k	0,023442934	d^{-1}	eq. (56)
Initial concentration after 10 years	$C_{agr.soil\ 10}(0)$	2,34E-06	mg. kg^{-1}	eq. (63)

$PECloca l_{agr.soil}$=	**$Cloca l_{agr.soil}$**	5,46586E-07	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	$PECloca l_{agr.soil}$	5,46586E-07	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)

$PECloca l_{grw,skin}$ =	**$PECloca l_{agr.soil,\ porewater,skin}$**	1,30873E-07	mg.L^{-1}	O

Calculations 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

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

INPUTS		Value	Unit	Origin
Local emission rate to wastewater	$Elocal_{water}$	1,77E-07	kg. d^{-1}	D
Effluent discharge rate of STP (34)	$EFFLUENT_{STP}$	2000000	$l.d^{-1}$	eq. (34)

PEC_{STP}=	**$Clocal_{inf}$**	8,87E-08	mg. L^{-1}	O

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

INPUTS		Value	Unit	Origin
Concentration in untreated wastewater	$Clocal_{inf}$	8,86938E-08	mg. L^{-1}	eq. (32)
Fraction of emission directed to water by STP	$Fstp_{water}$	0,972	-	EUSES

$Clocal_{eff}$		8,62E-08	mg. L^{-1}	O

Surface water

$K_{p,susp} = Foc_{susp} \times K_{oc}$ **(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

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

INPUTS		Value	Unit	Origin
Concentration of the substance in the STP effluent	$Clocal_{eff}$	8,62E-08	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

$PEClocal_{water}$=	**$Clocal_{water}$**	8,62E-09	mg. L^{-1}	O

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)

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

INPUTS		**Value**	**Unit**	**Origin**
Concentration in surface water during emission episode	**$PEClocal_{water}$**	8,61806E-09	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)

$PEClocal_{sed}$=	4,98E-08	mg. kg^{-1}	O

Soil

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

(despreciamos emisiones al aire)

INPUTS		**Value**	**Unit**	**Origin**
Averaging time	T	180	d	Table 11
First order rate constant for removal from top soil	k	0,005468651	d^{-1}	eq. (56)

Initial concentration after 10 years	$C_{agr.soil\ 10}$ (0)	1,18626E-08	mg. kg^{-1}	eq. (63)

$PECloca l_{agr.soil}$=	**$Cloca l_{agr.soil}$**	7,54788E-09	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	$PECloca l_{agr.soil}$	7,54788E-09	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)

$PECloca l_{grw}$ =	**$PECloca l_{agr.soil,\ porewater,skin}$**	1,80724E-09	mg. L^{-1}	O

Calculations for Scenario 6

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

INPUTS		Value	Unit	Origin
Local emission rate to wastewater	$Elocal_{water}$	4,61E-05	$kg.d^{-1}$	D
Effluent discharge rate of STP (34)	$EFFLUENT_{STP}$	2000000	$l.d^{-1}$	eq. (34)

PEC_{STP}=	**$Clocal_{inf}$**	2,31E-05	$mg.L^{-1}$	O

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

INPUTS		Value	Unit	Origin
Concentration in untreated wastewater	$Clocal_{inf}$	2,3064E-05	$mg.L^{-1}$	eq. (32)
Fraction of emission directed to water by STP	$Fstp_{water}$	0,972	-	EUSES

$Clocal_{eff}$	2,24E-05	$mg.L^{-1}$	O

Surface water

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

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

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

INPUTS		Value	Unit	Origin
Concentration of the substance in the STP effluent	$Clocal_{eff}$	2,24E-05	$mg.L^{-1}$	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

$PEClocal_{water}$=	**$Clocal_{water}$**	2,24E-06	$mg.L^{-1}$	O

		^{1}	

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)

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

INPUTS		**Value**	**Unit**	**Origin**
Concentration in surface water during emission episode	**$PEClocal_{water,skin}$**	2,24104E-06	$mg.L^{-1}$	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)

$PEClocal_{sed}$=	1,30E-05	$mg.kg^{-1}$	O

Soil

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

(despreciamos emisiones al aire)

INPUTS		**Value**	**Unit**	**Origin**
Averaging time	T	180	d	Table 11
First order rate constant for removal from top soil	k	0,00268768	d^{-1}	eq. (56)
Initial concentration after 10 years	$C_{agr.soil\ 10}(0)$	4,26434E-06	$mg.kg^{-1}$	eq. (63)

$PEClocal_{agr.soil}$=	**$Clocal_{agr.soil}$**	3,38085E-06	$mg.kg^{-1}$	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	$PECloca l_{agr.soil}$	3,38085E-06	$mg.kg^{-1}$	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)

$PECloca l_{grw,skin}$ =	**$PECloca l_{agr.soil,\ porewater,skin}$**	8,095E-07	$mg.L^{-1}$	O

3.3 New information on the active substance

New information on the active substance has not been submitted.

3.4 Residue behaviour

MAGNUM GEL HORMIGAS PLUS provides control against ants (Product Type 18).

Active substance(s): Imidacloprid 0.01% w/w

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

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

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

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

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

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

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

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

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

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

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

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

3.6 Confidential annex

See Confidential PAR