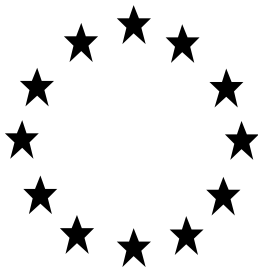
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(Submitted by the evaluating Competent Authority)



TX3 GEL

Product type 18

Imidacloprid

Case Number in R4BP: BC-LX026815-06

Evaluating Competent Authority: ITALY

Date: October 2019

1 CONCLUSION

The overall conclusion from the evaluation of TX3 GEL, containing 2.15% w/w imidacloprid as pure a.s. (2.19% w/w as technical material), is that the biocidal product will not present any unacceptable risk to humans, animal health or the environment when using the biocidal product according to the conditions as stated in the SPC. **Please note that the applicant's intended use #2 as applied for by the applicant (ready-to-use insecticide gel bait in bait box) was evaluated, although eventually not authorized due to the lack of appropriate efficacy data.**

The product TX3 GEL can be authorized in compliance with article 19(1) of Regulation (EU) No 528/2012. The active substance imidacloprid shall be considered a candidate for substitution using the criteria in Article 10(1) of the BPR. The product TX3 GEL can be authorized for a period not exceeding 5 years in accordance with Article 23(6) of the BPR.

The physical-chemical properties of the biocidal product have been evaluated and have been deemed acceptable for the appropriate use and storage of the biocidal product. Long-term storage stability studies support a shelf-life of 36 months.

Data on the biocidal product, as loose gel in cartridges/syringes, have demonstrated sufficient efficacy against different species of cockroaches (*Blattella germanica, Blatta orientalis, Supella longipalpa*), and long term efficacy up to 3 months after product application.

An acceptable level of risk to human health has been demonstrated.

An acceptable level of risk has been demonstrated for each environmental compartment.

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)**
TX3 GEL	Italy*
TX3 SCARAFAGGI GEL	Italy
KAPTER FLUOGEL	Italy
SKULD SCARAFAGGI FLUOGEL	Italy
SKULD FLUOGEL	Italy
SKULD SCARAFAGGI GEL	Italy
SKULD GEL	Italy
SKULD FLUOGEL SCARAFAGGI	Italy
SKULD GEL SCARAFAGGI	Italy
PROTEMAX SCARAFAGGI GEL BOX	Italy

*In this Product Assessment Report the first trade name is used to indicate the product.

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	Zapi S.p.A.
	Address	Via terza strada 12, 35026 Conselve (PD)
Authorisation number	IT/2018/00526/aut	
R4BP asset number	IT-0015264-0000	
Date of the authorisation	31/10/2018	
Expiry date of the authorisation	31/10/2023	

2.1.1.3 Manufacturer of the products

Name of manufacturer	Zapi S.p.A.
Address of manufacturer	Via Terza Strada 12, 35026 Conselve (PD)
Location of manufacturing sites	Via Terza Strada 12, 35026 Conselve (PD)

2.1.1.4 Manufacturer of the active substance

Active substance	Imidacloprid
Name of manufacturer	Ningbo Generic Chemical Co., Ltd.
Address of manufacturer	Room 10-6, Shidal Square 8, 315010, Zhejiang, China
Location of manufacturing site	Shaanxi Hengtian Chemical Co., Ltd., Plant address: Dali Core Zone, Wei nan National Agricultural Science and Technology Park, Shanxi province, China

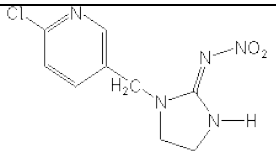
2.1.2 Product composition and formulation

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 X

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Imidacloprid (ISO)
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	98.1%
Structural formula	

2.1.2.2 Candidates for substitution

The active substance imidacloprid shall be considered a candidate for substitution using the criteria in Article 10(1) of the BPR.

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 (% w/w)**	**Classification according to Regulation 1272/2008**
Imidacloprid	(2E)-1-[(6-chloropyridin-3-yl) methyl]-N-nitroimidazolidin-2-imine	Active substance	138261-41-3	428-040-8	2.19% (technical a.s. 98.1%) 2.15% (pure active substance)	Aquatic Acute 1 H400; Aquatic Chronic 1 H410; Acute Tox. 4 H302

Information on the full composition is provided in the confidential annex of this document. **Access level: "RESTRICTED" to applicant and Authority only.**

2.1.2.4 Information on technical equivalence

The active substance used in TX3 GEL is not from a reference source. Therefore, the assessment of technical equivalence by ECHA was necessary. The process has been positively concluded: the source of imidacloprid used in TX3 GEL was concluded to be technically equivalent [redacted]

2.1.2.5 Information on the substances of concern

There is no substance, other than the active substance, present in the biocidal product in a sufficient concentration to be considered substance of concern. Please, refer to the confidential annex and to the NOTE therein for further details.

2.1.2.6 Type of formulation

RB, Bait (ready for use).

2.1.3 Hazard and precautionary statements

Based on the ingredients classification, the classification of TX3 GEL according to Regulation (EC) No 1272/2008 is the following:

Table 1: Classification and labelling according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Aquatic Acute 1 H400 Very toxic to aquatic life. Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.
Hazard pictograms	GHS09
Labelling	
Signal words	Warning
Hazard statements	H410 Very toxic to aquatic life with long lasting effects.
Supplemental hazard information	EUH208 Contains 1, 2-benzisothiazol-3(2H)-one. May produce an allergic reaction.
Precautionary statements	P102 Keep out of reach of children (Only for non-professional use). P103 Read label before use (Only for non-professional use). P273 Avoid release to the environment. P270 Do not eat, drink or smoke when using this product. P391 Collect spillage. P501 Dispose of contents/container in accordance with local regulations.
Note	//

2.1.4 Authorised use

2.1.4.1 Use description

Use 1. – NON-PROFESSIONAL AND PROFESSIONAL USE - BAIT APPLICATION

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Ready-to-use insecticide gel bait for cockroaches control
Target organisms (including development stage)	*B. germanica* (adults and nymphs) *B. orientalis* (adults and nymphs) *S. longipalpa* (adults and nymphs)
Field of use	Indoors Use indoor in cracks and crevices
Application method	Bait application Ready-to-use insecticide gel bait
Application rate and frequency	*Blattella germanica/Supella longipalpa/Blatta orientalis*: 3 drops/m^2 A drop of about 6-7 mm in diameter corresponds to 0.08 g of TX3 GEL. Regularly verify the consumption of TX3 GEL and replace it when it is exhausted. Apply no more than once a week.
Categories of users	Trained professional, Professional, General public (non-professional)
Pack sizes and packaging material	**<u>Non-professional use:</u>** The product is packed in: - Natural PP/LDPE cartridge from 30 g up to 35 g (with increment of 1 g) - LDPE/HDPE syringe from 5 g up to 35 g (with increment of 1 g) Cartridges and syringes are packed in: - Box (carton or plastic, or a combination of plastic and carton) containing from 1 to 6 pcs (with increment of 1 pcs) - Blister (carton or plastic, or a combination of plastic and carton) containing from 1 to 6 pcs (with increment of 1 pcs) - Carton box (carton) containing from 1 to 6 pcs (with increment of 1 pcs) - Bag (plastic or aluminium) containing from 1 to 6 pcs (with increment of 1 pcs) **<u>Professional use:</u>** The product is packed in: - Natural PP/LDPE cartridge from 30 g up to 35 g

	(with increment of 1 g) - LDPE/HDPE syringe from 5 g up to 35 g (with increment of 1 g) Cartridges and syringes are packed in: - Box (carton or plastic, or a combination of plastic and carton) containing from 1 to 24 pcs (with increment of 1 piece) - Blister (carton or plastic, or a combination of plastic and carton) containing from 1 to 24 pcs (with increment of 1 piece) - Carton box (carton) containing from 1 to 24 pcs (with increment of 1 piece) - Bag (plastic or aluminium) containing from 1 to 24 pcs (with increment of 1 piece)

2.1.4.1 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.2 Use-specific risk mitigation measures

See section 2.1.5.2.

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

See section 2.1.5.3.

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

See section 2.1.5.4.

2.1.4.5 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

Apply the biocidal product only in cracks and crevices. Regularly verify the consumption of TX3 GEL and replace it when it is exhausted. Apply the biocidal product no more than once a week. Wash hands after applying the product, and before eating, drinking or smoking. At the end of treatment, remove any residues of bait and dispose of them in accordance

with local regulations.

It is suggested not to apply the product on very dirty surfaces or to surfaces that undergo frequent washing or that have recently been treated with other insecticides. In any case, do not apply other insecticides or insect repellents in areas treated with TX3 GEL.

Do not apply the product near to heat sources (for example under radiator).

To optimize the effectiveness of the treatment, follow the good hygiene practices: eliminate or prevent any access to food sources.

For non-professional users:

- Always read the label or leaflet before use and follow all the instructions provided.
- Inform the registration holder if the treatment is ineffective.

For professional users:

- Always read the label or leaflet before use and follow all the instructions provided.
- Inform the registration holder if the treatment is ineffective.
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc).
- Alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population).

2.1.5.2 Risk mitigation measures

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

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

Avoid contact with treated surfaces.

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

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

For professional users:

Wear disposable gloves during application of the biocidal product.

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

Likely direct or indirect effects:

• May produce an allergic reaction.

First aid measures:

• In case of eye exposure; check for and remove contact lenses, wash eyes with plenty of water maintaining eye lids open for at least 15 minutes.

• Skin contact; wash affected area with plenty of water and soap, without scrubbing.

• Oral exposure; wash mouth with water, DO NOT induce vomiting or administer anything by mouth if unconscious. Seek medical advice.

• If necessary take the affected individual to a healthcare center and bring packaging or label whenever possible.

NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

•Provide symptomatic and supportive treatment.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ☏ [INSERT LOCAL NUMBER HERE].

2.1.5.4 Instructions for safe disposal of the product and its packaging

Do not release to the environment. Do not re-use the empty container. Product and its container shall be disposed of in accordance with local regulations

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

Store the container closed in a cool and well ventilated place away from frost and heat sources. Store away from light.

Shelf-life: 36 months

2.1.6 Other information

The product contains a bittering agent that makes it repulsive to people or pets.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Cartridge	From 30 g up to 35 g	natural PP/LDPE	natural PP/LDPE	Professional Non – professional	YES
Syringe	From 5 g up to 35 g	LDPE/HDPE	LDPE/HDPE	Professional Non – professional	YES
Bait Box*	From 2 g up to 12 g	PVC/PE	PVC/PE	Professional Non – professional	YES
Bait Box*	From 2 g up to 12 g	PS	PS	Professional Non – professional	YES

***This type of packaging (in grey), though evaluated, has not been eventually authorized, due to the lack of suitable efficacy data**

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance have been submitted.

2.1.8.2 Access to documentation

The applicant is inscribed in art. 95 list as substance and product supplier.

2.2 Assessment of the biocidal product

2.2.1 Intended use as applied for by the applicant

Use 1 – NON-PROFESSIONAL AND PROFESSIONAL USE - BAIT APPLICATION

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Ready-to-use insecticide gel bait for cockroaches control
Target organism (including development stage)	*B. germanica* (adults and nymphs); *B. orientalis* (adults and nymphs); *S. longipalpa* (adults and nymphs); *P. americana* (adults and nymphs)
Field of use	Indoors Use indoor in cracks and crevices
Application method(s)	Bait application
Application rate(s) and frequency	*Blattella germanica/Supella longipalpa*: 1 drop/m^2 (low infestation); 2 drops/m^2 (high infestation). *Blatta orientalis/Periplaneta americana:* 2 drops/m^2 (low infestation); 3 drops/m^2 (high infestation). A drop of about 6-7 mm in diameter corresponds to 0.08 g of TX3 GEL. Apply the lowest dosage in case of low infestation or as a preventive or maintenance treatment; apply the highest dosage in case of high infestation or as curative treatment. Regularly verify the consumption of TX3 GEL and replace it when it is exhausted.
Category(ies) of users	Trained professional, Professional, General public (non-professional)
Pack sizes and packaging material	**<u>Non-professional use:</u>** The product is packed in: - Natural PP/LDPE cartridge from 30 g up to 35 g (with increment of 1 g) - LDPE/HDPE syringe from 5 g up to 35 g (with increment of 1 g) Cartridges and syringes are packed in: - Box (carton or plastic, or a combination of plastic and carton) containing from 1 to 6 pcs (with increment of 1 pcs) - Blister (carton or plastic, or a combination of plastic and carton) containing from 1 to 6 pcs (with increment of 1 pcs) - Carton box (carton) containing from 1 to 6 pcs (with increment of 1 pcs)

	- Bag (plastic or aluminum) containing from 1 to 6 pcs (with increment of 1 pcs) **<u>Professional use:</u>** The product is packed in: - Natural PP/LDPE cartridge from 30 g up to 35 g (with increment of 1 g) - LDPE/HDPE syringe from 5 g up to 35 g (with increment of 1 g) Cartridges and syringes are packed in: - Box (carton or plastic, or a combination of plastic and carton) containing from 1 to 24 pcs (with increment of 1 piece) - Blister (carton or plastic, or a combination of plastic and carton) containing from 1 to 24 pcs (with increment of 1 piece) - Carton box (carton) containing from 1 to 24 pcs (with increment of 1 piece) - Bag (plastic or aluminium) containing from 1 to 24 pcs (with increment of 1 piece).

Use 2 – NON-PROFESSIONAL AND PROFESSIONAL USE - BAIT BOX APPLICATION

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Ready-to-use insecticide gel bait in bait box for cockroaches control
Target organism (including development stage)	*B. germanica* (adults and nymphs); *B. orientalis* (adults and nymphs); *S. longipalpa* (adults and nymphs)
Field of use	Indoors
Application method(s)	In bait boxes
Application rate(s) and frequency	One bait box for a room of about 15 – 20 m^2. In case of high infestation or in case cockroaches presence is noticed in different places, it is advisable to place more bait boxes in the area to be treated. If necessary, replace the bait box at the latest 3 months after its activation.
Category(ies) of users	Trained professional, Professional, General public (non-professional)
Pack sizes and packaging material	**<u>Non-professional use:</u>** The product is packed in:

	- PVC/PE bait box from 2 g up to12 g (with increment of 1 g) - PS bait box from 2 g up to12 g (with increment of 1 g) The bait boxes (each individually packed or not in single plastic or aluminium bags) are packed in: - Box (carton or plastic, or a combination of plastic and carton) containing from 1 to 6 pcs (with increment of 1 pcs) - Blister (carton or plastic, or a combination of plastic and carton) containing from 1 to 6 pcs (with increment of 1 pcs) - Carton box (carton) containing from 1 to 6 pcs (with increment of 1 pcs) - Bag (plastic or aluminium) containing from 1 to 6 pcs (with increment of 1 pcs) **Professional use:** The product is packed in: - PVC/PE bait box from 2 g up to12 g (with increment of 1 g); - PS bait box from 2 g up to12 g (with increment of 1 g). The bait boxes (each individually packed or not in single plastic or aluminium bags) are packed in: - Box (carton or plastic, or a combination of plastic and carton) containing from 1 to 24 pcs (with increment of 1 piece); - Blister (carton or plastic, or a combination of plastic and carton) containing from 1 to 24 pcs (with increment of 1 piece); - Carton box (carton) containing from 1 to 24 pcs (with increment of 1 piece); - Bag (plastic or aluminium) containing from 1 to 24 pcs (with increment of 1 piece).

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical state at 20°C and 101.3 kPa	OPPTS 830.6303 (physical state) Visual examination at 20°C by 3 inspectors	TX3 GEL: 2.16% imidacloprid Batch No. 071015-32	Solid (gel-like ready-to-use bait)	IUCLID TOC_3.1
Colour at 20°C and 101.3 kPa	OPPTS 830.6302 (color) Visual examination at 20°C by 3 inspectors	TX3 GEL: 2.16% imidacloprid Batch No. 071015-32	Light brown	IUCLID TOC_3.1
Odour at 20°C and 101.3 kPa	OPPTS 830.6304 (odour) Olfactory assessment at 20°C by 3 inspectors	TX3 GEL: 2.16% imidacloprid Batch No. 071015-32	Characteristic odour	IUCLID TOC_3.1
Acidity / alkalinity	CIPAC MT 75.3	TX3 GEL: 2.16% imidacloprid Batch No. 071015-32	pH=6.8 (1% w/v) at ca. 20°C Note: Not required owing to the physical state and nature of the product and its use pattern	IUCLID TOC_3.2
Relative density / bulk density	CIPAC MT 3.2(iv), OECD No. 109, EC 440/2008 No. A.3 (5 ml volumetric flask; n-hexane)	TX3 GEL: 2.16% imidacloprid Batch No. 071015-32	D^{20}_4 =1.2863	IUCLID TOC_3.3
Storage stability test – accelerated storage	**(1)**: CIPAC MT 46.3 (54°C for 2 weeks) Test was carried out on a product sample in its original primary packaging (2 g PS bait box) The a.s. content was determined by the HPLC method as in sec. 2.2.4 below	TX3 GEL: 2.20% imidacloprid Batch No. IN280915-32	After 2 weeks at 54°C: - no change in the appearance of the test item was observed, apart from colour (from light brown at t_0, to brown at t_{2weeks}); -no deformation in both bottom and lateral layers, or loss of sample or evident corrosion phenomena were observed in the container; - no significant change in the relative density was found; - viscosity measurements were not technically feasible, either at T_0 and at T_{2weeks}; -the weight loss proved to be -1.77%;	IUCLID TOC_3.4.1

			-the a.s. variation was +3.1% (T_0: 1.92% w/w; $T_{12weeks}$: 1.98%).	
	(2): CIPAC MT 46.3 (54°C for 2 weeks) Tests were carried out on three product samples, each in its original primary packaging: 5 g Syringe (LDPE/HDPE), 30 g Cartridge (natural PP/LDPE), 2 g Bait box (PVC/PE) The a.s. content was determined by the HPLC method as in sec. 2.2.4 below	TX3 GEL: 2.16% imidacloprid Batch No. 071015-32	After 2 weeks at 54°C: -no change in the appearance of the three product samples was observed; -both the syringe and the cartridge worked properly. No deformation in both bottom and lateral layers, or loss of sample or evident corrosion phenomena were observed in the three containers; -no significant change in the relative density was found; -viscosity measurements were feasible: a slight viscosity decrease was observed after the test items were equilibrated at 20°C at the end of the accelerated storage; -the weight loss proved to be +0.02%, -0.07%, and -4.38% (for syringe, cartridge, and bait box, respectively) -the a.s. content proved to be 2.15%, 2.11% and 2.18% in the three product samples (syringe, cartridge, and bait box, respectively). The % a.s decrease turned out to be -1.8%, -3.7%, and -0.5%, respectively ('time zero' concentration: 2.19%)	IUCLID TOC_3.4.1
Storage stability test – long term storage at ambient temperature	Study is ON GOING, completion EXPECTED in August 2019 The a.s. content was determined by the HPLC method as in sec. 2.2.4 below	TX3 GEL: 2.20% imidacloprid Batch No. IN280915-32 2 g PS bait box	The available interim data were submitted by the applicant. After 12 and 18 months: - no change in the appearance of the test item was observed; -no deformation in both bottom and lateral layers, or loss of sample or evident corrosion phenomena were observed in the container; - no significant change in the relative density was found;	IUCLID TOC_3.4.1

			- viscosity measurements were not technically feasible; -the weight loss proved to be -1.41% and -1.52%, respectively; - an a.s. variation of +3.1%, and +2.6%, respectively, was observed (T_0: 1.92%, $T_{12months}$: 1.98%, $T_{18months}$: 1.97%)	
	Three-yr storage stability study was completed in February 2019 The a.s. content was determined by the HPLC method as in sec. 2.2.4 below	TX3 GEL: 2.16% imidacloprid Batch No. 071015-32 5 g Syringe (LDPE/HDPE) 30 g Cartridge (natural PP/LDPE) 2 g Bait box (PVC/PE)	After 36 months: - no change in the appearance of the three test items was observed; -both the syringe and the cartridge worked properly. No deformation in both bottom and lateral layers, or loss of sample or evident corrosion phenomena were observed in the containers; - no significant change in the relative density was found; - viscosity measurements were technically feasible also at 20°C; a slight viscosity decrease was observed at 40°C; -the weight loss proved to be -0.22%, -0.56%, and -6.56% (syringe, cartridge, and bait box, respectively); - an a.s. decrease of -4.1%, -4.1% and -5.5% was observed for syringe, cartridge, and bait box, respectively (T_0: 2.19%; $T_{36months}$: 2.10%, 2.10% and 2.07%)	
Storage stability test – low temperature stability test for liquids	CIPAC MT 39.3	TX3 GEL: 2.16% imidacloprid Batch No. 071015-32	After 7 days at 0±2°C, no visual separation of solid or liquid material was observed. The physical state of the test item was maintained, too	IUCLID TOC_3.4.1
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Justification for the non-submission of data	—	Not required. Though the a.s. in TX3 GEL is sensitive to light, exposure to sunlight is negligible, when the product is correctly stored and used. Label claims "Store the product away from light"	IUCLID TOC_3.4.2.1
Effects on content of the active substance	Justification for the non-	--	As for the effect of temperature, the product	IUCLID TOC_3.4.2.2

and technical characteristics of the biocidal product - **temperature and humidity**	submission of data		is expected to be stable when subject to higher than normal temperatures (please, see above under **accelerated storage**). As for humidity, packaging is supposed to preserve the product from contact with external humidity during storage and transportation until use. According to the label instructions the biocidal product has to be stored tightly closed in a cool and well ventilated place away from frost and heat sources	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Justification for the non-submission of data	--	TX3 GEL is stable in its commercial packaging under the tested accelerated storage conditions (please, see above under **accelerated storage**)	IUCLID TOC_3.4.2.3
Wettability	Justification for the non-submission of data	--	The biocidal product is a ready-to-use gel formulation, so not intended to be dispersed in water. Owing to the physical state and nature of the product and its use pattern, this test does not need to be performed	IUCLID TOC_3.5.1
Suspensibility, spontaneity and dispersion stability	Justification for the non-submission of data	--	The biocidal product is a ready-to-use gel formulation, so not intended to be dispersed in water. Owing to the physical state and nature of the product and its use pattern, these tests do not need to be performed	IUCLID TOC_3.5.2
Wet sieve analysis and dry sieve test	Justification for the non-submission of data	--	The biocidal product is a ready-to-use gel formulation. Owing to the physical state and nature of the product and its use pattern, these tests do not need to be performed	IUCLID TOC_3.5.3
Emulsifiability, re-emulsifiability and emulsion stability	Justification for the non-submission of data	--	The biocidal product is a ready-to-use gel formulation. Owing to the physical state and nature of the product and its use pattern, these tests do not need to be performed	IUCLID TOC_3.5.4

Disintegration time	Justification for the non-submission of data	--	The biocidal product is a ready-to-use gel formulation. Owing to the physical state and nature of the product and its use pattern, this test does not need to be performed	IUCLID TOC_3.5.5
Particle size distribution, content of dust/fines, attrition, friability	Justification for the non-submission of data	--	The biocidal product is a ready-to-use gel formulation. Owing to the physical state and nature of the product and its use pattern, this test does not need to be performed	IUCLID TOC_3.5.6
Persistent foaming	Justification for the non-submission of data	--	The biocidal product is a ready-to-use gel formulation, not intended for dilution with water before use. Owing to the physical state and nature of the product and its use pattern, this test does not need to be performed	IUCLID TOC_3.5.7
Flowability/Pourability /Dustability	Justification for the non-submission of data	--	The biocidal product is a ready-to-use gel formulation. Owing to the physical state and nature of the product and its use pattern, these tests do not need to be performed	IUCLID TOC_3.5.8
Burning rate — smoke generators	Justification for the non-submission of data	--	Since the biocidal product is not a smoke generator, this test does not need to be performed	IUCLID TOC_3.5.9
Burning completeness — smoke generators	Justification for the non-submission of data	--	Since the biocidal product is not a smoke generator, this test does not need to be performed	IUCLID TOC_3.5.10
Composition of smoke — smoke generators	Justification for the non-submission of data	--	Since the biocidal product is not a smoke generator, this test does not need to be performed.	IUCLID TOC_3.5.11
Spraying pattern — aerosols	Justification for the non-submission of data	--	Since the biocidal product is not an aerosol, this test does not need to be performed	IUCLID TOC_3.5.12
Physical compatibility	Justification for the non-submission of data	--	The product is not applied in combination with other products	IUCLID TOC_3.6
Chemical compatibility	Justification for the non-submission of data	--	The product is not applied in combination with other products	IUCLID TOC_3.6
Degree of dissolution and dilution stability	Justification for the non-submission of data	--	The biocidal product is a ready-to-use gel formulation. Owing to the physical state and nature of the product and its	IUCLID TOC_3.7

			use pattern, these tests do not need to be performed	
Surface tension	Justification for the non-submission of data	--	Only required for liquid formulations	IUCLID TOC_3.8
Viscosity	CIPAC MT 192, OECD No. 114 Rotational viscosimeter (non-Newtonian liquids)	TX3 GEL: 2.15% imidacloprid Batch No. 071015-32	Dynamic viscosity: technically not feasible at 20°C, due to the high viscosity of the test item; measurements were carried out at 40.1°C using the rotational viscosimeter at different shear rates. The dynamic viscosity at 40.1°C proved to change depending on the shear rate, so the test item is non-Newtonian. The following results were obtained: 1372667 mPa s (0.3 rpm) 1055333 mPa s (0.5 rpm) 954000 mPa s (0.6 rpm) Spindle: S-64	IUCLID TOC_3.9

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

TX3 GEL is a light brown gel-like 'ready-to-use' formulation, with a characteristic odour. Though required only for aqueous liquid preparations or for solid or non-aqueous liquid preparation to be diluted/dispersed in water upon use, the pH of 1% w/v dispersion in water was measured at ca. 20°C (6.8). Relative density proved to be 1.2683.

Several storage stability tests were performed on TX3 GEL:

✓ Accelerated storage stability tests

(1) The study was conducted on TX3 GEL in its original packaging, i.e. 2 g PS bait box. After 2 weeks at 54±2 °C, the a.s. variation proved to be +3.1%. This 'apparent' increase can be ascribed to a slight sample concentration (consistent with the observed weight loss of -1.77%). No change in the appearance of the test item was observed, apart from colour (from light brown at T_0, to brown at T_{2weeks}). No change in packaging integrity was reported; no significant relative density change was observed, either. Viscosity measurements were not technically feasible, either at the beginning and at the end of the adopted storage regime.

(2) The tests were conducted on TX3 GEL in the following types of original packaging, i.e. 5 g Syringe (LDPE/HDPE), 30 g Cartridge (natural PP/LDPE), 2 g Bait box (PVC/PE). After 2 weeks at 54±2 °C, the a.s. decrease with respect to the 'time zero' concentration proved to be acceptable in each case (a.s. decrease: -1.8%, -3.7%, and -0.5%, respectively). No change in the appearance of the formulation or in packaging integrity was reported. No significant weight loss or relative density change were observed, either. Only a slight viscosity decrease was observed after the test items were equilibrated at 20°C at the end of the adopted accelerated storage regime (viscosity measurements became feasible).

TX3 GEL is concluded to be stable when subject to higher than normal temperatures. In any case, the label claims 'Store the container closed in a cool and well ventilated place away from frost and heat sources'. The overall results obtained under accelerated storage conditions anticipate a shelf-life of 2 years.

✓ Low temperature stability test

TX3 GEL was investigated by CIPAC MT 39.3. No separation of solid/liquid matter was observed. The test item maintained its physical state.

✓ Long-term storage stability studies

Studies in four different types of primary packaging were submitted (one is still on-going, but interim data have been made available by the applicant):

- 2 g Bait box (PS): After 12 and 18 months, the a.s. variation proved to be +3.1% and +2.6%, respectively. This 'apparent' increase can be ascribed to a slight sample concentration (consistent with the observed weight loss). No change in the appearance of the test item was observed. No change in packaging integrity was reported; no significant relative density change was observed, either. Viscosity measurements were not technically feasible, either at the beginning and after 12/18 months.
- 5 g Syringe (LDPE/HDPE), 30 g Cartridge (natural PP/LDPE), 2 g Bait box (PVC/PE): After 36 months, the a.s. decrease proved to be -4.1%, -4.1% and -5.5%, respectively. No change in the appearance of the three test items was observed. No change in packaging integrity was reported; no significant relative density change was observed, either. Only a slight viscosity decrease was observed on the test items (viscosity measurements became feasible also at 20°C).

CONCLUSION: Based on the satisfactory long-term storage stability data submitted for 5 g Syringe (LDPE/HDPE), 30 g Cartridge (natural PP/LDPE), 2 g Bait box (PVC/PE), the shelf-life of the product can be extended to 36 months. It shall be noted that this shelf-life claim is also supported by the palatability tests on the 36-month aged product, submitted by the applicant for the three authorized species *B. germanica*, *B. orientalis* and *S. Longipalpa,* as summarized under section 2.2.5.5 Table 3 of this document.

Owing to the physical state and nature of the product and its use pattern (ready-to-use gel-like bait), no further testing is deemed necessary for technical characteristics. TX3 GEL is not intended to be used in combination with other products.

Surface tension is not applicable. Due to the high viscosity of the test item, the measurement of the viscosity at 20°C was not technically feasible. Viscosity was tentatively measured using the smallest spindle at the lowest speed, but results proved to be out of the measuring range. Whereas, measurements were feasible at 40°C, using the rotational viscosimeter at different shear rates. The dynamic viscosity proved to change depending on the shear rate, so the test item at 40°C is confirmed to be non-Newtonian.

2.2.3 Physical hazards and respective characteristic

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Explosives	Justification for non-submission of data	--	The a.s. was concluded to be 'not explosive'. There are no chemical groups associated with explosive properties in any of the co-formulants, either. Since none of the ingredients are officially classified or self-classified as explosives, TX3 GEL is not expected to possess explosive properties	IUCLID TOC_4.1
Flammable gases	Justification for non-submission of data	--	Not applicable (solid gel-like formulation)	IUCLID TOC_4.2
Flammable aerosols	Justification for non-submission of data	--	Not applicable (solid gel-like formulation)	IUCLID TOC_4.3
Oxidising gases	Justification for non-submission of data	--	Not applicable (solid gel-like formulation)	IUCLID TOC_4.4
Gases under pressure	Justification for non-submission of data	--	Not applicable (solid gel-like formulation)	IUCLID TOC_4.5
Flammable liquids	Justification for non-submission of data	--	Not applicable (solid gel-like formulation)	IUCLID TOC_4.6
Flammable solids	EU Method A.10 (screening test)	TX3 GEL: 2.15% imidacloprid Batch No. 071015-32	Since the test item did not ignite and propagate combustion in the preliminary screening test, the product is not a flammable solid and no further testing is deemed necessary	IUCLID TOC_4.7
Self-reactive substances and mixtures	Justification for non-submission of data	--	The a.s. is not classified as 'explosive' or 'self-reactive substance'. There are no chemical groups associated with explosive or self-reactive properties in any of the co-formulants, either	IUCLID TOC_4.8
Pyrophoric liquids	Justification for non-submission of data	--	Not applicable (solid gel-like formulation)	IUCLID TOC_4.9
Pyrophoric solids	Justification for non-submission of data	--	Based on the available information and experience in production and handling, TX3 GEL	IUCLID TOC_4.10

			does not ignite spontaneously on coming into contact with air at normal temperatures	
Self-heating substances and mixtures	Justification for non-submission of data	--	TX3 GEL should not be considered for classification in this class. The product is solid (gel formulation), but it is expected to be completely molten up to 160°C	IUCLID TOC_4.11
Substances and mixtures which in contact with water emit flammable gases	Justification for non-submission of data	--	Experience in handling shows that TX3 GEL does not react with water to emit flammable gases	IUCLID TOC_4.12
Oxidising liquids	Justification for non-submission of data	--	Not applicable (solid gel-like formulation)	IUCLID TOC_4.13
Oxidising solids	Justification for non-submission of data	--	The a.s. was concluded to be 'not oxidising'. As for the co-formulants, there are no chemical groups associated with oxidising properties, either. Some ingredients contain oxygen, but this element is chemically bonded only to carbon or hydrogen. Since none of the ingredients are officially classified or self-classified as oxidising, TX3 GEL is not expected to be an oxidising solid	IUCLID TOC_4.14
Organic peroxides	Justification for non-submission of data	--	No organic peroxides are present. TX3 GEL should not be considered for classification in this class	IUCLID TOC_4.15
Corrosive to metals	Justification for non-submission of data	--	Application of classification criteria in the UN-MTC, Section 37.4 excludes solids, while 'liquids and solids that may become liquids (during transport)' have to be considered for such a classification. TX3 GEL is a solid gel-like formulation, not expected to become liquid during transportation, as far as label instructions are adopted	IUCLID TOC_4.16
Auto-ignition temperatures of products (liquids and gases)	Justification for non-submission of data	--	Not applicable (solid gel-like formulation)	IUCLID TOC_4.17.1
Relative self-ignition temperature for solids	Justification for non-	--	Based on the information as available in MSDSs or	IUCLID TOC_4.17.

	submission of data		in data-bases, for the majority of the ingredients the relative self-ignition/ auto-ignition T is >100°C (i.e. the majority of the components are known to be non-auto-flammable)	2
Dust explosion hazard	Justification for non-submission of data	NA	Not applicable TX3 GEL is a solid gel-like formulation and, therefore, not dusty	IUCLID TOC_4.17.3

Conclusion on the physical hazards and respective characteristics of the product

The a.s. is not classified as 'explosive', 'oxidising' or 'self-reactive'. As for the co-formulants, there are no chemical groups associated with explosive or oxidising or self-reactive properties, either. It can be anticipated that TX3 GEL has neither explosive nor oxidising properties. TX3 GEL is not expected to be self-reactive, either.

TX3 GEL is not a flammable solid. Experience in production and handling shows that TX3 GEL does not ignite spontaneously on coming into contact with air at normal temperatures. Experience in handling and use shows that the product does not react with water, either.

TX3 GEL should not be considered for classification in the hazard classes of organic peroxide and corrosive to metals. As a gel-like formulation, dust formation is not expected; so the dust explosion hazard class is not applicable, either.

On the basis of the available data/information, TX3 GEL does not pose any physical hazards. Therefore, the need for a risk characterisation for physical hazards is not envisaged.

2.2.4 Methods for detection and identification

Table 2: Analytical methods for the analysis of the product as such including the active substance, impurities and residues

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte	**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. in TX3 GEL)	HPLC-UV (270 nm) [redacted]	1.6% w/w (n=2) 2.15% w/w (n=2) 2.6% w/w (n=2)	Single determinations at 5 conc. levels over the range 1.3–3.0% w/w y = 475029x + - 82593 R^2= 0.99982	[redacted]	101.20-101.16 99.50-98.59 99.42-99.46	101.2% 99.0% 99.3%	-	Not required	IUCLID TOC_5.1

Conclusion on the methods for detection and identification of the product
A method by HPLC with UV detection at 270 nm has been developed and validated according to SANCO/3030/99 rev. 4 for the determination of imidacloprid in TX3 GEL. Imidacloprid proved to be 2.19% w/w in the investigated test item (TX3 GEL, batch 071015-32). The method is sufficiently specific, linear (over the range 1.3–3.0% w/w), accurate (with recovery rates in the acceptable range 93-103% at spiking levels of 1.6, 2.15 and 2.6% w/w, corresponding to ca. 75, 100 and 125% of the nominal a.s. content 2.15% w/w) and precise (being $\%RSD_{n=6}$= 1.40% below the limit of 2.38% given by the modified Horwitz equation).

Analytical methods for residues

Acceptable analytical methods for the detection and identification of imidacloprid residues in soil (down to 0.05 mg/kg), air (down to 60 µg/m³), drinking water and surface water (down to 0.1 and 0.6 µg/L, respectively) are available in the CAR of the active substance drafted by the DE (eCA) under PT18.

No analytical methods for imidacloprid residues in body fluids & tissues are necessary, since the a.s is neither toxic nor highly toxic. No analytical methods for imidacloprid residues in food of plant/animal origin are necessary, either, taking into consideration the use pattern of the product.

Two co-formulants in TX3 are classified as hazardous for the environment. However, such co-formulants are dispersed in the product matrix at a very low concentrations and do not lead/contribute to the classification of TX3 GEL. In conclusion, none of the co-formulants needs to be monitored.

2.2.5 Efficacy against target organisms

The biocidal product was tested in simulated-use alternative food trials and field trials demonstrating a high efficacy against target organism reported below in section 2.2.5.2.

2.2.5.1 Function and field of use

PT18: Insecticides, acaricides and products to control other arthropods.

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

Organism intended to be controlled: Cockroaches.

Species:

- *Blattella germanica* (adults and nymphs)
- *Blatta orientalis* (adults and nymphs)
- *Supella longipalpa* (adults and nymphs)

Humans, food and feeding stuffs are to be protected.

2.2.5.3 Effects on target organisms, including unacceptable suffering

All the target organisms die briefly after bait ingestion.

2.2.5.4 Mode of action, including time delay

Imidacloprid is a systemic insecticide that acts as an insect neurotoxin and belongs to a class of chemicals called the neonicotinoids which act on the central nervous system of insects, with much lower toxicity to mammals. The chemical works by interfering with the transmission of stimuli in the insect nervous system. Specifically, it causes a blockage of the nicotinergic neuronal pathway. By blocking nicotinic acetylcholine receptors, imidacloprid prevents acetylcholine from transmitting impulses between nerves, resulting in the insect's paralysis and eventual death. The product controls an ant colony in two weeks after application.

Time delay: TX3 GEL controls infestation in 1 week after its application (according to field studies, the population reduction exceeds 80% relative to either untreated sites or pre-treatment levels).

2.2.5.5 Efficacy data

Table 3: Experimental data on the efficacy of the biocidal product against target organism(s)

Experimental data on the efficacy of the biocidal product against target organisms				
Test substance	**Test organisms**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
TX3 GEL: 2.15% imidacloprid	Insects: *B. germanica*	*Laboratory test:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy and palatability after administration and spontaneous intake to a cockroach population of *Blattella germanica* (*B. germanica*). The product was applied at a total dose of 0.24 g per test arena. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	The test material "Imidacloprid 2.15% cockroach gel bait" provided 100% of killing of the test insects in 14 days and it is therefore PALATABLE AND EFFECTIVE against *B. germanica* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 4% - Bait consumption: With regards of mean bait consumption, the amount of bait consumed during the entire duration of the test was of 0.117 grams.	Drago A., 2016. Report 's code: ZAPL32290915 - 01
		Laboratory test: A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy and palatability after administration and spontaneous intake to a cockroach population of *Blattella germanica* (*B. germanica*). The product was applied at a total dose of 0.24 g per test arena. The gel was applied on small pieces (10 cm x 10 cm) of transparent PVC and left at room temperature for a period of 3 months before introducing it into test arenas. This operation was intended to simulate the exposure of a gel for 3 months to environmental condition. Indeed, PVCs containing 0.24 g of gel were stored in a room at the following environmental settings: 25±1°C and 60±5% RH for 3 months. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5%	The test material "Imidacloprid 2.15% cockroach gel bait" provided 100% of killing of the test insects in 12 days and it is therefore PALATABLE AND EFFECTIVE up to 3 months against *B. germanica* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 0% - Bait consumption: With regards of mean bait consumption, the amount of bait consumed during the entire duration of the test was of 0.067 grams.	Drago A., 2016. Report 's code: ZAPSBR240615 - 03

		- Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3		
		<u>*Laboratory test*</u>*:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy and palatability against a cockroach population of *Blattella germanica* (*B. germanica*) up to three years of aging in order to test the storage stability of the product. The product was applied at a total dose of 0.24 g per test arena. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	The test material "Imidacloprid 2.15% cockroach gel bait" provided 98.67±1.33 % of killing of the test insects in 21 days and it is therefore PALATABLE AND EFFECTIVE up to 3 years of storage against *B. germanica* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 0% - Bait consumption: With regards of mean bait consumption, the amount of bait consumed during the entire duration of the test was of 0.091 grams.	Drago A., 2016. Report 's code: ZAPI3Y141015 - 01
	B. orientalis	<u>*Laboratory test*</u>*:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy and palatability after administration and spontaneous intake to a cockroach population of *Blatta orientalis* (*B. orientalis*). The product was applied at a total dose of 0.24 g per test arena. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	The test material "Imidacloprid 2.15% cockroach gel bait" provided 100% of killing of the test insects in 12 days and it is therefore PALATABLE AND EFFECTIVE against *B. orientalis* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 6% - Bait consumption: With regards of mean bait consumption, the amount of bait consumed during the entire duration of the test was of 0.172 grams.	Drago A., 2016. Report 's code: ZAPSBR240615 - 08
		<u>*Laboratory test*</u>*:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its residual efficacy and palatability after administration and spontaneous intake to a cockroach population of *Blatta orientalis*	The test material "Imidacloprid 2.15% cockroach gel bait" provided 91.33% of killing of the test insects in 21 days and it is therefore PALATABLE AND EFFECTIVE up to 3 months against	Drago A., 2016. Report 's code: ZAPSBR240615 - 10

		(*B. orientalis*). The product was applied at a total dose of 0.24 g per test arena. The gel was applied on small pieces (10 cm x 10 cm) of transparent PVC and left at room temperature for a period of 3 months before introducing it into test arenas. This operation was intended to simulate the exposure of a gel for 3 months to environmental condition. Indeed, PVCs containing 0.24 g of gel were stored in a room at the following environmental settings: 25±1°C and 60±5% RH for 3 months. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	*B. orientalis* adults and nymphs. The product "Imidacloprid 2.15% cockroach gel bait" satisfies the requirements to achieve the claim: "residual effect up to 3 months". The product "Imidacloprid 2.15% cockroach gel bait" satisfies the requirements to achieve the claim: "residual effect up to 3 months". - Result of untreated controls: mean mortality of the control was of 0% - Bait consumption: With regards of mean bait consumption, the amount of bait consumed during the entire duration of the test was of 0.270 grams.	
		<u>*Laboratory test*</u>*:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy and palatability against a cockroach population of *Blatta orientalis* (*B. orientalis*) up to three years of aging in order to test the storage stability of the product. The product was applied at a total dose of 0.24 g per test arena. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102cm in diameter; 36cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	The test material "Imidacloprid 2.15% cockroach gel bait" provided 98.00±2.00% of killing of the test insects in 21 days and it is therefore PALATABLE AND EFFECTIVE against *B. orientalis* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 0% - Bait consumption: With regards of mean bait consumption, the amount of bait consumed during the entire duration of the test was of 0.179 grams.	Drago A., 2016. Report 's code: ZAP32150116/3Y-01
	S. longipalpa	<u>Laboratory test</u>: A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy and palatability after administration and spontaneous intake to a cockroach population of *Supella longipalpa* (*S. longipalpa*). The product was applied at a total dose of 0.24 g per test arena.	The test material "Imidacloprid 2.15% cockroach gel bait" provided 100% of killing of the test insects in 15 days and it is therefore PALATABLE AND EFFECTIVE against *S. longipalpa* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 4% - Bait consumption: With regards of	Drago A., 2016. Report 's code: ZAPSBR240615 - 05

		The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	mean bait consumption, the amount of bait consumed during the entire duration of the test was of 0.047 grams.	
		<u>*Laboratory test*</u>*:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its residual efficacy and palatability after administration and spontaneous intake to a cockroach population of *Supella longipalpa* (*S. longipalpa*). The product was applied at a total dose of 0.24 g per test arena. The gel was applied on small pieces (10 cm x 10 cm) of transparent PVC and left at room temperature for a period of 3 months before introducing it into test arenas. This operation was intended to simulate the exposure of a gel for 3 months to environmental condition. Indeed, PVCs containing 0.24 g of gel were stored in a room at the following environmental settings: 25±1°C and 60±5% RH for 3 months. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	The test material "Imidacloprid 2.15% cockroach gel bait" provided 100% of killing of the test insects in 16 days and it is therefore PALATABLE AND EFFECTIVE up to 3 months against *S. longipalpa* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 1% - Bait consumption: With regards of mean bait consumption, the amount of bait consumed during the entire duration of the test was of 0.050 grams.	Drago A., 2016. Report 's code: ZAPSBR240615 - 03
		<u>*Laboratory test*</u>*:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy and palatability against a cockroach population of *Supella longipalpa* (*S. longipalpa*) up to three years of aging in order to test the storage stability of the product. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102cm in diameter; 36cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice.	The test material "Imidacloprid 2.15% cockroach gel bait" provided 96.00±0.00 of killing of the test insects in 21 days and it is therefore PALATABLE AND EFFECTIVE against *S. longipalpa* adults and nymphs. - Number of replicates: 3 - Result of untreated controls: mean mortality of the control was of 4% - Bait consumption: With regards of mean bait consumption, the amount of bait consumed during the entire duration of the test was of 0.056	Drago A., 2016. Report 's code: ZAPI3Y141015 - 02

		- Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4)	grams.	
	P. americana	**<u>Laboratory test on fresh bait: Study waiving.</u>** Robust field trials against *P. americana* demonostrates product efficacy against American cockroach under real condition. Therefore, we demand a derogation to perform laboratory testing on this species. Moreover, further laboratory studies against a large cockroach (i.e. *B. orientalis*) already demonstrated product insecticidal efficacy.	Not accepted	
		<u>Laboratory test to demonstrate 3 months residuality: Study waiving.</u> Robust field trials against *P. americana* demonstrates product efficacy against American cockroach under real condition for more than 70 days. Therefore, we demand a derogation to perform laboratory testing on this species. Moreover, further laboratory studies against a large cockroach (i.e. *B. orientalis*) already demonstrated product residual efficacy up to three months.	Not accepted	
		<u>Laboratory test to demonstrate efficacy at 3 years end-storage: Study waiving.</u> Laboratory studies against a large cockroach (i.e. *B. orientalis*) already demonstrated product efficacy at end-storage (3 years).	Not accepted	
	B. germanica – BAIT BOX	*<u>Laboratory test</u>:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" in bait box to evaluate its efficacy after administration and spontaneous intake to a cockroach population of *Blattella germanica* (*B. germanica*). One bait box containing 2 g of gel bait was applied per test arena. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	The test material "Imidacloprid 2.15% cockroach gel bait" in bait box provided 98.00% of killing of the test insects in 21 days and it is therefore PALATABLE AND EFFECTIVE against *B. germanica* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 3%	Drago A., 2016. Report 's code: ZAPMBS160616-02
		<u>Laboratory test to demonstrate 3 months residuality: Study waiving.</u>	Not accepted	

		Laboratory study on product within bait box against *B. germanica* supported the efficacy claim. A three months residuality studies against *B. germanica* was already performed using loose gel in arena which represents the "worst-case" because the gel is more exposed to environmental agent compared to the gel within a bait box.		
		<u>*Laboratory test*</u>*:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" in bait box to evaluate its efficacy after administration and spontaneous intake to a cockroach population of *Blattella germanica* (*B. germanica*) up to three years of aging in order to test the storage stability of the product. One bait box containing 2 g of gel bait was applied per test arena. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	The test material "Imidacloprid 2.15% cockroach gel bait" in bait box provided 100% of killing of the test insects in 12 days and it is therefore PALATABLE AND EFFECTIVE against *B. germanica* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 0%	Drago A., 2016. Report 's code: ZAPMBS 160616/3Y-02
	B. orientalis – BAIT BOX	<u>*Laboratory test*</u>*:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" in bait box to evaluate its efficacy after administration and spontaneous intake to a cockroach population of *Blatta orientalis* (*B. orientalis*). One bait box containing 2 g of gel bait was applied per test arena. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	The test material "Imidacloprid 2.15% cockroach gel bait" in bait box provided 95.33% of killing of the test insects in 21 days and it is therefore PALATABLE AND EFFECTIVE against *B. orientalis* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 2%	Drago A., 2016. Report 's code: ZAPMBS160616-01
		<u>Laboratory test to demonstrate 3 months residuality: Study waiving.</u> Laboratory study on product within bait box against	Not accepted	

		B. orientalis supported the efficacy claim. A three months residuality studies against *B. orientalis* was already performed using loose gel in arena which represents the "worst-case" because the gel is more exposed to environmental agent compared to the gel within a bait box.		
		Laboratory test: A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" in bait box to evaluate its efficacy after administration and spontaneous intake to a cockroach population of *Blatta orientalis* (*B. orientalis*) up to three years of aging in order to test the storage stability of the product. One bait box containing 2 g of gel bait was applied per test arena. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	The test material "Imidacloprid 2.15% cockroach gel bait" in bait box provided 94.67% of killing of the test insects in 21 days and it is therefore PALATABLE AND EFFECTIVE against *B. orientalis* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 2%	Drago A., 2016. Report 's code: ZAPMBS160616/3Y-01
	S. longipalpa – BAIT BOX	**Laboratory test on fresh bait: Study waiving.** Field trials against *S. longipalpa* demonstrated product insecticidal efficacy under real condition. Studies on the product within a bait box demonstrated efficacy against a small cockroach like *B. germanica*. Therefore, we demand a derogation to perform laboratory testing on this species.	Not accepted	
		Laboratory test to demonstrate 3 months residuality: Study waiving. Field trials against *S. longipalpa* demonstrated product insecticidal efficacy under real condition. A lab trial to assess residuality up to three months claim have been successfully conducted. That study represented the "worst-case" because the gel was more exposed to environmental agent compared to the gel within a bait box. A study on the product within a bait box demonstrated efficacy against a small cockroach like *B. germanica*. Therefore, we demand a derogation to perform laboratory testing on this species.	Not accepted	

		Laboratory test to demonstrate efficacy at 3 years end-storage: Study waiving. Field trials against *S. longipalpa* demonstrated product insecticidal efficacy under real condition. A lab trial to assess efficacy at product end-storage was successfully conducted. That study represented the "worst-case" because the gel was more exposed to environmental agent compared to the gel within a bait box. A study on the product within a bait box demonstrated efficacy of the product at end-storage time against a small cockroach like *B. germanica*. Therefore, we demand a derogation to perform laboratory testing on this species.	Not accepted	
	P. americana – BAIT BOX	**Laboratory test on fresh bait: Study waiving.** Robust field trials against *P. americana* demonstrates product efficacy against American cockroach under real condition for more than 70 days. A study on the product within a bait box demonstrated efficacy against a large cockroach like *B. orientalis*. Therefore, we demand a derogation to perform laboratory testing on this species.	Not accepted	
		Laboratory test to demonstrate 3 months residuality: Study waiving. Robust field trials against *P. americana* demonstrates product efficacy against American cockroach under real condition for more than 70 days. A study on the product within a bait box demonstrated efficacy against a large cockroach like *B. orientalis*. A lab trial to assess residuality up to three months claim have been successfully conducted against a large cockroach such as *B. orientalis*. That study represented the "worst-case" because the gel was more exposed to environmental agent compared to the gel within a bait box. Therefore, it is possible to infer that the product will maintain its residuality feature also against *P. americana*. For this purpose, we demand a derogation to perform laboratory testing on this species.	Not accepted	
		Laboratory test to demonstrate efficacy at 3 years end-storage: Study waiving. Robust field trials against *P. americana* demonstrates product efficacy against American cockroach under real condition for more than 70 days. A lab trial to assess efficacy at product end-storage was successfully conducted on a large cockroach like *B. orientalis*. A study on the product within a bait box	Not accepted	

		demonstrated efficacy of the product at end-storage time against a large cockroach like *B. orientalis*. Therefore, we demand a derogation to perform laboratory testing on this species.		
	B. germanica – SECONDARY KILLING	<u>*Laboratory test:*</u> A lab test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate the secondary killing action on *Blattella germanica* (*B. germanica*). Several adults and nymphs of B. germanica were placed into an arena were Imidacloprid 2.15% bait gel was available. After 24 hours the dead insects (KC) were collected and frozen, the same number and class (adult males, adult females, nymphs) of cockroaches was killed by freezing (Control Cockroaches CC). All the killed insects were marked on pronotum with tempera colors, red for the KC and green for the CC in order to recognize the insects dead during the test from the ones used as food. Once the cockroaches to be used as food were prepared, the secondary killing test could start. In each arena 6 male adults, 6 female adults and 8 nymphs (stage 3 and 4) were introduced. This set up was the one permitted by the number of cockroaches KC killed in one night, considering the need to use the same number of males and females. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage. - Number of insects: 6 males + 6 females + 8 nymphs (stage 3 and 4) - Number of replicates: 3	The 100% of killing was reached in all the three replications (Replication 1: 24 days; Replication 2: 33 days; Replication 3: 35 days). It is expected that, after several days without alternative food and water, with the sole exception for KC, insects started to suffer for desiccation (Gunn 1935; Shimamura 1994; Tabaru 2003). However, this event is obviously shared by both treated and control cockroaches. Considering that the secondary killing action is not intended as the main biocidal effect of "Imidacloprid 2.15% cockroach gel bait" product, but a secondary, ameliorative, feature of the product, the study was successfully completed. Indeed, the statistical significative difference between SK treated cockroaches and CC treated cockroaches allows to conclude that "Imidacloprid 2.15% cockroach gel bait" possesses a secondary killing action only in a no-choice lab test.	Drago A., 2016. Report 's code: ZAPSBR240615 - 12
	B. orientalis – SECONDARY KILLING	<u>*Laboratory test:*</u> A lab test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate the secondary killing action on *Blatta orientalis* (*B. orientalis*). Several adults and nymphs of *B. orientalis* were placed into an arena were Imidacloprid 2.15% bait gel was available. After 24 hours the dead insects (KC) were collected and frozen, the same number and class (adult males, adult females, nymphs) of cockroaches was killed by freezing (Control Cockroaches CC). All the killed insects were marked on pronotum with tempera colors, red for the KC and	Secondary killing against *B. orientalis* was of 41.67% in 24 days. It is expected that, after several days without alternative food and water, with the sole exception for KC, insects started to suffer for desiccation (Gunn 1935; Shimamura 1994; Tabaru 2003). However, this event is obviously shared by both treated and control cockroaches. Considering that the secondary killing action is not intended as the main	Drago A., 2016. Report 's code: ZAPSBR240615 - 11

<table>
<tr><td></td><td></td><td>green for the CC in order to recognize the insects dead during the test from the ones used as food.
Once the cockroaches to be used as food were prepared, the secondary killing test could start.
In each arena 6 male adults, 6 female adults and 8 nymphs (stage 3 and 4) were introduced. This set up was the one permitted by the number of cockroaches KC killed in one night, considering the need to use the same number of males and females.

- Temperature: 25°C
- Rel. Humidity: 60+/-5%
- Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage.
- Number of insects: 6 males + 6 females + 8 nymphs (stage 3 and 4)
- Number of replicates: 3</td><td>biocidal effect of "Imidacloprid 2.15% cockroach gel bait" product, but a secondary, ameliorative, feature of the product, the study was successfully completed.
Indeed, the statistical significative difference between SK treated cockroaches and CC treated cockroaches allows to conclude that "Imidacloprid 2.15% cockroach gel bait" possesses a secondary killing action only in a no-choice lab test.</td><td></td></tr>
<tr><td></td><td>S. longipalpa – SECONDARY KILLING</td><td><u>Laboratory test on secondary killing: Study waiving.</u>
A study to assess a secondary killing action of the product against B. germanica was successfully conducted. Therefore, it is possible to infer that the product possesses the same action on another small cockroach like S. longipalpa.</td><td>Not accepted</td><td></td></tr>
<tr><td></td><td>P. americana – SECONDARY KILLING</td><td><u>Laboratory test on secondary killing: Study waiving.</u>
A study to assess a secondary killing action of the product against B. orientalis was successfully conducted.
Therefore, it is possible to infer that the product possesses the same action on another large cockroach like P. americana.</td><td>Not accepted</td><td></td></tr>
<tr><td></td><td>B. germanica</td><td><u>Field test</u>: Field tests were conducted in different sites in the Italian province of Padua on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy in controlling the infestation of the target insects, the German cockroach, Blattella germanica (B. germanica), under real field conditions. The product was applied in trial sites according to label instruction for B. germanica high infestation: 3 droplets of 0.08 g/m^2.

<table>
<tr><td>Site</td><td>Description</td><td>Area of treatment</td><td>City</td><td>Level of infestation</td><td>Application rate</td><td>Number of applications during trials</td></tr>
<tr><td>Kitchen</td><td>Private house</td><td>9.6m^2</td><td>Padua</td><td>62 insects before application</td><td>3 droplets/m^2 in spots where presence of</td><td>1</td></tr>
</table></td><td>Under the test conditions, the product provided a mean reduction of the population of American cockroach, which was over 82% since 7 days after the application of the product until the end of the test (two months long test). Starting from the 31st day of treatment the mean reduction was above 99%. In the sites n° 2 and 3 the reduction after two months was complete (100%).</td><td>Drago A., 2016. Report 's code: ZAPsbr240615-02</td></tr>
</table>

						insects were detected		
		Kitchen	Restaurant	120m^2	Pisa	20 insects before application	3 droplets/m^2 in spots where presence of insects were detected	1
		Kitchen	Restaurant	48m^2	Pisa	58 insects before application	3 droplets/m^2 in spots where presence of insects were detected	1
	B. orientalis	<u>*Field test*</u>*:* Field tests were conducted in 3 different sites in the Italian provinces of Padua and Pisa on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy in controlling the infestation of the target insects, the Oriental cockroach, *Blatta orientalis* (*B.orientalis*), under real field conditions. The product was applied in trial sites according to label instruction for *B. germanica* high infestation: 3 droplets of 0.08 g/m^2						Depending on the trial site the percentage of cockroach reduction was above 80% after one week (or 10 days for the site n° 2). After one month, the reduction percentage ranged between 90 and 100%. After two months the reduction of the cockroach population was between 90 and 100%, with two sites on three were the reduction was complete (100%, sites 2 and 3).	Drago A., 2016. Report 's code: ZAPSBR240615 - 07
		Site	Description	Area of treatment	City	Level of infestation	Application rate	Number of applications during trials		
		Butcher's shop	Shop	96m^2	Padua	94 insects before application	3 droplets/m^2 in spots where presence of insects were detected	1		
		Kitchen and bar	Restaurant	127.75m^2	Pisa	46 insects before application	3 droplets/m^2 in spots where presence of insects were detected	1		
		Copy shop	Shop	103.25m^2	Pisa	24 insects before application	3 droplets/m^2 in spots where presence of insects were detected	1		
	S. longipalpa	<u>*Field test*</u>*:* A field tests was conducted in a site in the Italian city of Livorno on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy in controlling the infestation of the target insects, the Brown banded cockroach, *Supella longipalpa* (*S. longipalpa*), under real field conditions. The product was applied in trial sites according to label instruction for *B. germanica* high infestation: 3 droplets of 0.08 g/m^2						Under the test conditions, the product provided a reduction of the population of *S. longipalpa* cockroach, which was over 91.6% starting from 4 days after the treatment. Moreover starting from two weeks after product application, the reduction was of 100% for the entire duration of the field trial (two months).	Drago A., 2016. Report 's code: ZAPsbr240615-11
		Site	Description	Area of treatment	City	Level of infestation	Application rate	Number of applications during trials		
		Kitchen and bedroom	Private house	87m^2	Livorno	14 insects before application	3 droplets/m^2 in spots where presence of insects were detected	1		

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<td><u>Field test</u>: A field tests was conducted in a site in the Italian city of Saluzzo on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy in controlling the infestation of the target insects, the Brownbanded cockroach, Supella longipalpa (S. longipalpa), under real field conditions. The product was applied in trial sites according to label instruction for B. germanica high infestation:
3 droplets of 0.08 g/m^2
<table>
<tr><th>Site</th><th>Description</th><th>Area of treatment</th><th>City</th><th>Level of infestation</th><th>Application rate</th><th>Number of applications during trials</th></tr>
<tr><td>Public rest home</td><td>First floor</td><td>500m^2</td><td>Saluzzo</td><td>178 insects before application</td><td>3 droplets/m^2 in spots where presence of insects were detected</td><td>1</td></tr>
<tr><td>Public rest home</td><td>First floor</td><td>500m^2</td><td>Saluzzo</td><td>148 insects before application</td><td>3 droplets/m^2 in spots where presence of insects were detected</td><td>1</td></tr>
</table>
</td>
<td>Under the test conditions, the product provided a reduction of the population of S. longipalpa cockroach, which was over 90% starting from 14 days after the treatment. Moreover, two months after product application, the reduction was of over 95%.</td>
<td>Drago A., 2016. Report 's code: ZAPsbr240615-11b</td>
</tr>
<tr>
<td></td>
<td>P. americana</td>
<td><u>Field test</u>: Field tests were conducted in 3 different sites in the Italian province of Reggio Calabria on test material "Imidacloprid 2.15% cockroach gel bait" to evaluate its efficacy in controlling the infestation of the target insects, the American cockroach, Periplaneta americana (P. americana), under real field conditions. The product was applied in trial sites according to label instruction for B. germanica high infestation: 3 droplets of 0.08 g/m^2
<table>
<tr><th>Site</th><th>Description</th><th>Area of treatment</th><th>City</th><th>Level of infestation</th><th>Application rate</th><th>Number of applications during trials</th></tr>
<tr><td>Kitchen, laundry, 3 lobbies</td><td>Religious site</td><td>900m^2</td><td>Reggio Calabria</td><td>13 insects before application</td><td>3 droplets/m^2 in spots where presence of insects were detected</td><td>1</td></tr>
<tr><td>Supermarket</td><td>Shop</td><td>78m^2</td><td>Locri</td><td>22 insects before application</td><td>3 droplets/m^2 in spots where presence of insects were detected</td><td>1</td></tr>
<tr><td>Bar</td><td>Shop</td><td>8m^2</td><td>Africo</td><td>21 insects before application</td><td>3 droplets/m^2 in spots where presence of insects were detected</td><td>1</td></tr>
</table>
</td>
<td>Under the test conditions, the product provided a mean reduction of the population of American cockroach, which has been always over 81% for 78 days, starting from 5 days after the treatment.
In particular, after 78 days since the treatment the mean of the reduction was % of 99.04.
In the site n° 1, the lower percentage of population reduction was 84.79.
In the site n ° 2, the reduction decreased until 73% at the 35th day of post-treatment but after 78 days after the treatment, the value increased until 97.13%. This could be explained by the fact that it is impossible to find trial sites completely sealed, i.e. all the field trials could be affected by re-invasion from adjacent areas. The results obtained, suggests that the product Imidacloprid 2.15% gel cockroach bait is effective also in case of re-infestation after several weeks from the application.</td>
<td>Drago A., 2016. Report 's code: ZAPsbr240615-02</td>
</tr>
<tr>
<td></td>
<td>B. germanica</td>
<td><u>Laboratory test</u>: A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" in bait box to evaluate its efficacy after administration and spontaneous intake to a cockroach population of Blattella germanica (B. germanica) up to three years of aging in order to</td>
<td>The test material "Imidacloprid 2.15% cockroach gel bait" in bait box provided 100% of killing of the test insects in 15 days and it is therefore PALATABLE AND EFFECTIVE against B. germanica adults and nymphs.</td>
<td>Drago A., 2016. Report 's code: ZAPINE100616-01</td>
</tr>
</table>

		test the storage stability of the product. One bait box containing 2 g of gel bait was applied per test arena. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	- Result of untreated controls: mean mortality of the control was of 2%	
	B. orientalis	<u>*Laboratory test*</u>*:* A free choice semi-field test was conducted on test material "Imidacloprid 2.15% cockroach gel bait" in bait box to evaluate its efficacy after administration and spontaneous intake to a cockroach population of *Blatta orientalis* (*B. orientalis*) up to three years of aging in order to test the storage stability of the product. One bait box containing 2 g of gel bait was applied per test arena. The tests are simulated use test with bait choice. - Temperature: 25°C - Rel. Humidity: 60+/-5% - Size of arena: circular, 102 cm in diameter; 36 cm deep (275 L volume) containing water ad libitum, a shelter to mimick harbourage and alternative food for bait choice. - Number of insects: 10 males + 10 females + 30 nymphs (stage 3 and 4) - Number of replicates: 3	The test material "Imidacloprid 2.15% cockroach gel bait" in bait box provided 96.67% of killing of the test insects in 21 days and it is therefore PALATABLE AND EFFECTIVE against *B. orientalis* adults and nymphs. - Result of untreated controls: mean mortality of the control was of 5%	Drago A., 2016. Report 's code: ZAPINE100616-02

Conclusion on the efficacy of the product
The efficacy of the biocidal product TX3 GEL as loose gel (cartridges/synges) bait was properly demonstrated through laboratory and field studies, against the species *Blattella germanica, Blatta orientalis and Supella longipalpa.* The ability of the product to control the infestation up to three months period was demonstrated. Although a field study supporting the efficacy of the gel bait against *Periplaneta americana* was provided, the lack of palatability lab studies did not allow the inclusion of this species among the authorized targets. No secondary killing action can be claimed, as the data provided are based only on no-choice tests, thus not sufficient to support the claim. **Concerning the bait box application, no sufficient data were provided to satisfy the criteria laid out in guidance documents, against any of the claimed species.**

2.2.5.6 Occurrence of resistance and resistance management

No resistance phenomena occurred during product testing. For the intended uses as a biocidal product TX3 GEL should only be used against adults and nymphs of cockroaches. The application as a spot takes place above the lethal level. Therefore, it is expected that development of resistance in target insects does not occur. Moreover, as specified in product labels, it is recommended to use TX3 GEL within an integrated control program against the cockroaches that includes the use of insecticidal formulations with different modes of action and active ingredients.

2.2.5.7 Known limitations

There are no known limitations.

2.2.5.8 Evaluation of the label claims

The data provided have been deemed sufficient by the refMS-IT to substantiate a claim of the loose gel bait application against *B. germanica*, *B. orientalis* and *S. longipalpa* at a dosage of 3 drops/m^2 for trained professional, professional and general public users.

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

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

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	**IT-CA**: No specific skin irritation/corrosion study with the product TX3 GEL is available. Data waiving is acceptable. In the absence of a specific study, the skin irritation/corrosion potential of the biocidal product TX3 GEL has to be estimated by considering the available data on each of the components.
Justification for the value/conclusion	**Applicant considerations:** A skin irritation study has not been conducted. With regard to **skin corrosion and irritation** the Applicant proposed to deduce toxicological properties and classification of the biocidal product from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). The active substance is not classified as skin corrosive/irritant. With regard to co-formulants used in the product, although a few of them are classified as skin corrosive/irritant, on the basis of additivity criteria for such hazard, the sum of such co-formulants concentrations does not trigger a classification for the product as skin corrosive/irritant according to Regulation (EC) No 1272/2008 (CLP) criteria.
Classification of the product according to Regulation (EC) CLP	According to Regulation (EC) No 1272/2008 (CLP), no classification for skin corrosion/irritation is necessary for the product TX3 GEL.

Data waiving	
Information requirement	**Applicant considerations:** Study scientifically unjustified. **IT-CA:** Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
Justification	**Applicant considerations:** The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological

	properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). TX3 GEL contains the active substance imidacloprid that is not classified as skin corrosive/irritant; only some co-formulants in the product are classified for such hazard. However, the sum of the concentrations of such co-formulants does not lead to the product to be classified as skin corrosive/irritant, in accordance with the additivity criteria established by Regulation (EC) No 1272/2008 (CLP). For the previously mentioned reasons, criteria for classification as a skin corrosive/irritant do not apply to the product TX3 GEL. **IT-CA:** According to the Guidance on information requirements (2018) and Regulation 1272/2008/EC, for animal welfare reasons, the IT CA agrees that a specific skin irritation study is not required. Data are available on the active substance and other co-formulants and possible effects of components on the toxic potential of the total mixture are very likely ascribed to additivity of the components classified for this endpoint. In the absence of a specific skin irritation study, the classification of the product TX3 GEL has to be performed by the calculation method.

For skin corrosion and irritation no human data is available.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	**IT-CA**: No specific eye irritation/corrosion study with the product TX3 GEL is available. Data waiving is acceptable. In the absence of a specific study, the eye irritation/corrosion potential of the biocidal product TX3 GEL has to be estimated by considering the available data on each of the components.
Justification for the value/conclusion	**Applicant considerations:** An eye irritation study has not been conducted. With regard to **eye irritation** applicant proposed to deduce toxicological properties and classification of the biocidal product from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). The active substance is not classified as eye irritant. With regard to co-formulants used in the product, although a few of them are classified as eye corrosive/irritant, on the basis of additivity criteria for such hazard, the sum of co-formulants

	concentrations does not trigger a classification according to Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to Regulation (EC) CLP	According to Regulation (EC) No 1272/2008 (CLP), no classification for eye irritation is necessary.

Data waiving	
Information requirement	**Applicant considerations:** Study scientifically unjustified. **IT-CA:** Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
Justification	**Applicant considerations:** The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). TX3 GEL contains the active substance imidacloprid that is not classified as eye irritant; only some co-formulants in the product are classified for such hazard. However, the sum of the concentrations of such co-formulants does not lead to the product to be classified as eye irritant, in accordance with the additivity criteria established by Regulation (EC) No 1272/2008 (CLP). For the previously mentioned reasons, criteria for classification as eye irritant do not apply to the product TX3 GEL. **IT-CA:** According to the Guidance on information requirements (2018) and Regulation 1272/2008/EC, for animal welfare reasons, the IT CA agrees that a specific eye irritation study is not required. Data are available on the active substance and other co-formulants and possible effects of components on the toxic potential of the total mixture are very likely ascribed to additivity of the components classified for this endpoint. In the absence of a specific eye irritation study, the classification of the product TX3 GEL has to be performed by the calculation method.

For eye damage and eye irritation no human data is available.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	**IT-CA**: There are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation. Nevertheless, account should be taken of any existing and available data that provide evidence of the respiratory irritation potential of the components of a product.
Justification for the conclusion	**Applicant considerations:** A respiratory tract irritation study has not been conducted. With regard to **respiratory tract irritation** applicant proposed to deduce toxicological properties and classification of the biocidal product from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). None of the ingredients of the product (a.s. or co-formulants) is classified as respiratory tract irritant and therefore a classification according Regulation (EC) No 1272/2008 (CLP) criteria is not necessary.
Classification of the product according to Regulation (EC) CLP	Regulation (EC) No 1272/2008 (CLP), no classification for respiratory tract irritation is necessary.

Data waiving	
Information requirement	**Applicant considerations:** Study scientifically unjustified. **IT-CA**: There are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation.
Justification	**Applicant considerations:** The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Considered that neither the active substance nor the co-formulants contained in the product are classified as respiratory tract irritants, the criteria for classification as respiratory tract irritant do not apply to the product TX3 GEL. **IT-CA**: According to the Guidance on information requirements (2018) and Regulation 1272/2008/EC, for animal welfare reasons, the IT CA agrees that a specific respiratory tract irritation study is not required, considering also the product intrinsic properties and its

	uses.

For respiratory tract irritation no human data is available.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	**IT-CA**: Data waiving is acceptable. In the absence of a specific study, the skin sensitisation potential of the biocidal product TX3gel has to be estimated by considering the available data on each of the components.
Justification for the value/conclusion	**Applicant considerations:** A skin sensitization study has not been conducted. With regard to **skin sensitization** applicant proposed to deduce toxicological properties and classification of the biocidal product from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). TX3 GEL contains 1,2-benzisotiazol-3(2H)-one [redacted] For this reason, TX3 GEL needs to be classified as EUH208. SPC and product label should duly report it.
Classification of the product according to Regulation (EC) CLP	Regulation (EC) No 1272/2008 (CLP), no classification for skin sensitisation is necessary. However, the label must report the supplemental hazard information EUH208: "Contains 1,2-benzisotiazol-3(2H)-one. May produce an allergic reaction".

Data waiving	
Information requirement	**Applicant considerations:** Study scientifically unjustified. **IT-CA:** Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).
Justification	**Applicant considerations:** The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Based on the concentration of the co-formulant 1,2-benzisotiazol-3(2H)-one, the product needs to be classified with EUH208.

	IT-CA: According to the Guidance on information requirements (2018) and Regulation 1272/2008/EC, for animal welfare reasons, the IT CA agrees that a specific skin sensitization study is not required. Data are available on the active substance and other co-formulants only one component is classified for this endpoint. In the absence of a specific skin sensitization study, the classification of the product TX3 GEL has to be performed by the calculation method.

For skin sensitisation no human data is available.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	**IT-CA:** No specific respiratory sensitization study is available. Data waiving is acceptable.
Justification for the value/conclusion	**Applicant considerations:** A respiratory sensitization study has not been conducted. With regard to **respiratory sensitization** applicant proposed to deduce toxicological properties and classification of the biocidal product from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). None of the ingredients of the product (a.s. or co-formulants) is classified as respiratory sensitizer and therefore a classification according Regulation (EC) No 1272/2008 (CLP) criteria is not necessary. **IT-CA:** None of the components in TX3 GEL are classified as respiratory sensitizers. One of the co-formulant is classified as skin sensitizer. Based on the a.s. and the co-formulant intrinsic properties, the Applicant requested the waiving of the respiratory sensitization study.
Classification of the product according to Regulation (EC) CLP	no classification for respiratory sensitisation is necessary according to Regulation (EC) No 1272/2008 (CLP)

Data waiving	
Information requirement	**Applicant considerations:** Study scientifically unjustified. **IT-CA:** No study is available. There are currently no standard tests and no OECD test guidelines

	available for respiratory sensitisation.
Justification	**Applicant considerations:** The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Considered that neither the active substance nor the co-formulants contained in the product are classified as respiratory sensitizer, the criteria for classification as respiratory sensitizer do not apply to the product TX3 GEL. **IT-CA:** Data waiving is acceptable. No standard tests or guidelines exist for this endpoint. None of the components in TX3 GEL are classified as respiratory sensitizers, only one of the components is classified as skin sensitizer. However, based on the a.s. intrinsic properties and the intended uses of the biocidal product, the exposure of humans via inhalation is considered unlikely, as the Applicant showed during this submission. Moreover, the active substance is of low vapour pressure ($9x10^{-7}$ mPa at 25°C). In the absence of a specific study, data on the active substance and other co-formulants have to be taken into account for the classification.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	**IT-CA**: No specific acute oral toxicity study with the product TX3 GEL is available. Data waiving is acceptable. In the absence of a specific study, the Acute oral toxicity of the biocidal product TX3 GEL has to be estimated by considering the available data on each of the components.
Justification for the selected value	**Applicant considerations:** Acute toxicity by oral route study has not been conducted. With regard to **acute toxicity by oral route** the Applicant proposed to deduce toxicological properties and classification of the biocidal product from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Although a.s. and some co-formulants are classified as acute toxic

	by oral route, considering their respective oral LD_{50} and concentrations in the biocidal product, a classification according Regulation (EC) No 1272/2008 (CLP) criteria is not necessary.
Classification of the product according to Regulation (EC) CLP	no classification for acute oral toxicity is necessary according to Regulation (EC) No 1272/2008 (CLP)

Data waiving	
Information requirement	**Applicant considerations:** Study scientifically unjustified. **IT-CA:** Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
Justification	**Applicant considerations:** The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Imidacloprid active substance and some co-formulants contained in the product TX3 GEL are classified as acute toxic by oral route. However, considering their respective oral LD_{50} and concentrations in the biocidal product, according to Regulation (EC) No 1272/2008 (CLP) criteria a classification for acute oral toxicity is not applicable for the product TX3 GEL. **IT-CA:** According to the Guidance on information requirements (2018) and Regulation 1272/2008/EC, for animal welfare reasons, the IT CA agrees that a specific skin irritation study is not required. Data are available on the active substance and other co-formulants and possible effects of components on the toxic potential of the total mixture are very likely ascribed to additivity of the components classified for this endpoint. In the absence of a specific acute oral toxicity study, the classification of the product TX3 GEL has to be performed by the calculation method.

For acute oral toxicity no human data is available.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	**IT-CA:** No study is available. Data waiving is acceptable. In the absence of a specific study, the acute inhalation toxicity of the biocidal product TX3 GEL has to be estimated by calculation.
Justification for the selected value	**Applicant considerations:** Acute toxicity by inhalation study has not been conducted. With regard to **acute toxicity by inhalation** applicant proposed to deduce toxicological properties and classification of the biocidal product from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Although a few co-formulants are classified as acute toxic by inhalation, considering their respective LC_{50} for inhalation and concentrations in the biocidal product, a classification according Regulation (EC) No 1272/2008 (CLP) criteria is not necessary. **IT-CA:** Some of the components of the b.p. are classified for this endpoint. However, considering that testing by the inhalation route is appropriate only if exposure of humans via inhalation is likely, taking into account: • the vapour pressure of the a.s. (> 1 x 10^{-2} Pa at 20 °C) and/or • the active substance is included in products that are powders or are applied in a manner that generates exposure to aerosols, particles or droplets of an inhalable size (MMAD <50 micrometers), data waiving for TX3 GEL can be considered acceptable.
Classification of the product according to Regulation (EC) CLP	According to Regulation (EC) No 1272/2008 (CLP), no classification for acute inhalation toxicity is necessary.

Data waiving	
Information requirement	**Applicant considerations:** Study scientifically unjustified. **IT-CA:** Testing by the inhalation route can be waived considering both the intrinsic properties of the active substance and the co-formulants and the intended use of the product.
Justification	**Applicant considerations:** The toxicity of the active substance and the co-formulants is

	known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Imidacloprid active substance and some co-formulants contained in the product TX3 GEL are classified as acute toxic by inhalation. However, considering their respective LC_{50} for inhalation and concentrations in the biocidal product, according to Regulation (EC) No 1272/2008 (CLP) criteria a classification for acute inhalation toxicity is not applicable for the product TX3 GEL. **IT-CA:** The study with the product is scientifically not justified. Data are available on the active substance and other co-formulants (some of the components are classified for this endpoint) and based on regulation 1272/2008/EC, the acute inhalation toxicity of the biocidal product TX3 GEL has to be estimated by calculation considering the information on all the components in the product. Furthermore, based on intrinsic characteristics of a.s. and the biocidal product, together with the type of formulation and intended uses, an inhalation exposure is not expected, as the Applicant showed during this submission.

For acute inhalation toxicity no human data is available.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No specific acute dermal toxicity study on the product TX3 GEL is available. Data waiving is acceptable. In the absence of a specific study, the acute dermal toxicity of the biocidal product has to be estimated by calculation. With this regard, neither the a.s. nor the co-formulants are classified for this endpoint.
Justification for the selected value	Acute toxicity by dermal route study has not been conducted. With regard to **acute toxicity by dermal route** applicant proposed to deduce toxicological properties and classification of the biocidal product from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). The active substance is not classified for acute toxicity by dermal route. None of the co-formulants is classified for acute toxicity by dermal route; therefore, a classification according Regulation (EC) No 1272/2008 (CLP) criteria is not necessary.
Classification of the product according to Regulation (EC) CLP	According to Regulation (EC) No 1272/2008 (CLP), no classification for acute dermal toxicity is necessary.

Data waiving	
Information requirement	**Applicant considerations:** Study scientifically unjustified. **IT-CA:** Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
Justification	**Applicant considerations:** The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Considered that neither the active substance nor the co-formulants contained in the product are classified for acute toxicity by dermal route, criteria for classification for acute toxicity by dermal route do not apply to the product TX3 GEL. **IT-CA:** According to the Guidance on information requirements (2018) and Regulation 1272/2008/EC, for animal welfare reasons, the IT CA agrees that a specific skin irritation study is not required. Data are available on the active substance and other co-formulants. None of the co-formulants is classified for acute toxicity by dermal route. In the absence of a specific acute dermal toxicity study, the classification of the product TX3 GEL has to be performed by the calculation method.

For acute dermal toxicity no human data is available.

Information on dermal absorption

Value used in the Risk Assessment – Dermal absorption	
Substance	Imidacloprid
Value	75%
Justification for the selected value	**Applicant proposal:** A default value of 75% dermal absorption, according to EFSA guidance document (2012), was used to perform risk assessment evaluation as *worst-case.*

	IT-CA: The Applicant required the data waiving and proposed a default dermal absorption value of 75% as a worst case. According to the BPR and the EFSA Guidance on Dermal Absorption (2012), the proposed default dermal absorption value of 75% for the product (<5% a.s.) is considered acceptable.

Data waiving	
Information requirement	**Applicant considerations:** Other justification. **IT-CA:** No specific dermal absorption study with TX3 GEL has been performed and therefore provided. According to the guidance on the BPR: The establishment of a value for dermal absorption may be performed by use of a tiered approach from a worst case to a more refined estimate.
Justification	**Applicant considerations:** The biocidal product is a gel bait preparation which contains 2.15% Imidacloprid. Data of the active substance imidacloprid were evaluated by DE eCA during active substance approval. A default value of 75% dermal absorption, according to EFSA guidance document, was used to perform risk assessment evaluation as *worst-case.* **IT-CA:** No specific dermal absorption study with TX3 GEL has been performed and therefore provided. The Applicant required the data waiving and proposed a default dermal absorption value of 75% as *a worst case*. According to the BPR and the EFSA Guidance on Dermal Absorption (2012), the waving of the study and proposed default dermal absorption value of 75% for the product (<5% a.s.) is considered acceptable.

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

There are no non-active substances to be assessed for this product.

Conclusion on risk assessment for human health
The eCA agrees with the argumentations provided by the applicant.

Available toxicological data relating to a mixture

There are no toxicological data to be considered which relates to a mixture.

2.2.6.2 Exposure assessment

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

Table 4: Summary table: Relevant paths of human exposure

Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	No	No	No	No	No	No	No
Dermal	No	Yes	Yes	No	No	Yes	No
Oral	No	No	No	No	No	Yes	No

The most relevant route of exposure to the active substance is the dermal route.

Any potential oral exposure will be via indirect exposure to children.

The active substance has a very low vapour pressure and therefore the potential for breathing the active via evaporation is negligible. The application method of the gel is also not conducive to inhalation of the product and hence the potential for inhalation exposure is considered negligible.

The HEEG 13 opinion (endorsed at TM IV 2011) on the Assessment of Inhalation Exposure of Volatilised Biocide Active Substances, "some dossiers have dismissed potential risks from inhaling vapours of an active substance volatilised from treated surfaces by informing that "due to the a.s.'s low vapour pressure risks from inhaling the vapour are negligible". Such assessments wrongly ignore the toxicology of the active substance's vapour. Even though an active substance might have a low vapour pressure, the vapour – even at low concentrations in the air – can still be inhaled. Therefore, the exposure to inhaled vapour needs to be estimated and then compared to an appropriate toxicological endpoint."

*The HEEG 13 opinion is really intended only for the exposure to active which can evaporate off a **treated surface** <u>after</u> application and is not really intended for exposure during application or for exposure to the active in a bait.*

However, in order to support the statement that inhalation due to evaporation should be ignored, the calculation in the HEEG opinion is still used.

The HEEG 13 opinion proposes a tier 1 screening to determine whether the inhalation exposure can be neglected or included in the risk assessment.

Let *mw* and *vp* denote the molecular weight (in g/mol) and the vapour pressure (in Pa). For a infant (based on an inhalation rate of 5.4 m^3/24 hr and bw of 8 kg) and using an AEL in mg a.s./kg bw/d, if:

$$0.279 \ \frac{\text{mw. vp}}{AEL_{long-term}} \leq 1$$

then risk from inhalation exposure for the infant is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the infant is negligible then the inhalation risk for the child and for the adult can also be considered to be negligible.

Calculation for imidacloprid (using worst-case vapour pressure at 25°C):

$$0.279 \text{ x } \frac{255.7X9E-10}{0.06} = 0.0000011$$

It can clearly be seen from the above calculation (> 5 orders of magnitude less than 1) that the risk from inhalation exposure due to any evaporation is negligible for the infant and therefore is also negligible for a child/adult. Therefore, no further detailed assessment for inhalation is required.

Table 5: Summary table: scenarios

Scenario number	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure Description of scenario**	**Exposed group (e.g. professionals, non-professionals, bystanders)**
1.	Gel application	Primary dermal exposure during product application and handling of empty cartridge	Professionals

2.	Gel application	Primary dermal exposure during product application handling of empty cartridge	Non-professionals
3.	Gel mouthing	Secondary exposure: dermal and oral	Non-professionals: infants (worst-case)

Industrial exposure

No industrial exposure is foreseen.

Professional exposure

Scenario [1]

Table 6: Description of scenario

Gel application (Professional): Primary dermal exposure during product application and handling of empty cartridge. For syringes, in the Assessment Report List of Endpoints, an acceptable exposure scenario is indicated which would be applicable in this case since a gel of similar active concentration and same use-pattern. The exposure scenario accepted for the a.s. approval has been consistently applied for authorizing the product TX3 GEL. For the a.s., and its representative b.p., it was agreed that under the normal use, for spot application with the gel formulation, dermal exposure via splashes/drift is extremely unlikely, and the use of cartridge/syringe allows reducing risks due to the contact with the product during the placing of the gel spots. So that, risk can occur for hand exposure when sealing partially used cartridges, with the end cap provided by the manufacturer, and/or when removing the end cap. So that, it was agreed to consider that only a string of 0.5 cm of the gel is transferred to the hand during sealing or opening the cartridge. In addition to that, at the TOX WG II 2019 the "Addendum to HEAdhoc Recommendation 6 for pest control products" was discussed and agreed. For "*Application with a cartridge gun*" scenario (solid, gel-like), the document prescribes a default number of 10 contacts (5 openings + 5 sealing). The latter is in line with the approach followed for either the a.s. approval and the authorization of TX3 GEL. [redacted]		
	Parameters[1]	Value
Tier 1: Assessment of dermal exposure during 5 opening and 5 sealing operations, based on the estimation that a string of 0.5 cm gel per opening and sealing is transferred	Total length of gel deposited onto hands (5 openings and 5 sealings)	10 x 0.5 cm = 5 cm
	[redacted]	0.15 cm
	Diameter of the gel string is 0.15 cm and that the gel strip can be considered as a cylinder	Volume of 1 strip of gel = Πr2h = 3.142 x 0.075 cm x 0.075 cm x 0.5 cm = 0.009 cm^3

to the hand.	Active content (Assuming density of 1.3)	0.252mg
	1 handling empty cartridge	10% of this (based on AR approach)
	Total external dermal exposure	2.77 mg imidacloprid
	Systemic dose (no gloves, 75% dermal absorption)	(2.77/60 kg bw)* 0.75(d.abs.) = 0.0346mg/kg bw
Tier 2[2]: Use of PPE (gloves)	Systemic dose (with gloves, 75% dermal absorption)	(2.77/60 kg bw)* 0.75(d.abs.) * 10% = 0.00346mg/kg bw

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

[2] Only include the parameters changed with respect to the previous Tier.

Calculations for Scenario [1]

As it can be seen from table 2-3 of substance CAR, for all the professional exposure scenarios the total internal body burden (caused by potential exposure of the active substance imidacloprid) is significantly below the long-term AEL.

Unfortunately, no explicit calculation are reported in the substance AR. The most relevant aspect is that the method of calculation was based on assessment of dermal exposure during 5 opening and 5 sealing operations and on the estimation that a string of 0.5 cm gel per opening or sealing will be transferred to the hand.

[redacted] Therefore, the exposure levels have been estimated considering a gel string diameter of 0.15 cm.

Therefore, for TX3 GEL Biocidal Product we obtain:
Total length of gel deposited onto hands (5 openings and 5 sealings) = 10 x 0.5 cm = 5 cm.
Assuming that the diameter of the gel string is 0.15 cm[redacted] and that the gel strip can be considered as a cylinder;
Volume of 1 strip of gel = $\Pi r^2 h$ = 3.142 x 0.05 cm x 0.05 cm x 0.5 cm = 0.009 cm^3
Assuming density of 1.3, weight = 0.009 g x 1.3 = 1.15E-02 g = 11.5 mg
Active content = 11.5 mg x 2.19% w/w = 0.252 mg.
Therefore,
10 strips = 2.52 mg
1 handling empty cartridge = 10% of this (based on AR approach) = 0.252mg
Total external dermal exposure = 2.77 mg imidacloprid

Assuming no gloves and 75% dermal absorption (worst-case default from guidance)

Systemic dose $_{(\text{no gloves, 75\% dermal absorption})}$ = (2.77/60 kg bw)* 0.75(d.abs.) = 0.0346 mg/kg bw

Assuming gloves and 75% dermal absorption
Systemic dose $_{(\text{gloves, 75\% dermal absorption})}$ = (2.77/60 kg bw)* 0.75(d.abs.) * 10% = 0.00346mg/kg bw.

The HI is given by the formula: exposure/AEL = 0.0346/0.06= 0.58 $_{(\text{no gloves, 75\% dermal absorption})}$
exposure/AEL = 0.00346/0.06= 0.058 $_{(\text{gloves, 75\% dermal absorption})}$

Table 7: Summary table: estimated exposure from professional uses

Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	1/ NO PPE (gloves)	0	0.0346 mg/kg bw	0	0.0346 mg/kg bw
Scenario [1]	2/ WITH PPE (gloves)	0	0.00346 mg/kg bw	0	0.00346 mg/kg bw

Further information and considerations on scenario [1]

No in vivo as well as in vitro data for dermal absorption of the product Imidacloprid GL 2.15 were submitted by the participant retrievable in the AR. However, the applicant has submitted test results with an oil formulation for the assessment of imidacloprid as pesticide for the inclusion in Annex I of Directive 91/414/EEC.

As reported in the CAR, Imidacloprid Cockroach Gel was tested for oral and dermal acute toxicity. The LD50 for both were > 5000 mg/kg bodyweight. Imidacloprid Cockroach Gel is not irritating to the skin and to the eyes. The biocidal product used in acute toxicity testing contains another antifoaming agent than the biocidal product in this dossier. Due to the low concentration and the toxicological properties of this component this change is considered to have no effect on study results. The biocidal product was not tested for inhalation toxicity. Due to the physicochemical properties of the product and the mode of application non-submission was accepted. The sensitisation study submitted by the applicant in the CAR suggests that the biocidal product is not sensitising. When assessing dermal exposure to Imidacloprid GL 2.15 (scenario 3) the special application pattern of the product – spot application using a suitable gel applicator – has to be taken into account. The spot application together with the gel formulation avoids dermal exposure to the operator via splashes or drift during application. However there might be a risk for hand exposure when opening and /or sealing the end cap of the cartridge. The assessment of dermal exposure during 5 opening and 5 sealing operations is

based on the estimation that a string of 0.5 cm gel per opening or sealing will be transferred to the hand. Despite the high concentration of the gel (2.15 % gel vs. 0.33% bait paste) the resulting level of potential dermal exposure is ten times lower than it is estimated for the brushing scenario for Imidacloprid GR 0.5. This is reasonable against the background of a product design which significantly reduces the dermal exposure to the active substance.

Monitoring data

No further information on surveys or studies with the actual product or with a surrogate is submitted.

Dietary exposure

Food, drinking water or livestock exposure of imidacloprid can be excluded when applied according to the recommended uses.

However, the active substance imidacloprid is approved as an insecticide under regulation (EC) No 1107/2009. In 2013 the use of imidacloprid in plant protection products was restricted by Commission Implementing Regulation (EU) No. 485/2013 to provide for specific risk mitigation measures for the protection of bees. European Commission Implementing Regulation (EU) 2018/783 has since restricted the use of plant protection products containing imidacloprid to greenhouse crops (only). The EU pesticide database lists 378 MRL product/commodity values for imidacloprid; these MRL values range from 0.05 to 10 mg/kg. In considering the proposed PT18 biocidal use of the active substance imidacloprid as a cockroach gel bait, it is not considered appropriate to individually list the 378 product MRLs relating to the plant protection uses of the active substance.

Information of non-biocidal use of the active substance			
Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1	Plant protection products	Insecticide (authorised under Reg. 1107/2009)	MRL range of 0.05 - 10 mg/kg imidacloprid

Combined scenarios

No combined exposure is foreseen. The product contains only one active substance.

Conclusion

No transfer of biocidal active substances into foods as a result of professional application(s) is estimated.

Non-professional exposure

Scenario [2]

Table 8: Description of scenario

Gel application (general public): Primary dermal exposure during product application and handling of empty cartridge. For syringes, the exposure scenario (including exposure model and assumptions) - accepted for the a.s. approval in the CAR - has been consistently applied for the exposure assessment of the product TX3 GEL.		
	Parameters[1]	Value
Tier 1: Assessment of dermal exposure during 5 opening and 5 sealing operations, based on the estimation that a string of 0.5 cm gel per opening and sealing is transferred to the hand.	Amount of exposure to reach $AEL_{chronic}$ as worst-case value:	Given professional exposure of 0.0346 mg/kg bw is ≈2 times the $AEL_{chronic}$ (0.06): 0.06/0.0346 = 1.73

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

[2] Only include the parameters changed with respect to the previous Tier.

Calculations for scenario [2]

Non – Professional will use a Biocidal Product against cockroach not on a daily basis as Professionals for work reason might do. Therefore, the exposure will not be a chronic one but an acute one. The evaluation of risk for Non – professional use, however, was conducted considering as a conservative assumption the value of $AEL_{chronic}$.

Starting from the point that the potential Professional dermal exposure to a gel bait is of 0.00346 mg/kg bw (no gloves) and using a reverse approach considering as limit value for an acceptable exposure the $AEL_{chronic}$ value of 0.06 mg/kg bw, ≈2 times s more manipulations have to be performed by a consumer to reach the risk level. In other words, this means that a general public has to repeatedly open and seal a cartridge ≈ 9 times (8.65). The total length of the gel onto the consumer hands will be of 2 cm. Considering the limited use and number of application for a consumer in comparison to a professional, the dermal exposure for a non-professional is expected to be lower than for a professional user. Furthermore, the use of a similar Biocidal Product by Non-Professional is not expected to occur on a daily basis. According to this, the $AEL_{short\text{-}term}$ (0.4 mg/kg bw/day) value should be used. 11 manipulations

during an exposure event would be required to reach the acute AEL which cannot be considered as realistic.

Table 9: Summary table: estimated exposure from general public use

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	1/ NO PPE (gloves)	0	0.0346 mg/kg bw	0	0.0346 mg/kg bw

Further information and considerations on scenario [2]

Monitoring data

No further information on surveys or studies with the actual product or with a surrogate is submitted.

Dietary exposure

Food, drinking water or livestock exposure of imidacloprid can be excluded when applied according to the recommended uses.

Combined scenarios

No combined exposure is foreseen. The product contains only one active substance.

Conclusion

No transfer of biocidal active substances into foods as a result of non-professional (general public) application(s) is estimated.

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

The disposal of the biocidal product has been treated in scenario no. 1 for Professional use and in scenario no. 2 for general public use.

Moreover, all the packs are not refillable and therefore at the end of their life-cycle they should be disposed: label instructions clearly state to observe local norms and regulation for a safe disposal of the biocidal product.

Secondary exposure

Scenario [3]

Table 10: Description of scenario *[3]*

Gel mouthing (Infant): Secondary exposure for infants (8kg) touching and mouthing residual bait. This event is considered the worst-case.		
	Parameters[1]	Value
Tier 1	Droplet weight	0.08g
	Active concentration	2.19%
	Toddler weight	8 kg from HEEG opinion n. 13
	Dermal absorption	75% default value from dermal absorption guidance
	External dose	0.219 mg/kg bw
	Systemic dose	0.164 mg/kg bw
	Hand-to-mouth contact	100% of external dermal dose: worst-case
	Combined exposure (dermal + oral)	0.383 mg/kg bw

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

[2] Only include the parameters changed with respect to the previous Tier.

Calculations for scenario [3]

The event of a infant of 8kg taking up a dried bait as calculated in substance AR was adopted. Additionally it has considered that the droplet taken up could also be mouthed. The scenario was considered to represent the *"worst-case"*.

Weight of droplet: 0.08 g

External dermal dose: 0.08* 2.19/ 8 kg = 0.219 mg/kg bw

Systemic exposure from dermal dose: 0.219* 0.75 (default dermal absorption) = 0.164 mg/kg bw

Systemic exposure after mouthing: 0.219 mg/kg bw

Combined systemic exposure: 0.383 mg/kg bw

The HI is given by the formula: exposure/AEL= 0.383/0.4 = 0.96

Table 11: Summary table: secondary exposure estimation

Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [3]	1/NO PPE	0	0.164 mg/kg bw	0.219 mg/kg bw	0.383 mg/kg bw

Further information and considerations on scenario [3]

This scenario represents the *"worst-case"*.

Risk characterisation for human health

Table 12: Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term	Substance AR	Substance AR	Substance AR	Substance AR	0.4 mg/kg bw/day
AELmedium-term	Substance AR	Substance AR	Substance AR	Substance AR	0.2 mg/kg bw/day
AELlong-term	Substance AR	Substance AR	Substance AR	Substance AR	0.06 mg/kg bw/day

[1] Please explain background and reason for assessment factor.

Risk for professional users

Table 13: Systemic effects

Task/ Scenario	Tier	Systemic Exposure mg/kg bw/d	AEL mg/kg bw/d	Exposure/ AEL (%)	Acceptable (yes/no)
1	1	0.0346	0.06	58	Yes
1	2	0.00346	0.06	5.8	Yes

Local effects: None

Conclusion: There are no concerns for Professional from dermal exposure to the active during application and disposal.

Conclusion on the risk characterization for professional users
The provided calculations are made on a *worst-case* situation. The AEL is neither reached nor exceeded by the estimated exposures. The local risk is considered acceptable. An acceptable level of risk to professional users has been demonstrated for the biocidal product TX3 GEL.

Risk for general public users

Table 14: Systemic effects

Task/ Scenario	**Tier**	**Systemic Exposure mg/kg bw/d**	**AEL mg/kg bw/d**	**Exposure/ AEL (%)**	**Acceptable (yes/no)**
2	1	0.0346	0.06	56	Yes

Local effects: None

Conclusion: There are no concerns for general public from dermal exposure to the active during application and disposal of the product in cartridge/syringe.

Conclusion on the risk characterization for general public users
The provided calculations are made on a *worst-case* situation already covered in scenario 1 (professional application of the product). The AEL is neither reached nor exceeded by the estimated exposures. The local risk is considered acceptable. The use of TX3 GEL as loose by non-professionals (general public) is safe for a human health point of view.

Risk for infant (secondary exposure worst-case)

Table 15: Systemic effects

Task/ Scenario	**Tier**	**Systemic Exposure mg/kg bw/d**	**AEL mg/kg bw/d**	**Exposure/ AEL (%)**	**Acceptable (yes/no)**
3	1	0.383	0.4	96%	Yes

Local effects: None

Conclusion: There are no concerns for general public, especially infant from getting in touch to applied baits. The scenario is a worst-case scenario which considers that an entire droplet is taken up with hands and completely ingested. Moreover, label instruction clearly states that the Biocidal Product has to be applied in cracks and crevices or in places difficult to reach by babies or animals.

According to the afore-mentioned points, there are no concerns for general public from dermal and oral exposure to the active applied as droplet of gels.

This evaluation cover also secondary exposure to the Biocidal Product applied in bait boxes.

Conclusion on the risk characterization for secondary exposure
The provided calculations are made on a *worst-case* situation. It is recommended that on product label it is clearly stated that the product has to be applied in places of difficult reach by children or animals. As reported by the applicant the product contains a bittering agent do deter ingestion of the product. Based on all these considerations the AEL is neither reached nor exceeded by the estimated exposures. The local risk is considered acceptable. The use of TX3 GEL as loose do not pose any unacceptable risk to by-standers.

Risk for consumers via residues in food

No risk for consumers via residues in food are expected to occur. Indeed, label instruction clearly states that the product should be applied away from food, drink source or feeding stuffs. Moreover, the application of the product in cracks and crevices will limit *per se* the possible food contamination occurrence.

Risk assessment for animal health

The Biocidal Product is intended to be used indoor in cracks and crevices. No additional or different risks emerged for animal health which have not be covered in the human health section.

2.2.7 Risk assessment for the environment

2.2.7.1 Effects assessment on the environment

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

Regarding the ecotoxicological properties, the formulation is very toxic to aquatic life with long lasting effects. The proposed classification of the biocidal product according to CLP Regulation is Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). For further details, please refer to the Confidential Annex to the PAR.

Further Ecotoxicological studies

Data waiving	
Information requirement	No further ecotoxicological studies are required.
Justification	The biocidal product contains the active substance imidacloprid. The toxicity of the active substance (a.s.) and the co-formulants is known and no synergistic effects are expected. Thus, ecotoxicological properties and classification of the biocidal product (biocidal product) can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method according to Regulation (EC) No 1272/2008 (CLP). Data of the a.s. imidacloprid were evaluated by the Rapporteur Member State (RMS) Germany and published as Competent Authority Report (CAR).
	The rMS accepts the non-submission of ecotoxicity studies, considering the available data are sufficient to carry out a risk assessment.

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

Data waiving	
Information requirement	Information on effects on any other specific, non-target organisms (flora and fauna) believed to be at risk is not required for the biocidal product.
Justification	Biocidal formulation occurs in the EU. All wastes are recycled back into the biocidal product production process or are sent for specialist disposal. There will be no release of the product from the formulation process. The gel formulation will be used indoors only. The label instructions indicate that the worst-case treatment regime is application of *three* spots of 0.08 g each for high infestation of Oriental

	and American cockroaches. This application would per m^2 and would be as inaccessible (to children, pets) as possible within the treated area. The Predicted Environmental Concentrations (PECs) for this emission scenario are calculated using EUSES 2.1.2 insecticide scenario 18.2.2: Indoor, gel application. The *Transitional Guidance on mixture toxicity assessment for biocidal products for the environment* requires that possible synergy between components and the active are considered and that PEC/PNEC ratios should be for the mixture. However, this only works if the whole mixture remains together all the way from the source of emission to the relevant environmental compartments. Therefore, the transitional guidance allows for the normal PEC/PNEC approach where separation of the active from the product is likely, as is the case here. There is no indication that any of the components will have a synergistic effect on the active. Physical-chemical data used in the model was taken from the List of Endpoints in the Assessment Report.
	The rMS accepts the non-submission of ecotoxicity studies to non-target organisms.

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

Data waiving	
Information requirement	Information on the risks to non-target organisms under field conditions is not required.
Justification	The biocidal product is to be used indoors. Thus, a primary poisoning of non-target organisms is no matter of concern.
	The rMS agrees with the justification statement.

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

Data waiving	
Information requirement	Information on the acceptance by ingestion of the biocidal product by any non-target organisms is not need required.
Justification	The biocidal product is to be used indoors. Thus, a primary poisoning of non-target organisms is no matter of concern.
	The rMS agrees with the justification statement.

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

The bait box containing the product is applied indoors. This type of use is not expected to cause secondary ecological effects. No additional information is required.

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

Indoors applications are considered for this product form.

In summary, the indoor use of the biocidal product TX3 GEL does not lead to noteworthy emissions of imidacloprid to the environment.

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

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment are not required.
Justification	Additional data concerning abiotic and biotic degradation or distribution of the product are not required as its environmental behaviour can be extrapolated from data on its active ingredient imidacloprid.
	The rMS agrees with the justification statement.

Leaching behaviour (ADS)

Data on the leaching behaviour was considered unreasonable and thus, is not available.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	Information on distribution and dissipation in soil is not required.
Justification	There are no indications for a widespread distribution of substances in environmental compartments caused by the use of the biocidal product. Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.

	The rMS agrees that sufficient data is available to perform the risk assessment for the soil compartment.

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

Data waiving	
Information requirement	Information on distribution and dissipation in water and sediment is not required.
Justification	There are no indications for a widespread distribution of substances in environmental compartments caused by the use of the biocidal product. Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.
	The rMS agrees that sufficient data is available to perform the risk assessment for the water and compartment.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Information on distribution and dissipation in air is not required.
Justification	There are no indications for a widespread distribution of substances in environmental compartments caused by the use of the biocidal product. Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.
	The rMS agrees with the justification statement.

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)

Data waiving	
Information requirement	Information on risks to aquatic organisms or plants under field conditions is not required.
Justification	This formulation is not applied by spray. A risk assessment for spray application is therefore deemed unreasonable.
	The rMS agrees with the justification statement.

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)

This formulation is not applied by spray. A risk assessment for spray application is therefore considered not relevant.

Conclusion on risk assessment for the environment
eCA conclusion The rMS agrees with the argumentations provided by the applicant.

2.2.7.2 Exposure assessment

Table 16: General information

Assessed PT	*PT 18*
Assessed scenarios	*Scenario 1: Professional use indoor of domestic and civil buildings: worst case in comparison to non-professional use (only domestic application)* *Scenario 2: Non-professional bait box application indoor*
ESD(s) used	*Emission Scenario Document for Product Type 18: EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES*
Approach	*Scenario 1: ESD model* *Scenario 2: ESD model*
Distribution in the environment	*Calculated based on ESD model*
Groundwater simulation	*NO*
Confidential Annexes	*YES: In the confidential Annex 2 EUSES outputs are given.*
Life cycle steps assessed	*Biocidal Product life cycle steps*
Remarks	

Emission estimation

Scenario [1]

Table 17: Input parameters for calculating the local emission

Input	Value	Unit	Remarks
Scenario: *Professional use indoor of domestic and civil buildings*			
Application rate of biocidal product	0.24	*g/m²*	3 droplet/m^2 for high infestation (droplet weight: 0.08 g
Concentration of active substance in the product	2.19	%	
Area treated: Household	2	m^2	Default: Cracks and crevices
Area treated: Larger buildings	9.3	m^2	Default: Cracks and crevices
Cleaning efficiency	3	%	Default
Number of houses per STP*	4000	-	Default
Number of larger buildings per STP	300**	-	Default
Simultaneity factor	5.5 2.75***	%	Default as worst-case Realistic worst-case

* as stated in TAB for targeted application areas in houses and larger buildings

** as stated in TAB for commercial buildings. Note that the same MOTA also states that *no separate assessment for hospitals will be included* and that the number of commercial buildings of 300 is considered to ***include also hospitals***. Therefore, the assessment for larger buildings in this risk assessment also covers use in hospitals.

*** a weekly application of the product is more realistic for domestics as well as civil buildings. So, a simultaneity factor of 2.75% is more applicable.

Calculations for scenario [1]

Table 18: Resulting local emission to relevant environmental compartments

Compartment	Local emission ($Elocal_{compartment}$) [kg/d]	Remarks
Total emission to air from one house	0	
Total emission to wastewater from one house	3.2E-07 Default as worst-case 1.6E-07 Realistic worst-case	
Total emission to solid waste from larger building	0	
Total emission to air from one larger building	0	
Total emission to wastewater from one large building	1.47E-06 Default as worst-case 7.33E-07 Realistic worst-case	

Compartment	Local emission ($Elocal_{compartment}$) [kg/d]	Remarks
Total emission to solid waste from one large building	0	
Total emission to wastewater during episode	9.36E-05 Default as worst-case 4.68E-05 Realistic worst-case	
Local emission to wastewater entering STP	9.36E-05 Default as worst-case 4.68E-05 Realistic worst-case	
Local emission to air from STP during episode	3.1E-16 Default as worst-case 1.55E-05 Realistic worst-case	

Table 19: Input parameters for calculating the fate and distribution in the environment

Input	Value	Unit	Remarks
Molecular weight	255.7	g/mol-1	
Melting point	144	°C	
Boiling point		°C	
Vapour pressure (at 20°C)	4E-10	Pa	
Water solubility (at 20°C)	613	mg/l	
Log Octanol/water partition coefficient	0.57	Log 10	
Organic carbon/water partition coefficient (Koc)	230	l/kg	
Henry's Law Constant (at 25°C)*[if measured data available]*	3.5E-10	$Pa/m^3/mol$	
Biodegradability	*Not biodegradable*		
Rate constant for STP *[if measured data available]*	0	h^{-1}	
DT_{50} for biodegradation in surface water	185.4	d (at 12ºC)	
DT_{50} for biodegradation in aerated sediment	184.5	d (at 12ºC)	
DT_{50} for photolysis in surface water	135.1	d (at 12ºC)	

Table 20: Calculated fate and distribution in the STP

Compartment	Percentage [%]		Remarks
	Scenario 1		
Air	3.37E-10		
Water	97.2		
Sludge	2.79		
Degraded in STP	0		

Table 21: Calculated PEC values

	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}***	**PEC_{GW}***	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/l]	[mg/m^3]
Scenario 1						
Worst-case	4.55E-05	4.455E-06	2.63E-05	5.09E-06	8.42E-07	2.36E-22
Realistic worst-case	2.28E-05	2.28E-06	1.32E-05	2.55E-06	4.21E-07	1.18E-22

* Calculated by EUSES.

Scenario [2]

Table 22: Input parameters for calculating the local emission

Input	Value	Unit	Remarks
Scenario: *bait box application indoor*			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	3	*Bait boxes*	
Concentration of active substance in the product	2.19	%	
Area treated: Household	2	m^2	Default: Cracks and crevices
Cleaning efficiency	0	%	Default as indicated in ESD for PT18

Calculations for scenario [2]

Table 23: Resulting local emission to relevant environmental compartments

Compartment	Local emission ($Elocal_{compartment}$) [kg/d]	Remarks
Total emission to air from one house	0	
Total emission to wastewater from one house	0	
Total emission to solid waste from one larger building	0	
Total emission to air from one larger building	0	
Total emission to wastewater from one house	0	
Total emission to solid waste from one house	0	
Total emission to wastewater during episode	0	
Local emission to wastewater entering STP	0	
Local emission to air from STP during episode	0	

Table 24: Input parameters for calculating the fate and distribution in the environment

Input	Value	Unit	Remarks
Molecular weight	255.7	g/mol-1	
Melting point	144	°C	
Boiling point		°C	
Vapour pressure (at 20°C)	4E-10	Pa	
Water solubility (at 20°C)	613	mg/l	
Log Octanol/water partition coefficient	0.57	Log 10	
Organic carbon/water partition coefficient (Koc)	230	l/kg	
Henry's Law Constant (at 25°C	3.5E-10	$Pa/m^3/mol$	
Biodegradability	*Not biodegradable*		
Rate constant for STP	0	h^{-1}	
DT_{50} for biodegradation in surface water	185.4	d (at 12ºC)	

DT_{50} for biodegradation in aerated sediment	184.5	d (at 12ºC)	
DT_{50} for photolysis in surface water	135.1	d (at 12ºC)	

Table 25: Calculated fate and distribution in the STP

Compartment	Percentage [%]		Remarks
	Scenario 2		
Air	0		
Water	0		
Sludge	0		
Degraded in STP	0		

Table 26: 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/m^3]	[µg/l]	[mg/m^3]
Scenario 2	0	0	0	0	0	0	0	0

Primary and secondary poisoning

No consideration of primary poisoning is required based on the indoor use pattern and the strict label requirement to ensure the product is applied in places which are inaccessible to companion animals.

Secondary poisoning is not considered relevant in the case of imidacloprid and therefore PEC calculations in non-target organisms are not required.

Justification for non-relevance

1. Log Kow = 0.57 leading to a calculated BCF of 0.61 for fish (ref: Assessment Report)

2. No accumulation was observed in a toxico-kinetic study in rat (ref: Assessment Report)

According to the new ECHA guidance on environmental assessment (v.1, volume IV, part B), if log Kow is less than 3 and there are other mitigating properties (which in this case is the lack of observed accumulation in the toxico-kinetic study in rat) then there is no potential for bioaccumulation.

In addition, the Assessment Report also states no potential for accumulation of imidacloprid.

Metabolites

According to the new ECHA guidance on environmental assessment (v.1, volume IV, part B) in general, an environmental risk assessment for the relevant compartments needs to be performed for all major metabolites.

In ECHA guidance document volume IV A, part 1 it is stated that *major metabolites are metabolites formed ≥ 10% on a molar basis, of the active substance in any relevant environmental compartment or appear at two consecutive sampling points at amounts ≥ 5% on a molar basis, or if at the end of the study the maximum of formation is not yet reached but accounts for ≥ 5% on a molar basis, of the active substance at the final time point.*

According to the List of Endpoints in the Assessment Report, there are three metabolites ranging from 12.6 to 17.2% in photolysis studies. However, it is not clear how much photolysis contributes to total degradation in the environment, as photolysis would be restricted to the upper zones of water bodies. Metabolites which are observed in water-sediment biodegradation studies are considered to be more certain to form in environmental conditions. The List of Endpoints in the Assessment Report indicates a single major metabolite identified as NTN33893-desnitro formed during water-sediment tests.

In a 92-day aerobic biodegradation study in the dark, 6% was observed in water and 6.3% in sediment (12.3% total system). In a 358-day anaerobic biodegradation study, a maximum of 20% of the metabolite was observed in water after 60 days and a maximum of 51.5% in sediment after 249 days (total system: max. 66% after 249 days). In a 366-day open water aerobic study in the dark, the same metabolite was observed in water at a maximum of 26.4% after 274 days, reducing to 19.2% after 366 days.

From these results it seems reasonable to take the worst-case as 26.4% in water, and 51.5% in sediment for the purpose of PEC calculations. The ECHA guidance (v.1, volume IV, part B) allows as a first step a "*semi-quantitative assessment of these metabolites using the available data and expert judgement to fill data gaps may be sufficient".*

PECs for NTN33893-desnitro have been calculated according to the following equation:

$PEC_{metabolite,compartment} = PEC_{parent,compartment} \times F_{compartment} \times$ (M metabolite/M parent)

where
F = percentage formed in the relevant compartment
M = molecular weight of each compound

The calculated PECs for the metabolite are compared to the PNEC of the active (if no PNEC is available for the metabolite). Therefore, a similar approach is considered appropriate here.

The calculated PECs for NTN33893-desnitro in water and sediment are shown in the table below:

Table 27: Local PECs for NTN33893-desnitro in aquatic compartments.

	Local PEC (imidacloprid)	Maximum % NTN33893-desnitro	$M_{metabolite}/M_{parent}$	Local PEC NTN33893-desnitro
Local PEC in surface water during emission episode	4.46E-06 mg/L	26.4	210.7/255.7 = 8.64	9.70E-07 mg/L
Local PEC in freshwater sediment during emission episode	2.58E-05 mg/kg_{wwt}	51.5	210.7/255.7 = 8.64	1.09E-05 mg/kg_{wwt}

2.2.7.2 Risk characterisation

Atmosphere

Conclusion: Negligible effect to atmosphere compartment. The Biocidal Product is a solid bait. Active substance and co-formulants have low vapour pressure. Therefore no risk for air compartment is expected to occur after Biocidal Product application.

Sewage treatment plant (STP)

$PNEC_{STP}$: 100 mg/l

Table 28: PEC/PNEC values

	PEC_{STP}	**$PNEC_{STP}$**	**$PEC/PNEC_{STP}$**
Scenario 1	4.55E-05 Default as worst-case 2.28E-05 Realistic worst-case	100 mg/l	4.55E-07 Default as worst-case 2.28E-07 Realistic worst-case
Scenario 2	0	100 mg/l	0

Conclusion: No unacceptable risk for the STP compartment is expected to occur after Biocidal Product application.

Aquatic compartment

$PNEC_{water}$: 4.8E-06 mg/l

$PNEC_{sediment}$: 2.6E-05 mg/kg_{wwt}

Table 29: PEC/PNEC values

	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**
Scenario 1	0.95 Default as worst-case 0.48 Realistic worst-case	**1.01** Default as worst-case 0.51 Realistic worst-case
Scenario 2	0	0

Conclusion: No unacceptable risk for the aquatic compartment is expected to occur after Biocidal Product weekly application.

The PEC/PNEC ratios are very close to 1, for sediment is higher than 1 when worst-case assumption are considered based on daily application by professional users applying the product at high dosage. Therefore, due to unacceptable risks, only weekly applications are allowed.

Terrestrial compartment

Table 30: PEC/PNEC values

	PEC	**PNEC**	**PEC/PNEC**
Scenario 1	5.09 E-06 Default as worst-case 2.55 E-06 Realistic worst-case	0.01575 mg/kg wwt	3.23E-04 Default as worst-case 1.62E-04 Realistic worst-case
Scenario 2	0	0.01575 mg/kg wwt	0

Conclusion: No unacceptable risk for the terrestrial compartment is expected to occur after Biocidal Product application.

Groundwater

Conclusion: No unacceptable risk for groundwater compartment is expected to occur after Biocidal Product application, since PECgw is below the trigger of 0.1 µ/L, as required by the Guidance on the BPR - Volume IV.

Risk from metabolites

No major metabolites were observed in soil metabolism studies.

One major metabolite from water-sediment studies was identified in the Assessment Report; NTN33893-desnitro.

A long-term study with *Chironomus riparius* produced a 28d-EC10 of 9.45 mg/L This indicates that the metabolite is orders of magnitude less toxic than the parent substance imidacloprid. Therefore, the derivation of a $PNEC_{water}$ for this metabolite is not required (ref: Assessment Report).

For the purpose of this risk assessment, if the PNECs used for the active are also used for comparison with the metabolite PECs, this will represent an extreme worst-case PEC/PNEC.

Table 31: PEC for NTN33893-desnitro in aquatic compartments.

	Local PEC NTN33893-desnitro	**PNECs for imidacloprid**	**$PEC_{metabolite}/PNEC_{imid}$**
Local PEC in surface water during emission episode	9.07E-07 mg/L	4.8E-06 mg/L	0.189
Local PEC in freshwater sediment during emission episode	1.09E-05 mg/kg $_{wwt}$	2.6E-05 mg/kg w/w	0.419

Conclusion

There is no concern in the aquatic compartment for the main metabolite identified. Risks to other compartments are considered negligible.

Primary and secondary poisoning

Not relevant.

PBT and endocrine disruption assessment

PBT

Although the P- and the T-criteria are fulfilled, the active substance imidacloprid is neither PBT- nor vP/vB–candidate, since the B-criterion is not fulfilled. Imidacloprid does not fulfil the POP criteria.

Endocrine Effects

According to document "CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants", a hazard assessment was conducted by checking whether there is existing information suggesting an 'indication' of ED properties, as set under Commission Delegated Regulation (EU) 2017/2100, for any of the ingredients in the Biocidal Product. The assessment was conducted collecting and evaluating the information available in the following sources:
- REACH Candidate List of SVHC;
- BPR substance evaluation;
- PPPR substance evaluation;
- Regulation EC 178/2002;
- EU Priority List database;
- ECHA Public activities coordination tool (PACT);
- REACH Reg. Dossier information;
- IPCS Inchem database;
- USEPA EDSP21 database;
- USEPA TOXCAST database;
- Classification (according to CLP Regulation 1272/2008) for the hazards on Repr Tox or STOT-RE (thyroid);
- Literature (last 2 years) that can indicate ED properties on non-target organisms.

On the basis of the data collected it can be concluded that there are no evidences that the product contains any ingredient possessing endocrine disrupting activity on human health and non-target organisms. Therefore, it can be concluded that the product is not ED.

For further details, please refer to the Confidential Annex to this PAR.

Mixture toxicity

A risk assessment for metabolites was presented by the applicant. Nevertheless, according to the Final CAR Doc-II of imidacloprid, metabolites were found to be very less toxic than imidacloprid itself: therefore no risk assessment for metabolites is actually needed. However, it

was decided to maintain it in the PAR, since it represents an extreme worst-case risk assessment while not challenging the overall conclusions.

With regard to those co-formulants that could have a potential toxicity for the environment (please refer to p. 4-5 in the Confidential Annex to this PAR), these were taken into account but considered as not relevant, [redacted]

Therefore, even in those cases when PNECs values are lower than those defined for imidacloprid, such co-formulants are not expected to contribute to the overall ecotoxicity of the product nor to affect the conclusions of the environmental risk assessment.

Overall conclusion on the risk assessment for the environment of the product
The provided calculations are made on a *worst-case* situation. An acceptable level of risk to the environment has been demonstrated for the biocidal product TX3 GEL.

Aggregated exposure

The active substance Imidacloprid is approved for use in products only within a single product type (PT18) under BPR and it is approved also under PPPR, it does not share the same emission pattern as the biocidal emission pattern.
It is unrealistic that an overlap in time and space between different uses (BPR and PPPR) and user categories (professionals and non-professionals) may occur on a daily basis in the same exposed area.
On these basis no aggregated exposure assessment is deemed necessary for this biocidal product. A qualitative assessment is deemed sufficient to conclude that no overlap in time and space for the simultaneous use of the product and its active substance will occur on a regular (daily) basis. Moreover, taking into account the authorised uses and the RMM (application in crack and crevices), emissions are not expected to cumulate in the STP compartment.

2.2.8 Measures to protect man, animals and the environment

The product is used only in areas that are inaccessible to infants, children, companion animals and non-target animals. This reduces the risk of exposure and also the amount of the active which can be cleaned off the surface and washed to drain.

Other insecticides are not applied onto the same treated area.

An acceptable level of risk when using the biocidal product TX3 GEL was demonstrated if label instructions are followed. It is clearly stated to consult the nearest Poison Information Service in case of accidental poisoning.

An acceptable level of risk for human and animal health or for environmental health were evidenced from the risk assessment evaluation.

2.2.9 Assessment of a combination of biocidal products

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

2.2.10 Comparative assessment

The biocidal product TX3 GEL is an insecticide containing one active substance, imidacloprid. The product is claimed to be used indoor by professional and non-professional users to control cockroaches.

Imidacloprid is considered to be very persistent (vP) and toxic (T) and therefore meets two of the criteria for being PBT. Therefore in line with Article 23(1) of the Regulation, the Italian CA has conducted a comparative assessment for the product TX3 Gel according to the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a).

In accordance with the Technical Guidance Note on comparative assessment of biocidal products (CAMay-15-Doc-4.3a-final) the biocidal product was compared to the alternative biocidal products authorised in Italy.

According to the information available to the IT CA on the June 2018, the Italian CA has granted 36 biocidal products authorised under Product Type 18 (insecticide) of the Biocidal Products Directive and Biocidal Products Regulation.

Screening phase

Article 23(3) and the Note for Guidance focus the comparative assessment on the uses specified in the application of the biocidal product, as the comparative assessment has to be product specific.

Table: Claimed uses of the biocidal product

Product Type	18
Where relevant, an exact description of the authorized use	Insecticide
Target organism (including, where relevant) development stage)	Cockroaches
Field(s) of use	Indoor
Application method(s)	Bait application Ready-to-use insecticide gel bait
Category(ies) of users	T. Professional Professional Non professional

The product TX3 GEL is a ready to use insecticide gel bait. The product is effective against:

- *Blattella germanica* (adults and nymphs)
- *Blatta orientalis* (adults and nymphs)
- *Supella longipalpa* (adults and nymphs)

The active substance imidacloprid acts as an insect neurotoxin and belongs to a class of chemicals called the neonicotinoids which act on the central nervous system of insects.

According to the information available to the IT CA on the June 2018, the Italian CA has granted 36 biocidal products authorised under Product Type 18 (insecticide) of the Biocidal Products Directive and Biocidal Products Regulation.

Among the 36 biocidal products, only 8 products are intended to be used indoors against cockroaches. Considering the use of the product TX3 GEL, these products are considered as eligible alternative biocidal products.

Accordingly, the only alternative products for the control of cockroaches in Italy are Deltametrin, Indoxacarb, Etofenprox, Fipronil and Abamectin. The mode of action of these active substances are listed in the following table:

Table: Mode of action for PT18 insecticides

Active substance	Mode of action
Imidacloprid	Imidacloprid acts as an insect neurotoxin and belongs to a class of chemicals called the neonicotinoids which act on the central nervous system of insects.
Deltametrin	Deltamethrin is a pyrethroid insecticide which acts on insects by contact and ingestion. It expresses a strong knock-down effect. The primary site of activity of deltamethrin is the voltage sensitive sodium channel in nerve membrane. Deltamethrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyper-excitability.

Indoxacarb	Indoxacarb acts via blocking of nerve sodium channels resulting in mild convulsions, paralysis and ultimately death. Belongs to class of oxadiazine insecticide.
Etofenprox	Etofenprox acts on the nerve system by disturbing the normal neurotransmittance (as a sodium channel modulator).
Fipronil	Fipronil 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.
Abamectin	Abamectin exerts its pesticidal effect by interfering with the inhibitory neurotransmitter GABA by altering the gating mechanism and permeation of chloride ions at the neuromuscular junction, causing paralysis. Although death can be delayed for up to a few hours, the intoxicated insect irreversibly stops feeding.

Chemical diversity

In the technical guidance note on comparative assessment of biocidal products, it is stated that:

- a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection;
- as a general rule, at least three different and independent ”active substance/mode of action” combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

Taking into account the weak diversity of active substances in biocidal products authorized for indoor use against coackroaches by professional and non-professional users, the IT CA concludes that there is no adequate chemical diversity in line with Article 23(3)(b) and the technical guidance note on comparative assessment.

Since imidacloprid does not meet the exclusion criteria as outlined in Article 5(1), the IT CA considers it valid to not conduct further assessment at this point.

Overall conclusion

The comparative assessment for TX3 GEL can be finalised at the screening stage and the product can be authorized for a period not exceeding 5 years in accordance with Article 23(6) of BPR.

3 ANNEXES

3.1 Human health exposure calculations

From substance AR it can be extrapolated the following points:

Absorption - dermal route

The dermal absorption of imidacloprid contained in three different concentrations in the formulation Confidor 200 OD was studied in vitro on human and rat skin. In a well-performed 24-hour study on human skin with an 8-hour exposure period, dermal absorption rates of < 1% for the concentrate and 6% or 8% for the diluted formulations were obtained. For risk assessment purposes, values of < 1% and 8% should be used. Permeability of rat skin membranes was much higher especially for the concentrate reaching a ratio as high as 22:1 whereas for the formulations penetration through rat skin was 2 or 4 times higher than through human skin.

Imidacloprid GL 2.15:

No in vivo as well as in vitro data for dermal absorption of the product Imidacloprid GL 2.15 were submitted by the participant. But the applicant has submitted test results with an oil formulation for the assessment of imidacloprid as pesticide for the inclusion in Annex I of Directive 91/414/EEC.

Imidacloprid Cockroach Gel was tested for oral and dermal acute toxicity. The LD_{50} for both were > 5000 mg/kg bodyweight. Imidacloprid Cockroach Gel is not irritating to the skin and to the eyes. The biocidal product used in acute toxicity testing contains another antifoaming agent than the biocidal product in this dossier. Due to the low concentration and the toxicological properties of this component this change is considered to have no effect on study results. The biocidal product was not tested for inhalation toxicity. Due to the physicochemical properties of the product and the mode of application non-submission was accepted. The sensitisation study submitted by the applicant suggests that the biocidal product is not sensitising.

When assessing dermal exposure to Imidacloprid GL 2.15 (scenario 3) the special application pattern of the product – spot application using a suitable gel applicator – has to be taken into account. The spot application together with the gel formulation avoids dermal exposure to the operator via splashes or drift during application. However there might be a risk for hand exposure when opening and /or sealing the end cap of the cartridge. The assessment of dermal exposure during 5 opening and 5 sealing operations is based on the estimation that a string of 0.5 cm gel per opening or sealing will be transferred to the hand. Despite the high concentration of the gel (2.15% gel vs. 0.33% bait paste) the resulting level of potential dermal exposure is ten times lower than it is estimated for the brushing scenario for

Imidacloprid GR 0.5. This is reasonable against the background of a product design which significantly reduces the dermal exposure to the active substance (for details please see Table 2-3 below).
A detailed list of the exposure determinants and the models used is listed in Appendix I.

Risk assessment for Professional users:

As can be seen from table 2-3, for all the professional exposure scenarios the total internal body burden (caused by potential exposure of the active substance imidacloprid) is significantly below the long-term AEL.
Unfortunately, no explicit calculation are reported in the substance AR. The most relevant aspect is that the method of calculation was based on assessment of dermal exposure during 5 opening and 5 sealing operations and on the estimation that a string of 0.5 cm gel per opening or sealing will be transferred to the hand.

[redacted] Therefore, the exposure levels have been estimated considering a gel string diameter of 0.15 cm.
Therefore, for TX3 GEL Biocidal Product we obtain:
Total length of gel deposited onto hands (5 openings and 5 sealings) = 10 x 0.5 cm = 5 cm.
Assuming that the diameter of the gel string is 0.15 cm [redacted] and that the gel strip can be considered as a cylinder;
Volume of 1 strip of gel = $\Pi r^2 h$ = 3.142 x 0.075 cm x 0.075 cm x 0.5 cm = 0.009 cm^3
Assuming density of 1.3, weight = 0.009 g x 1.3 = 1.15E-02 g = 11.5 mg
Active content = 11.5 mg x 2.19% w/w = 0.252 mg.
Therefore,
10 strips = 2.52 mg
1 handling empty cartridge = 10% of this (based on AR approach) = 0.252mg
Total external dermal exposure = 2.77 mg imidacloprid

Assuming no gloves and 75% dermal absorption (worst-case default from guidance)
Systemic dose $_{\text{(no gloves, 75\% dermal absorption)}}$ = (2.77/60 kg bw)* 0.75(d.abs.) = 0.0346 mg/kg bw insecticide gel
Assuming gloves and 75% dermal absorption
Systemic dose $_{\text{(gloves, 75\% dermal absorption)}}$ = (2.77/60 kg bw)* 0.75(d.abs.) * 10% = 0.00346mg/kg bw.

The HI is given by the formula: exposure/AEL = 0.0346/0.06= $0.58_{\text{(no gloves, 75\% dermal absorption)}}$
exposure/AEL = 0.00346/0.06= $0.058_{\text{(gloves, 75\% dermal absorption)}}$

Conclusion: There are no concerns for Professional from dermal exposure to the active during application and disposal.

Revision of the exposure assessment after the commenting period launched for the Mutual Recognition in sequence.

[redacted]

Professional users **TIER I**		
Application		
A	Length of gel string [cm]	0.5
B	Diameter of gel string [cm]	0.15
C	Resulting radius [r]	0.075
D	Volume of cylinder: π x C2 x A [cm3]	0.009
E	Density of b.p. [g/cm3]	1.3
F	Amount b.p. transferred to hands per opening or sealing: D x E [g b.p. per one opening or sealing]	0.0115
G	Concentration a.s. [%]	2.19
H	Amount a.s. transferred to hands per opening or sealing: F x G [mg a.s. per opening or sealing]	2.52E-01
I	Number of openings + sealings per day	10
J	Amount a.s. transferred to hands per day: H x I [mg a.s./day]	2.52
Post-application		
L	Numer of handling per day	1

M	Amount a.s. transferred to hands per post-application: H x L [mg a.s./day]	0.252
N	Total potential dermal exposure all phases a.s. (mg a.s.) J + M [mg a.s./day]	2.77
O	Body weight [kg]	60
P	Dermal absorption [%]	75
Q	Total exposure (Tier I) N*P/100/O [mg a.s. / kg bw / day]	3.46E-02
TIER II		
R	PPE - gloves [%]	10
S	Total exposure (Tier II) Q*R/100 [mg a.s. / kg bw / day]	3.46E-03

Risk assessment for Non - Professional users:

0.346 mg/kg bw is ≈ 2time the AEL (0.06): 0.06/0.0346= 1.73

Therefore 2 time more manipulation has to be performed by a consumer to reach the risk level.

In other words, this means that a Non – professional user has to repeatedly open and seal a cartridge ≈9times more than a Professional. The total length of the gel onto the consumer hands will be of 1cm! Considering the limited use and number of application for a consumer in comparison to a professional, the dermal risk for a Non - professional is lower than those for a Professional user.

Moreover, the calculation was performed adopting $AEL_{chronic}$ value which represents the most conservative approach. Indeed, adopting the most realistc $AEL_{short\text{-}term}$ value of 0.4 a 11 time more manipulation will be required to reach the AEL limit concentration to trigger a risk to Non- professional users. This event is therefore considered as extremely not realistic.

Conclusion: There are no concerns for Non - Professional from dermal exposure to the active during application and disposal.

Risk assessment from secondary exposure:

The event of a infant of 8 kg taking up a dried bait as calculated in substance AR was adopted. Additionally it has considered that the droplet taken up could also be mouthed. The scenario was considered to represent the *"worst-case"*.

Weight of droplet: 0.08 g

External dermal dose: 0.08* 2.19%/ 8kg = 0.219 mg/kg bw

Systemic exposure from dermal dose: 0.219* 0.75 (default dermal absorption) = 0.164 mg/kg bw

Systemic exposure after mouthing: 0.219 mg/kg bw

Combined systemic exposure: 0.383 mg/kg bw

The HI is given by the formula: exposure/AEL= 0.383/0.4 = 0.96

Conclusion: There are no concerns for general public, especially infant from getting in touch to applied baits.

3.2 Confidential annex

See separate document.