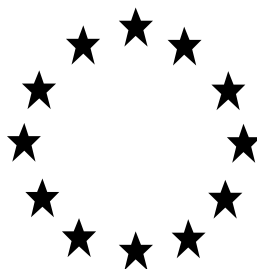


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT FOR THE MAYOR
CHANGE OF A NATIONAL AUTHORISATION**

(submitted by the evaluating Competent Authority)



ECOPRO CUCARACHAS FUSION

Product type 18

IMIDACLOPRID

Case Number in R4BP: BC-TC049470-45

Evaluating Competent Authority: SPAIN

March 2020

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Overview of applications

Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)
NA-APP	ES	BC-HT026276-22	June 2013	Initial assessment
NA-APP	ES	ES-0017700-0000	August 2017	First authorisation
NA-AAT	ES	ES-0017700-0000	February 2018	Modification of authorisation.
NA-AAT	ES	ES-0017700-0000	January 2019	Modification of authorisation.
NA-AAT	ES	ES-0017700-0000	April 2019	Modification of authorisation.
NA-ADC	ES	ES-0017700-0000	March 2019	Additional name.
NA-MAC	ES	BC-TC049470-45	March 2020	Change of composition

ECOPRO CUCARACHAS FUSION was authorised as NA-BBS of MAGNUM GEL CUCARACHAS in August 2017.

The information presented in this report only includes the mayor change submitted by the applicant of ECOPRO CUCARACHAS FUSION. All those sections that have not been modified with respect to the first authorisation for MAGNUM GEL CUCARACHAS are not included in this PAR but they will be refer to the PAR of MAGNUM GEL CUCARACHAS.

The information regarding the application of mayor change (NA-MAC) is found in section 3.7. Addendum and 3.8. Confidential annex.

1 CONCLUSION

MAGNUM GEL CUCARACHAS was authorised in Spain in August 2017. ECOPRO CUCARACHAS FUSION was authorised in Spain in October 2017 according to Implementing Regulation (UE) n° 414/2013 and now a major change has been requested by the applicant. The major change consists in the modification of the co-formulants of the product with the consequent update in other sections from dossier (physic-chemical and stability studies, risk assessment report and efficacy). Moreover, the addition of a new administration device has also been requested.

The assessment presented in this report includes the major change submitted by the applicant according to Implementing Regulation 354/2013 in order to modify the co-formulants and the addition of a new administration device.

Regarding the modification of the co-formulants, EUH 208 "Contains 1,2-Benzisothiazol-3(2H)-one and 2-octyl-1,2-thiazol-3-one. May produce an allergic reaction" has been removed of the labelling of the biocidal products.

New study on determination of the accelerated storage stability and corrosion characteristics has confirmed that ECOPRO CUCARACHAS FUSION is stable in its commercial packaging under the tested accelerated storage conditions.

Interim data for 1 year storage stability and corrosion characteristics are acceptable and therefore a shelf life of 2 years can be granted. The study about four years storage Stability and Corrosion Characteristics is still on-going and will be finished on August 2022 and the final report will be available on December 2022

New efficacy data, laboratory and field trials, have confirmed that ECOPRO CUCARACHAS FUSION is effective in the proposed areas of use, at the recommended dose rate.

Regarding the risk assessment for human health the conclusion from the former assessment remains valid.

Regarding the risk assessment for the environment the conclusion from the former assessment remains valid.

Please refer to the former product assessment report related to MAGNUM GEL CUCARACHAS

The biocidal product contains one substance which is under assessment as endocrine disrupting in the frame of the Community Rolling Action Plan (CoRAP). However, this evaluation has not been finalised yet. If this substance is considered an endocrine disrupting, the assessment for this biocidal product might have to be revised accordingly. Based on the available information the product ECOPRO CUCARACHAS FUSION is not considered to have ED properties.

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)
ECOPRO CUCARACHAS FUSION MAGNUM GEL OPTIMUN MAGNUM GEL NOA	SPAIN

2.1.1.2. Authorisation holder

Name and address of the authorisation holder	Name	MYLVA, S.A..
	Address	Via Augusta, 48 08006 Barcelona Telephone: +34 934 153226 Fax: +34 934156344 E-mail: mylva@mylva.eu
Authorisation number	ES/BB(NA)-2017-18-00469	
Date of the authorisation	27/10/2017	
Expiry date of the authorisation	29/08/2022	

2.1.1.3. Manufacturer of the products

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

2.1.1.4. Manufacturer of the active substance

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

Location of manufacturing sites	D-41538 Dormagen (Germany)
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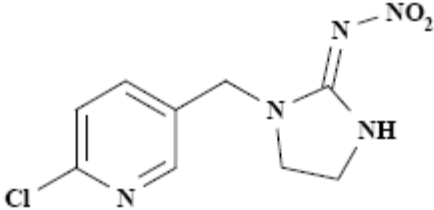
2.1.2 Product composition and formulation

NB: the full composition of the product has been provided in the confidential annex.

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

Yes
 No

2.1.3 Identity of the active substance

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

2.1.4 Candidate for substitution

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Imidacloprid	(2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine	Active substance	138261-41-3	428-040-8	2.15

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
-	-	Non-active substance	-	-	-

2.1.6 Information on technical equivalence

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

2.1.7 Information on the substance(s) of concern


Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

2.1.8 Type of formulation

Gel bait (ready to use, RB)

2.1.9 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Acute 1, Aquatic Chronic 1
Hazard statement	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Hazard pictograms	 GHS09
Signal words	Warning
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. P501 Dispose of contents/containers in accordance with local regulations.

2.1.10 Authorised uses

2.1.10.1. Use description. Table 1

Table 1. Use # 1 – Indoor, crack and crevices.- gel bait applied as drops – professional user.

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

2.1.10.1.1 Use-specific instructions for use.

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

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

Do not use on wood or porous surfaces.

Avoid contact with treated surfaces.

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

2.1.10.1.2 Use-specific risk mitigation measures

Avoid contact with eyes and skin.

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

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

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

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

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

See section 2.1.11.3

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

See section 2.1.11.4.

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

See section 2.1.11.5.

2.1.10.2. Use description. Table 2

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

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

Pack sizes and packaging material	LDPE plastic syringes of 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10g LDPE plastic cartridge of 15, 20, 25, 30, 35, 40 y 50 g.
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2.1.10.2.1 Use-specific instructions for use.

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

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

Do not use on wood or porous surfaces.

Avoid contact with treated surfaces.

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

2.1.10.2.2 Use-specific risk mitigation measures

Wear appropriate gloves during application.

Avoid contact with eyes and skin.

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

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

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

The product will be applied in the food industry in absence of foodstuff except in storerooms where the stored products are kept properly packaged.

Proper measures must be taken in order to ensure that food, equipment or any utensil handled in sites previously treated with the product do not contain residues of the active substance. Use only in concealed areas difficult to access and kept away from water.

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

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

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

See section 2.1.11.3

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

See section 2.1.11.4.

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

See section 2.1.11.5.

2.1.10.3. Use description. Table 3.

Table 3. Use # 3 – Indoor - Gel bait applied as bait stations – professional user.

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

2.1.10.3.1 Use-specific instructions for use

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

General instructions for use in bait stations:

1. Open the bait station: cut the end of the plastic box on the pre-cut line.
2. Activate the bait station: completely push the capsule until the gel has been deposited in the central compartment. Do not separate the capsule after activation.
3. Place the activated bait station at recommended places.

2.1.10.3.2 Use-specific risk mitigation measures

The stations should not be opened or handled.

Never introduce the fingers through the holes in the bait station.
At the end of the treatment campaign, collect bait boxes for disposal.

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

See section 2.1.11.3.

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

See section 2.1.11.4.

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

See section 2.1.11.5.

2.1.10.4. Use description. Table 4.

Table 4. Use # 4 – Indoor - Gel bait applied as bait stations – trained professional user.

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

Category of user	Trained professional
Pack sizes and packaging material	Plastic bait station with 1, 1.2, 1.5, 2, 2.5 g of gel bait.

2.1.10.4.1 Use-specific instructions for use

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

General instructions for use in bait stations:

1. Open the bait station: cut the end of the bait station on the pre-cut line.
2. Activate the bait station: completely push the capsule until the gel has been deposited in the central compartment. Do not separate the capsule after activation.
3. Place the activated bait station at recommended places.

2.1.10.4.2 Use-specific risk mitigation measures

The stations should not be opened or handled.

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

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

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.

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

See section 2.1.11.3.

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

See section 2.1.11.4.

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

See section 2.1.11.5.

2.1.11 General directions for use

2.1.11.1. Instructions for use

Always read the label or leaflet before use and respect all the instructions provided.
Make an inspection before applying the product to check the level of infestation and affected areas.
Use only indoor.

2.1.11.2. Risk mitigation measures

This product should be used in alternation with other products not containing the same a.s. to avoid resistant populations.
Baits should not be placed where food, feeding stuffs or drinking water could be contaminated.
The product should be reapplied when finished only until the pest is controlled.
Use products at recommended doses and intervals.
To optimise the treatment efficacy, respect good hygiene practices: remove or prevent access to all source of food. The bait must be the main source of food available for the cockroaches.
To optimise the efficacy, check the bait once a week and replace/replenish bait if they are damaged or soiled.
Product must be securely applied in a way so as to minimize the risk of consumption by other animals or children.
Do not throw the product on the ground, into a water course, into the sink or down the drain.
Avoid release to the environment (P273).
Use only in concealed areas difficult to access and kept away from water.
At the end of the treatment campaign, collect bait boxes for disposal.
Dispose of unused product, its packaging and all other waste (i.d. dead insects) in accordance with local regulations.

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

Basic First aid procedures:

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

Medical advice for doctors and sanitary staff

- Symptomatic and supportive treatment

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

Emergency measures to protect the environment:

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

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

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

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

The storage stability of this product in its original container is 2 years under normal condition of storage.

Store in the original container.

Keep containers tightly closed in a dry, cool and well-ventilated place.

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

2.1.12 Other information

Definitions:

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

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

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

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

2.1.13 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Syringe	1, 2, 3, 4, 5, 6, 7, 8, 9 and 10g	LDPE	Plastic	Professional Trained professional	Yes
Cartridge	15, 20, 30, 35, 40 y 50 g	LDPE	Plastic	Trained professional	Yes
Bait station	1, 1.2, 1.5, 2 and 2.5 g.	PET	Plastic	Professional Trained professional	Yes

2.1.14 Documentation

2.1.15 Data submitted in relation to product application

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

2.1.16 Access to documentation.

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

The applicant is the same as the Magnum Cockroach Gel, therefore does not need a letter of access for all documents. In any case, all the technical information is found in PAR of MAGNUM GEL CUCARACHAS.

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant.

Table 1. Intended use 1 - Insecticide gel bait by drops - Indoors - Trained professional and professional.

Product Type(s)	PT18
Where relevant, an exact description of the authorised use	Insecticide against cockroaches
Target organism (including development stage)	The insecticide is for controlling the following target insects (nymphs and adults): <ul style="list-style-type: none"> - German cockroach (<i>Blattella germanica</i>) - Oriental cockroach (<i>Periplaneta americana</i>) - American cockroach (<i>Blatta orientalis</i>)
Field of use	Indoor
Application method(s)	Application via droplets by using a syringe and a cartridge.

Application rate(s) and frequency	1-4 gel drops/m ² against <i>Blattella germanica</i> and 2-6 gel drops/m ² against <i>Blatta orientalis</i> and <i>Periplaneta americana</i>
Category(ies) of user(s)	Trained professional Professional
Pack sizes and packaging material	Plastic syringes of 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10g. Plastic cartridge of 15, 20, 30, 35, 40 y 50 g.

Table 2. Intended use 2 - Insecticide gel bait in bait stations - Indoors - Trained professional and professional.

Product Type	18
Where relevant, an exact description of the authorised use	Insecticide to control cockroaches.
Target organism (including development stage)	The insecticide is for controlling the following target insects (nymphs and adults): <ul style="list-style-type: none"> - German cockroach (<i>Blattella germanica</i>) - Oriental cockroach (<i>Periplaneta americana</i>) - American cockroach (<i>Blatta orientalis</i>)
Field of use	Residential and commercial buildings. Indoors
Application method(s)	Ready-to-use bait stations
Application rate(s) and frequency	The recommended application rate is: <ul style="list-style-type: none"> - 2 bait stations per room for <i>low</i> infestations (ca. 5 g/22 m²) - 4 bait stations per room for <i>high</i> infestations (ca. 10 g/22 m²) <p>After about 4 weeks, bait stations should be replenished with fresh ones if the infestation persists.</p> <p>Three months after the infestation's end, treatment may be repeated.</p>
Category(ies) of users	Trained professional. Professional.
Pack sizes and packaging material	Plastic bait station with 1, 1.2, 1.5, 2, 2.5 g of gel bait.

2.2.2 Physical, chemical and technical properties

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

Additional information on the application of mayor change is available in section 3.7. Addendum.

2.2.3 Physical hazards and respective characteristics

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

2.2.4 Methods for detection and identification

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

2.2.5 Efficacy against target organisms

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

Additional information on the application of mayor change is available in section 3.7. Addendum.

2.2.6 Risk assessment for human health

2.2.6.1. Assessment of effects on Human Health

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

Additional information on the application of mayor change is available in section 3.7. Addendum.

2.2.6.2. Exposure assessment

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

2.2.6.3. Risk characterisation for human health

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

2.2.7 Risk assessment for the environment

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

2.2.8 Measures to protect man, animals and the environment

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

2.2.9 Assessment of a combination of biocidal products

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

2.2.10 Comparative assessment

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

3 ANNEXES

3.1 List of studies for the biocidal product

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

3.2 Output tables from exposure assessment tools

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

3.3 Environmental risk assessment (PEC Calculations)

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

3.4 New information on the active substance

No applicable.

3.5 Residue behaviour

Please, refer to the PAR of MAGNUM GEL CUCARACHAS (ES-0008960-0000).

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

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

3.7 Addendum (February 2020)

The studies are owned by MYLVA, S.A. which is the owner of this product. Even so, the applicant has provided the original essays of MYLVA, S.A.

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

The information submitted will be add in each of its corresponding sections.

2.2.2. Physiscal, chemical and technical properties:

Accelerated Storage Stability and Corrosion Characteristics		2.15% w/w Imidacloprid Batch: BCBT2267	
Packaging			Initially: Plastic cartridge "Z" After 14 days at 54°C Plastic cartridges, labelled from "A1" to "A8"
Weight variation (%)	By technical balance		Initially: - After 14 days at 54°C A1: -0.06 %; A2: -0.06 %; A3: -0.06 %; A4: -0.08 %; A5: -0.08 %; A6: -0.02 %; A7: -0.08 %; A8: -0.04 %
Imidacloprid active ingredient content	Study No. 23119 supplied by the Sponsor		Initially: 2.135 ± 0.014 % w/w After 14 days at 54°C 2.108 ± 0.018 % w/w
Appearance (Colour, odour and physical state)	OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304		Initially: Brown gel with characteristic odour After 14 days at 54°C: Brown gel with characteristic odour
Compatibility (resistance) of the packaging material	Visual examination of both external and internal packaging		Initially: - After 14 days at 54°C: The plastic cartridges didn't present loss of sample and evident corrosion phenomena

pH value (1% aqueous dilution)	CIPAC MT 75.3; OECD No. 122		Initially: 6.2± 0,01 After 14 days at 54°C: 6.2±0.004
Viscosity of liquids by rotational viscometry	CIPAC MT 192; OECD No. 114		Initially: Test at 20°C Dynamic viscosity: from 135653.0 cP to 48144.3 cP Shear rate range: from 10.05 to 96.96 sec ⁻¹ Test at 40°C Dynamic viscosity: from 60802.0 cP to 12819.7 cP Shear rate range: from 10.06 to 91.73 sec ⁻¹ After 14 days at 54°C: Test at 20°C Dynamic viscosity: from 116690.0 cP to 44698.9 cP Shear rate range: from 10.06 to 96.96 sec ⁻¹ Test at 40°C Dynamic viscosity: from 50267.1 cP to 12161.7 cP Shear rate range: from 10.06 to 96.97 sec ⁻¹
4 Years storage stability (ambient temperature)		2.18% w/w Imidacloprid Batch: M429	Interim data after 1 year storage at ambient temperature
Packaging			Plastic cartridges, labelled from "B1" to "B6"
Weight variation (%)	By technical balance		B1: -0.04 %; B2: -0.06 %; B3: -0.06 %; B4: -0.06 %; B5: 0.00 %; B6: -0.02 %;

Active Ingredient Content	No. 23119 supplied by the Sponsor		Initially: 2.135 ± 0.014 % w/w After 1 year at ambient temperature: 2.093 ± 0.045 % w/w Difference: -1,97%
Homogeneity of application	PA-U10- METAPPLGEL		Amount of product deposited in form of spots of 5 mm diameter (n = 9) 47.1 mg Amount of product deposited in form of spots of 5 mm diameter (n = 9) 49.3 mg No significant difference
Appearance and stability of the package	OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304		Initially: Brown gel with characteristic odour After 1 year at ambient temperature: Brown gel with characteristic odour
pH of the test item	CIPAC MT 75.3; OECD No. 122		Initially: 6.2 ± 0.01 After 1 year at ambient temperature: 6.3 ± 0.02
Viscosity of liquid by rotational viscometry Temperature : 20°C ± 0.5°C	CIPAC MT 192 (equivalent to OECD 114)		Initially: Test at 20°C Dynamic viscosity: from 135653.0 cP to 48144.3 cP Shear rate range: from 10.05 to 96.96 sec ⁻¹ Test at 40°C Dynamic viscosity: from 60802.0 cP to 12819.7 cP Shear rate range: from 10.06 to 91.73 sec ⁻¹

<p>Compatibility (resistance) of the packaging material</p>	<p>Visual</p>		<p>After 1 year at ambient temperature: Test at 20°C Dynamic viscosity: from 127491.5 cP to 45363.5 cP Shear rate range: from 10.06 to 96.96 sec⁻¹ Test at 40°C Dynamic viscosity: from 60824.2 cP to 13824.4 cP Shear rate range: from 10.06 to 96.97 sec⁻¹</p> <p>The plastic cartridges didn't present loss of sample and evident corrosion phenomena</p>
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Conclusion on the physical, chemical and technical properties of the product

At the time of first authorisation the long term stability study was still on-going. Data for accelerated storage stability, interim data for 1 year storage stability and corrosion characteristics are acceptable and therefore a shelf life of 2 years can be granted.

2.2.5.5. Efficacy data:

DROPS:

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Test substance	Field of use envisaged	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Insecticide	Imidacloprid 2.15 % Gel Bait	Laboratory	<i>Blatta orientalis</i> N: 30 nymphs and 30 adults.	Laboratory bioassay with aged bait. Mortality and palatability.	Choice test arena. 2 replicates and control.	Dose: 0.16 g/m ² Dose: 0.24 g/m ² Palatable bait.	III-B.5.10.5

			<p><i>Blattella germanica</i></p> <p>N: 40 nymphs and 40 adults.</p>	According to TNSG 18-19	High and low dose.	<p>Mean acumulative mortality: >95% in 10 days.</p> <p>Control: 4.17%</p>	
			<p><i>Periplaneta Americana.</i></p> <p>N: 30 nymphs and 30 adults.</p>			<p>Dose: 0.12 g/m²</p> <p>Dose: 0.16 g/m²</p> <p>Palatable bait.</p> <p>Mean acumulative mortality: >95% in 10 days.</p> <p>Control: 2.5%</p>	
			<p><i>Blatta orientalis</i></p>	<p>Laboratory bioassay with aged bait.(4 years)</p> <p>Mortality and palatability.</p> <p>According to TNSG 18-19</p>		<p>Dose: 0.16 g/m²</p> <p>Palatable bait.</p> <p>Mean acumulative mortality: >95% in 9 days.</p> <p>Control: 3.75%</p>	<p>III-B.5.10.5</p> <p>Amendment of the study</p>
	<p>Imidacloprid</p> <p>2.15 % Gel</p> <p>Bait</p>	Laboratory	<p><i>Blattella germanica</i></p>		<p>Choice test arena.</p> <p>2 replicates and control.</p> <p>Low dose.</p>	<p>Dose: 0.12g/m²</p> <p>Palatable bait.</p> <p>Mean acumulative mortality: >95% in 9 days.</p> <p>Control: 2.19%</p>	
			<p><i>Periplaneta americana</i></p>			<p>Dose: 0.16g/m²</p> <p>Palatable bait.</p> <p>Mean acumulative mortality: >95% in 8 days.</p> <p>Control: 3.33%</p>	

Conclusion on the efficacy of the product

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

Although we do not think that two replicates per assay is very appropriate, we consider that the contribution of both, elaborated with the same protocol, gives reliability to the data where it is clearly demonstrated that the product is deadly and palatable.

Efficacy tests have demonstrated that the modification of coformulants does not affect the efficacy and palatability of the product. Taking into account that the change has been only of preservatives and additives, new field trials are not considered necessary.

2.2.6.1. Assessment of effects of the product on human health

Taking into account the modification of the co-formulants, EUH 208 "Contains 1,2-Benzisothiazol-3(2H)-one and 2-octyl-1,2-thiazol-3-one. May produce an allergic reaction" has been removed from the labelling of the biocidal product ECOPRO CUCARACHAS FUSION

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitizer
Justification for the value/conclusion	Based on the classification of the Imidacloprid and the coformulants and, their respective content in the final formulation
Classification of the product according to CLP.	MAGNUM GEL CUCARACHAS is not classified as skin sensitizer.

Data waiving	
Information requirement	Skin sensitisation study
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) N° 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. So this study does not need to be conducted.

Endocrine disrupting properties

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disruption assessment of active substance and co-formulants is mandatory according to the article 19 of BPR.

According to the CAR for imidacloprid, there is no indication for endocrine disrupting properties of the active substance. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the "*Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption*" will need to be performed at the renewal stage.

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), the biocidal product contains one substance which is under assessment as endocrine disrupting in the frame of the Community Rolling Action Plan (CoRAP). However, this evaluation has not been finalised yet. If that substance is identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised. Please refer to the confidential annex for more information. There are no other co-formulants of concern.

Annexes:**3.1 List of studies for the biocidal product.**

IIIB, 3.7.	██████	2019	Title: MAGNUM GEL OPTIMUM: Determination of the Accelerated Storage Stability and Corrosion Characteristics
IIIB, 5.10.5	██████	2018	Title: Laboratory bioassay to determine the efficacy of Magnum Gel Optimum against <i>Blattella germanica</i> , <i>Blatta orientalis</i> and <i>Periplaneta americana</i> . Test Facility: Mylva, S.A
Amendment	██████	2019	Amendment of the study.

