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 HORMIGAS

Product type 18

IMIDACLOPRID

Case Number in R4BP: BC-CT010826

Evaluating Competent Authority: SPAIN

August 2020

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Overview of applications

Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	ES	BC-CT010826-28	June 2013	Initial assessment
NA-APP	ES	ES-0009318-0000	August 2018	First authorisation
NA-MIC	ES	BC-GM054442-40	August 2020	Extension of shelf-life.

The new information is found in section 3.6. Addendum and 3.7. Confidential annex.

1 CONCLUSION

The assessment presented in this report has shown that the ready-to-use product, VICTOR GEL HORMIGAS, with the active substance Imidacloprid, at a level of 0.01% w/w, may be authorised for use as a insecticide (product-type 18) for the control against ants for trained professional, professional and general public.

VICTOR GEL HORMIGAS is an insecticide product against garden ants (*Lasius niger*). It is to be used indoors and outdoors by trained professional, professional and general public (non-professional). It is a ready to used bait to be applied as bait station (bait station).

The biocidal product VICTOR GEL HORMIGAS contains 0.01% w/w Imidacloprid and given the nature of the formulation it is not considered explosive, oxidizing, highly flammable or auto-flammable.

The accelerated storage study indicates that the variation of the active ingredient content on VICTOR GEL HORMIGAS product after 14 days in the oven was 2.41%. 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).

The applicant has submitted an acceptable stability study after 1 and 2 years. Data about storage stability for 5 years is ongoing.

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

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

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

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

The product was shown to be efficacious against garden ants (*Lasius niger*) in the proposed area for use (indoors and outdoors in residential areas and commercial buildings) and it is proved to be effective applied as bait station (bait station).. Please find more information on efficacy of the product in chapter 2.2.5.

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

According to the intented uses submitted by the applicant, the biocidal product VICTOR GEL HORMIGAS is a ready-to-use product to be applied indoor and outdoor as gel drops/lines and using bait stations.Human exposure takes place via dermal contamination through hands taking into account the quantities that could potentially enter into contact

with operator's or consumer's hands during opening, sealing and disposal of the cartridge or syringe, respectively. No exposure to the product is expected by differents users during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63). Indirect exposure is expected for toddlers via dermal and hand to mouth contact after application of the product.

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

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

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

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 environment are not contained in the product in such quantity as to lead to classification.

A risk assessment of the product has been carried out (chapter 3.7) and for the intended use by the applicant, comments from the ES CA are also included.

Considering the risk to this product of non- target arthropods when the product is applied outdoor we should limited its use to be used inside of bait stations and not to grant authorisation for using the product outdoors by uncovered spot applications

Comparative assessment:

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

The Spanish CA concludes that there is not an adequate chemical diversity for products to control ants for indoor and outdoor uses by different users because at least three different active substances-mode of action combinations should remain available through authorised biocidal product for a given use (indoor and outdoor uses by different categories 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 HORMIGAS	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)2018-18-00481	
Date of the authorisation		
Expiry date of the authorisation	5 years since the date of the authorisation	

2.1.1.3 Manufacturer of the product.

Name of manufacturer	ADAMA Celsius, B.V. Amsterdan.(NL)
Address of manufacturer	ADAMA Group Spitalstrasse, 5 8200 Schaffhausen Switzerland. Phone: (+41) 52 6300255
Location of manufacturing sites	MYLVA, S.A. San Galderic 23 San Pol de Mar 08395, BARCELONA Phone: (+34) 937601471. 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	BAYER CROPSCIENCE ag.	ADAMA AGRICULTURE ESPAÑA, S.A

manufacturer		
Address of manufacturer	16 rue Jean-Marie Leclair 90106 Lyon Cedex France	Calle Mendez Álvaro, 20 -5 28045 MADRID Telf: (+34) 91 585 23 80
Location of manufacturing sites	Industrial Operations Alfred-Nobel-Strabe 50 40789 Monheim (Germany)	**Site 1**: Adama Makhteshim Ltd. Neot-Hovav Eco-Industrial Park Beer Sheva 84100, Israel **Site 2**: Jiangsu Yangnong Chemicals Group Co. Ltd 39 Wenfeng Road Yangzhou 225009 China

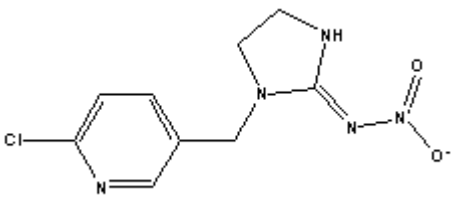
2.1.2 Product composition and formulation

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

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

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

Biocidal product VICTOR GEL HORMIGAS 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 HORMIGAS 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 HORMIGAS is an indoor/outdoor gel insecticide to be applied via droplets by using a cartridge/syringe or bait stations. It has an effective control against ants (*Lasius* spp.) The product is intended for the general public (non-professional use) as well as professional and trained professional users.

The product has been only compared with alternative products authorised in Spain as the searchable SPCs and a corresponding search tool in the Register for Biocidal Products (R4BP) is currently not available. The Spanish CA has used the information available to the ES CA on the 10th of January 2017 of the biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012. In Spain 26 products PT18 have been authorised. These products are based in four active substances but only four of these actives substances are use for the control of ants: Indoxacarb, spinosad, fipronil and deltamethrin. The biocidal product containing indoxacar is for professional users so, this product is not considered as eligible alternative BP and therefore is not include in the comparative assessment. Neither of the BPs mentioned above control all the species of ants controlled by VICTOR GEL HORMIGAS. 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 use by non professionals; outdoor use by professionals). An inadequate chemical diversity for one user category could lead to resistance occurrence, which might spread afterwards across the target organism population. The ES CA has checked whether the chemical diversity of the available active substances/ mode action within the identified alternative biocidal products can be considered adequate to minimise the occurrence of resistance in the target harmful organism (i.e. cockroaches). The Spanish CA concludes that there is not an adequate chemical diversity for products to control ants for indoor use by professional and non professional users. Therefore, the comparative assessment is finalised at the screening phase. The product VICTOR GEL HORMIGAS 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	0.01
Non-active substances	See Annexes, 3.6 Confidential Annex				

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 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

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

2.1.2.6 Type of formulation

RB - gel bait (ready to use)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Aquatic Chronic 2
Hazard statement	H411: Toxic to aquatic life with long lasting effects.
Labelling	

	 GHS09
Signal words	----
Hazard statements	H411: Toxic to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P103: Read label before use. P273: Avoid release to the environment. P391: Collect spillage. P501: Dispose of contents/containers in accordance with local regulations.

2.1.4 Authorised uses.

2.1.4.1 Use description. Table 1.

Table 1. Use 1 – Gel bait applied as bait station –Trained professional, professional and general public (non professional)

Product Type	PT18.
Where relevant, an exact description of the authorised use	Insecticide against
Target organism (including development stage)	Insecticide against the following target insects (adults) - *Lasius niger* (adults).
Field of use	Indoors. Residential and commercial buildings. Around buildings. Outdoors. Terraces and paved.
Application method	Closed application by bait stations.
Application rate and frequency	Dose: 5g (1 bait station) / 22m^2 (or 1 bait station/room). If the nest is located, apply 1 bait station/12m2 near it (it is assumed that the range of action of a nest is 12m2). Frequency of application: after 14 days, replice the bait stationsif the infestation persist. Frequency of treatment:. Three months after the infestation's end, treatment may be repeated.
Category(ies) of users	Trained professional user Professional user General Public (non-professional user)
Pack sizes and packaging material.	Bait station made of HIPS with 5 grams of gel bait.

2.1.4.1.1 Use-specific instruction for use.

See section 2.1.5.1.

2.1.4.1.2 Use-specific mitigation measures.

See section 2.1.5.2.

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.

2.1.5 General directions for use

2.1.5.1 Instructions for use.

Protect the bait station from sun and rain. Read carefully the label before use the product. Remove alternative food source that may be in competition from near areas.

2.1.5.2 Risk mitigation measures

The bait stations should not be open or handle. Never introduce the fingers through the holes in the bait station. Hazardous to bees. The areas of product handling must be well-ventilates, with natural or exhausted ventilation. Keep away from heat, open and sparks. Keep out of the reach of childrens. This product should be used in alternation with other products not containing the same

a.s. to avoid resistant populations.

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

Use products at recommended doses and intervals.

Trained professional uses:

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

Professional and non-professional uses:

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

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

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

Basic First aid procedures:

- If contact in eyes, rinse with plenty of water for at least 15 minutes. Do NOT forget to remove the contact lenses
- If contact on skin, wash with soap and plenty of water, without rubbing

Medical advice for doctors and sanitary staff

- Symptomatic and supportive treatment

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

Emergency measures to protect the environment:

Environmental Precautions:

Avoid contamination of drains, surface and groundwater as well as soil.

Do not discharge into the environment.

If the product enters sewers or public waters, notify to the authorities.

Methods for cleaning up:

Adsorb the spilled product by sand or adsorbent inert materials. Deposit it in closed packages and manage it following the legislation for industrial residues. In case of great spill, use dikes of inert materials. Make sure the total decontamination of the tools and equipment used in the cleaning works.The recovered product must be disposed according with local law. Contact with the competent authorities if the situation cannot be controlled.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with current regulations. (P501).

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

Shelf life: 33 months. Keep only in the original container Store in dry, cool and well-ventilated place. Avoid direct sun. Keep away from water, food and animal feeding-stuffs.

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.

2.1.7 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Bait station (bait station)	5 g	HIPE.(High impact poliestyrene) Cover of HDPE.		General public Professional Trained professional.	

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

The aplicant has provided four laboratory and field trials against ants to support efficacy. The trials have been elaborate with a product called AB-020 and VICTOR GEL ANTS BAIT STATIONS. The applicant has declarated that this products are identical to VICTOR GEL HORMIGAS. The sponsor is ADAMA AGRICULTURE ESPAÑA, S.A (old ARAGONESAS AGRO, S.A.), so a letter of acces to the studies have not been necessary.

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

In relation to human health, six studies have been provided by the applicant to address the acute ora and dermal toxicity, dermal and eye irritation/corrosion, skin sensitization and dermal absorption. These studies have been elaborated with the product VICTOR GEL CUCARACHAS and AB-010 (wich are the same product). The sponsor is ADAMA AGRICULTURE ESPAÑA, S.A (old ARAGONESAS AGRO, S.A.), so a letter of acces to the studies have not been necessary. The data provided for these studies refer to a worst case.

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 HORMIGAS provides control against ants
Target organism (including development stage)	Ants (Lasius spp, Tetramorium caespitum, Myrmica rubra, Tapinoma erraticum) and tropical ants (Linepithema humile, Monomotium pharaonis)
Field of use	Indoors/Outdoors
Application method(s)	VICTOR GEL HORMIGAS is applied by • using a cartridge with pistol applicator in form of drops or lines in/near ant rows or nests. • using a syringe in form of drops or lines in/near ant rows or nests. inside a bait station placed near ant rows and nests and activated by opening slits allowing ants to feed on the bait formulation.
Application rate(s) and frequency	**Cartridge**: per treatment an amount of 0.4g spot per m^2 or per linear meter is applied. **Syringes**: per treatment an amount of 0.4g spot per m^2 or per linear meter is applied. **Bait station**: One bait station per 12 m^2 is used. Repeat treatment until total control of the swarm.
Category(ies) of user(s)	Professional user
Pack sizes and packaging material	**Cartridge**: 30g, 35g, 75g and 300g cartridges made of polypropylene. **Syringes** (polyethylene of low density)**:** 3, 5, 10 and 20 g of gel bait. **Bait stations** (High impact polystyrene)**:** 5g of gel bait. The cover is made of HDPE.

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

Product Type(s)	PT 18
Where relevant, an exact description of the authorised use	VICTOR GEL HORMIGAS provides control against ants
Target organism (including development stage)	Ants (Lasius spp, Tetramorium caespitum, Myrmica rubra, Tapinoma erraticum) and tropical ants (Linepithema humile, Monomotium pharaonis)
Field of use	Indoors/Outdoors
Application method(s)	VICTOR GEL HORMIGAS is applied by • using a cartridge with pistol applicator in form of drops or lines in/near ant rows or nests. • using a syringe in form of drops or lines in/near ant rows or nests. inside a bait station placed near ant rows and nests and

	activated by opening slits allowing ants to feed on the bait formulation.
Application rate(s) and frequency	**Cartridge**: per treatment an amount of 0.4g spot per m^2 or per linear meter is applied. **Syringes**: per treatment an amount of 0.4g spot per m^2 or per linear meter is applied. **Bait station**: One bait station per 12 m^2 is used. Repeat treatment until total control of the swarm.
Category(ies) of user(s)	General public. (non-professional).
Pack sizes and packaging material	**Cartridge**: 30g, 35g, 75g and 300g cartridges made of polypropylene. **Syringes** (polyethylene of low density)**:** 3, 5, 10 and 20 g of gel bait. **Bait stations** (High impact polystyrene)**:** 5g of gel bait. The cover is made of HDPE.

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	Batch F295	liquid	[redacted]
Plastic cartridge Plastic syringe Bait station	Visual inspection	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.	<u>Initially:</u> Gel <u>After storage at 54 °C for 14 days:</u> Gel <u>After 1 year at 25°C ± 2°C:</u> Gel <u>After 2 years at 25°C ± 2°C:</u> Gel <u>Initially:</u> Gel <u>After 1 year at 25°C ± 2°C:</u> Gel <u>After 2 years at 25°C ± 2°C:</u> Gel Not available	[redacted]
Colour at 20 °C and 101.3 kPa	Visual inspection	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.		[redacted]
Plastic cartridge			<u>Before at 54 °C for 14 days:</u> 2.5 Y 9/2 (scale according to Gardner) <u>After storage at 54 °C for 14 days:</u> *7.5 Y R 7/12 (*scale according to Gardner*)* <u>Initially:</u> 7.5 GY 9/2 (Munsell scale) <u>After 1 year at 25°C ± 2°C:</u> 10 Y 9/6 (Munsell scale)	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Plastic syringe Bait station			After 2 years at 25°C ± 2°C: 10 Y 9/6 (Munsell scale) Initially: 7.5 GY 9/2 (Munsell scale) After 1 year at 25°C ± 2°C: 10 Y 9/6 (Munsell scale) After 2 years at 25°C ± 2°C: 10 Y 9/6 (Munsell scale) Not available	
Odour at 20 °C and 101.3 kPa	Olfactory inspection	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.		[redacted]
Plastic cartridge Plastic syringe Bait station			Initially: Slight sweet smell After storage at 54 °C for 14 days: Slight sweet smell After 1 year at 25°C ± 2°C: Slight sweet smell After 2 years at 25°C ± 2°C: Slight sweet smell Initially: Slight sweet smell After 1 year at 25°C ± 2°C: Slight sweet smell After 2 years at 25°C ± 2°C: Slight sweet smell Not available	
Acidity/Alkalinity	CIPAC method MT 75	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.		[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Plastic cartridge			pH = 6.26	
Plastic syringe			Not available	
Bait station			Not available	
Relative density/bulk density	EC method A.3	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.		[redacted]
Plastic cartridge			1.3012 ± 0.0009 g/mL	
Plastic syringe			Not available	
Bait station			Not available	
Storage stability test – **accelerated storage (14 days at 54ºC)**	CIPAC method MT 46.3	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.		[redacted]
<u>Imidacloprid content</u>	HPLC method		The biocidal product is stable at 54 °C for 14 days.	
Plastic cartridge			<u>Initially:</u> **0.0083% w/w** <u>After 14 days at 54°C ± 2°C:</u> **0.0081% w/w** Diference: -2.40%	
Plastic syringe			Not available	
Bait station			Not available	
<u>Homogeneity of application</u>				
Plastic cartridge			Not available	
Plastic syringe			Not available	
Bait station			Not available	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Appearance and stability of the package				
Plastic cartridge			Not available	
Plastic syringe			Not available	
Bait station			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	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.	Two studies for the determination of the room storage stability are in progress and will be submitted as soon as they are finalised.	[redacted]
Active Ingredient Content	HPLC method			
Plastic cartridge			Initially: **0.0083% w/w** Diference: +2.41% After 1 year at 25°C ± 2°C: **0.0085% w/w** Diference: +2.40% After 2 years at 25°C ± 2°C: **0.0092% w/w** Diference: +10.84%	
Plastic syringe			Initially: **0.0084% w/w** After 1 year at 25°C ± 2°C: **0.0088% w/w** Diference: +4.76% After 2 years at 25°C ± 2°C: **0.0090% w/w** Diference: +7.14%	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Bait station			Not available	
Homogeneity of application				
Plastic cartridge			Not available	
Plastic syringe			Not available	
Bait station			Not available	
Appearance and stability of the package				
Plastic cartridge			Not available	
Plastic syringe			Not available	
Bait station			Not available	
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	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.	The biocidal product is stable at 0 °C for 7 days. No solid or oily material was generated after the storage.	[redacted]
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Not available	
Effects on content of the active substance and technical characteristics of			Not available	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
the biocidal product – **temperature and humidity**				
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Not available	
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	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning completeness — smoke generators			Not available	
Composition of smoke — smoke generators			Not available	
Spraying pattern — aerosols			Not available	
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	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.	73.0 mN/m at 20 °C ± 0.4 °C	[redacted]
Viscosity	OECD guideline 114	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.	4389 to 11520 mPa·s at 20 °C ± 0.2 °C 1853 to 5634 mPa·s at 40 °C ± 0.1 °C	[redacted]

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

IMPORTANT NOTE:
The applicant should submit all interim GLP reports to evaluate the storage stability test in commercial type packagings.

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.

Storage stability
The accelerated storage study indicates that the variation of the active ingredient content on VICTOR GEL HORMIGAS product after 14 days in the oven was 2.41%. 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 storage stability test in commercial type packagings. Tests are performed with two commercial packages of the formulation (cartridges and syringes).

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 Gel, based on its formulation type and use pattern (RTU without dilution) is viscosity.

Viscosity
The viscosity was tested using share rates from 10 to 100 s^{-1}..

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosive properties			The biocidal product does not present explosive properties.	
Oxidising properties			The biocidal product does not present oxidising properties.	
Flash point			Not applicable because the biocidal product is not liquid.	
Auto-ignition			The biocidal product	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			does not present flammable properties.	
Other indications of flammability			The biocidal product does not present flammable properties.	

Conclusion on the physical hazards and respective characteristics of the product
The justification for non-submission of data is accepted, therefore VICTOR GEL HORMIGAS is not considered to be potentially explosive or contain an oxidising or reducing agent. The preparation is not recommended for use with other products. The technical properties indicate that no particular problems are to be expected when it is handled, stored or applied as recommended.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Imidacloprid (a.s.)	HPLC-MS	0.0099 % w/w SD = 0.0002 % w/w RSD = 2.11% 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 imidaclorid.	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.	[redacted]
Imidacloprid (a.s.)	HPLC-UV	0.0084 and 0.0168% n = (2 x 2)	0.0021 to 0.021 mg/mL	The specificity is given as a	105.3 to 106.2%	105.8%	0.49 %	Not determined since the analytical	[redacted]

			r^2 = 0.9998 n = 5	result of selective UV detection. No interferences occurred at the retention time corresponding to imidaclopprid.				method is only used to check if the active substance content in the biocidal product complies with the respective specification.	
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 (soil)	LC-MS/MS	0.005 mg/kg	CAR (2011)
Parent compound (soil)	HPLC-UV RP-18 and CN column	0.005 mg/kg	CAR (2011)

Analytical methods for air			
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Limit of quantification (LOQ) or other limits**	**Reference**

Parent compound (air)	HPLC-UV RP-18 column	0.005 mg/m^3	CAR (2011)
Parent compound (air)	HPLC-UV CN column	0.005 mg/m^3	CAR (2011)

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

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

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
No relevant residues expected									CAR (2011)

Conclusion on the methods for detection and identification of the product
Validated analytical methods are 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 HORMIGAS is presented as a ready-to use gel bait insecticide and packaged in, a syringe or a cartridge or bait stations (bait station). It is used by trained professionals, professionals and general public (Non professional)

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

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

VICTOR GEL HORMIGAS is used against garden ants (*Lasius niger*).

The products, organisms or objects to be protected in and around and outdoors from private houses and commercial buildings.

2.2.5.3 Effects on target organisms, including unacceptable suffering

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

2.2.5.4 Mode of action, including time delay

Ants are attracted by some nutritional ingredients that are present in the formulation and spread the gel insecticide by moving and causing poisoning (by contact and ingestion) and the indirect death of the individuals who live in the colony, regardless their stage of development (larvae, 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 0.01 % Gel Bait*	*Laboratory*	*Lasius niger*	*Mortality*	*Non choice arena test. 4 replicates, one control and a reference product. Dose:0.1g.. N: 30 workers*	*Mortality:* *- Fresh:100% at 4 days* *- 2 year aged bait 100% at 3 days* *- 3 year aged bait 100% at 3 days.*	[redacted] III.B.5.10.3
				Mortality	*Non choice arena test. 4 replicates, 1 control and a reference product.*	*Mortality: 100% at 2 days. Dose: 1 bait station of 5g product. N: 500 worker ants and 200 larvae.*	[redacted] III.B.5.10.4
				Palatability test.	*Choice test arena. 3 replicates. 1 Control. Drops and bait station. Fresh and aged bait.*	*Mortality:* *- Fresh(drop):69.65% at 8 days* *- 2 year aged bait (drop) 71% at 8 days.* *- Fresh (bait station): 100% at 4 days.* *- 2 year aged bait (bait station): 78,48% at 8 days,*	[redacted]
				Residual efficacy	*Non choice arena test. 4 replicates, one control and a reference product. Dose: 0.1g N: 30 worker ants.*	*Mortality on non–pororus surfaces:* ▪ *7 days ageing: 100% on 5 days.* ▪ *15 days ageing: 100% on 7 days.* *Mortality on pororus surfaces:* ▪ *7 days ageing: 95.83% on 14 days.* ▪ *15 days ageing: 90.93% on 14 days.*	[redacted] III.B5.10.1
			Linephitema humile	*Mortality*	*Non choice arena test. 4 replicates, one control and a reference product. Dose:0.1g N: 30 worker ants*	*Mortality:* *- Fresh:62.50% at 14 days* *- 2 year aged bait 69.17% at 14 days* *- 3 year aged bait 68.33% at 14 days.*	[redacted] III-B.5.10.3
				Mortality	*Non choice arena test. 4 replicates, one control and a reference product.*	*Mortality: 96.45% at 14 days. Dose: 1 bait station of 5g product. N: 500 worker ants and 200 larvae.*	[redacted] III-B.5.10.4

				Efficacy residual	*Non choice arena test.* *4 replicates, one control and a reference product.* *Dose: 0.1g* *N: 30 worker ants.*	*Mortality on non–pororus surfaces:* ▪ *7 days ageing: 78.88% at 14 days* *15 days ageing: 75.11% at 14 days.* *Mortality on pororus surfaces:* ▪ *7 days ageing: 69.89% on 14 days.* ▪ *15 days ageing: 70.75% on 14 days.*	[redacted] III-B.5.10.1
		Field trial	*Lasius niger*	*Outdoors Drops*	*Field trial A Coruña.* *plots of kiwi orchard and 1 plot of vine line.* (4 replicates). *1 plot=30m²* *A control.*	*Efficacy: 89.90% at 17 days.* *Dose rate: 1.6g/30m²* *Two nest had residual population of adult workers and one was still active and reproductive.*	[redacted] III-B.5.10.2
				Outdoors. Bait stations	*Field trial A Coruña.* *3 plots of kiwi orchard and 1 plot of vine line.* *(4 replicates)* *A control.*	*Efficacy: 93.31% at 17 days.* *Dose: 1 bait station (5g)/30m²* *All nest showing not residual activity.*	[redacted] III-B.5.10.2

Conclusion on the efficacy of the product
The applicant has been submitted five efficacy trials. Four laboratory trials and one field trials against *Lasius niger* and *Linephitema humile*. The description off the trials have been summarized in annex 3. Section 3.5. Concusions about efficacy trials. - *Lasius niger* Three mortality tests (IIIB5.10.1-3-4), one palatability test (IIIB5.10.5) and an outdoor field test (IIIB5.10.2) have been provided that meet the efficacy criteria of TNsG in both bait station and droplets. The IIIB5.10.3 test has incorporated a palatability test comparing a toxic bait against our product. We consider that this does not demonstrate the palatability under conditions of use like indicates the TNsG. A new choice test has been submitted with drops/ bait station and fresh and aged bait. The test has demonstrated the palatabilityof the product only with fresh bait in bait station. The residual efficacy test shows that the product is effective up to 15 days in porous and non-porous conditions by drops. The field test has been evaluated outdoors with droplets and with bait station. It shows very good efficacy against bait station and with droplets reaches 89.90% at 17 days. Spain is of the opinion of accepting the test in droplets. In addition the trial has shown that it kills the colony completely with bait stationsand it significantly reduces the viability of the colony with the droplets Likewise we consider that the field test provided in outdoor is a worse case against indoor. Therefore, we conclude that **the product is effective against *Lasius niger* by bait station, indoors and outdoors.**. - *Linephitema humile* Three mortality test (IIIB.5.10.1-3-4) have been submitted to support the efficacy against Linephitema humile. The test IIIB5.10.3 does no meet the criteria of TNsG, and the product has proved not to have residual efficacy. In addition the applicant has not submitted a field trials against this specie. **The product will be not authorize against *Linepithema humile.***

2.2.5.6 Occurrence of resistance and resistance management

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

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

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

The resistance of target insects (ants) to Imidacloprid was searched for in the literature during the evaluation of VICTOR GEL HORMIGAS but no updated references and documentation was found about neonicotinoides insecticide resistance of ants. According to the TNsG (point.1.3.14), ant is an insect "*with one or few queens who lay eggs for a*

long period, and a biocide that kills the whole colony most of the time, so it is not to be expected that resistance will build up". In addition, ants are not considered a serious threat to public health or threat to crops, which could justify the lack of such research in this field of study. Even so, in the 70s, cases of resistance argentine ant were recorded against the actives substances *aldrin* and *diedrin*, currently not allowed, who acted on GABA channels. (Ettershank, G. (1975). In: Kerr 1977.)

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

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

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

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

The proposed resistance management strategy includes the following actions:

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

2.2.5.7 Known limitations

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

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

- Do not mix with other chemicals.
- 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 product has proven effective for the following label claims:

- The product is effective against *Lasius niger*, indoors and outdoors.
- The method of application is by bait station.
- The product has demonstrate a total destruction of the colony by bait stations, outdoors.

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 HORMIGAS is composed of the active substance Imidacloprid (0.01% w/w), combined with a number of co-formulants. Current classification is proposed in accordance with the provisions laid down in Regulation (EC) Nº 1272/2008. Proposed classification for the biocidal product based on the toxicology studies 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 and DSD	The preparation Imidacloprid 2.15% Gel is is not classified

Data waiving	
Information requirement	Skin corrosion and irritation study for Imidacloprid 0.01% Gel formulation
Justification	Skin corrosion and irritation study for Imidacloprid 0.01% Gel formulation has not been submitted. The formulation VICTOR GEL HORMIGAS contains 0.01% (w/w) of the active substance Imidacloprid and other co-formulants, several of which are classified for human toxicity. However, the concentration of these substances in the preparation does not exceed the classification limits set in Regulation (EC) Nº 1272/2008 and the biocidal product can be considered as no irritant to skin and does not meet the criteria for classification as irritant or corrosive on the basis of their presence in the preparation. Therefore it is proposed that the formulation VICTOR GEL HORMIGAS

	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, OECD Guideline 405, GLP yes, Reliability 1	Rabbit, Himalayan, ♂, 3 animals	Victor gel undiluted, 0.1 ml, 24 hr exposure, 72 hr post exposure	conjunctival redness of the treated eye (grade 1) in one animal after one hour (reversible). Chemosis, ocular lesions of the iris and opacity of the cornea not observed in any animal.	None	[redacted] IIIB6.2.2

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 and DSD	The preparation Imidacloprid 2.15% Gel is not classified

Data waiving	
Information requirement	Eye irritation study for Imidacloprid 0.01% Gel formulation
Justification	Skin corrosion and irritation study for Imidacloprid 0.01% Gel formulation has not been submitted. The formulation VICTOR GEL HORMIGAS contains 0.01% (w/w) of the active substance Imidacloprid and other co-formulants, several of which are classified for human toxicity. However, the concentration of these substances in the preparation does not exceed the classification limits set in Regulation (EC) Nº 1272/2008 and the biocidal product can be considered as no irritant to skin and does not meet the criteria for classification as irritant or corrosive on the basis of their presence in the preparation. Therefore it is proposed that the formulation VICTOR GEL HORMIGAS is not classified.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Imidacloprid 0.01% Gel is not irritant to respiratory tract
Justification for the conclusion	Exposure via inhalation route is unlikely due to the low vapour pressure of the a.s., the formulation of b.p. (gel) and mode of application (using syringe or inside bait station). In addition the product is not irritant to skin and eyes. In addition, based on the classification of Imidacloprid and the coformulants and their respective content in the final formulation
Classification of	The formulation VICTOR GEL HORMIGAS is not classified.

the product according to CLP and DSD	

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	X [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 and DSD	The preparation Imidacloprid 2.15% Gel is not classified

Data waiving	
Information requirement	Skin sensitisation study for Imidacloprid 0.01% Gel formulation
Justification	Skin sensitisation studies for Imidacloprid 0.01% Gel have not been performed. Imidacloprid 2.15% Gel is not skin sensitizer; it is proposed that the behaviour regarding skin sensitization properties will be similar in both products and can be exbait stationolated from the available data, avoiding further testing on vertebrates. In addition, there are no skin sensitisants as co-formulants. Therefore it is proposed that the formulation VICTOR GEL HORMIGAS is not classified.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Imidacloprid 0.01% Gel is not respiratory sensitiser
Justification for the value/conclusion	Based on the classification of Imidacloprid and the coformulants and their respective content in the final formulation.
Classification of the	The formulation VICTOR GEL HORMIGAS is not classified.

product according to CLP and DSD	

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 and DSD	The preparation Imidacloprid 2.15% Gel is not classified

Data waiving	
Information requirement	Acute oral toxicity studies for Imidacloprid 0.01% Gel
Justification	Acute oral toxicity studies for Imidacloprid 0.01% Gel have not been performed. The data provided for acute toxicity studies refer to a worstcase gel formulation Imidacloprid 2.15%. The main component contributing to the toxicity of the formulation is the active substance Imidacloprid, which is in a lower concentration than that present in the test item (Imidacloprid 2.15% Gel formulation). Therefore, the tests results can be exbait stationolated to the Imidacloprid 0.01% Gel formulation. It is therefore proposed that the preparation VICTOR GEL HORMIGAS is not harmful by the oral route and will remain unclassified.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Imidacloprid 2.15% Gel is not harmful by the inhalation route
Justification for the selected value	Based on the classification of 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 and DSD	The preparation Imidacloprid 2.15% Gel is not classified

Data waiving	
Information requirement	Acute inhalation toxicity studies for Imidacloprid 0.01% Gel
Justification	Acute inhalation toxicity studies for for Imidacloprid 0.01% Gel have not been performed. Taking into account the nature of the active substance, Imidacloprid, present in the formulation, 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. It is therefore proposed that the preparation VICTOR GEL HORMIGAS is not harmful by the oral route and will remain unclassified.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
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	[redacted] 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 and DSD	The preparation Imidacloprid 2.15% Gel is not classified

Data waiving	
Information requirement	Acute dermal toxicity studies for Imidacloprid 0.01% Gel preparation
Justification	Acute dermal toxicity studies for Imidacloprid 0.01% Gel have not been performed. The data provided for acute toxicity studies refer to a worstcase gel formulation Imidacloprid 2.15%. The main component contributing to the toxicity of the formulation is the active substance Imidacloprid, which is in a lower concentration than that present in the test item (Imidacloprid 2.15% Gel formulation). Therefore, the tests results can be exbait stationolated to the Imidacloprid 0.01% Gel formulation. It is therefore proposed that the formulation VICTOR GEL HORMIGAS is not harmful by the dermal route and will remain unclassified.

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] July 2013 Final, IIIB 6.4

Absorption data for each compartment	**Percentage of dose (%, mean ± SD)**
Amount in Receptor Fluid	1.20 ± 0.50
Amount in receptor compartment wash	0.03 ± 0.01
Amount in (stripped) skin	0.89 ± 0.49
Amount in tape strips 1+2	0.11 ± 0.08
Amount in tape strips 3-15	0.26 ± 0.12
Amount in skin wash	94.5 ± 2.7
Total recovery	97.0 ± 2.4
Absorbed dose [1]	2.11 ± 0.97
Potentially abosrbed dose [2]	2.37 ± 1.08
Maximal flux (µg/cm^2/h)	0.00088 ± 0.00045

[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 HORMIGAS (0.1% Imidacloprid)
Value(s)	3%
Justification for the selected value(s)	Study report, July 2013 Final, IIIB6.4

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

The biocidal product contains 0.01% (w/w) of the active substance Imidacloprid and other co-formulants. Three components of the biocidal product carry toxicological hazard classification. However, their concentration in the product does not exceed the limit for classification of the mixture according to Regulation UE Nº 1272/2008 and these co-formulants are not considered to be substances of concern.

Available toxicological data relating to a mixture

Not applicable.

Other

No other additional tests relating to exposure of Imidacloprid or the formulated product Imidacloprid 0.01% Gel, other than those outlined in previous data points are considered necessary due to the lack of risk of the different population groups that are exposed as a consequence of the intended uses.

2.2.6.2 Exposure assessment

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

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

There are no substances of concern.

Relevant exposure routes of VICTOR GEL HORMIGAS 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	**Primary (direct) exposure**	**Secondary (indirect) exposure**

path	Trained profesional use	Professional use*	Non-professional use.* (General public)	Trained profesional 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 trained-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 (trained-professional, 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**	**Exposd group[1]**
1.	Application	Primary exposure: gel application using a cartridge	Trained professionals
2.	Post application	Primary exposure: disposal of used cartridge	Trained professionals
3.	Application	Primary exposure: gel application using a cartridge/syringe	Professionals/ Non professionals
4.	Post application	Primary exposure: disposal of used cartridge/syringe	Professionals/ Non professionals
5.	Application	Primary exposure: gel application using bait stations*	all users
6.	Post application	Primary exposure: collection of used bait stations*	all users
7.	Post application	Secondary exposure: dermal and hand to mouth contact with gel	Bystander (toddler)

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

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

Industrial exposure

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

Trained professional exposure

Scenario 1. Application of VICTOR GEL HORMIGAS by trained professional users

Description of Scenario 1
For 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 pest control operators. The gel is applied in form of drops or lines in/near ant rows or nests. Per treatment an amount of 0.4g spot per m^2 or per linear meter is applied. According to the CAR the only relevant exposure route of Imidacloprid 0.01% 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	0.01%
	Dermal absorption[b]	3%
	Body weight adult[c]	60 kg

[a] *According to the CAR a string of gel estimated to be 0.5 cm long is transferred to the hand during opening or sealing the cartridge. To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information (diameter of the nozzle lumen) is not available for the packaging of AB-010 Victor Gel (see Annex 3.2).*
[b] *CAR.*
[c] *Study report July 2013 Final, IIIB6.4.*
[d] *HEEG Opinion 17.*

Calculations for Scenario [1]

See relevant calculations in Annex 3.2

Summary table: estimated systemic exposure from trained professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1	1/none	-	1.00E-05	-	1.00E-05

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

Scenario 2 Disposal of used cartridges by trained professional users

Description of Scenario 2		
For 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 event [a]	20 mg product
	number of disposed cartridges per day [b]	1
	content of active substance in product	0.01%
	Dermal absorption[c]	3%
	Body weight adult[d]	60 kg

[a] According to the CAR a string of gel estimated to be 0.5 cm long is transferred to the hand during opening or sealing the cartridge. To calculate the amount of product, the CAR assumes that the inner diameter of the "gage needle" is 1 mm. However, this information (diameter of the nozzle lumen) is not available for the packaging of AB-010 Victor Gel (see Annex 3.2).
[b] CAR.
[c] Study report July 2013 Final, IIIB6.4
[d] HEEG Opinion 17

Calculations for Scenario [2]
See calculations in Annex 3.2

Summary table: estimated systemic exposure from trained professional uses (mg/kg bw/d)

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario 2	1/none	-	1.00E-06	-	1.00E-06

Combined scenarios

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

Summary table: combined systemic exposure from 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	-	1.10E-05	-	1.10E-05

Professional exposure

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

General public (Non-professional) exposure

Scenario 3. Application of VICTOR GEL HORMIGAS 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. For non professionals exposure is estimated using the models and assumptions presented in the original CAR adapted to consumer use according to expert judgment. It is assumed as a worst case that a consumer applies the product every two weeks during 6 months per year (ants are expected during spring and summer). Medium term exposure is expected. The gel is applied as round spots or thin lines close to ant harborages, foraging and feeding areas such as corners and cracks and crevices for indoor and outdoor control of ants. 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	0.01%

	Dermal absorption[c]	3%
	Body weight adult[d]	60 kg

[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] Study report July 2013 Final, IIIB6.4
[d] HEEG Opinion 17.

Calculations for Scenario [3]

See calculations in Annex 3.2

Summary table: estimated systemic exposure from non-professional uses (mg/kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 3	1/none	-	2.00E-06	-	2.00E-06

Further information and considerations on scenario [3]

None.

Scenario 4 Disposal of used syringe of VICTOR GEL HORMIGAS 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 (ants 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 syringe disposed off per event [b]	1
	content of active substance in product	0.01%
	Dermal absorption [c]	3%
	Body weight adult [d]	60 kg

[a] Packaging specifications for syringes do not include information on the diameter of the nozzle lumen. In a similar way as above, 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] Study report July 2013 Final, IIIB6.4
[d] HEEG Opinion 17.

Calculations for Scenario 4
See calculations in Annex 3.2

Summary table: estimated 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	-	1.00E-06	-	1.00E-06

Further information and considerations on scenario 4
None

Combined scenarios

Total exposure of consumers during the use of VICTOR GEL HORMIGAS 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	-	3.00E-06	-	3.00E-06

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

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

Indirect (Secondary) Exposure of Bystanders

Indirect exposure scenarios are described in the following

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

Description of Scenario 7

According to the definitions in HEEG Opinion 17, the population under consideration here are toddlers (1-2 years old) who can explore their environment and exhibit hand to mouth transfer of residues. Secondary exposure can be considered as occasional and of short-term (not continuous) and therefore the exposure is considered as acute. Considering that the product is applied in lines/drops on localized spots (there is not an uniform application on surfaces as paints, for example), the following scenario assumes that a toddler contacts certain amount 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 3% dermal absorption.		
	Parameters[1]	Value
Tier 1	Amount of product contacted per event [a]	40 mg product
	content of active substance in product	0.01%
	Dermal absorption [b]	3%
	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.*
[b] *Study report July 2013 Final, IIIB6.4*
[c] *ConsExpo Pest product fact sheet RIVM report 320005002 (Crack & Crevice Use – Post Application; pp. 28)*
[d] *HEEG Opinion 17.*

Calculations for Scenario 7

See calculations in Annex 3.2

Summary table: systemic indirect exposure as result of use (mg/ kw bw)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 7	1/none	-	1.20E-05	2.00E-04	3.20E-04

Further information and considerations on scenario 7

Tier 1 estimations presented here is a worst case assumption where the dislodgeability is 100% and the effect of the bittering substance in the ingestion is not considered.

Considering the application pattern of VICTOR GEL HORMIGAS 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).

Reverse reference scenario

The maximum amount of active substance allowable for toddlers can be estimated using a reverse reference scenario. As exposure is considered occasional, AEL short term will be used for calculations. Considering that the dermal absorption of the product is 3% and the oral absorption is 100%, the allowable dose is estimated below assuming oral exposure as a worst case.

AEL short term is 0.4 mg/kg bw;

Given that toddler body weight is 10 kg, then active substance contamination would need to exceed:

0.4 mg /kg bw * 10 kg = 4 mg active substance (in a single event).

As the maximum concentration of active substance in the product is 0.01% w/w, then the weight of gel product containing 4 mg active substance will be:

4/0.01 x100 = 40,000 mg.

The value of 40 grams of biocidal product is compared to the amount of product ingested per event in Scenario 7 described above (20 mg). On this basis, for acute exposure, it is concluded that a margin of safety of a least 2,000 will be achieved.

Combined scenarios

Not applicable

Monitoring data

Not applicable

Dietary exposure

Food contamination as result of use

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

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

Conclusion

Dietary risk does not have to be further considered.

The following label restrictions preclude food contamination:

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

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference values [2]**
1.	Plant protection product	Seed, soil, trunk and foliar treatments	MRL[2]
2.	Veterinary use	treatment of domestic pets to control fleas	Withdrawal period n.a.[3]

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

Estimating Livestock Exposure to Active Substances used in Biocidal Products

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

In conclusion, the label must include restrictions or instructions of use to avoid exposure of animals or contamination of feedstuff in the event that the biocidal product is applied in animal husbandry by professional 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.
- Keep away from feedingstuff or feed contact surfaces.

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

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

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

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

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.

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

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	1.00E-05 mg/kg bw/ d
2. Post-application	Trained professional	Tier 1 /none	1.00E-06 mg/kg bw/d
3. Application	Professional, Non-professional	Tier 1 /none	2.00E-06 mg/kg bw/d
4. Post-application	Professional, Non-professional	Tier 1 /none	1.00E-06 mg/kg bw/d
7. Indirect exposure	Bystanders (toddler)	Tier 1 /none	3.2E-04 mg/kg

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-	two year chronic toxicity study in	6 mg/Kg bw/day	100	-	0.06 mg/Kg

term	rats				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	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application/ Scenario 1	1	6	0.06	1.00E-05	0.02	yes
Post application/ Scenario 2	1	6	0.06	1.00E-06	0.00	yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application/ Scenario 1 & Post application/ Scenario 2	1	6	0.06	1.10E-05	0.02	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 dose of 1.1E-5 mg/kg bw/day during the application and postapplication processes combined. The estimated uptake represents less than 0.1% of the proposed AEL of 0.06 mg/kg bw/day.

The assessment indicates an acceptable risk for professional users.

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

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

Systemic effects: combined exposure for professionals and non-professionals

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application / Scenario 3	1	20	0.2	2.00E-06	0.00	Yes
post application/ Scenario 4	1	20	0.2	1.00E-06	0.00	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Application/ Scenario 3 & Post application/ Scenario 4	1	20	0.2	3.00E-06	0.00	yes

Local effects.

Not applicable

Conclusion

The medium term exposure assessment for professional and non-professional users under worst case assumptions yields a potential dermal exposure leading to systemic doses below 1E-05 during the application and postapplication processes combined. The estimated uptake represents less than 0.1% of the proposed AEL of 0.2 mg/kg bw/day.

The assessment indicates an acceptable risk for professional and non-professional users.

No risk is envisaged for the use of VICTOR GEL HORMIGAS 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	AEL mg/kg bw	Estimated uptake mg/kg bw	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Dermal and hand to mouth contact for toddlers/ Scenario7	1	40	0.4	3.2E-04	0.09	Yes

Combined scenarios secondary exposure

No combined exposure is foreseen.

Local effects

Not applicable.

Conclusion

The short term exposure assessment for toddlers under worst case assumptions leads to systemic doses below 1E-03 mg/kg bw during the indirect exposure via oral and dermal route after the application of the biocidal product. The estimated uptake represents less than 0.1% of the proposed AEL of 0.4 mg/kg bw.

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

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

Risk for consumers via residues in food

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

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

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

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

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

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

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):

- Keep away from feedingstuff or feed contact surfaces.

No risk is envisaged for animal health.

2.2.8 Risk assessment for the environment

VICTOR GEL HORMIGAS is an indoor/outdoor gel insecticide to be applied via droplets by using a cartridge/syringe or bait stations. It is going to be used against ants (*Lasius* spp., *Tetramorium caespitum*, *Myrmica rubra*, *Tapinoma erraticum*) and tropical ants (*Linepithema humile*, *Monomorium pharaonis*). This product is going to be used by general public (non-professional use), professional users and trained professional.

VICTOR GEL HORMIGAS is a gel contained 0.01% of the active substance imidacloprid combined with a number of co-formulants. The Annex I assessment of this active substance, imidacloprid, was supported by two active formulations GR0.5 and GL2.15, contained 0.5 and 2.15% of the active substance, respectively. The biocidal product GL2.15, is a gel; it is a ready-to-use bait for indoor use. The product GR 0.5, is a ready-to-use granular bait. It is a bait for '*indoor use in rural hygiene situations*' that is '*for use in animal houses and/ or other agricultural buildings*', leading to '*rapid knockdown and mortality of insect*'. VICTOR GEL HORMIGAS is the same type of formulation as GL2.15, both are gel. 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. The applicant has calculated the exposure level in each environmental compartment and compared this to the most sensitive PNEC value. The applicant, as it is stated in the

imidacloprid CAR, has used the last version of ESD PT 18 and the Manual Technical Agreements (MOTA).

The applicant has a letter of access to all data presented by Bayer Environmental Science that supported the original Annex I listing of imidacloprid. At Annex I level Bayer Environmental Science was able to demonstrate the safe use of GL2.15 for the emission scenario, gel application. 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.

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

2.2.8.1 Effects assessment on the environment

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

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

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

$PNEC_{sediment}$, 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.**

$PNEC_{microorganisms}$ (STP) = 100 mg/l. According to the TGD on Risk Assessment (ECB Part II, 2003), the PNEC for microorganisms in a STP is derived by dividing the NOEC from a respiration inhibition test (OECD 209) by a factor of 10 or by dividing the EC_{50} by a

factor of 100. The lowest value should be chosen for PNEC derivation. The NOEC and EC_{50} values of Imidacloprid were determined to be 10000 mg/l (Document IIA 4.2.1).

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

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

Further Ecotoxicological studies

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

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.

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

The biocidal product VICTOR GEL HORMIGAS is a ready to use insecticide gel contained either in sealed cartridges/syringes for spot/line applications in cracks and crevices and it is contained in ant bait stationsto be placed close to ant rows and nests. The biocidal product is intended to be used in- and outdoors. Due to this kind of formulation and application of both ready to use products (syringe/cartridge and bait station), the following release pathways can be identified or excluded to be relevant for environmental exposure:

Indoor application

Mixing/loading

In the biocidal product VICTOR GEL HORMIGAS the gel is contained in sealed systems (syringe/cartridge and bait stations) and marketed as a ready to use form. Emissions from mixing and loading steps are not to be expected and are therefore not assessed.

Application

Evaporative loss of imidacloprid from the product is negligible because of its low vapour pressure (4×10^{-10} Pa at 20°C). A release to air during the application of VICTOR GEL HORMIGAS is not expected.

Due to the product form (sealed syringe/cartridge and bait station), the mode of application, and the characteristics of the active substance (non-volatile), exposure to the applicator is not expected.

Releases to the environment may occur when contaminated insects carry the active substance to the surrounding area. Ants are social insects and may also bring back the active substance with them when returning to the colony. However, this amount is going to be minute and hardly to quantify. All releases are therefore expected to be emitted from treated surfaces of the target areas.

Cleaning step

For the indoor application, removal by wet cleaning is considered to be the major route of environmental release. The removal can occur to the applied gel as well as to ant faeces that can be spread on exposed surfaces. As explained in the section "Application" above, only negligible amounts of bait material may be dispersed by the ants on their pathways. Furthermore according to the ESD (OECD, 2008), the nature of the product application either in the form of gel drops (syringe and cartridge use) in targeted areas is such, that the biocidal product is largely protected from cleaning processes. At the end of the efficacy period, the product or waste water containing product residues must not be disposed of in municipal sewer systems, drains or rivers, but at authorized municipal waste collecting points. Furthermore it is assumed that no release will occur during the service life for gels deployed in bait stations (OECD, 2008). Consequently, emission to STPs is therefore not expected for both formulations.

In summary, the indoor use of the biocidal product VICTOR GEL HORMIGAS does not lead to noteworthy emissions of imidacloprid to the environment. But for reasons of completeness, a risk assessment for the exposure route via wet cleaning is performed for

the potential release of imidacloprid from the application of gel drops or lines in/near ant rows or nests.

Outdoor application

Mixing/loading

Cf. Indoor application.

Application

Due to the formulation of the product and the characteristics of the active substance, no emissions to air and to the applicator are to be expected.

Most of the utilisation of the biocidal product takes place during spring and summer, when target organism populations increase (OECD, 2008).

In the case of the drop application via syringe or cartridge, it is recommended to treat with small deposits of gel on ant pathways, around terraces or patios close to habitation entrances. The gel 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 general practice to collect 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). The main compartments potentially being exposed to substances applied to paved surfaces are the surface water via rainwater and/or sewage treatment plants (STP) and subsequently, soil from sludge application and groundwater from soil leaching. 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. Applying the biocidal product outdoors can result in residues reaching terraces where the gel drops have been placed. These residues can be washed-off, ending up in the surrounding garden soil. Therefore 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 HORMIGAS.

In the case of the bait station, the insecticide is contained in a sealed box and placed in the neighbourhood of insect's tracks. Bait stations are generally placed on hard surfaces such as terrace or patio close to habitations entrance. The placing of these bait stations on bare soil or on lawn is not a regular consumer practice. The insecticides used in ant bait stations act by ingestion/contact and are carried back to the nest by contaminated animals. For these products, emissions to the environment during the treatment are negligible. Furthermore, the bait stations are made of plastic which do not allow spillage of substance around the bait station. The only possible emission may occur from the transport of product by contaminated insects or following flooding from a rain event. It might be more likely that a proportion of wash-off from a treated terrace will enter the soil in the surrounding garden.

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 ants or by the consumption of earthworms from contaminated soils. Hence, potential concentrations in earthworms and ants 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.

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

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

Leaching behaviour (ADS)

No relvant.

Testing for distribution and dissipation in soil (ADS)

No relevant.

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

No relevant.

Testing for distribution and dissipation in air (ADS)

No relevant.

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

No relevant.

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

No relevant.

2.2.8.2 Exposure assessment

General information

Assessed PT	*PT 18*
Assessed scenarios	Scenario 1: Private houses and large buildings. Indoor use. Crack and crevices Scenario 2: Private houses and large buildings. Indoor use. Surface treatment Scenario 3: Private houses and large buildings. Outdoor use, direct emissions. Scenario 4: Private houses and large buildings. Outdoor use, indirect emissions.
ESD(s) used	Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses.
Approach	A consumption based approach has been used as a suitable protective measure at the local level.
Distribution in the environment	Calculated based on TGD 2003 (alternative: based on measured data)
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	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.
Remarks	None

Emission estimation

The biocidal product VICTOR GEL HORMIGAS (AB-020) is an insecticidal gel (PT 18) containing 0.01% of the insecticidal active substance imidacloprid. The biocidal product is efficacious against ants (*Lasius* spp.). The biocidal product is meant to be applied in- and outdoors of private houses and large buildings.

VICTOR GEL HORMIGAS is available in two forms:

The ready to use product for the spot application in cracks and crevices is contained in cartridges and syringes. For big uses, the product is contained in a cartridge (size of 30, 35, 75, and 300 g) and applied with a pistol applicator; for small uses, the product is

contained in a syringe (sizes of 3, 5, 10, and 20 g) ready to use for application. For indoor use, the gel should preferably be applied in the form of drops or lines in/near rows and/or nests of ants. The applied amount per indoor treatment is 1 point of gel or 1 thin line of gel of 0.4 g product per m^2 (one point of gel of 1cm is equivalent to 0.4g of product and one thin line of gel of 5cm is equivalent to 0.4g of product) equivalent to 0.04 mg imidacloprid per m^2. For outdoor use, a 5 g gel spot is to be applied near ant rows or nests resulting in 0.4 g product per m^2 (0.04 mg a.s./m^2) assuming a nest activity range of 12 m^2.

The ant bait station is to be used near ant rows or nests for both in- and outdoor use. Each bait station contains 5 g of the insecticidal gel resulting in 0.04 mg a.s./m^2 assuming a nest activity range of 12 m^2.

Indoor use, scenarios: 1 and 2

In the case of the syringe and cartridge ready to use product, the biocidal product VICTOR GEL HORMIGAS is applied indoors in localized spots such as cracks and crevices in the form of drops or lines near rows of ants when they enter places and their nests under food cabinets, sinks, ovens, refrigerators, garages, cellars, bathrooms, closets, etc . These areas are usually inaccessible to man and animal. However as worst case consideration, emissions of imidacloprid to the environment 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 main exposed environmental compartments comprise STP and the adjacent surface water and sediment compartment. According to the use instructions and the infestation level, the application rate of VICTOR GEL HORMIGAS is 1 spot (with 0.4 g product each spot) per m^2 being equivalent to 0.04 mg imidacloprid per m^2. As a general approach, a single indoor application against heavy infestation with ants is assumed with 1 spot per m^2 containing in total 0.04 mg imidacloprid. This application is followed by a wet cleaning event. The emissions from the spot application of VICTOR GEL HORMIGAS in targeted areas such as cracks and crevices are calculated for both applications in private houses and large buildings using the default values as agreed upon in the MOTA (2011). The default value used for spot or crack and crevice treatment for a domestic house and a large building is 2 and 9.3 m^2, respectively; and and the default values for surface treatment in private house and large building is 38.5 and 609 m^2, respectively,

In the case of the indoor use of ant bait stations, emission to the surrounding area is not to be expected during the service life stage of the bait station containing VICTOR GEL HORMIGAS. At the end of the service life, the product waste is to be disposed in municipal waste collecting points. Consequently, no product will be exposed to cleaning and the calculation of emissions to STP is not deemed appropriate.

Scenario 1

Application in crack and crevices

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Scenario: outdoor use, direct release			
Quantity of b.p. applied (Q_{bp})	0.4	g/m^2	

Fraction of the active substance in the product (F_{ai})	0.0001		
Quantity of a.s. applied (Q_{as})	$4x10^{-5}$	g	
Number applications per day	1	-	
Number of point per area	1	-	
Fraction emitted to treated surfaces during application (F_{appl})	1	-	
Area treated with the product [m^2] (private houses)	2		
Area treated with the product [m^2] (large buildings)	9.3		

Calculations for Scenario 1

Cleaning

The ESD provides fractions of insecticide being exposed to cleaning by either wet or dry cleaning methods. Wet cleaning refers to any method that uses water. According to the nature of gel spot applications (OECD PT18, 2008), the biocidal product is placed in areas difficult to access which results in a low cleaning efficacy. Moreover waste waters containing product residues are not to be exposed into drains or the environment according to the disposal considerations. For worst case considerations, wet cleaning of the surfaces with a 3% removal rate is assumed. The residues removed enter the wastewater compartment via the drainage system (OECD PT18, 2008).

Table: Emission scenario for calculating the release of imidacloprid during cleaning

Parameter	**Definition**	**Value**	
		Private houses	**Large buildings**
Emission to floor during application step [g/d]	$E_{application, floor}$	0	
Emission to treated surfaces during application step [g/d]	$E_{application, surface}$	0.00008	0.000372
Fraction emitted to wastewater during the cleaning step	F_{WW}	1	
Cleaning efficiency	F_{CE}	0.03	
Emission from treated surface to wastewater during cleaning step [g/d]	**$Elocal_{ww} = (E_{application, floor} + E_{application, surface}) \times F_{WW} \times F_{CE}$**	**2.400×10^{-6}**	**1.116×10^{-5}**

For the emission estimation for insecticides for the indoor uses, the default number of private households and larger buildings per STP is set to 4000 and 300, respectively. 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) + (32.15*1.9) + (37.82 * 0.54))/100).

Regarding the environmental compartments, the water releases from households and larger buildings have to be summed up to perform a cumulative assessment.

Table: Summary of imidacloprid emissions to wastewater by indoor use of VICTOR GEL HORMIGAS

Parameter	Definition	Value	
		Private houses	Large buildings
Emission from treated surface to wastewater during cleaning step [g/d]	$Elocal_{ww}$	2.400×10^{-6}	1.116×10^{-5}
Simultaneously treated houses per STP [-] [1]	N_{houses}	4000	300
Simultaneity factor [-]	$F_{simultaneity}$	0.0275	
Emission to wastewater [g/d]	$\mathbf{E_{ww} = Elocal_{ww} \times N_{houses} \times F_{simultaneity}}$	$\mathbf{2.64 \times 10^{-4}}$	$\mathbf{9.57 \times 10^{-5}}$
Total emission to wastewater [kg/d]	$\mathbf{E_{ww\ total} = \Sigma(E_{ww})/1000}$	$\mathbf{3.597 \times 10^{-7}}$	

For the indoor use of VICTOR GEL HORMIGAS, the cumulative assessment results in a release of 3.597×10^{-7} kg imidacloprid per day.

Scenario 2

Surface treatment

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: surface application in a house and large buildings.			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	0.4	g/m²	1 drops/ m^2 (each drop contains 0.4 g of product)
Concentration of active substance in the product	0.1	g/Kg	
Number applications per day	1	-	
Number of point per area	1	-	
Area treated with product (private houses)	38.5	m^2	

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

Calculations for Scenario *2*

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

Table 2.8.1-1: Release of imidacloprid during application (ESD PT18, 2008)

Parameter	**Definition**	**Value**	
		Private houses	**Large buildings**
Number of application per day	N_{appl}	1	
Number of point per area	N_{point}	1	
Fraction emitted to treated surfaces during application	F_{appl}	1	
Quantity of commercial product applied per point of gel [g/point]	$Q_{prod,\ point}$	0.4	
Fraction of active substance in the commercial product	F_{ai}	0.0001	
Area treated with product [m2]	$AREA_{treated}$	38.5	609
Emission rate to treated surface during application [g/d]	$\mathbf{E_{application,\ surface} = Q_{prod,\ point} \times N_{point} \times F_{ai} \times AREA_{treated} \times F_{appl} \times N_{appl}}$	**1.54E-03**	**2.44E-02**

Cleaning

Releases to wastewater during cleaning event depend on the efficiency of the cleaning. It is considered that the cleaning efficiency (FCE) for the use of the VICTOR GEL HORMIGAS represents a maximum exposition to cleaning of 25% for household and large buildings according to the CEFIC Insecticides Working Group, considering that this type of product is applied in areas difficult to access and not subject to cleaning (ESD PT18, 2008).

Table 2.8.1-2: 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 [g/d]	$E_{application, surface}$	1.54E-03	2.44E-02
Fraction emitted to wastewater during cleaning step	F_{ww}	1	
Cleaning efficiency	F_{CE}	0.25	
Emission rate to wastewater during cleaning step [g/d]	**$Elocal_{ww}$ = ($E_{application, floor}$ + $E_{application, surface}$) x F_{ww} x F_{CE}**	**3.85E-04**	**6.09E-03**

Emissions have been calculated for one house and one large building, according to the ESD these values have to be multiplied by the number of houses, 4000, and large buildings, 1000. The number of large buildings has been refined from 1000 to 300 (TMI 2010)

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

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

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

Table 2.8.1-3: 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]	$Elocal_{ww}$	3.85E-04	6.09E-03
Simultaneously treated houses per STP [-]	N_{houses}	4000	300
Simultaneity factor[-]	$F_{simultaneity}$	0.00815	
Emission to wastewater [g/d]	**$Elocal_{ww}$ = $Elocal_{ww}$ x N_{houses} x $F_{simultaneity}$**	**1.26E-02**	**1.49E-02**
Total emission to wastewater [kg/d]	**$E_{ww\ total}$ = Σ(E_{ww})/1000**	**2.74E-05**	

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	**2.74E-05**	Worst case private house + large buildings

Outdoor use, scenarios: 3 and 4

Due to the propose use of the biocidal product outdoor, the application mode can be described as spot application. Environmental exposure may arise following flooding form 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.

Scenario 3

Outdoor application (direct emissions)

As it is stated by the applicant, two application modes apply for VICTOR GEL HORMIGAS: application of a 5 g gel drop close to ant nests and application of a 5 g gel contained in a bait station near ant rows or nests. Assuming a nest activity range of 12 m^2 and a concentration of 0.01% (w/w) imidacloprid in the insecticidal gel, an amount of 0.04 mg imidacloprid per m^2 is expected. Emissions of imidacloprid to the outdoor environment may occur when the biocidal product is applied near ant nests or pathways, generally on terraces or patios close to habitation entrances. Placing bait stations on bare soil or on lawn is not a regular consumer practice. However, residues reaching terraces may be washed-off to adjacent garden soil via rainwater and flooding events.

In the case of the uncovered spot application (syringe/cartridge), it is considered that the gel is applied on paved ground such as terraces, but not on bare soil. It is not common practice to collect unconsumed product. Therefore, it is considered that the fraction released during gel application to the environment is 90%, either directly or through ultimate release after target insect death. A fraction $F_{spot,gel}$ = 0.9 is assumed to be potentially released to the environment from the uncovered spot application.

In the case of the bait station, the device is made from hard material which would not allow the spillage of substance around. Nevertheless releases may occur from the transport of product by contaminated insects or following flooding from a rain event. According to the ESD PT18 (OECD, 2008), about 80% is consumed by the insects whereas 20% remain in the bait station and can be emitted into the environment. Therefore, a fraction $F_{spot,bait}$ = 0.2 is assumed to be potentially released to the environment from the ant bait station.

In both cases, the product VICTOR GEL HORMIGAS is applied outdoors on paved ground such as terraces. In the ESD for PT 18 (OECD, 2008) typical buildings are defined and their dimensions are determined. For private houses, the size of the terrace is assumed to

amount to 30 m^2. According to the intended use of VICTOR GEL HORMIGAS, the product application of 5 g gel covers a nest activity area of 12 m^2. This results in a possible application of three uncovered spots or three bait stations on the terrace target area.

Product residues are assumed to reach the surrounding garden soil of the terrace due to wash-off with rainwater or flooding events. In the following table, the local emission to the adjacent garden soil is calculated.

Parameter	**Definition**	**Value**	
		Uncovered spot	**Bait station**
Amount of product each spot [g]	Q_{prod}	5	
Fraction of active substance in product [-]	F_{AI}	0.0001	
Number of application sites [-]	N_{sites}	3	
Number of application [-]	N_{appl}	1	
Fraction emitted to soil during outdoor gel application [-]	$F_{spot,gel}$	0.9	0.2
Emission rate of the active substance to soil from a campaign [g/d]	**$E_{spot,soil} = Q_{prod} \times F_{AI} \times N_{sites} \times N_{appl} \times F_{spot,gel}$**	**0.00135**	**0.0003**

Concentrations in the soil around the spot application after direct release can be stimated by equation (60) from ESD PT18:

Parameter	**Definition**	**Value**	
		Uncovered spot	**Bait station**
Emission rate of the active substance to soil from a campaign [g]	**$E_{spot,soil}$**	**0.00135**	**0.0003**
Area directly exposed to insecticide [m^2]	$AREA_{exposed}$	0.25	
Depth of exposed soil [m]	$DEPTH_{soil}$	0.5	
Volume of soil exposed [m^3]	$VOLUME_{soil}$	0.125	
Density of exposed soil RHO [kg· m^{-3}]	RHO_{soil}	1700	
Local concentration in soil due to direct release after a campaign [mg kg]	**$C_{spot,soil} = E_{spot,soil} / AREA_{exposed} \times DEPTH_{soil} \times RHO_{soil}$**	**6.35×10^{-6}**	**1.41×10^{-6}**

Scenario 4

Outdoor application (indirect emissions)

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

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: outdoor use, indirect releases			
Quantity of b.p. applied (Q_{bp})	0.4	g	
Fraction of the active substance in the product (F_{ai})	0.0001	-	
Quantity of a.s. applied (Q_{as})	4x10-5	g	
Application rate of the b.p. ($APP_{b.p.}$)	1	Spot/m	
Perimeter treated with the product ($PERIMETER_{Treated}$)	250	m	
Number applications per day (N_{appl})	1	d^{-1}	
Number of point per area (N_{sites})	250	-	
Fraction emitted to STP during outdoor gel application ($F_{spot,gel}$)	0.9	-	
Number of houses connected to SPT (N_{houses})	300		
Simultaneitey factor (F_{sim})	0.03		

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

Calculations for Scenario 4

Local direct emission rate to STP per treatment

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

$E_{spot,\ STP} = 9 \times 10^{-3}\ g.d^{-1}$

Simultaneous emission to waste water during outdoor use:

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

$Elocal_{water,\ sim} = 8.1x10^{-2}\ g.d^{-1}$

Sumary of local emissions

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{water, sim}$) [kg/d]**	**Remarks**
STP	3.59×10^{-7}	Scenario 1, indoor use, crack and crevices
STP	2.74×10^{-5}	Scenario 2, indoor use, surface treatment
SOIL	6.35×10^{-6}	Scenario 3, outdoor use (direct emissions), uncovered spot as worst case
STP	8.1×10^{-5}	Scenario 4, outdoor use (indirect emissions)

Fate and distribution in exposed environmental compartments

[If no data is available, delete the tables and indicate only that no data is available.]

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	Descomposition	°C	
Vapour pressure (at XC)	<0.1	Pa	
Water solubility (at X°C)	613	mg/l	
Log Octanol/water partition coefficient	0.57	Log 10	
Organic carbon/water partition coefficient (Koc)	230	l/kg	
Henry's Law Constant (at X C)*[if measured data available]*	1.7×10^{-10}	Pa/m3/mol	
Biodegradability	No		
Rate constant for STP *[if measured data available]*	2.75 years at 12 ºC/ pH 9	d or hr (at 12ºC /pH)	
DT_{50} for biodegradation in surface	DT50 calculated:	d	

water	1.4 - 16 days (fall, winter) 0.5-1.6 days (spring, summer) 0. 2 - 1.6 days (spring, summer)		
DT_{50} for hydrolysis in surface water	295 days	d (at 12ºC)	
DT_{50} for photolysis in surface water	2.54	hr	
DT_{50} for degradation in soil	295	days	
DT_{50} for degradation in air	144	°C	

Calculated fate and distribution in the STP *[if STP is a relevant compartment]*		
Compartment	Percentage [%]	Remarks
	Scenario 1 and 2	
Air	3.72×10^{-10}	
Water	97.2	
Sludge	2.79	
Degraded in STP	0	

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}[1]**	**PEC_{air}**
	[mg/L]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg]	[µg/l]	[mg/m^3]
Scenario 1	$1.74x10^{-7}$	$1.74x10^{-8}$	$1.01x10^{-7}$	-	-	$2.63x10^{-8}$	$6.30x10^{-6}$	
Scenario 2	$1.33x10^{-5}$	$1.33x10^{-6}$	$7.70x10^{-6}$			$2.01x10^{-6}$	$4.81x10^{-4}$	
Scenario 3	-	-	-	-	-	$6.35x10^{-6}$	$1.52x10^{-3}$	
Scenario 4	$3.94x10^{-5}$	$3.94x10^{-6}$	$2.28x10^{-5}$			$5.94x10^{-6}$	$1.42x10^{-3}$	

PEC values has been calculated according to Guidance on the BIocidal Products Regulation (April 2015) and using EUSES 2.

Primary and secondary poisoning

Primary poisoning

Effects 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 0.038 µg per bee, respectively (Imidacloprid IIA, 8.3.1.1/01(BAY 158/901384). The product VICTOR GEL HORMIGAS contain a concentration of imidacloprid of 0.01% w/w, the quantity of product necessary to reach LD_{50} oral and the LD_{50} contact are 37 µg and 810 µg, respectively. The product is a ready to use gel bait with a high contain of sugar. VICTOR GEL HORMIGAS is applied by drops or lines (elongated drops) where ants are present, the application rate is 1 drop/m^2 (1 drop=1 line of 5 cm lenght=0.4 g of gel bait). Therefore, the exposure of a honeybee to the product and its mortality after consuming the biocidal product, VICTOR GEL HORMIGAS cannot be excluded.

Secondary poisoning

During the utilisation of VICTOR GEL HORMIGAS in the form of gel droplets, birds and mammals may be poisoned secondarily through the ingestion of contaminated ants or by the consumption of earthworms from contaminated soils (release from treated terrace via wash-off).

Secondary poisoning via the consumption of contaminated worms

Parameter	**Value**	
	Mammals	**Birds**
Estimated theoretical exposure [mg/kg x d]	1.97×10^{-4}	1.55×10^{-4}

Secondary poisoning for insectivorous species via the consumption of contaminated ants

Parameter	**Value**	
	Acute toxicity	**Short-term toxicity**
Estimated theoretical exposure-Small insectivorous bird 1 [mg/kg x d]*	2.70×10^{-9}	1.51×10^{-9}
Estimated theoretical exposure-Small insectivorous bird 2 [mg/kg x d]	5.20×10^{-10}	2.90×10^{-10}

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	1.74E-09
Scenario 2	1.33E-07
Scenario 4	3.94E-07

Conclusion:

Scenarios 1 and 3: As the PEC/ PNEC values are less than 1, an acceptable level of risk to STP is predicted from this scenario.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Scenario 1	3.63E-03	3.88E-03		
Scenario 2	0.27	0.29		
Scenario 4	0.82	0.86		

Conclusion:

Scenarios 1 and 3: As the PEC/ PNEC values are less than 1, an acceptable level of risk to the aquatic compartment is predicted from this scenario.

Terrestrial compartment

Calculated PEC/PNEC values

	PEC/PNEC$_{soil}$
Scenario 1	1.67E-6
Scenario 2	1.27E-4
Scenario 3	4.03E-4
Scenario 4	3.77E-4

Conclusion:

Scenario 1, 2 and 3: As the PEC/ PNEC values are less than 1, an acceptable level of risk to soil is predicted from this scenario

Groundwater

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

Primary and secondary poisoning

Primary poisoning

The product is a ready to use gel bait with a high contain of sugar. VICTOR GEL HORMIGAS is applied by drops or lines (elongated drops) where ants are present, the application rate is 1 drop/m^2 (1 drop=1 line of 5 cm lenght=0.4 g of gel bait). Therefore, the exposure of a honeybee to the product and its mortality after consuming the biocidal product, VICTOR GEL HORMIGAS , cannot be excluded.

Considering the risk to this product of non- target arthropods when the product is applied outdoor we should limited its use to be used inside of bait stations and not to grant authorisation for using the product outdoors by uncovered spot applications

Secondary poisoning

Risk quotients for secondary poisoning (worm eating predators)

Compartment	**ETE$_{earthworm}$ [mg /kg bw earthworm]**	**PNEC$_{earthworm}$ [mg a.s./kg bw/d]**	$\frac{PEC}{PNEC}$
Earthworms-eating mammals	1.97×10^{-4}	0.66	2.98×10^{-4}
Earthworms-eating birds	1.55×10^{-4}	0.31	5.00×10^{-4}

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

For insectivorous species, the estimated theoretical exposure was also calculated. Insectivorous mammals are assumed to eat large insects; therefore an assessment for mammals is not indicated in this context. Small birds are assumed to prefer small insects,

therefore the residue values of 52 and 29 mg/kg (acute and short-term exposure, respectively) and the food intake rate per body weight (FIR/bw) of 1.04 were set as the default values for small insectivorous birds to cover the worst case.

Risk quotients for secondary poisoning (Small insectivorous bird species)

Compartment	**ETE [mg a.s./kg]**	**PNEC oral, birds [mg a.s./kg bw/d]**	$\frac{PEC}{PNEC}$
Small insectivorous bird - acute toxicity	2.70×10^{-9}	0.31	8.77×10^{-9}
Small insectivorous bird - short-term toxicity	1.51×10^{-9}	0.31	4.87×10^{-9}

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.

Conclusion:
PEC/ PNEC values are less than 1, an acceptable level of risk from the the secondary poisoning is predicted from this scenario.

Overall conclusion on the risk assessment for the environment of the product
Based upon the calculated PEC/ PNEC ratios, it should be noted that acceptable risks are predicted to all environmental compartments for the following proposed indoor and outdoor uses of this product. PEC/PNEC ratios has been calculated for the worst case, utdoor use as a gel in private house and commercial buildings. Hence the authorisation of the product can be granted from an environmental fate and behaviour perspective.

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 the product is kept properly packaged.

- Proper measures must be taken in order to ensure that food, equipment or any utensil handled in sites previously treated with the product do not contain residues of the active substance.

Professional/Non-professional uses:

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

Emergency measures to protect the environment:
Environmental Precautions:

Prevent the contamination of sewers, water and ground. Do not discharge into the environment. If the product enters sewers or public waters, notify to the authorities.

Methods for cleaning up:

Adsorb the spilled product by sand or adsorbent inert materials. Deposit it in closed packages and manage it following the legislation for industrial residues. In case of great spill, use dikes of inert materials. Make sure the total decontamination of the tools and equipment used in the cleaning works.

2.2.10 Assessment of a combination of biocidal products

Not applicable.

2.2.11 Comparative assessment

Background
The Spanish competent authority has been processing an application for a biocidal product, VICTOR GEL HORMIGAS 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 HORMIGAS 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-CT010826-28
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 HORMIGAS

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 HORMIGAS is an insecticide (PT18) which contains the active substance imidacloprid. The product is to be used indoors and outdoors by trained professionals, professionals and non-professionals to control ants.

Table 3.1 List of intended uses of the biocidal product:

Product type	Insecticide (PT 18)
Where relevant, an exact description of the authorised use	This product can only be used to control ants
Target organism (including, where relevant, development stage)	*Lasius spp, Tetramorium caespitum, Myrmica rubra, Tapinoma erraticum Linepithema humile, Monomotium pharaonis*
Field(s) of use	Indoor and outdoor use
Application method(s)	Gel, ready to use product
Categories of users	Trained professionals, professionals and non-professionals.

4.- Mapping of existing alternatives to the relevant BP

4.1.- Identified eligible alternative BPs

The product VICTOR GEL HORMIGAS has been only compared with alternative products authorised in Spain as the searchable SPCs and a corresponding search tool in the Register for Biocidal Products (R4BP) is currently not available. The Spanish CA has used the information available to the ES CA on the 30th of January 2017 of the biocidal products authorised under the Directive 98/8/EC or Regulation (EU) No 528/2012. In Spain, 26 products PT18 have been authorised. These products are based in ten active substances but only four of these actives substances are used for the control of ants: indoxacarb, espinosad, fipronil and deltamentrin.

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

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

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

Active substance/ mode of action combination

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

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

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

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

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

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

5.3.- Conclusion of the screening phase:

Stop the comparative assessment. The ES CA concludes that there is not an adequate chemical diversity for products to control ants for indoor and outdoor use by pofesionals and non-professionals.

The comparative assessment is finalised at this stage. The product VICTOR GEL HORMIGAS 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	Authors (s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Data Owner
B3.1(01) IIB, III 3.1 *also filed B3.5(01)* *also filed B3.6(01)* *also filed B3.7(01)*	[redacted]	2013a	Title: Accelerated storage stability study, low temperature storage stability study and physicochemical properties of Victor Gel Ants AB-20 (gel, professional use, 0.014 ± $1 \cdot 10^{-4}$% w/w imidacloprid). Date: 2013-08-05 Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain Proyect number: E-13/0003 GLP	Yes	Aragonesas Agro S.A.
B3.1(02) IIB, III 3.1	[redacted]	2014	Title: Expert Statement Determination of the Physical State of Victor Gel Hormigas (Cod AB-020) Test facility: IBACON GmbH, Rossdorf, Germany Project number: 88911203 GLP	Yes	Celsius Property BV Amsterdam (NL)
B3.7(02) IIB, III 3.7	[redacted]	2013b	Study plan. Room storage stability study of Victor Gel Ants AB-20 (gel, professional use, 0.014 ± $1 \cdot 10^{-4}$%w/w imidacloprid). Date: 2013-05-03 12 months values: Date: 2016-11-14 24 months values: 2016-11-14 Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain Proyect number: E-13/0004 GLP	Yes	Aragonesas Agro S.A.

Section Nº	Authors (s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Data Owner
B3.7(03) IIB, III 3.7	[redacted]	2013c	Title: Study plan. Room storage stability study of Victor Gel Ants AB-20 (gel, household use, 0.014 ± $1 \cdot 10^{-4}$%w/w imidacloprid). Date: 2013-05-03 12 months values: Date: 2016-11-14 24 months values: 2016-11-14 Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain Proyect number: E-13/0005 GLP	Yes	Aragonesas Agro S.A.
B3.10(01)	[redacted]	2014a	Title: Determination of the Surface Tension of an aqueous solution of Victor Gel Hormigas (Code AB-020). Date: 2014-07-29 Test facility: IBACON GmbH, Rossdorf, Germany Project number: 88911184 GLP	Yes	Celsius Property BV Amsterdam (NL)
B3.10(02)	[redacted]	2014b	Title: Determination of the Viscosity of Victor Gel Hormigas (Code AB-020). Date: 2014-06-23 Test facility: IBACON GmbH, Rossdorf, Germany Proyect number: 88911196 GLP	Yes	Celsius Property BV Amsterdam (NL)

Section Nº	Authors (s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Data Owner
B4.1(01) IIB, IV 4.1	[redacted]	2013	Title: Victor Gel Ants (AB-20). Validation of analytical method and content determination in imidacloprid. Date: 2013-10-30 Test facility: Cambium, S.L., Constantí (Tarragona), Spain Proyect number: E13090 GLP	Yes	Aragonesas Agro S.A.
B.5.10.(01)	[redacted]	2013	Title: Residual efficacy of the formulation "AB-020 (Imidacloprid 0.01% w/w)" against ants under laboratory conditions. Test facility: Trialcamp. Investigación Agricola. Poligono Industrial Les Valletes, C/ Artes Gráficas 44, Nave 1 A. Monserrat (Valencia). Proyect number: TRC13-004BC	Yes	Celsius property B.V. Representando a Aragonesas agro.
B.5.10.(02)	[redacted]	2013	Title: Efficacy of the formulation "AB-020 (imidaclorpid 0.01% w/w)" against the ant *Lasius niger* under field conditions.. Test facility: Trialcamp. Investigación Agricola. Poligono Industrial Les Valletes, C/ Artes Gráficas 44, Nave 1 A. Monserrat (Valencia). Proyect number: TRC13-005BC	Yes	Celsius property B.V. Representando a Aragonesas agro
B.5.10.(03)	[redacted]	2013	Title: Efficacy and palatability of the formulation "AB-020 (Imidacloprid 0.01% w/w)" against ants under laboratory conditions. Test facility: Trialcamp. Investigación Agricola. Poligono Industrial Les Valletes, C/ Artes Gráficas 44, Nave 1 A. Monserrat (Valencia). Proyect number: TRC13-007BC	Yes	Celsius property B.V. Representando a Aragonesas agro

Section Nº	Authors (s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Data Owner
B.5.10.(04)	[redacted]	2013	Title: Efficacy of VICTOR GEL ANT BAIT STATION (Imidacloprid 0.01% w/w)" against ants under laboratory conditions. Test facility: Trialcamp. Investigación Agricola. Poligono Industrial Les Valletes, C/ Artes Gráficas 44, Nave 1 A. Monserrat (Valencia). Proyect number: TRC13-008BC	Yes	Celsius property B.V. Representando a Aragonesas agro
B5.10.(05)	[redacted]	2018	Title: Insecticidal evaluation of the gel AB-020 (imidacloprid 0.01%) against *Lasius niger* in a free choice test arena. Test facility: Entoestudio, S.r.l.	Yes	ADAMA Celsius B.V.
B6.1.1(01), IIIB	[redacted]	2007a	Title: Acute Oral Toxicity Study of Victor Gel in Rats. Date: 2007-12-12. Test facility: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG Proyect number: 21672 GLP	Yes	Aragonesas Agro S.A.
B6.1.2(01), IIIB	[redacted]	2007b	Title: Acute Dermal Toxicity Study of Victor Gel in Rats. Date 2007-12-12 Test facility: LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG Proyect number: 21673 GLP	Yes	Aragonesas Agro S.A.

Section Nº	Authors (s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published	Data Protection Claimed (Yes/No)	Data Owner
B6.2.1(01), IIIB	[redacted]	2007a	Title: Acute Dermal Irritation/ Corrosion Test (Patch Test) of Victor Gel in Rabbits. Date: 2007-08-08 Tst facility:LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG Proyect number:21674	Yes	Aragonesas Agro S.A.
B6.2.2(01), IIIB	[redacted]	2007b	Acute Eye Irritation/Corrosion Test of Victor Gel in Rabbits. Date: 2007-08-06 LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG Proyect number:21675 GLP	Yes	Aragonesas Agro S.A.
B6.3(01), IIIB	[redacted]	2007c	Examination of Victor Gel in the Skin Sensitisation Test in Guinea Pigs according to Magnusson and Kligman (Maximisation Test). Date: 2007-12-12 Test facility:LPT Laboratory of Pharmacology and Toxicology GmbH & Co. KG Proyect number:21676 GLP	Yes	Aragonesas Agro S.A.
B6.4, IIIB	[redacted]	2013	Title: In vitro percutaneous absorption of Imidacloprid, formulated as AB-010, through human skin Test facility:TNO Triskelion B.V., HE Zeist, NL Proyect number. V20330/25. Final, date: 3 July 2013 GLP	Yes	Aragonesas Agro S.A.

3.2 Output tables from exposure assessment tools

EXPOSURE ASSESSMENT

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

Therefore, human exposure when using bait stations is not considered in this assessment.

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

Relevant exposure routes of VICTOR GEL HORMIGAS 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 (trained-) 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 ((trained-) professional and non-professional uses) the formulation as gel applied as targeted spot, precludes 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]
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.	Application	Primary exposure: gel application using bait stations*	all users
6.	Post application	Primary exposure: collection of used bait stations*	all users
7.	Post application	Secondary exposure: dermal and hand to mouth contact with gel	Bystanders-toddlers

[1] The exposed groups are separated for exposure assessment purposes.
** No exposure to the product is expected by either (trained-) professionals or non professionals during product application or disposal when using bait stations (RIVM report 320005002 Pest Control Fact Sheet, page 63: 'the exposure due to the use of ant and cockroach bait stations is considered to be negligible. Accidents (swallowing, children who open bait stations) do not form a part of a standard assessment'). Therefore, human exposure to biocidal product when using bait stations is not considered in this assessment. Primary and secondary exposure assessment performed with the application of gel in drops is the worst case with regard to human exposure and cover the risk derived from the use of bait stations.*

Trained professional exposure

Scenario 1 Application of VICTOR GEL HORMIGAS by trained professional users

The product is a ready-to use bait in cartridges for the controlled placement using a suitable gel applicator by pest control operators only. The gel is applied as drops in inaccessible places as crack, crevices, behind furnitures, etc. The gel is applied in form of drops or lines in/near ant rows or nests. Per treatment an amount of 0.4g spot per m^2 or per linear meter is applied.

For 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 0.01% 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 HORMIGAS. Hence, the CA can not perform the same estimation. 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 event[a]	20 mg product
	number of opening and sealing per day[b]	10
	content of active substance in product	0.01%
	Dermal absorption[c]	3%
	Body weight adult[d]	60 kg

[a] *worst case assumption.*
[b] *CAR*
[c] *Study report July 2013 Final, IIIB6.4.*
[d] *HEEG Opinion 17.*

Calculations for Scenario 1

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

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

Estimated dermal uptake Tier 1= [10 * 20 mg * 0.01% * 3%]/ 60 kg

Scenario 1: application of VICTOR GEL HORMIGAS by trained professionals		**Estimated Internal Exposure as [mg /kg bw/d]**			
		Oral uptake	**Inhalation uptake**	**Dermal uptake**	**Total uptake**
Tier 1	**(no PPE)**	-	-	1.00E-05	1.00E-05

Scenario 2 Disposal of used cartridges by trained professional users

For 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 0.01% 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 cartridge disposal. This amount of product is difficult to estimate.

[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.

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. (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	0.01%
	Dermal absorption [c]	3%
	Body weight adult[d]	60 kg

[a] *worst case assumption.*
[b] *CAR*
[c] *.Study report July 2013 Final, IIIB6.4.*
[d] *HEEG Opinion 17.*

Calculations for Scenario 2

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

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

Estimated dermal uptake Tier 1= [1 * 20 mg * 0.01% * 3%]/ 60 kg

Scenario 2: application of VICTOR GEL HORMIGAS by trained professionals		**Estimated Internal Exposure as [mg /kg bw/d]**			
		Oral uptake	**Inhalation uptake**	**Dermal uptake**	**Total uptake**
Tier 1	**(no PPE)**			1.00E-06	1.00E-06

Combined scenarios

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

Summary table: combined systemic exposure from 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	-	1.10E-05	-	1.10E-05

Professional and Non-professional exposure

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

The product is a ready-to use bait in syringes for professionals/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 ants.

For Professionals/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 (ants are expected during spring and summer). Medium term exposure is expected.

The only relevant exposure route of VICTOR GEL HORMIGAS to professional/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. (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	0.01%
	Dermal absorption[c]	3%
	Body weight adult[d]	60 kg

[a] *worst case assumption.*
[b] *CAR, adapted for consumer use.*
[c] *Study report July 2013 Final, IIIB6.4*
[d] *HEEG Opinion 17.*

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 * 20mg * 0.01% * 3%]/ 60 kg

Scenario 3: application of VICTOR GEL HORMIGAS by professionals/non-professionals		**Estimated Internal Exposure as [mg /kg bw/d]**			
		Oral uptake	**Inhalation uptake**	**Dermal uptake**	**Total uptake**
Tier 1	**(no PPE)**	-	-	2.00E-06	2.00E-06

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

The product is a ready-to use bait in syringes for 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 ants.

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 disposes of an used syringe every two weeks during 6 months per year (ants are expected during spring and summer). Medium term exposure is expected.

The only relevant exposure route of VICTOR GEL HORMIGAS to 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 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 event [b]	1
	content of active substance in product	0.01%
	Dermal absorption [c]	75%
	Body weight adult [d]	60 kg
Tier 2	Dermal absorption [e]	3%

[a] *worst case assumption*
[b] *CAR, adapted for consumer use.*
[c] *Guidance on Dermal Absorption, EFSA Journal 2012;10(4):2665.*
[d] *HEEG Opinion 17.*
[e] *Study report Reus, A.A.; July 2013 Final, IIIB6.4*

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 * 0.01% * 3%]/ 60 kg

Scenario 4: post application of VICTOR GEL HORMIGAS by professionals/non-professionals		**Estimated Internal Exposure as [mg /kg bw/d]**			
		Oral uptake	**Inhalation uptake**	**Dermal uptake**	**Total uptake**
Tier 1	**(no PPE)**	-	-	1.00E-06	1.00E-06

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 professional and non-professional uses (mg/kg bw/d)				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 3 & 4 Tier 1	-	3.00E-06	-	3.00E-06

Indirect (Secondary) Exposure of Bystanders

Indirect exposure scenarios are described in the following

Scenario 7: Toddler: Accidental contact with gel, dermal exposure and hand to mouth transfer

Considering the application pattern of VICTOR GEL HORMIGAS 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 40 mg 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 (external dermal load) is taken in orally due to hand-mouth contact (Crack & Crevice Use – Post Application; RIVM report 320005002 pp. 28).

Tier 1 assumes 100% dislodgeability, 100% oral absorption and 3% dermal absorption.

	Parameters	Value
Tier 1	Amount of product contacted per event[a]	40 mg product
	content of active substance in product	0.01%
	Dermal absorption[b]	3%
	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] *worst case assumption.*
[b] *Study report July 2013 Final, IIIB6.4*
[c] *ConsExpo Pest product fact sheet RIVM report 320005002 (Crack & Crevice Use – Post Application; pp. 28)*
[d] *HEEG Opinion 17.*

Calculations for Scenario 7

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% * 0.01% = 0.004 mg active substance

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

*Estimated dermal uptake = (0.004 mg * 3%) /10 kg*

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

*Estimated oral uptake = [0.004 * 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 [7]	1/none	-	1.20E-05	2.00E-04	3.20E-04

3.3 New information on the active substance

New information on the active substance has not been submitted.

3.4 Residue behaviour.

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

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

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

VICTOR GEL HORMIGAS is supplied as ready to use gel intended for use by (trained-) professional and non-professional users to control ants.

The biocidal product is manually applied by using syringes and cartridges with pistol applicator: the gel is applied in form of drops or lines in/near ant rows or nests. The product is also available inside bait stations that are placed near ant rows and nests and activated by opening slits allowing ants to feed on the bait formulation.

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

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

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

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

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

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

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

The following label restrictions preclude the exposure of animals:

- The treatment must be restricted to areas out of reach of animals
- The product can not be applied on surfaces where feed is prepared, consumed or stored..
- 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.5.10.1-4)

III.B.5.10.1 Residual efficacy of the formulation "AB-20' (Imidacloprid 0'01% ww/) against ants under laboratory conditions.

Non-choice test arena was carried out to determinate the residual toxicilty of VICTOR GEL HORMIGAS, against *Lasius niger* and *Linephitema humile* after application to two different types of substrates: one porous (ceramic) and non-pororus (tile).

A control group and a referent product were also tested. Four replicates were evaluated for treatment. Each treatment is done with the product at 7 days and after 15 days of being open.

The study was considerate valid as the results obtained on control group meet both validy criteria.

The results were summarized on table of section 2.2.5.5. This results indicate that VICTOR GEL HORMIGAS was very effective at killing *Lasius niger* via exposure to aged deposits. On the other hand, residual efficacy was moderate against the specie *Linephitema humile*. Mortality rates ranged between 90.83 and 100% in *Lasius niger* and between 69.89 and 78.88 % in *Linephitema humile*.

III.B.5.10.2. Efficacy of the formulation "AB.020 (Imidacloprid 0.01%W/W)" against the ant Lasisus niger (Hymenoptera:formicidae) under field conditions.

The test product was tested with two diferents methods of application: one single Imidaclorpid bait bait station containing 5g bait sample placed close to the nest entrance and four bait stations (Petri dish containing 0.4g of gel bait sample each) applied following a lineal distribution within the plots (four per treatment of 30m^2 each plot). They were

placed on the ground and they were covered with a stone to protect the bait from direct exposition to the sun, rainfalls and unwanted consumers.

Bait station were replaced by new ones after 14 days or earlier if they were completely depleted.

All the nests at the end of the treatment were opened to see if it had killed the colony.

The test product was compared with an untreat control and was carried under GLP conditions and the corrected efficacy for both treatments was calculated with the abbots`s formula.

The results were summarized on table of section 2.2.5.5.

III.B.5.10.3 Efficacy and palatability of the formulation "AB-020 (Imidacloprid 0.01% W/W)" against ants under laboratory conditions.

Tests arena staudy was carried out to determinate the toxicity and palatability against *Laisus niger* and *Linephitema humile*.

Newly manufacturer product and aged product after two and three years of storage were tested.Four replicates were evaluated per treatment group and for the toxic reference and control. Echa replicates consisted of either workers (efficacy test).

For the efficacy test, mortality was recorder for 7 days or until 100% mortality was occurred. The application rate was 0.1g.

The study was considerate valid as the results obtained on control group meet both validy criteria.

The results were summarized on table of section 2.2.5.5.

The study included a palatability test comparing the toxic reference bait and our product VICTOR GEL HORMIGAS. The ants should choice between a toxic gel bait formulation and the VICTOR GEL HORMIGAS. The insect behaviour and the number of approaches the ants made to each of the baits were recorded. The results showed that VICTOR GEL HORMIGAS appeared more attractive than the reference product because our product was chosen more often.

III.B.5.10.4 Efficacy of VICTOR GEL ANTS BAIT STATION (imidacloprid 0.01%W/W) against ants under laboratory conditions.

A test arena was carried out to determinate the efficacy by bait stations against *Lassius niger* and *Linephitema humile*. A control group per species and a toxic reference group per species were concurrently tested.

The application rate was 1 bait station of 5g. Four replicates were evaluated per treatment group. Echa replicate consisted a portion of colony with approximately 500 worker ant and 200 larvae and other brood.

The study was considerate valid as the results obtained on control group meet both validy criteria.

The results were summarized on table of section 2.2.5.5.

III.B.5.10.5 Insecticidal Evaluation of the gel AB-020 (Imidacloprid 0.01%) against *Lasius niger* in a free choice test.

A choice test arena was carried out to determinated the palatability of the product by bait station and drops with fresh and aged bait against Lasius niger.

Three replicates were evaluated per treatment group. Each group composed of about 100 workers ants. The test only meets the criterion of TNsG for fresh bait in bait station.

The results were summarized on table of section 2.2.5.5.

3.6 Addendum (October 2019)

Data for storage stability of 5 years has been submitted to change the currently authorised shelf life of 1 years to 5 years. In addition, the applicant has provided an efficacy trial with bait aged to 33 months.

After the evaluation of both tests, the request is accepted and the relevant documents have been modified. Data are acceptable and therefore a shelf life of 33 months can be granted.

This information will be updated in section 5.5. of the SPC with the sentence:
The storage satability if this product in its original packaging is 33 months under normal storage conditions.

The following added information will be taken into account in each of its corresponding sections.

2.2.2. Physiscal, 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	0.0104 ± 0.0001% Imidacloprid Batch F275.		[redacted]
Plastic cartridge			Initially: Gel After 1 year at 25°C ± 2°C: Gel After 2 years at 25°C ± 2°C: Gel After 5 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 After 5 years at 25°C ± 2°C: Gel	
Colour at 20 °C and 101.3 kPa	Visual inspection	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.		[redacted]
Plastic cartridge			Initially: colourless with mild grey After 1 year at 25°C ± 2°C: colourless with yellowish tone After 2 years at 25°C ± 2°C: colourless with yellowish tone After 5 years at 25°C ± 2°C: colourless with yellowish tone	
Plastic syringe			Initially: colourless with mild grey After 1 year at 25°C ± 2°C: colourless with yellowish tone After 2 years at 25°C ± 2°C:	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			colourless with yellowish tone After 5 years at 25°C ± 2°C: colourless with yellowish tone	
Odour at 20 °C and 101.3 kPa	Olfactory inspection	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.		[redacted]
Plastic cartridge			Initially: Sweet smell After 1 year at 25°C ± 2°C: Sweet smell After 2 years at 25°C ± 2°C: Sweet smell After 5 years at 25°C ± 2°C: Sweet smell	
Plastic syringe			Initially: Sweet smell After 1 year at 25°C ± 2°C: Sweet smell After 2 years at 25°C ± 2°C: Sweet smell After 5 years at 25°C ± 2°C: Sweet smell	
Storage stability test – long term storage at ambient temperature	Comparable to GCPF Technical Monograph No. 17	0.0104 ± 0.0001% w/w Imidacloprid Batch F295.	The product is stable after 5 years at 25ºC in both studied packaging.	[redacted]
Active Ingredient Content	HPLC method			
Plastic cartridge			Initially: 0.0083% w/w After 1 year at 25°C ± 2°C: 0.0085% w/w Difference: +2.41% After 2 years at 25°C ± 2°C:	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			0.0099% w/w Difference: +19.28% After 5 years at 25°C ± 2°C: 0.0094% w/w Difference: +13.25%	
Plastic syringe			Initially: 0.0084% w/w After 1 year at 25°C ± 2°C: 0.0088% w/w Difference: +4.76% After 2 years at 25°C ± 2°C: 0.0097% w/w Difference: +15.48% After 5 years at 25°C ± 2°C: 0.0095% w/w Difference: +13.10%	
Homogeneity of application			Not available	
Appearance and stability of the package			Not available	
Effects on content of the active substance and technical characteristics of the biocidal product - light			Not available	
Effects on content of the active substance and technical characteris			No changes were observed.	[redacted]

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
tics of the biocidal product – temperatu re and humidity				
Effects on content of the active substance and technical characteris tics of the biocidal product - reactivity towards container material			Not available	

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

NOTE:
The physical and chemical properties have been measured according to the type of formulation of the biocidal product (RB - gel bait (ready to use): A formulation designed to attract and be eaten by the target pests).

Long term storage at ambient temperature
Tests are performed with two commercial packages of the formulation (professional and non-professional use).
The long term storage study indicates that the variation of the active ingredient content on VICTOR GEL HORMIGAS product after 5 years was 13% aprox. but after 2 years was 15% and 19% aprox, respectively. Due to the aim of the study was the stability at 60 months, the variation at 24 months was not calculated during the study. The applicant has revised the data and he considers that the higher variation at 24 months could be because of the plastic cartridge used for this point was wrong sealed.
The content did not suffer any modification in its appearance during the storage stability (except in the colour). Also there were changes in the packaging (cartridges and syringes).

Effects of light
Not applicable. The product is stored in the dark.

Effects of temperature and humidity

No adverse effects were observed.

Effects of reactivity towards container material
Not available. Some deformation is only visually detected in the long term storage stability study.

Conclusions
Victor Gel Hormigas is a sweet smell colourless gel ready for use product in a cartridge with pistol applicator, in a syringe in form drops or lines and inside bait station.
The Victor Gel Hormigas product has been marketed for years in Spain. The absence of negative effects is demonstrated by the history of the product.
The biocidal product could be deemed stable after 5 years at 25ºC.

2.2.5.5. Efficacy data:

BAIT STATION

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Test substance**	**Field of use envisaged**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	*Imidacloprid 0.01 % Gel Bait*	*Laboratory*	*Lasius niger*	*Laboratory bioassay with fresh and aged bait.(33 months) Mortality and palatability. According to TNsG 18-19*	*Choice test arena. 5 replicates for each treatment and 5 controls. Dose: 5g of gel in a bait station. N= 100 workers /replicate*	*No palatability data. Mean of mortality: Fresh bait: 92% in 22 days. Aged bait: 98.8% in 22 days Control: 8 %*	[redacted] III-B.5.10.6

Conclusion on the efficacy of the product
The applicant has submitted a laboratory test with fresh bait and 33 months aged bait to claim a period of storage longer. Fresh bait mortality does not meet with the efficacy guidelines criteria, with at least 95% of the test insects killed at a given time point. Even so, a laboratory essay with fresh bait had already been submitted on the first authorisation and demonstrated the mortality/palatability of the product. The mortality with aged bait reaches 98.8% in 22 days. Therefore, according to the efficacy guidelines, the formulation has demonstrated an acceptable toxicity in competition

with alternative food sourse and the product can be claim to be effective after a period of storage of 33 months.

Annexes:
3.1 List of studies for the biocidal product.

IIIB, 3.7.	[redacted]	2013b	Study plan. Room storage stability study of Victor Gel Ants AB-20 (gel, professional use, 0.014 ± $1 \cdot 10^{-4}$%w/w imidacloprid). Date: 2013-05-03 12 months values: Date: 2016-11-14 24 months values: 2016-11-14 60 months values: 2018-09-17 Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain Proyect number: E-13/0004 GLP
IIIB, 3.7.	[redacted]	2013c	Title: Study plan. Room storage stability study of Victor Gel Ants AB-20 (gel, household use, 0.014 ± $1 \cdot 10^{-4}$%w/w imidacloprid). Date: 2013-05-03 12 months values: Date: 2016-11-14 24 months values: 2016-11-14 60 months values: 2018-09-17 Test facility: Labs & Technological Services AGQ, S.L., Burguillos / Seville, Spain Proyect number: E-13/0005 GLP
IIIB, 5.10.5	[redacted]	2020	Title: INSECTICIDAL EVALUATION OF ANT BAIT STATION "VICTOR GEL HORMIGAS" AGAINST *Lasius niger* IN A FREE CHOICE ARENA TEST. Laboratory: ENTOSTUDIO S.r.l. Sponsor: Kollant , S.r.l. (part of Adama group) Test report: Q063-20