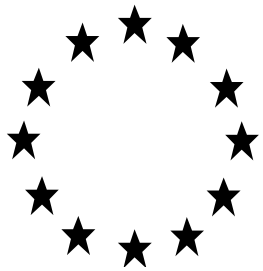
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



MAGNUM GEL HORMIGAS IGR PLUS

Product type 18

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

Case Number in R4BP: BC-XK019347-22

Evaluating Competent Authority: Spain

Date: December 2021

Overview of applications

Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	ES	BC-XK019347-22	May 2015	Initial assessment
NA-APP	ES	ES-0015195-0000	August 2021	First authorisation
NA-AAT	ES	ES-0015195-0000	August 2021	Amendment
NA-AAT	ES	ES-0015195-0000	September 2021	Amendment. Removal of Frech trade names.
NA-ADC	ES	ES-0015195-0000	December 2021	Amendment. 1. Addition Spanish trade names. 2. Replacement source Imidacloprod active substance.

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1 CONCLUSION

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

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

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

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

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

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

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

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

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

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

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

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

Risk assessment for the environment

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

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

Comparative assessment

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

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

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 IGR PLUS EC GEL HORMIGAS IGR X GEL IGR HORMIGAS	Spain
MAGNUM GEL ANTS IGR MIRMEX GEL	Italy
MAGNUM GEL ANTS IGR	Hungary
MAGNUM GEL ANTS IGR	Poland
MAGNUM GEL ANTS IGR	UK
MAGNUM GEL ANTS IGR PLUS	Bulgaria
MAGNUM GEL AMEISEN IGR	Austria
MAGNUM GEL AMEISEN IGR	Germany
MAGNUM GEL FOURMIS IGR	France

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Mylva S.A.
	Address	Via Augusta, 48 08006 Barcelona, Spain
Authorisation number	ES/APP(NA)-2021-18-00768	
Date of the authorisation	05/08/2021	
Expiry date of the authorisation	05/08/2026	

2.1.1.3 Manufacturer of the product

Name of manufacturer	Mylva S.A.
Address of manufacturer	Via Augusta, 48 08006 Barcelona, Spain
Location of manufacturing sites	C/ Sant Galderic 23, Poligon industrial ponent, 08395 Sant Pol de Mar Barcelona, Spain

2.1.1.4 Manufacturers of the active substances

Active substance	**Imidacloprid**
Name of manufacturer	ADAMA AGRICULTURE ESPAÑA S.A.
Address of manufacturer	Príncipe de Vergara 110-5ª, 28002 Madrid Spain

Location of manufacturing sites 1	Alte Heerstr D-41538 Dormagen (Germany)
Location of manufacturing sites 2	Jiangsu Yangnong Chemicals Group Co. Ltd - 39 Wenfeng Road, 225009 Yangzhou (China)

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

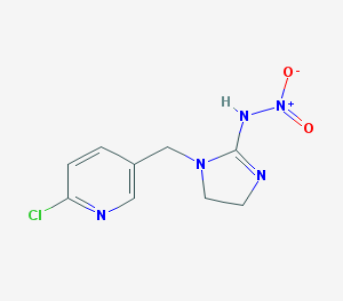
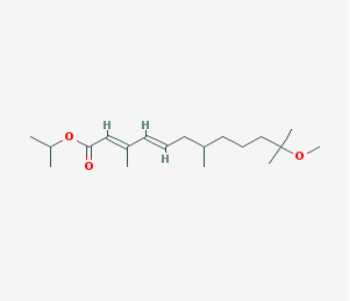
2.1.2 Product compoition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate for sustitution

The active substance imidacloprid fulfills the criteria for substitution under Article 10 of Regulation (EU) 528/2012, notably it meets two of the criteria for being PBT in accordance

with the Annex XIII to Regulation (EC) No 1907/2006. An evaluation of comparative assessment has been carried out.

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

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

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

2.1.2.4 Information on technical equivalence

The manufacturer of the active substances and the manufacturing site of the active substances used in the biocidal product are identical to the manufacturer of the active substances and the production site of the active substances included in Annex I of Directive 98/8/EC. Therefore no check for equivalence is necessary.
December 2021 – Replacemnet source of Imidacloprid: Bayer CropScience AG by ADAMA Agriculture España S.A.T.
ADAMA Agriculture España sources have been granted technically equivalent to the Annex I source by ECHA (Decision Nº TAP-D-1096667-13-00/F and decision Nº TAPD-1099666-08-00/F).

2.1.2.5 Information on the substances of concern

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

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

RB – Bait (ready for use)

2.1.3 Hazard and precautionary statements

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

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

2.1.4 Authorised uses

2.1.4.1 Use description 1

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

Product Type	PT18.
Where relevant, an exact description of	Insecticide against ants.

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

2.1.4.1.1 Use-specific instructions for use

Use only indoor.

Apply the biocidal product in restricted area as spot application behind furniture and engines. It is recommended to wash the hands before using the bait, to avoid contamination with offensive odors such as tobacco, etc...

No spraying or misting chemicals near the areas where MAGNUM GEL HORMIGAS IGR PLUS is applied, they can contaminate and make inappetent for ants.

Do not apply on porous surfaces. In case where it is not possible apply the product on a plastic sheet Do not apply in areas recently treated with another insecticide.

2.1.4.1.2 Use-specific risk mitigation measures

Avoid contact with eyes and skin.

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 2.1.5.6

2.1.4.2 Use description 2 (NOT RELEVANT FOR SPAIN)

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

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

	350, 400, 450 and 500 g of gel bait. LDPE syringe of 1, 2, 3, 4, 5,6, 7, 8,9, 10,15,20,25,30,35,40 and 50 g of gel bait.

2.1.4.2.1 Use-specific instructions for use

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

2.1.4.2.2 Use-specific risk mitigation measures

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

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 2.1.5.6

2.1.4.3 Use description 3.

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

Product Type	PT18.
Where relevant, an exact description of the authorised use	Insecticide against ants.

Target organism (including development stage)	Insecticide against the following target insects (adults): • Argentine ants (*Linepithema humile*), • Black ants (*Lasius niger*).
Field of use	Indoors. Residential, industrial, public and commercial or institutional buildings.
Application method	Ready-to-use bait stations.
Application rate and frequency	Dose: 0.3-0.6 g/m^2, depending on the infestation level, preferably divided in several bait stations for better efficacy For example, place 2 to 3 bait stations (with 5-15 g of bait in all) per 25 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. Maximum of 8 applications per year.
Categoryies of users	General Public (non-professional user) Professional Trained professional
Pack sizes and packaging material	*General public and professional users:* Plastic bait stations with 1, 2, 3, 4, 5 and 6 g of gel bait. *Trained professional user:* Plastic bait stations with 1, 2, 3, 4, 5, 6, 8, 10, 15, 20, 25 30 and 60g of gel bait.

2.1.4.3.1 Use-specific instruction for use.

Gel bait in transparent traps (bait stations).

Place the bait stations in areas (indoors) where ants are present near the ant trails or nests.

Inspect frequently the point of applications and place a new bait station if the bait has been consumed and the infestation is not controlled yet.

2.1.4.3.2 Use-specific mitigation measures.

The stations should not be manipulated after opening.

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

Remove bait stations at the end of the treatment.

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.4.4 Use description 4.

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

Product Type	PT18.
Where relevant, an exact description of the authorised use	Insecticide against *Linephitema humile*. (adults)
Target organism (including development stage)	• Argentine ants (*Linepithema humile*),
Field of use	Outdoors (around buildings, terraces…): near ant trails or nests on paved surfaces.
Application method	Ready-to-use bait stations.
Application rate(s) and frequency	Dose: 0.2-0.6 g/m^2, depending on the infestation level, preferably divided in several bait stations for better efficacy. For example, place 2 to 3 bait stations (with 5-15 g of bait in all) per 25 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. Maximum of 8 applications per year.
Category of users	Trained professional users
Pack sizes and packaging material	Plastic bait stations with 1, 2, 2.5, 3, 4, 5, 6, 8, 10, 15, 20, 25 and 30 g of bait.

2.1.4.4.1 Use-specific instruction for use.

Gel bait in transparent traps (bait stations). Place the bait stations in areas (outdoors) where ants are present near the ant trails or nests. Place the bait stations only on paved surfaces and in places where are protected from rainfall events to avoid release of the product into the environment and in places to

avoid exposure to direct sunlight.

Outdoor use (terraces, patios, backyards or gardens), apply MAGNUM GEL HORMIGAS IGR PLUS places where it is more likely to find ants.

Inspect frequently the point of applications and place a new bait station if the bait has been consumed and the infestation is not controlled yet.

2.1.4.4.2 Use-specific mitigation measures.

The stations should not be manipulated after opening.

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

Remove bait stations at the end of the treatment.

Put the bait stations only in places where they are protected from rainfall events to avoid release of the product into the environment.

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

See section 2.1.5.3

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

See section 2.1.5.4

2.1.4.4.5 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

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

After extensive inspection to determine the infestation level (low or high), place the bait points where ants are detected.

Remove alternative food source that may be in competition from near areas.

The product has shown an efficacy of more than 90% mortality of adult ants within 15 days.

This biocidal product contains imidacloprid which is dangerours to bees.

2.1.5.2 Risk mitigation measures

Keep away from heat, open flames and sparks.

Do not mix with other chemicals.

Do not use on wood or porous surfaces.

Avoid contact with treated surfaces.

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

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

Use products at recommended doses and intervals.

Use only in areas inaccessible to children and animals
Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.

Trained professional uses:
- -Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc).
- -Do not apply the product in areas where resistance to the active substance (s) contained in this product is suspected or established.

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

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 SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

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

IF MEDICAL ADVICE IS NEEDED, KEEP THE LABEL OR CONTAINER HANDY AND CONSULT THE MEDICAL SERVICE FOR TOXICOLOGICAL INFORMATION
Telephone: (please include the telephone number of each country)
To include this telephone number on the label, you must notify the INTCF in accordance with the procedure established in Order JUS / 909/2017.

Emergency measures to protect the environment:
Environmental Precautions: Avoid contamination of drains, surface and groundwater as well as soil.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Trained professionals:

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.

Code the waste according to Decision 2014/955 / EU.

Do not release to soil, ground, surface water or any kind of sewer.

General public and professionals:

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.

Do not release to soil, ground, surface water or any kind of sewer.

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 4 years under normal conditions of storage.

Protect from frost.

Store in the original container tightly closed.

Store in a dry , cool and well-ventilated place.

It is recommended to store the product at a temperature preferably between 5ºC and 45ºC.

Store away from light.

Keep out of reach of children and non-target animals/pets.

2.1.6 Other information

According to national legislation, in Spain there are until three user categories:

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

At the same time, there are also some restrictions of packaging in relation to those user categories and product types.

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

The applicant must ensure that the general public can understand the difference between species and the level of infestation for correct use of the dose.

The drops should have 0.2 g of gel bait. The applicant should indicate in the label the size of a drop with 0.2 g of product.

The number of bait stations should be indicated in the label depending on the amount of product included in the bait station. E.g. 0.2 g/m^2 = 1 bait station with 5 g in a room of 25 m^2.

For trained professional only:
The users should inform if the treatment is ineffective and report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

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)
Cartridge	1, 2, 3, 4, 5, 6, 7, 8,9, 10, 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 125, 150, 175, 200,250,300,350, 400, 450 and 500 g	LDPE	Plastic	Trained Professional	Yes
Syringe	1, 2, 3, 4, 5, 6, 7, 8, 9, 10 g	LDPE	Plastic	General public and professional	Yes
	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 50 g	LDPE	Plastic	Trained professional	
Bait station	1, 2, , 3, 4, 5, 6 g	LDPE	Plastic	General public Professional	Yes
	1, 2,2.5, 3, 4, 5, 8, 10, 15, 20, 25, 30 g	LDPE	Plastic	Trained Professional	

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the biocidal product described within this application.
The reference list (including updates) for the studies submitted in support of the BPD dossier has been included in Annex 3.1 whilst the reference list for the studies considered confidential has been included in the Confidential PAR.

2.1.8.2 Access to documentation

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

The applicant has provided the Physical, Chemical and Technical Properties of the biocidal product for supporting the Physical hazards and respective characteristics.
The applicant has provided the suitable analytical methods for identifying the active substances in the biocidal product.
The applicant has also provided the rest of analytical methods. This information is complementary to the included data in the Competent Authority Reports on the active

substances Imidacloprid and S-Methoprene supported by Bayer SAS and Babolna Bioenvironmental Centre Ltd. respectively.

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

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

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

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant

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

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Imidacloprid 0.01 % and 0.08% S-Methoprene Gel is an indoor an outdoor gel bait insecticide against Monoronium Pharaonis, Linepithema Humile and Lasius Niger. Imidacloprid 0.01% and 0.08% S-methoprene Gel is designed for the controlled placement of bait in the following situations: -User: Trained professional, Non-trained professional and general public (Nonprofessional).
Target organism (including development stage)	Monomorium Pharaonis-Adults, Nymphs-Pharaoh Ant Linepithema Humile-Adults, Nymphs-Argentine Ant Lasius Niger-Adults, Nymphs-Black Ant
Field of use	Indoor Outdoor Other
Application method	Bait application - Indoor use: Place spots or lines of gel or baitstation near ant trails, or where ants have been seen, in their nests, or in the areas where ants are detected. Places where it is more probable to find ants are: hollowwalls, kitchen, bathrooms, sinks, windowsills, ventilation grilles, garages, attics, etc. Outdoor use: Place gel inside their nests, or place gel or bait station next to ant trails and where ants are detected, avoiding sunlight sothat the gel does not dry. Places where it is more probable to find ants are: eaves, cornices, draining holes,where cables and pipes enter the building structure, trees, stumps, roots, wood roofs, fences, plant pots,

	etc.Place on windowsills and doorways to avoid ant entering houses or buildings.After some days, inspect application points and repeat treatment if necessary until total colony control isachieved. Get rid of other near sources of food that could compete with the bait.
Application rates and frequency	Cartridge and syringe : Apply spots or lines of Gel on infested areas. Use 1-3 lines per bait placement. / Bait station: 5g/25m^2 - 0 - Check the baits and replace the consumed ones daily during treatment.
Category of users	Trained professional
Pack sizes and packaging material	Three packaging are of plastic material. Cartridge and syringe are provided with a security cap. Cartridge: -Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450 and 500 g. Syringe: -Size: 1, 2, 3, 4, 5, 6, 7, 8,9, 10,15, 20, 25, 30, 35, 40, 50 g. Bait station: -Size: 1, 2, 2.5, 3, 4, 5, 8, 10, 15, 20, 25, 30 g.

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

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Imidacloprid 0.01 % and 0.08% S-Methoprene Gel is an indoor an outdoor gel bait insecticide against Monoronium Pharaonis, Linepithema Humile and Lasius Niger. Imidacloprid 0.01% and 0.08% S-methoprene Gel is designed for the controlled placement of bait in the following situations: -User: Trained professional, Non-trained professional and general public (Nonprofessional).
Target organism (including development stage)	Monomorium Pharaonis-Adults, Nymphs-Pharaoh Ant Linepithema Humile-Adults, Nymphs-Argentine Ant Lasius Niger-Adults, Nymphs-Black Ant
Field of use	Indoor Outdoor Other
Application method	Bait application - Indoor use: Place spots or lines of gel or baitstation near ant trails, or where ants have been seen, in their nests, or in the areas where ants are detected. Places where it is more probable to find ants are: hollowwalls, kitchen , bathrooms, sinks, windowsills, ventilation grilles, garages, attics, etc. Outdoor use: Place gel inside their nests, or place gel or bait station next to ant trails and where ants are detected, avoiding sunlight sothat the gel does not dry. Places where it is more probable to find ants are: eaves, cornices,

	draining holes,where cables and pipes enter the building structure, trees, stumps, roots, wood roofs, fences, plant pots, etc.Place on windowsills and doorways to avoid ant entering houses or buildings.After some days, inspect application points and repeat treatment if necessary until total colony control isachieved. Get rid of other near sources of food that could compete with the bait.
Application rates and frequency	Cartridge and syringe : Apply spots or lines of Gel on infested areas. Use 1-3 lines per bait placement. / Bait station: 5g/25m^2 - 0 - Check the baits and replace the consumed ones daily during treatment.
Category of user	Professional
Pack sizes and packaging material	Three packaging are of plastic material. Cartridge and syringe are provided with a security cap. Cartridge: -Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450 and 500 g. Syringe: -Size: 1, 2, 3, 4, 56, 7, 8, 9, 10,15, 20, 25, 30, 35, 40, 50 g. Bait station: -Size: 1, 2, 2.5, 3, 4, 5, 8, 10, 15, 20, 25, 30 g.

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

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Imidacloprid 0.01 % and 0.08% S-Methoprene Gel is an indoor an outdoor gel bait insecticide against Monoronium Pharaonis, Linepithema Humile and Lasius Niger. Imidacloprid 0.01% and 0.08% S-methoprene Gel is designed for the controlled placement of bait in the following situations: -User: Trained professional, Non-trained professional and general public (Nonprofessional).
Target organism (including development stage)	Monomorium Pharaonis-Adults, Nymphs-Pharaoh Ant Linepithema Humile-Adults, Nymphs-Argentine Ant Lasius Niger-Adults, Nymphs-Black Ant
Field of use	Indoor Outdoor Other
Application method(s)	Bait application - Indoor use: Place spots or lines of gel or baitstation near ant trails, or where ants have been seen, in their nests, orin the areas where ants are detected. Places where it is more probable to find ants are: hollowwalls, kitchen , bathrooms, sinks, windowsills, ventilation grilles, garages, attics, etc. Outdoor use: Place gel inside their nests, or place gel or bait station next to ant trails and where ants are detected, avoiding sunlight so that the gel does not dry. Places

	where it is more probable to find ants are: eaves, cornices, draining holes,where cables and pipes enter the building structure, trees, stumps, roots, wood roofs, fences, plant pots, etc. Place on windowsills and doorways to avoid ant entering houses or buildings.After some days, inspect application points and repeat treatment if necessary until total colony control isachieved. Get rid of other near sources of food that could compete with the bait.
Application rate(s) and frequency	Cartridge and syringe : Apply spots or lines of Gel on infested areas. Use 1-3 lines per bait placement. / Bait station: 5g/25m^2 - 0 - Check the baits and replace the consumed ones daily during treatment.
Category of user	General public (non-professional)
Pack sizes and packaging material	Three packaging are of plastic material. Cartridge and syringe are provided with a security cap. Cartridge: -Size: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 50, 60, 75, 80, 100, 125, 150, 175, 200, 250, 300, 350, 400, 450 and 500 g. Syringe: -Size: 1, 2, 3, 4, 5, 6, 7, 8, 9,,10,15, 20, 25, 30, 35, 40, 50 g. Bait station: -Size: 1, 2, 2.5, 3, 4, 5, 8, 10, 15, 20, 25, 30 g.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	US EPA Product Properties Test Guidelines: OPPTS 830.6303 Physical State [EPA 712-C-96-020].	0.01% (Imidacloprid) 0.08% (S-methoprene) Batch J709	Initially: Gel After 14 days at 54ºC: Gel After 17, 24, 36 & 48 months at 25ºC: Gel.	Final Report AGQ E-15/0003
Colour at 20 °C and 101.3 kPa	US EPA Product Properties Test Guidelines: OPPTS 830.6302 Color [EPA 712-C-96-019].	0.01% (Imidacloprid) 0.08% (S-methoprene) Batch J709	Initially: 10Y8/6 – yellowish traslucent After 14 days at 54ºC: 7.5YR5/10 - brown After 17, 24, 36 & 48 months at 25ºC: 10Y8/6 – yellowish traslucent	Final Report AGQ E-15/0003
Odour at 20 °C and 101.3 kPa	US EPA Product Properties Test Guidelines: OPPTS 830.6304 Odor [EPA 712-C-96-021].	0.01% (Imidacloprid) 0.08% (S-methoprene) Batch J709	Initially: Odourless After 14 days at 54ºC: Odourless After 17, 24, 36 & 48 months at 25ºC: Odourless.	Final AGQ E-15/0003
Acidity / alkalinity	Standard Methods for drinking water and wastewater, ALPHA-AWWA-WPCF, Edition 17th. CIPAC MT 75 "Determination of pH Values" Handbook F, p 205, 1995. Free acidity or alkalinity. MT 31. Collaborative International Pesticides	0.01% (Imidacloprid) 0.08% (S-methoprene) Batch J709	Not required.	Final Report AGQ E-15/0003

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
	Analytical Council Limited (CIPAC) handbook. Volume F.			
Relative density / bulk density	European Union EEC Method A.3. Pycnometer method. Council Regulation (EC) No 440/2008, of 30 May 2008, laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).	0.01% (Imidacloprid) 0.08% (S-methoprene) Batch J709	1.3046 ±0.0003 g/mL	Final Report AGQ E-15/0003
Storage stability test – **accelerated storage**	CIPAC Guideline MT46.3 "Accelerated Storage Procedure"	0.01% (Imidacloprid) 0.08% (S-methoprene) Batch J709	No change in physical conditions, colour or odour of the product was observed. Also there was no change in the packaging.	Final Report AGQ E-15/0003
Active Ingredient Content	HPLC-MS (analytical method has been successfully validated)		IMIDACLOPRID Initially: **0.0098 ± 0.0004 % w/w** After storage at 54 °C for 14 days: **0.0093 ± 0.0004 % w/w** Diference: -5.10% S-METHOPRENE Initially: **0.0845 ± 0.0055 % w/w** After storage at 54 °C for 14 days:	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			0.0832 ± 0.0025 % w/w Difference: -1.54%	
Homogeneity of application			The application system in both the syringe and the application gun for the cartridge container allow a precise and homogeneous application of the product in the form of drops of the same size and weight	
Appearance and stability of the package			There was no change in the packaging (LDPE)	
pH	Standard for Analysis of Water and Wastewater, ALPHAAWWA-WPCF, Edition 17th. CIPAC MT 75.3 "Determination of pH Values" Handbook F, p 205, 1995.		Initially: pH = 6.62 ± 0.01 After storage at 54 °C for 14 days: pH = 6.27 ± 0.01	
Storage stability test – **long term storage at ambient temperature**	Guidelines for Specifying the Shelf Life of Plant Protection Products (Technical Monograph number 17, 2nd edition)	0.01% (Imidacloprid) 0.08% (S-methoprene) Batch J709	The formulation is stable for 4 years stored at ambient temperature.	Final Report AGQ E-15/0003
Active Ingredient Content	HPLC-MS (analytical method has been successfully validated)		IMIDACLOPRID Initially: **0.0098 ± 0.0004 % w/w** After storage at 25 °C for 12 months: **0.0098 ± 0.0003 % w/w** Diference: 0.00% After storage at 25 °C for 24 months: **0.0095 ± 0.0002 % w/w** Diference: 3.06% After storage at 25 °C for 36 months:	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			0.0097 ± 0.0002 % w/w Difference: 1.02% After storage at 25 °C for 48 months: **0.0096 ± 0.0002 % w/w** Difference: -2.04% S-METHOPRENE Initially: **0.0845 ± 0.0055 % w/w** After storage at 25 °C for 12 months: **0.0848 ± 0.0040 % w/w** Difference: +0.36% After storage at 25 °C for 24 months: **0.0846 ± 0.0011 % w/w** Difference: 0.12% After storage at 25 °C for 36 months: **0.0802 ± 0.0040 % w/w** Difference: -5.09% After storage at 25 °C for 48 months: **0.085 ± 0.0009 % w/w** Difference: 1.02%	
Homogeneity of application			The application system in both the syringe and the application gun for the cartridge container allow a precise and homogeneous application of the product in the form of drops of the same size and weight	
Appearance and stability of the package			There was no change in the packaging (LDPE)	
pH	Standard for Analysis of Water and Wastewater, ALPHAAWWA-WPCF, Edition 17th. CIPAC MT 75.3		Initially: pH = 6.62 ± 0.01 After storage at 25 °C for 17 months: pH = 6.31 ± 0.02	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
	"Determination of pH Values" Handbook F, p 205, 1995.		After storage at 25 °C for 24 months: pH = 6.39 ± 0.02 After storage at 25 °C for 36 months: pH = 6.57 ± 0.02 After storage at 25 °C for 48 months: pH = 6.12 ± 0.01	
Storage stability test – **low temperature stability test for liquids**			Not applicable	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Not relevant.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			The formulation is stable for 4 years stored at ambient temperature.	Final Report AGQ E-15/0003
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The formulation is stable for 4 years stored at ambient temperature.	Final Report AGQ E-15/0003
Wettability			Not relevant. Not applicable as the product is a GL.	
Suspensibility, spontaneity and dispersion stability			Not relevant. Not applicable as the product is a GL.	
Wet sieve analysis and dry sieve test			Not relevant. Not applicable as the product is a GL.	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Emulsifiability, re-emulsifiability and emulsion stability			Not relevant. Not applicable as the product is a GL.	
Disintegration time			Not relevant. Not applicable as the product is a GL.	
Particle size distribution, content of dust/fines, attrition, friability			Not relevant. Not applicable as the product is a GL.	
Persistent foaming			Not relevant. Not applicable as the product is a GL.	
Flowability/Pourability/Dustability			Not relevant. Not applicable as the product is a GL.	
Burning rate — smoke generators			Not applicable	
Burning completeness — smoke generators			Not applicable	
Composition of smoke — smoke generators			Not applicable	
Spraying pattern — aerosols			Not applicable	
Other technical characteristics				
Determination whether a material is liquid or solid	ASTM D 4359-90	0.01% (Imidacloprid) 0.08% (S-methoprene) Batch J709	Biocidal product is a liquid.	Interim Report M PG007-14/05
Physical compatibility			Not relevant.	
Chemical compatibility			Not relevant.	
Degree of dissolution and dilution stability			Not applicable	
Surface tension	European Union EEC Method A.5. Ring Method – Council Regulation (EC) No 440/2008, of 30 May 2008, laying down test methods pursuant to	0.01% (Imidacloprid) 0.08% (S-methoprene) Batch J709	43.8 ± 0.4 mM/m Therefore the sample is classified as a surface-active material.	Final Report AGQ E-15/0003

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
	Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Chemistry and Physics, CRC Handbook (75th Edition). "Surface Tension of Aqueous Solutions". OECD Guideline for the testing of chemicals 115. 27 July 1995.			
Viscosity	"Viscosity of liquids". OECD Guideline for testing of chemicals 114. 12 May 1981.	0.01% (Imidacloprid) 0.08% (S-methoprene) Batch J709	Initially: 86052 mPa.s at 20 °C and 4 rpm. 67542 mpa.s at 20ºC and 6 rpm 46515 mpa.s at 40 °C and 4 rpm 35796 mPa.s at 40ºC and 6 rpm After 14 days at 54ºC: 53233 mPa.s at 20 °C and 4 rpm. 41673 mpa.s at 20ºC and 6 rpm 30644 mpa.s at 40 °C and 4 rpm 24565 mPa.s at 40ºC and 6 rpm After 17 months at 25ºC: 100832 mPa.s at 20 °C and 4 rpm. 80584 mpa.s at 20ºC and 6 rpm 62771 mpa.s at 40 °C and 4 rpm 56978 mPa.s at 40ºC and 6 rpm After 24 months at 25ºC: 100878 mPa.s at 20 °C and 4 rpm. 86996 mpa.s at 20ºC and 6 rpm 68832 mpa.s at 40 °C and 4 rpm	Final Report AGQ E-15/0003

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			52967 mPa.s at 40ºC and 6 rpm After 36 months at 25ºC: 71892 mPa.s at 20 °C and 4 rpm. 58043 mpa.s at 20ºC and 6 rpm 62776 mpa.s at 40 °C and 4 rpm 40338 mPa.s at 40ºC and 6 rpm After 48 months at 25ºC: 73518 mPa.s at 20 °C and 4 rpm. 58133 mpa.s at 20ºC and 6 rpm 61884 mpa.s at 40 °C and 4 rpm 40227 mPa.s at 40ºC and 6 rpm	

Conclusion on the physical, chemical and technical properties of the product

NOTE: The applicant has declared that the composition of all batches used in the dossier is the same as the composition to be marketed.
Batch J709 - due to Mylva's long experience in design, development and manufacture of gel-based formulations, the stability of the product at room temperature for 4 years has been established by previous stability tests.

Appearance
Magnum Gel Hormigas IGR Plus is a colourless practically odourless gel.

Acidity / alkalinity
No acidity/alkalinity has been reported as pH of sample is within the range 4-10.

pH
pH of a 1% w/v dilution.

Relative density / bulk density
The relative density of the biocidal product at 20ºC was determined according to EU Method A.3 (relative density), CIPAC MT 3.3.2 and Calculation under GLP. The determined relative density is 1.3046 ± 0.0003. The key study is supported by weight of evidences data from internal quality control that was adquired under GLP conditions.

Storage stability test – accelerated storage
After the inspection, no change in physical conditions, colour or odour of the product was observed.
The data obtained in the simulation study of stability through accelerated storage indicate that the variation of the active ingredients contents (Imidacloprid and S-Methoprene) on MAGNUM GEL HORMIGAS IGR PLUS product after 14 days in the oven at 54 ± 2ºC were -5.10% and 1.54% respectively according to the data at t=0 days and at t=14 days.
These results are within the range indicated in the Study for both active ingredients, according to "Guidelines for Specifying the Shelf Life of Plant Protection Products. Technical Monograph n°17, 2nd Edition".

Storage stability test – long term storage at ambient temperature
After the inspection, no change in physical conditions, colour or odour of the product was observed.
The data obtained at t=0 days and t=48 months during the long term storage study indicate that the variation of the active ingredients contents (Imidacloprid and S-Methoprene) on MAGNUM GEL HORMIGAS IGR PLUS product after 48 months in the incubator at 25 ± 2ºC was -2.04 % and 1.02% w/w, respectively.
These results are within the range indicated in the Study for both active ingredients, according to "Guidelines for Specifying the Shelf Life of Plant Protection Products. Technical Monograph n°17, 2nd Edition".

Storage stability test – low temperature stability test for liquids
The biocidal product is a Liquid. Therefore, if this study is not submitted the phrase 'protect from frost' must be included in the label.

Effects on content of the active substance and technical characteristics of the biocidal product - light
Not relevant. Product is stored away from light.

Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity & reactivity towards container material
Temperature and humidity were monitored throughout storage. The product had approximately the same appearance and the packing remains unchanged after the accelerated storage and long term storage.

Technical characteristics of the biocidal product
Not applicable as the product is a GL.

Other technical characteristics - determination whether a material is a liquid or a solid
According to the interpretation of results, the Biocidal Product behaves as a liquid since all the product came out immediately when the can was put upside down.

Physical and chemical compatibility with other products
The product is ready to use and it is not intended to be used in mixture with any other product.

Surface tension
Under the conditions of this method, a substance showing a surface tension lower than 60 mN/m should be regarded as being a surface-active material.
The average value obtained for surface tension of an aqueous solution of the analysed sample (178 mg/L) at 20ºC is 43.8 ± 0.4 mN/m. Therefore the analysed sample is classified as a surface-active material.

Viscosity
The viscosity of the biocidal product was determined under GLP condicions according to EU methods.

Conclusions
Magnum Gel Hormigas IGR Plus is a colourless practically odourless gel. The product has a density of 1.3046 ± 0.0003 g/mL and a viscosity of $>2 \cdot 10^5$ mPa.s at 20ºC and 40ºC.
Accelerated storage stability study (14 days, 54ºC ± 2ºC) has been performed to demonstrate that the product "MAGNUM GEL HORMIGAS IGR PLUS " is likely to be stable for two years at ambient storage.
However, a long-term storage stability study of 4 years and compatibility with the LDPE original container concludes that the test product is storage stable at 25 ± 2 ° C for at least 48 months.
The phrase 'protect from frost' must be included in the label because the low temperature stability test has not been submitted by the applicant.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Explosives			Not explosive properties	
Flammable gases			Not applicable	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Flammable aerosols			Not applicable	
Oxidising gases			Not applicable	
Gases under pressure			Not applicable	
Flammable liquids	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. Not flammable	See PAR confidential
Flammable solids			Not applicable	
Self-reactive substances and mixtures			Not self-reactive	
Pyrophoric liquids			Not applicable	
Pyrophoric solids			Not applicable	
Self-heating substances and mixtures			Not applicable	
Substances and mixtures which in contact with water emit flammable gases			Not applicable	
Oxidising liquids			Not oxidising properties	
Oxidising solids			Not applicable	
Organic peroxides			Not applicable	
Corrosive to metals	ASTM G 31 (equivalent to UN MTC C.1)		Not corrosive to metals	See confidential PAR
Auto-ignition temperatures of products (liquids and gases)			Not applicable	
Relative self-ignition temperature for solids			Not applicable	
Dust explosion hazard			Not applicable	

Conclusion on the physical hazards and respective characteristics of the product

NOTE: The applicant has declared that the composition of all batches used in the dossier is the same as the composition to be marketed.
Batch J709 - due to Mylva's long experience in design, development and manufacture of gel-based formulations, the stability of the product at room temperature for 4 years has been established by previous stability tests.

Explosiveness
The concentration of imidacloprid in the biocidal product is 0.01% and its contribution to the biocidal product explosiveness is anticipated to be very low.
S-methoprene is not explosive and the co-formulants (water, the different sugars,

glycerol) do not comprise any structural markers for explosive properties.
In addition, the biocidal product is a water-based product (>30%).
Hence, in spite of the presence of chemical groups in the molecule which are associated with explosive properties, there are no substances present in the biocidal product associated with explosive properties, or, the sole substance that might be associated to explosive properties shows a minimum effect, or, the explosive properties of the biocidal product are not foreseen.

Furthermore, a read across can be established with other neonicotinoids (e.g. thiametoxam, acetamiprid, chlotianidin, thiacloprid) with similar oxygen balance and chemical groups indicators of explosive properties. These neonicotinoids have no explosive properties according to their ARs and CLH reports, therefore, it can be anticipated that the imidacloprid will not have explosive properties.

Finally, even thought OECD 113 could be considered similar but not 100% equivalent to the study included in the section 20.3.3.3 of the UN MTC, the conclusions reached characterize the behaviour of the biocidal product. We can conclude form this study:

- The biocidal product is stable at room temperature.
- The biocidal product is fully molten at 170ºC.
- Taking into account that the DSC of the b.p. presents a multistage decomposition above 200ºC with low enthalpies and Imidacloprid decomposes above 200ºC, it can be assumed that the imidacloprid does not contribute to the explosive properties of the biocidal product due to its low concentration and decomposition

Flammability
The product MAGNUM GEL HORMIGAS IGR PLUS is not expected to be flammable. See confidential PAR for more information on set read across.

Self-reactive substances and mixtures
The classification procedure for self-reactive properties does not need to be applied for imidacloprid according to the AR and CLH reports.
S-methoprene is not self-reactive according to its AR and CLH reports and the co-formulants (water, the different sugars, glycerol) do not comprise any structural markers for self-reactive properties.
Hence, in spite of the presence of the chemical groups in the imidacloprid which are associated with self-reactive propertie, the self-reactive propertie of the biocidal product is not foreseen and no new data are necessary and the classification procedure does not need to be applied.

Pyrophoric solids
The study does not need to be conducted based on the experience/handling of the biocidal product..

Self-heating substances and mixtures
The study does not need to be conducted based on the experience/handling of the biocidal product.

Substances and mixtures which in contact with water emit flammable gases
The study does not need to be conducted because none of the components is expected to emit flammable gases when they are in contact with water.

Oxidising properties
According to the ARs and the CLH reports of both active substances, Imidacloprid and s-Methopren do not show oxidising properties and their concentration is less than 0.1 %.
The other ingredients (water, the different sugars, glycerol) do not comprise any structural markers for oxidising properties and therefore testing is not necessary. Which means that they can be regarded as non-oxidising.
Additionally the "Guidance on the Application of the CLP Criteria" states that:
„An inert material by definition does not contribute to the oxidising capability of the oxidising substance. Hence, the mixture can never be classified into a more severe hazard category."
Therefore the mixture can be regarded as non-oxidising.

Organic peroxides
The study does not need to be conducted because none of the components does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual tests and criteria.

Corrosive to metals
It is not possible to waive an endpoint on physical hazards by the structure of the BP components, when one of the components (imidacloprid comprises chlorine) comprises a chemical group which indicates that the BP may corrode metals. Therefore, the test needs to be applied.
After the immersion test, the sample presents pitting corrosion; reaching up to one depth of approximately 26 µm (<120 µm) of the base material. Furthermore, the data, photos and micrographs in the report clearly show that the product Magnum Gel Hormigas IGR Plus is not corrosive.

Auto-ignition temperature (liquids and gases)
The 0.01 % w/w Imidacloprid and 0.08 % w/w S-methoprene Gel formulation is not expected to be flammable.
The test was omitted because the product MAGNUM GEL HORMIGAS IGR PLUS is not expected to have oxidizing and flammable properties. See confidential PAR for more information on set read across.

Conclusions
It is not considered as explosive and does not contain any ingredient which may indicate oxidizing properties on combustible material. It is not flammable and not corrosive to metals.
Magnum Gel Hormigas IGR Plus is not considered to be potentially explosive or contain an oxidising or reducing agent. The preparation is not recommended for use with other products.
The technical properties indicate that no particular problems are to be expected when it is handled, stored or applied as recommended.

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

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

Imidaclopri d (air)	HPLC-UV RP-18 column							0.005 mg/m^3	CAR (2011)
Imidaclopri d (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**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Imidaclop rid (drinking and surface water)	HPLC-UV RP-18 and CN column							0.03 µg/L	CAR (2011)
Imidaclop rid (surface water)	LC-MS/MS							0.1 µg/L	CAR (2011)
s-Methopr ene in Drinking water	GC-MS (m/z = 175, 191 and 219 m/z)	0.1 µg/L (n=5)	r >0.996 0.07 – 1.2 µg/L 8 point calibration	Retention time match between standard and sample for analyte. The method of analysis is considered to be highly specific (GC-MS with 3 ions > 100m/z used for identification)	74 – 107	95	13.3	0.1 µg/L	CAR (2013)
		1.0 µg/L (n=5)			97 – 110	105	5.15		

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
s-Methoprene in Surface water	GC-MS (m/z = 175, 191 and 219 m/z)	0.1 µg/L (n=5)	r >0.996 0.07 – 1.2 µg/L 8 point calibration	Retention time match between standard and sample for analyte. The method of analysis is considered to be highly specific (GC-MS with 3 ions > 100m/z used for identification)	70 – 82	75	6.1	0.1 µg/L	CAR (2013)
		1.0 µg/L (n=5)			77 – 110	96	17.3		
s-Methoprene in Ground water	*GC-MS (m/z = 175, 191 and 219 m/z)*	0.1 µg/L (n=5)	r >0.996 0.07 – 1.2 µg/L 8 point calibration	Retention time match between standard and sample for analyte. The method of analysis is considered to be highly specific (GC-MS with 3 ions > 100m/z used for identificat	74 – 96	82	10.6	0.1 µg/L	CAR (2013)
		1.0 µg/L (n=5)			89 - 110	99	8.5		

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
				ion)					

Conclusion on the methods for detection and identificationof the product

NOTE: The applicant has declared that the composition of all batches used in the dossier is the same as the composition to be marketed.
Batch J709 - due to Mylva's long experience in design, development and manufacture of gel-based formulations, the stability of the product at room temperature for 4 years has been established by previous stability tests.

Analytical methods for the analysis of the product as such including the active substance
The method was validated according to the requirements guideline SANCO 3030/99 rev.4

Analytical methods for soil
It is proposed that the analytical methods for the determination of Imidacloprid and S-methoprene content in the preparation Magnum Gel Hormigas IGR Plus is also relevant to determinate the Imidacloprid and S-methoprene content in soil. No additional residues are formed in the product. Please refer to the letter of access granted by BAYER and Babolna Bio Ltd to MYLVA S.A. for the information regarding the active ingredients Imidacloprid and S-methoprene.

Analytical methods for air
It is proposed that the analytical methods for the determination of Imidacloprid and S-methoprene in air are not applicable according to the physicochemical properties of the biocidal product.

Analytical methods for water
It is proposed that the analytical methods for the determination of Imidacloprid and S-methoprene content in the preparation Magnum Gel Hormigas IGR Plus is also relevant to determinate the Imidacloprid and s-methoprene content in water. No additional residues are formed in the product. Please refer to the letter of access granted by BAYER and Babolna Bio Ltd to MYLVA S.A. for the information regarding the active ingredients Imidacloprid and S-methoprene.

Analytical methods for animal and human body fluids and tisues
It is proposed that the analytical methods for the determination of Imidacloprid and s-methoprene content in the preparation Magnum Gel Hormigas IGR Plus is also relevant to determinate the Imidacloprid and s-methoprene contenct in animal and human body fluids and tisues. No additional residues are formed in the product. Please refer to the letter of

access granted by BAYER and Babolna Bio Ltd to MYLVA S.A. for the information regarding the active ingredients Imidacloprid and S-methoprene.

Analytical methods for monitoring of active substances and residues in food and feeding stuff

It is proposed that the analytical methods for the determination of Imidacloprid and s-methoprene in treated food or feeding stuffs are not applicable according to the intended use of the biocidal product.

Conclusions

Determination of the active substances Imidacloprid and S-methoprene has been performed by a HPLC-MS system. The method has been successfully validated and is considered acceptable.

The applicant has submitted the Letter of Access granted by Bayer Environmental Science for information on Analytical methods for the Imidacloprid active substance and to the Letter of Access granted by Babolna Bioenvironmental Centre Ltd for information on Analytical methods for the S-methoprene active substance:

IMIDACLOPRID

Residue analytical methods are available for determination of Imidacloprid in soil, air, drinking and surface water. The analytical method for the determination of residues in surface water is also validated for the metabolites guanidine, olefinic compound and urea compound.

Validated confirmatory methods for soil, drinking and surface water were presented. An analytical method for the determination of residues in air using a column of different selectivity was presented. Although the method is not validated in the necessary extent, it is considered to be appropriate for confirmatory purposes.

According to the residue definition and the intended uses for the Annex I inclusion no analytical methods for residues in body fluids and tissues, plants and animal matrices are necessary.

S-METHOPRENE

Analytical methods for determination of S-methoprene in soil, food and foodstuffs were not submitted based on the specific use of the product.

An acceptable method was supplied for analysis of residues of parent S-methoprene in surface, ground and drinking water to an LOQ of 0.1 µg/L.

A method for residues in air is not required based on the results of the vapour pressure study (v.p. <0.01 Pa).

Because the molecule does not classify as either toxic or very toxic, a method for residues in body fluids and tissues is not required.

Finally, the available methods are considered acceptable and scientifically valid.

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

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

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

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

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

2.2.5.3 Effects on target organisms, including unacceptable suffering

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

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

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

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 causing poisoning (by contact and ingestion) and the indirect death of the individuals who live in the colony, regardless their stage of development (pupae, adults). In field trials most ants were killed after 2 weeks of exposure to the gel bait (either by drops or by bait stations).

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

2.2.5.5 Efficacy data

DROPS:

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Laboratory	Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait)	*Linepithema humile*	Laboratory bioassay: Mortality and palatability Gel bait applied as drops/lines on slide	Choice test arena. 4 replicates and control. N ≈ 320 workers Arena 18 x 18 cm Dose: 3 cm line (0.2 g) per replicate. Continuous exposure until day 44	≥ 95% average mortaility in 44 days (controls 11.4%). Palatable bait (fresh bait).	Test report: ES0018-13/23 See confidential annex
			Monomorium pharaonis			≥ 95% average mortaility in 44 days (controls 33.8%). Low palatability (fresh bait).	
			Lasius niger			≥ 95% average mortaility in 18 days (controls 19.3%). Palatable bait (fresh bait).	
Insecticide	Indoors	Imidacloprid 0.01% w/w and s-Methoprene 0.08% w/w (gel bait)	*Lasius niger*	Simulated-use Gel bait applied as spot treatment on Petri dishes (non-porous) 1 drop= 1 line of 3 cm length=0.2g of gel bait.	Simulated kitchen (6.25 m^2) with AFS 3 replicates per treatment and control n ≈ 800 workers and one queen. A total of 1.25 g of the product was applied. Dose rate: 0.2 g/m^2. (1 drop/$m^{2)}$ No re-application.	Av. population reduction 98.9% in 15 days. Control 4.9%	Test report ES0034-A/7 See confidential annex
Insecticide	Outdoors	Imidacloprid 0.01% w/w. gel bait)	*Lasisu niger*	Field trial. Gel bait applied as spot treatment.	Site 4: open area, 5.5m^2 Initial application: 1.1g Initial dose rate:		Test report:

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
				1 drop= 1 line of 3 cm length=0.2g of gel bait	0.2g/m^2 Day 6: re-aplication 1.1g Total amount: 2.2 g Average dose in 15 days: 0.2 g/m^2. <u>Site 5</u>: open area, 4m^2 Initial application: 0.8 g Initial dose rate: 0.2g/m^2 Day 6: re-aplication 0.8 g Day 9: re-aplication 0.4g Total amount: 2 g Average dose in 15 days: 0.5 g/m^2. <u>Site 6</u>: open area, 3m^2 Initial application: 0.6 g Initial dose rate: 0.2g/m^2 Day 6: re-aplication 0.6 g Total amount: 1.2 g Average dose in 15 days: 0.2 g/m^2.	Average mortality: 97.1% after 15 days. 0% in control. The population of the control colonies has remained stable.	13/062 Complementary study.
Insecticide	Outdoors	Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait)	*Linepithema humile*	Field trial Gel bait in bait station or as spot treatment on non porous surfaces. . Reapplication when consumed.	<u>Site 1</u>: open area, 100.5m^2 11 bait stations (5 g/trap).Ínitial application: 55g. Initial dose rate: 0.5g/m^2 Day 2: 3 traps were cancelled and 2 traps	Average population reduction 98.7% after 15 days. The population of the control colonies has remained stable.	Test report: ES0032-4/12 See confidential annex

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					were replaced. (10 g) Day 4: 2 traps were replaced. (10g) Day 10: 2 traps were replaced. (10 g) Total amount: 85 g Average dose in 15 days: 1.18g/m^2. Site 2: around building. 70.5 m^2. Initial application: 14.1g. Initial dose rate:0.2g/m^2. Day 2: re-application 2.3g. Day 4: re-application 2g. Day 10: re-application 2g. Total amount: 20.4g. Average dose in 15 days: 0.28g/m^2 Site 3: around building, 61 m^2. Initial application:12.2g Initial dose rate:0.2g/m^2 Day 2: re-application 3g. Day 4: re-application 3.5g. Day 10: re-application 1.5g. Total amount 20.2 g. Average dose in 15 days; 0.3g/m^2		

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Site 4: around building. 59 m^2, Initial application:11.8g Initial dose rate:0.2g/m^2 Day 2: re-application 2.5g. Day 4: re-application 3g. Day 10: re-application 2. Total amount 19.3 g. Average dose in 15 days: 0.3g/m^2		
Insecticide	Indoors		*Monomorium pharaonis*	Simulated-use Gel bait applied as spot treatment on petri dishes (non-pororus surfaces). 1 drop= 1 line of 3 cm length=0.2g of gel bait..	Simulated kitchen (3.24 m^2) with AFS 3 replicates per treatment and controls n ≈ 900-1500 workers + 20 queens A total of 2 g of the product was applied. Dose rate: 0.6 g/m^2. (3 drops/m^2) No re-application.	Average population reduction 99.1% after 15 days. Untreated control:25.4%	
Insecticide	Laboratory	S-methoprene 0.08% w/w (gel bait)	*Linepithema humile*	Laboratory trail: Egg production. Gel bait as lines in slide.	Choice test (AFS) in arenas. Fresh bait. 3 replicates and 2 controls n ≈ 100 workers + 1 gravid queen + eggs + larvae	Average reduction of no. of eggs 100% in 6 weeks The total population (larvae, eggs and pupae) of the controls have remained stable.	ES0046.A-3/19 See confidential annex

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Arenas 18 x 18 x 12 cm Dose 0.1 g (1 line of 2 cm per arena) Continuous exposure until 6 weeks.		
Insecticide	Laboratory	Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait). 3 years of being manufactured and stored.	*Lasius grandis*	LaboratorySimulated-use test:. Mortality and palatability. Gel bait applied as drops/lines on slide	Test ARENA 18x18x12 cm. Dose: 2cm line (0.1g) 3 replicates and an untreated control. Continuous exposure until 11 days.	100% mortality in 11 days. (control 4.4%) Palatable bait (aged bait). N=233-262	Study ES0035-3/12 See confidential annex
			Linephitema humile			100% mortality in 11 days. (control 6.5%) Palatable bait with aged bait. N=209-260	
			Monomorium pharaonis			100% mortality in 11 days.(control 8.5%) Palatable bait with aged bait. N=171-236	
Insecticide	Laboratory	Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait). 4 years of being manufactured	*Lasius grandis*	LaboratorySimulated-use test:. Mortality and palatability. Gel bait applied as drops/lines on slide	Test ARENA 18x18x12 cm. Dose: 2cm line (0.1g) 3 replicates and an untreated control. Continuous exposure until 11 days	100% mortality in 11 days (control 3.29%) Palatable bait (aged bait). N=161-229 workers	Study ES0035-11/19 See confidential annex.
			Linephitema humile			100% mortality in 11 days (control 7.37%) Palatable bait N=178-	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
		and stored.				258 workers	
			Monomorium pharaonis			100% mortality in 11 days. (control 8.86%) Palatable bait (aged bait). N=208-225 workers.	

BAIT STATION:

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Laboratory	Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait)	*Linepithema humile*	Laboratory bioassay: Mortality and palatability. Gel bait in bait station.	Choice test in arenas. Three replicates were conducted for each treatment with black ant (*Lasius niger*) and argentine ant (*Linepithema humile*). Four replicates were conducted for pharaoh ant (*Monomorium pharaonis*). Each replicate consisting for one ant colony in one test arena. Arenas 28 x 15 cm (420 cm^2) Dose rate: 1 bait station per arena (1g of product) Continuous exposure until day 35	≥ 95% average mortality in 14 days (control 14%). N:400 workers+ 3 queens. Palatable bait (fresh bait).	Study ES0039/02 See confidential annex
			Monomorium pharaonis			≥95% average mortality in 35 days (control 9%). N:400 workers. Palatable bait (fresh bait).	
			Lasius niger			100% moratilty in 13 days (control 7%). N:400 workers. Palatable bait (fresh bait).	

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Indoors / outdoors	Imidacloprid 0.01% w/w and S-methoprene 0.08% w/w (gel bait)	*Linepithema humile*	Field trial Gel bait in bait station. Reapplication when consumed.	Site 1: indoors, 9 m^2, 2 stations (1 g/trap), 0 bait station were replaced. Dose rate: 0,23g/m^2 Site 2: outdoors, 115m^2, 3 stations (5 g/trap), one trap were replaced at 10 days. Dose rate:0.18g/m^2 Site 3:indoors, 15 m^2 3 stations, 1 g/trap, 0 bait station were replaced. Dose rate: 0.2 g/m^2	Average population reduction 97.8% after 15 days- The population of the control colonies has remained stable.	Study: ES0036-7/13 See confidential annex
			Monomorium pharaonis	Simulated-use trial Gel bait in bait station. No re-application.	Simulated kitchen (6.25 m^2) with AFS including proteins 3 replicates and a control per organism. n ≈ 800 workers + 20 pharaoh queens.	Av. population reduction 98.5% after 15 d. Untreated control 5.84%	
			Lasius niger		n≈ 800 workers +1 black ant queen. Dose rate: 0.32 g/m^2. Total amount: 2 bait stations (1 g/station).	Av. population reduction 98.4% after 15 d. Untreated control 6.15%	
Insecticide	outdoors	Imidacloprid 0.01% w/w (gel bait)	*Linephitem humile*	Field trial Gel bait in bait station. Reapplication when consumed.	Site 1: outdoors, 120 m^2, Initial aplication: 3 stations (5 g/trap), Initial dose: 0.125g/m^2 Day 9: 1bait station were replaced. Total amount: 20g (4 bait stations) Average dose in 15 days: 0,16 g/m^2 Site 2: outdoors, 129m^2,	Average population reduction 98.4% after 15 days- The population of the control colonies has remained stable.	Test report: ES0036-7/12 (2014) Complementary study

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					Initial application:3 stations (5 g/trap), Initial dose: 0.11g/m^2 Day 9: 1bait station were replaced Total amount: 20g. (4 bait stations) Average dose in 15 days:0.15g/m^2 <u>Site 3</u>:outdoors 210 m^2 Initial applications: 5 stations, (5 g/trap). Initial dose: 0.11g/m^2 Day 5: 2 bait station were replaced. Total amount: 35 g (7 bait stations) Average dose in 15 days: 0.16 g/m^2		

Conclusion on the efficacy of the product

EFFICACY AS ADULTICIDE

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

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

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

GEL BAIT BY DROPS/LINES

The Applicant submitted three laboratory trials and two simulated-use trials against *Lasius niger, Monomorium pharonis and Linepithema humile*. The application method is by drops/lines.

The simulated use study with fresh was conducted in a test arena (18 x 18 cm) with 4 replicates per treatment and 1 control replicate. A population of around 340 workers was tested in each replicate. The gel bait was applied onto an acetated sheet as 3cm line (1 drop=0.2g per replicate). An AFS (honey) was included to investigate the palatability of the product.

Lasius niger:
The study proved the efficacy against this species. Average mortality was ≥ 95% in 18 days. The average mortality in controls was 19,3%, probably for additional stress. Even so, these high controls mean that the study cannot be validated for this species, but the applicant has also provided laboratory tests with bait aged at 3 (Study ES0035-3/12) and 4 years (Study ES0035-11/19) , which do allow to demonstrate the efficacy of the product in laboratory.

Monomorium pharaonis:
The study proved the efficacy against this species. Average mortality was ≥ 95% in 44 days. The average mortality in controls is very high was 33.8% average, but it is a normal thing when working with small colonies for this specie in laboratory tests that run for a long period. Even so, these high controls mean that the study cannot be validated for this species, but the applicant has also provided laboratory tests with bait aged at 3 (Study ES0035-3/12) and 4 years (Study ES0035-11/19) , which do allow to demonstrate the efficacy of the product in laboratory.

Linepithema humile:
The study proved the efficacy against this species. Average mortality was was ≥ 95% in 44 days. The average mortality in controls was 11.4%.

There was a field trial against *Linepithema humile*, including one outdoor site with application by traps and three around building sites with spot application of the gel bait as droplets. The application rate was 0.2-0.6g/m^2. The product was re-applied where the bait had been consumed after few days/weeks following the first application. If we only take into account the sites applied by droplets, the data show that there is an average reduction of more than 90% of the population in 15 days. Therefore the product demonstrated the efficacy under worst-case conditions in actual field sites.

There were two simulated-use studies with spot application of the product as drops/lines. Trying to gain access to possible sites infested with *Lasius niger* and *Monomorium pharaonis* was a significant challenge and following almost one year in trying to find suitable and cooperatives sites the laboratory decided to conduct a simulated use test.

The test systems were built up in a simulated kitchen of 3.24 m^2 (*M. pharaonis*) and 6.25 m^2 for (*L. niger*) in the presence of an AFS. There were 3 replicates per treatment and controls. The population included 800 worker balck ants and one queen and 900-1500 pharaoh workers plus 20 queens.

Lasius niger:
The study proved the efficacy against this species. In total, 1.25 g of bait was applied in Petri dishes, giving a tested dose of 0.2g/m^2 were used. The study proved the efficacy against this species. Average population reduction was 98.9% after 15 days. The average mortality in controls was 4.9%.

In addition, as a complementary study, a field test against *Lasius niger* is incorporated. The test has been carried out with the MAGNUM GEL HORMIGAS PLUS product.(Go to confindential PAR to see the composition and justification of the read across).

The doses and exposure time of the bait is the same. The test shows that the product is effective when applied at a dose of 0.2-0.5 g/m^2. Average mortality: 97.1% after 15 days. The population of the control colonies has remained stable.

Monomorium pharaonis:
The study proved the efficacy against this species. In total, 2.0 g of bait was applied in Petri dishes, giving a tested dose of 0.6 g/m^2 were used. Average population reduction was 99.1% after 15 days. The average mortality in controls was 25.4%. As we mentioned before, is a normal thing when working with small colonies for this specie for a long period.

No field trials have been provided against this species, therefore the data package is incomplete and cannot be authorized.

The eCA concludes that the product MAGNUM GEL HORMIGAS IGR PLUS is effective against *Lasius niger, and Linephitema humile* (adults) with the method of application by droplets on non-porous surfaces indoors. In relation to open areas, it has only been demonstrated against *Linephitema humile*. We think that it cannot be guaranteed that the general public will be able to distinguish this species. Therefore, only trained professional will be authorized to use outdoors against *Linephitema humile*.

BAIT STATIONS INCLUDING GEL BAIT INSIDE

In a simulated use, MAGNUM GEL HORMIGAS IGR PLUS demonstrated its efficacy as

insecticide against three species of ants (adults) living in houses and other commercial buildings. The product was applied by placement of ready-to-use bait stations (1 g/station) inside the arenas (1 station/arena) in the presence of AFS. Arenas (28 x 15 cm) included a population of around 400 workers. 4 replicates per treatment and controls were set up. Palatability was demonstrated for the three species.

Lasius niger:
The study proved the efficacy against this species. Average mortality was 100% in 13 days. The average mortality in controls was 7%.

Monomorium pharaonis:
The study proved the efficacy against this species. Average mortality was 97% in 35 days. The average mortality in controls was 9%.

Linepithema humile:
The study proved the efficacy against this species. Average mortality was 99% in 14 days. The average mortality in controls was 14%.

There was a field trial against *Linepithema humile*, including one outdoor and two indoor sites, and application of the gel bait by placement of bait stations. The initial application rate was 0.2 g/m^2 (range 0.17-0.23 g/m^2). The average population reduction was 97.8% after 15 days.

In addition, as we have already discussed, there is another field study with *L. humile* including one site in an open area (outdoors). A preliminar assessment was made to estimate the infestation level. 5 stations containing 5 g of gel bait were placed at start. In total 11 bait stations were needed to control the infestation (i.e. 55 g). The average population reduction was 100% after 4 days.

In addition, as a complementary study, a field test against *Linephitema humile* is incorporated. The test has been carried out with the MAGNUM GEL HORMIGAS PLUS product.(Go to confindential PAR to see the composition and justification of the read across).

The doses and exposure time of the bait is the same. The test shows that the product is effective outdoors when applied at a dose of 0-2 g/m^2. Average mortality: 98.4% after 15 days. The population of the control colonies has remained stable.

Therefore the product demonstrated efficacy against this species under outdoor and indoor conditions.

There were two simluated- studies against *Monomorium pharaonis* and *Lasius niger* with application of the product in bait stations.Tthe laboratory justification is the same as for droplet tests.
The test systems were built up in a simulated kitchen of 3.24 m^2 (*M. pharaonis*) and 6.25 m^2 for (*L. niger*) in the presence of an AFS. There were 3 replicates per treatment and controls. The population included 800 worker black ants and 900-1500 pharaoh workers plus 20 queens. A total of 2 bait stations with 1 g/station were applied in each site, starting with 1 station. Therefore the dose was estimated as 0.32 g/m^2.

Lasius niger:
The study proved the efficacy against this species. Average population reduction was 98.4% after 15 days. The average reduction in controls was 6.15%.

No field trials have been provided against this species, but taking into account that a simulated-use trial with traps has been provided, and a field trial with droplets, (which is a worse case) we accept the data package to authorize this species with bait stations.

Monomorium pharaonis:
The study proved the efficacy against this species. Average population reduction was 98.5% after 15 days. The average reduction in controls was 5.8%.

No field trials have been provided against this species, therefore the data package is incomplete and cannot be authorized.

The eCA concludes that the product MAGNUM GEL HORMIGAS IGR PLUS is effective against *Lasius niger, and Linephitema humile* (adults) with the method of application by placement of bait stations indoors. In relation to open areas, it has only been demonstrated against *Linephitema humile*. We think that it cannot be guaranteed that the general public will be able to distinguish this species. Therefore, only trained professional will be authorized to use outdoors against Linephitema humile. .

EFFICACY AS OVICIDE
MAGNUM GEL HORMIGAS IGR PLUS was also studied in a laboratory study (choice test) to test its effect as ovicide against *Linepithema humile*. The study tested the same formulation excluding the a.s. Imidacloprid, in the presence of AFS (agar, eggs, honey, vitamins, and minerals). In the trials the formulation containing S-Methoprene (0.08 %) was tested against a population of ca. 100 workers, 1 gravid queen, eggs, pupae and larvae for 6 weeks. 3 replicates and 2 controls (i.e. 0% S-Methoprene) were included. Observed parameters were the total number of laid eggs, larvae, pupae and total brood (sum of the former stages). The product was applied as a 2-cm line of gel bait (0.1 g) placed on a slide inside the arenas.

The number of eggs produced in the controls increased from week 1 to week 2, but from week 4 there was a gradual reduction. After 6 weeks controls produced less eggs than at the beginning of the study, maybe showing the effect of captive breeding. In the treated arenas after 6 weeks of continuous treatment, 100% reduction of the number of eggs was achieved. There were still some other individuals (larvae and pupae) which are not affected by the product, since it acts only on the eggs laid by the queen. However it was clear that the formulation containing only S-Methoprene produced the inhibition of fertility of gravid queens compared to the controls.
On the other hand, to achieve infertility in females, the product must be kept for at least 6 weeks in a continuous exposure that does not comply with the instructions for use, nor the mortality tests. Therefore **the product cannot be claimed as an ovicide.**

Long period of storage:
The applicant has submitted 2 laboratory test with 3 and 4 years aged bait.
The trials have been made with the garden ant *Lasius grandis*, instead of the usual *Lasius niger* ant. Both species are very similar in terms of feeding and behaviour, the factors that set one type of control or another. *Lasius niger* and *Lasius grandis* are monogynic, meaning they have one single queen per nest.
They form big colonies with between 4.000 and 7.000 ants. Their diet is mainly based on sugary liquids obtained by grazing aphids. They also sometimes supply of proteins obtained by consuming the aphids themselves or other small arthropods. Being that similar, it can be assumed that the efficacy against *L.grandis* can be extrapolated to

L.niger
Both the three-year and four-year laboratory tests showed mortality for the three species of 100% in 11 days. Mortality of untreated controls are acceptable.
The tests have been carried out with the application by droplets.
Palatability tests with fresh bait on bait station and droplets, storage stability test with the worst packaging (syringes) and tests with aged bait have been provided.
Taking into account that the bait product is the same for bait station and syringes, we can authorize a shel-life of the product to 4 years, both droplets and bait stations.

We accept the trials and consider that a shelf-life up to 4 years, in relation to the efficacy, can be authorized.

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 and s-Methoprene were available to the applicant.

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

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

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

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

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

In conclusion the potential for resistance is high as a neonicotinoid but particular problems have not arisen for imidacloprid. Nevertheless, to minimise the chances of resistance

developing in the future, it is advisable to avoid using products containing Imidacloprid exclusively and continuously as the sole agent for ant control. Therefore Imidacloprid containing products should be used as one component of an integrated pest management program which features products from alternative chemical classes.

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

The proposed resistance management strategy includes the following actions:

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

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

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

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:

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

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

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 product has proven effective for the following label claims.

- Insecticide for kill worker ants (*Linepithema humile* and *Lasius niger)*. The a.s. Imidacloprid produces kill of ants in 2 weeks. - Ready-to-use gel bait with application by droplets on non-porous surfaces (cartridge or syringe) indoors against the three species and all users.
- Ready-to-use gel bait with application of bait stations bait outdoors only against *Linephitema humile*, and for trained profesionar users.
- The fresh gel bait is palatable for ants.
- The 4 years aged bait is palatable for ants.

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

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

2.2.6 Risk assessment for human health

The biocidal product Magnum Gel Hormigas IGR Plus is composed of the active substances Imidacloprid 0.01% w/w and S-Methoprene 0.08% w/w, combined with a number of co-formulants. Current classification is proposed in accordance with the provisions laid down in Regulation (EC) Nº 1272/2008. Proposed classification for Magnum Gel Hormigas IGR Plus based on the acute toxicity results performed with other formulated product Magnum Gel for human health effects has been included as part of this submission. Magnum Gel is composed of the active substance Imidacloprid 2.15% w/w combined with a number of co-formulants.
Two studies GLP compliant (2013) have been submitted by the applicant to address the acute oral and dermal toxicity. These studies were conducted with the product Magnum Gel Cucarachas which is a gel formulation containing Imidacloprid 2.15% (w/w) as active substance. The Spanish-CA accepts that the data generated for this product can be extrapolated to the product Magnum Gel Hormigas IGR Plus because the concentration of imidacloprid is higher and the rest of the co-formulants do not classify for these routes of toxicity. So, it is a worse case.

On the other hand, the applicant has submitted a justification for non-submission data for acute inhalation toxicity, dermal, skin and eye irritation, skin sensitisation and dermal absorption. Spanish-CA accepts these justifications.
See also DETAILED INFORMATION ABOUT COMPOSITION AND TOXICOLOGY OF THE BIOCIDAL PRODUCT in the confidential section. It must be noted that S-Methoprene is not classified for human health hazards.

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 Imidacloprid, S-Methoprene and the coformulants, and their respective content in the final formulation
Classification of the product according to CLP and DSD	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, **no classification is required**

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

Eye irritation

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

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

Respiratory tract irritation

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

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

Skin sensitization

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

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

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitiser
Justification for the value/conclusion	Based on the classification of Imidacloprid, S-Methoprene and the coformulants, and their respective content in the final formulation.

Classification of the product according to CLP and DSD	The preparation Magnum Gel Hormigas IGR Plus is not classified as respiratory sensitiser.

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

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
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 14 day post exposure period	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.	[redacted]

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{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 and DSD	Imidacloprid 0.01% & S-Methoprene 0.08% gel formulation is not classified as Oral Acute Toxic, according the addition method of CLP Regulatory for mixtures, from components data, because the ATE_{mix} > 2000. Gel formulation is not classified as harmful by the oral route

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

Acute toxicity by inhalation

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

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

Acute toxicity by dermal route

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		[redacted]

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50}>2000mg/kg bw
Justification for the selected value	No toxicity effects at the maximum dose rate of 2000 mg/Kg bw
Classification of the product according to CLP and DSD	Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for dermal acute toxicity.

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

	Plus is not harmful by the dermal route and will remain unclassified.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Imidacloprid / S-Methoprene	Imidacloprid / S-Methoprene
Value(s)*	75% for primary exposure	75% for secondary exposure
Justification for the selected value(s)	EFSA Journal 2012;10(4):2665[1]	EFSA Journal 2012;10(4):2665[1]

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

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

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

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

Available toxicological data relating to a mixture

No data.

Endocrine disruption

Assessment of the ED properties of the active substances:

The biocidal product contains S-Methoprene and imidacloprid.

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

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

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

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

Overall conclusion on the biocidal product regarding ED properties:

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

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

Other

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

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

2.2.6.2 Exposure assessment

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

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

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

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

There are no substances of concern.

The eCA considers the authorised dose should be 0.2-0.6 g/m^2 using gel bait by bait stations and gel bait by drops/lines where 1 drop = 1 line of 3 cm = 0.2 g (200 mg), according to the efficacy section.

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

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

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

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

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

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

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

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

List of scenarios

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

** No exposure to the product is expected by users during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63: 'the exposure due to the use of ant and cockroach*

bait stations is considered to be negligible. Accidents (swallowing, children who open bait stations) do not form a part of a standard assessment'). Therefore, human exposure to biocidal product when using bait stations is not considered in this assessment. Primary and secondary exposure assessment performed with the application of gel in drops is the worst case with regard to human exposure and cover the risk derived from the use of bait stations.

Industrial exposure

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

Trained Professional exposure

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

Description of Scenario [1]		
For trained professionals (pest control operators) exposure is estimated using the models and assumptions presented in the original CAR of Imidacloprid. The product is a ready-to use bait in cartridges/syringes for the controlled placement using a suitable gel applicator by trained professionals (pest control operators). The gel is applied as drops in inaccessible places as behind furnitures, etc. In the following, the application of gel using cartridge is considered for exposure assessment purposes (worst case). Chronic exposure is expected. According to Imidacloprid CAR the only relevant exposure route of the gel product to professional users is via dermal contamination through hands. Exposure estimations were performed taking into account the quantities that could potentially enter into contact with operator's hands during opening and sealing the cartridge (5 opening and 5 sealing operations per day). The product remaining on the tip of the cartridge (or cartridge nozzle) will contaminate operator's hand during removal or placing the cap before and after the application, respectively. Exposure during use of cartridges is estimated worst case compared to syringes.		
	Parameters	Value
Tier 1	Equivalence 0.5 cm gel[a]	33.3 mg product
	number of opening and sealing per day[b]	10
	content of active substance in product	0.01% Imidacloprid 0.08% S-Methoprene
	Body weight adult[c]	60 kg
	Dermal absorption absorption[d]	75%

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

[b] *CAR.*

[c] *HEEG Opinion 17.*
[d] *EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665)*

Calculations for Scenario [1]
See calculations in Annex 3.2

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

Further information and considerations on scenario [1]
Not applicable.

Scenario 2 Disposal of used cartridges by trained professional users

Description of Scenario 2		
For trained professionals (pest control operators) exposure is estimated using the models and assumptions presented in the original CAR. In the following the disposal of used cartridge is considered for exposure assessment purposes. Chronic exposure is expected. Exposure takes place via dermal contamination through hands. Exposure estimation is performed taking into account the quantities that could potentially enter into contact with operator's hands during disposal of used cartridges (1 operation a day). The product remaining on the tip of the cartridge (or cartridge nozzle) will contaminate operator's hand during cartridge disposal.		
	Parameters	Value
Tier 1	Equivalence 0.5 cm gel[a]	33.3 mg product
	number of disposed cartridges per day[b]	1
	content of active substance in product	0.01% Imidacloprid 0.08% S-Methoprene
	Body weight adult[c]	60 kg
	Dermal absorption absorption[d]	75%

[a] *According to the CAR a string of gel estimated to be 0.5 cm long is transferred to the hand during opening or sealing the cartridge. To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information (diameter of the nozzle lumen) is not available for the packaging of of MAGNUM GEL HORMIGAS PLUS. The CA uses the amount of product in a line of gel 0.5 cm length as indicated in CAR (aprox. 33.3 mg of product) to estimate the exposure of trained professionals via dermal route, taking*

into account that the applicant has noted that a drop of 3 cm diameter of Magnum Gel Hormigas IGR Plus equals aprox. 200 mg of product (see Annex 3.2)
[b] *CAR.*
[c] *HEEG Opinion 17.*
[d] *EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665)*

Calculations for Scenario 2

See calculations in Annex 3.2

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

Further information and considerations on scenario [2]
Not applicable.

Combined scenarios
Total exposure of trained professionals during a working day is estimated by a combination of scenarios 1 & 2.

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

Professional exposure

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

Non-professional (general public)exposure

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

Description of Scenario [3]		
The product is a ready-to use bait in cartridges/syringes for professionals and non-professional uses. The gel is applied as round spots in hidden places with difficult access such as behind furniture, etc. For both categories of users exposure is estimated using the models and assumptions presented in the original CAR of Imidacloprid adapted to consumer use according to expert judgment. In the following it is assumed as a worst case that a consumer applies the product every two weeks during 6 months per year (ants are expected during spring and summer). As a worst case, medium term exposure is expected. Exposure takes place via dermal contamination through hands. Exposure is estimated taking into account the quantities that could potentially enter into contact with consumer's hands during opening and sealing the cartridge (1 opening and 1 sealing operations per application are assumed).		
	Parameters	Value
Tier 1	Equivalence 0.5 cm gel[a]	33.3 mg product
	number of opening and sealing per day[b]	2
	content of active substance in product	0.01% Imidacloprid 0.08% S-Methoprene
	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 CAR (aprox. 33.3 mg of product) to estimate the exposure of professionals and non-professionlas via dermal route, taking into account that the applicant has noted that a drop of 3 cm diameter of Magnum Gel Hormigas IGR Plus equals aprox. 200 mg of product (see Annex 3.2)*

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

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

[d] *HEEG Opinion 17.*

Calculations for Scenario [3]

See relevant calculations in Annex 3.2

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

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [3]	1/none	-	6.66E-04	-	6.66E-04

Further information and considerations on scenario [3]
Not applicable

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

Description of Scenario [4]		
For professional / non-professional users exposure is estimated using the models and assumptions presented in the original CAR of Imidacloprid adapted to consumer use according to expert judgment. In the following it is assumed as a worst case that a consumer discharges a used cartridge every two weeks during 6 months per year (cockroaches are expected during spring and summer). As a worst case, medium term exposure is expected. Exposure takes place via dermal contamination through hands. Exposure estimation is performed taking into account the quantities that could potentially enter into contact with consumer's hands during disposal of used cartridge (1 operation per day of application is assumed). The CA assumes that one drop of gel enters in contact with consumer's hand during disposal off used cartridge.		
	Parameters	Value
Tier 1	Equivalence 0.5 cm gel[a]	33.3 mg product
	number of cartridges disposed off per event [b]	1
	content of active substance in product	0.01% Imidacloprid 0.08% S-Methoprene
	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 CAR) to estimate the exposure of the general public via dermal route (see Annex 3.2).*
[b] *CAR, adapted for consumer use.*
[c] *EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665)*
[d] *HEEG Opinion 17.*

Calculations for Scenario [4]
See calculations in Annex 3.2

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

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

Combined scenarios

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

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

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

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

Indirect exposure of the general public

Indirect exposure scenarios are described in the following

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

Description of Scenario [7]		
According to the definitions in HEEG Opinion 17, the population under consideration here are toddlers (1-2 years old) who can explore their environment and exhibit hand to mouth transfer of residues. Secondary exposure can be considered as occasional and of short-term (not continuous) and therefore the exposure is considered as acute. Considering that the product is applied in lines/drops in localized spots (there is not an uniform application on surfaces as paints, for example), the following scenario assumes that a toddler contacts certain amount of product in one event. Additionally to dermal absorption, hand to mouth transfer may take place: the hands form about 20% of the total uncovered skin. It is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact. This means that via hand-mouth contact 10% of the external dermal exposure is ingested (RIVM report 320005002 pp. 28). The ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth contact. Tier 1 assumes that the amount dislodged is 100%; 100% oral absorption and 75% dermal absorption are considered.		
	Parameters	Value
Tier 1	Equivalence of 1 line of gel 5 cm[a]	333.3 mg product
	number of lines contacted per event[b]	1
	content of active substances in product	0.01% Imidacloprid 0.08% S-Methoprene
	Dermal absorption[c]	75%
	Dislodged amount[b]	100%
	Amount of product available for oral intake[d]	10% of external dermal load
	Oral absorption[e]	100% Imidacloprid 35% S-Methoprene
	Body weight toddler[f]	10 kg

[a] The CA uses the amount of product in a line of gel 5 cm length as indicated in CAR (aprox. 333.3 mg of product) to estimate the exposure of general public via dermal route, taking into account that the applicant has noted that a drop of 3 cm diameter of Magnum Gel Hormigas IGR Plus equals aprox. 200 mg of product (see Annex 3.2).
[b] assumption
[c] EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665)
[d] ConsExpo Pest product fact sheet RIVM report 320005002 (Post Application; pp. 28)
[e] Assessment Reports for Imidacloprid and S-Methoprene
[f] HEEG Opinion 17

Calculations for Scenario [7]
See calculations in Annex 3.2

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

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

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

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

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

Combined scenarios
Not applicable.

Monitoring data
Not applicable.

Dietary exposure

Food contamination as result of use

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

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

Conclusion

Dietary risk does not have to be further considered.

The following label restrictions preclude food contamination:

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

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses of Imidacloprid			
	Sector of use [1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection product	Not approved under Regulation Nº 1107/2009 [3]	MRL [4]
2.	Veterinary use	treatment of domestic pets to control fleas [5]	Withdrawal period n.a. [6]
Summary table of other (non-biocidal) uses of S-Methoprene			
	Sector of use [1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection product	Not approved under Regulation Nº 1107/2009 [7]	MRL [4]
2.	Veterinary use	Antiparasitic products, insecticides and repellents, avermectins [8]	Withdrawal period n.a. [5]

[1] e.g. plant protection products, veterinary use, food or feed additives
[2] e.g.: MRL: maximum residues levels
[3] Commission Implementing Regulation (EU) No 2020/1643
[4] Commission Regulation (EU) No 899/2012 of 21 September 2012: MRL set at the lower limit of analytical determination
[5] EMEA/V/C/000076
[6] n.a. not applicable
[7] Commission Regulation (EC) No 2076/2002 of 20 November 2002.
[8] EMEA/V/C/002700: Combined with other substances is used in cats with, or at risk from mixed infestations by cestodes, nematodes and ectoparasites.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

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

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

Conclusion
Livestock exposure does not have to be further considered.

The following label restriction preclude livestock exposure:

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

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

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

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

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

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

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

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

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

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

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

Summary of exposure assessment

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

2.2.6.3 Risk characterisation for human health

Reference values for Imidacloprid to be used in Risk Characterisation

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

[1] *EU agreed AEL values (please refer to the Assessment Report for Imidacloprid 2011)*
[2] *An ARfD and an ADI have not been derived for Imidacloprid used in biocidal products (PT 18).*

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

Reference	**Study**	**NOAEL** mg/Kg bw [d]	**AF[1]**	**Correction for oral absorption**	**Value** mg/Kg bw [d]
AELshort-term	rabbit developmental study	100	100	35%	0.35
AELmedium-term	90-day dog repeat oral dose study	100	100	35%	0.35
AELlong-term	2-year rat combined chronic and carcinogenicity study	21.7	100	35%	0.076
ARfD[2]	-	-	-	-	-
ADI[2]	-	-	-	-	-

[1] *EU agreed AEL values (please refer to the Assessment Report for S-Methoprene, 2013); Systemic NOAEL is estimated considering oral absorption*
[2] *An ARfD and an ADI have not been derived for S-Methoprene used in biocidal products (PT 18).*

Maximum residue limits or equivalent
No MRL for biocidal uses of the active substances Imidacloprid and S-Methoprene are set.

Risk for trained professional users
Trained professional users are expected to use the biocidal product on a daily basis. Hence exposure levels are compared to $AEL_{long\text{-}term}$ for risk assessment purposes.

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

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

See Tables below.

Systemic effects: exposure to Imidacloprid from trained professional uses

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

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

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

Combined scenarios: systemic exposure to Imidacloprid from trained professional uses

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

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

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

Local effects

Not applicable

Conclusion

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

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

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

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

Hence, exposure estimates are compared to the relevant $AEL_{medium\text{-}term}$ for Imidacloprid and S-Methoprene for risk assessment purposes.

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

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

See Tables below.

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

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

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

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

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

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

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

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

Local effects

Not applicable

Conclusion

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

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

Risk for the indirect exposure

Systemic effects: indirect exposure to Imidacloprid for toddlers

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

Systemic effects: indirect exposure to S-Methoprene for toddlers

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

Combined scenarios secondary exposure

No combined exposure is foreseen.

Local effects

Not applicable.

Conclusion

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

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

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

Risk for consumers via residues in food

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

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

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

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

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

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

No risk is envisaged for consumers via residues in food.

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

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

Preliminary step:

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

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

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

Primary exposure Trained professional use as mg/kg bw/d

	Imidacloprid	**S-Methoprene**
Value of exposure (without PPE)	4,58E-04	3,66E-03

Primary exposure general public /professional use as mg/kg bw/d

	Imidacloprid	**S-Methoprene**
Medium term value of exposure	1,25E-04	9,99E-04
Chronic value of exposure	1,25E-04	9,99E-04

Secondary exposure Toddler as mg/kg bw

	Imidacloprid	**S-Methoprene**
Acute value of exposure	2,58E-03	1,89E-02

TIER 1 and TIER 2:

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

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

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

Primary exposure: Trained professional, chronic exposure

Without PPE	**Imidacloprid**	**S-Methoprene**	**conclusion**
Tier 1	0.76 %AEL	4.82 %AEL	acceptable
Tier 2	0.0076	0.0482	acceptable
	HI = 0.0558		

Primary exposure: consumer/ professional, medium term exposure

Without PPE	**Imidacloprid**	**S-Methoprene**	**conclusion**
Tier 1	0.06 %AEL	0.29 %AEL	acceptable

Tier 2	0.0006	0.0029	acceptable
	HI = 0.0035		

Primary exposure: professional, chronic exposure

Without PPE	**Imidacloprid**	**S-Methoprene**	**conclusion**
Tier 1	0.21 %AEL	1.31 %AEL	acceptable
Tier 2	0.0021	0.0131	acceptable
	HI = 0.0152		

Indirect exposure: toddler, acute exposure

	Imidacloprid	**S-Methoprene**	**conclusion**
Tier 1	0.65 %AEL	5.41 %AEL	acceptable
Tier 2	0.0065	0.0541	acceptable
	HI = 0.0606		

Conclusion:

For trained professional use:

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

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

For professional and consumer use:

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

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

For the indirect exposure of toddlers:

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

TIER 2: Mixture risk assessment is acceptable in T2.

2.2.7 Risk assessment for animal health

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

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

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

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

No risk is envisaged for animal health.

2.2.8 Risk assessment for the environment

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

2.2.8.1 Effects assessment on the environment

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

*according to the addendum from 2018 to the AR for S-methoprene
No ecotoxilogical data are available to a set a PNEC value for birds for s-methoprene

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

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

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

Further Ecotoxicological studies
No new data is available.

Supervised trials to assess risks to non-target organisms under field conditions
No additional trials to assess risk to non-target organisms have been conducted

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
No additional studies on acceptance of ingestion of the biocidal product by non-target organisms have been performed.

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

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

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

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

No new data is available.

Leaching behaviour (ADS)

No relevant.

Testing for distribution and dissipation in soil (ADS)

No relevant.

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

No relevant.

Testing for distribution and dissipation in air (ADS)

No relevant.

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

No relevant.

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

No relevant.

Assessment of Endocrine Disruption (ED)

Assessment of the ED properties of the active substances:

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

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

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

- ECHA data for identification of ED and PBT, under REACH, BPR or CLP
- Identified as ED by United States EPA (https://comptox.epa.gov/dashboard/)

- Identified as ED by the United Nations Environment Programme (July 2017) (http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

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

2.2.8.2 Exposure assessment

General information

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

Emission estimation

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

Scenario [1]: outdoor use around the buildings.

Spot application around large buildings

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

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: outdoor use, indirect releases			
Quantity of b.p. applied (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. ($APP_{b.p.}$)	3	Spot/m	
Perimeter treated with the product ($PERIMETER_{Treated}$)	100	m	
Perimeter width ($PERIMETER_{width}$)	0.5	m	
Number applications per day (N_{appl})	1	d^{-1}	
Number of point per area (N_{sites})	300	-	
Fraction emitted to STP during outdoor gel application ($F_{spot,gel}$)	0.9	-	
Number of larger buildings per STP	300		
Simultaneity factor (F_{sim})	0.03		

S-methoprene

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: outdoor use, indirect releases			
Quantity of b.p. applied (Q_{bp})	0.2	g	
Fraction of the active substance in the product (F_{ai})	0.0008	-	
Quantity of a.s. applied (Q_{as})	$1.6x10^{-4}$	g	
Application rate of the b.p. ($APP_{b.p.}$)	3	Spot/m	
Perimeter treated with the product ($PERIMETER_{Treated}$)	100	m	
Perimeter width ($PERIMETER_{width}$)	0.5	m	
Number applications per day (N_{appl})	1	d^{-1}	
Number of point per area (N_{sites})	300	-	
Fraction emitted to STP during outdoor gel application ($F_{spot,gel}$)	0.9	-	
Number of larger buildings per STP	300		
Simultaneity factor (F_{sim})	0.03		

According to TAB, Version 2.1, December 2019, for outdoor applications of insecticides around commercial buildings, a default perimeter of 100 m is proposed with a perimeter

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

Calculations for Scenario [*1*]
Local direct emission rate to STP per treatment:

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

Imidacloprid, $E_{spot,\ STP}$ = 0.00270 $g.d^{-1}$
S-methoprene, $E_{spot,\ STP}$ = 0.0216 $g.d^{-1}$

Simultaneous emission to waste water during outdoor use:

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

Imidacloprid, Elocalwater, sim = 0.0243 g.d-1
S-methoprene, Elocalwater, sim = 0.194 g.d-1

Resulting local emission to relevant environmental compartments		
Compartment STP	**Local emission ($Elocal_{water,\ sim}$) [kg/d]**	**Remarks**
Imidacloprid	2.43 E-05	
S-methoprene	1.94 E-04	

Scenario [2]: outdoors use, terrace scenario.

Spot application on paved surfaces

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

According to the TAB, Version 2.1, terrace length in 6 m and the soil area exposed in 8.5 m^2. The ESD PT 18 (2008) indicates that about 90% of the insecticidal products deposited to the treated spot can be released to the environment, either directly or through ultimate release after target insect death.

Input values for determining direct emissions to soil:

Imidacloprid

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

Quantity of b.p. applied (Q_{bp})	0,2	g/drop	
Fraction of the active substance in the product (F_{ai})	1,00E-04		
Quantity of a.s. applied (Q_{as})	2,00E-05		
Terrace length	6	m	
Perimeter treated with the product ($PERIMETER_{Twidth}$)	0,5	m	
Number applications per day	1	-	
Number of point per area	3	drops/m2	
Fraction emitted to soil during outdoor gel application ($F_{spot,gel}$)	0,9	-	
Soil area exposed (Areaexposed)	8,5	m2	
Soil depht (Depthsoil)	0,5	m	
RHO_{soil}	1700	kg/m3	

S-methoprene

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

Calculations for Scenario [*2*]

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

Imidacloprid, $E_{spot,\ SOIL}$ = 1.62 E-04E $g.d^{-1}$
S-methoprene, $E_{spot,\ SOIL}$ = 1.30 E-03 $g.d^{-1}$

Cspot, soil =(Espot, soil / (Areaexposed x Depthsoil x RHOsoil))*10^3

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

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

This scenario is cover for scenario 4

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

Indoor use spot treatment private houses and large buildings

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

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: spot treatment in a house and large buildings.			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	0.2	*g/drop*	3 drops/ 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	3	-	
Area treated with product (private houses)	2	m^2	
Area treated with product (large buildings)	9.3	m^2	

S-methoprene

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

Calculations for Scenario [*4*]

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

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

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

Parameter	Definition	Imidacloprid		s-methoprene	
		Private houses	Large buildings	Private houses	Large buildings
Number of application per day	N_{appl}	1		1	
Number of point per area	N_{point}	3		3	
Fraction emitted to treated surfaces during application	F_{appl}	1		1	
Quantity of commercial product applied per point of gel [g/point]	$Q_{prod,\ point}$	0.2		0.2	
Fraction of active substance in the commercial product	F_{ai}	0.0001		0.0008	
Area treated with product [m^2]	$AREA_{treated}$	2	9.3	2	9.3
Emission rate to treated surface during application [g/d]	$\mathbf{E_{application,\ surface} = Q_{prod,\ point} \times N_{point} \times F_{ai} \times AREA_{treated} \times F_{appl} \times N_{appl}}$	**1.20 E-04**	**5.58E-04**	**9.6E-04**	**4.46E-03**

Cleaning

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

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

Parameter	Definition	imidacloprid		s-methoprene	
		Private houses	Large buildings	Private houses	Large buildings
Emission to floor during application step [g/d]	$E_{application,\ floor}$	0	0	0	0
Emission to treated surfaces during application step	$E_{application,\ surface}$	1.20 E-04	5.58E-04	9.6E-04	4.46E-03
Fraction emitted to wastewater during	F_{ww}	1			

cleaning step				1	
Cleaning efficiency	F_{CE}	0.25		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}**	**3.00E-05**	**1.40E-04**	**2.40E-04**	**1.12E-03**

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

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

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

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

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

Parameter	**Definition**	**imidacloprid**		**s-methoprene**	
		Private houses	**Large buildings**	**Private houses**	**Large buildings**
Emission from treated surface to wastewater during cleaning step [g/d]	$Elocal_{ww}$	3.00E-05	1.40E-04	2.40E-04	1.12E-03
Simultaneously treated houses per STP [-]	N_{houses}	4000	300	4000	300
Simultaneity factor[-]	$F_{simultaneity}$	0.00815		0.00815	
Emission to wastewater [g/d]	**$Elocal_{ww}$ = $Elocal_{ww}$ x N_{houses} x $F_{simultaneity}$**	**9.78E-04**	**3.14E-04**	**7.82E-03**	**274E-03**
Total emission to wastewater [kg/d]	**$E_{ww\ total}$ = Σ(E_{ww})/1000**	**1.32E-06**		**1.06E-05**	

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP (imidacloprid)	**1.32E-06**	Worst case private house + large

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
		buildings
STP (s-methoprene)	**1.06E-05**	Worst case private house + large buildings

Scenario [5]: outdoor use in bait station.

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

Scenario [6]_ indoors use in bait station.

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

Fate and distribution in exposed environmental compartments

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

Input parameters (only set values) for calculating the fate and distribution in the environment Imidacloprid			
Input	Value	Unit	Remarks
Molecular weight	255.7		
Melting point	144	°C	
Boiling point	Descomposition	°C	
Vapour pressure (at 20ºC)	<0.1	Pa	
Water solubility (at 20°C)	613	mg/l	
Log Octanol/water partition coefficient	0.57	Log 10	

Organic carbon/water partition coefficient (Koc)	230	l/kg	
Henry's Law Constant (at 20 C)*[if measured data available]*	$1.7x10^{-10}$	Pa/m3/mol	
Biodegradability	No		
DT_{50} for hydrolysis in surface water	2.75 years at 12ºC/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) 1.6 days (spring, summer)	d or hr	
DT_{50} for degradation in soil	135.1 days	d or hr (at 12ºC)	N=4
DT_{50} for degradation in air	2.54	d or hr	
BCF fish	0.61	$L.kg^{-1}$	
BMF fish	1	-	
BCF worm	0.88	$L.kg^{-1}$	

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

Input parameters (only set values) for calculating the fate and distribution in the environment S-methoprene			
Input	Value	Unit	Remarks
Molecular weight	310.48		
Melting point		°C	
Boiling point	279.9	°C	
Vapour pressure (at 20ºC)	0.623 mPa at 20°C	mPa	
Water solubility (at 20°C)	6.85 at 20ºC	mg/l	
Log Octanol/water partition coefficient (log P_{OW}) (pH 7)	6.34	Log 10	
Organic carbon/water partition coefficient (Koc)	876	l/kg	
Henry's Law Constant (at 20 C)*[if measured data available]*	0.0306	Pa/m3/ mol	
Biodegradability	Inherently biodegradable, not fulfilling the criteria		
Degradation in soil (DT_{50}) (at 12°C)	1.55	days	
DT_{50} for hydrolysis in surface water	*S-Methoprene technical was found to be hydrolytically stable at pH 4, 7 and 9 (examined at 25, 37 and 50°C). In strong acid solution (pH 1.2), hydrolysis is*	d or hr (at 12ºC /pH)	

	rapid with a half-life of 17 hours at 37°C.		
BCF fish	516	$L.kg^{-1}$	
BMF fish	10	-	
BCF earthworms	26253.98	$L.kg^{-1}$	

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

Calculated PEC values

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

Summary table on calculated PEC values

		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: outdoor use around the buildings	Imidacloprid	$1.18x10^{-5}$	$1.18x10^{-6}$	$6.81x10^{-6}$	-	-	$1.35x10^{-6}$	$2.22\ x10^{-4}$	-
	S-methoprene	$8.77x10^{-5}$	$8.76x10^{-6}$	$1.74x10^{-4}$	-	-	$2.64x10^{-6}$	$2.83x10^{-5}$	-
Scenario 2; Outdoor use terraces.	Imidacloprid	-	-	-	-	-	$2.24x10^{-5}$	$5.37x10^{-3}$	-
	S-methoprene	-	-	-	-	-	$1.79x10^{-4}$	$4.29x10^{-2}$	-
Scenario 4: Indoor sue, spot treatment, private and large buildings	Imidacloprid	$6.41x10^{-7}$	$6.41x10^{-8}$	$3.71x10^{-7}$			$7.31x10^{-8}$	$1.25x10^{-5}$	-
	S-methoprene	$4.76x10^{-6}$	$4.75x10^{-7}$	$9.42x10^{-6}$			$1.43x10^{-7}$	$1.53x10^{-6}$	-

Primary and secondary poisoning

Primary poisoning

Primary poisoning is the direct consumption of insecticide by birds or mammals. No primary poisoning as consequence of the application of MAGNUM GEL HORMIGAS IGR PLUS is envisaged. According to the ESD for PT 18 (OECD, 2008), a gel formulation is not a form that could be sufficiently appetent to bird and mammals. In addition, the biocidal product should be applied only in places inaccessible by pets so that primary exposure is

unlikely. Furthermore, the product contains a bittering agent that should prevent the consumption of the product by animals up in the food chain (vertebrates).A risk assessment for non-target animals primary exposed to imidacloprid and S-methoprene is therefore not deemed reasonable.

Secondary poisoning

Mammals and birds may consume contaminated worms from the contaminated soil. The concentration of the active substance in earthworms is calculated according to the guidance for the biocidal product assessment (2015).
Imidacloprid has a low potential for bioaccumulation and as such there is no significant risk of secondary poisoning from this product. However, a risk assessment for secondary poisoning has been included for informational purposes. It is has a log Kow < 3 (log Kow = 0.57) and a BCF< 100 (BCF in earthworm = 0.88 L.kg-1).
The active substance S-Methoprene has a log Kow > 3 (log Kow = 6.34) and a BCF > 100 (BCF in fish = 516 L.kg-1, BMF = 1 and BCF in earthworm = 26253.9 L.kg-1). According to the scenario secondary poisoning may occur via the aquatic food chain and/or via the terrestrial food chain. The concentration of S-Methoprene in food (i.e. in fish and in earthworm) of fish-eating and worm-eating predators (mammals) has been calculated.

Sencondary poisoning has been calculated for the worst case, scenario 1.
In accordance with the equations of the Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0, 2017, $PEC_{oral,predator}$ for both food chain were calculated as followed:

Imidacloprid

Parameter / variable	**Symbol**	**Unit**	**Value**
Aquatic food chain:			
Predicted environmental concentration during episode	$PEC_{local,water}$	[$mg.l^{-1}$]	1.18E-06
Bioconcentration factor for fish on wet weight basis	BCF_{fish}	[$l.kg^{-1}_{wet\ fish}$]	0.61
Biomagnification factor in fish	BMF	[-]	1
Predicted environmental concentration in food (considering that predators feed at 50% on local level)	**$PEC_{oral,predator}$**	**[$mg.kg^{-1}_{wet\ fish}$]**	**7.20E-07**
Terrestrial food chain :			
log of partition coefficient n-octanol-water	Log K_{ow}	[-]	0.57
Bioconcentration factor for earthworm on wet weight basis	$BCF_{earthworm}$	[$l.kg^{-1}_{wet\ earthworm}$]	0.88
Concentration in porewater	$C_{porewater}$	[$mg.l^{-1}$]	2.22E-04
Concentration in soil	C_{soil}	[$mg.kg^{-1}_{wwt}$]	1.35E-06
Fraction of gut loading in worm	F_{gut}	[$kg_{dwt}.kg^{-1}_{wwt}$]	0.1
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	[$kg_{wwt}.kg^{-1}_{dwt}$]	1.13
Predicted environmental concentration in food (considering that predators feed at 50% on local level)	**$PEC_{oral,predator}$**	**[$mg.kg^{-1}_{wet\ earthworm}$]**	**3.12E-07**

S-methoprene

Parameter / variable	Symbol	Unit	Value
Aquatic food chain:			
Predicted environmental concentration during episode	$PEC_{local,water}$	$[mg.l^{-1}]$	8.76E-06
Bioconcentration factor for fish on wet weight basis	BCF_{fish}	$[l.kg^{-1}_{wet\ fish}]$	516
Biomagnification factor in fish	BMF	[-]	10
Predicted environmental concentration in food (considering that predators feed at 50% on local level)	**$PEC_{oral,predator}$**	**$[mg.kg^{-1}_{wet\ fish}]$**	**4.52E-02**
Terrestrial food chain :			
log of partition coefficient n-octanol-water	Log K_{ow}	[-]	6.34
Bioconcentration factor for earthworm on wet weight basis	$BCF_{earthworm}$	$[l.kg^{-1}_{wet\ earthworm}]$	26263.9
Concentration in porewater	$C_{porewater}$	$[mg.l^{-1}]$	2.83E-05
Concentration in soil	C_{soil}	$[mg.kg^{-1}_{wwt}]$	2.64E-06
Fraction of gut loading in worm	F_{gut}	$[kg_{dwt}.kg^{-1}_{wwt}]$	0.1
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	$[kg_{wwt}.kg^{-1}_{dwt}]$	1.13
Predicted environmental concentration in food (considering that predators feed at 50% on local level)	**$PEC_{oral,predator}$**	**$[mg.kg^{-1}_{wet\ earthworm}]$**	**6.68E-04**

2.2.8.3 Risk characterisation

Atmosphere

Conclusion.

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

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

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

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values		
		$PEC/PNEC_{STP}$
Scenario 1: , outdoor use around building.	Imidacloprid	1.92×10^{-7}
	S-methoprene	1.28×10^{-5}
Scenario 4: , indoor use, spot treatment, large buildings and private houses.	Imidacloprid	1.05×10^{-8}
	S-methoprene	6.95×10^{-7}

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

Aquatic compartment

Summary table on calculated PEC/PNEC values					
		$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**PEC/PNEC sea-water**	**$PEC/PNEC_{sed}$ ased**
Scenario 1: outdoor use aroung buildings	Imidacloprid	$2.45X10^{-1}$	$2.62X10^{-1}$		
	S-methoprene	$4.61X10^{-2}$	$4.57X10^{-1}$		
Scenario 4: , indoor use, spot treatment, private houses and large buildings.	Imidacloprid	$1.34X10^{-2}$	$1.43X10^{-2}$		
	S-methoprene	$2.50X10^{-3}$	$2.48X10^{-2}$		

Conclusion:

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

Terrestrial compartment

	Calculated PEC/PNEC values	
		$PEC/PNEC_{soil}$
Scenario 1: , outdoor use around buildings.	Imidacloprid	8.60×10^{-5}
	S-methoprene	1.78×10^{-5}
Scenario 2: , outdoor use, terrace scenario.	Imidacloprid	1.42×10^{-3}
	S-methoprene	1.21×10^{-3}
Scenario 4: , indoor use, spot treatment, private houses and large buildings	Imidacloprid	4.63×10^{-6}
	S-methoprene	9.69×10^{-7}

Conclusion:

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

Groundwater

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

Primary and secondary poisoning

Primary poisoning

Risk to bees:

Imidacloprid was shown to be highly toxic to bees both by oral and contact exposure with LD50 of 0.0037 µg per bee and 0.038 µg per bee, respectively (Imidacloprid IIA, 8.3.1.1/01(BAY 158/901384)). The product MAGNUM GEL HORMIGAS IGR PLUS contain a concentration of imidacloprid of 0.01% w/w, the quantity of product necessary to reach LD50 oral and the LD50 contact are 37 µg and 810 µg, respectively. The product is a ready to use gel bait with a high contain of sugar. MAGNUM GEL HORMIGAS IGR PLUS is applied by drops or lines (elongated drops) where ants are present, the application rate is 3 drops/ m^2 (1 drop=0.2 g of gel bait). Therefore, the exposure of a honeybee to the product and its mortality after consuming the biocidal product, MAGNUM GEL HORMIGAS IGR PLUS cannot be excluded.

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

Secondary poisoning

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

		Imidacloprid	S-methoprene
Aquatic	Birds	1.71×10^{-7}	-
	Mammals	8.64×10^{-8}	1.04×10^{-3}
Terrestrial	Birds	7.44×10^{-8}	-
	Mammals	3.75×10^{-8}	1.53×10^{-5}

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

MYSTURE TOXICITY

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

Summary table on calculated ΣPEC/PNEC values					
	$\Sigma PEC/PNEC_{STP}$	**$\Sigma PEC/PNEC_{water}$**	**$\Sigma PEC/PNEC_{sed}$**	**$\Sigma PEC/PNEC_{soil}$**	**ΣPEC_{GW}**
Scenario 1, outdoor use aroundo buildings.	1.30×10^{-5}	2.92×10^{-1}	7.19×10^{-1}	1.35×10^{-4}	2.51×10^{-4}
Scenario 2, outdoor use, terrace scenario.	-	-	-	5.26×10^{-4}	9.66×10^{-3}

Scenario 4, indoor use, spot treatment, private houses and large buildings.	$7.05x10^{-7}$	$1.59x10^{-2}$	$3.91x10^{-2}$	$5.60x10^{-6}$	$1.36x10^{-5}$
.	-	-	-	.	-

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

Overall conclusion on the risk assessment for the environment of the product

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

Summary table for the risk assessment of this product.

	$PEC/PNEC_{stp}$	$PEC/PNEC_{water}$	$PEC/PNEC_{sed}$	$PEC/PNEC_{soil}$	$PEC/PNEC_{GW}$
Scenario 1, outdoor use around the building	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
Scenario 2, outdoor use, terrace scenario				Acceptable	Acceptable
Scenario 4, indoor use spot treatment	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
.					

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

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

2.2.9 Measures to protect man, animals and the environment

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

Handling:
Avoid contact with eyes and skin.

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

- 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.

2.2.10 Assessment of a combination of biocidal products

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

2.2.11 Comparative assessment

Comparative Assessment for the biocidal product "MAGNUM GEL HORMIGAS IGR PLUS"

Background

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

1.- Application administrative details:

Procedure: NA
Purpose: Authorisation
Case Number in R4BP: -
Evaluating Competent Authority: ES CA
Applicant: Mylva, S.A..
(Prospective) Authorisation holder: Mylva, S.A.

2.- Administrative information of the BP/BPF
Trade name: MAGNUM GEL HORMIGAS IGR PLUS
Product type: 18 (insecticide)
Active substance: Imidacloprid (CAS number: 138261-41-3)

3.- Intended uses for the relevant BP in the application
According to the applicant MAGNUM GEL HORMIGAS PLUS is an insecticide (PT18) which contains the active substance imidacloprid. The product is to be used indoors and outdoors to kill ants.

Table 3.1 List of intended uses of the biocidal product:

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

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

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

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

4.2.- Identified eligible non-chemical alternatives
Not relevant in the screening phase.

5.- Screening phase
5.1.- Description of the assessment of the adequate chemical diversity in authorised BPs to minimise the occurrence of resistance and conclusion.
In accordance with Article 23(b) of the BPR, the eCA has to check first if the chemical diversity of the available ASs within the identified alternative BPs can be considered as adequate to minimise the occurrence of resistance in the target harmful organism(s). In the Technical Guidance Note on comparative assessment of biocidal products (document: CA-May15-Doc.4.3.a - Final - TNG on comparative assessment.doc) is proposed as a general rule, at least three different "active substances/ mode action" combination should remain available through authorised BPs for a given use in order to consider that the

chemical diversity is adequate. This availability of ASs should be also looked at taking into account the different user categories, so that chemical diversity is adequate in BPs authorised both for professional and non-professional users. An inadequate chemical diversity for one user category could lead to resistance occurrence, which might spread afterwards across the target organism population.

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

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

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

5.3.- Conclusion of the screening phase:

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

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

3 ANNEXES

3.1 List of studies for the biocidal product

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
2.1.2	Anonymous	2015	MSDS of MAGNUM GEL HORMIGAS IGR PLUS Sheet Facility: MYLVA S.A.; Vía Augusta, 48, 08006-BARCELONA, Spain.
2.1.2	Anonymous	2015	MSDS of IMIDACLOPRID TC Sheet Facility: Bayer CropScience AG; Alfred-Nobel-Straße 50, 40789 Monheim am Rhein, Germany.
2.1.2	Anonymous	2017	MSDS of S-(+)-Methoprene Sheet Facility: Bábolna Bioenvironmental Centre Ltd.; H-1107 Budapest, Szállás u. 6. Hungary.
2.1.2	Anonymous	2014	MSDS of Co-formulant 1 Sheet Facility: Emilio Peña, S.A.; Pol.Ind. Masía del juez; C/ Dels Llibrers, 19 – 46900; Torrente – Valencia – España
2.1.2	Anonymous	2018	MSDS of Co-formulant 2 Sheet Facility: Johnson Matthey plc; Wheatfield Road, Edinburgh, EH11 2QA; Scotland
2.1.2	Anonymous	2014	MSDS of Co-formulant 3 Sheet Facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS -MADRID
2.1.2	Anonymous	2012	MSDS of Co-formulant 4 Sheet Facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS -MADRID
2.1.2	Anonymous	2016	MSDS of Co-formulant 5 Sheet Facility: SUCESORES DE JOSÉ ESCUDER, S.L.; Avda. Antoni Gaudí, 60 - 62 Pol. Ind. Rubí-Sud 08191; Rubí; Barcelona; Spain.
2.1.2	Anonymous	2014	MSDS of Co-formulant 6 Sheet Facility: Gadot Biochemical Industries Ltd; 117 Hahistadrut Ave; P.O.B 10636; Haifa Bay 26118; Israel
2.1.2	Anonymous	2015	MSDS of Co-formulant 7 Sheet Facility: SPI Pharma Inc.; Rockwood Office Park; 503 Carr Road; Wilmington, Delaware 19809
2.1.2	Anonymous	2018	MSDS of Co-formulant 8 Sheet Facility: SUCESORES DE JOSÉ ESCUDER, S.L.; Avda. Antoni Gaudí, 60 - 62 Pol. Ind. Rubí-Sud 08191; Rubí; Barcelona; Spain.
2.1.2	Anonymous	2018	MSDS of Co-formulant 9 Sheet Facility: Emilio Peña, S.A.; Pol.Ind. Masía del juez; C/ Dels Llibrers, 19 – 46900; Torrente – Valencia – España
2.2.2	[redacted]	2015	Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL HORMIGAS IGR PLUS (IMIDACLOPRID 0.01% W/W AND S-METHOPRENE 0.08% W/W)

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
			Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain. Study code: E-15/0002 at July 2015 GLP compliance → Yes Data protection claimed → Yes
2.2.2 / 2.2.4	[redacted]	2017	Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL HORMIGAS IGR PLUS (IMIDACLOPRID 0.01% W/W AND S-METHOPRENE 0.08% W/W) Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain. Study code: E-15/0003 at March 2017 GLP compliance → Yes Data protection claimed → Yes
2.2.2 / 2.2.4	[redacted]	2017	Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL HORMIGAS IGR PLUS (IMIDACLOPRID 0.01% W/W AND S-METHOPRENE 0.08% W/W) Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain. Study code: E-15/0003 at August 2017 GLP compliance → Yes Data protection claimed → Yes
2.2.2 / 2.2.4	[redacted]	2018	Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL HORMIGAS IGR PLUS (IMIDACLOPRID 0.01% W/W AND S-METHOPRENE 0.08% W/W) Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain. Study code: E-15/0003 at August 2018 GLP compliance → Yes Data protection claimed → Yes
2.2.2 / 2.2.4	[redacted]	2020	Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL HORMIGAS IGR PLUS (IMIDACLOPRID 0.01% W/W AND S-METHOPRENE 0.08% W/W) Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain. Study code: E-15/0003 at January 2020 GLP compliance → Yes Data protection claimed → Yes
2.2.2	[redacted]	2015	Title: Determination of whether the bait samples Magnum Gel Cucarachas IGR Plus 2.15 % and Magnum Gel Hormigas IGR Plus 0’01 % are a solid or a liquid. Test Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain. Study code: PG007-14/05 GLP Data protection claimed → Yes
2.2.3	[redacted]	2021	Title: Determination of DSC of Magnum Gel Cucarachas IGR Plus.

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
	[redacted]		Test Facility: Laboratory of Magnetic and Thermal Measurements (LMT), Universidad de Barcelona, Edifici Cn Campus de la UAB 08193 Bellaterra (Cerdanyola del Vallès) Barcelona. Spain Tel.: 34 - 93 581 34 74 / 34 93 581 16 57 - Fax: 34 - 93 581 21 55 LMT@uab.es http://sct.uab.cat/lmt/ Study code: 210603 Non-GLP Data protection claimed → Yes
2.2.3	[redacted]	2021	Title: IMMERSION CORROSION TESTING S/ASTM-G 31.REF.: MAGNUM ANT GEL IGR PLUS BATCH: P649 F. EXPIRY DATE: 06-2023 Test Facility: metal test – laboratorio de ensayos y verificacion 3D. Pol. Ind. Del Circuit C/ Mass Moreneta, esq. Can Cabanyes, 08160, Montmeló, Barcelona. Tel.: +34 - 93 564 54 53 - Fax: +34 - 93 564 50 73 Study code: E-01430.00001 Non-GLP Data protection claimed → Yes
2.2.5	[redacted]	2016	Title: Laboratory bioassay to determine the efficacy of Magnum Gel/Ecogel hormigas IGR Plus (Bait station) against *Linepithema humile*, *Monomorium pharaonis* and *Lasius niger.* Test facility: Mylva S.A. Report no. ES0039/02 Data protection claimed → Yes
2.2.5	[redacted]	2015	Title: Laboratory bioassay to determine the efficacy of Magnum Gel Hormigas IGR Plus against *Linepithema humile*, *Monomorium pharaonis* and *Lasius niger.* Test facility: Mylva S.A. Report no. ES0018-13/23 Data protection claimed → Yes
2.2.5	[redacted]	2016	Title: Field trial to determine the efficacy of Magnum Gel / Ecogel Hormigas IGR Plus (Bait Station) against *Linepithema humile*, *Monomorium pharaonis* and *Lasius niger* Test facility: Mylva S.A. Report no. ES0036-7/13 Data protection claimed → Yes
2.2.5	[redacted]	2016	Title: Semi-field trial to determine the efficacy of Magnum Gel / Ecogel Hormigas IGR Plus against *Lasius niger* Test facility: Mylva S.A. Report no. ES0034-A/7 Data protection claimed → Yes
2.2.5	[redacted]	2015	Title: Field trial to determine the efficacy of Magnum Gel Hormigas IGR Plus against *Linepithema humile* , *Monomorium pharaonis* and *Lasius niger* Test facility: Mylva S.A.

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
			Report no. ES0032-4/12 Data protection claimed → Yes
2.2.5	[redacted]	2019	Title: Laboratory bioassay to determine the the effect of 0.08% S-methoprene against Argentine ant, *Linepithema humile*. Test facility: Mylva S.A. Report no. ES0046.A-3/19 Data protection claimed → Yes
2.2.5.	[redacted]	2018	Title: Laboratory bioassay to determine the efficacy of Magnum Gel Hormigas IGR Plus against *Linepithema humile, Monomorium pharaonis and Lasius grandis*. (·3 years) Test facility: Mylva S.A. Report no. ES0035-3/12 Data protection claimed → Yes
2.2.5.	[redacted]	2019	Title: Laboratory bioassay to determine the efficacy of Magnum Gel Hormigas IGR Plus against *Linepithema humile, Monomorium pharaonis and Lasius grandis*. (4 years) Test facility: Mylva S.A. Report no. ES0035-11/19 Data protection claimed → Yes
2.2.6	Mylva Regulatory Affairs	2015	Acute Toxicity of the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUS Test Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain. Toxicity Report: ATR004.1-08/15
2.2.6	[redacted]	2015	Risk Characterisation of the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUS Test Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain. Report code: RC002.2-08/15
2.2.6	Mylva Regulatory Affairs	2017	Risk Characterisation of the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUS Test Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain. Report code: RC002.2-09/17
2.2.6	Mylva Regulatory Affairs	2018	Risk Characterisation of the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUS Test Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain. Report code: RC002.2-10/18
2.2.6	[redacted]	2015	Effects and Exposure Assessment for the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUS Test Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain. Report code: EA002.1-08/15
2.2.6	Mylva Regulatory Affairs	2017	Effects and Exposure Assessment for the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUS Test Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain.

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
			Report code: EA002.1-09/17
2.2.6	Mylva Regulatory Affairs	2018	Effects and Exposure Assessment for the Biocidal Product MAGNUM GEL HORMIGAS IGR PLUS Test Facility: Mylva, S.A., Via Augusta, 48; 08006 Barcelona, Spain. Report code: EA002.1-10/2018
	ECHA	2011 (revised version: July 2015)	Competent Authority Report and Assessment Report of IMIDACLOPRID.
	ECHA	2013	Competent Authority Report and Assessment Report of S-METHOPRENE.
	Official Journal of the European Union	2011	COMMISSION DIRECTIVE 2011/69/EU
	Official Journal of the European Union	2014	COMMISSION IMPLEMENTING REGULATION (EU) No 91/2014

3.2 Output tables from exposure assessment tools

3.2.1 Exposure assessment

3.2.1.1 Calculations for Scenario [1]

Exposure is estimated using the following calculations:
*Exposure = (Number of events * quantity of product per event * Fraction of active substance/Kg bw/person) * dermal absorption*

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

3.2.1.2 Calculations for Scenario [2]

Exposure is estimated using the following calculations:
*Exposure = (Number of events * quantity of product per event * Fraction of active substance/Kg bw/person) * dermal absorption*

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

3.2.1.3 Calculations for Scenario [3]

Exposure is estimated using the following calculations:
*Exposure = (Number of events * quantity of product per event * Fraction of active substance/Kg bw/person) * dermal absorption*

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

3.2.1.4 Calculations for Scenario [4]

See section 3.2.1.2

3.2.1.5 Calculations for Scenario [7]

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

Parametres	S-Methoprene	Imidacloprid	Units
bw toddler	10	10	kg
amount b.p. (worst case)	333.3	333.3	mg
Oral absorption	35%	100%	%
DA	75%	75%	%
content as	0,08%	0,01%	%
potential exp	0,27	3,33E-02	mg as

absorbed dermal dose	0,20	2,50E-02	mg as
actual exp dermal toddler	2,00E-02	2,50E-03	mg/kg bw
90% external dermal load	1,80E-02	2,25E-03	mg/kg bw
actual exp oral tod (10% external dermal ingested)	9.33E-04	3.33E-4	mg/kg bw
combined exposure toddler	1,89E-02	2,58E-03	**mg/kg bw**

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 efficacy to kill ants (Product Type 18).

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

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

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

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

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

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

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

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

- Do not apply on surfaces or utensils that can be in contact with foodstuff. The following label restrictions preclude the exposure of animals:
- The treatment must be restricted to areas out of reach of animals
- The product can not be applied on surfaces where feed is prepared, consumed or stored.

- Do not apply on surfaces or utensils that can be in contact with feedingstuff. It is concluded that dietary exposure i.e., food contamination and exposure of livestock to residues of the biocidal product is not expected.

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

Please, see efficacy data table.