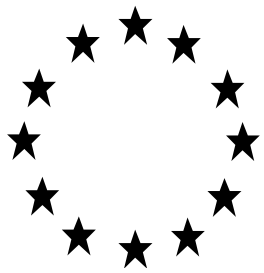
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



VICTOR GEL

Product type 18

IMIDACLOPRID

Case Number in R4BP: BC-UG051421-45

Evaluating Competent Authority: SPAIN

July 2019

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Overview of applications

Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	ES	BC-CQ010606-40	October 2018	Initial assessment
NA-APP	ES	ES-0008725-0000	October 2018	First authorisation
NA-MIC	ES	BC-UG051421-45	-	Post-authorisation condition

1 CONCLUSION

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

The biocidal product is a brown sweet smell gel. The formulation exhibited stability under accelerated storage and storage for 2 years at room temperature. The formulation does not have a corrosive effect and it does not react with the packing material. The formulation is not considered flammable. It is predicted to be neither explosive nor oxidizing. Even so, there may not be hazards associated with the physico-chemical properties of the product under normal conditions of use.

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

VICTOR GEL has demonstrated sufficient efficacy against four species of cockroaches (Blatta orientalis, Blattella germanica, Periplaneta Americana and Supella longipalpa) living in houses and commercial buildings with the method of application by droplets indoors Even so, a new data package should be provided in the renewal of this product, which will be evaluated according to the current guidelines at that time.

No substances of concern has been identified for human health. The risk assessment has been carried out the active substance imidacloprid. The biocidal product only has been classified with EUH208 Contains 1,2-Benzisothiazol-3(2H)-one and 2-octyl-1,2-thiazol-3-one. May produce an allergic reaction.

Based on the risk assessment results, the use of VICTOR GEL 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 professional/non-professional 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 beeen also included. See point 2.2.7. Risk assessment for animal health

Risk assessment for the environment

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

Three different use patterns were considered in the risk assessment based on the intended uses of the product: indoor crack and crevice use (private house plus large buildings), outdoor use applied on sewer covers and outdoor use around private houses (direct releases) and commercial buildings (indirect releases).

Based on the risk assessment, it is unlikely that the indoor and sewer covers intended uses cause any unacceptable risk for the environment if the directions for use according to chapter 2.1.5 and, if applicable, to 2.1.4 are followed. In case of outdoor use of the product VICTOR GEL around private houses and commercial buildings and assuming flooding of the product caused by rain events, an unacceptable risk for surface water, sediment and groundwater from indirect release via STP, as well as an unacceptable risk for groundwater resulting from direct release to the terrestrial compartment is resulting. Risk for groundwater can be excluded due to the refinement of the groundwater assessment performed with FOCUS PEARL simulation. Risks for surface water and sediment cannot be reduced to an acceptable level, thus outdoor use of the product will not be authorised.

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.(indoors and sewer convers by different of users.)

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)
VICTOR GEL	SPAIN

2.1.1.2 Authorisation holder

Name and address of the authorisation holder.	Name	ADAMA AGRICULTURE ESPAÑA, S.A.
	Address	Calle Mendez Álvaro, 20 -5 28045 MADRID Telf: (+34) 91 585 23 80 Web: www.adama.com
Authorisation number	ES/APP(NA)-2018-18-00546	
Date of the authorisation	11/10/2018	
Expiry date of the authorisation	11/10/2023	

2.1.1.3 Manufacturer of the product.

Name of manufacturer	ADAMA Celsius, B.V. Amsterdan.(NL)
Address of manufacturer	ADAMA Group Spitalstrasse, 5 8200 Schaffhausen Switzerland.
Location of manufacturing sites	MYLVA, S.A. San Galderic 23 San Pol de Mar 08395, BARCELONA COMERCIAL QUIMICA MASSÓ, S.A. P.I. San Pere Molanta Avda. del Cadí 7-14 08799 Olerdola (Barcelona)

2.1.1.4 Manufacturer of the active substance

Active substance	Imidacloprid.	
Name of Manufacturer	BAYER CROPSCIENCE ag.	ADAMA AGRICULTURE ESPAÑA, S.A

Address of Manufacturer	16 rue Jean-Marie Leclair 90106 Lyon Cedex France	Calle Mendez Álvaro, 20 -5 28045 MADRID.
Location of manufacturing sites	Industrial Operations Alfred-Nobel-Strabe 50 40789 Monheim (Germany)	Site 1: ADAMA Makhteshim Ltd. Neot-Hovat Eco-Industrial Park.Beer Sheva 84100, Israel Site 2: Jiangsu Yangnong Chemicals Group Co. Ltd 39 Wenfeng Road Yangzhou 225009 China

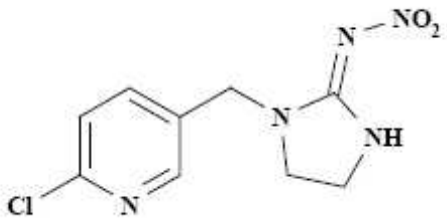
2.1.2 Product composition and formulation

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

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

2.1.2.2 Candidate for substitution

Biocidal product VICTOR GEL 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 VICTOR GEL 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).

VICTOR GEL is an insecticide (PT 18) to be used indoor and sewer covers by differente users to control cockroaches (German cockroaches [Blattella germanica], Oriental cockroaches [Blatta orientalis], American cockroaches [Periplaneta americana], Supella longipalpa). The product has been only compared with alternative products authorised in Spain as the searchable SPCs and a corresponding search tool in the Register for Biocidal Products (R4BP) is currently not available. The Spanish CA has used the information available to the ES CA on the 27th February 2016 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 use for the control of cockroaches: Indoxacarb, nitrogen, abamectin, fipronil and deltamethrin. Abamectin and fipronil are themselves candidates for substitution. Abamectin is only persistent while fipronil and imidacloprid are very persistent. 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 VICTOR GEL, 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 VICTOR GEL. On the other hand, no eligible non-chemical alternatives were identified on the screening phase.

As a general rule at least three different active substances – mode of action combinations should remain available through authorised biocidal product for a given use (indoor and outdoor use by differente users). An inadequate chemical diversity for one user category could lead to resistance occurrence, which might spread afterwards across the target organism population. The Spanish CA has checked whether the chemical diversity of the available active substances/ mode action within the identified alternative biocidal products can be considered adequate to minimise the occurrence of resistance in the target harmful organism (i.e. cockroaches). The Spanish CA concludes that there is not an adequate chemical diversity for products to control cockroaches for indoor and outdoor use by professional and non-professional users. Therefore, the comparative assessment is finalised at the screening phase. The product VICTOR GEL is authorised for a period not exceeding 5 years in accordance with Article 23 (6).

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

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

2.1.2.4 Information on technical equivalence

The notified sources of imidacloprid of ADAMA AGRICULTURE ESPAÑA, S.A are not the sames as that considered for Annex I inclusion under Council Directive 98/8/EC (BAYER CROPSCIENCE AG). However, the ADAMA sources have been granted technically equivalent to the Annex I source by ECHA (Decisión Nº TAP-D-1096667-13-00/F and decision Nº TAP-D-1099666-08-00/F).

Bayer owns the active substance (Annex II) dossier and has provided the applicant (ADAMA AGRICULTURE ESPAÑA, S.A.) with a letter of access to these data and therefore no further consideration is required from a chemistry perspective.

2.1.2.5 Information on the substance of concern

Please see the confidential annex for further details.

Two components of the biocidal product may be present at percentages less than or equal to the relevant concentration limits according to Regulation 1272/2008 to classify the mixture as Skin Sens. 1; H317: (Specific Concentration limit C ≥ 0.05%). Hence, they may be considered as substances of concern as defined in Regulation UE Nº 528/2012.

However, the biocidal product VICTOR GEL is not classified as skin sensitisant according to the study report IIIB B6.3(01), submitted by the applicant and accepted by the CA.

Other co-formulant present in the product carries toxicological hazard classification. However, its concentration in the product does not exceed the limit for classification of the mixture according to Regulation UE Nº 1272/2008 and it is not considered to be a substance of concern.

The three different compounds from the active substance (imidacloprid) are classified as dangerous for the environment. The bittering agent (denatonium benzoate), should not be considered a substance of concern due to the low percentage in which it is present in the biocidal product. The product also contains two preservatives currently in the review program of active substances for PT6 and PT7 (2-octyl-2H-isothiazol-3-one and 1,2-benzisothiazol-3(2H)-one). The data related to these preservatives shall be taken into

account in the evaluation after their approvals at European level, at product's renewal stage.

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

2.1.2.6 Type of formulation

Gel bait (ready to use, RB)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Acuatic Acute 1, Aquatic Chronic 1
Hazard statement	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
Labelling	
	 GHS09
Signal words	Warning
Hazard statements	H410 Very toxic to aquatic life with long lasting effects EUH208 Contains 1,2-Benzisothiazol-3(2H)-one and 2-octyl-1,2-thiazol-3-one. May produce an allergic reaction.
Precautionary statements	P102 Keep out of reach of children. P103 Read label before use. P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of contents/containers in accordance with local regulations.

2.1.4 Authorised uses.

2.1.4.1 Use description. Table 1.

Table 1. Use 1 – Indoor, cracks and crevices - Gel bait applied as drops –General public (non 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. German cockroaches (Blattella germanica) Adults an nymphs Oriental cockroaches (Blatta orientalis). Adults and nymphs. American cockroaches (Periplaneta Americana). Adults and nymphs. Brown-banded cockroaches (Supella longipalpa). Adults.
Field of use	Indoors, crack and crevices.
Application method	Open application of a gel bait applied as a drops from a syringe.
Application rate and frequency	- Dose: 2-6 drops/m^2. Depends on the level of infestation. Frequency of application: Check the bait points every 7-14 days and re-apply if the bait has been consumed and the infestation persist. Do not apply more than four times per bait point during the treatment. Frequency of treatment: Three months after the infestation's end, treatment may be repeated.
Categoryof users	General Public (non-professional users).
Pack sizes and packaging material	LDPE plastic syringes of 3, 5, 10 and 20 g.

2.1.4.1.1 Use-specific instructions for use

Use only indoor. Apply the biocidal product only in crack and crevices, behind furniture and engines. The product can not be used on surfaces. Do not expose bait drops to sunlight or heat source (i.e. radiator). Please contact pest control operators if the infestation persists after treatment.

2.1.4.1.2 Use-specific risk mitigation measures

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

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.4.2 Use description. Table 2.

Table 2. Use 2 – Indoor, cracks and crevices - Gel bait applied as drops, professional user.

Product Type	PT18.
Where relevant, an exact description of the authorised use	Insecticide against cockroaches.
Target organism (including development stage)	Insecticide against the following target insects. German cockroaches (Blattella germanica) Adults and nymphs Oriental cockroaches (Blatta orientalis). Adults and nymphs. American cockroaches (Periplaneta Americana). Adults and nymphs. Brown-banded cockroaches (Supella longipalpa).. Adults.
Field of use	Indoors, craks and crevices.
Application method	Open application of a gel bait applied as a drops from a syringe.
Application rate and frequency	Dose: 2-6 drops/m^2. Depends on the level of infestation. Frequency of application: Check the bait points every 7-14 days and re-apply if the bait has been consumed and the infestation persist. Do not apply more than four times per bait point during the treatment. Frequency of treatment: Three months after the infestation's end, treatment may be repeated.
Category of user	Professionals user
Pack sizes and packaging material	LDPE plastic syringes of 3, 5, 10 and 20 g.

2.1.4.2.1 Use-specific instruction for use.

Use only indoor. Apply the biocidal product only in crack and crevices, behind furniture and engines. The product can not be used on surfaces. Do not expose bait drops to sunlight or heat source (i.e. radiator). Please contact pest control operators if the infestation persists after treatment.

2.1.4.2.2 Use-specific mitigation measures.

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

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5.

2.1.4.3 Use description. Table 3.

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

Product Type	PT18.
Where relevant, an exact description of the authorised use	Insecticide against cockroaches.
Target organism (including development stage)	Insecticide against the following target insects. German cockroaches (Blattella germanica). Adults and nymphs Oriental cockroaches (Blatta orientalis) adults and nymphs) American cockroaches (Periplaneta Americana) Adults and nymphs.

	Brown-banded cockroaches (Supella longipalpa) Adults.
Field of use	Indoors, craks and crevices.
Application method(s)	Open application of a gel bait applied as a drops from a syringe/cartridge.
Application rate(s) and frequency	Dose: depends on the level of infestations and species of cockroaches. (1 drop = 0'04 g). - German cockroaches (Blattella germanica): 0'04-0'16 g/m^2 (1-4 drops/m^2) - Oriental cockroaches (Blatta orientalis): 0'08-0'24 g/m^2 (2-6 drops/m^2) - American cockroaches (Periplaneta Americana): 0'08 g/m^2 -0'24 g/m^2(2-6 drops/m^2) - Brown-banded cockroaches (Supella longipalpa): 0'04-0'16 g/m^2 (1-4 drops/m^2) Frequency of application: Check the bait points every 7-14 days and re-apply if the bait has been consumed and the infestation persist. Do not apply more than four times per bait point during the treatment. Frequency of treatment: Three months after the infestation's end, treatment may be repeated.
Category(ies) of users	Trained professional users.
Pack sizes and packaging material	LDPE plastic syringes of 3, 5, 10 and 20 g. LDPE plastic cartridge of 30 and 35 g.

2.1.4.3.1 Use-specific instruction for use.

Use only indoor.

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

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

2.1.4.3.2 Use-specific mitigation measures.

Do not perform the operation in public places in presence of people and/or pets.

The product will be applied in the food industry in absence of foodstuff except in storerooms where the stored foodsuff 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.

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.

2.1.4.3.3 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 2.1.5.5.

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

See section 2.1.5.5.

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

See section 2.1.5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use.

Make a thorough inspection to determine the infestation level (low or high).

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

Do not use on wood or porous surfaces.

Avoid contact with treated surfaces.

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

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

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

Use products at recommended doses and intervals.

Dangerous for bees.

2.1.5.2 Risk mitigation measures

Do not smoke, eat or drink while you are using the product.

Avoid contact with eyes and skin.

Avoid contact of children with treated surfaces.

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

Do not perform the operation in presence of children and/or pets.

Do not apply directly to surfaces on which food or feed is stored, prepared or eaten.

Do not (use/apply) 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.

The product should be applied so that pets, food, feedstuff and livestock do not come in contact with the product.

Place inaccessible to children, companion animals and non-target animals.

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).

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

First aid Instructions:

- In case of skin contact wash the affected area with plenty of water without scrubbing. If skin irritation/sensitization occurs, persist or intensifies seek medical advice.
- In case of eye exposure; check for and remove contact lenses, wash eyes with plenty of water maintaining eye lids open for at least 15 minutes.
- In case of ingestion wash mouth with plenty of water, do NOT induce vomiting, do NOT give anything by mouth to an unconscious individual. If you experience severe abdominal pain or feel unwell seek medical advice.
- If necessary take the affected individual to a healthcare center and bring packaging or label whenever possible.

NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

- Provide symptomatic and supportive treatment.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PACKAGING OR LABEL AT HAND AND CONTACT YOUR LOCAL POISON CONTROL CENTER [INSERT LOCAL

NUMBER HERE].

Emergency measures to protect the environment

Precautions: Prevent product from entering the environment (surface and ground water), sewerage (expect if the specific field of use are sewer covers), 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.

2.1.5.4 Instructions for safe disposal of the product and its packaging

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

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 2 years under normal condition of storage.

Store in the original container.

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

Avoid direct sunlight.

Keep away from the water, food and animal feeding-stuffs.

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

2.1.6 Other information

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

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

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

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

For trained professionals, wear appropriate gloves during application is recommended.

2.1.7 Packaging of the biocidal product

Type of	Size/volume	Material	Type and	Intended user	Compatibility of

packaging	of the packaging	of the packaging	material of closure(s)	(e.g. professional, non-professional)	the product with the proposed packaging materials (Yes/No)
Syringe	3, 5, 10 and 20 g	LDPE	Plastic	General public Professional Trained professional	Yes
Cartridge	30 and 35 g	LDPE	Plastic	Trained professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

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

2.1.8.2 Access to documentation

The applicant has submitted the following letters of access:

- ✓ a letter of access from Bayer Environmental Science (notifier and having on all the data included in the dossier for Imidacloprid presented by Bayer Environmental Science) to all the documents about the active substance associated to the Annex I listing.
- ✓ a letter of access from CELSIUS PROPERTY, B.V. where they allow to ADAMA AGRICULTURE ESPAÑA, S.A. to register, develop and commercialize any product used by CELSIUS PROPERTY, B.V. and use their studies.

The applicant has not provided any environmental study with the biocidal product. The environmental risk assessment for VICTOR GEL has been done using the Competent Authority Report on the active substance imidacloprid supported by Bayer Environmental Science.

The applicant has provided nine trials against four species of cockroaches to support efficacy and six toxicology studies to support the assessment of the effects in human health of the biocidal product The trials have been elaborated with the product AB-010. This is the generic name of our product and therefore, they have the same composition. Moreover, the sponsor was ADAMA AGRICULTURE ESPAÑA, S.A., so a letter of access to the studies and the composition certificated of product tested have not been necessary.

The applicant has not provided any exposure study with the biocidal product.

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 include in a cartridge/syringe. Indoors and outdoors. Professional users.

Product Type(s)	PT 18
Where relevant, an exact description of the authorised use	VICTOR GEL provides control against cockroaches
Target organism (including development stage)	German cockroaches (Blattella germanica), Oriental cockroaches (Blatta orientalis) and American cockroaches (Periplaneta Americana) and Supella longipalpa. Nimphs and adults
Field of use	Indoors/Outdoors
Application method(s)	VICTOR GEL is applied by using a cartridge with pistol applicator or a syringe in drops of gel
Application rate(s) and frequency	1 to 6 spots (0.04g product each spot)per m^2 Treatment should be repeated until complete control of the swarm
Category(ies) of user(s)	Professional user
Pack sizes and packaging material	Cartridges made of polypropylene with 30 g and 35 g of gel bait Syringes made of polyethylene of low density with 3, 5, 10 and 20 g of gel bait

Table 2. Intended use # 2 – Insecticide. Gel bait included in a cartridge/syringe. Indoors and Outdoors. General public (non-professional users).

Product Type	18
Where relevant, an exact description of the authorised use	VICTOR GEL provides control against cockroaches
Target organism (including development stage)	German cockroaches (Blattella germanica), Oriental cockroaches (Blatta orientalis) and American cockroaches (Periplaneta Americana) and (Supella longipalpa). Nimphs and adults.
Field of use	Indoors/Outdoors
Application method(s)	VICTOR GEL is applied by using a cartridge with pistol applicator or a syringe in drops of gel
Application rate(s) and frequency	1 to 6 spots (0.04g product each spot)per m^2 Treatment should be repeated until complete control of the swarm
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Cartridges made of polypropylene with 30 g and 35 g of gel bait Syringes made of polyethylene of low density with 3, 5, 10 and 20 g of gel bait

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state and nature at 20 °C and 101.3 kPa	Visual inspection	2.23 ± 0.01% w/w Imidacloprid Batch F275.		See confidential annex
Plastic cartridge			Initially: Gel After storage at 54 °C for 14 days: Gel After 1 year at 25°C ± 2°C: Gel After 2 years at 25°C ± 2°C: Gel	
Plastic syringe			Initially: Gel After 1 year at 25°C ± 2°C: Gel After 2 years at 25°C ± 2°C: Gel	
Colour at 20 °C and 101.3 kPa	Visual inspection	2.23 ± 0.01% w/w Imidacloprid Batch F275.		See confidential annex
Plastic cartridge			Initially: 2.5 Y 7/8 (Munsell scale) (Brown) After storage at 54 °C for 14 days: 7.5 Y R 1/2 (Munsell scale) After 1 year at 25°C ± 2°C: 7.5 Y R 1/2 (Munsell scale)	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Plastic syringe			After 2 years at 25°C ± 2°C: 7.5 Y R 1/2 (Munsell scale) Initially: 2.5 Y 7/8 (Munsell scale) (Brown) After 1 year at 25°C ± 2°C: 7.5 Y R 1/2 (Munsell scale) After 2 years at 25°C ± 2°C: 7.5 Y R 1/2 (Munsell scale)	
Odour at 20 °C and 101.3 kPa	Olfactory inspection	2.23 ± 0.01% w/w Imidacloprid Batch F275.		See confidential annex
Plastic cartridge Plastic syringe			Initially: Slightly sweet smell After storage at 54 °C for 14 days: Sweet smell After 1 year at 25°C ± 2°C: Sweet smell After 2 years at 25°C ± 2°C: Sweet smell Initially: Slightly sweet smell After 1 year at 25°C ± 2°C: Sweet smell After 2 years at 25°C ± 2°C: Sweet smell	
Acidity/Alkalinity	CIPAC method MT 75	2.23 ± 0.01% w/w Imidacloprid		See confidential

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Batch F275.		annex
Plastic cartridge Plastic syringe			pH = 6.35 (1% w/v in water) pH = 5.76 Not available	
Relative density/bulk density	EC method A.3	2.23 ± 0.01% w/w Imidacloprid Batch F275.		See confidential annex
Plastic cartridge Plastic syringe			1.2793 ± 0.0008 g/mL Not available	
Storage stability test – accelerated storage (14 days at 54ºC)	CIPAC method MT 46.3	2.23 ± 0.01% w/w Imidacloprid Batch F275.		See confidential annex
<u>Imidacloprid content</u> Plastic cartridge Plastic syringe	HPLC method		The biocidal product is stable at 54 °C for 14 days. <u>Initially:</u> 1.8638% w/w <u>After 14 days at 54°C ± 2°C:</u> 1.8073% w/w Diference: -3.03% Not available	
<u>Homogeneity of application</u> Plastic cartridge Plastic syringe			Not available Not available	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Appearance and stability of the package Plastic cartridge Plastic syringe			Not available Not available	
pH	See Acidity/Alkalinity point	See Acidity/Alkalinity point	See Acidity/Alkalinity point	
Storage stability test – long term storage at ambient temperature	Comparable to GCPF Technical Monograph No. 17		Two studies for the determination of the room storage stability are in progress and will be submitted as soon as they are finalised.	See confidential annex
Active Ingredient Content Plastic cartridge Plastic syringe	HPLC method		Initially: 1.8638% w/w After 1 year at 25°C ± 2°C: 1.8976% w/w Diference: +1.81% After 2 years at 25°C ± 2°C: 1.9083% w/w Diference: +2.39% Initially: 1.9046% w/w After 1 year at 25°C ± 2°C: 1.9038% w/w Diference: -0.04% After 2 years at 25°C ± 2°C: 1.9632% w/w	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Diference: +3.08%	
Homogeneity of application				
Plastic cartridge			Not available	
Plastic syringe			Not available	
Appearance and stability of the package				
Plastic cartridge			Not detected	
Plastic syringe			Not detected	
pH	See Acidity/Alkalinity point	See Acidity/Alkalinity point	See Acidity/Alkalinity point	
Storage stability test – low temperature stability test for liquids	CIPAC method MT 39.3	2.23 ± 0.01% w/w Imidacloprid Batch F275.	The biocidal product is stable at 0 °C for 7 days. No solid or oily material was generated after the storage.	See confidential annex
Effects on content of the active substance and technical characteristics of the biocidal product - light			Not available. The product is stored in the dark.	
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity			Not detected	
Effects on content of the			Not detected	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
active substance and technical characteristics of the biocidal product - reactivity towards container material				
Wettability			Not relevant. Not applicable as the product is a GL	
Suspensibility, spontaneity and dispersion stability			Not relevant. Not applicable as the product is a GL	
Wet sieve analysis and dry sieve test			Not relevant. Not applicable as the product is a GL	
Emulsifiability, re-emulsifiability and emulsion stability			Not relevant. Not applicable as the product is a GL	
Disintegration time			Not relevant. Not applicable as the product is a GL	
Particle size distribution, content of dust/fines, attrition, friability			Not applicable because the biocidal product is not supplied as powder or granules.	
Persistence of foaming			Not relevant. Not applicable as the product is a GL	
Flowability/Pourability/ Dustability			Not relevant. Not applicable as the product is a GL	
Burning rate — smoke generators			Not available	
Burning completeness — smoke generators			Not available	
Composition of smoke — smoke generators			Not available	
Spraying pattern —			Not available	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
aerosols				
Other technical characteristics				
Determination whether a material is liquid or solid	ASTM D 4359 90	2.11 ± 0.02% w/w Imidacloprid Batch E220	Biocidal product is a liquid	See confidential annex
Compatibility with other products			Not applicable since the biocidal product will not be used with other products including other biocidal products.	
Degree of dissolution and dilution stability			Not available	
Surface tension	EC method A.5	2.23 ± 0.01% w/w Imidacloprid Batch F275.	The surface tension cannot be investigated because the solubility of the test substance in water is < 1 mg/mL.	See confidential annex
Viscosity	OECD guideline 114	2.23 ± 0.01% w/w Imidacloprid Batch F275.		See confidential annex
Plastic cartridge			Initially: 1444688.33 mPa s at 20 °C 696671.67 mPa s at 40 °C After storage at 54 °C for 14 days: 1589506 mPa s at 20 °C 711827.33 mPa s at 40 °C After 1 year at 25°C ± 2°C: > 2.000.000 mPa s After 2 years at 25°C ± 2°C: > 2.000.000 mPa s	
Plastic syringe			Not available	

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

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

NOTE:
The applicant has declared that the composition of all batches used in the dossier is the same than the composition to be marketed.

Appearance
The biocidal product is a brown slightly sweet smell gel.

Acidity / Alkalinity
Determination of acidity or alkalinity is not applicable because the pH-value of the biocidal product is between 4 and 10.

Relative density / Bulk density
Determination of the bulk density is not applicable because the biocidal product is not supplied as powder or granules.
Relative density determination has been conduced inserting the liquid in a pycnometer or volumetric flask with known volume up ti flask mark. The density of a liquid is obtained by means of volumetric flask volume and weight of the substance (difference between volumetric flask full or empty).

Storage stability
The accelerated storage study indicates that the variation of the active ingredient content on Victor Gel product after 14 days in the oven was 3.03%. The content did not suffer any modification in its appearance during the storage stability (except in the colour). Also there was no change in the packaging (cartridges).

Furthermore, the biocidal product is stable at 0 °C for 7 days, therefore the phrase “Protect from freezing” has not to be included on the label.

The applicant should submit the final GLP report to evaluate the long term storage stability test (5 years at ambient temperature) in commercial type packagings. Tests are performed with two commercial packages of the formulation (cartridges and syringes, professional and non-professional use).
No effects after 2 years storage at ambient or elevated temperatures so far. The product seems stable for 2 years.

Technical characteristics
Not applicable as the product is a GL. A test conducted under GLP conditions is required for the stage of product authorisation.

According to the CAR, the only technical characteristic appropriate for assessment for Imidacloprid 2.15% Gel, based on its formulation type and use pattern (RTU without dilution) is viscosity.

Other technical characteristics
The test method (ASTM D4359) covers the determination of wheather a viscous material is

a liquid or a solid for regulatory purposes. The gel flowed from the can for > 50 mm in 25", therefore the biocidal product is a liquid.

Surface tension

Previous to the surface tension determination, the aqueous solubility of the substance was determined in order to check if it is necessary to carry out the surface tension test (substances with aqueous solubility lower than 1 mg/L do no need to be tested). In the preliminary assay, the aqueous solubility was lower than 1 mg/L. Therefore, the surface tension determination was not carried out and the justification for non-submission of data for surface tension is accepted.

Viscosity

Viscosity of liquids with range from 0.5 to 2106 mPa*s. is conducting by a rotational viscosimeter. Each viscosity determination include the temperature at which the test was conducted (20ºC and 40ºC), as well as all measurements and the arithmetical mean of such measurements.

Conclusions

The biocidal product Imidacloprid 2.15% Gel is based in the active substance Imidacloprid. Imidacloprid 2.15% Gel is a brown slightly sweet smell gel.
Determination of acidity or alkalinity is not applicable because the pH-value of the biocidal product is between 4 and 10 (pH of 6.35 at 19ºC).
The product has a density of 1.28 g/mL and the viscosity is 1444688.33 mPa s at 20 °C and 696671.67 mPa s at 40 °C.
The data submitted in the storage stability study shows a storage stability of 2 years, so far.
The preparation is not recommended for use with other products.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosive Properties	EC method A.14	2.23 ± 0.01% w/w Imidacloprid Batch F275.	The biocidal product has no explosive properties.	See confidential annex
Oxidising Properties	EC method A.21	2.23 ± 0.01% w/w Imidacloprid Batch F275.	The biocidal product has no oxidising properties.	See confidential annex
Flash point	ISO 3679:2015 procedure B, Setaflash apparatus	2.23 ± 0.01% w/w Imidacloprid Batch F275	The flash point is 69.5°C	See condifential annex
Auto-ignition	EC method	2.23 ± 0.01% w/w	The auto-ignition	See

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	A.15 (ASTM E 659)	Imidacloprid Batch F275	temperature is 416ºC.	confidential annex
Other indications of flammability			The biocidal product does not present flammable properties.	

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.

Explosive Properties
The biocidal product does not present danger of explosion to thermal or mechanical stimuli.

Oxidising Properties
The biocidal product is not to be considered as an oxidiser.

Flash-Point and other indications of flammability or spontaneous ignition
The flash point study carried out by the applicant notes that the value is more than 60ºC (69.5ºC) and therefore auto-flammability study is necessary according to the CLP guideline (the auto ignition temperature has been determined to be 416ºC).

Conclusion
Therefore, the technical properties of the biocidal product indicate that no particular problems are to be expected when it is handled, stored or applied as recommended.

Finally, the physico chemical properties determination was done with retain samples of batch F275. They were used for the determination, both for the sake of coherence and because of practical reasons of availability. These ones were the same samples used for the analytical studies in the original dossier and they were available in the laboratory when the new tests were demanded in a short deadline.
Due to the sample was concluded to be a liquid sample it was requested a flash point test. This test was carried out following the ISO 3679. Determination of flash point – Rapid equilibrium closed cup method (updated March 2015). The result was 69.5°C which means that the product is not flammable as having a flash point higher than 60°C.

Due to the flash point is 69.5ºC, the auto-ignition temperature has been determined according to EU Regulation (EC) 440/2008, Annex Part A test A.15 .

It can be stated that all the results are valid but we consider that in the renewal all physico chemical and technical properties must be done at one stage in order to provide homogeneous and reliable results.

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		
Imidaclorid (a.s.)	HPLC-MS	2.2159 % w/w SD = 0.0344 % w/w RSD = 1.55% n = 5	0.025 to 0.500 mg/L R = 0.9967 n = 7	The specificity is given as a result of selective MS detection. No interferences >3% occurred at the retention time corresponding to imidaclopri d.	Recovery data do not have to be determined because the analytical matrix is a simple solution of preparation in a solvent.			Not determined since the analytical method is only used to check if the active substance content in the biocidal product complies with the respective specification.	See confidential annex
coformulants	-	-	-	-	-	-	-	-	-

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

Analytical methods for soil			
Analyte (type of analyte e.g. active substance)	Analytical method	Limit of quantification (LOQ) or other limits	Reference
Parent compound	LC-MS/MS	0.005 mg/kg	CAR (2011)

(soil)			
Parent compound (soil)	HPLC-UV RP-18 and CN column	0.005 mg/kg	CAR (2011)

Analytical methods for air			
Analyte (type of analyte e.g. active substance)	Analytical method	Limit of quantification (LOQ) or other limits	Reference
Parent compound (air)	HPLC-UV RP-18 column	0.005 mg/m^3	CAR (2011)
Parent compound (air)	HPLC-UV CN column	0.005 mg/m^3	CAR (2011)

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

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Not required since not classified as toxic or highly toxic									CAR (2011)

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		

No relevant residues expected	CAR (2011)

Conclusion on the methods for detection and identificationof the product
A validated analytical method is available for determining the concentration of Imidacloprid in the biocidal product. The applicant has showed that they have access rights to the analytical methods studies contained in the CAR. The LoA has been submitted. Therefore, validated analytical methods are also available for the determination of Imidacloprid in soil, water and air matrices. Other analytical methods are not required

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main Group 03: Pest Control

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

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

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

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

VICTOR GEL is used against small ang big cockroaches (Blattela germanica, Blatta orientalis, Periplaneta Americana and Supella longipalpa).

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

2.2.5.3 Effects on target organisms, including unacceptable suffering

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

2.2.5.4 Mode of action, including time delay

Cockroaches are attracted by some nutritional ingredients that are present in the formulation and spread the gel insecticide by moving and causing poisoning (by contact and ingestion) and the indirect death of the individuals who live in the colony, regardless their stage of development (nymphs, adults).

2.2.5.5 Efficacy data

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	Blatta orientalis	Laboratory bioassay: Mortality and palatability. (gel bait by drops) According to TNsG 18-19	Choice test arena. 4 replicates, control and positive control. Fresh and age bait (2 and 4 years)Dose: 0.20g N:40 adults and 30 nymphs Food sourse: dog food.	Mortality at 21 days: Fresh bait: 98.21% Two years aged bait: 96.79% Four years aged bait: 98.21% Palatable bait (fresh and aged bait).	[redacted] III-B.5.10.6
			Blattela germanica		Non-choice and choice test arena. 3 replicates and control (nymphs and adults). Fresh bait. Dose: 2 drops x 0'1g/petri dish Food sourse: dog food.	Average mortaility on non-choice test of 98'9% nymphs and 86,7% on 30 days. Average mortality on choice test of 91,1% nymphs and 84,4% on 30 days. Palatable bait. N:30 adults and 30 nymphs.	[redacted] III-B.5.10.1
					Choice test arena. replicates, control and positive control. Fresh and age bait (2 and 4 years) Dose: 0.10g N:40 adults and 40 nymphs Food sourse: dog food.	Mortality at 21 days: Fresh bait: 97.38% Two years aged bait: 91.56% Four year aged bait: 93.41% Palatable bait (fresh and aged bait).	[redacted] III-B.5.10.6
				Laboratory bioassay Efficacy residual	Choice test arena. 4 replicates, a negative control and a positive control. Fresh bait. Dose: 0.10g Food sourse: dog food.	Mortality at 21 days: Ceramic tile /7 days: 100% Plaster /7 days: 99.38 % Ceramic tile /15 days: 100% Plaster /15 days: 100 % N:40 adults and 40 nymphs.	[redacted] III-B.5.10.7

			Periplaneta americana	Laboratory bioassay: Mortality and palatability. (gel bait by drops) According to TNsG 18-19	Non choice and choice test arenas. 3 replicates and control (nymphs and adults. Fresh bait.) Dose: 2 drops x 0.1g/petri dish Food source: dog food.	Average on non choice test of 73,3% nymphs and 97,8% adults on 30 days. Average on choice test of 100% nymphs and 95,6% adults on 30 days. Palatable bait. N:15 adults and 15 nymphs.	[redacted] III-B.5.10.1.
					Choice test arenas. replicates, a negative control, a positive control. Fresh and age bait (2 and 4 years) Dose: 0.20g Food source: dog food.	Mortality at 21 days: Fresh bait: 46.25% Two years aged bait: 54.17 % Four years aged bait: 48.75 % Palatable bait (fresh and aged bait). N:30 adults and 30 nymphs.	[redacted] IIIB.5.10.6
				Laboratory bioassay: Efficacy residual	Choice test arenas. 4 replicates, a negative control, a positive control. Fresh bait. Dose: 0.20g Food source: dog food.	Mortality at 21 days: Ceramic tile /7 days: 43.33% Plaster /7 days: 49.17 % Ceramic tile /15 days: 52.92% Plaster /15 days: 48.75 % N:30 adults and 30 nymphs.	[redacted] IIIB.5.10.7
		Field conditions	Blatta orientalis	Indoors	Field trial. Valencia. Medium infestation level. Frequency of application: 1 application between 7-14 days.	Drops applied in cracks and crevices and surfaces. Efficacy: 85% in 5,5 weeks. Dose rate: 0.08-0.24g/m^2	[redacted] IIIB.5.10.4
			Blattela germanica	Indoors	Field trial. Valencia. High infestation level. Frequency of application: 1 application between 7-14 days.	Drops applied in cracks and crevices and surfaces. Efficacy: 92.4% in 5,5 weeks. Dose rate: 0.04-0.16g/m^2	[redacted] IIIB.5.10.2.
				Indoors	Field trial. Alicante. High infestation level. Frequency of application: 1 application between 7-14	Drops applied in cracks and crevices and surfaces. Efficacy: 93.43% in 5 weeks. Dose rate: 0.04-0.16g/m^2	[redacted] IIIB.5.10.3.

					days.		
			Periplaneta americana	Indoors	Field trial. Valencia. High infestation level. Frequency of application: 1 application between 7-14 days.	Drops applied in cracks and crevices and surfaces. Efficacy: 88% in 5,4 weeks. Dose rate: 0.08-0.24g/m^2	[redacted] III-B.5.10.5
				Inner side of sewers covers	Field trial. Alicante. High infestation level. Frequency of application: 1 application between 7-14 days.	Efficacy: 86,7% in 5,8 weeks. Dose rate: 0.08-0.24g/m^2	[redacted] III-B.5.10.9
			Supella longipalpa	Indoors	Field trial. Barcelona. High infestation level. Frequency of application: 1 application between 7-14 days.	Drops applied in cracks and crevices and surfaces. Efficacy: 88,5% in 5,4 weeks. Dose rate: 0.04-0.16g/m^2	[redacted] III-B.5.10.8

Conclusion on the efficacy of the product
The applicant has been submitted nine efficacy trials. Three laboratory trials and six field trials against Periplaneta americana, Blatta orientalis, Supella longipalpa and Blattella germanica. The description off the trials have been summarized in annex 3. Section 3.5. Concusions about efficacy trials. - Blattella germanica: the efficacy trials against this cockroach demonstrate that the product is efficacy according to the TNsG (2008). The laboratory trial (IIIB5.10.1) can not be considered valid since the mortality of cockroaches exceed the percentages of validity. Even so, the applicant has submitted another essay (IIIB5.10.6) who meets the criterion of TNsG (adults an nymphs) for fresh bait. The residual efficacy test (IIIB.5.10.7) clearly demonstrates that the product is effective for adults and nymphs within 15 days of application for both porous and non-porous surfaces. The field tests (IIIB5.10.2 and IIIB.5.10.3) demonstrate that the product is effective according to the instructions for use. - Blatta orientalis: Two trials have been carried out against this cockroaches, one laboratory with fresh and aged bait (IIIB.5.10.6) and another indoor field trial (IIIB.5.10.4).The product has proven to be effective against this specie for both fresh and aged bait.. . - Periplaneta Americana: Five trials have been provided to demonstrate the efficacy of the product against Periplaneta americana. The choice test (III.B.5.10.1) for this specie is considered valid and meets the criteria of the TNsG (2008). After evaluating the tests IIIB5.10.6 and IIIB5.10.7, it has been shown that the efficacy for fresh and aged bait against Periplaneta americana has not been demonstrated and the residual efficacy on both porous and non-porous surfaces has not been demonstrated either. The field trial indoors (IIIB5.10.5) demonstrate that the product is effective according to the instructions for use. The field test in sewers meets a reduction of more than 85% mortality. Even so, the test cannot prove clearly that the population reduction was only caused by the application at the inner side of the sewer covers. Therefore we cannot authorize theintended use in inner side of the sewer covers. - Supella longipalpa: No laboratory tests of this specie have been provided. Only a field trial (IIIB5.10.8) that clearly demonstrates that the product is effective. We consider that the efficacy tests provided for this product against larger cockroaches show that the product is effective. Also, the field test is a worse case against the lack of laboratory tests. Therefore we accept that the product is effective against Supella longipalpa. We can concluded that according to the TNsG (2008) the product VICTOR GEL is effective against Blatella germanica, Blatta orientalis, Periplaneta Americana and Supella longipalpa indoors, applied by droplets at the recommended dose rate of 0.04-0,16 g/m^2 for small species and 0.08-0.24 g/m^2 for large species. No outdoors efficacy tests have been provided, therefore outdoors use is not authorized. There have also been no efficacy test with bait stations/traps so this method of application is not authorized. In face of a renewal new efficacy tests that meet the criteria of the current TNsG will have to be submitted.

2.2.5.6 Occurrence of resistance and resistance management

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

In the final CAR of Imidacloprid, the RMS was aware of the potential for the development of resistance against the a.s. and suggested to further address this issue at product authorisation stage. Imidacloprid belongs to a new class of insecticides, the neonicotinoids that has not been used, previously, for cockroach control in Europe. Neonicotinoids have a different mode of action to other classes of insecticide such as pyrethroids and organophosphates.

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

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

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

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

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

The proposed resistance management strategy includes the following actions:

- The incorporation of a label warning: ‘this product should be used in alternation with other products not containing the same a.s. to avoid resistant populations’.
- The label warning should be included ‘the product should be reapplied when finished only until the pest is controlled’

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

For trained professional only:

- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.)
- Check the efficacy of the product on site: if need be, cause of reduced efficacy must be investigated to ensure that there is no resistance or t identify potential resistance.
- Do not use the product in areas where resistance is suspected or established.
- Inform the authorisation holder if the treatment is ineffective.

2.2.5.7 Known limitations

These known limitations should be followed for the safe use of this biocidal product and therefore they should be incorporated in the product label:

- The product contains a bitter substance that makes it repulsive to people or pets. Do not use on food or utensils. May not be applied on surfaces where food is handled, prepared or served or consumed.
- Avoid contact of children with treated surfaces.
- Do not perform the operation in the presence of children 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 product has proven effective for the following label claims:

- Insecticide for cockroaches control (Blatta orientalis, Blattella germanica, Periplaneta Americana and Supella longipalpa) in cracks and crevices.
- Ready to use gel bait indoors.

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

Not be applied in areas recently treated with another insecticide

2.2.6 Risk assessment for human health

The biocidal product VICTOR GEL against cockroaches is composed of the active substance Imidacloprid (2.15% 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 the biocidal product based on the acute toxicity

results performed with the formulated product for human health effects has been included as part of this submission

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	Species, Strain, Sex, No/group	Test substance, Vehicle, Dose levels, Duration of exposure	Results Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings	Remarks (e.g. major deviations)	Reference
Acute Dermal Irritation / Corrosion Test (Patch Test) of Victor Gel in Rabbits, OECD 404, GLP yes, Reliability 1	Rabbit, Himalayan, ♂, 3 animals	Victor Gel undiluted, 0.5 ml, 4 hr exposure, 72 hr post exposure	no remarkable signs of dermal irritation at any of the observation intervals	None	[redacted] IIIB6.2.1

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Imidacloprid 2.15% Gel is not skin corrosive, not irritant to skin
Justification for the value/conclusion	Based on primary irritation index
Classification of the product according to CLP.	The preparation Imidacloprid 2.15% Gel is is not classified

Eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	Species, Strain, Sex, No/group	Test substance, Dose levels, Duration of exposure	Results Average score (24, 48, 72h)/ observations and time point of onset, reversibility	Remarks (e.g. major deviations)	Reference
Acute Eye Irritation / Corrosion Test of Victor Gel in Rabbits,	Rabbit, Himalayan, ♂, 3 animals	Victor gel undiluted, 0.1 ml, 24 hr exposure, 72 hr post	conjunctival redness of the treated eye (grade 1) in one animal after one hour (reversible). Chemosis, ocular lesions of the iris and opacity of	None	[redacted] IIIB6.2.2

OECD Guideline 405, GLP yes, Reliability 1		exposure	the cornea not observed in any animal.		

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Imidacloprid 2.15% Gel is not irritating to eyes
Justification for the value/conclusion	Based on corneal opacicy, iris, conjunctivae and chemosis effects
Classification of the product according to CLP.	The preparation Imidacloprid 2.15% Gel is not classified

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Based on the classification of the Imidacloprid and the coformulants and, their respective content in the final formulation
Classification of the product according to CLP.	The preparation Imidacloprid 2.15% Gel is not classified as "specific target organ toxicity - single exposure, Category 3 H335

Data waiving	
Information requirement	Respiratory tract irritation data
Justification	No data on respiratory tract irritation is submitted. Furthermore, this data is not required under Biocides Regulation. However, there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation).

Skin sensitization

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	Results	Remarks	Reference
Guinea –pig Maximisation Test (Magnusson and Kligman); OECD 406 EC B.6. (96/54/EEC); GLP Yes, Reliability 1	Guinea pig, Dunkin Hartley, male; animals/ group: 8 pre-test, 10 induced, 5 negative control, 20 positive control	Victor gel; 10% in water intradermal induction; undiluted test item for topical induction and challenge; Induction: Day 0 intradermal induction, Day 7 topical induction (for 48 h) Challenge: Day 21 challenge exposure (for 24 hr); Rechallenge: No	Examinations: Induction and challenge 24 h and 48 h, after patch removal; No response in any animal of treatment group; Positive response in all animals of positive control group (Benzocaine).	None	[redacted] IIIB6.3

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Imidacloprid 2.15% Gel is not skin sensitizer.
Justification for the value/conclusion	Based on no response in any animal of treatment group.
Classification of the product according to CLP.	The preparation Imidacloprid 2.15% Gel is not classified
Remarks: labelling requirements	The label on the packaging shall bear the statement: EUH208 — 'Contains (1,2-benzisothiazol-3(2H)-one and 2-octyl-2H-isothiazol-3-one). May produce an allergic reaction'.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Imidacloprid 2.15% Gel is not respiratory sensitiser
Justification for the value/conclusion	Based on the classification of the Imidacloprid and the coformulants and, their respective content in the final formulation.
Classification of the product according to CLP.	The preparation Imidacloprid 2.15% Gel is not classified

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

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method, Guideline, GLP status, . Reliability	Species, Strain, Sex, No/group	Test substance Dose levelsType of administration (gavage, in diet, other)	Signs of toxicity (nature, onset, duration, severity, reversibility)	Value LD50	Remarks (e.g. major deviations)	Reference
Acute Oral Toxicity Study of Victor Gel in Rats (limit test), OECD- 423, Method B1 bis Commission Regulation (EC) No. 440/2008, GLP Yes, Reliability 1	Rats, CD, Female (nulliparous and non-pregnant, 6 animals	Imidacloprid 2.15% gel, 2000 mg/kg body weight, Oral (gavage),	No deaths, No signs of systemic toxicity, No abnormalities at necropsy	>2000 mg/kg body weight	None	[redacted] IIIB6. 1.1

Value used in the Risk Assessment – Acute oral toxicity	
Value	DL50>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.	The preparation Imidacloprid 2.15% Gel is not classified

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Imidacloprid 2.15% Gel is not harmful by the inhalation route
Justification for the selected value	Based on the classification of the Imidacloprid and the coformulants and, their respective content in the final formulation, as well as the low vapour pressure of the components and te physical state of the product.
Classification of the product according to CLP.	The preparation Imidacloprid 2.15% Gel is not classified

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

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
Acute Dermal Toxicity Study of Victor Gel in Rats (Limit test), OECD No. 402 Method B3 Commission Regulation (EC) No. 440/2008, GLP Yes, Reliability 1	Rat. CD, 5 males and 5 females (nulliparous and non-pregnant)	2000 mg/kg Imidacloprid 2.15% gel undiluted, Occlusive, No vehicle, Approximately 10% of body surface area, 24 hours exposure	no systemic or topical signs of toxicity were noted, no treatment related findings were noted, No abnormalities at necropsy, no deaths	>2000 mg/Kg bw	None	Hafer korn, J. (2007 b), IIIB6. 1.2

Value used in the Risk Assessment – Acute dermal toxicity	
Value	DL50>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	The preparation Imidacloprid 2.15% Gel is not classified

Information on dermal absorption

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	Species, Number of skin samples tested per dose, Other relevant information about the study	Test substance, Doses	Absorption data for each compartment and final absorption value	Remarks	Reference
In-vitro dermal absorption study; OECD 428; EFSA 'Guidance on Dermal Absorption' (EFSA Journal 2012; 10(4):2665); GLP Yes Reliability 1	Human skin 8 samples (breast & abdomen); single dose 8 hours exposure; Samples: Receptor fluid 0-1 h, 1-2 h, followed by 2-h intervals until 24 h post dose; Skin wash tissue swabs: 8 h after application; Tape strips, remaining receptor fluid and washings digested skin at study termination (24 h).	^{14}C-Imidacloprid, 2.32% w/w [Imidazolidine-2-^{14}C] in AB-010 formulation; 8.4 mg/cm²	See table below; Dermal absorption (potentially absorbed dose) is 0.5%	Target amount is 1-5 mg.cm^{-2} skin (not feasible for AB-010 due to high viscosity); Standard deviations are >25%, DA is estimated as mean plus SD (EFSA guidance, p.11)	[redacted] IIIB 6.4

Absorption data for each compartment	Percentage of dose (%, mean ± SD)
Amount in Receptor Fluid	0.14 ± 0.08
Amount in receptor compartment wash	0.00 ± 0.00
Amount in (stripped) skin	0.17 ± 0.10
Amount in tape strips 1+2	0.03 ± 0.01
Amount in tape strips 3-15	0.06 ± 0.02
Amount in skin wash	101.0 ± 4.7
Total recovery	101.4 ± 4.7
Absorbed dose [1]	0.31 ± 0.15
Potentially abosrbed dose [2]	0.37 ± 0.16
Maximal flux (µg/cm^2/h)	0.017 ± 0.012

[1] The absorbed dose is defined as the amount in the receptor fluid, the receptor compartment wash and skin membrane, excluding tape strips.
[2] The potentially absorbed dose is defined as the amount in the receptor fluid, thew

receptor compartment wash, the skin and stratum corneum (except for the first 2 tape strips)

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Victor Gel (2.15% Imidaclorpid)
Value(s)	0.5%
Justification for the selected value(s)	Study report IIIB6.3(01)

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

The formulation contains 2.15% (w/w) of the active substance Imidacloprid and other co-formulants. Two components of the biocidal product may be present at percentages greater than or similar to the relevant concentration limits according to Regulation 1272/2008 to trigger the classification of the mixture as Skin Sens. 1; H317: (Specific Concentration limit C ≥ 0.05% for both substances); they might be considered as substances of concern as defined in Regulation UE Nº 528/2012.

However, the biocidal product is not classified as skin sensitisant, (study report IIIB B6.3), neither for acute toxicity/irritation according to the available studies on the formulation. As the predicted hazard is not confirmed by the formulation test data, then the product is no longer classified for acute toxicity/irritation/sensitisation and there is no need to perform an evaluation of the initial SoC (CA-Nov14-Doc.5.11: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products).

Other co-formulant present in the product carries toxicological hazard classification. However, its concentration in the product does not exceed the limit for classification of the mixture according to Regulation UE Nº 1272/2008 and the biocidal product is not classified with regard to their presence in the product. Hence, this co-formulant is not considered to be a substance of concern.

The conclusion being that there are not substances of concern.

It must be noted that the label on the packaging shall bear the statement: EUH208 — ‘Contains (1,2-benzisothiazol-3(2H)-one and 2-octyl-2H-isothiazol-3-one). May produce an allergic reaction’ as both co-formulants are classified as sensitising and are above the specific limite for elicitation. For products no intended for the general public the label on the packaging shall bear the statement: EUH210 — ‘Safety data sheet available on request’.

The special labelling requirements of Annex II section 2.8 and section 2.10 in Regulation (EC) Nº 286/2011 amending Regulation (EC) Nº 1272/2008 are applicable. For each component the specific concentration limit to protect already sensitised individuals is 0.005% (w/w), (Table 3.4.6, Note 1 of Annex I).

Isothiazolinones are known contact sensitizers. Contact allergy to methylisothiazolinone (MI) in the European population is high and retrospective observational studies of patients with contact allergy to MI have shown that concomitant reactions between MI, octylisothiazolinone (OIT) and benzisothiazolinone (BIT) may exist.

Although immunological cross-reaction between OIT and BIT has not be documented so far, this possibility can not be ruled out.

Available toxicological data relating to a mixture

Not applicable.

Other

No other additional tests relating to exposure of Imidacloprid or the formulated product Imidacloprid 2.15% Gel, other than those outlined in previous data points are considered necessary due to the lack of risk of the different population groups that are exposed as a consequence of the intended uses.

2.2.6.2 Exposure assessment

VICTOR GEL is a ready-to-use product to be applied indoor and inner side of the sewer covers as gel drops.

There are no substances of concern (see Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)).

Relevant exposure routes of VICTOR GEL to humans for gel application are described in the following.

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

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

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

[1] exposure via inhalation route is considered negligible due to the low vapour pressure of the active substance (9E-10 Pa, 25ºC).

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

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

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

Industrial use: Imidacloprid and the biocidal product are produced in the EU. The exposure during the production of the active substance and the formulation of the biocidal product are not assessed by the rapporteur under the requirements of the BPR. However,

the rapporteur assumes that the production is performed in conformity with national and European occupational safety and health regulations.

List of scenarios

Summary table: scenarios			
Scenario number	Scenario	Primary or secondary exposure Description of scenario	Exposed group
1.	Application	Primary exposure: gel application using a cartridge	Trained professional
2.	Post application	Primary exposure: disposal of used cartridge	Trained Professional
3.	Application	Primary exposure: gel application using a syringe	Professional, Non-professional
4.	Post application	Primary exposure: disposal of used syringes	Professional, Non-professional
5.	Post application	Secondary exposure: Removing baits	Bystander (adults)
6.	Post application	Secondary exposure: dermal and hand to mouth contact with gel	Bystander (toddler)

Trained Professional exposure

Scenario 1 Application of VICTOR GEL 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. In the following, the application of gel using cartridge is considered for exposure assessment purposes. Chronic exposure is expected. The product is a ready-to use bait in cartridges 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. The application rate varies according to the crockroach species being treated; the maximum corresponds to 6 drops (0.24 g each) per m^2. According to the CAR the only relevant exposure route of Imidacloprid 2.15% Gel 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. This amount of product is difficult to estimate. In absence of information and

as a worst case, the CA assumes that 20 mg of product is transferred to the hand during opening or sealing the cartridge.		
	Parameters	Value
Tier 1	Amount of product contacted per operation [a]	20 mg product
	number of opening and sealing per day[b]	10
	content of active substance in product	2.15%
	Body weight adult[c]	60 kg
	Dermal absorption absorption[e]	0.5%

[a] According to the CAR a string of gel estimated to be 0.5 cm long is transferred to the hand during opening or sealing the cartridge. To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information (diameter of the nozzle lumen) is not available for the packaging of VICTOR GEL (see Annex 3.2).
[b] CAR.
[c] HEEG Opinion 17.
[d] Study report IIIB B6.3(01)

Calculations for Scenario 1

Summary table: estimated exposure from professional uses					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 1	1/none	-	3.58E-04	-	3.58E-04

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. This amount of product is difficult to estimate. In absence of information and as a worst case, the CA assumes that 20 mg of product is transferred to the hand during this operation.		
	Parameters	Value
Tier 1	Amount of product contacted per operation [a]	20 mg product

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. This amount of product is difficult to estimate. In absence of information and as a worst case, the CA assumes that 20 mg of product is transferred to the hand during this operation.		
	Parameters	Value
	number of disposed cartridges per day[b]	1
	content of active substance in product	2.15%
	Body weight adult[c]	60 kg
	Dermal absorption absorption[d]	0.5%

[a] According to the CAR a string of gel estimated to be 0.5 cm long is transferred to the hand during opening or sealing the cartridge. To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information (diameter of the nozzle lumen) is not available for the packaging of VICTOR GEL (see Annex 3.2).
[b] CAR.
[c] HEEG Opinion 17.
[d] Study report IIIB B6.3(01)

Calculations for Scenario 2
See calculations in Annex 3.2

Summary table: estimated exposure from professional uses (mg/kg bw/d)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 2	1/none	-	3.58E-05	-	3.58E-05

Further information and considerations on scenario 2.
Not applicable.

Combined scenarios

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

Summary table: combined systemic exposure from professional uses (mg/kg bw/d)				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake

Scenarios [1 & 2] /Tier 1	-	3.94E-04	-	3.94E-04

Professionals exposure

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

Non-professional (General public) exposure

Scenario 3. Application of VICTOR GEL by non-professional users

Description of Scenario 3
In the following, the application of the ready-to use bait in syringes for non-professional uses is considered for exposure assessment purposes. The product is a ready-to use bait in syringes for non-professional uses. The gel is applied as round spots or thin lines close to ant harborages, foraging and feeding areas such as corners and cracks and crevices for indoor control of cockroaches. For non-professionals, exposure is estimated using the models and assumptions presented in the original CAR 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 estimation is performed taking into account the quantities that could potentially enter into contact with consumer's hands during opening and sealing the syringe (1 opening and 1 sealing operations per application are assumed).

	Parameters[1]	Value
Tier 1	Amount of product contacted per event [a]	20 mg product
	number of opening and sealing per day[b]	2
	content of active substance in product	2.15%
	Body weight adult[c]	60 kg
	Dermal absorption[d]	0.5%

[a] Packaging specifications for syringes do not include information on the diameter of the nozzle lumen. In a similar way as for professionals, the CA uses 20 mg of gel to estimate the exposure of non-professionals via dermal route (see Annex 3.2).
[b] CAR, adapted for consumer use.
[c] HEEG Opinion 17.
[d] Study report IIIB B6.3(01)

Calculations for Scenario 3

See calculations in Annex 3.2

Summary table: systemic indirect exposure as result of use (mg/ kw bw)

Exposure scenario	Tier / PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 3	1/none	-	7.17E-05	-	7.17E-05

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

Scenario 4 Disposal of used syringe of VICTOR GEL by non-professional users

Description of Scenario 4		
For non-professionals exposure is estimated using the models and assumptions presented in the original CAR adapted to consumer use according to expert judgment. In the following it is assumed as a worst case that a consumer discharges an used syringe 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 syringe (1 operation per application is assumed).		
	Parameters	Value
Tier 1	Amount of product contacted per event [a]	20 mg product
	number of syringes disposed off per day[b]	1
	content of active substance in product	2.15%
	Body weight adult[c]	60 kg
	Dermal absorption[d]	0.5%

[a] Packaging specifications for syringes do not include information on the diameter of the nozzle lumen. In a similar way as for professionals, the CA uses 20 mg of gel to estimate the exposure of non-professionals via dermal route (see Annex 3.2).
[b] CAR, adapted for consumer use.
[c] HEEG Opinion 17.
[d] Study report IIIB B6.3(01)

Calculations for Scenario 4

See calculations in Annex 3.2

Summary table: systemic exposure from non-professional uses (mg/kg bw/d)					
Exposure scenario	Tier / PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 4	1/none	-	3.58E-05	-	3.58E-05

Further information and considerations on scenario [4]

None

Combined scenarios

Total exposure of consumers during the use of VICTOR GEL in syringes is estimated by a combination of scenarios 3 & 4.

Summary table: combined systemic exposure from non-professional uses (mg/kg bw/d)				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios 3 & 4 Tier 1	-	1.08E-04	-	1.08E-04

Indirect (Secondary) Exposure of Bystanders

Indirect exposure scenarios are described in the following

Scenario 5. Adult: Removal of baits

Description of Scenario 5		
This Scenario has been evaluated according to Imidacloprid assessment report. Removal of old baits/gel spots is the task of the trained professional users. Nevertheless it is expected that inhabitants of treated areas may remove bait spots manually after a certain time. This scenario has been identified as foreseeable misuse (TNsG, Human exposure to biocidal products, part 3, page 3) by the RMS. It is not described in any reference document. According to the applicant the maximum dose that is applied is 0.24 g of the biocidal product/m2 (= 6 spots/m2). If a whole apartment of 100 m2 is treated with the biocidal product according to instruction 516 mg imidacloprid is applied. Since the baits are gel and only handled for a very short time it is reasonable to assume a dislodgeable fraction (df) of 1 %. The dermal absorption (da) is expected as 0.5 % and the body weight (bw) of an adult as 60 kg.		
	Parameters	Value
Tier 1	Amount of product contacted per event [a]	240 mg product/m^2
	Content of active substance in product	2.15%
	Dermal absorption [b]	0.5%
	Dislodged fraction [a]	1%
	Adult body weight[c]	60 kg

[a] assumed worst case.
[b] Study report IIIB B6.3(01)
[c] HEEG Opinion 17.

Calculations for Scenario 5

See calculations in Annex 3.2

Summary table: systemic indirect exposure as result of use (mg/ kw bw)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake

Scenario 5	1/none	-	4.30E-04	-	4.30E-04

Further information and considerations on scenario 5

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

Scenario 6. Toddler: dermal contact with VICTOR GEL and hand to mouth transfer after application

Description of Scenario 6
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 (worst case). Secondary exposure can be considered as occasional and of short-term (not continuous) and therefore the exposure is considered as acute. Considering that the product is applied in lines/drops on localized spots (there is not an uniform application on surfaces as paints, for example), the following scenario assumes that a toddler contacts one 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 100% dislodgeablility, 100% oral absorption and 0.5% dermal absorption.

	Parameters	Value
Tier 1	Amount of product contacted per event [a]	40 mg product
	Content of active substance in product	2.15%
	Dermal absorption [b]	0.5%
	Dislodged amount [a]	100%
	Amount of product available for oral intake[c]	50% of external dermal load
	Oral absorption	100%
	Body weight toddler[d]	10 kg

[a] assumed worst case.
[b] Study report IIIB B6.3(01)
[c] ConsExpo Pest product fact sheet RIVM report 320005002 (Crack & Crevice Use – Post Application; pp. 28)
[d] HEEG Opinion 17.

Calculations for Scenario 6
See calculations in Annex 3.2

Summary table: systemic indirect exposure as result of use (mg/ kw bw)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 5	1/none	-	4.30E-04	0.043	0.0434

Further information and considerations on scenario 6

Estimations presented here are 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 VICTOR GEL as a gel application (drops) in hidden places with difficult access such as crack and crevice, exposure may occur accidentally for toddler via dermal contact. Although toddlers can explore their environment and exhibit hand to mouth transfer of residues, it is reasonable to assume that the gel would not be ingested due to the presence of the bittering agent.

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

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.

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

Conclusion

Dietary risk does not have to be further considered.

The following label restrictions preclude food contamination:

- The product can not be applied on surfaces where foodstuff is prepared, consumed or stored.
- The product will be applied in the food industry in absence of foodstuff except in storerooms where foodsuff 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.
- Do not apply on surfaces or utensils wich can be in contact with feed/foodstuff.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	Intended use	Reference values [2]
1.	Plant protection product	Seed, soil, trunk and foliar treatments	MRL[2]

2.	Veterinary use	treatment of domestic pets to control fleas	Withdrawal period n.a.[3]

[1] e.g. plant protection products, veterinary use, food or feed additives
[2] COMMISSION REGULATION (EU) No 491/2014 No agreement on the residue definition during peer review (EFSA Scientific Report (2008) 148, 1-120, Conclusion on the peer review of Imidacloprid)
[3] Product number: EMEA/V/C/000076; n.a. not applicable

Estimating Livestock Exposure to Active Substances used in Biocidal Products

The biocidal product is a gel formulation applied directly on localized spots difficult to access. This precise formulation prevents the formation of splashes making surface contamination unlikely. 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 and/or non-professionals users.

Conclusion

Livestock exposure does not have to be further considered.

The following label restrictions preclude livestock exposure:

- The treatment must be restricted to areas out of reach of animals
- The product can not be applied on surfaces where feedingstuff is prepared, consumed or stored.

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 professional uses is not expected due to the formulation as a gel that prevent surface contamination (e.g. splashes) and the application pattern in localized spots difficult to access.

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

- The product can not be applied on surfaces where food/feedingstuff is prepared, consumed or stored.
- The product will be applied in the food industry in absence of foodstuff except in storerooms where foodsuff 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.

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 non-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 apply on surfaces or utensils wich can be in contact with feed/foodstuff.

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

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

Aggregated exposure

Not applicable.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group	Tier/PPE	Estimated total uptake
1. Application	Trained professional	Tier 1 /none	3.58E-04 mg/kg bw/d
2. Postapplication	Trained professional	Tier 1 /none	3.58E-05 mg/kw bg/d
3. Application	Professional, Non-professional	Tier 1 /none	7.17E-05 mg/kg bw/d
4. Postapplication	Professional, Non-professional	Tier 1 /none	3.58E-05 mg/kg bw/d
5. Indirect exposure	Bystanders (adults)	Tier 1 /none	4.3E-04 mg/kg bw
6. Indirect exposure	Bystanders (toddler)	Tier 1 /none	0.0434 mg/kg bw

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

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

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

For acute, medium-term, and long-term exposure to Imidacloprid, the following systemic Acceptable Exposure Levels (AEL) were derived:
an AEL acute = 0.4 mg/kg bw/d, based on the NOAEL of ca. 40 mg/kg bw from the acute neurotoxicity study in rats and supported by the results from the 28-d oral toxicity study in dogs,
an AEL medium-term = 0.2 mg/kg bw/d, based on the overall NOAEL of ca. 20 mg/kg bw/d established for the rat multigeneration study and supported by the dog 90-d and rabbit developmental studies,
an AEL long-term = 0.06 mg/kg bw/d, based on the NOAEL of ca. 6 mg/kg bw/d obtained in the 2-yr study in rats.
In all cases, standard assessment factors of 100 were applied.
[2] An ARfD and an ADI have not been derived for Imidacloprid used in biocidal products (PT 18). However it should be noted that these values have been set analogously to the acute and long-term AELs above by the WHO JMPR in 2001 and have been confirmed by the RMS during the preparation of the Draft Assessment Report for inclusion of Imidacloprid in Annex I of Dir 91/414/EEC.

Maximum residue limits or equivalent

Residue definition: Imidacloprid.

MRL values: see Commission Regulation (EU) No 491/2014.
See also Regulation (EU) No 485/2013: restriction of the uses of clothianidin, thiamethoxam and imidacloprid, to provide for specific risk mitigation measures for the protection of bees.

Risk for trained professional users

Systemic effects Combined exposure for trained professionals

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AELlong-term mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application/ Scenario 1	1	6	0.06	3.58E-04	0.6	yes
Post application/ Scenario 2	1	6	0.06	3.58E-05	0.06	yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AELlong-term 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	3.94E-04	0.7	yes

Local effects

Not applicable.

Conclusion

The chronic exposure assessment for trained professional users under worst case assumptions yields a potential dermal exposure leading to systemic doses of 3.94E-04

mg/kg bw/day during the application and postapplication processes combined. The estimated uptake represents less than 1% of the proposed AEL of 0.06 mg/kg bw/day.

Assessment indicates an acceptable risk for trained professional users.

No risk is envisaged for the use of VICTOR GEL by trained professional users when no PPE is considered.

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

Systemic effects combined exposure for professionals and non-professionals

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AELmedium-term mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application / Scenario 3	1	20	0.2	7.17E-05	0.04	Yes
post application/ Scenario 4	1	20	0.2	3.58E-05	0.02	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AELmedium-term mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application/ Scenario 3 & Post application/ Scenario 4	1	20	0.2	1.08E-04	0.06	yes

Local effects

Not applicable

Conclusion

The medium term exposure assessment for professionals and non-professional users under worst case assumptions yields a potential dermal exposure leading to systemic doses below 0.1 mg/kg bw/day during the application and postapplication processes combined. The estimated uptake represents less than 1% of the proposed AEL of 0.2 mg/kg bw/day.

Assessment indicates an acceptable risk for professional and non-professional users.
No risk is envisaged for the use of VICTOR GEL by professional and non-professional users.

Risk for indirect (secondary) exposure for bystanders

Systemic effects combined indirect exposure for toddlers

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw	AELshort-term mg/kg	Estimated uptake mg/kg bw	Estimated uptake/ AEL	Acceptable (yes/no)

			bw		(%)	
Dermal for adults removing baits Scenario 5	1	40	0.4	4.3E-04	0.1	Yes
Dermal and hand to mouth contact for toddlers/ Scenario 6	1	40	0.4	0.0434	11	Yes

Combined scenarios secondary exposure

No combined exposure is foreseen.

Local effects

Not applicable.

Conclusion

The short term exposure assessment for adults removing baits under worst case assumptions leads to a systemic dose of 4.3E-04 mg/kg bw during the indirect exposure via dermal route after the application of biocidal product. The estimated uptake represents 0.1% of the proposed AEL short-term of 0.4 mg/kg bw.

The short term exposure assessment for toddlers under worst case assumptions leads to a systemic dose of 0.0434 mg/kg bw during the indirect exposure via oral and dermal route after the application of biocidal product. The estimated uptake represents 11% of the proposed AEL of 0.4 mg/kg bw.

Assessment indicates an acceptable risk for the indirect exposure of adults and toddlers.

Risk for primary and secondary exposure for professional and non-professional users (general public)

Taking into account that, as described in previous sections, general public may be affected by primary (application and disposal) and secondary (removal) exposure, characterization of risk for this situation has been carried out.

In a worst case, professionals and non-professionals are supposed to remove old baits before applying the product, so, AEL medium-term is used to assess the risk .

Systemic effects combined exposure for professionals and non-professionals

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL medium-term mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application / Scenario 3	1	20	0.2	7.17E-05	0.04	Yes
post application/	1	20	0.2	3.58E-05	0.02	Yes

Scenario 4						
Dermal for adults removing baits Scenario 5	1	20	0.2	4.3E-04	0.22	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL médium -term mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application/ Scenario 3 & Post application/ Scenario 4 & Dermal for adults removing baits Scenario 5	1	20	0.2	5.38E-04	0.28	Yes

Based on the risk assessment results, the use of VICTOR GEL as an insecticide is considered safe when taking into account primary and secondary exposure to the biocidal product as a consequence of use.

Risk for consumers via residues in food

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

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

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

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

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

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

No risk is envisaged for consumers via residues in food

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

Not applicable.

2.2.7 Risk assessment for animal health

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

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

The following label restrictions preclude the exposure of animals:

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

In addition:

The following label restrictions preclude feed contamination (professional uses):

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

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

- Do not apply from feedingstuff or feed contact surfaces.

No risk is envisaged for animal health

2.2.8 Risk assessment for the environment

VICTOR GEL is formulated as gel insecticide intended to be used via droplets by using a cartridge/syringe for indoor and outdoor use in targeted areas where cockroaches congregate such as crack and crevices, corners, wall voids, behind stoves, under sinks, and sewer covers. It is against Supella longipalpa, German cockroaches (Blattella germanica), Oriental cockroaches (Blatta orientalis), and American cockroaches (Periplaneta americana). This product is going to be used for private house and private house and/or large buildings.

VICTOR GEL is a gel containing 2.15% of the active substance imidacloprid combined with a number of co-formulants. The Annex I assessment of this active substance, imidacloprid, was supported by two active formulations GR0.5 and GL2.15, contained 0.5 and 2.15% of the active substance, respectively. The biocidal product GL2.15, is a gel; it is a ready-to-use bait for indoor use. This product is used by pest control operators only (trained professional users). The product GR0.5, is a ready-to-use granular bait. It is a bait for ‘indoor use in rural hygiene situations’, that is ‘for use in animal houses and/or other agricultural buildings’, leading to ‘rapid knockdown and mortality of insect’. The product is used by professionals only. VICTOR GEL is the same type of formulation as GL2.15, both are gel, and they have the same concentration of the active substance, imidacloprid, although they have different co-formulants. The co-formulants, in the product, are not at concentrations enough to be triggered as substances of concern, so, the risk assessment arising from the product can be adequately determined based on the assessment of the

active substance, imidacloprid. Product GL2.15 is for indoor use, while VICTOR GEL is intended for indoor and outdoor use. The applicant has calculated the exposure level in each environmental compartment and compared this to the most sensitive PNEC value. The applicant, as it is stated in the imidacloprid CAR, has used the last version of ESD PT18 and the Manual Technical Agreements (MOTA).

The applicant has a letter of access to all data presented by Bayer Environmental Science that supported the original Annex I listing of imidacloprid. No new data have been submitted in support of this application. At Annex I level Bayer Environmental Science was able to demonstrate the safe use of GL2.15 for the emission scenario, gel application, at the same application rate as those being requested for the proposed product here. For the use 'indoor' acceptable risk assessment was performed at Annex I with a bait application rate of 0.3 g of product per point (2.15% imidacloprid). The environmental exposure assessment has been carried out on the basis of the updated emission scenario for PT18, the Emission Scenario Document for Insecticides, Acaricides and Products to control other Arthropods (PT18) for household and professional uses (July 2008), and the Manual Technical Agreements (MOTA), as it is indicated in the Annex I assessment.

2.2.8.1 Effects assessment on the environment

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

The following PNEC values were derived in the Assessment Report of Imidacloprid less the PNEC water which has been reviewed:

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

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

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

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

$PNEC_{secondary\ poisoning}$:

A PNECoral,bird of 4.2 mg/kg food and a PNECoral,mammal of 8.33 mg/kg food was derived. For the assessment of primary poisoning the PNECoral related to dose are 0.31 mg/kg bw/d for birds and 0.66 mg/kg bw/d for mammals.

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

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

Further Ecotoxicological studies

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

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

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

Supervised trials to assess risks to non-target organisms under field conditions

No additional trials to assess risk to non-target organisms have been conducted.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No additional studies on acceptance of ingestion of the biocidal product by non-target organisms have been performed. The biocidal product VICTOR GEL is a insecticide to be used indoors and therefore this study is not required

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant.

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

VICTOR GEL is intended to be applied as spots in areas where cockroaches congregate such as cracks and crevices, corners, wall voids, behind stoves, under skins, sewer covers, and places inaccessible to man and animal. The biocidal product is meant to be applied in- and outdoors in private houses and large buildings. An assessment to consider possible routes of exposure is necessary.

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

Exposure to the receiving environmental compartments such as soil, water and air depends on the physical-chemical properties of the active substance as well as its formulation type, mode of application, use and disposal. For the environmental risk assessment, the relevant compartments for emissions have to be defined and a numerical assessment of the potential residues in each area of importance has to be conducted. The emission scenario document (ESD) for PT18 provided models to calculate emission to the environment and concentration in the receiving compartment at a local scale.

The ESD for PT18 covers the following life-cycle steps as being potentially relevant for the environmental emissions:

- Mixing/loading
- Application
- Releases from indoor treated surfaces by cleaning and outdoor treated surfaces for weathering.

The biocidal product VICTOR GEL is a ready to be use insecticide gel for spot applications in crack and crevices and around buildings. This product is intended to be used in- and outdoors. Due to this kind of formulation and application of this product, the following release pathways can be identified or excluded to be relevant for environmental exposure:

<u>Indoor application</u>

- Mixing/loading:

VICTOR GEL is a ready to use product, thus, emissions from mixing and loading steps are not expected and therefore not assessed.

- Application

A release to air during the application of the product is not expected due to the low vapour pressure of the active substance, imidacloprid ($4x10^{-10}$ at 20ºC). Due to the product form (sealed cartridge), the mode of application, and the characteristics of the active substance (non-volatile), exposure to the applicator is not expected.

All the releases are expected to be emitted from the treated surfaces of the target areas.

- Cleaning step

For the indoor application, removal by wet cleaning is considered to be the mayor route of environmental release. The removal can occur to the applied gel as well as to roach faeces that can be spread on exposed surfaces.

Outdoor application

- Mixing/loading:

VICTOR GEL is a ready to use product, thus, emissions from mixing and loading steps are not expected and therefore not assessed.

- Application

A release to air during the application of the product is not expected due to the low vapour pressure of the active substance, imidacloprid ($4x10^{-10}$ at 20ºC). Due to the product form (sealed cartridge), the mode of application, and the characteristics of the active substance (non-volatile), exposure to the applicator is not expected.

Drop application on sewer covers: This application is intended for the suppression of cockroach populations inhabiting sewer systems. For this use, gel drops are applied on the sewer cover of manholes where cockroaches can emerge from the sewer systems. Furthermore, it is considered that the fraction released during gel application to the environment is 90% ($F_{spot,gel}$ = 0.9), either directly or through ultimate release after target insect death (OECD, 2008). The main compartment potentially being directly exposed to substances applied on sewer covers is the waste water via rain and cleaning water run-off from pavements and streets. Following the release of VICTOR GEL into the STP via waste water and the subsequent waste water treatment in STP, further compartments being exposed to VICTOR GEL are the surface water and sediment.

Drop application on paved surfaces: Considering the application around buildings/houses, applicant recommended to treat with small deposits of gel around terraces, on building entrances such as windows or on wall holes for cockroaches. The gel should be placed in areas where cockroaches congregate, usually inaccessible areas such as cracks and crevices, and should not be placed on porous surfaces. For the purpose of this scenario, it is considered that the gel is applied on paved ground such as terraces, but not on bare soil. It is not a general practice to collect the unconsumed product. Therefore, it is considered that the fraction released during gel application to the environment is 90% ($F_{spot,gel}$= 0.9)), either directly or through ultimate release after target insect death (OECD, 2008). Environmental exposure may arise following flooding from a rain event. These emissions may enter directly into the surrounding soil of the application spot or will be released to a STP system with subsequent indirect release to the environmental compartments surface water, sediment, soil (via sludge application) and groundwater. Releases to STP following the removal of the gel product by rainwater are expected to be low, due to losses during transport from application site to STP. It is more likely that a proportion of wash-off from a treated terrace will enter the soil on the surrounding garden. Hence, the exposure of the surrounding garden soil following wash-off of the terrace by rainfall is considered the relevant scenario for all insecticidal gel products (OECD, 2008) and consequently for the biocidal product VICTOR GEL. Nevertheless, releases to STP are also assessed, considering that outdoor areas of private houses, such as gardens, terraces

and balconies, are not connected to an STP system. Therefore, release to STP is only considered for the use of the biocidal product around commercial buildings

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

Leaching behaviour (ADS)
Not relevant.

Testing for distribution and dissipation in soil (ADS).
Not relevant.

Testing for distribution and dissipation in water and sediment (ADS).
Not relevant.

Testing for distribution and dissipation in air (ADS).
Not relevant.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)
Not relevant.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)
Not relevant.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Crack and crevice application in private houses and/or large buildings (Indoor use). Scenario 2: Outdoor application on sewer covers. Scenario 3: Outdoor application on paved surfaces (direct release). Scenario 4: Outdoor application on paved surfaces (indirect release).
ESD(s) used	Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses.
Approach	A consumption based approach has been used as a suitable protective measure at the local level.

Distribution in the environment	Calculated based on TGD 2003 (alternative: based on measured data)
Groundwater simulation	FOCUS has been used
Confidential Annexes	No
Life cycle steps assessed	Imidacloprid 2.15% Gel is produced in small batches in closed systems with appropriate control measurements in place to exclude release of the active substance to the environment during formulation of the product (the substance is manufactured outside the EU). In addition to this according to the Technical Notes for Guidance on Human Exposure to Biocidal Products (June 2007) processes including the manufacturing of the active substance and the biocidal product are regulated under various other Directives. It is therefore considered acceptable that the exposure during the production/formulation of the insecticide Imidacloprid is not considered here.
Remarks	None.

Emission estimation

Scenario 1

Indoor application:

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

Calculations for Scenario 1

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

According to the applicant the worst scenario is 6 drops (with 0.04 g of product each drop) per m^2 in 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 2.2.11-1: Release of imidacloprid during application (ESD PT18, 2008)

Parameter	Definition	Value	
		Private houses	**Large buildings**
Number of application per day	N_{appl}	1	
Number of point per area	N_{point}	6	
Fraction emitted to treated surfaces during application	F_{appl}	1	
Quantity of commercial product applied per point of gel [g/point]	$Q_{prod, point}$	0.04	
Fraction of active substance in the commercial product	F_{ai}	0.0215	
Area treated with product [m^2]	$AREA_{treated}$	2	9.3
Emission rate to treated surface during application [g/d]	**$E_{application, surface} = Q_{prod, point} \times N_{point} \times F_{ai} \times AREA_{treated} \times F_{appl} \times N_{appl}$**	**0.01032**	**0.04799**

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 VICTOR GEL represents a maximum exposition 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 2.2.11-2: Release of imidacloprid during cleaning (ESD PT18, 2008)

Parameter	Definition	Value	
		Private houses	**Large buildings**
Emission to floor during application step [g/d]	$E_{application, floor}$	0	0
Emission to treated surfaces during application step	$E_{application, surface}$	0.01032	0.04799
Fraction emitted to wastewater during cleaning step	F_{ww}	1	
Cleaning efficiency	F_{CE}	0.03	
Emission rate to wastewater during cleaning step [g/d]	**$Elocal_{ww} = (E_{application, floor} +$**	**3.10E-04**	**1.44E-03**

	$E_{application, surface}$) x F_{ww} x F_{CE}		

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 the interval between applications depends on the level of infestation and is minimum 7-14 days. Therefore, the product application frequency is assumed on a weekly basis. With this application rate, the simultaneity factor is:

$F_{simultaneity}$ = ((9.51 * 14.3) + (17.74 * 3.22) + (32.15 * 1.9) + (37.82 * 0.54))/100 = 2.75%

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

Table 2.2.11-3: Total emissions in wastewater of imidacloprid during cleaning (ESD PT18, 2008)

Parameter	Definition	Value	
		Private houses	Large buildings
Emission from treated surface to wastewater during cleaning step [g/d]	$Elocal_{ww}$	3.10E-04	1.44E-03
Simultaneously treated houses per STP [-]	N_{houses}	4000	300
Simultaneity factor[-]	$F_{simultaneity}$	0.0275	
Emission to wastewater [g/d]	**$Elocal_{ww}$ = $Elocal_{ww}$ x N_{houses} x $F_{simultaneity}$**	**3.41E-02**	**1.19E-02**
Total emission to wastewater [kg/d]	**$E_{ww\ total}$ = ∑(E_{ww})/1000**	**4.59E-05**	

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ($Elocal_{compartment}$) [kg/d]	Remarks
STP	**4.59E-05**	

Scenario 2

Outdoor application (sewer covers)

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario: outdoor application on sewer covers.			
Application rate of biocidal product [alternative: annual tonnage in the EU]	0.04	g/m²	The worst scenario is 6 drops (with 0.04 g of product each drop) per m²

Concentration of active substance in the product	21.5	g/Kg	
Number applications per day	1	-	
Number of point per area	6	-	
Area treated with product	0.29	m^2	

As developed above, VICTOR GEL is intended to be applied on sewer covers for the suppression of cockroach populations inhabiting sewer systems. For this use, gel drops are applied on the sewer cover of manholes where cockroaches can emerge from the sewer systems. Furthermore, it is considered that the fraction released during gel application to the environment is 90% ($F_{spot,gel}$ = 0.9), either directly or through ultimate release after target insect death (OECD, 2008). The main compartment potentially being directly exposed to substances applied on sewer covers is the waste water via rain and cleaning water run-off from pavements and streets. Therefore the main exposed environmental compartments comprise STP and the adjacent surface water and sediments. A new scenario has been developed for this specific use based on the ESD PT18 and the ESD PT14 document

Calculations for Scenario 2

As the worst case scenario, a single application against heavy infestation with Blatta orientalis and Periplaneta americana respectively is assumed, meaning 6 spots with 5.16 mg imidacloprid per m^2 being followed by a run-off from the street. The emission rate of imidacloprid to the treated surface during application was calculated assuming an interior diameter of 0.605 m for a sewer cover (UNE-EN 124) and thus, an area of the sewer cover of 0.29 m^2.

Table 2.2.11-4: Release of imidacloprid from sewer covers during application (ESD PT18, 2008)

Parameter	Definition	Value	
		Private houses	Large buildings
Number of application per day	N_{appl}	1	
Number of point per area	N_{point}	6	
Fraction emitted to treated surfaces during application	F_{appl}	1	
Quantity of commercial product applied per point of gel [g/point]	$Q_{prod,\ point}$	0.04	
Fraction of active substance in the commercial product	F_{ai}	0.0215	
Area treated with product [m^2]	$AREA_{treated}$	0.29	
Emission rate to treated surface during application	$\mathbf{E_{application,\ surface} = Q_{prod,\ point} \times N_{point} \times F_{ai}}$	**0.00148**	

[g / d]	**x $AREA_{treated}$ x F_{appl} x N_{appl}**	

Considering the release into the sewer system, a fraction of 90% is assumed to be released during gel application to the environment ($F_{spot,gel}$ = 0.9), either directly or through ultimate release after target insect death (OECD, 2008). The release to the sewer system is due to rain and cleaning water run-off from pavements or streets. This value is much higher than the set value for outdoors in the ESD-PT18 and it is set as a conservative approach that covers the frequent contact of street drains with water.

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The default value of 300 manholes with sewer covers for a city of 10 000 population equivalents (PE) was used. This value corresponds to the realistic worst case value reported in the PT14 ESD for sewer systems

The worst case to consider in a coordinated treatment would be that all sewers in an specific area receive the treatment the same day, but to our understanding, this would be quite improbable and not the most realistic scenario. In these terms, a coordinated treatment of 5 working days would be reasonable for the treatment of 300 manholes (20% of manholes treated each day of the total 5 working days). Thus, both scenarios are assessed (realistic and worst case).

Table 2.2.11-5:Emission scenario for calculating the release of imidacloprid due to water run-off from pavements and streets

Parameter	Definition	Value
		Sewer cover
Emission to treated surfaces during application [g/d]	$E_{application, surface}$	0.00148
Fraction emitted to soil during outdoor gel application [-]	$F_{spot,gel}$	0.9
Number of manholes connected to an STP	$N_{manholes}$	300
Simultaneity factor [-]	$F_{simultaneity}$	0.2
Total emission to wastewater [g/d] (worst case)	$E_{ww\ total}$ = $E_{application, surface}$ x $F_{spot,gel}$ x $N_{manholes}$ x $F_{simultaneity}$	0.4040
Total emission to wastewater [g/d] (realistic case)	$E_{ww\ total}$ = $E_{application, surface}$ x $F_{spot,gel}$ x $N_{manholes}$ x $F_{correction}$	0.081

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ($Elocal_{compartment}$) [kg/d]	Remarks
STP (worst case)	**4.04E-04**	

STP (Realistic case)	**8.08E-05**	

Scenario 3

Outdoor application on paved surfaces (direct release)

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario: outdoor application on paved surfaces (direct emissions).			
Application rate of biocidal product [alternative: annual tonnage in the EU]	0.04	g/m²	The worst scenario is 6 drops (with 0.04 g of product each drop) per m^2
Concentration of active substance in the product	21.5	g/Kg	
Number applications per day	1	-	
Number of point per area	6	-	
Fraction emitted to soil during outdoor gel application ($F_{spot,gel}$)	0.9	m^2	

As developed above, emissions of imidacloprid to the environment may occur when the biocidal gel is applied in the form of drops around terraces, on building entrances such as windows or on wall holes for cockroaches. Residues can be washed off by rainwater and may reach the adjacent soil. The release to the environment is assessed by the emission scenario described in chapter 3.3.2 and 4.4.5 of OECD ESD No. 18 (2008). The input values for determining direct releases to soil in the course of spot application are summarised in the table above.

Calculations for Scenario 3

In the ESD for PT 18 (OECD, 2008) typical buildings are defined and their dimensions are determined. In the case of outdoor applications of insecticidal gels, only private houses are considered relevant. For private houses, the size of the terrace is assumed to amount to 30 m^2. As size for the garden, the 10^{th} percentile value of the French study cited in the ESD, i.e., 140 m^2 is taken. According to the intended use for VICTOR GEL, 1 to 6 drops per m^2 are recommended; for worst case considerations, 6 drops per m^2 are used for the current risk assessment. Usually, small deposits of gel around terraces, on building entrances such as windows or on wall holes are applied, mainly on wall-floor junctions, where the roaches' nests can be found. Generally, the joint area between terrace and house meets this condition. The current scenario assumes a 30 m^2 quadratic terrace (5m x 6m); one side of the terrace border (6 m) will be adjacent to the house, while the other three borders will be surrounded by soil. Taking into account that the terrace border adjacent to the house measures 6 m, 6 application sites (one application site per m^2 of the house-terrace junction) and six drops each m^2 are thus considered. The assumed soil area for run off considered is 8.5 m^2 (see TAB ENV 121).

Parameter	Definition	Value
		Private house
Amount of product each drop [g]	Q_{prod}	0.04
Fraction of active substance in product [-]	F_{AI}	0.0215
Number of application sites [-]	N_{sites}	6
Number of application [-]	N_{appl}	6
Fraction emitted to soil during outdoor gel application [-]	$F_{spot,gel}$	0.9
Emission rate of the active substance to soil from a campaign [g]	$E_{spot,soil} = Q_{prod} \times F_{AI} \times N_{sites} \times N_{appl} \times F_{spot,gel}$	0.027864

Resulting local emission to relevant environmental compartments		
Compartment	Local emission ($Elocal_{compartment}$) [g]	Remarks
Soil	**2.79E-02**	

Scenario 4

Outdoor application on paved surfaces (indirect release)

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario: outdoor application on paved surfaces (indirect emissions)			
Application rate of biocidal product [alternative: annual tonnage in the EU]	0.04	g/m²	The worst scenario is 6 drops (with 0.04 g of product each drop) per m^2
Concentration of active substance in the product	21.5	g/Kg	
Application rate of the b.p. ($APP_{b.p.}$)	6	Spot/m	
Perimeter treated with the product ($PERIMETER_{Treated}$)	250	m	
Number applications per day	1	d^{-1}	
Fraction emitted to STP during outdoor gel application ($F_{spot,gel}$)	0.9	-	
Number of houses connected to SPT (N_{houses})	300		
Simultaneity factor (F_{sim})	0.0275		

According to ESD PT18 (2008) for outdoor applications of insecticides around commercial buildings, a default perimeter of 250m is proposed with a perirmeter width of 0.5 m. Considering an application rate of 6 drops per meter as a worst-case approach, this leads to 1500 gel spots applied for each commercial building. The ESD PT 18 (2008) indicates that about 90% of the insecticidal products deposists to the treated spot can be released

to the environment, either directly or through ultimate release after target insect death. Thus, the fraction emitted to soil is 90%. According to the summary of intended uses, the interval between applications depends on the level of infestation and is minimum 7-14 days. Therefore the product application frequency is assumed on a weekly basis. With this application pattern, a simultaneity factor of 2.75% is derived (((9.51 * 14.3) + (17.74 * 3.22) + (32.15 * 1.9) + (37.82 * 0.54))/100).
In addition, following the instructions agreed in the Manual of Technical Agreements, Version 5; 2013, it is assumed that the number of larger buildings per STP is 300.

Calculations for Scenario 4

Parameter	Definition	Value
Amount of product each drop [$g.m^{-1}$]	$Q_{b.p}$	0.04
Fraction of active substance in product [-]	F_{AI}	0.0215
Application rate of the b.p. [drops. m^{-1}]	$APP_{b.p}$	6
Perimeter treated with the product [m]	$PERIMETER_{Treated}$	250
Number of application sites $N_{sites} = APP_{b.p} \times PERIMETER_{Treated}$	N_{sites}	1500
Number of application [d^{-1}]	N_{appl}	1
Fraction emitted to STP during outdoor gel application [-]	$F_{spot,gel}$	0.9
Number of houses connected to STP (commercial buildings)	N_{houses}	300
Simultaneity factor	F_{sim}	0.0275

Local direct emission rate to STP per treatment

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

$E_{spot,\ STP} = 1.161\ g.d^{-1}$

Simultaneous emission to waste water during outdoor use:

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

$Elocal_{water,\ sim} = 9.578\ g.d^{-1}$

Fate and distribution in exposed environmental compartments

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

Scenario 3	No	No	No	No	No	No	Yes	Yes	
Scenario 4	Yes	Yes	No	No	Yes	No	Yes	Yes	

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	255.7		
Melting point	144	°C	
Boiling point	Descompositio n	°C	
Vapour pressure (at XC)	<0.1	Pa	
Water solubility (at X°C)	613	mg/l	
Log Octanol/water partition coefficient	0.57	Log 10	
Organic carbon/water partition coefficient (Koc)	230	l/kg	
Henry's Law Constant (at X C)[if measured data available]	$1.7x10^{-10}$	Pa/m3/mol	
Biodegradability	No		
DT_{50} for hydrolysis in surface water	2.75 years at 12 ºC/ pH 9	d or hr (at 12ºC /pH)	
DT_{50} for photolysis in surface water	DT50 calculated: 1.4 - 16 days (fall, winter) 0.5-1.6 days (spring, summer)	d	
DT_{50} for degradation in soil	295 days	d (at 12ºC)	n=4
DT_{50} for degradation in air	2.54	hr	

Calculated fate and distribution in the STP		
Compartment	Percentage %	Remarks
	Scenario 1, 2	
Air	4.9E-10	
Water	97.2	
Sludge	2.79	
Degraded in STP	0	

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	PEC_{water}	PEC_{sed}	$PEC_{seawater}$	PEC_{seased}	PEC_{soil}	PEC_{GW}	PEC_{air}
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg]	[µg/l]	[mg/m^3]
Scenario 1[1]	2.23E-05	2.23E-06	1.29E-05	-	-	1.45E-05	3.38E-03	-

Scenario 2 (worst case)	1.94E-04	1.94E-05	1.12E-04	-	-	1.26E-04	2.95E-02	-
Scenario 2 (realistic case)	3.93E-05	3.93E-06	2.27E-05	-	-	2.55E-05	5.95E-03	-
Scenario 3	-	-	-	-	-	3.86E-03	0.92	-
Scenario 4	4.67E-03	4.66E-04	2.7E-03	-	-	3.03E-03	0.707	-
[1] Refers to total professional emissions i.e. domestic + large buildings summed (worst case)								

PEC_{gw} are above 0.1 µg/l limit value in scenarios 3 and 4, being higher in scenario 3. Therefore, a further refinement for PEC_{gw} is required.

A refinement step, which leads to a more realistic estimation, is the use of a standard assessment tool to examine the potential mobility of imidacloprid in soil and the leaching behaviour to groundwater. A scenario based transport and fate simulation tool is provided by EU FOCUS models (e.g. PELMO and PEARL models). The simulation model FOCUS PEARL 4.4.4 is used for the refinement of PECgroundwater. Calculations have been performed for all FOCUS scenarios by consideration of the input parameters in the table below.

As a worst case assumption, scenario 3 (outdoor terrace scenario) is proposed to be used as mentioned in TAB ENV 121, with a default area of the terrace of 30 m^2, and the conclusion of WG-IV/17 ENV 8-2. Therefore, the application rate of imidacloprid is calculated assuming a number of 16 terraces per hectare. Considering an emission of about 0.029 g s.a. to the soil due to the outdoor use of VICTOR GEL from one treatment of one terrace, and assuming a number of 16 terraces per hectare, the application rate is 0.45 g/ha. According to the indented us of VICTOR GEL, an interval of seven days for four times is proposed as a worst case, and the application of the biocidal product will be repeated after three months with the same interval of seven days for four times. This release is spread evenly trough out the year, starting on 3th January.

Summary of input parameters used for FOCUS PEARL refinement	
Input parameter	Value
Molar mass [$g.mol^{-1}$]	255
Saturated vapour pressure [Pa] at 285 K	2.25E-10
Solubility in water [$mg.L^{-1}$] at 285 K	510.85
Koc [$L.kg^{-1}$]	186.6
Kom (coeff. for sorption on organic matter) [$L.kg^{-1}$]	108.24
Freundlich Sorption Exponent [1/n]	0.9
Half life [d] at 285 K	135
Years of simulation	26 (including 6 yrs “warming-up” period)
Application rate	0.45 g/ha x 4 (interval of seven days for four times)

Application method	To the soil surface
Application time	4 times per year (max): 3rd January, 3rd April, 3rd July, 3rd October
Crop type	Grassland/Winter cereal
Plant uptake factor	0.0

The resulting PECgw (as FOCUS standard output; 80th percentile annual average PECgw at 1 m depth) are shown in the table below. These results show that the predicted groundwater concentrations of imidacloprid following the intended use of the product are <0.1 µg/L for all FOCUS scenarios.

	PECgw, µg/L	
Scenario	Grassland	Winter Cereal
Chateaudun	0.000111	0.000005
Hamburg	0.000800	0.000840
Jokioinen	0.000036	0.000014
Kremsmuenster	0.000292	0.000437
Okehampton	0.000714	0.000898
Piacenza	0.000689	0.000380
Porto	0.000238	0.000179
Sevilla	0.000001	0.000000
Thiva	0.000022	0.000001

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 VICTOR GEL is envisaged. According to the ESD for PT 18 (OECD, 2008), a gel formulation is not a form that could be sufficiently appetent to bird and mammals. In addition, the biocidal product should be applied only in places inaccessible by children and pets so that primary exposure is unlikely. Furthermore, the product contains a bittering agent that should prevent the consumption of the product by animals up in the food chain (vertebrates).A risk assessment for non-target animals primary exposed to imidacloprid is therefore not deemed reasonableEffects on bees:

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	

Imidacloprid was shown to be highly toxic to bees both by oral and contact exposure with LD_{50} of 0.0037 µg per bee and 0.081 µg per bee, respectively (Imidacloprid IIA, 8.3.1.1/01(BAY 158/901384). The product VICTOR GEL is a ready to use gel bait that contains 2.15% w/w of imidacloprid, which is highly toxic to bees. Therefore, the exposure of a honeybee to the product and its mortality after consuming the biocidal product VICTOR GEL cannot be excluded. Consequently, the label should state “Dangerous for bees”. No other RMMs are suggested, as the outdoor use of the product will not be authorised.

Secondary poisoning

During the utilisation of VICTOR GEL, birds and mammals may be poisoned secondarily through the ingestion of contaminated roaches or by the consumption of earthworms from contaminated soils (gel droplet release via wash-off). ESD for PT 18 (OECD, 2008) establishes exposure models for evaluating the risk of secondary poisoning to non-target animals based on existing models including the EU TGD (E.C.2003) and guidance document (SANCO/4145 2002) to the outdoor uses of household insecticide.The “estimated theoretical exposure” (ETE) is used instead of the usual term PEC_{oral} since this scenario was adapted from (SANCO/4145 2002). ETE corresponds to the PEC_{oral} per day.

Secondary poisoning via the consumption of contaminated worms

Mammals and birds may consume contaminated worms from the adjacent soil. Concentrations are derived from the exposure scenario established for plant protection products in the EU (European Commission, 2002). The calculations of the estimated theoretical exposure (ETE) for earthworm-eating mammals and birds were done assuming the standardised worst-case scenario.

Summary table on calculated ETES values for earthworm-eating mammals and birds		
	Mammals	Birds
Estimated theoretical exposure [mg/kg x d]	4.08E-03	3.20E-03

Secondary poisoning for insectivorous species via the consumption of contaminated roaches

For insectivorous species, the estimated theoretical exposure (ETE) is calculated, representing the estimated daily intake and corresponding to the PEC_{oral} per day. The theoretical exposure of vertebrates is a function of the estimated concentration of the insecticide found in food sources (cockroaches) of insectivorous birds and mammals. Concentrations are derived from the exposure scenario established for plant protection products in the EU (European Commission, 2002). The imidacloprid concentration in the fresh diet is assessed for acute and short-term exposure, and the estimated theoretical exposure is calculated for the corresponding indicator species (insectivorous bird) assuming the standardised worst-case scenario.

Summary table on calculated ETES values for indicator species (insectivorous birds)		
	Acute toxicity	Short-term toxicity

ETE – Medium insectivorous bird (blackbird) [mg/kg x d]	6.36E-10	2.32E-10
ETE – Omnivorous bird (magpie) [mg/kg x d]	2.89-10	1.05E-10

Non compartment specific exposure relevant to the food chain

The very low predicted concentrations of imidacloprid in environmental compartments as well as in organisms being food for non-target birds and mammals suggest that a secondary exposure route to man via the food chain is unlikely for this use pattern. There is no need to assess this exposure route further

2.2.8.3 Risk characterisation

Atmosphere

Conclusion:

Imidacloprid has a low vapour pressure (9 x 10^{-10} Pa at 25°C). The Henry's law constant was calculated as 1.7 x 10^{-10} Pa x m^3 x mol^{-1} (25°C) for imidacloprid. In air, imidacloprid will be degraded immediately by indirect photodegradation with an experimental DT_{50} of 57 min (pH 7, 30-50° latitude, calculation).

Therefore, the compound is rapidly degraded by photochemical processes and neither accumulation in the air nor transport over longer distances is to be expected.

A risk assessment for the atmosphere is therefore not considered necessary

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1[1]	2.23E-07
Scenario 2 (worst case)	1.94E-06
Scenario 2 (realistic case)	3.93E-07
Scenario 3	-
Scenario 4	4.67E-05

[1] Refers to total professional emissions i.e. domestic + large buildings summed

Conclusion:

Scenarios 1, 2 and 4: As the PEC/PNEC values are less than 1, an acceptable level of risk to STP is predicted from these scenarios.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{water}$	PEC/PNEC$_{sed}$	PEC/PNEC$_{seawater}$	PEC/PNEC$_{seased}$
Scenario 1 [1]	0.465	0.496	-	-
Scenario 2 (worst case)	4.042	4.308	-	-
Scenario 2 (realistic case)	0.819	0.873	-	-
Scenario 3	-	-	-	-
Scenario 4	97.08	103.84	-	-

[1] Refers to total professional emissions i.e. domestic + large buildings summed

Conclusion:

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

Scenario 2: Worst case scenario shows PEC/PNEC values greater than 1, so unacceptable risk for both surface water and sediment from this scenario is predicted. However, if we applied a realistic scenario in which a coordinated treatment is administered to 300 manholes in 5 working days (20% of manholes treated each day), no unacceptable risks for surface water and sediment are to be expected.

Scenario 4: As the PEC/PNEC values are greater than 1, an unacceptable risk for both the surface water and sediment from indirect release via STP is resulting in case of outdoor use of the product.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1[1]	9.2E-04
Scenario 2 (worst case)	8.0E-03
Scenario 2 (realistic case)	1.62E-03
Scenario 3	0.24
Scenario 4	0.19

[1] Refers to total professional emissions i.e. domestic + large buildings summed

Conclusion:

Scenarios 1, 2, 3 and 4: As the PEC/PNEC values are less than 1, an acceptable level of risk to soil is predicted from these scenarios.

Groundwater

Calculated PEC$_{GW}$ (µg/l)

Scenario 1[1]	3.38E-03
Scenario 2	8.11E-04
Scenario 3	0.92
Scenario 4	0.707

[1]Refers to total professional emissions i.e. domestic + large buildings summed

Conclusion:

Scenarios 1 and 2: As the predicted PEC_{GW} values does not exceed the limit value of 0.1 µg/L from the groundwater directive, an acceptable level of risk to groundwater is predicted from these scenarios.
Scenarios 3 and 4: As the predicted PEC_{GW} values exceed the limit value of 0.1 µg/L from the groundwater directive, an unacceptable risk to groundwater is predicted from these scenarios. Thus, a refinement of the groundwater assessment was performed for scenario 3 (outdoor terrace scenario) as a worst case assumption. Using FOCUS PEARL simulation the following values were determined:

	PECgw, µg/L	
Scenario	Grassland	Winter Cereal
Chateaudun	0.000111	0.000005
Hamburg	0.000800	0.000840
Jokioinen	0.000036	0.000014
Kremsmuenster	0.000292	0.000437
Okehampton	0.000714	0.000898
Piacenza	0.000689	0.000380
Porto	0.000238	0.000179
Sevilla	0.000001	0.000000
Thiva	0.000022	0.000001

All of the 9 representative locations from the FOCUS scenario are clearly below the limit concentration of 0.1 µg/L. Therefore, a risk for the groundwater from the outdoor use of VICTOR GEL can be excluded.

Primary and secondary poisoning

Primary poisoning

No primary poisoning as consequence of the application of VICTOR GEL is envisaged.

Secondary poisoning

Risk quotients for secondary poisoning (worm eating predators).

Risk quotients for secondary poisoning (worm eating predators)			
Compartment	$ETE_{earthworm}$	$PNEC_{earthworm}$ [mg a.s./ kg	PEC/PNEC

	[mg/ kg bw/d]	bw/d]	
Earthworms-eating mammals	4.08E-03	0.66	0.0062
Earthworms-eating birds	3.20E-03	0.31	0.0103

Conclusion:
The assessment reveals ETE/PNEC ratios below 1. Hence, no adverse effects for earthworm-eating predators are to be expected.

Risk quotients for secondary poisoning (Small insectivorous bird species)

For insectivorous species, the estimated theoretical exposure was also calculated. Medium size birds are assumed to prefer large insects, therefore the residue values of 14 and 5.1 mg/kg (acute and short-term exposure, respectively) and the food intake rate per body weight (FIR/bw) of 0.44 were set as the default values for insectivorous birds to cover the worst case.

Risk quotients for secondary poisoning (**small insectivorous bird species)**			
Compartment	ETE [mg / kg bw/d]	$PNEC_{oral,birds}$ [mg a.s./ kg bw/d]	PEC/PNEC
Insectivorous bird - acute toxicity	6.36E-10	0.31	2.05E-09
Insectivorous bird - short-term toxicity	2.32E-10	0.31	7.48E-10

Conclusion:

Neither acute nor short-term expose scenarios reveal risk quotients for secondary poisoning above 1. Hence, no adverse effects for insectivorous bird species are to be expected.

Mixture toxicity

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

Screening step

This product contains the active substance, imidacloprid which produce the biocidal activity in the product, and two preservatives which are both currently in the review program of active substances (2-octyl-2H-isothiazol-3-one (OIT) and 1,2-benzisothiazol-3(2H)-one (BIT)). The product also containg one compound which has the potential to classified as “Substaces of Concern”: denatonium benzoate, classified as C3.

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

Although SoC denatonium benzoate could be considered in the assessment, the overall contribution to the risk of the formulation can be considered negligible, considering that it is present at low levels in the formulation and is significantly less toxic than the PT 18 active substance imidacloprid

Overall conclusion on the risk assessment for the environment of the product
The biocidal product VICTOR GEL contains no substance of concern for the environment. Thus the risk assessment is based on the active substance imidacloprid. An environmental risk assessment was performed for the intended use of the biocidal product as a ready to use gel. Three different use patterns were considered: indoor crack and crevice use, outdoor use applied on sewer covers and outdoor use around private houses (direct releases) and commercial buildings (indirect releases). Based upon the calculated PEC/PNEC ratios, it should be noted that acceptable risks are predicted to all environmental compartments for the proposed indoor crack and crevice uses of this product. For the sewer covers use of the product VICTOR GEL, unacceptable risks for surface water and sediment are expected when the product is applied in a coordinated treatment in which all sewers in an specific area (300 manholes corresponding to ESD-PT14 sewer systems) receive the treatment the same day. To our understanding, this would be the worst case to consider, but not the realistic one. A coordinated treatment of 5 working days would be more reasonable for the treatment of 300 manholes (20% of manholes treated each day of the total 5 working days). When this realistic scenario is applied, no unacceptable risks for surface water and sediment are to be expected. In case of outdoor use of the product VICTOR GEL around private houses and commercial buildings and assuming flooding of the product caused by rain events , an unacceptable risk for surface water, sediment and groundwater from indirect release via STP as well as an unacceptable risk for groundwater resulting from direct release to the terrestrial compartment is resulting. Risk for groundwater can be excluded due to the refinement of the groundwater assessment performed with FOCUS PEARL simulation. Risks for surface water and sediment cannot be reduced to an acceptable level, thus outdoor use of the product will not be authorised. The product VICTOR GEL is a ready to use gel bait that contains 2.15% w/w of imidacloprid, which is highly toxic to bees. Therefore, the exposure of a honeybee to the product and its mortality, after consuming the biocidal product cannot be excluded. Consequently, the label of the product should state “Dangerous for bees”. No other RMMs are suggested, as the outdoor use of the product will not be authorised.

2.2.9 Measures to protect man, animals and the environment

Handling: Avoid contact with eyes and skin

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

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

Trained professional uses:

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

- Do not apply on or near food/feedingstuff, eating utensils or food/feed contact surfaces.

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

Emergency measures to protect the environment:

Precautions: Prevent product from entering the environment (surface and ground water), sewerage, drainage, etc. with the construction of protective barriers and closing drains.

Communicate to the relevant authorities or tipping leaks into waterways, drains, sewers...

Methods and materials for containment and cleaning: Absorb spill on inert material (sand, kaolin ...), collect and place in containers for later properly identified as a hazardous waste management.

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are 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, VICTOR GEL 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 VICTOR GEL 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-CQ010606-40
Evaluating Competent Authority: ES-CA
Applicant: Adama Agriculture España, S.A.
(Prospective) Authorisation holder: Adama Agriculture España, S.A.

2.- Administrative information of the BP/BPF

Trade name(s): VICTOR GEL
Product type(s): 18 (insecticide)
Active substance(s): Imidacloprid (CAS number: 138261-41-3)

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

According to the applicant VICTOR GEL is an insecticide (PT18) which contains the active substance imidacloprid. The product is to be used indoors and outdoors 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)	German cockroaches (Blattella germanica), Oriental cockroaches (Blatta orientalis), American cockroaches (Periplaneta americana), Brown banded cockroaches (Supella longipalpa).
Field(s) of use	Indoor use Outdoor use
Application method(s)	Gel, ready to use product or into bait stations
Category(ies) of users	Professionals/non-professionals and trained professionals

4.- Mapping of existing alternatives to the relevant BP

4.1.- Identified eligible alternative BPs

The product VICTOR GEL 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 2017 of the biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012.

In Spain 25 products PT18 have been authorised. These products are based in ten active substances but only 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 VICTOR GEL, 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 VICTOR GEL.

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 VICTOR GEL is authorised for a period not exceeding 5 years in accordance with Article 23 (6).

3 ANNEXES

3.1 List of studies for the biocidal product.

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
IIIB3.1 / IIIB3.2 / IIIB3.3. / IIIB3.5. / IIIB3.6 / IIIB3.7-1 / IIIB3.10. / IIIB4.1	[redacted]	2013a	Title: Accelerated storage stability study, low temperature storage stability study and physicochemical properties of Victor Gel Roaches AB-010 (gel, professional use, 2.23 ± 0.01% w/w imidacloprid). Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain. Study code: E-13/0006 GLP
IIIB3.1-1	[redacted]	2018	Title: Victor Gel Roaches AB-10. Determination of physical state ASTM D4356 – 90. Test facility: Kollant S.r.l., Via Trieste, 49/53, 35121 Padova (PD), Italy. Study code: K18/0001 GLP
IIIB3.4-1	[redacted]	2018	Title: Physicochemical properties (Flash Point) of Victor Gel Roaches AB-010 (gel, professional use, 2.23 ± 0.01% w/w imidacloprid). Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain. Study code: E-13/0007 GLP
IIIB3.4-2	[redacted]	2019	Title: Auto flammability Testing on a Sample of AB-010 (Victor Gel). Test facility: Chilworth Technology Ltd, Process Safety Laboratories, Phi House, Southampton Science Park, Southampton, SO16 7NS, United Kingdom. Study code: GLP/3016005395 GLP
IIIB3.7-2	[redacted]	2013b-2016	Title: Study plan. Room storage stability study and physicochemical properties of Victor Gel Roaches AB-10 (gel, professional use, 2.23 ± 0.01% w/w imidacloprid).12 months values and 24 months values. Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain Study code: E-13/0007 GLP
IIIB3.7-3	[redacted]	2013c	Title: Study plan. Room storage stability study of Victor Gel Roaches AB-10 (gel, household use, 2.23 ± 0.01% w/w imidacloprid).12 months values. 24 months values Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain Study code: E-13/0008 GLP

IIIB5.10-1	[redacted]	2008	Title: Evaluation of the efficacy of Victor Cockroach Gel against American and German Cockroach under laboratory conditions. Test facility: Agrisearch Service Pty Ltd. 50 Leewood Drive, PO Box 972. Orange. NSW 2800. Australia. Report number: MAANZ/0701-1
IIIB5.10-2	[redacted]	2013a	Title: Determination of the efficacy of AB-010 (IMIDACLOPRID 21.5g/kg) against cockroaches: Blatella germanica (Field trial) in an infested home warehouse (indoor) in Spain. Test facility:GMW Bioscience, SL. Avenida de Valencia, nº 39. 46611 Benimuslem (Valencia. (Spain) Sudy code: 13613-BSTI.S1.
IIIB5.10-3	[redacted]	2013b	Title: Determination of the efficacy of AB-010 (Imidacloprid 21.5g/kg) against cockroaches: Blatella germanica (Field trial) in an infested home warehouse (indoor) in Spain. Test facility:GMW Bioscience, SL. Avenida de Valencia, nº 39. 46611 Benimuslem (Valencia. (Spain) Sudy code: 13613-BSTI.S2.
IIIB5.10-4	[redacted]	2013c	Title: Determination of the efficacy of AB-010 (Imidacloprid 21.5g/kg) against cockroaches: Blatta orientalis (Field trial) in an infested home warehouse (indoor) in Spain. Test facility:GMW Bioscience, SL. Avenida de Valencia, nº 39. 46611 Benimuslem (Valencia. (Spain) Sudy code: 14113-BSTI.S3.
IIIB5.10-5	[redacted]	2013d	Title: Determination of the efficacy of AB-010 (Imidacloprid 21.5g/kg) against cockroaches: Periplaneta americana (Field trial) in an infested home warehouse (indoor) in Spain. Test facility:GMW Bioscience, SL. Avenida de Valencia, nº 39. 46611 Benimuslem (Valencia. (Spain) Sudy code: 14113-BSTI.S1.
IIIB5.10-6	[redacted]	2013a	Title: Efficacy and palatability of the formulation “AB-101 (Imidacloprid 21.5 g/kg)” against cockroaches under extended laboratory conditions. Test facility:TRIALCAMP. Pol. Ind. Les Valletes, C/ Artes gráficas 44, Nave 1ª 46192 Monserrat (Valencia)- Spain. Sudy code: TRC13-001BC GLP
IIIB5.10-7	[redacted]	2013b	Title: Residual efficacy of the formulation “AB-101 (Imidacloprid 21.5 g/kg)” against cockroaches under laboratory conditions. Test facility:TRIALCAMP. Pol. Ind. Les Valletes, C/ Artes gráficas 44, Nave 1ª 46192 Monserrat (Valencia)- Spain. Sudy code: TRC13-003BC
IIIB5.10-8	[redacted]	2013e	Title: Determination of the efficacy of AB-010 (Imidacloprid 21.5g/kg) against brown-banded cockroach: Supella longipalpa (Field trial) in an infested home warehouse (indoor) in Spain.

			Test facility:GMW Bioscience, SL. Avenida de Valencia, nº 39. 46611 Benimuslem (Valencia. (Spain) Sudy code: 13613-BSTI.S6.
IIIB5.10-9	[redacted]	2013f	Title: Determination of the efficacy of AB-010 (Imidacloprid 21.5g/kg) against cockroaches Periplaneta Americana (Field trial) in an infested sewers (outdoors) in Spain. Test facility:GMW Bioscience, SL. Avenida de Valencia, nº 39. 46611 Benimuslem (Valencia. (Spain) Sudy code: 13613-BSTI.S5.
IIIB6.1-1	[redacted]	2007a	Title: Acute Oral Toxicity Study of Victor Gel in Rats. Test facility: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG. Redderweg 8. 21147 Hamburg. Germany. LPT Report Nº: 21672 GLP
IIIB6.1-2	[redacted]	2007b	Title: Acute Dermal Toxicity Study of Victor Gel in Rats. Test facility: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG. Redderweg 8. 21147 Hamburg. Germany. LPT Report Nº: 21673 GLP
IIIB6.2-1 (01)	[redacted]	2007a	Title: Acute Dermal Irritation/Corrosion Test (Patch Test) of Victor Gel in rabbits. Test facility: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG. Redderweg 8. 21147 Hamburg. Germany. LPT Report Nº: 21674 GLP
IIIB6.2-2 (01)	[redacted]	2007b	Title: Acute Eye Irritation/Corrosion Test of Victor Gel in rabbits. Test facility: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG. Redderweg 8. 21147 Hamburg. Germany. LPT Report Nº: 21675 GLP
IIIB6.3-1	[redacted]	2007c	Title: Examination of Victor Gel in the Skin Sensitisation Test in Guinea Pigs according to Magnusson and Kligman (Maximisation Test). Test facility: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG. Redderweg 8. 21147 Hamburg. Germany LPT respor Nº: 21676 GLP
IIIB6.4	[redacted]	2013	Title: In vitro percutaneous absorption of Imidacloprid formulated as AB-010 through human skin. Test facility: TNO Triskelion. Utrechtseweg 48 3704 HE Zeist P.O. Box 844 3700 AV Zeist. The Netherlands Study code: V20330/25

			GLP
IIIB8.1	Anonymous	2014	MSDS of VICTOR GEL (2.15% of Imidacloprid) Sheet facility: ARAGONESAS AGRO, S.A.; Paseo Recoletos No. 16, 2 y 3ª planta, 28001, Madrid
IIIB8.2	Anonymous	2014	MSDS of AQUILES CUCARACHAS (2.15% of Imidacloprid) Sheet facility: Adama Agriculture España, S.A.; Calle Méndez Álvaro, 20, 5ª planta, 28045, Madrid
IIIB8.3	Anonymous	2013	MSDS of Imidacloprid Technical (97.5% of Imidacloprid) Sheet facility: Makhteshim Chemical Works Ltd.; PO Box 60; Beer Sheva 84100 Israel
IIIB8.4	Anonymous	2012	MSDS of NEOSORB® 70/70 B – SORBITOL Sheet facility: ROQUETTE FRERES; 1 Rue de la Haute Loge; 62136 LESTREM - France
IIIB8.5	Anonymous	2018	MSDS of LYCASIN® 85/55 - MALTITOL SYRUP Sheet facility: ROQUETTE FRERES; 1 Rue de la Haute Loge; 62136 LESTREM - France
IIIB8.6	Anonymous	2017	MSDS of ACTICIDE OTW Sheet facility: Thor Especialidades S.A.; Poligono Industrial EL PLA; Avenida de la Industria, 1; 08297 CASTELLGALI; Barcelona - España
IIIB8.7	Anonymous	2016	MSDS of ACTICIDE B 20 Sheet facility: Thor Especialidades S.A.; Poligono Industrial EL PLA; Avenida de la Industria, 1; 08297 CASTELLGALI; Barcelona - España
IIIB8.8	Anonymous	2017	MSDS of Glicerol Sheet facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS -MADRID
IIIB8.9	Anonymous	2008	MSDS of Sweet Whey Powder Valformoso Sheet facility: INSULAC - Produtos Lácteos Açoreanos, S.A.; Address: Caminho da Mafoma – Ribeira Seca; 9600-211 Ribeira Grande; S. Miguel – Açores
IIIB8.10	Anonymous	2015	MSDS of Phytagel™ Sheet facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS -MADRID
IIIB8.11	Anonymous	2015	MSDS of Aceite de Girasol Sheet facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS -MADRID
IIIB8.12	Anonymous	2015	MSDS of Corn oil Sheet facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS -MADRID
IIIB8.13	Anonymous	2015	MSDS of Soybean oil Sheet facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS -MADRID
IIIB8.14	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
IIIB8.15	Anonymous	2016	MSDS of Benzoato de denatonio Sheet facility: Sigma-Aldrich Quimica, S.L.; Ronda de Poniente, 3; Aptdo.Correos 278; E-28760 TRES CANTOS -MADRID

IIIB8.16	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; Provincia: Barcelona
	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 riskassessment 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.

3.2 Output tables from exposure assessment tools

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

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

[1] exposure via inhalation route is considered negligible due to the low vapour pressure of the active substance (9E-10 Pa, 25ºC).

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

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

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

List of scenarios

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

Trained professional exposure

Scenario 1 Application of VICTOR GEL by trained professional users

The product is a ready-to use bait in cartridges 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. The application rate varies according to the crockroach species being treated; the maximum corresponds to 6 drops (0.04 g each) per m^2.

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

According to the CAR the only relevant exposure route of Imidacloprid 2.15% Gel 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 these activities.

The CAR considers that a string of gel 0.5 cm long is transferred to the hand during opening or sealing the cartridge. To calculate the amount of biocidal product transferred, the CAR assumes that the inner diameter of the "gage needle" is 1 mm [1] . The CAR then estimates that 5mg of biocidal product contacts operator's hand per operation.

However, this information (diameter of the nozzle lumen) is not available for the packaging of VICTOR GEL for professional uses. Hence, the CA can not perform the same estimation. Considering that the amount of product in a drop of gel of VICTOR GEL is 40 mg weight approximately (Storage Stability Studies test, Section Nº IIIB3.7 & Efficacy of the active substance tests. Section No. IIIB.5.10.2, 3, 4 and 5), the CA assumes as a worst case that hands are contaminated with 20mg of gel each time that the operator opens or closes the cartridge.

	Parameters	Value
Tier 1	Amount of product contacted per operation [a]	20 mg product
	number of opening and sealing per day[b]	10
	content of active substance in product	2.15%
	Body weight adult[c]	60 kg
	Dermal absorption absorption[e]	0.5%

[a] Assumed: one drop of gel weighs 40 mg.
[b] CAR.
[c] HEEG Opinion 17.
[d] Study report IIIB B6.3(01)

Calculations for Scenario 1

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

1 The term 'gauge needle' or 'gage needle' is used to describe the outer diameter of the hypodermic needles, which are available in a wide variety described by gauge numbers. The CA uses 'nozzle' and 'nozzle lumen' to name the tip of a syringe/cartridge and its inner diameter, respectively.

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

Estimated dermal uptake Tier 1= [10 * 20 mg * 2.15% * 0.5%]/ 60 kg

Scenario 1: application of VICTOR GEL against cockroaches by professionals		Estimated Internal Exposure as [mg /kg bw/d]			
		Oral uptake	Inhalation uptake	Dermal uptake	Total uptake
Tier 1	(no PPE)	-	-	3.58E-04	3.58E-04

Scenario 2 Disposal of used cartridges by trained professional users

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

Chronic exposure is expected.

According to the CAR the only relevant exposure route of Imidacloprid 2.15% Gel 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 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 this activity.

The CAR considers that a string of gel 0.5 cm long is transferred to the hand during opening or sealing the cartridge. To calculate the amount of biocidal product transferred, the CAR assumes that the inner diameter of the "gage needle" is 1 mm [2]. The CAR then assumes that 5mg of biocidal product contacts operator's hand per operation.

However, this information (diameter of the nozzle lumen) is not available for the packaging of VICTOR GEL for professional uses. Hence, the CA can not perform the same estimation. Considering that the amount of product in a drop of gel of VICTOR GEL is 40 mg weight approximately, the CA assumes as a worst case that hands are contaminated with 20mg of gel during disposal of used cartridges. (See explanations in Scenario 1 above).

	Parameters	Value
Tier 1	Amount of product contacted per operation [a]	20 mg product
	number of disposed cartridges per day[b]	1
	content of active substance in product	2.15%
	Body weight adult[c]	60 kg
	Dermal absorption absorption[d]	0.5%

[a] Assumed:one drop of gel weighs 40 mg.
[b] CAR.
[c] HEEG Opinion 17.

[2] The term 'gauge needle' or 'gage needle' is used to describe the outer diameter of the hypodermic needles, which are available in a wide variety described by gauge numbers. The CA uses 'nozzle' and 'nozzle lumen' to name the tip of a syringe/cartridge and its inner diameter, respectively.

[d] Study report IIIB B6.3(01)

Calculations for Scenario [2]

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

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

Estimated dermal uptake Tier 1= [1 * 20 mg * 2.15% * 0.5%]/ 60 kg

Scenario 2: post application of VICTOR GEL against cockroaches by professionals		Estimated Internal Exposure as [mg /kg bw/d]			
		Oral uptake	Inhalation uptake	Dermal uptake	Total uptake
Tier 1	(no PPE)			3.58E-05	3.58E-05

Combined scenarios

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

Summary table: combined systemic exposure from trained professional uses (mg/kg bw/d)				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios 1 & 2 /Tier 1	-	3.94E-04	-	3.94E-04

Professional and Non-professional (general public) 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.

Scenario 3: Application of VICTOR GEL by professional and non-professional users

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

For professionals and non-professionals exposure is estimated using the models and assumptions presented in the original CAR adapted to consumer use according to expert judgment.

In the following, it is assumed as a worst case that these users apply the product every two weeks during 6 months per year (cockroaches are expected during spring and summer). Medium term exposure is expected.

The only relevant exposure route of VICTOR GEL to professional and non-professional users is via dermal contamination through hands. Exposure estimations were performed taking into account the quantities that could potentially enter into contact with consumer's hands during opening and sealing the syringe (1 opening and 1 sealing operations per day of use are assumed). The product remaining on the tip of the syringe (or syringe nozzle)

will contaminate consumer's hand during these activities. This amount of product is difficult to estimate. In absence of information and as a worst case, the CA assumes that 20 mg of product is transferred to the hand each time that the consumer opens or closes a syringe. (See explanations in Scenario 1 above).

	Parameters	Value
Tier 1	Amount of product contacted per event [a]	20 mg product
	number of opening and sealing per day[b]	2
	content of active substance in product	2.15%
	Body weight adult[c]	60 kg
	Dermal absorption[d]	0.5%

[a] One drop of gel weighs 40 mg.
Packaging specifications for syringes do not include information on the diameter of the nozzle lumen. In a similar way as for trained professionals, the CA uses 20 mg of gel to estimate the exposure of non-professionals via dermal route.
[b] CAR, adapted for consumer use.
[c] HEEG Opinion 17.
[d] Study report IIIB B6.3(01)

Calculations for Scenario 3

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

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

Estimated dermal uptake Tier 1 = [2 * 20 mg * 2.15% * 0.5%]/ 60 kg

Scenario 3: application of VICTOR GEL by non-professionals		Estimated Internal Exposure as [mg /kg bw/d]			
		Oral uptake	Inhalation uptake	Dermal uptake	Total uptake
Tier 1	(no PPE)	-	-	7.17E-05	7.17E-05

Scenario [4] Disposal of used syringe of VICTOR GEL by non-professional users

The product is a ready-to use bait in syringes for professionals and non-professionals. The gel is applied as round spots or thin lines (equivalent to a spot) close to ant harborages, foraging and feeding areas such as corners and cracks and crevices for indoor and outdoor control of cockroaches.

For professionals and non-professionals, exposure is estimated using the models and assumptions presented in the original CAR adapted to these uses according to expert judgment.

The highest application rate as well as the interval between applications are not stated. In the following, it is assumed as a worst case that user disposes off an used syringe every two weeks during 6 months per year (cockroaches are expected during spring and summer). Medium term exposure is expected.

The only relevant exposure route of VICTOR GEL to professional and non-professional users is via dermal contamination through hands. Exposure estimations were performed

taking into account the quantities that could potentially enter into contact with user's hands during disposal of the used syringe (1 operation per day is assumed).

In absence of information and as a worst case, the CA assumes that 20 mg of product is transferred to the hand. is transferred to the hand of a consumer during disposal of an used syringe. (See explanations in Scenario 1 above).

	Parameters	Value
Tier 1	Amount of product contacted per event [a]	20 mg product
	number of syringe disposed off per day[b]	1
	content of active substance in product	2.15%
	Body weight adult[c]	60 kg
	Dermal absorption[d]	0.5%

[a] one drop of gel weighs 40 mg.
Packaging specifications for syringes do not include information on the diameter of the nozzle lumen. In a similar way as for trained professionals, the CA uses 20 mg of gel to estimate the exposure of non-professionals via dermal route.
[b] CAR, adapted for consumer use.
[c] HEEG Opinion 17.
[d] Study report IIIB B6.3(01)

Calculations for Scenario 4

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

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

Estimated dermal uptake Tier 1= [1* 20 mg * 2.15% * 0.5%]/ 60 kg

Scenario 4: post application of VICTOR GEL by non-professionals		Estimated Internal Exposure as [mg /kg bw/d]			
		Oral uptake	Inhalation uptake	Dermal uptake	Total uptake
Tier 1	(no PPE)	-	-	3.58E-05	3.58E-05

Combined scenarios

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

Summary table: combined systemic exposure from non-professional uses (mg/kg bw/d)				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios 3 & 4 Tier 1	-	1.08E-04	-	1.08E-04

Indirect (Secondary) Exposure of Bystanders

Indirect exposure scenarios are described in the following

Scenario 5. Adult: Removal of baits

This Scenario has been evaluated according to Imidacloprid assessment report.

Removal of old baits/gel spots is the task of the trained professional users. Nevertheless it is expected that inhabitants of treated areas may remove bait spots manually after a certain time. This scenario has been identified as foreseeable misuse (TNsG, Human exposure to biocidal products, part 3, page 3) by the RMS. It is not described in any reference document. According to the applicant the maximum dose that is applied is 0.24 g of the biocidal product/m2 (= 6 spots/m2). If a whole apartment of 100 m2 is treated with the biocidal product according to instruction 516 mg imidacloprid is applied.

Since the baits are gel and only handled for a very short time it is reasonable to assume a dislodgeable fraction (df) of 1 %. The dermal absorption (da) is expected as 0.5 % and the body weight (bw) of an adult as 60 kg.

	Parameters	Value
Tier 1	Dose	6 spots/m^2
	1 spot	0.04 g
	Amount of product contacted per event [a]	240 mg product/m^2
	Content of active substance in product	2.15%
	Apartment surface	100 m^2
	Dermal absorption [b]	0.5%
	Dislodged fraction [a]	1%
	Adult body weight[c]	60 kg

[a] assumed worst case.
[b] Study report IIIB B6.3(01)
[c] HEEG Opinion 17.

Calculations for Scenario 5

Exposure is estimated using the following calculations:

External dermal load (EDL) = Quantity of product contacted * dislodgeable fraction * content of a.s. in the product

EDL = 240 mg/m^2 *100 m^2 * 1% * 2.15% = 5.16 mg active substance

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

Estimated dermal uptake = (5.16 mg * 0.5%)/60 kg = 4.3E-04 mg/kg bw/day

Summary table: systemic indirect exposure as result of use (mg/ kw bw/day)					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 5	1/none	-	4.30E-04	-	4.30E-04

Further information and considerations on scenario 5

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

Scenario [6]: Toddler: Accidental contact with gel, dermal exposure and hand to mouth transfer

Considering the application pattern of VICTOR GEL as a gel application on localized spots in hidden places with difficult access such as crack and crevice,behind furniture, etc., exposure may occur accidentally for toddler via dermal contact.

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

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

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

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

Secondary exposure can be considered as occasional and of short-term (not continuous) and therefore the exposure is considered as acute.

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

Tier 1 assumes 100% dislodgeability, 100% oral absorption and 0.5% dermal absorption.

	Parameters	Value
Tier 1	Amount of product contacted per event [a]	40 mg product
	Content of active substance in product	2.15%
	Dislodged amount [a]	100%

	Amount of product available for oral intake[b]	50% of external dermal load
	Oral absorption	100%
	Body weight toddler[c]	10 kg
	Dermal absorption [d]	0.5%

[a] worst case assumption.
[b] ConsExpo Pest product fact sheet RIVM report 320005002 (Crack & Crevice Use – Post Application; pp. 28)
[c] HEEG Opinion 17.
[d] Study report IIIB B6.3(01)

Calculations for Scenario 6

Exposure is estimated using the following calculations:

External dermal load (EDL) = Quantity of product contacted * dislodgeable residue * fraction of a.s. in the product

EDL = 40 mg * 100% * 2.15% = 0.86 mg active substance

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

Estimated dermal uptake = (0.86 mg * 0.5%)/10 kg

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

Estimated oral uptake = [0.86 * 50% * 100%] /10 kg

Estimated total uptake = Estimated dermal uptake + Estimated oral uptake

Summary table: systemic indirect exposure as result of use (mg/ kw bw); dermal and hand to mouth contact with gel/ Toddler					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [6]	1/none	-	4.30E-04	0.043	0.0434

Environmental exposure assessment

3.2.1 PEC calculations

Predicted Environmental Concentrations for this primary target of emissions will be calculated for the life-cycle stages of product use only. Direct or indirect emissions of imidacloprid residues from production and product formulation processes to the different environmental compartments are not to be expected due to the waste management requirements for the production, transport and storage of dangerous substances according to national legislations implementing the European Waste Framework Directive (Directive 2008/98/EC). Environmental exposure assessment for the production and product formulation processes is therefore deemed unreasonable.
For safety reasons, the soil pore water concentration as an indicator for potential concentrations in groundwater is also assessed. Primary poisoning of non-target organisms is not a topic since imidacloprid is inaccessible for other organisms. However, during the utilisation of the biocidal product, birds and mammals may be poisoned secondarily through the ingestion of contaminated cockroaches or by the consumption of earthworms from contaminated soils. Hence, potential concentrations in earthworms and cockroaches will be calculated.

A determination of regional concentrations for the proposed use pattern of the biocidal product has not been made since the product's use is not considered to be of sufficiently large scale to warrant such prediction.

3.2.1.1 Indoor application

The calculated emission rates have been inserted into EUSES Version 2.1.2 using the following input values, and the PEC values can be calculated.

Inputs used in EUSES Version 2.1.1

Parameter	Value
Molecular weight	255.7
Boiling point (°C)	Decomposes before boiling
Vapour pressure (mPa)	< 0.1
Octanol water coefficient (log10)	0.57
Solubility in water (mg/L)	613
Organic carbon-water partition coefficient (L/Kg)	230
Henry´s Law constant (Pa m^{-3} mol^{-1})	1.7E-10

The following PEC values were obtained for indoor application using EUSES Version 2.1.2:

Summary of PEC values calculated

EUSES Exposure scenario	PEC
	Indoor (Gel application)
STP [mg/l]	2.23E-05
Surface water [mg/l]	2.23E-06
Sediment [mg/kg]	1.29E-05
Groundwater [µg/l]	3.38E-03
Soil [mg/kg]	1.45E-05

3.2.1.2 Sewer covers

The calculated emission rates have been inserted into EUSES Version 2.1.2 using the following input values, and the PEC values can be calculated.

Inputs used in EUSES Version 2.1.1

Parameter	Value
Molecular weight	255.7
Boiling point (°C)	Decomposes before boiling
Vapour pressure (mPa)	< 0.1
Octanol water coefficient (log10)	0.57
Solubility in water (mg/L)	613
Organic carbon-water partition coefficient (L/Kg)	230
Henry´s Law constant (Pa m^{-3} mol^{-1})	1.7E-10

The following PEC values were obtained for sewer cover application using EUSES Version 2.1.2:

Summary of PEC values calculated

EUSES Exposure scenario	PEC	PEC
	Sewer covers (worst case)	Sewer covers (realistic case)
STP [mg/l]	1.94E-04	3.93E-05
Surface water [mg/l]	1.94E-05	3.93E-06
Sediment [mg/kg]	1.12E-04	2.27E-05
Groundwater [µg/l]	2.95E-02	5.95E-03
Soil [mg/kg]	1.26E-04	2.55E-05

3.2.1.3 Outdoor – Terraces (direct release)

PEC in soil

As developed above, emissions of imidacloprid to the environment may occur when the biocidal gel is applied in the form of drops around terraces, on building entrances such as windows or on wall holes for cockroaches. The relevant scenario for the exposure of the soil due to outdoor use is the release of the biocidal product to surrounding garden soil following wash-off of the terrace by rainfall (OECD, 2008).

The ESD defines the directly exposed area when spots of insecticides are placed e.g. on soil surfaces, however a definition of the receiving compartment for the current scenario is not worked out. In concordance with scenarios where houses are treated by spray applications, a 0.5 m soil strip adjacent to the terrace is defined as the receiving compartment. It is assumed that the 30 m^2 terrace of a private house is quadratic, one side of the terrace borders is adjacent to the house (6 m) whereas the other three sides are surrounded by garden soil. Hence, the soil area exposed amount to 8.5 m^2.

As agreed at the WG-V-2014 and included in the Manual of Technical Agreements for Biocides (ECHA, 2015), the soil depth is set to 50 cm in restricted areas (e.g. for the soil adjacent to the building, , (i.e. 50 cm distance from the treated wall, terraces, etc.)).

PEC in soil for imidacloprid (AB-010-Victor Gel) (outdoor application, direct release)

Parameter	**Definition**	**Value**
Emission rate of the active substance to soil from a campaign [g]	$E_{spot,soil}$	**0,027864**
Area directly exposed to insecticide [m^2]	$AREA_{exposed}$	8,5
Depth of exposed soil [m]	$DEPTH_{soil}$	0,5
Density of exposed soil [kg/m^3_{ww}]	RHO_{soil}	1700
Local concentration in soil due to direct release [g/kg] PECsoil	**$C_{spot,\ soil} = E_{spot,\ soil}$ / ($AREA_{exposed}$ x $DEPTH_{soil}$ x RHO_{soil})**	**3,856E-06**

PEC in groundwater

According to the ESD, the exposure of groundwater is considered negligible during the use of gel spot applications. In addition, the sorption characteristics of imidacloprid indicate a moderate to low sorption to soil components and an increased potential for mobility.

For reasons of completeness, the soil pore water concentration will be assessed as an indicator of potential residues occurring in groundwater.

Most of the parameters used for the PEC calculation in soil pore water have default values, which are provided in the TGD (TGD, 2003). For characterisation of the adsorption potential of imidacloprid in soils, the K_{OC} value of 230 L/kg is used.

Calculation of the solid-water partition coefficient in soil (cf. TGD, Eq. 23)

Parameter	Definition	Value
Weight fraction of organic carbon in compartment soil [kg/kg]	Foc_{soil}	0.02
Partition coefficient organic carbon-water [L/kg]	K_{oc}	230
Partitioning coefficient solid-water in soil [L/kg]	$Kp_{soil} = Foc_{soil} \times Koc$	4.6

As input parameter for the calculation table below the Henry´s Law constant for imidacloprid of 1.7 x 10^{-10} Pa x m^3/mol is used.

Calculation of the air-water partitioning coefficient (cf. TGD, Eq. 22)

Parameter	Definition	Value
Henry´s Law constant [Pa×m^3/mol]	HENRY	1.7E-10
Gas constant [Pa×m^3/mol×K]	R	8.314
Temperature at the air-water interface [K]	TEMP	285
Air-water partitioning coefficient [-]	$K_{air\text{-}water} = \frac{HENRY}{R \text{ x } TEMP}$	7.17E-14

Calculation of the soil-water partitioning coefficient (cf. TGD, Eq. 24)

Parameter	Definition	Value
Fraction air in compartment soil [m^3/m^3]	$Fair_{soil}$	0.2
Air-water partitioning coefficient [-]	$K_{air\text{-}water}$	7.17E-14
Fraction water in compartment soil [m^3/m^3]	$Fwater_{soil}$	0.2
Fraction solids in compartment soil [m^3/m^3]	$Fsolid_{soil}$	0.6
Solids-water partitioning coefficient in compartment soil [L/kg]	Kp_{soil}	4.6
Density of the solid phase [kg/m^3]	RHO_{solid}	2500
Soil-water partitioning coefficient [m^3/m^3]	$K_{soil\text{-}water} = Fair_{soil} \times K_{air-water} + Fwater_{soil} + Fsolid_{soil} \text{ x } \frac{Kp_{soil}}{1000} \text{ x } RHO_{solid}$	7.1

As result, a soil-water partitioning coefficient of 7.1 m^3/m^3 is calculated and used as input parameter in the table below to calculate the local pore water concentration. For worst case considerations, degradation of imidacloprid in soils is not considered.

Calculation of the predicted environmental concentration in pore water (cf. TGD, Eq. 67)

Parameter	Definition	Value Private house
Local concentration in soil due to direct release [mg/kg]	$C_{spot,\ soil}$	3.99E-03
Bulk density of wet soil [kg/m^3]	RHO_{soil}	1700
Soil-water partitioning coefficient [m^3/m^3]	$K_{soil\text{-}water}$	7.1
Predicted Environmental Concentration in pore water [mg/L]	$PEClocal_{soil,porewater} = \frac{PEClocal_{soil} \times RHO_{soil}}{K_{soil\text{-}water} \times 1000}$	9.55E-04

The predicted environmental concentration in pore water amounts to 0.95 µg/L. According to Council Directive 98/83/EC relating to the quality of water intended for human consumption, the maximum admissible concentration for pesticides in drinking water is 0.1 µg/L. Consequently, the $PEClocal_{soil,porewater}$ of the active substance imidacloprid in the biocidal product VICTOR GEL clearly overestimates this limit necessitating model-based groundwater calculations.

3.2.1.4 Outdoor – Terraces (indirect releases)

The calculated emission rates have been inserted into EUSES Version 2.1.2 using the following input values, and the PEC values can be calculated.

Inputs used in EUSES Version 2.1.1

Parameter	Value
Molecular weight	255.7
Boiling point (°C)	Decomposes before boiling
Vapour pressure (mPa)	< 0.1
Octanol water coefficient (log10)	0.57
Solubility in water (mg/L)	613
Organic carbon-water partition coefficient (L/Kg)	230
Henry´s Law constant (Pa m^{-3} mol^{-1})	1.7E-10

The following PEC values were obtained for indoor application using EUSES Version 2.1.2:

Summary of PEC values calculated

EUSES Exposure scenario	PEC
	Outdoor (Gel application)
STP [mg/l]	4.67E-03
Surface water [mg/l]	4.66E-04
Sediment [mg/kg]	2.70E-03
Groundwater [µg/l]	0.707
Soil [mg/kg]	3.03E-03

3.3 New information on the active substance

New information on the active substance has not been submitted.

3.4 Residue behaviour

VICTOR GEL provides control against cockroaches (Product Type 18).

Active substance(s): Imidacloprid 2.15% w/w

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

VICTOR GEL is supplied as ready to use gel intended for use by professional and non-professional users to control cockroaches.

The biocidal product is manually applied by using a cartridge/syringe in drops (up to six drops of gel according to the cockroach species).

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. Also, the product should be placed in spots inaccessible to children and animals.

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

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

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

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

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

The following label restrictions preclude the exposure of animals.

Professional uses:

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

Non-professional uses:

- Keep away from feedingstuff or feed contact surfaces

It is concluded that dietary exposure i.e., food contamination and exposure of livestock to residues of the biocidal product is not expected.

3.5 Summaries of the efficacy studies (B.5.10.1-9)

Summary of laboratory trials:

IIIB5.10-1. **EVALUATION OF THE EFFICACY OF VICTOR COCKROACH GEL AGAINST AMERICAN AND GERMAN COCKROACHES UNDER LABORATORY CONDITIONS. (2008)**

The essay has three parts: a palatability test, a mortality test (non-choice test) and a choice test.

Palatability test:

The test compares the palatability of the VICTOR GEL product against another similar product against Blattela germanica and Periplaneta Americana (nymphs and adults).

Dose: 4g/slide on palatability test.

N: 15 nymphs and 15 adults of Periplaneta Americana and 30 nymphs and 30 adults of Blattella germanica.

There was no stadistically significant difference in the mean number of approaches and the VICTOR GEL was of equal palatability to the other product to the Blattela germanica and Periplaneta Americana.

In spite of considering the bait palatable thanks to this test, we not consider that this information is relevant for the evaluation of the product since it is not possible to quantify the mortality of VICTOR GEL. Therefore, this information is not included in efficacy data table.

Mortality (non.choice test) and choice test:

They were carried out simultaneously: a mortality test and a choice test for both the VICTOR GEL product and another reference product with common untreated controls.

Dose rate: 2dropsx0.1g/petri dish.

Food sourse: dog food.

The data on the percentage of mortality and choice test are summary in the table above for efficacy data (2.2.5.5.)

IIIB5.10.6. **EFFICACY AND PALATABILITY OF THE FORMULATION AB-010 AGAINST COCKROACHES UNDER LABORATORY CONDITIONS.**

Assay provided to compare the palatability of the VICTOR GEL product against another similar product against Blattela germanica, Blatta orientalis and Periplaneta Americana (nymphs and adults). It also contributes efficacy tests with alternative food.

The test was elaborated in accordance ith the Good Laboratories Practice Standars (GLP).

Palatability:

There was no stadistically significant difference in the mean number of approaches and the VICTOR GEL was of equal palatability to the other product to the Blattela germanica, Blatta orientalis and Periplaneta Americana.
Dose rate: 1g/petri dish.
N Periplaneta Americana: 30 nymphs and 30 adults.
N Blattella germanica: 40 nymphys and 40 adults.

In spite of considering the bait palatable thanks to this test, we not consider that this information is relevant for the evaluation of the product since it is not possible to quantify the mortality of VICTOR GEL. Therefore, this information is not included in efficacy data table.
Choice test:
Efficacy trials are provided for three species (Blattella germanica, Blatta orientalis, and periplaneta Americana, adults and nymphs), both with fresh bait and aged bait 2 and 4 years old.

Four replicates were evaluated por treatment group and for the toxic reference and control. Each replicate consisted of mixted population of cockroachs including young adults of both sexes and alte nymphal stage.

The study was considerate valid since mean mortality recorderd in the control group was ≤10% and the percent mortality observed in the each of the control raplicates was ≤15%.

The data on the percentage of mortality are summary in the table above for efficacy data (2.2.5.5.)

IIIB5.10.7. **RESIDUAL EFFICACY OF THE FORMULATION "AB.010 AGAINST COCKROACHES UNDER LABORATORY CONDITIONS**

The study was carried out to determine the residual toxicity of VICTOR GEL to the species Blattella germanica and Periplaneta Americana.

The formulated product was applied to one porous and one non-porous substrate (plaster and ceramic tile). Cockroaches were exposed to the product at two time intervals after application (7 and 15 days).

Four replicates were evaluated por treatment group and for the toxic reference and control. Each replicate consisted of mixted population of cockroachs including young and adults of both sexes and nymphal stages.

The data on the percentage of mortality are summary in the table above for efficacy data (2.2.5.5.)

The gel bait AB-010 demostrate excellent residual efficacy against the specie Blattella germanica independently of the treated surface. The result of the residual activity efficacy against Periplaneta Americana was not effective to aged bait.

Summary of field trials

IIIB5.10.2. **DETERMINATION OF EFFICACY OF AB-010 AGAINST COCRKOACHES: Blattella germanica, (FIELD TRIAL) IN AN INFESTED HOME OR WAREHOUSE (INDOOR) 2013**

Field trail against Blattella germanica.

The essay was conducted in a house in Valencia. The drops treatment was applied in the kitchen and in an indoor room.

The pre-test showed a high infestation level. Dose rate was one to four gram of spots per m^2 The timing application was every 8-9 days up to 5,5 weeks.

The fiel trial demonstrated a good level of efficacy of 92,4 % mortality.

IIIB5.10.3. **DETERMINATION OF EFFICACY OF AB-010 AGAINST COCRKOACHES: Blattella germanica, (FIELD TRIAL) IN AN INFESTED HOME OR WAREHOUSE (INDOOR) 2013**

Field trail against Blattella germanica.

The essay was conducted in a house in Alicante. The drops treatment was applied in the kitchen and in an indoor room.

The pre-test showed a high infestation level (104 cockroaches). Dose rate was one to four gram of spots per m^2 The timing application was every 8-9 days up to 5 weeks.

The fiel trial demonstrated a good level of efficacy of 93,3 % mortality.

IIIB.10.4. **DETERMINATION OF EFFICACY OF AB-010 AGAINST COCKROACHES: *BLATTA ORIENTALIS* IN AN INFESTED HOME OR WAREHOUSE (INDOOR) IN SPAIN**.

Field trail against Blatta orientalis.

The essay was conducted in a house in Valencia. The drops treatment was applied in the dining room and in the larder.

The pre-test showed a medium infestation level (20 cockroaches). Dose rate was two to four spots per m^2 The timing application was every 9-10 days up to 5,5 weeks.

The fiel trial demonstrated a level of efficacy of 85,0% mortality.

IIIB5.10.5. **DETERMINATION OF EFFICACY OF AB-010 AGAINST COCKROACHES: PERIPLANETA AMERICANA IN AN INFESTED HOME OR WAREHOUSE (INDOOR) IN SPAIN**

Field trail against Periplaneta americana.

The essay was conducted in a house in Valencia. The drops treatment was applied in two larders.

The pre-test showed a high infestation level (25 cockroaches). Dose rate was two to four spots per m^2. The timing application was every 9-10 days up to 5,4 weeks.

The fiel trial demonstrated a level of efficacy of 88,0% mortality.

IIIB5.10.9. **DETERMINATION OF AB-010 AGAINST COCKROACHES: PERIPLANETA AMERICANA IN AN INFESTED SEWER IN SPAIN.**

Field trail against Periplaneta Americana.

The essay was conducted in Alicante (Spain) in a garden zone with several sewer entrances and in a built zone with courtyard . The drops treatment was applied indoor the sewer entrances and around them. The average temperature during the field trial was 23ºC and the average humidity was 60ºC.

The pre-test (one glue trap placed in each zone) showed a high infestation level (30 cockroaches). Dose rate was two to four drops per m^2. The timing application was every 9-12 days up to 5,8 weeks.

The fiel trial demonstrated a level of efficacy of 86,7% mortality.

IIIB5.10.8. **DETERMINATION OF EFFICACY OF AB-010 AGAINST COCKROACHES: SUPELLA LONGIPALPA IN AN INFESTED HOME OR WAREHOUSE (INDOOR) IN SPAIN**.

Field trail against Supella longipalpa.

The essay was conducted in a house in Barcelona. The drops treatment was applied in a bar.

The pre-test showed a high infestation level (61 cockroaches). Dose rate was one to four spots per m2. The timing application was every 9-10 days up to 5,4 weeks.

The fiel trial demonstrated a level of efficacy of 88,5% mortality.

During the pre-treatment a high population level of Blattella germanica was obserbed and was included in the conclusions. The field trial desmostrated a level of efficacy against B. germanica of 93,3% mortality.