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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

Magnum gel Cucarachas IGR Plus

Product type 18

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

Case Number in R4BP: BC-KH019263-49

Evaluating Competent Authority: Spain

Date: October 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-KH019263-49	August 2015	Initial assessment
NA-APP	ES	ES-0015195-0000	March 2021	First authorisation
NA-AAT	ES	ES-0015195-0000	April 2021	Amendment
NA-AAT	ES	ES-0015195-0000	April 2021	Amendment
NA-ADC	ES	ES-0015195-0000	July 2021	Amendment
NA-AAT	ES	ES-0015195-0000	September 2021	Amendment. Removal of Frech trade names.
NA-ADC	ES	BC-WU068846-86	October 2021	Amendments- ADD trade name in SPAIN and replacement of supplier active substance – Imidacloprid-.

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1 CONCLUSION

The assessment presented in this report has shown that the ready-to-use product, MAGNUM GEL CUCARACHAS IGR PLUS contains 2.15 % w/w imidacloprid & 0.5 % w/w S-methoprene, may be authorised for use as an insecticide (product-type 18) for the control against cockroaches (*Blatta orientalis, Blatella germanica* and *Periplaneta americana*) for trained professionals, professional and general public.

The biocidal product is a brown practically odourless gel and given the nature of the formulation it is not considered explosive, oxidizing, highly flammable or auto-flammable. Therefore, there not be hazards associated with the physico-chemical properties of the product under normal conditions of use. Moreover, the formulation exhibited stability under long term storage for 4 years at room temperature.

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

MAGNUM GEL CUCARACHAS IGR PLUS has demonstrated sufficient efficacy indoors in laboratory tests and field trials against three species of cockroaches (*Blatta orientalis, Blatella germanica* and *Periplaneta americana*) on infesting houses and commercial buildings with the methods of application by droplets (cartridge/syringe) and by placement of bait stations. The product kills adult and nymph cockroaches and prevents females from developing the eggs of the new breeds.

The product is not classified with regard to human health according to the Regulation (EC) Nº 1272/2008. No substances of concern have been identified for human health. The biocidal product contains the skin sensitising co-formulants 2-octyl-2H-isothiazol-3-one (OIT, CAS-No. 26530-20-1) and 1,2-benzisothiazol-3-(2H)-one (BIT, CAS-No. 2634-33-5), in relevant concentrations leading to labelling of the product with EUH208 ("Contains 2-octyl-2H-isothiazol-3-one and 1,2-benzisothiazol-3-(2H)-one. May produce an allergic reaction.").

Magnum Gel Cucarachas IGR Plus is a ready-to-use product to be applied by trained professionals/ professionals and the general public using a cartridge/syringe and bait station. The risk assessment has been carried out for the active substances Imidacloprid and S-Methoprene.

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 users during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63). Indirect exposure is expected for toddlers via dermal and hand to mouth contact after application of the product.

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

Based on the risk assessment results, the use of Magnum Gel Cucarachas 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.

Exposure of consumers via residues in food as result of product uses is not expected due to the application method and the physical properties of product. Moreover, some

label restrictions to avoid this contamination have been included. See point 2.2.6.3 Risk for consumers via residues in food.

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

Environment
The risk assessment for the environment has been performed for the two active substances, imidacloprid and s-methoprene, and the substance of concern OIT.
In conclusion, for the MAGNUM GEL CUCARACHAS IGR PLUS, risks to the environment are acceptable only to be used indoor (directly or in bait stations) in crack and crevices

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

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

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
Magnum gel Cucarachas IGR Plus **Magnum gel Cucarachas IGR**	**Spain**
Magnum Gel Cafards IGR	France
Magnum Gel Schaben IGR	Germany
Ecogel Schaben IGR	
Magnum Gel Schaben IGR	Austria
Magnum Gel Roaches IGR PLUS	Bulgaria
Magnum Gel Roaches IGR	United Kingdom
Magnum Gel Roaches IGR	Hungary
Glock BP	Poland

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)-2021-18-00746	
Date of the authorisation	23/03/2021	
Expiry date of the authorisation	23/03/2026	

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 actives substances

Active substance	**Imidacloprid**
Name of manufacturer	ADAMA Agriculture España S.A.
Address of manufacturer	C/ Príncipe de Vergara 110, 5th floor 28002 – Madrid ESPAÑA

Location of manufacturing sites	Adama Makhteshim Ltd. - Neot-Hovav Eco-Industrial Park, 84100 Beer Sheva ISRAEL
Location of manufacturing sites	Jiangsu Yangnong Chemicals Group Co. Ltd - 39 Wenfeng Road, 225009 Yangzhou CHINA
Active substance	**S-Methoprene**
Name of manufacturer	Babolna Bioenvironmental Centre Ltd.
Address of manufacturer	H-1107 Budapest, Szallas u. 6. 1107 Szallas, Budapest, Hungary
Location of manufacturing sites	H-1107 Budapest, Szallas u. 6. 1107 Szallas, Budapest, Hungary

2.1.2 Product composition and formulation

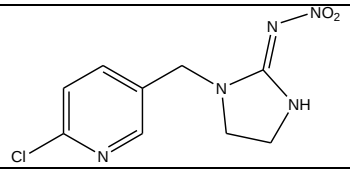
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

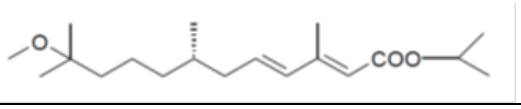
Yes ☐
No ☒

2.1.2.1 Identity of the active substance

The biocidal product has four active substances.

Main constituents	
ISO name	Imidacloprid
IUPAC or EC name	(2E)-1-[(6-chloropyridin-3-yl) methyl]-N-nitroimidazolidin-2-imine
EC number	428-040-8
CAS number	138261-41-3
Index number in Annex VI of CLP	612-252-00-4
Minimum purity / content	≥97,5%
Structural formula	

Main constituents	
ISO name	S-methoprene
IUPAC or EC name	Isopropyl-(2E,4E,7S)-11- methoxy-3,7,11-trimethyl- 2,4-dodecadienoate
EC number	Not available
CAS number	65733-16-6
Index number in Annex VI of CLP	Not available
Minimum purity / content	≥95,0 %

Structural formula	

2.1.2.2 Candidate for substitution

The active ingredient Imidacloprid, contained in the product Magnum Gel Cucarachas IGR Plus is candidate for substitution according to the PBT criteria. Imidacloprid is classified as very persistent and toxic substance.

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	2.15 (technical) 2.09 (pure)
S-Methoprene	Isopropyl-(2E,4E,7S)-11- methoxy-3,7,11-trimethyl- 2,4-dodecadienoate	Active substance	65733-16-6	Not available	0.50 (technical) 0.48 (pure)
OIT	2-octyl-2H-isothiazol-3-one		26530-20-1	247-761-7	0.04

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.

NA-ADC – Sept 2021 - The holder submitted information of new supplier of active substance ADAMA Agriculture España S.A. in order to proced a replacement of manufacturer & manufacturing location of the active substance. The new source have been granted technically equivalent to the Annex I source by ECHA (Decision Nº TAP-D-1096667-13-00/F – asset: EU-0006162-0000 and Decision Nº TAPD-1099666-08-00/F – asset: EU-0006161-0000).

2.1.2.5 Information on the substances of concern

According to Annex A in *Guidance on the BPR: Volume III Human Health, Assessment & Evaluation (Parts B+C)*, *December 2017*, the product is not considered to contain any substance of concern (SoC).

Regarding to the environment, the product MAGNUM GEL CUCARACHAS IGR PLUS contais, beside the active substances, two substances of concern, 1,2-benzisothiazolin-3-one (BIT)

(CAS: 2634-33-5) and 2-octyl-2H-isothiazol-3-one (OIT) (CAS: 26530-20-1). Both are biocidal active substances from other PTs.

BIT is a biocidal active substance stil under review as preservative thus, at the moment this substace is not considered as substance of concern. However, the content of this substance in the product does not contribute to the classification of the product and although, this substance is an active substance from another product type, it is present in the product in a concentration lower than 0.1%, criterion stablish in the Guidance on the Biocidal Products Regulation (Version 2.0, 2017) to be considered as substance of concern.

OIT is an active substance in PT8 (Wood preservative). This substance is considered substance of concern because although the content of this substance in the product is lower tha the criterion stablish in the Biocidal Products Regulation (Version 2.0, 2017), this substance classified as hazardous and meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and it is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation. So, this substance is included in the risk assessment

2.1.2.6 Type of formulation

RB – Bait (ready to 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 Acute 1, Aquatic Chronic 1
Hazard statement	H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Labelling	
Signal words	Warning  GHS09
Hazard statements	H410 Very toxic to aquatic life with long lasting effects
Precautionary statements	P102 Keep out of reach of children P103 Read label before use P273 Avoid release to the environment P391 Collect spillage *Trained Professionals:* P501 Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations *Professionals and Non-professionals:* P501 Remove the content and / or its container as hazardous waste according to the regulations in force.

	EUH208 : Contains 2-octyl-2H-isothiazol-3-one (OIT) and 1,2-benzisothiazol-3-(2H)-one (BIT). May produce an allergic reaction.

2.1.4 Authorised uses.

2.1.4.1 Use description 1

Table 1. Use # 1– Indoors, cracks and crevices - Gel bait applied as drops - General public (non-professional users)

Product Type	PT18
Where relevant, an exact description of the authorised use	Insecticide and growth regulator product against cockroaches,
Target organism (including development stage)	Insecticide against the following target insects (adults, nymphs) - German cockroaches (*Blatella germanica*). - Oriental cockroaches (*Blatta orientalis*). - American cockroaches (*Periplaneta americana*).
Field of use	Indoors, crack and crevices. Private houses.
Application method	Open application of a gel bait applied as drops from a syringe.
Application rates and frequency	Dose: depends on the level of infestations and species of cockroaches (1 drop = 0.04 g). German cockroaches (*Blatella germanica*): 0.12-0.16 g/m^2 (3-4 drops/m^2). Oriental cockroaches (*Blatta orientalis*): 0.16-0.24 g/m^2 (4-6 drops/m^2) American cockroaches (*Periplaneta americana*): 0.16 g/m^2 - 0.24 g/m^2 (4-6 drops/m^2) Frequency of application: 1 application in 2 weeks. Reapply only once more if the infestation persists. Frequency of treatment: Three months after the infestation's end, treatment may be repeated.Maximum of 6 application per year.
Category of user	General Public (non-professional)
Pack sizes andpackaging material	LDPE plastic syringes of 1, 2, 3, 4, 5, 8 and10 grams of gel bait.

2.1.4.1.1 Use-specific instructions for use

Ready-to-use gel bait to be applied as drops deposited with the syringe. Drops adhere to non-porous surfaces. Apply only in crack and crevices. Use indoors in private houses.

Before treatment, remove all natural source of food from the infested area to encourage the ingestion of the gel

Apply the biocidal product only as spot application in cracks and crevices in places where cockroaches may be present out of the reach of children and animals:

- In inaccessible places

- In dark places: under the sink, behind the toilet, near the drain, etc.

- In warm temperature places: cracks and crevice behind the engines, refrigerators, washing machines, dishwashers, etc.

- In places with food waste or organic materials: under or behind kitchen cupboards, near the dustbin, in storerooms, in cellars, in courtyards, etc.

Do not use on wood or porous surfaces.

Avoid contact with treated surfaces.

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

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

2.1.4.1.2 Use-specific risk mitigation measures

Avoid contact with treated spots.

Avoid contact with eyes and skin.

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

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

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.

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

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.

2.1.4.1.5 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.

2.1.4.2 Use description 2

Table 2. Use # 2 – Indoors, cracks and crevices - Gel bait applied as drops - Professional users.

Product Type	PT18
Where relevant, an exact description of the authorised use	Insecticide and growth regulator product against cockroaches.
Target organism (including development stage)	Insecticide against the following target insects (adults, nymphs) - German cockroaches (*Blatella germanica*). - Oriental cockroaches (*Blatta orientalis*). - American cockroaches (*Periplaneta americana*)
Field of use	Indoors, crack and crevices. Houses and commercial buildings.
Application method	Open application of a gel bait applied as drops from a syringe
Application rates and frequency	Dose: depending on the level of infestations and species of cockroaches (1 drop = 0.04 g). German cockroaches (*Blatella germanica*): 0.12-0.16 g/m^2 (3-4 drops/m^2). Oriental cockroaches (*Blatta orientalis*): 0.16-0.24 g/m^2 (4-6 drops/m^2) American cockroaches (*Periplaneta americana*): 0.16 g/m^2 - 0.24 g/m^2 (4-6 drops/m^2) Frequency of application: 1 application in 2 weeks. Reapply only once more if the infestation persists. Frequency of treatment: Three months after the infestation's end, treatment may be repeated. Maximum of 6 application per year.
Category of users	Professional
Pack sizes and packaging material	LDPE plastic syringe of 1, 2, 3, 4, 5, 8, 10 grams of gel bait.

2.1.4.2.1 Use-specific instructions for use.

Ready-to-use gel bait to be applied as drops deposited with the cartridge. Drops adhere to non-porous surfaces.

Apply only in crack and crevices. Use indoors in houses and commercial buildings.

Before treatment, remove all natural source of food from the infested area to encourage the ingestion of the gel

Apply the biocidal product only as spot application in cracks and crevices where cockroaches may be present out of the reach of children and animals:

- In inaccessible places.

- In dark and wet places: craks and crevices under the sink, behind the toilet, near the drain, etc.

- In warm temperature places: behind the engines, refrigerators, washing machines,

dishwashers, etc.

- In places with food waste or organic materials: under or behind kitchen cupboards, near the dustbin, in storerooms, in cellars, in courtyards, etc.The product cannot be used on surfaces.

Do not use on wood or porous surfaces.

Avoid contact with treated surfaces.

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

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

2.1.4.2.2 Use-specific risk mitigation measures.

Avoid contact with treated spots.

Avoid contact with eyes and skin.

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

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

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.

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

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.

2.1.4.2.5 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.

2.1.4.3 Use description 3

Table 3. Use # 3 – Indoors, crack and crevices - Gel bait applied as drops – Trained professional users.

Product Type	PT18
Where relevant, an exact description of the authorised use	Insecticide and growth regulator product against cockroaches.

Target organism (including development stage)	Insecticide against the following target insects (adults, nymphs) - German cockroaches (*Blatella germanica*), - Oriental cockroaches (*Blatta orientalis*), - American cockroaches (*Periplaneta americana*)
Field of use	Indoors, crack and crevices. Houses and commercial buildings.
Application method	Open application of a gel bait applied as drops from a cartridge.
Application rates and frequency	Dose: depending on the level of infestations and species of cockroaches (1 drop = 0.04 g). German cockroaches (*Blatella germanica*): 0.12-0.16 g/m^2 (3-4 drops/m^2). Oriental cockroaches (*Blatta orientalis*): 0.16-0.24 g/m^2 (4-6 drops/m^2) American cockroaches (*Periplaneta americana*): 0.16 g/m^2 - 0.24 g/m^2 (4-6 drops/m^2) Frequency of application: 1 application in 2 weeks. Reapply only once more if the infestation persists. Frequency of treatment: Three months after the infestation's end, treatment may be repeated. Maximum of 6 application per year.
Category of users	Trained professional users
Pack sizes and packaging material	LDPE Cartridge of 1, 2, 3, 4, 5, 8, 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 syringe of 1, 2, 3,4, 5, 8,10,15, 20, 25, 30, 35, 40, 50g..

2.1.4.3.1 Use-specific instructions for use.

Ready-to-use gel bait to be applied as drops deposited with the cartridge. Drops adhere to non-porous surfaces.

Apply only in crack and crevices. Use indoors in houses and commercial buildings.

Before treatment, remove all natural source of food from the infested area to encourage the ingestion of the gel.

Apply the biocidal product only as spot application in craks and crevices where cockroaches may be present out of the reach of children and animals:

- In inaccessible places.

- In dark and wet placescracks and crevices the sink, behind the toilet, near the drain, etc.

- In warm temperature places: behind the engines, refrigerators, washing machines, dishwashers, etc.

- In places with food waste or organic materials: under or behind kitchen cupboards, near the dustbin, in storerooms, in cellars, in courtyards, etc.

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

Do not use on wood or porous surfaces.

Avoid contact with treated surfaces.

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

In storerooms the product may only be applied in the presence of properly packaged food.

2.1.4.3.2 Use-specific risk mitigation measures.

Avoid contact with treated spots.

Wear appropriate gloves during application.

Avoid contact with eyes and skin.

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

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

Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.)

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

Do not use the product in areas where resistance is suspected or established.
Inform the authorisation holder if the treatment is ineffective.

2.1.4.3.3 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.

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

Empty containers, unused product, washing water, containers 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.

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.

2.1.4.4 Use description 4.

Table 4. Use # 4 – Indoors-Gel bait applied in bait stations – General public (non-professional users)

Product Type	PT18
Where relevant, an exact description of the authorised use	Insecticide and gwoth regulator product against cockroaches.
Target organism (including development stage)	Insecticide against the following target insects (adults, nymphs) - German cockroaches (*Blatella germanica*), - Oriental cockroaches (*Blatta orientalis*), - American cockroaches (*Periplaneta americana*)
Field of use	Indoors. Private houses.
Application method	Ready-to-use bait stations.
Application rate and frequency	Dose: depending on the level of infestations: - For low infestations, 0.16 g/m^2 - For high infestations, 0.24 g/m^2 Frequency of application: After about 4 weeks, bait stations should be replaced with fresh ones if the infestation persists. Frequency of treatment: Three months after the infestation's end, treatment may be repeated.
Category of users	General Public (non-professional user)
Pack sizes and packaging material	Plastic (PET) bait station/bait station capsule with 1, 2, 2.5, 3, 4 and 5 grams of gel bait.

2.1.4.4.1 Use-specific instructions for use.

Ready-to-use gel bait in bait stations.

Use indoors in private houses.

Before treatment, remove all natural source of food from the infested area to encourage the ingestion of the gel

Apply the biocidal product by placement of bait stations only in places where cockroaches may be present out of the reach of children and animals:

- In inaccessible places: behind furniture, etc.

- In dark and wet places: under the sink, behind the toilet, near the drain, etc.

- In warm temperature places: behind the engines, refrigerators, washing machines, dishwashers, etc.

- In places with food waste or organic materials: under or behind kitchen cupboards, near the dustbin, in storerooms, in cellars, in courtyards, etc.

2.1.4.4.2 Use-specific risk mitigation measures.

Do not force open the bait station. Never introduce the fingers through the holes in the bait box.

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

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

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

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

2.1.4.5 Use description 5.

Table 5. Use # 5 – Indoors - Gel bait applied in bait stations – Professional users.

Product Type	PT18
Where relevant, an exact description of the authorised use	Insecticide and growth regulator product against cockroaches.
Target organism (including development stage)	Insecticide against the following target insects (adults, nymphs) - German cockroaches (*Blatella germanica*), - Oriental cockroaches (*Blatta orientalis*), - American cockroaches (*Periplaneta americana*)
Field of use	Indoors. Houses and commercial buildings.
Application method	Ready-to-use bait stations.
Application rates and frequency	Dose: depending on the level of infestations: - For low infestations, 0.16 g/m^2 - For high infestations, 0.24 g/m^2 Frequency of application: After about 4 weeks, bait stations should be replaced with fresh ones if the infestation persists. Frequency of treatment: Three months after the infestation's end, treatment may be repeated.

Category of users	Professional
Pack sizes and packaging material	Plastic (PET) bait station/bait station capsule with 1, 2, 2.5, 3, 4 and 5 grams of gel bait..

2.1.4.5.1 Use-specific instructions for use.

Ready-to-use gel bait in bait stations.

Use indoors in houses and commercial buildings.

Before treatment, remove all natural source of food from the infested area to encourage the ingestion of the gel

Apply the biocidal product by placement of bait stations only in places where cockroaches may be present out of the reach of children and animals:

- In inaccessible places: behind furniture, etc.

- In dark and wet places: under the sink, behind the toilet, near the drain, etc.

- In warm temperature places: behind the engines, refrigerators, washing machines, dishwashers, etc.

- In places with food waste or organic materials: under or behind kitchen cupboards, near the dustbin, in storerooms, in cellars, in courtyards, etc.

2.1.4.5.2 Use-specific risk mitigation measures.

Do not force open the bait station.

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

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

See section 2.1.5.

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

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.

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

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

See section 2.1.5.

2.1.4.6 Use description 6.

Table 6. Use # 6 – Indoors - Gel bait applied bait stations – Trained professional users.

Product Type	PT18
Where relevant, an exact description of the authorised use	Insecticide and growth regulator product against cockroaches.
Target organism (including development stage)	Insecticide against the following target insects (adults, nymphs) - German cockroaches (*Blatella germanica*), - Oriental cockroaches (*Blatta orientalis*), - American cockroaches (*Periplaneta americana*)
Field of use	Indoors. Houses and commercial buildings.
Application method	Ready-to-use bait stations.
Application rates and frequency	Dose: depending on the level of infestations: - For low infestations, 0.16 g/m^2 - For high infestations, 0.24 g/m^2 Frequency of application: After about 4 weeks, bait stations should be replaced with fresh ones if the infestation persists. Frequency of treatment: Three months after the infestation's end, treatment may be repeated.
Category of users	Trained professional
Pack sizes and packaging material	Plastic (PET) bait station/bait station capsule with 1, 2, 2.5, 3, 4, 5, 8, 10, 15, 20, 25 and 30 grams of gel bait.

2.1.4.6.1 Use-specific instructions for use.

Ready-to-use gel bait in bait stations.

Use indoors in houses and commercial buildings.

Before treatment, remove all natural source of food from the infested area to encourage the ingestion of the gel

Apply the biocidal product by placement of bait stations only in places where cockroaches may be present out of the reach of children and animals:

- In inaccessible places: behind furniture, etc.

- In dark and wet places: under the sink, behind the toilet, near the drain, etc.

- In warm temperature places: behind the engines, refrigerators, washing machines, dishwashers, etc.

- In places with food waste or organic materials: under or behind kitchen cupboards, near the dustbin, in storerooms, in cellars, in courtyards, etc.

2.1.4.6.2 Use-specific risk mitigation measures.

Do not force open the bait station. Never introduce the fingers through the holes in the station. Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.) Check the efficacy of the product on site: if need be, cause of reduced efficacy must be investigated to ensure that there is no resistance or t identify potential resistance. Do not use the product in areas where resistance is suspected or established. Inform the authorisation holder if the treatment is ineffective.

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

See section 2.1.5.

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

Empty containers, unused product, washing water, containers 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. At the end of the treatment campaign, collect bait boxes for disposal. Code the waste according to Decision 2014/955 / EU. Do not release to soil, ground, surface water or any kind of sewer.

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

See section 2.1.5.

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. Make an inspection before applying the product to check the level of infestation and affected areas. Use only indoors out of the reach of children and animals.

2.1.5.2 Risk mitigation measures

This product should be used in alternation with other products not containing the same

a.s. to avoid resistant populations.

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

Use products at recommended doses and intervals.

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

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

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

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

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

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

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

Basic First aid procedures:

IF ON SKIN:

Wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.

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.

- If necessary take person to a hospital and show the label or packaging when possible. Do not leave poisoned person alone.

Medical advice for doctors and sanitary staff

- Symptomatic and supportive treatment

IF MEDICAL ADVICE IS NEEDED, KEEP THE LABEL OR CONTAINER HANDY AND CONSULT THE MEDICAL SERVICE FOR TOXICOLOGICAL INFORMATION
Telephone:915620420

To include this telephone number on the label, you must notify the INTCF in accordance with the procedure established in Order JUS / 909/2017

2.1.5.4 Instructions for safe disposal of the product and its packaging

See the specific sections 2.1.4.1.4., 2.1.4.2.4, 2.1.4.3.4, 2.1.4.4.4., 2.1.4.5.4. and 2.1.4.6.4.

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 condition of 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 5ºC and 45ºC. Store away from light. Protect from frost. Do not store near food, drink and animal feedingstuff.

2.1.6 Other information

Definitions: Trained professional: pest control operators, having received specific training in insecticide control according to the national legislation in force. Professional: User applying biocidal products in the workplace. This user has some knowledge and skills in the handling of chemicals, and is able to correctly use personal protective equipment (PPE) if necessary. General public (non-professional user): Users who are not professionals and who apply the product in the context of their private life. The product contains a bitter substance that makes it repulsive to people or pets. 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 0.04 g of gel bait. The applicant should indicate in the label the size of a drop with 0.04 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. 0.16 g/m^2 = 4 bait station with 1 g in a room of 25 m^2.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Syringe	1, 2, 3, 4, 5, 8, 10	LPDE		General	Yes

	g	plastic		public	
Cartridge	1, 2, 3, 4, 5, 8, 10, 15, 20, 25, 30, 35, 40 and 50 g	LPDE plastic		Professional and trained professional	Yes
Bait station	1, 2, 2.5, 3, 4 and 5 g	PET plastic		General public, Professional and 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 substances ingredients Imidacloprid and S-Methoprene from Bayer S.A.S. and Babolna Bio Ltd., as notifiers and owners data for active substances respectively.

The applicant has provided laboratory and field trials against three species of cockroaches to support efficacy. The trials have been elaborated with our product MAGNUM GEL/ECOGEL CUCRACHAS IGR PLUS and MAGNUM GEL/ECOGEL CUCRACHAS IGR PLUS (bait station). Moreover, the sponsor of all studies is MYLVA, so a letter of access to the studies and the composition certificated of product tested are not necessary.

In relation to human health, 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 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 Cucarachas IGR Plus.
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.

NA-ADC-Sept. 2021: Mylva S.A. has submitted Letter of Access for a new sources of active substances ingredient - Imidacloprid - from ADAMA Agriculture España S.A. as owners data for two Technical Equivalences of active substances. This new source replace the previous source provided by Bayaer S.A.S.

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant

Table 1. Intended use # 1 – Trained professional user.

Product Type	PT18
Where relevant, an exact description of the authorised use	Imidacloprid 2.15% and 0.5% S-Methoprene Gel is an indoor gel bait insecticide against German cockroaches, *Blatta orientalis*, American cockroaches and *Periplaneta americana*. Imidacloprid 2.15% and 0.5% S-methoprene Gel is designed for the controlled placement of bait in the following situations: -User: Industrial, professional and general public (non-professional).
Target organism (including development stage)	German cockroach (adults and late nymphs), oriental cockroach (adults and late nymphs), american cockroach (adults and late nymphs).
Field of use	-In inaccessible places: cracks, crevices, behind furniture, etc. where cockroaches may be present. - In dark and wet places: under the sink, behind the toilet, near the drain. -In high temperature places: behind the engines, refrigerators, washing machines, dishwashers. -In places with food waste or organic materials: under or behind kitchen cupboards, near the dustbin, in the storeroom, in the cellars, in the courtyards.
Application method	Bait application
Application rates and frequency	For normal infestation, one application is effective for three months. For high infestation, inspect the bait after one month. Doses: German cockroach: 1 to 4 drops per square meter. American cockroach: 2 to 6 drops per square meter, depending on infestation degree. Eastern cockroach: 2 to 6 drops per square meter, depending on infestation degree.
Category of user	Trained professional
Pack sizes and packaging material	LDPE Cartridge of 1, 2, 3, 4, 5, 8, 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 syringe of 1, 2, 3,4, 5, 8,10,15, 20, 25, 30, 35, 40, 50 g. PET bait station of 1, 2, 2.5, 3, 4, 5, 8, 10, 15, 20, 25, 30 g

Table 2. Intended use # 2 – non-trained professional user

Product Type	PT18
Where relevant, an exact description of the authorised use	Imidacloprid 2.15% and 0.5% S-Methoprene Gel is an indoor gel bait insecticide against German cockroaches, *Blatta orientalis*, American cockroaches and *Periplaneta americana*. Imidacloprid 2.15% and 0.5% S- methoprene Gel is designed for the controlled placement of bait in the following situations: -User: Industrial, professional and general public (non-professional).
Target organism (including development stage)	German cockroach (adults and late nymphs), oriental cockroach (adults and late nymphs), american cockroach (adults and late nymphs).

Field of use	-In inaccessible places: cracks, crevices, behind furniture, etc. where cockroaches may be present. - In dark and wet places: under the sink, behind the toilet, near the drain... -In high temperature places: behind the engines, refrigerators, washing machines, dishwashers. -In places with food waste or organic materials: under or behind kitchen cupboards, near the dustbin, in the storeroom, in the cellars, in the courtyards...
Application method(s)	Bait application
Application rate(s) and frequency	German cockroach: 1 to 4 drops per square meter. American cockroach: 2 to 6 drops per square meter, depending on infestation degree. Eastern cockroach: 2 to 6 drops per square meter, depending on infestation degree. For normal infestation, one application is effective for three months. For high infestation, inspect the bait after one month. Doses:
Category of user	Non-trained professional user.
Pack sizes and packaging material	LDPE Cartridge of 1, 2, 3, 4, 5, 8, 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 syringe of 1, 2, 3,4, 5, 8,10,15, 20, 25, 30, 35, 40, 50g. PET bait station of 1, 2, 2.5, 3, 4, 5, 8, 10, 15, 20, 25, 30 g

Table 3. Intended use # 3 – non-professional user

Product Types	PT8
Where relevant, an exact description of the authorised use	Imidacloprid 2.15% and 0.5% S-Methoprene Gel is an indoor gel bait insecticide against German cockroaches, *Blatta orientalis*, American cockroaches and *Periplaneta americana*. Imidacloprid 2.15% and 0.5% S- methoprene Gel is designed for the controlled placement of bait in the following situations: -User: Industrial, professional and general public (non-professional).
Target organism (including development stage)	German cockroach (adults and late nymphs), oriental cockroach (adults and late nymphs), american cockroach (adults and late nymphs).
Field of use	-In inaccessible places: cracks, crevices, behind furniture, etc. where cockroaches may be present. - In dark and wet places: under the sink, behind the toilet, near the drain. -In high temperature places: behind the engines, refrigerators, washing machines, dishwashers. -In places with food waste or organic materials: under or behind kitchen cupboards, near the dustbin, in the storeroom, in the cellars, in the courtyards.

Application method	Bait application
Application rate(s) and frequency	German cockroach: 1 to 4 drops per square meter. American cockroach: 2 to 6 drops per square meter, depending on infestation degree. Eastern cockroach: 2 to 6 drops per square meter, depending on infestation degree. For normal infestation, one application is effective for three months. For high infestation, inspect the bait after one month. Doses:
Category of user	Non-professional user (general public)
Pack sizes and packaging material	LDPE Cartridge of 1, 2, 3, 4, 5, 8, 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 syringe of 1, 2, 3,4, 5, 8,10,15, 20, 25, 30, 35, 40, 50g. PET bait station of 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].	2.15% (Imidacloprid) 0.50% (S-methoprene) Batch number: J706	Initially: Gel After storage at 54 °C for 14 days: Gel After 17 months at 25°C ± 2°C: Gel After 2 years at 25°C ± 2°C: Gel After 3 years at 25°C ± 2°C: Gel After 4 years at 25°C ± 2°C: Gel	Final Report AGQ E-15-0002
Colour at 20 °C and 101.3 kPa	US EPA Product Properties Test Guidelines: OPPTS 830.6302 Color [EPA 712-C-96-019].	2.15% (Imidacloprid) 0.50% (S-methoprene) Batch number: J706	Initially: Brown After storage at 54 °C for 14 days: brown After 17 months at 25°C ± 2°C: Brown After 2 years at 25°C ± 2°C: Brown After 3 years at 25°C ± 2°C: Brown After 4 years at 25°C ± 2°C: Brown	Final Report AGQ E-15-0002
Odour at 20 °C and 101.3 kPa	US EPA Product Properties Test Guidelines: OPPTS 830.6304 Odor [EPA 712-C-96-021].	2.15% (Imidacloprid) 0.50% (S-methoprene) Batch number: J706	Initially: Practically Odourless After storage at 54 °C for 14 days: Practically Odourless After 17 months at 25°C ± 2°C: Practically Odourless After 2 years at 25°C ± 2°C: Practically Odourless After 3 years at 25°C ± 2°C: Practically Odourless After 4 years at 25°C ± 2°C: Practically Odourless	Final Report AGQ E-15-0002
Acidity / alkalinity	CIPAC MT 31 "Free acidity or	2.15% (Imidacloprid)	Not applicable	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
	alkalinity" Handbook F CIPAC MT 191 "Acidity or Alkalinity of Formulations" Handbook L	0.50% (S-methoprene) Batch number: J706		Final Report AGQ E-15-0002
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).	2.15% (Imidacloprid) 0.50% (S-methoprene) Batch number: J706	1.2467 ± 0.0002 g/mL	Final Report AGQ E-15-0002
Storage stability test – **accelerated storage**	CIPAC Guideline MT46.3	2.15% (Imidacloprid) 0.50% (S-methoprene) Batch number: J706	The product had the same appearance and the packaging remains unchanged after accelerated storage study.	Final Report AGQ E-15-0002
Active Ingredient Content	LC-MS		IMIDACLOPRID Initially: **2.35 ± 0.06 % w/w** After storage at 54 °C for 14 days: **2.28 ± 0.08 % w/w** Diference: -2.98% S-METHOPRENE Initially: **0.45 ± 0.02 % w/w** After storage at 54 °C for 14 days: **0.43 ± 0.02 % w/w** Diference: -4.44%	
Homogeneity of application			The biocidal product application is accurate and homogeneous in the form	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Appearance and stability of the package 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.		of drops of the same size and weight (0.04 g and 4 mm of diameter) There was no change in the packaging (plastic cartridges) Initially: pH = 6.56 ± 0.01 After storage at 54 °C for 14 days: pH = 5.47 ± 0.01	
Storage stability test – **long term storage at ambient temperature**	Guidelines for Specifying the Shelf Life of Plant Protection Products. Technical Monograph n°17, 2nd Edition		The product had the same appearance and the packaging remains unchanged after 48 months of storage	Final Report AGQ E-15-0002
Active Ingredient Content	LC-MS		IMIDACLOPRID Initially: **2.35 ± 0.07 % w/w** After 12 months at 25°C ± 2°C: **2.24 ± 0.07 % w/w** Diference: -4.68% After 2 years at 25°C ± 2°C: **2.25 ± 0.06 % w/w** Diference: -4.26% After 3 years at 25°C ± 2°C: **2.20 ± 0.06 % w/w** Diference: -6.38% After 4 years at 25°C ± 2°C: **2.17 ± 0.05 % w/w** Diference: -7.66% S-METHOPRENE	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			Initially: **0.45 ± 0.02 % w/w** After 12 months at 25°C ± 2°C: **0.44 ± 0.01 % w/w** Diference: -2.22% After 2 years at 25°C ± 2°C: **0.45 ± 0.01 % w/w** Diference: 0.00% After 3 years at 25°C ± 2°C: **0.49 ± 0.01 % w/w** Diference: +8.89% After 4 years at 25°C ± 2°C: **0.49 ± 0.02 % w/w** Diference: +8.89%	
Homogeneity of application			The biocidal product application is accurate and homogeneous in the form of drops of the same size and weight (0.04 g and 4 mm of diameter)	
Appearance and stability of the package			There was no change in the packaging (plastic cartridges)	
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 = 6.56 ± 0.01 After 17 months at 25°C ± 2°C: pH = 5.44 ± 0.01 After 2 years at 25°C ± 2°C: pH = 5.73 ± 0.02 After 3 years at 25°C ± 2°C: pH = 5.18 ± 0.01 After 4 years at 25°C ± 2°C: pH = 5.01 ± 0.01	
Storage stability test – **low temperature**			Not available	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
stability test for liquids				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Not available	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			The product had the same appearance and the packaging remains unchanged after 48 months of storage	Final Report AGQ E-15-0002
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The product had the same appearance and the packaging remains unchanged after 48 months of storage	Final Report AGQ E-15-0002
Wettability			Not applicable	
Suspensibility, spontaneity and dispersion stability			Not applicable	
Wet sieve analysis and dry sieve test			Not applicable	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable	
Disintegration time			Not applicable	
Particle size distribution, content of dust/fines,			Not applicable	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
attrition, friability				
Persistent foaming			Not applicable	
Flowability/Pourability /Dustability			Not applicable	
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	2.15% (Imidacloprid) 0.50% (S-methoprene) Batch J706	Biocidal product is a solid.	PG007-14/05
Physical compatibility			Not applicable	
Chemical compatibility			Not applicable	
Degree of dissolution and dilution stability			Not applicable	
Surface tension			Not available	
Viscosity	"Viscosity of liquids". OECD Guideline for testing of chemicals 114. 12 May 1981.		Values at 20ºC and 40ºC. Initially: >2x10^6 mPa.s at 20 ºC and 40ºC After storage at 54 °C for 14 days: >2x10^6 mPa.s at 20 ºC and 40ºC After 17, 24, 36 and 48 months at 25°C ± 2°C: >2x10^6 mPa.s at 20 ºC and 40ºC	Final Report AGQ E-15-0002

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.

Appearance
Brown, 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.

Storage stability test – accelerated storage
According to the Guidance, the applicant has set the plastic cartridge as worst case packaging. Therefore, the plastic cartridge results can be extrapolated to different packaging types.
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 CUCARACHAS IGR PLUS product after 14 days in the oven at 54 ± 2ºC were -2.98% and -4.44% respectively according to the data at t=0 days and at t=14 days.

Storage stability test – long term storage at ambient temperature
According to the Guidance, the applicant has set the plastic cartridge as worst case packaging. Therefore, the plastic cartridge results can be extrapolated to different packaging types.
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 CUCARACHAS IGR PLUS product after 48 months in the incubator at 25 ± 2ºC were -7.66 % and +8.89 %, respectively.

Storage stability test – low temperature stability test for liquids
The product is deemed as a GL. Therefore, the label phrase "protect from frost" must be included because it is recommended to store the product at a temperature preferably between 5ºC and 45ºC.

Effects on content of the active substance and technical characteristics of the biocidal product - light
Not relevant. Product is stored away from light. Therefore, the label phrase "store away from light" must be included.

Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity
After a period of 48 months at 25±2 ºC, the content of Imidacloprid and S-methoprene will be analysed according to the method described in the AGQ Internal Procedures, and the physical-chemical properties will be analysed according to the guidelines and methods above.
Data included in the long term stability storage study.

Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material
After a period of 48 months at 25±2 ºC, the content of Imidacloprid and S-methoprene will be analysed according to the method described in the AGQ Internal Procedures, and the physical-chemical properties will be analysed according to the guidelines and methods above.
Data included in the long term stability storage study.

Technical characteristics of the biocidal product
Not relevant. Not applicable as the product is a GL.
Particle size distribution is not applicable as the product is a GL. For GRs, WDPS, Powders and Dusts.
Moreover, according to the ARs, the only technical characteristic appropriate for assessment for MAGNUM GEL CUCARACHAS IGR PLUS, based on its formulation type and use pattern (RTU without dilution) is viscosity.

Other technical characteristics - determination whether a material is a liquid or a solid
According to the interpretation of results, the Biocidal Product can be considered as a solid since the specimen did not flow during the test.

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

Surface tension
Not applicable as the product is considered as a solid.
The applicant's version is not acceptable. The product is deemed as a GL and the surface tension should be measured.
Finally, the surface tension cannot be investigated because the solubility in water of the active substances included in the biocidal product are < 1 mg/mL (0.00685 mg/mL for S-methoprene and 0.613 mg/mL for imidacloprid).

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

Conclusions
Magnum Gel Cucarachas IGR Plus is a brown practically odourless gel. The product has a density of 1.2467 ± 0.0002 g/mL and a viscosity of $>2\cdot 10^6$ mPa.s at 20ºC.
No change in physical conditions, colour or odour of the product was observed. The product has the same appearance and the packaging remains unchanged after storage at 54ºC ± 2ºC and after 48 months at 25ºC ± 2ºC.

The label phrases 'protect from frost' and 'store away from light' must be included.

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	
Flammable aerosols			Not applicable	
Oxidising gases			Not applicable	
Gases under pressure			Not applicable	
Flammable liquids			Not applicable	
Flammable solids			Not flammable	
Self-reactive substances and mixtures			Not applicable	
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			Not applicable	
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.

Explosiveness

The test substance does not contain any ingredient with molecular structure which may indicate explosive properties. Therefore, 2.15 % w/w Imidacloprid and 0.5% w/w S-methoprene Gel is not expected to have explosive properties in the sense of EC Guidelines A14.

Flammability

The 2.15 % w/w Imidacloprid, 0.5 % w/w S-methoprene Gel formulation is not expected to be flammable.

Self-reactive substances and mixtures

The study does not need to be conducted because there are no chemicals groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.

Pyrophoric solids
The study does not need to be conducted because there are no chemicals groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.

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
The test substance does not contain any ingredient with molecular structure which may indicate oxidizing properties on combustible material. Therefore, "Imidacloprid 2.15 % w/w and S-methoprene 0.5 % w/w Gel is not expected to have oxidizing properties in the sense of the EC-Guidelines A17.

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
The study does not need to be conducted because the formulation is not intend to contact with metal neither during use nor storage.

Relative self-ignition temperature for solids
The 2.15 % w/w Imidacloprid and 0.5 % w/w S-methoprene Gel formulation is not expected to be flammable.
The test was omitted, 2.15 % w/w Imidacloprid and 0.5 % w/w S-methoprene Gel is not expected to have oxidizing properties. There are no data about Flash-point or other indications of flammability or spontaneous ignition. Therefore the product is not expected to be flammable according to the Assessment Report for Imidacloprid (18th February 2011) and to the Assessment Report for S-methoprene (December 2013).

Dust explosion hazard
The study does not need to be conducted because the test item has no explosive properties as neither the active ingredient nor other components, did not contain any "phosphorus" grouping.

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.
Magnum Gel Cucarachas 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 (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Imidacloprid	LC-MS	--	0,025-0,500 mg/L n=7 r=0.9986	All peaks are well separated and there is no evidence of interferences with the test item peaks	/	/	/	/	FINAL REPORT E-15/0002
S-Methoprene	LC-MS	--	0,2-1,0 mg/L n=7 r=0.9992	All peaks are well separated and there is no evidence of interferences with the test item peaks	/	/	/	/	

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

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Imidacloprid (air)	HPLC-UV RP-18 column							0.005 mg/m^3	CAR (2011)
Imidacloprid (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		
Imidacloprid (drinking and surface water)	HPLC-UV RP-18 and CN column							0.03 µg/L	CAR (2011)
Imidacloprid (surface water)	LC-MS/MS							0.1 µg/L	CAR (2011)
s-Methoprene in Drinking water	GC-MS (m/z = 175, 191 and 219 m/z)	0.1 µg/L (n=5)	r >0.996 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		
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	Retention time match between standard and sample for analyte. The method of	70 – 82	75	6.1	0.1 µg/L	CAR (2013)

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		
		1.0 µg/L (n=5)	µg/L 8 point calibration	analysis is considered to be highly specific (GC-MS with 3 ions > 100m/z used for identification)	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	Retention time match between standard and sample for analyte. The method of analysis is considered to be highly specific (GC-MS with 3 ions > 100m/z used for identification)	74 – 96	82	10.6	0.1 µg/L	CAR (2013)
		1.0 µg/L (n=5)	8 point calibration		89 - 110	99	8.5		

Conclusion on the methods for detection and identification 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.

Analytical methods for the analysis of the product as such including the active substance

The method was validated according the requirements guideline SANCO 3030799 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 Cucarachas IGR 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 Cucarachas IGR 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 Cucarachas IGR is also relevant to determinate the Imidacloprid and s-methoprene content 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.

The biocidal product MAGNUM GEL CUCARACHAS IGR PLUS is a bait preparation to be used against cockroach infestations in private houses and industrial/commercial buildings at indoor premises.

MAGNUM GEL CUCARACHAS 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 general public (non-professional).

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

Magnum Gel Cucarachas IGR Plus is intended to be used against small and large cockroaches (*Blatta orientalis, Blatella germanica* and *Periplaneta Americana*).

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

2.2.5.3 Effects on target organisms, including unacceptable suffering

MAGNUM GEL CUCARACHAS 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 inhibits the ovarian development thus producing sterility of females. It also produces the continuation of the larval stage inhibiting the maturation of the nymphs to the adult stage (individuals develop physical deformities and cannot mature to reproductive adults).

2.2.5.4 Mode of action, including time delay

Cockroaches are attracted by some nutritional ingredients that are present in the formulation and spread the gel insecticide by moving and causing poisoning (by contact and ingestion) and the indirect death of the individuals who live in the colony, regardless their stage of development (nymphs, adults). In field trials most cockroaches were killed after 2 or 3 weeks of exposure to the gel bait (either by drops or by bait stations).

In addition females will not be able to reproduce and nymphs will not be able to become reproductive adults as a consequence of the Insect Growth Regulator (S-Methoprene). These effects will be noticed after two/three months of exposure to the gel bait.

2.2.5.5 Efficacy data

DROPS

Experimental data on the efficacy of the biocidal product against target organisms							
Function	**Test substance**	**Field of use envisaged**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Imidacloprid 2.15 % and S-Methoprene 0.5% Gel Bait	Laboratory	*Blatta orientalis*	Laboratory bioassay: Mortality and palatability. According to TNsG 18-19	Choice test arena. 3 replicates and control. Micro-drop treatment 1drop=0.04g/m^{2}Test ARENA: 60x40x15 cm	Mortality of 100% of adults and nymphs in 15 days. 2.4 ±0.5 mortality of control. Palatable fresh bait Dose: 0.24 g/m^2 N:70 (adults and nymph)	Test report: ES0018-14/09
			Blatella germanica			Mortality of 100% of adults and nymphs in 10 days. 2.9 ±0.4 mortality of control. Palatable fresh bait. Dose: 0.16 g/m^2 N: 80 (adults and nymphs)	
			Periplaneta americana			Mortality of 100% of adults and nymphs in 21 days. 1.1 ±0.6 mortality of control. Palatable fresh bait Dose: 0.24 g/m^2 N: 60 (adults and nymphs)	
		Field trial. Indoors/out doors	*Blatta orientalis*	Field trial: (micro-drop treatment, 0.04g/drop) According to TNsG 18-19	3 replicates (sites) Dose: 0.08-0.24 g/m^2 The product was re-applied where the bait had been consumed after few days/weeks. Indoors	Average mortality of 94.8% from 3rd week and100% in 5 weeks.	Test report: ES0028-13/23

			Blatella germanica		3 replicates (sites) Dose: 0.04-0.16 g/m^2 The product was re-applied where the bait had been consumed after few days/weeks. Indoors	Average mortality of 89.2% from 2nd week and 100% in 3 weeks.	
			Periplaneta americana		3 replicates (sites) Dose: 0.08-0.24 g/m^2 The product was re-applied where the bait had been consumed after few days/weeks. Indoors and outdoors.	Average mortality of 88.3% from4^{rt} week and 97.2 % in 5 weeks.	
Insecticide	S-Methoprene 0.25% and 0.5% Gel Bait (same formulation)	Laboratory	*Blatella germanica*	Laboratory bioassay: Mortality by gender and stage; no. of deformed males and females; and gravid females. (gel bait by drops)	3 replicates for each treatment and control; N=10 gravid females/arena. Time:4 months. Dose: ad libitum; no alternative food. Test ARENA: 25x14x16.4 cm	After 4 months: Control: - N=376 - Gravid females: 9 0.25% a.s. - N= 49 - Gravid female (from 2 months)=2 0.50% a.s: - N=29 - Gravid females(from 2 months)=0 The number of deformed adults for the effect of s-methophren is bigger in the system treated with 0.5% of s-metophren.	[redacted] Test report: ES0034-03.5
Insecticide	S-	Laboratory	*Periplaneta*	Laboratory	2 replicates and 2	**Significant deviation**: in August '15	[redacted]

	methoprene 0.5% gel bait (same formulation but differ in terms of concentration of a.s.)		*americana*	bioassay: Mortality by gender and stage; no. of deformed males and females; and gravid females. (gel bait by drops)	control. N=7 gravid females. Dose: ad libitum with alternative food. Period of time: 16 months. (april 2015-july 2016) Test ARENA: 40x20x25 cm	the cockroaches remained without water for three weeks and there was a high mortality. Although this event, the trial continued but with only one control. The data showed that: In terms of general population, there is a difference between population of control and the systems treated. The populations of the treated system decrease until extinction, whereas the control has more new oothecas and little nymphs.	[redacted] Test report: ES0033.A Complementary study.
Insecticide	Magnum gel cucarachas IGR plus.	Laboratory.	*Blatella germanica*	Laboratory bioassay: Mortality and palatability. (3 years aged gel bait gel bait by drops) According to TNsG 18-19	Choice test arenas. 2 replicates and a control. Micro-drop treatment. 1drop=0.04g/m^2 Test ARENA: 120x100x15	Mortality of 100% for adults and nymphs in 15 days. 5.0 ±0.00 mortality of control. Very palatable bait. Dose: 0.12-0.16g/m^2 N=80 (adults and nymphs)	[redacted] Test report: ES0018-13/23
			Blatta orientialis			Mortality of 100% for adults and nymphs in 16 days. 3.3 ±1.18 mortality of control. Palatable bait. Dose: 0.16-0.24g/m^2 N=60 (adults and nymphs)	
			Periplaneta americana			Mortality of 100% for adults and nymphs in 14 days. 5.0 ±0.00 mortality of control. Palatable bait. Dose: 0.16- 0.24g/m2 N=60 (adults and nymphs)	
Insecticide	Magnum gel cucarachas IGR plus.	Laboratory.	*Blatella germanica*	Laboratory bioassay: Mortality and palatability. (4 years	Choice test arenas. 3 replicates and a control.	100% average mortality in 13 days for adults and nymphs. 0.00 ±0.00 mortality of male control. 0.00 ±0.00 mortality of female control. 3.33 ±5.00 mortality of nymphs control. Palatable bait	[redacted] Test report: ES0018-

				aged gel bait by drops) According to TNsG 18-19	Micro-drop treatment. 1drop=0.04g/m^2 Test ARENA: 120x100x15	Dose: 0.12 g/m^2 N=40 (adults and nymphs)	11/19
			Blatta orientialis			100% average mortality in 13 days for adults and nymphs. 0.00 ±0.00 mortality of male control. 6.67 ±11.55 mortality of female control. 3.33 ±5.77 mortality of nymphs control. Palatable bait Dose: 0.16 g/m^2 N=20 (adults and nymphs)	
			Periplaneta americana			100% average mortality in 13 days for adults and nymphs. 0.00 ±0.00 mortality of male control. 0.00 ±0.00 mortality of female control. 6.67 ±5.77 mortality of nymphs control. Palatable bait Dose: 0.16 g/m^2 N=20 (adults and nymphs)	
Validation	No active substance.	Laboratory	*Blatella germanica*	Laboratory bioassay to justify the high mortality of control replicates in 4 year aged bait study.	3 replicates Dog feed. N=90 (adults and nymphs) Time: 14 days.	2.78±2.00 average mortality	[redacted] Test report: ES0018-05/20 Complementary study.
			Blatta orientialis		3 replicates Dog feed. N=90 (adults and nymphs) Time 14 days	2.22±0.00 average mortality	
			Periplaneta americana		3 replicates Dog feed. N=90 (adults and nymphs) Time 14 days	1.11±0.00 average mortality	

BAIT STATIONS

Experimental data on the efficacy of the biocidal product against target organisms.							
Function	**Test substance**	**Field of use envisaged**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Imidacloprid 2.15 % and 0.5 s-methoprene gel Bait	Laboratory	*Blatta orientalis*	Laboratory bioassay: Mortality and palatability. Dose rate for all species: 1 g gel bait in baitstation According to TNsG 18-19	3 replicates and 3 controls. N=70 (adults and nymphs) Test ARENA=60x40x15	100% average mortality in 17 days for adults and nymphs. 3.8 ±0.5 mortality of control. Palatable bait.	[redacted] Test report: ES0018-16/07
			Blatella germanica		3 replicates and a 3 controls. N=80 (adults and nymphs) Test ARENA=60x40x15	100% average mortality in 16 days for adults and nymphs. 2.9 ±0.8 mortality of control. Palatable bait.	
			Periplaneta americana		3 replicates and a 3 controls. N=60 (adults and nymphs) Test ARENA=60x40x15	100% average mortality in 21 days for adults and nymphs. 3.3 ±1.0 mortality of control. Palatable bait	
		Field trial. Indoors	*Blatta orientalis*	Field trial: (gel bait in bait stations) According to TNsG 18-19 3 replicate (site)/ cockoaches	Site 1: 41m^2. Initial dose: 0.07g/m^2 (3 traps with 1g). 1 trap with 3 g was replaced. Average dose per area: 0.14g/m^2 Site 2: 33m^2. Initial dose: 0.15g/m^2 (5 traps with 1g). 1 trap with 3 g was replaced. Average dose per area: 0.24g/m^2 Site 3: 41m^2. Dose: 0.14g/m^2 (3 traps	≥ 95 % mortatity after 3 weeks. ~ 100% mortality after 4 weeks.	[redacted] Test report: ES0028-16/11

					with 2g). 0 traps were replaced. Low & high infestation		
			Blatella germanica		Site 1: 12m^2. Dose: 0.16g/m^2 (2 traps with 1g). 0 traps were replaced. Site 2: 17m^2. Dose: 0.11g/m^2 (3 traps with 1g). 0 traps were replaced. Site 3: 11m^2. Dose: 0.18g/m^2 (2 traps with 1g). 0 traps were replaced. High infestation.		
			Periplaneta americana		Site 1: 63m^2. Initial dose: 0.12g/m^2 (2 traps with 4g). 1 trap with 2 g was replaced. Average dose per area: 0.15g/m^2 Site 2: 45m^2. Initial dose: 0.06g/m^2 (1 traps with 3g). 1 trap with 4 g was replaced. Average dose per area: 0.15g/m^2 Site 3: 124m^2. Dose: 0.16g/m^2 (4 traps with 5g). 0 were replaced. Low-med. Infestation..		

Conclusion on the efficacy of the product

EFFICACY AS ADULTICIDE

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

The applicant has submitted laboratory and field trials with the product included in bait stations and applied as drops (deposited by syringe or cartridge). The studies were performed according to the TNsG for PT 18 and PT 19 (CA-Dec12-Doc.6.2.a-Final).

The biocidal product is formulated as bait, containing attractive nutritional elements for the cockroaches. In case of baits, the guidance indicates that intrinsic palatability of the formulated bait should be enough to prove acceptable toxicity in competition with the alternative food source. Palatability of the fresh bait containing MAGNUM GEL CUCARACHAS IGR PLUS was demonstrated for the three species.

Gel bait by drops.

The applicant has submitted 3 palatability and mortality laboratory trials (fresh bait and 3 and 4 years aged bait) and a field trial against three species: *Blatella germanica, Blatta orientalis and Periplaneta americana* (nymphs and adults). The application method is by micro-drops.

The laboratory studies were conducted in a test arena with 2 or 3 replicates and 1 control. The bait was applied onto an acetated sheet. Standard food was supplied to investigate the palatability.

In general terms, the laboratory studies have demonstrated 100% efficacy at a dose rate of 0.12-0.16 g/m^2 against *Blatella germanica* at 15 days, 0.16-0.24 g/m^2 againts *Periplaneta americana* at 21 days and *Blatta orientalis* at 16 days with fresh bait and with aged bait of 3 and 4 years.

The applicant has also submitted a laboratory study without active substance to demonstrate the high standard deviation of the controls in the aged bait tests. The test provided is consided acceptable and therefore, the tests with aged bait are valid.

There was a field trial against the three cockroach species, mainly at indoor sites, and application of the gel bait as droplets. 3 replicates for each of the species were considered. The product was re-applied where the bait had been consumed after few days/weeks following the first application.

The study has demonstrated 100% efficacy at a dose of 0.04-0.16 g/m^2 against *Blatella germanica* at 3 weeks, 0.08-0.24 g/m^2 against *Blatta orientalis* and *Periplaneta americana* at 5 weeks.

Only one replicate, against *P. americana,* was located outdoors with very low infestation level. 100% mortality was achieved in 3 weeks with application dose of 0.08 g/m$^{2.}$ In any case, the product cannot be authorized for outdoors due to unacceptable risk in the environmental assessment.

The eCA concludes that the product MAGNUM GEL CUCARACHAS IGR PLUS is effective against cockroaches (nymphs and adults) with the method of application by droplets, at indoor premises.

According to the environmental evaluation, there is an unacceptable risk when the application is made on surfaces, and it restricts its use only to cracks and crevices.
The efficacy tests provided have been developed mainly on surfaces, therefore, we consider that at least, a simulated use test in cracks and crevices should be provided at the renewal.

Gel bait by bait-stations.

The applicant has submitted a palatability and mortality laboratory trials (fresh bait) an a field trial against three species: *Blatella germanica, Blatta orientalis and Periplaneta americana* (nymphs and adults) with bait station.

In a laboratory study, the product was applied by the placement of ready-to-use bait stations (1 g each one) inside the arenas (1 station/arena) in the presence of alternative food source.

The laboratory is aware that the dose rate in test arena is in excess, but there is not a bait station containing less than 1 gram of product. Therefore, taking into account that the product has already demonstrated the efficacy in drops trials according to the dose rate, we consider it more important to demonstrate the non-repulsivity of the bait station and palatability.

The product has shown a mortality of 100% at 17 days against *B. orientalis*, 16 days against *B. germanica* and 21 days against *P. americana*. Palatability was also demonstrated for the three species.

In a field trial, MAGNUM GEL CUCARACHAS IGR PLUS also demonstrated efficacy when applied in bait stations.

There was a field trial against the three cockroaches species, at indoor sites, and application of the gel bait as bait station, mainly with 1 gram, but in some cases using other sizes to adjust the size of the site. 3 replicates for each of the species were considered.

The study has demonstrated ~ 100% efficacy at a dose of 0.14-0.24 g/m^2 against *Blatta orientalis*, 0.16-0.18 against *Blatella germanica* and 0.15-0.16 g/m^2 against *Periplaneta americana* at 4 weeks.

No replica was made outdoors, therefore only indoors will be authorized.

The eCA concludes that the product MAGNUM GEL CUCARACHAS IGR PLUS is effective against cockroaches with the method of application by placement of bait stations, at indoor premises.

The authorised dose must be set in terms of grams per square metre. The number of bait stations should be indicated in the label depending on the amount of product included in the bait station.

EFFICACY AS INSECT GROWTH REGULATOR.

Two laboratory trails were been submitted by the applicant to demonstrated the activity of s-methoprene as insect growth regulator..

The study tested against *Blatella germanica* is the same formulation excluding the a.s.

Imidacloprid. In the trial three concentrations of the a.s. S-Methoprene (0, 0.25 and 0.5 %) were tested against a population of gravid females (10 ind/arena) for 4 months. 3 replicates and controls (i.e. 0% S-Methoprene) were included. Observed parameters were the total number of females with oothecae, adult females, deformed adult females, adult males, deformed adult males, early nymphs and late nymphs, and total population.

The results showed that the systems treated with 0.5% a.s. reduced the population to 29 individuals while in controls there were 376 cockroaches after 4 months. The number of deformed adults was higher in the systems treated with 0.50% and deformations were more evident. Regarding the oothecae production, after 2 months, new oothecae were not observed in the treatments with 0.50%. However, with 0.25% there was still some ootheca production after 4 months, although a marked reduction was observed. In controls, the number of gravid females remained constant at around 9 individuals.

The study against *Periplaneta americana* informs of a significant deviation that makes the test lose reliability and accuracy. Even so, we think that a trial of these characteristics (choice test and long term), can give information about how s-methoprene 0.5% affects in cockroaches therefore, despite the deviation, it was considered a complementary test..

Initially the test starts with 7 gravid females.
During the first three months (before the event) a decrease was observed in the replicas compared to the controls.
After the big decrease of August, in case of the no treated system during 5 months the population estabilized and in January ’16 increased with new ootheca and little nymphs.
In the system treated with s-methoprene, however, the populations decrease until the extinction because the adults could not reproduce, therefore females did not create new oothecas.

The eCA concludes that the product MAGNUM GEL CUCARACHAS IGR PLUS is effective as Insect Growth Regulator.

Shel-life:

The applicant has provided trials with bait aged 3 and 4 years. The product has been shown to be effective. 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.

2.2.5.6 Occurrence of resistance and resistance management

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

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

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

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

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

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

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

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

The eCA also searched the literature about possible resistance of cockroaches to S-Methoprene, however no information was found. Several studies were found on the resistance of other insects (mainly mosquitoes and flyes) to this a.s. Therefore in the future, it may be possible to find new studies addressing the resistance of cockroaches. Nevertheless the management strategy described before should also be useful for S-Methoprene.

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.
- Avoid contact of children with treated surfaces.
- Do not perform the operation in the presence of people and / or pets.
- Do not mix with other chemicals.
- Do not use on wood or porous surfaces.
- Avoid contact with treated surfaces.
- To avoid risks to man and the environment follow the instructions.

2.2.5.8 Evaluation of the label claims

The label claims reflected the expected use of the products (insecticide) for the specific target organisms and the kind of use, but above all they must be supported by efficacy trials.
The Applicant has not supported residual efficacy trials and palatability tests with aged bait.

The product has proven effective for the following label claims:
- Insecticide for cockroaches control (*Blatta orientalis, Blatella germanica, Periplaneta americana*). The a.s. Imidacloprid produces kill of cockroaches in 2-3 weeks. In addition the a.s. S-Methoprene produces infertility in females and nymphs will not be able to become reproductive adults.
- Ready-to-use gel bait by droplets on non-porous surfaces (cartridge or syringe) and included in bait stations.
- The fresh gel bait and 4 years aged bait are palatable for cockroaches.
- Insecticide for use in private houses and commercial buildings at indoor premises.

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

The product is not intended to be used in combination with other biocidal product.

2.2.6 Risk assessment for human health

The biocidal product Magnum Gel Cucarachas IGR Plus is composed of the active substances Imidacloprid 2.15% w/w and S-Methoprene 0.5% 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 Cucarachas 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. And one study GLP compliant (2016) has been submitted to address the skin sensitization These studies were conducted with the product Magnum Gel Roaches 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 Cucarachas IGR Plus. See the confidential annex
On the other hand, the applicant has submitted a justification for non-submission data for acute inhalation toxicity, dermal, skin and eye irritation 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	The preparation Magnum Gel Cucarachas IGR Plus is not classified as corrosive or irritant to skin.

Data waiving	
Information requirement	Skin Irritation
Justification	skin irritation toxicity studies for Magnum Gel Cucarachas 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 cucarachas 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 Cucarachas 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	The preparation Magnum Gel Cucarachas IGR Plus is not classified as irritant to eyes.

Data waiving	
Information requirement	Eye irritation
Justification	eye irritation toxicity studies for MAGNUM Gel Cucarachas 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 Cucarachas 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	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 Cucarachas 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

Summary table of animal studies on skin sensitisation

Method, Guideline, GLP status, . Reliability	***Species, Strain, Sex, No/group***	***Test substance, Vehicle, Dose levels, duration of exposure Route of exposure (topical/intrader mal, if relevant)***	***Results (EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)***	***Remarks (e.g. major deviation s)***	***Reference***
Modification of the Buehler method (OED 406) (Ritz, HL, and Buehler, EV, "Planning, Conduct, and Interpretatio n of Guinea Pig Sensitization Patch Tests" GLP: yes,	Short-haired albino guinea pigs Hartley 15 male and 15 female	Naive control group animals remained untreated during induction phase of the study. Test group animals were treated with 0.4 mL of undiluted test substance (selected from range-finding). Test animals were treated once weekly for three weeks, for a total of three inductions. After a two-week rest period, all animals (both groups) were challenged at a virgin test site with an application of 0.4 mL of undiluted test substance.	0	None	[redacted]

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	The preparation Magnum Gel Cucarachas IGR Plus is not classified as skin sensitiser.

Data waiving	
Information requirement	Skin sensitisation
Justification	Skin sensitisation study for MAGNUM GEL ROACHES have been performed. ES CA accept read across The test substance produced no reaction in either test animals or nave control animals after the challenge treatment.Therefore , Magnum Gel Cucarachas IGR Plus is not sensitizer in guinea pigs.

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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	The preparation Magnum Gel Cucarachas IGR Plus is not classified as respiratory sensitiser.

Data waiving	
Information requirement	Respiratory sensitization study
Justification	No data on the respiratory sensitisation of the product Magnum Gel Cucarachas IGR Plus has been submitted, because of its physical nature (gel) and the low vapour pressure of the components. Magnum Gel Cucarachas 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 levels Type 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	Imidacloprid 2.15% gel formulation is not classified as harmful by the oral route

Data waiving	
Information requirement	Acute oral toxicity studies
Justification	Acute oral toxicity studies for product Magnum Gel Cucarachas IGR Plus have not been performed. The data provided for acute toxicity studies refer to an Imidacloprid 2.15% Gel formulation. Magnum Gel Cucarachas IGR Plus contains 2.15% (w/w) of the active substance Imidacloprid, 0.5% (w/w) of the active substance S-Methoprene and other co-formulants, several of which are classified for acute oral toxicity. The main component contributing to the toxicity of the formulation is the active substance Imidacloprid, which is in higher concentration than the active ingredient S-Methoprene. Results from the acute oral toxicity study performed with the gel formulation with same Imidacloprid concentration (2.15%) is taken into account to assess the toxicity of the product Magnum Gel Cucarachas IGR Plus. The concentrations of the co-formulants in the preparation are well below the limit of the toxicity calculation estimations set in Regulation (EC) Nº 1272/2008 and the biocidal product does not meet the criteria for classification as toxic by the oral route on the basis of their presence in the preparation. Hence, the tests results can be extrapolated to the Magnum Gel Cucarachas IGR Plus formulation. It is therefore proposed that the product Magnum Gel Cucarachas 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	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 Cucarachas 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 Cucarachas 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	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 Cucarachas IGR Plus have not been performed. The data provided for acute toxicity studies refer to at Imidacloprid 2.15% Gel formulation. Magnum Gel Cucarachas IGR Plus contains 2.15% (w/w) of the active substance Imidacloprid, 0.5% (w/w) of the active substance S-Methoprene and other co-formulants, several of which are classified for acute dermal toxicity. The main component contributing to the toxicity of the formulation is the active substance Imidacloprid, which is in higher concentration than the active ingredient S-Methoprene. Results from the acute dermal toxicity study performed with the gel formulation with same Imidacloprid concentration (2.15%) is taken into account to assess the toxicity of the product Magnum Gel Cucarachas IGR Plus.

	The concentrations of the co-formulants in the preparation are well below the limit of the toxicity calculation estimations set in Regulation (EC) Nº 1272/2008 and the biocidal product does not meet the criteria for classification as toxic by the dermal route on the basis of their presence in the preparation. Therefore, the tests results can be extrapolated to the Magnum Gel Cucarachas IGR Plus formulation. 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 for Magnum Gel Cucarachas IGR Plus		
Substances	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 Cucarachas IGR Plus formulation are not required.
Justification	Dermal absorption studies for the biocidal product Magnum Gel Cucarachas IGR Plus have not been submitted. The relevant exposure route during application of the biocidal product Magnum Gel Cucarachas IGR Plus is only dermal for the gel formulation applied as drops. No exposure is expected for the bait station application. According to EFSA guidance 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 Cucarachas 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 Cucarachas IGR Plus.

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

The formulation contains 2.15% (w/w) of the active substance Imidacloprid, 0.5% (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*"

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

Regarding *CA-March18-Doc.7.3.b-final* document, the co-formulants have not been assessed or identified for endocrine disruption properties.

The co-formulant tert-butyl-4-methoxyphenol (BHA, CAS-No. 25013-16-5) is currently under ED assessment by France.

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the data provided in substances CAR there is no indication of concern regarding the ED properties of the substances used in the biocidal product MAGNUM GEL CUCARACHAS 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 Cucarachas 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 CUCARACHAS IGR PLUS it will not come into contact with food, foodstuffs or feeding stuffs.

2.2.6.2 Exposure assessment

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

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 2.15% w/w and 0.5% 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 g/m^2 for high infestations and 0.15 g/m^2 for low infestations using gel bait by bait stations and 0.04-0.2 g/m^2 using gel bait by drops where 1 drop (0.4 cm diameter) = 0.04 g (40 mg), according to sections 2.2.2 and 2.2.5.

The exposure assessment during the application of gel using cartridges/syringes is performed taking into account the principles and assumptions used for the estimation of human exposure for Annex I inclusion of the active substance Imidacloprid [Assessment Report for Imidacloprid, 2011].

Relevant exposure routes of Magnum Gel Cucarachas IGR Plus to humans for gel 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: application by gel drops, relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Trained professional use	**Professional use**	**Non-professional use* (General public)**	**Trained professional use**	**Professional use**	**Non-professional use* (General public)**	**Via food**
Inhalation[1]	No	No	No	No	No	No	No
Dermal	Yes	Yes	Yes	No	No[2]	Yes[3]	No
Oral	No	No	No	No	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 of professionals after application of gel is not expected (as indicated in the CAR); neither is secondary exposure of consumers after application.*

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Application	Primary exposure: gel application using a cartridge/syringe	Trained professionals
2.	Post application	Primary exposure: disposal of used cartridge/syringe	Trained Professionals
3.	Application	Primary exposure: gel application using a cartridge/syringe	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 Cucarachas 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 crack, crevices, 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. The CA assumes that one drop of gel enters in contact with operator's hand during each operation.

	Parameters[1]	Value
Tier 1	Equivalence 0.5 cm gel [a]	50 mg product
	number of opening and sealing per day[b]	10
	content of active substance in product	2.15% Imidacloprid 0.5% S-Methoprene
	Body weight adult[c]	60 kg
	Dermal absorption absorption[d]	75%
Tier 2	PPE	Gloves (PF 10)

[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 (professional use). To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information is not available for the packaging of Magnum Gel Cucarachas IGR Plus. The CA uses the amount of product in a line of gel 0.5 cm length as indicated in CAR (aprox. 50 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 0.4 cm diameter of Magnum Gel Cucarachas IGR Plus equals aprox. 40 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]

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	-	1,34E-01	-	1,34E-01
Scenario 1	2/gloves	-	1,34E-02	-	1,34E-02
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	-	3,13E-02	-	3,13E-02
Scenario 1	2/gloves	-	3,13E-03	-	3,13E-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]	50 mg product
	number of disposed cartridges per day[b]	1
	content of active substance in product	2.15% Imidacloprid 0.5% S-Methoprene
	Body weight adult[c]	60 kg
	Dermal absorption absorption[d]	75%
Tier 2	PPE	Gloves (PF 10)

[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 (professional use). To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information is not available for the packaging of Magnum Gel Cucarachas IGR Plus. The CA uses the amount of product in a line of gel 0.5 cm length as indicated in CAR (aprox. 50 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 0.4 cm diameter of Magnum Gel Cucarachas IGR Plus equals aprox. 40 mg of product (see Annex 3.2) (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	-	1,34E-02	-	1,34E-02
Scenario 2	2/gloves	-	1,34E-03	-	1,34E-03
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	-	3,13E-03	-	3,13E-03
Scenario 2	2/gloves	-	3,13E-04	-	3,13E-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	-	1,48E-01	-	1,48E-01
Scenario 1 + 2	2/gloves	-	1,48E-02	-	1,48E-02
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	-	3,44E-02	-	3,44E-02
Scenario 1 + 2	2/gloves	-	3,44E-03	-	3,44E-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 Cucarachas 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 crack and crevices, 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 (cockroaches are expected during spring and summer). 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]	50 mg product
	number of opening and sealing per day [b]	2
	content of active substance in product	2.15% Imidacloprid 0.5% 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 (professional use). To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information is not available for the packaging of Magnum Gel Cucarachas IGR Plus. Section 2.2.2 storage stability study, indicates that a drop of 5 mm diameter of Magnum Gel Cucarachas IGR Plus from a cartridge equals aprox. 40 mg of product. The CA uses this value to estimate the exposure of non professionals (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	-	2,69E-02	-	2,69E-02
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	-	6,25E-03	-	6,25E-03

Further information and considerations on scenario [3]
Not applicable

Scenario [4] Disposal of used cartridges of Magnum Gel Cucarachas 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). 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).		
	Parameters	Value
Tier 1	Equivalence 0.5 cm gel [a]	50 mg product
	number of cartridges disposed off per event [b]	1
	content of active substance in product	2.15% Imidacloprid 0.5% 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 (aprox. 50 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 0.4 cm diameter of Magnum Gel Cucarachas IGR Plus equals aprox. 40 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 [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	-	1,34E-02	-	1,34E-02
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	-	3,13E-03	-	3,13E-03

Combined scenarios
Total exposure of professionals or consumers during the use of Magnum Gel Cucarachas 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	-	4,03E-02	-	4,03E-02
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	-	9,38E-03	-	9,38E-03

Scenario 5 & Scenario 6. Use and disposal of bait stations containing Magnum Gel Cucarachas 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 Cucarachas 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 one drop of product in one event. Additionally to dermal absorption, hand to mouth transfer may take place: it is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact (Crack & Crevice Use – Post Application; RIVM report 320005002 pp. 28); consequently 50% of external dermal load is absorbed via dermal route. Tier 1 assumes that the amount dislodged is 100%; 100% oral absorption and 75% dermal absorption are considered.		
	Parameters[1]	Value
Tier 1	One drop of gel 5 mm diameter [a]	50 mg product
	Number of drops contacted per event [b]	1
	Dislodged amount [b]	100%
	content of active substance in product	2.15% Imidacloprid 0.5% S-Methoprene
	Dermal absorption [c]	75%
	Amount of product available for oral intake[d]	50% 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 mm length as indicated in CAR (aprox. 50 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 4 mm diameter of Magnum Gel Cucarachas IGR Plus equals aprox. 40 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 (Crack & Crevice Use – 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]	-	4,03E-02	5,38E-02	9,41E-02
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]	-	9,38E-03	4,38E-03	1,38E-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 Cucarachas IGR Plus as a gel application (drops/lines) in hidden places with difficult access such as crack and crevice, exposure may occur accidentally for toddler via dermal contact. Although toddlers can explore their environment and exhibit hand to mouth transfer of residues, it is reasonable to assume that the gel would not be ingested due to the presence of the bittering agent.

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

Combined scenarios
Not applicable.

Monitoring data
Not applicable.

Dietary exposure
Food contamination as result of use

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

In addition, the label must include restrictions or instructions of use, so that, food contamination is 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.
- In storerooms the product may only be applied in the presence of properly packaged food.

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 restrictions 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.
- In storerooms the product may only be applied in the presence of properly packaged food.

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	1,34E-01	3,44E-02
1. Application	Trained professionals	Tier 2 /gloves	1,34E-02	3,13E-03
2. Post-Application	Trained professionals	Tier 1 /none	1,34E-02	3,13E-03
2. Post-Application	Trained professionals	Tier 2 /gloves	1,34E-03	3,13E-04
3. Application	Professionals and Non-professionals	Tier 1 /none	2,69E-02	6,25E-03
4. Post-application	Professionals and Non-professionals	Tier 1 /none	1,34E-02	3,13E-03

7. Indirect	Bystanders (toddlers)	Tier 1 /none	9,41E-02	1,38E-02

2.2.6.3 Risk characterisation for human health

Reference values 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 0.148 and 3.44E-02 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 Cucarachas IGR Plus containing 2.15% Imidacloprid cause health risk for trained professionals not wearing protective equipment, as indicated by the resulting value of 224 expressed as %AEL, whereas no risk is envisaged for trained professionals when exposed to S-Methoprene 0.5% in Magnum Gel Cucarachas IGR Plus without PPE.

Trained professional users are those operators who have expert knowledge and skill in handling hazardous biocidal products; they will probably use protective gloves when handling these products during pest control operations. Having this in mind, a refined assessment is conducted where the operator uses gloves (PF 10). The resulting combined exposure levels expressed as % of the respective $AEL_{long\text{-}term}$ indicates that the use of Magnum Gel Cucarachas IGR Plus containing 2.15% Imidacloprid and 0.5% S-Methoprene, does not cause any risk for pest control operators if gloves are worn.

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	1,34E-01	223,96	no
Post application/ Scenario 2	1	6	0.06	1,34E-02	22,40	yes
Application/ Scenario 1	2	6	0.06	1,34E-02	22,396	yes
Post application/ Scenario 2	2	6	0.06	1,34E-03	2,240	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	7.6	0.076	3,13E-02	41,12	yes
Post application/ Scenario 2	1	7.6	0.076	3,13E-03	4,11	yes
Application/ Scenario 1	2	7.6	0.076	3,13E-03	4,112	yes
Post application/ Scenario 2	2	7.6	0.076	3,13E-04	0,411	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	1,48E-01	246,35	No
Application/ Scenario 1 & Post application/ Scenario 2	2	6	0.06	1,48E-02	24,635	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	7.6	0.076	3,44E-02	45,23	yes
Application/ Scenario 1 & Post application/ Scenario 2	2	7.6	0.076	3,44E-03	4,523	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 2 estimation considering the use of protective gloves (PF10).

The use of Magnum Gel Cucarachas IGR Plus containing 2.15% Imidacloprid and 0.5% S-Methoprene, does not cause any health risk for pest control operators if gloves are worn

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 (cockroaches 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 0.03225 mg/kg bw/day and 7.5E-03 mg/kg bw/day (combined systemic exposure to Imidacloprid and S-Methoprene, respectively). The estimated uptake represents 20% of the proposed $AEL_{medium\text{-}term}$ of 0.2 mg/kg bw/day for Imidacloprid and 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 67% and 12% 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	AEL mg/kg bw/d	Estimated uptake mg/kg	Estimated uptake/ AEL	Acceptable (yes/no)

		bw/d		bw/d	(%)	
Application/ Scenario 3	1	20	0.2	2,69E-02	13,44	Yes
Post application/ Scenario 4	1	20	0.2	1,34E-02	6,72	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	4,03E-02	20,16	yes
Non-professionals Application/ Scenario 3 & Post application/ Scenario 4	1	6	0.06	4,03E-02	67,19	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	6,25E-03	1,79	yes
Post application/ Scenario 4	1	35	0.35	3,13E-03	0,89	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)
Professionals Application/ Scenario 3 & Post application/ Scenario 4	1	35	0.35	9,38E-03	2,68	yes
Non-professionals Application/ Scenario 3 & Post application/ Scenario 4	1	7.6	0.076	9,38E-03	12,34	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 Cucarachas 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	9,41E-02	23.52	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	1,38E-02	3,93	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 9.41E-02 mg/kg bw and 1,38E-02 mg/kg during the indirect exposure via oral and dermal route after the application of biocidal product (combined systemic exposure to Imidacloprid and S-Methoprene, respectively, Tier 1). The estimated uptake represents 24% of the proposed $AEL_{short\text{-}term}$ of 0.4 mg/kg bw for Imidacloprid and 4% 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 Cucarachas 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.
- In storerooms the product may only be applied in the presence of properly packaged food.

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)	1,48E-01	3,44E-02
Value of exposure (with PPE)	1,48E-02	3,44E-03

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

	Imidacloprid	S-Methoprene
Medium term value of exposure	4,03E-02	9,38E-03
Chronic value of exposure	4,03E-02	9,38E-03

Secondary exposure Toddler as mg/kg bw

	Imidacloprid	S-Methoprene
Acute value of exposure	9,41E-02	1,38E-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 and Tier 2 assessments are shown in the following table.

Primary exposure: Trained professional, chronic exposure

Without PPE	**Imidacloprid**	**S-Methoprene**	**conclusion**
Tier 1	246.35 %AEL	45.23 %AEL	No acceptable
Tier 2	2.46	0.45	No acceptable
	HI = 2.92		
With PPE	**Imidacloprid**	**S-Methoprene**	**conclusion**
Tier 1	24.64 %AEL	4.52 %AEL	acceptable
Tier 2	0.25	0.05	acceptable
	HI = 0.29		

Primary exposure: consumer/ professional, medium term exposure

Without PPE	**Imidacloprid**	**S-Methoprene**	**conclusion**
Tier 1	20.16 %AEL	2.68 %AEL	acceptable
Tier 2	0.20	0.03	acceptable
	HI = 0.23		

Primary exposure: professional, chronic exposure

Without PPE	**Imidacloprid**	**S-Methoprene**	**conclusion**
Tier 1	67.19 %AEL	12.34 %AEL	acceptable
Tier 2	0.67	0.12	acceptable
	HI = 0.80		

Indirect exposure: toddler, acute exposure

	Imidacloprid	**S-Methoprene**	**conclusion**
Tier 1	23.52 %AEL	3.93 %AEL	acceptable
Tier 2	0.24	0.04	acceptable
	HI = 0.27		

Conclusion:

For trained professional use:

TIER I: Risk assessment is not acceptable for Imidacloprid in the product without PPE, but is acceptable using PPE. For S-Methoprene in the product risk assessment is acceptable with and without PPE.

TIER 2: Mixture risk assessment is not acceptable in T2 without PPE but is acceptable with gloves during application.

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 restrictions 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

2.2.8.1 Effects assessment on the environment

	Imidacloprid	S-Methoprene	OIT
PNECwater (mg/L)	4.8E-06	1.9E-04	7.1E-06
PNECmicroorganisms STP (mg/L)	61.3	6.85	3.04E-01
PNECsediment (mg/kg wwt)	2.6E-05	3.8E-04	1.6E-04
PNECsoil (mg/kg wwt)	1.58E-02	0.0.148	7.53E-01
PNECoral bird (mg/kg food)	4.2		0.39
PNECoral mammal (mg/kg food)	8.33	43.60	16.67

**according to the addendum from 2018 to the AR for S-methoprene*
No ecotoxilogical data are available to a set a MENEC 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.

Also for the OIT several metabolites are identified in the aquatic compartment (M1, M4, M5, M6 and M7). These metabolites are included in the assessment of scenario 2 (crack and crevices for professional users) where no unacceptable risk has been found with the other active substnances.

As it is have been indicated above (section 2.1.2.5) the product MAGNUM GEL IGR PLUS also contain BIT as a coformulant. BIT is a biocidal active substance from another PT but, since this active substance is still under evaluation, at this moment, BIT is not considered in this assessment report.

Effect on honeybees
The summarises the data available for the active substance imidacloprid:

Toxicity to honeybees

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

Doe to the use proposed for the product, the risk to the bees is not expecte

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
No data is available.

Further Ecotoxicological studies
No data is available.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
No data is available.

Supervised trials to assess risks to non-target organisms under field conditions
No data is available.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
No data is available.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)
No data is available.

Foreseeable routes of entry into the environment on the basis of the use envisaged
See fate and distribution in exposed environmental compartments

Further studies on fate and behaviour in the environment (ADS)
No data is available.

Leaching behaviour (ADS)
Leaching tests are not relevant for PT18. Leaching test is not applicableaccording to the intended use of the biocidal product.

Testing for distribution and dissipation in soil (ADS)
No data is available.

Testing for distribution and dissipation in water and sediment (ADS)
No data is available.

Testing for distribution and dissipation in air (ADS)
No data is available.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)
MAGNUM GEL CUCARACHAS IGR PLUS is not formulated to be sprayed.

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)

Not relevant.

Endocrine disruption

.

Based on the existing knowledge and the data provided in substances CAR it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. This is further assessed in the frame of the REACH Regulation. 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

2.2.8.2 Exposure assessment

General information

Assessed PT	*PT 18*
Assessed scenarios	Scenario 13: Indoor use crack and crevices private houses. Scenario 2: Indoor use crack and crevices private houses and large buildings. Scenario 3: Indoor use in bait station. Scenario 4: Indoor use surface treatment.
ESD(s) used	Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses. 17 July 2008.
Approach	A consumption based approach has been used as a suitable protective measure at the local level.
Distribution in the environment	Calculated based on TGD 2003 (alternative: based on measured data)
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Magnum Gel Cucarachas IGR Plus is produced in small batches in closed systems with appropriate control measurements in place to exclude release of the active substance for Guidance on Human Exposure to Biocidal Product. In addition to this according to the Technical Notes for Guidance on Human Exposure to Biocidal Products (June 2007) processes including the manufacturing of the active substance and the biocidal prouct are regulated under various other Directives. It is therefore considered acceptable that the exposure during the production/formulation of the insecticidal active substances is not considered here.
Remarks	None.

Emission estimation

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

Scenario [1] (Indoor use crack and crevices private houses)

This scenario is cover for scenario 4

Scenario [2] (Indoor use crack and crevices private houses and large buildings)

Imidacloprid

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: crack and crevice application in a house and large buildings.			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	2.4	*g/m²*	6 drops/ m^2 (each drop contains 0.04 g of product)
Concentration of active substance in the product	21.5	*g/Kg*	
Number applications per day	1	-	
Number of point per area	1	-	
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: crack and crevice application in a house and large buildings.			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	2.4	*g/m²*	6 drops/ m^2 (each drop contains 0.04 g of product)
Concentration of active substance in the product	5	*g/Kg*	
Number applications per day	1	-	
Number of point per area	1	-	
Area treated with product (private houses)	2	m^2	
Area treated with product (large buildings)	9.3	m^2	

OIT

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**

Scenario: crack and crevice application in a house and large buildings.			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	2.4	*g/m²*	6 drops/ m^2 (each drop contains 0.04 g of product)
Concentration of active substance in the product	0.4	*g/Kg*	See confidential annex.
Number applications per day	1	-	
Number of point per area	1	-	
Area treated with product (private houses)	2	m^2	
Area treated with product (large buildings)	9.3	m^2	

Calculations for Scenario [2]

Emissions of imidacloprid to the environment due to indoor use were assumed to only occur via the release from the treated surfaces to the sewer system and thus to the STP by wet cleaning. Therefore the exposed environmental compartments comprise STP, the adjacent surface water, sediment, soil and groundwater.
According to the applicant the worst scenario is 6 drops (with 0.04 g of product) per m^2 in crack and crevice followed by a wet cleaning event. The emissions from this application are calculated for both applications private houses and large buildings using a default value agreed in the MOTA (2011). Hence, the default value used for a private house and large building is 2 and 9.3 m^2, respectively.

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

Parameter	Definition	imidacloprid		s-methoprene		OIT	
		Private houses	Large buildings	Private houses	Large buildings	Private houses	Large buildings
Number of application per day	N_{appl}	1		1		1	
Number of point per area	N_{point}	6		6		6	
Fraction emitted to treated surfaces during application	F_{appl}	1		1		1	
Quantity of commercial product applied per point of gel [g/point]	$Q_{prod, point}$	0.04		0.04		0.04	
Fraction of active	F_{ai}	0.0215		0.005			

substance in the commercial product						0.0004	
Area treated with product [m^2]	$AREA_{treated}$	2	9.3	2	9.3	2	9.3
Emission rate to treated surface during application [g/d]	**$E_{application, surface} = Q_{prod, point} \times N_{point} \times F_{ai} \times AREA_{treated} \times F_{appl} \times N_{appl}$**	**1.03E-02**	**4.79E-02**	**2.40E-03**	**1.12E-02**	**1.92E-04**	**8.93E-04**

Cleaning

Releases to wastewater during cleaning event depend on the efficiency of the cleaning. It is considered that the cleaning efficiency (FCE) for the use of the MAGNUM GEL CUCARACHAS IGR PLUS represents a maximum exposure to cleaning of 3% for household and large buildings according to the CEFIC Insecticides Working Group, considering that this type of product is applied in areas difficult to access and not subject to cleaning (ESD PT18, 2008).

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

Parameter	**Definition**	**imidacloprid**		**s-methoprene**		**OIT**	
		Private houses	**Large buildings**	**Private houses**	**Large buildings**	**Private houses**	**Large buildings**
Emission to floor during application step [g/d]	$E_{application, floor}$	0	0	0	0	0	0
Emission to treated surfaces during application step	$E_{application, surface}$	0.0103	0.0479	0.0024	0.011	0.000192	0.0008934
Fraction emitted to wastewater during cleaning step	F_{ww}	1		1		1	

Cleaning efficiency	F_{CE}	0.03		0.03		0.03	
Emission rate to wastewater during cleaning step [g/d]	**$Elocal_{ww}$ = ($E_{application, floor}$ + $E_{application, surface}$) x F_{ww} x F_{CE}**	**3.09E-04**	**1.44E-03**	**7.2E-05**	**3.35E-04**	**5.76E-06**	**2.68E-05**

Emissions have been calculated for one house and one large building, according to the ESD these values have to be multiplied by the number of houses, 4000, and large buildings, 1000. The number of large buildings has been refined from 1000 to 300 (TMI 2010)
According to the applicant the product is going to be used a maximum of 6 times per year depending of the level of infestation (worst case according to the efficacy studies). As this frequency of use is not indicated in the ESD PT 18, we are going to use the frequency of 1 treatment a week therefore, the simultaneity factor is:
$F_{simultaneity}$ = (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**		**OIT**	
		Private houses	**Large buildings**	**Private houses**	**Large building**	**Private houses**	**Large buildings**
Emission from treated surface to wastewater during cleaning step [g/d]	$Elocal_{ww}$	**3.09E-04**	**1.43E-03**	**7.2E-05**	**3.35E-04**	**5.76E-06**	**2.68E-05**
Simultaneously treated houses per STP [-]	N_{houses}	4000	300	4000	300	4000	300
Simultaneity factor[-]	$F_{simultaneity}$	0.00815		0.00815		0.00815	
Emission to wastewater [g/d]	**$Elocal_{ww}$ = $Elocal_{ww}$ x N_{houses} x $F_{simultaneity}$**	1.01E-02	3.52E-03	2.35E-03	8.19E-04	1.88E-04	6.55E-05
Total emission to wastewater [kg/d]	**$E_{ww\ total}$ = Σ(E_{ww})/1000**	**1.36-05**		**3.17E-06**		**2.53E-07**	

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**	**Remarks**
STP (imidacloprid)	**1.36-05**	Worst case private house + large buildings
STP (s-methoprene)	**3.17E-06**	Worst case private house + large buildings
STP (OIT)	**2.53E-07**	Worst case private house + large buildings

Scenario [3] (Indoor use in bait station)

According to the guide ESD for PT18, it is assumed that emissions to the environment during the use indoor of gels inside of bait stations are negligible during service life stage and therefore, no environmental exposure assessment and risk is needed

Scenario [4] (Indoor use surface treatment private houses and large buildings)

Imidacloprid

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: crack and crevice application in a house and large buildings.			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	2.4	*g/m²*	6 drops/ m^2 (each drop contains 0.04 g of product)
Concentration of active substance in the product	21.5	*g/Kg*	
Number applications per day	1	-	
Number of point per area	1	-	
Area treated with product (private houses)	38.5	m^2	
Area treated with product (large buildings)	180	m^2	

S-methoprene

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: crack and crevice application in a house and large buildings.			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	2.4	*g/m²*	6 drops/ m^2 (each drop contains 0.04 g of product)
Concentration of active substance in the product	5	*g/Kg*	
Number applications per day	1	-	

Number of point per area	1	-	
Area treated with product (private houses)	38.5	m^2	
Area treated with product (large buildings)	180	m^2	

OIT

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: crack and crevice application in a house and large buildings.			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	2.4	*g/m²*	6 drops/ m^2 (each drop contains 0.04 g of product)
Concentration of active substance in the product	0.4	*g/Kg*	See confidential annex.
Number applications per day	1	-	
Number of point per area	1	-	
Area treated with product (private houses)	38.5	m^2	
Area treated with product (large buildings)	180	m^2	

Calculations for Scenario [4]

Emissions of imidacloprid to the environment due to indoor use were assumed to only occur via the release from the treated surfaces to the sewer system and thus to the STP by wet cleaning. Therefore the exposed environmental compartments comprise STP, the adjacent surface water, sediment, soil and groundwater.
According to the applicant the worst scenario is 6 drops (with 0.04 g of product) per m^2 in crack and crevice followed by a wet cleaning event. The emissions from this application are calculated for both applications private houses and large buildings using a default value agreed in the MOTA (2011). Hence, the default value used for a private house and large building is 38.5 and 180 m^2, respectively.

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

Parameter	**Definition**	**imidacloprid**		**s-methoprene**		**OIT**	
		Private houses	**Large buildings**	**Private houses**	**Large buildings**	**Private houses**	**Large buildings**
Number of application per day	N_{appl}	1		1		1	
Number of point per area	N_{point}	6		6		6	
Fraction emitted to treated	F_{appl}	1		1		1	

surfaces during application							
Quantity of commercial product applied per point of gel [g/point]	$Q_{prod,\ point}$	0.04		0.04		0.04	
Fraction of active substance in the commercial product	F_{ai}	0.0215		0.005		0.0004	
Area treated with product [m^2]	$AREA_{treated}$	38.5	180	38.5	180	38.5	180
Emission rate to treated surface during application [g/d]	**$E_{application,\ surface} = Q_{prod,\ point} \times N_{point} \times F_{ai} \times AREA_{treated} \times F_{appl} \times N_{appl}$**	**1.99E-01**	**9.29E-01**	**4.62E-02**	**2.16E-01**	**3.70E-03**	**1.73E-02**

Cleaning

Releases to wastewater during cleaning event depend on the efficiency of the cleaning. It is considered that the cleaning efficiency (FCE) for the use of the MAGNUM GEL CUCARACHAS IGR PLUS represents a maximum exposure to cleaning of 25% for household and large buildings according to the CEFIC Insecticides Working Group, considering that this type of product is applied in surface areas (ESD PT18, 2008).

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

Parameter	Definition	imidacloprid		s-methoprene		OIT	
		Private houses	Large buildings	Private houses	Large buildings	Private houses	Large buildings
Emission to floor during application step [g/d]	$E_{application,\ floor}$	0	0	0	0	0	0
Emission to treated surfaces during	$E_{application,\ surface}$	0.199	0.929	0.0462	0.216	0.0037	0.0173

application step							
Fraction emitted to wastewater during cleaning step	F_{ww}	1		1		1	
Cleaning efficiency	F_{CE}	0.25		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}**	**4.97E-02**	**2.32E-01**	**1.16E-02**	**5.40E-02**	**9.24E-04**	**4.32E-03**

Emissions have been calculated for one house and one large building, according to the ESD these values have to be multiplied by the number of houses, 4000, and large buildings, 1000. The number of large buildings has been refined from 1000 to 300 (TMI 2010)
According to the applicant the product is going to be used a maximum of 6times per year depending of the level of infestation (worst case according to the efficacy studies). As this frequency of use is not indicated in the ESD PT 18, we are going to use the frequency of 1 treatment a week therefore, the simultaneity factor is:
$F_{simultaneity}$ = (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**		**OIT**	
		Private houses	**Large buildings**	**Private houses**	**Large buildings**	**Private houses**	**Large buildings**
Emission from treated surface to wastewater during cleaning step [g/d]	$Elocal_{ww}$	**4.97E-02**	**2.32E-01**	**1.16E-02**	**5.40E-02**	**9.24E-04**	**4.32E-03**
Simultaneously treated houses per STP [-]	N_{houses}	4000	300	4000	300	4000	300
Simultaneity factor[-]	$F_{simultaneity}$	0.00815		0.00815		0.00815	
Emission to wastewater [g/d]	**$Elocal_{ww}$ = $Elocal_{ww}$ x N_{houses} x $F_{simultaneity}$**	**1.62**	**5.68E-01**	**3.77E-01**	**1.32E-1**	**3.01E-02**	**4.32E-03**

Total emission to wastewater [kg/d]	**$E_{ww\ total}$ = Σ(E_{ww})/1 000**	**2.19E-03**	**5.09E-04**	**4.07E-05**

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP (imidacloprid)	**2.19E-03**	Worst case private house + large buildings
STP (s-methoprene)	**5.09E-04**	Worst case private house + large buildings
STP (OIT)	**4.07E-05**	Worst case private house + large buildings

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	No	No	No	No	No	No	Yes	Yes	No
Scenario 2	Yes	Yes	No	No	Yes		Yes	Yes	No
Scenarios 3 and 4	Yes	Yes	No	No	Yes		Yes	Yes	No
Scenario 7	Yes	Yes	No	No	Yes		Yes	Yes	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 XC)	<0.1	Pa	
Water solubility (at X°C)	613	mg/l	
Log Octanol/water partition coefficient	0.57	Log 10	
Organic carbon/water partition coefficient (Koc)	230	l/kg	
Henry's Law Constant (at X C)*[if measured data available]*	$1.7x10^{-10}$	Pa/m3/mol	
Biodegradability	No		
DT_{50} for hydrolysis in surface water	2.75 years at 12ºC/pH 9	d or hr (at 12ºC /pH)	
DT_{50} for photolysis in surface water	DT50 calculated:	d or hr	

	1.4 -16 days(fall, winter) 0.5-1.6 days (spring, summer) 1.6 days (spring, summer)		
DT_{50} for degradation in soil	135 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 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 XC)	0.623 mPa at 20°C	mPa	
Water solubility (at X°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 X 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*	d or hr (at 12ºC /pH)	

	1.2), hydrolysis is 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

Input parameters (only set values) for calculating the fate and distribution in the environment OIT (Substance of concern)			
Input	Value	Unit	Remarks
Molecular weight	213.34		
Melting point		°C	
Boiling point		°C	
Vapour pressure (at XC)	0.0031 mPa at 20°C	mPa	
Water solubility (at X°C)	400at 20ºC	mg/l	
Log Octanol/water partition coefficient (log P_{OW}) (pH 7)	3.1	Log 10	
Organic carbon/water partition coefficient (Koc)	982	l/kg	
Henry's Law Constant (at X C)*[if measured data available]*	0.00104	Pa/m^3/mol	
Biodegradability	Inherently biodegradable, not fulfilling the criteria		
Degradation in soil (DT_{50}) (at 12°C)	0.9	days	
BCF fish	92.6	L.kg^{-1}	
BMF fish	1	-	

Calculated fate and distribution of OIT in the STP (EUSES model 2.1)	
Compartment	Percentage [%]
Air	
Water	16
Sludge	1.1
Degraded in STP	82.9

Calculated PEC values

		PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{sased}**	**PEC_{soil}**	**PEC_{GW}[1]**	**PEC_{air}**

		[mg/l]	[mg/l]	[mg/kg$_{wwt}$]	[mg/l]	[mg/kg$_{wwt}$]	[mg/kg]	[µg/l]	[mg/m^3]
Scenario 2	Imidacloprid	6.62x10^{-6}	6.61x10^{-6}	3.82x10^{-6}			7.55x10^{-7}	1.25x10^{-4}	
	S-methoprene	1.43x10^{-6}	1.43x10^{-7}	2.83x10^{-6}			4.30x10^{-8}	4.60x10^{-7}	
	OIT	2.03x10^{-8}	2.02x10^{-9}	4.48x10^{-8}			2.24x10^{-10}	2.14x10^{-9}	
Scenario 4	Imidacloprid	1.06x10^{-3}	1.06x10^{-4}	6.14x10^{-4}			1.21x10^{-4}	2.02x10^{-2}	
	S-methoprene	2.29x10^{-4}	2.29x10^{-5}	4.54x10^{-4}			6.91x10^{-6}	7.39x10^{-5}	
	OIT	3.25x10^{-6}	3.25x10^{-7}	7.19x10^{-6}			3.60x10^{-8}	3.44x10^{-7}	
	[1] If the PEC$_{GW}$ was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.								

Metabolites
PEC $_{SW}$

The PEC values for the relevant water metabolites derived from the OIT are calculated form the OIT PECsw values considering the maximum occurrence of the metabolite and molecular weight correction factor, the resulting PEC values are presented below.

PEC$_{STP}$ value calculated inscenario 1 (crack and crevices):

PEC$_{STP}$ = 1.72E-08 mg/L

PEC sw values obtained for the different metabolites:

Metabolite	*MW correction*	*Maximum %AR*	*PEC water*	*PECsw (mg/L)*
M1	*0,8775*	*22,9*	*Crack and crevices*	*3,4563E-07*
M4	*1,2952*	*6,5*	*Crack and crevices*	*1,44803E-07*
M5	*0,9528*	*15*	*Crack and crevices*	*2,45822E-07*
M6-1	*1,075*	*14,7*	*Crack and crevices*	*2,71803E-07*
M6-3	*1,0655*	*10,5*	*Crack and crevices*	*1,92429E-07*
M6-4	*1,5021*	*10,5*	*Crack and crevices*	*2,71279E-07*
M6-8	*1,4176*	*10,5*	*Crack and crevices*	*2,56019E-07*
M7	*1,3609*	*7,3*	*Crack and crevices*	*1,70875E-07*

PEC $_{SED}$

The PECsed values for the relevant water metabolites from the substance OIT are derived from the PECsw metabolite values presented above. The values have been calculated in line with Equation 53 of Volume IV Environment -assessment and Evaluation (Parts B + C) (Version 2.0, Oct 2017). These values have been only calculated for the crack and crevices scenario.

PEClocal$_{sediment}$ equation according to Part B (eq 53 p84)

$$PEClocal_{sed} = \frac{K_{susp\text{-}water}}{RHO_{susp}} \cdot PEClocal_{water} \cdot 1000$$

Where:
PEClocal$_{water}$ Concentration in surface water during emission episode [mg/L] (PEC$_{sw}$)
K$_{susp\text{-}water}$ Suspended matter-water partitioning coefficient [m^3/m^3] (equation 27 (Part B+C))
RHO$_{susp}$ Bulk density of suspended matter [kg/m^3] (equation 20 (Part B+C))

PEClocal$_{sed}$ Predicted environmental concentration in sediment [mg/kg]

The resulting PECsed values are reported below in following table.

Metabolite	***Henry Laws constant (Pa m^3 /Mol)***	***Koc (L/Kg)***	***PEClocal sediment (mg/kg)***
M1	***6,58E-08***	***1,00E+01***	***3,46E-07***
M4 (a-b)	***1,24E-17***	***8,25E+01***	***3,73E-07***
M5 (a-b)	***6,14E-10***	***1,00E+01***	***2,46E-07***
M6-1a + M6-2a	***1,33E-06***	***7,40E+01***	***6,50E-07***
M6-1b + M6-2b	***1,33E-06***	***6,22E+01***	***5,80E-07***
M6-1 (c-g) + M6-2 (c-g)	***1,33E-06***	***6,51E+01***	***5,97E-07***
M6-1h + M6-1h	***2,66E-05***	***6,65E+01***	***6,06E-07***
M6-3a	***2,53E-05***	***3,82E+01***	***3,10E-07***
M6-3b	***1,39E-05***	***6,91E+01***	***4,40E-07***
M6-3 (c-f)	***1,39E-05***	***1,01E+02***	***5,73E-07***
M6-3g	***2,78E-04***	***1,01E+02***	***5,73E-07***
M6-3h	***6,43E-02***	***2,12E+02***	***1,04E-07***
M6-4a	***1,84E-11***	***6,94E+02***	***4,31E-07***
M6-4b	***3,34E-12***	***5,94E+02***	***3,72E-07***
M6-8 (a-b)	***6,90E-12***	***3,26E+02***	***2,01E-07***
M7 (a+c)	***1,65E-17***	***1,35E+02***	***6,35E-07***
M7 (b+d)	***1,65E-17***	***1,22E+02***	***5,87E-07***

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 CUCARACHAS 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 indoor 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.

OIT has a Log kow <4.5 and a measured BCF in fish of 92.6 L kg^{-1}. The calculated BCF for earthworms was 10.82 L kg^{-1} wet earthworm.

Sencondary poisoning has been calculated for the worst case, scenario 4.

In accordance with the equations of the ECHA guidance vol.IV, part B (2015), $PEC_{oral,predator}$ for both food chain were calculated as followed:

Imidacloprid

Parameter / variable	**Symbol**	**Unit**	**Value**
Aquatic food chain:			
Predicted environmental concentration during episode	$PEC_{local,water}$	[$mg.l^{-1}$]	2.12E-04
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)	**$PEC_{oral,predator}$**	**[$mg.kg^{-1}_{wet\ fish}$]**	**1.29E-04**
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	$C_{porewater}$	[$mg.l^{-1}$]	2.23E-05

Concentration in soil	C_{soil}	[$mg.kg^{-1}_{wwt}$]	9.30E-05
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)	**$PEC_{oral,predator}$**	**[$mg.kg^{-1}_{wet\ earthworm}$]**	**2.45E-05**

S-methoprene

Parameter / variable	**Symbol**	**Unit**	**Value**
Aquatic food chain:			
Predicted environmental concentration during episode	$PEC_{local,water}$	[$mg.l^{-1}$]	2.29E-05
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)	**$PEC_{oral,predator}$**	**[$mg.kg^{-1}_{wet\ fish}$]**	**0.11**
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	$C_{porewater}$	[$mg.l^{-1}$]	8.22E-08
Concentration in soil	C_{soil}	[$mg.kg^{-1}_{wwt}$]	1.28E-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)	**$PEC_{oral,predator}$**	**[$mg.kg^{-1}_{wet\ earthworm}$]**	**3.46E-05**

OIT

Parameter / variable	**Symbol**	**Unit**	**Value**
Aquatic food chain:			
Predicted environmental concentration during episode	$PEC_{local,water}$	[$mg.l^{-1}$]	2.75E-07
Bi1oconcentration factor for fish on wet weight basis	BCF_{fish}	[$l.kg^{-1}_{wet\ fish}$]	92.6
Biomagnification factor in fish	BMF	[-]	1

Predicted environmental concentration in food (considering that predators feed at 50% on local level)	**$PEC_{oral,predator}$**	**[$mg.kg^{-1}_{wet\ fish}$]**	**2.54E-05**

The calculated BCF for earthworms was 10.82, indicating a low propensity to bioconcentrate. As such, no further consideration of this route of secondary poisoning is required.

2.2.8.3 Risk characterisation

ATMOSPHERE
Conclusion: Emissions and PECs in air are considered as negligible. It can be concluded that the use of this product will not pose a significant risk to the atmospheric compartment.

SEWAGE TREATMENT PLANT (STP)

	Summary table on calculated PEC/PNEC values		
		$PEC/PNEC_{STP}$	Conclusion
Scenario 2, crack and crevices	Imidacloprid	$1.08x10^{-7}$	Acceptable
	S-methoprene	$2.08x10^{-7}$	Acceptable
	OIT	$6.66x10^{-8}$-	Acceptable
Scenario 4, surface treatment	Imidacloprid	$1.73x10^{-5}$	Acceptable
	S-methoprene	$3.35x10^{-5}$	Acceptable
	OIT	$1.07x10^{-5}$	Acceptable

Conclusion: For all the assessed scenarios, risks to the STP compartment are acceptable

AQUATIC COMPARTMENT
Risk ratios for surface water and sediment are presented in the following tables:

	Summary table on calculated PEC/PNEC values in water		
		$PEC/PNEC_{water}$	Conclusion
Scenario 2, crack and crevices	Imidacloprid	$1.38x10^{-1}$	Acceptable
	S-methoprene	$7.50x10^{-1}$	Acceptable
	OIT	$2.85x10^{-4}$	Acceptable
Scenario 4, Surface treatment	Imidacloprid	22.1	**Unacceptable**
	S-methoprene	$1.21x10^{-1}$	Acceptable
	OIT	$4.58x10^{-2}$	Acceptable

	Summary table on calculated PEC/PNEC values in sediment		
		PEC/PNEC$_{sed}$	Conclusion
Scenario 2, indoor use crack and crevices	Imidacloprid	$1.47x10^{-1}$	Acceptable
	S-methoprene	$7.44x10^{-3}$	Acceptable
	OIT	$2.80x10^{-4}$	Acceptable
Scenario 4, indoor use surface treatment	Imidacloprid	23.6	**Unacceptable**
	S-methoprene	1.20^{-}	**Unacceptable**
	OIT	$4.5x10^{-2}$	Acceptable

Conclusion: the risk characterisation ratios for imidacloprid in water and sediment are above 1 scenario 4

Metabolites

The metabolite PEC:PNEC ratios are presented below

Metabolite	PECsw (mg/L)	PNEC (mg/L)	PEC/PNEC
M1	3,4563E-07	4,08E-03	8,47132E-05
M4	1,44803E-07	9,92E-02	1,45971E-06
M5	2,45822E-07	6,50E-03	3,78188E-05
M6-1	2,71803E-07	5,64E-05	0,004819202
M6-3	1,92429E-07	6,00E-05	0,003207155
M6-4	2,71279E-07	4,23E-03	6,41322E-05
M6-8	2,56019E-07	2,99E-03	8,56249E-05
M7	1,70875E-07	3,61E-03	4,73337E-05

TERRESTRIAL COMPARTMENT

Risk ratios for the terrestrial compartment are presented in the following tables:

	Summary table on calculated PEC/PNEC values		
		PEC/PNEC$_{soil}$	Conclusion
Scenario 2 indoor use crack and crevices	Imidacloprid	$4.78x10^{-5}$	Acceptable
	S-methoprene	$2.91x10^{7}$	Acceptable
	OIT	$2.98x10^{-10}$	Acceptable
Scenario 4, indoor use surface treatment	Imidacloprid	$7.67x10^{-3}$	Acceptable
	S-methoprene	$4.67x10^{5}$	Acceptable

	OIT	$4.79x10^{87}$	Acceptable

Conclusion: No risk has been indentified for this compartment

GROUNDWATER

Risk ratios for groundwater are presented in the following tables:

	Summary table on calculated PEC groundwater (µg/L) Acceptable risks for PEC < the limit value of 0.1 µg/L		
		PEC_{GW}	Conclusion
Scenario 2, indoor use crack and crevices	Imidacloprid	$1.25x10^{-4}$	Acceptable
	S-methoprene	$4.60x10^{-7}$	Acceptable
	OIT	$2.14x10^{-9}$	Acceptable
Scenario 4, indoor use surface treatment	Imidacloprid	$2.00x10^{-2}$	Acceptable
	S-methoprene	$7.39x10^{-5}$	Acceptable
	OIT	$3.44x10^{-7}$	Acceptable

Conclusion: the risk characterisation ratios for imidacloprid in groundwater is above 1 for direct emission of the product in outdoor use (scenario 1 and 2).

PRIMARY AND SECONDARY POISONING

Primary poisoning
Not relevant

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	OIT
Aquatic	Birds	3,07E-05	-	6,51E-05
	Mammals	1,55E-05	2,52E-03	1,52E-06
Terrestre	Birds	5,83E-06		
	Mammals	2,94E-06	7,94E-07	

Conclusion:
The risks of secondary poisoning are acceptable for imidacloprid,S-Methoprene and OIT when using this product for all the uses.

Mixture toxicity

The results of mixture toxicity assessment of the product containing two active substances (imidacloprid and S-Methoprene) the substance of concern OIT and its metabolites are summarised in the following table.

Summary table on calculated ΣPEC/PNEC values					
	ΣPEC/PNEC$_{STP}$	**ΣPEC/PNEC$_{water}$**	**ΣPEC/PNEC$_{sed}$**	**ΣPEC/PNEC$_{soil}$**	**ΣPEC$_{GW}$**
Scenario 2	$3.83x10^{-7}$	$1.47x10^{-1*}$	$1.55x10^{-1}$	$4.80x10^{-5}$	$1.25x10^{-4}$
Scenario 4	$6.15x10^{-5}$	22.3	24.9	$8.14x10^{-4}$	$2.01x10^{-2}$

*for this scenario/compartment metabolites derived from the substance OIT have been included

Conclusion:
Only the aggregate RCR values of imidacloprid,S-Methoprene and OIT for scenario 4 are below 1 for all the assessed compartments.
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Overall conclusion on the risk assessment for the environment of the product

Summary table for the risk assessment of this product.

	PEC/PNECstp	PEC/PNECwater	PEC/PNECsed	PEC/PNECsoil	PEC/PNECGW
Scenario 2, indoor use crack and crevices	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
Scenario 4, surface treatment	Acceptable	Unacceptable	Unacceptable	Acceptable	Acceptable

For the indoor use of the MAGNUM GEL CUCARACHAS IGR PLUS product for both gel spot application and with bait stations in crack and crevices, calculated RCR values were < 1 for all environmental compartments, and concentrations in groundwater were lower than the trigger value set by Directive 98/83/EC, indicating acceptable risks to these environmental compartments.

For the indoor use of the MAGNUM GEL CUCARACHAS IGR PLUS product for gel spot application in surface treatment, calculated RCR values were < 1 for STP and soil environmental compartments, and concentrations in groundwater was lower than the trigger value set by Directive 98/83/EC. However, for surface water and sediment, RCR values were >1, indicating unacceptable risks to these environmental compartments.

In conclusion, for the MAGNUM GEL CUCARACHAS IGR PLUS, risks to the environment are acceptable only to be used indoor (directly or in bait stations) in crack and crevices

2.2.9 Measures to protect man, animals and the environment

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

Handling:
Avoid contact with eyes and skin

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

- Avoid contact of children with treated surfaces.
- Product must be securely applied in a way so as to minimize the risk of consumption by other animals or children.
- The use of ready to use bait stations is in itself a risk mitigation measure. But the stations should not be open or handle.
- Never introduce the fingers through the holes in the trap. In any case, the trap has built-in block inside to prevent that if you introduce your finger, it can never get to touch the insecticide gel.
- This product should be used in alternation with other products not containing the same a.s. to avoid resistant populations.
- The product should be reapplied when finished only until the pest is controlled.
- Use products at recommended doses and intervals.
- The product contains a bitter substance that makes it repulsive to people or pets.

Trained professional uses:

- The product can not be applied on surfaces where feed or feedingstuff is prepared, served, consumed or stored.
- The product will be applied in the food industry in absence of foodstuff except in storerooms where the 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 and non-professional uses:

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

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

2.2.10 Assessment of a combination of biocidal products

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

2.2.11 Comparative assessment

Background

The Spanish competent authority has been processing an application for a biocidal product, MAGNUM GEL CUCARACHAS 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 CUCARACHAS 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: BC-KH019263-49
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 CUCARACHAS IGR PLUS
Product type: 18 (insecticide)
Active substance(s): Imidacloprid (CAS number: 138261-41-3)

3.- Intended uses for the relevant BP in the application
According to the applicant MAGNUM GEL CUCARACHAS IGR PLUS is an insecticide (PT18) which contains the active substance imidacloprid. The product is to be used indoors in private houses and private house and/ or large buildings to control cockroaches.

Table 3.1 List of intended uses of the biocidal product:

Product type	Insecticide (PT 18)
Where relevant, an exact description of the authorised use	This product can only be used to control cockroaches
Target organism (including, where relevant, development stage)	Insecticide against the following target insects (adults, nymphs, eggs) - German cockroaches (*Blatella germanica*), - Oriental cockroaches (*Blatta orientalis*), - American cockroaches (*Periplaneta americana*)
Field(s) of use	Indoor use
Application method(s)	Gel, ready to use product or into bait stations
Category(ies) of users	Professionals, non-professionals

4.- Mapping of existing alternatives to the relevant BP

4.1.- Identified eligible alternative BPs

The product MAGNUM GEL CUCARACHAS IGR PLUS has been only compared with alternative products authorised in Spain as the searchable SPCs and a corresponding search tool in the Register for Biocidal Products (R4BP) is currently not available. The Spanish CA has used the information available to the ES CA on the 27th February 2019 of

the biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012.

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

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

In Spain products based on nitrogen and indoxacarb are only allowed for use by trained professionals so these products have been excluded. Furthermore, the BP containing nitrogen is to be used in closed environment such as sealed fumigation chambers. The product based in fipronil is also for professional users. Products with abamectin (two products) are to be used indoor by non-professionals but not by professional users, and they only control two of the four species of cockroaches controlled by MAGNUM GEL CUCARACHAS IGR PLUS, so these products have been excluded too. The product containing deltamethrin is to be used indoor and outdoor, but only by professional users, so this product is not considered as eligible alternative BP. Neither of the BPs above controls all the species of cockroaches controlled by MAGNUM GEL CUCARACHAS IGR PLUS.

In conclusion, there isn't a suitable alternative authorised BP.

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. cockroaches).

Active substance/ mode of action combination

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

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

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

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

Deltamethrin: is a non-systemic insecticide belonging to the chemical class of synthetic pyrethroids. It acts by contact and ingestion preventing the transmission of nervous impulses in harmful organisms, and thereby disrupting their nervous system. Pyrethroids prevent the sodium channels from functioning so that no transmission of impulses can take place, resulting in convulsions and death. Pyrethroids are also believed to block GABA regulated chloride channel.

Nitrogen: The mode of action of nitrogen is through the exclusion of oxygen which the target insects require for respiration, and not through any direct effect on the insect's physiology. Given this, it is highly unlikely that the target insects would be able to develop a mechanism for resistance

In conclusion, there isn't a suitable number of available active substances with different modes of action and therefore there is no adequate chemical diversity to minimise the occurrence of resistance in line with Article 23(3)(b) and the technical guidance note on comparative assessment.

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

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

5.3.- Conclusion of the screening phase:

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

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

2.2.11.1 Overall conclusion

Environment
In conclusion, for the MAGNUM GEL CUCARACHAS IGR PLUS, risks to the environment are acceptable only to be used indoor (directly or in bait stations) in crack and crevices and for outdoor used only en bait stations. To use the product outside, the following risk mitigations are proposed for this product: "To be used autdoor, the product should be use always in bait boxes", " Places the bait stations only on paved surfaces" and "Protect bait boxes from rain. Put the bait boxes only in places where they are protected from rainfall events to avoid release of the product into the environment".

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 CUCARACHAS 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	2012	MSDS of NEOSORB 70/70 B – SORBITOL Sheet Facility: ROQUETTE FRERES, 1 Rue de la Haute Loge, 62136 LESTREM - France
2.1.2	Anonymous	2018	MSDS of LYCASIN® 85/55 - MALTITOL SYRUP Sheet Facility: ROQUETTE FRERES, 1 Rue de la Haute Loge, 62136 LESTREM – France
2.1.2	Anonymous	2016	MSDS of ACTICIDE B20 Sheet Facility: Thor Especialidades S. A.; Polígono Industrial EL PLA, Avenida de la Industria, 1, 08297, Castellgali, Barcelona, Spain.
2.1.2	Anonymous	2017	MSDS of ACTICIDE OTW Sheet Facility: Thor Especialidades S. A.; Polígono Industrial EL PLA, Avenida de la Industria, 1, 08297, Castellgali, Barcelona, Spain.
2.1.2	Anonymous	2018	MSDS of SUGIN 472C/IKV POLVO Sheet Facility: Mane Iberica; Molins de Rei a Sabadell, km 13.3; Apartado 08191; 08191 Rubí – Spain
2.1.2	Anonymous	2018	MSDS of B.H.A. E320 Sheet Facility: SUCESORES DE JOSÉ ESCUDER, S.L.; Avda. Antoni Gaudí, 60 - 62 Pol. Ind. Rubí-Sud 08191; Rubí; Barcelona
2.1.2	Anonymous	2015	MSDS of Phytagel™ Sheet Facility: Sigma-Aldrich Química, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS –MADRID
2.1.2	Anonymous	2015	MSDS of Aceite de Girasol Sheet Facility: Sigma-Aldrich Química, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS –MADRID
2.1.2	Anonymous	2015	MSDS of Aceite de maís Sheet Facility: Sigma-Aldrich Química, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS –MADRID
2.1.2	Anonymous	2015	MSDS of Soybean Oil

			Sheet Facility: Sigma-Aldrich Química, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS –MADRID
2.1.2	Anonymous	2018	MSDS of Bitrex Anhydrous Sheet Facility: Johnson Matthey plc; Wheatfield Road, Edinburgh, EH11 2QA; Scotland
2.1.2	Anonymous	2008	MSDS of Sweet Whey Powder Valformoso Sheet Facility: INSULAC - Produtos Lácteos Açoreanos, S.A.; Caminho da Mafoma – Ribeira Seca, 9600-211 Ribeira Grande, S. Miguel – Açores
2.1.2	Anonymous	2011	MSDS of GLICERINA VEGETAL GL99 (E422) Sheet Facility: Emilio Peña, S.A.; Pol.Ind. Masía del juez, C/ Dels Llibrers, 19 – 46900, Torrente – Valencia, Spain.
2.1.2	Anonymous	2009	MSDS of COLPROTEIN LVF2 Sheet Facility: PROTEIN, S.A.; Polígono Industrial, parcel·la B-9, 17460 Celrà (Gironès), Cataluña, Spain.
2.2.2	[redacted]	2015	Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL CUCARACHAS IGR PLUS (IMIDACLOPRID 2.15% W/W AND S-METHOPRENE 0.50% W/W) 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	[redacted]	2017	Title: PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY TESTS FOR MAGNUM GEL CUCARACHAS IGR PLUS (IMIDACLOPRID 2.15% W/W AND S-METHOPRENE 0.50% W/W) Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain. Study code: E-15/0002 at March 2017 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
2.2.5.5	[redacted]	2015	Title: Laboratory bioassay to determine the efficacy of Magnum Gel Cucarachas IGR Plus against *Blattella germanica, Blatta orientalis* and *Periplaneta Americana* Laboratory: Mylva lab, R+D Sponsor: Mylva. Report no. ES0018-14/09
2.2.5.5	[redacted]	2016	Title: Laboratory bioassay to determine the efficacy of Magnum Gel / Ecogel Cucarachas IGR Plus (Bait Station) against *Blattella germanica*, *Blatta*

			orientalis and *Periplaneta americana* Laboratory: Mylva lab, R+D Sponsor: Mylva. Report no. ES0018-16/07
2.2.5.5	[redacted]	2016	Title: Laboratorio bioassay to determine the efficacy of 0.50% s-methopren in *Periplaneta Americana*. Laboratory: Mylva lab, R+D Sponsor: Mylva. Report no. ES0033.A
2.2.5.5	[redacted]	2018	Title: Laboratorio bioassay to determine the efficacy of Magnum Gel cucarachas IGR Plus against *Blattella germanica, Blatta orientalis* and *Periplaneta Americana*. (3 years) Laboratory: Mylva lab, R+D Sponsor: Mylva. Report no. ES0018-13/23
2.2.5.5	[redacted]	2019	Title: Laboratorio bioassay to determine the efficacy of Magnum Gel cucarachas IGR Plus against *Blattella germanica, Blatta orientalis* and *Periplaneta Americana*. (4 years) Laboratory: Mylva lab, R+D Sponsor: Mylva. Report no. ES0018-11/19
2.2.5.5	[redacted]	2020	Title: Estudio de laboratorio para valider los controles negaticos frente a *Blattella germanica, Blatta orientalis* and *Periplaneta Americana*. Laboratory: Mylva lab, R+D Sponsor: Mylva. Report no. ES0018-05/20
2.2.6.1	[redacted]	2013	Title: GEL CUCARACHAS MYLVA IMIDACLOPRID 2.15%: Acute Oral Toxicity in the Rat – Acute Toxic Class Method Test facility: Harlan Laboratories Ltd. Shardlow, UK Study Number: 41300975 GLP yes unpublished
2.2.6.2	[redacted]	2013	Title: GEL CUCARACHAS MYLVA IMIDACLOPRID 2.15%: Acute Dermal Toxicity (Limit Test) in the Rat Test facility: Harlan Laboratories Ltd. Shardlow, UK Study Number: 41300976 GLP yes unpublished
2.2.6.1	[redacted]	2016	Title:Magnum Gel Roaches, skin sensitizacion in

			guinea pigs. Modification of the Buehler method (OED 406) (Ritz, HL, and Buehler, EV, "Planning, Conduct, and Interpretation of Guinea Pig Sensitization Patch Tests". Test facility: Stealmeadow GLP: yes
	ECHA	2011(revised version: July 2015)	Competent Authority Report and Assessment Report of IMIDACLOPRID.
	EUR-Lex	2011	COMMISSION DIRECTIVE 2011/69/EU of 1 July 2011 amending Directive 98/8/EC of the European Parliament and of the Council to include imidacloprid as an active substance in Annex I thereto
	EFSA (European Food Safety Authority)	2008	Conclusion regarding the peer review of the pesticide risk assessment of the active substance imidacloprid.
	EFSA (European Food Safety Authority)	2016	Conclusion on the peer review of the pesticide risk assessment for the active substance imidacloprid in light of confirmatory data submitted.
	ECHA	2013	Competent Authority Report and Assessment Report of S-METHOPRENE.
	EUR-Lex	2014	COMMISSION IMPLEMENTING REGULATION (EU) No 91/2014 of 31 January 2014 approving S-methoprene as an existing active substance for use in biocidal products for product- type 18

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	50	50	mg
number of opening and sealing per day	10	10	
content of active substance in product	0,0215	0,005	mg/kg
Dermal absorption	75%	75%	%

Body weight adult	60	60	kg
potential exposure a.s.	10,75	2,50	mg
aborbed dermal dose a.s.	8,06	1,88	mg
actual exposure	**1,34E-01**	**3,13E-02**	**mg/kg bw/d**
actual exposure (PPE)	**1,34E-02**	**3,13E-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	50	50	mg
number of opening and sealing per day	1	1	
content of active substance in product	0,0215	0,005	mg/kg
Dermal absorption	75%	75%	%
Body weight adult	60	60	kg
potential exposure a.s.	1,08	0,25	mg
aborbed dermal dose a.s.	0,81	0,19	mg
actual exposure	**1,34E-02**	**3,13E-03**	**mg/kg bw/d**
actual exposure (PPE)	**1,34E-03**	**3,13E-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)	50	50	mg
number of opening and sealing per day	2	2	--
content of active substance in product	0,0215	0,005	mg/kg
Dermal absorption	75%	75%	%
Body weight adult	60	60	kg
potential exposure a.s.	2,15	0,50	mg
absorbed dermal dose a.s.	1,61	0,38	mg
actual exposure	**2,69E-02**	**6,25E-03**	**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 0.5 cm length * dislodgeable residue * fraction of a.s. in the product*
- Estimated dermal uptake = (EDL * dermal absorption)/Kg bw
- Estimated oral uptake = (EDL * 50% * 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)	50	50	mg
Oral absorption	35%	100%	%
DA	75%	75%	%
content as	0,5%	2.15%	%
potential exp	0,25	1,08	mg as
absorbed dermal dose	0,1875	0,81	mg as
actual exp dermal toddler	1,88E-02	8,06E-02	mg/kg bw
50% external dermal load	9,38E-03	4,03E-02	mg/kg bw
actual exp oral tod (50% external dermal ingested)	4,38E-03	5,38E-02	mg/kg bw
combined exposure toddler	**1,38E-02**	**9,41E-02**	**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 Cucarachas IGR Plus (Magnum Gel Cucarachas IGR Plus) provides control against cockroaches (Product Type 18).

Magnum Gel Cucarachas IGR Plus is supplied as ready to use gel intended for use by non-professionals applied by using a syringe in drops (two to three drops of bait per site). The bait is placed at the appropriate spots where the ants may be present and close to the ants' nests.

The gel formulation is applied directly on localized spots difficult to access. This precise formulation prevents the formation of splashes making surface contamination unlikely. 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.

Label restrictions to preclude dietary exposure of man.

- The treatment must be restricted to areas out of reach of children.
- The product can not be used on foodstuff or kitchen ware.

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

Label restrictions to preclude 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 produced, stored and/or processed.

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

All efficacy tests information is summarised in the efficacy table, section 2.2.5.5.

3.6 Confidential annex

Confidential annex is in a separate PAR document