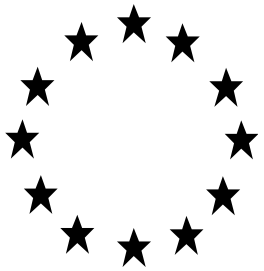
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	Imidasect Ants
Product type(s):	18 (Insecticide)
Active ingredient(s):	Imidacloprid
Case No. in R4BP	BC-RL056233-32
Asset No. in R4BP	DE-0009275-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/18.00008 710-05-18-00008-01-01-00-0000
Date	30.03.2022

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Changes history table

Application type	refMS	Case number in the refMS	Decision date[1]	Assessment carried out	Chapter
NA-RNL	DE	BC-RL056233-32	30.03.2022	Renewal of the authorisation	
NA-MAC	DE	BC-JM079160-36	06.11.2023	Addition of the target organism *Lasius niger* and elongation of the shelf-life stability from 24 to 48 months	1; 2.4; 3.1; 3.2; 3.4; 3.7.4.1; 4.1

[1] Date is entered when refMS DE takes decision in R4BP

1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use product, Imidasect Ants with the active substance Imidacloprid (0.01 % w/w) is used as an insecticide (product-type 18) for the control of Pharaoh ants (*Monomorium pharaonis*), Argentine ants (*Linepithema humile*) and Black garden ants (*Lasius niger*).

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[2] are fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.
General directions for use of the product are summarised in chapter 2.5.

A classification according to Regulation (EC) No 1272/2008[3] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the German Assessment Report for the approval of the active substance Imidacloprid including the “elements to be taken into account by Member States when authorising products” as requested by the German CA.
2. The specific provisions from Inclusion Directive for the active substance Imidacloprid (Commission Directive 2011/69/EU).

Approval of the active substance
The active substance Imidacloprid is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.

[2] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.
[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

- Products shall not be authorised for uses in animal housings where emission to a sewage treatment plant or direct emission to surface water cannot be prevented, unless data is submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
- Authorisations shall be subject to appropriate risk mitigation measures. In particular, appropriate risk mitigation measures shall be taken to minimise the potential exposure of infants and children. For products containing Imidacloprid that may lead to residues in food or feed, Member States shall verify the need to set new or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

Composition and formulation

The ready-to-use gel Imidasect Ants contains the active substance Imidacloprid

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore, no corresponding regulatory measures are required.

No substance of concern has been identified.

Please refer to chapter 2.2 (Composition and formulation) and **Fehler! Verweisquelle konnte nicht gefunden werden.** (**Fehler! Verweisquelle konnte nicht gefunden werden.**) for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

Physical-chemical hazard(s) were not identified (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.4. Please find more information on efficacy of the product in chapter 3.4.

Risk assessment for human health

Since no relevant substance of concern has been identified the human health risk assessment for this product is based on the active substance.

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3 and in the confidential annex).

A human health risk assessment has been carried out for non-professional/professional use of the product (see chapter 3.5) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to non-professional/professional users, bystanders and residents. Regarding non-professional/professional users health protection, there are no objections against the intended uses if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

Since no relevant substance of concern has been identified the risk assessment for the environment for this product is based on the active substance.

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3 and in the confidential annex).

A risk assessment for the environment has been carried out for non-professional/professional use indoors and outdoors (see chapter 3.7) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk for the environment if the directions for use according to chapter 2.5 and 2.4 are followed.

Comparative Assessment

Since the active substance Imidacloprid has been identified as a candidate for substitution (see also chapter 2.2.5) a comparative assessment has been necessary (see chapter 3.9). The corresponding Comparative Assessment Report was forwarded to ECHA on 14.03.2022.

The German CA concludes that without Imidacloprid based products there is not an adequate chemical diversity.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Imidasect Ants

2.1.2 Manufacturer(s) of the product

Name of manufacturer	Sharda Cropchem Limited (Formerly known as Sharda Worldwide Exports Pvt Ltd)
Address of manufacturer	Dominic Holm, 29th Road, Bandra 400050 Mumbai India
Location of manufacturing sites	Dominic Holm, 29th Road, Bandra 400050 Mumbai India
	DTS OABE S.L., Polígono Industrial Zabale, Parcela 3 48410 Orozco (Vizcaya) Spain

2.1.3 Manufacturer(s) of the active substance(s)

Active substance	Imidacloprid
Name of manufacturer	Sharda Cropchem Limited (Formerly known as Sharda Worldwide Exports Pvt Ltd)
Address of manufacturer	Dominic Holm, 29th Road, Bandra 400050 Mumbai India
Location of manufacturing sites	HEBEI VEYONG BIO-CHEMICAL CO.LTD 393 East Heping Road Shijizhuang China

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Imidacloprid	(2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine	Active substance	138261-41-3	428-040-8	0.01 (0.0097 pure)

- The product contains a bittering agent.
  - Information on the full composition is provided in the confidential[4] annex (see chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

- 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 ☒

- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one 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 ☒ (The technical equivalence of the active substance from the new source was established by the German CA in August 2013, see Technical Equivalence Report provided with first authorization)

2.2.3 Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product (see detailed assessment in the confidential annex). Therefore, no corresponding regulatory measures are required.

[4] Access level: “Restricted” to applicant and authority

2.2.4 Information on the substance(s) of concern

No substance of concern was identified.

For additional information please, consider the confidential annex.

2.2.5 Candidate(s) for substitution

The following candidate(s) for substitution was/were identified:

- Imidacloprid

Imidacloprid does meet the following criteria for substitution:

- Very persistent
- Toxic

2.2.6 Type of formulation

gel for direct application (GD)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[5]

Besides the active substance Imidacloprid, the other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance Imidacloprid is based on Commission Regulation (EU) No. 2021/849 (17th ATP)[6]. The substance is classified as Acute Tox. 3 (H301), Aquatic acute Cat. 1 (H400) and Aquatic chronic Cat. 1 (H410). While no M-factors are given in the 1st ATP, the most recent effect data from the publication Roessink *et al.* (2013) were considered and the following M factors derived:M100 (acute) and M1000 (chronic).

The classification of the biocidal product Imidasect Ants regarding the environment is solely based on the classification of the active substance Imidacloprid as H400 and H410 with M-factors 100 (acute) and

5 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
6 See: https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database

1000 (chronic). With an active substance content of 0.01 %, the classification of the biocidal product Imidasect Ants results in H411.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.5 and if applicable to chapter 2.4.

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Aquatic chronic 2	H411 (Toxic to aquatic life with long-lasting effects)

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS09	
Signal word	-	Warning
Hazard statements	H411	Toxic to aquatic life with long-lasting effects
Supplemental hazard information		
Supplemental label elements		
Precautionary statements	P273	Avoid release to the environment
	P391	Collect spillage
	P501	Dispose of contents/containers according to national legislation

Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.
It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

2.4 Use(s) appropriate for authorisation[7]

2.4.1 Use 1 appropriate for authorisation – Non-professional use

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Pharaoh ants (*Monomorium pharaonis*) (adults); Argentine ants (*Linepithema humile*) (adults); Black garden ants (*Lasius niger*) (adults)
Field(s) of use	Indoor use Outdoor use around buildings
Application method(s)	Application of a gel bait from a syringe, ampoule or dropper Bait application in bait trays
Application rate(s) and frequency	0.2g/m^2; 0.2g/m (- indoor) 0.2g/nest entry or ant trail; 0.2g/m building perimeter (- outdoor) Per square meter, apply maximum one drop of gel having a diameter of 1cm (approximately 0.2g). Open application indoor: Maximum 1 drop of gel per m^2. Apply gel drops with a diameter of about 1cm (about 0.2g). Open application outdoor: Apply 1 drop of gel directly at the nest entrance or 1 drop/m for the ant trail, apply drops of gel with a diameter of about 1cm (about 0.2g). 0.2g/m^2 (bait tray-indoor) (corresponding to one 0.75g bait tray per 3.8m^2, one 1g bait tray per 5m^2, one 1.2g bait tray per 6m^2, one 1.4g bait tray per 7m^2) 0.2 g /m building perimeter (bait tray-outdoor) (corresponding to one 0.75g bait tray per 3.8m, one 1g bait tray per 5m, one 1.2g bait tray per 6m, one 1.4g bait tray per 7m) Product can be used continuously for 2 months without replacing opened bait trays or unconsumed baits. Maximum of 12 applications per year.
Category(ies) of users	Non-professional
Pack sizes and packaging material	3g, 5g, 10g, 15g syringe (HDPE and transparent polypropylene) 5mL ampoule (HDPE) 4mL, 10mL dropper (HDPE) 0.75g, 1g, 1.2g, 1.4g in bait tray (HDPE and transparent polypropylene)

7 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

2.4.1.1 Use-specific instructions for use

Comply with the instructions for use.

2.4.1.2 Use-specific risk mitigation measures

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

If medical advice is needed, have product container or label at hand.

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

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

Keep out of reach of children and non-target animals/pets.-

2.4.2 Use 2 appropriate for authorisation – Professional use

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Pharaoh ants (*Monomorium pharaonis*) (adults); Argentine ants (*Linepithema humile*) (adults); Black garden ants (*Lasius niger*) (adults)
Field(s) of use	Indoor use Outdoor use around buildings
Application method(s)	Application of a gel bait from a cartridge, ampoule or dropper Bait application in bait trays
Application rate(s) and frequency	0.2g/m^2; 0.2g/m (indoor) 0.2g/nest entry orant trail; 0.2g/m building perimeter (outdoor) Per square meter, apply maximum one drop of gel having a diameter of 1cm (approximately 0.2g). Open application indoor: Maximum 1 drop of gel per m^2. Apply gel drops with a diameter of about 1cm (about 0.2g). Open application outdoor: Apply 1 drop of gel directly at the nest entrance or 1 drop/m for the ant trail, apply drops of gel with a diameter of about 1cm (about 0.2g). 0.2g/m² (bait tray-indoor) (corresponding to one 0.75g bait tray per 3.8m², one 1g bait tray per 5m², one 1.2g bait tray per 6m², one 1.4g bait tray per 7m²) 0.2 g /m building perimeter (bait tray-outdoor) (corresponding to one 0.75g bait tray per 3.8m, one 1g bait tray per 5m, one 1.2g bait tray per 6m, one 1.4g bait tray per 7m) Product can be used continuously for 2 months without replacing opened bait trays or unconsumed baits. Maximum of 12 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	30g, 35g, 50g, 75g, 100g cartridge (HDPE and transparent polypropylene) 5mL ampoule (HDPE) 4mL, 10mL dropper (HDPE) 0.75g, 1g, 1.2g, 1.4g in bait tray (HDPE and transparent polypropylene)

2.4.2.1 Use-specific instructions for use

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2.4.2.2 Use-specific risk mitigation measures

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

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

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

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2.5 General directions for use

2.5.1 Instructions for use

1) Before treatment, remove all natural source of food for ants (waste, food scraps ...) from the infested area to encourage the ingestion of the gel. 2) Where ants are present indoors, place the gel in drops near ant trails, points of entry and their nests. 3) Where ants are present outdoors, place the gel in drops in the ant nests or trails. 4) Where presence of ants is only suspected or detected sporadically, it is recommended to use the gel in a bait tray. 5) The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the kitchen sink, under the oven or the water heater. 6) Apply only in areas that are not liable to submersion or becoming wet, i.e protected from rain, floods and cleaning water. 7) Check the bait trays once a week.

8) During inspections, check the treated area and if necessary, replace the bait tray or apply a new dose of gel.
9) Do not apply the product on absorbing surfaces.
10) Apply the product away from direct sunlight or heat sources (e.g. do not place it under a radiator).
11) Avoid continuous use of the product.
12) Noticeable reduction of ants is expected within 4 weeks. The efficacy is only proven against adult workers, not against the whole nest.
13) If the infestation persists despite following the instructions of the label, contact a pest control professional.
14) Inform the authorisation holder if the treatment is ineffective.
15) The outdoor application of gel in drops should only be conducted on paved surfaces (do not apply on bare soil).
16) Remove bait trays when the plague ceases or is eliminated.
17) Use products at recommended doses and intervals.
18) Do not use neonicotinoids for follow-up treatment where resistance reduces effectiveness.
19) Monitor problematic pest populations in order to detect first shifts in sensitivity.
20) In order to avoid the occurrence of resistance to any active ingredient, products with different modes of action should be used in alternation and the frequent repeated use of the same active substance should be avoided.
21) The use of biocidal products can be combined with other sanitation measures.
22) Products should always be used in accordance with label recommendations.

2.5.2 Risk mitigation measures

1) Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks andlivestock/pets.
2) Avoid release to the environment.

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

1) - IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
2) - IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
3) - IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
4) IF INHALED: Not applicable.
5) This biocidal product contains Imidacloprid which is dangerous to bees.

2.5.4 Instructions for safe disposal of the product and its packaging

1) Dispose of Container/content in a safe way and according to national legislation
2) EWC: 200119 - European Waste Code: pesticides (SDS only)
3) EWC 150110 - European Waste Code: Packaging containing residues of or contaminated by dangerous substances (SDS only)
4) Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains
5) Dispose of unused product, its packaging and all other waste, in accordance with local regulations.
6) Do not clean the bait tray before disposal.

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

1) Do not store near food, drink and animal feeding stuff.
2) Product has to be stored away from light.
3) Shelf-life: 48 months

2.5.6 Other information

The product contains a bittering agent.

2.6 Packaging

Table 4

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Syringe	3g, 5g, 10g, 15g	HDPE and transparent polypropylene	-	Non-professional	Yes
Cartridge	30g, 35g, 50g, 75g, 100g	HDPE and transparent polypropylene	-	Professional	Yes
Bait tray	0.75g, 1g, 1.2g, 1.4g	HDPE and transparent polypropylene	-	Professional, non-professional	Yes
Ampoule	5mL	HPDE	-	Professional, non-professional	Yes
Dropper	4mL, 10mL	HDPE	-	Professional, non-professional	Yes

3 Assessment of the product

3.1 Intended use(s) as applied for by the applicant

3.1.1 Intended use 1 – Non-professional use

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Tropical ants (Pharaoh ants (*Monomorium pharaonis*); Argentine ants (*Linepithema humile*)) (eggs; larvae; nymphs; pupae; imagines, adults) Black garden ants (*Lasius niger*) (adults)[8]
Field(s) of use	Indoor use Outdoor use around buildings (Application aim: Health protection)
Application method(s)	Open application of a gel bait from a syringe, ampoule or dropper Bait application in bait trays
Application rate(s) and frequency	0.2-0.4g/m²; 0.2g/m (open application- indoor) 0.2g/lair entry or foraging trial; 0.2g/m building perimeter (open application- outdoor) Max. 0.35g/m² (bait tray-indoor) Max. 0.23 g /m building perimeter (bait tray-outdoor) Product can be used continuously for 2 - 3 months without replacing opened bait trays or unconsumed baits. Maximum of 12 applications per year.
Category(ies) of users	Non-professional
Pack sizes and packaging material	3g, 5g, 10g, 15g syringe (HDPE and transparent polypropylene) 5mL ampoule (HDPE) 4mL, 10mL dropper (HDPE) 0.75g, 1g, 1.2g, 1.4g in bait tray (HDPE and transparent polypropylene)

[8] Addition of the target organism was part of the major change (BC-JM079160-36) in 2022.

3.1.2 Intended use 2 – Professional use

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Tropical ants (Pharaoh ants (*Monomorium pharaonis*); Argentine ants (*Linepithema humile*)) (eggs; larvae; nymphs; pupae; imagines, adults) Black garden ants (*Lasius niger*) (adults)[8]
Field(s) of use	Indoor use Outdoor use around buildings (Application aim: Health protection)
Application method(s)	Open application of a gel bait from a cartridge, ampoule or dropper Bait application in bait trays
Application rate(s) and frequency	0.2-0.4g/m^2; 0.2g/m (open application- indoor) 0.2g/lair entry or foraging trial; 0.2g/m building perimeter (open application- outdoor) Max. 0.35g/m² (bait tray-indoor) Max. 0.23 g /m building perimeter (bait tray-outdoor) Product can be used continuously for 2 - 3 months without replacing opened bait trays or unconsumed baits. Maximum of 12 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	30g, 35g, 50g, 75g, 100g cartridge (HDPE and transparent polypropylene) 5mL ampoule (HDPE) 4mL, 10mL dropper (HDPE) 0.75g, 1g, 1.2g, 1.4g in bait tray (HDPE and transparent polypropylene)

3.2 Physical, chemical and technical properties

Table 5: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual. EPA OPPTS 830.6302	0.01% w/w Imidacloprid Batch SW-B-5697	Gel	S. Nichetti (2013) GLP-Study No. CH-216/2013
Colour at 20 °C and 101.3 kPa	Visual EPA OPPTS 830.6302	0.01% w/w Imidacloprid Batch SW-B-5697	Colourless	S. Nichetti (2013) GLP-Study No. CH-216/2013
Odour at 20 °C and 101.3 kPa	Olfactory EPA OPPTS 830.6302	0.01% w/w Imidacloprid Batch SW-B-5697	Slight characteristic smell	S. Nichetti (2013) GLP-Study No. CH-216/2013
Acidity / alkalinity	CIPAC Method MT 75.3	0.01% w/w Imidacloprid Batch SW-B-5697	pH= 7.9 after storage of 2 weeks/ 54°C: pH= 7.4	S. Nichetti (2013) GLP-Study No. CH-216/2013
Relative density / bulk density	OECD 109 Method EC A.3 CIPAC Method MT 3.2 Pyknometer method	0.01% w/w Imidacloprid Batch SW-B-5697	D^{20}_4: 1.3052	S. Nichetti (2013) GLP-Study No. CH-211/2013
Storage stability test – **accelerated storage**	Method No. 215/2013 OPPTS 830.6302, 830.6303 and 830.6304	0.01% w/w Imidacloprid Batch SW-B-5697 plastic syringe (HDPE and transparent polypropylene)	**Imidacloprid content** Initial: 0.010 ± 0.001 %w/w After 14 days at 54±2 ºC: 0.010 ± 0.001 %w/w **Appearance/weight Change and compatibility of the packaging material** Initial:	S. Nichetti (2013) GLP-Study No. CH-216/2013

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	CIPAC Method MT 75.3		Colourless liquid (gel) with characteristic odour After 14 days at 54±2 ºC: Colourless liquid (gel) with characteristic odour. Weight change: No significant weight variation. The container didn´t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena. **pH** Initial: pH (25ºC, 1% aqueous solution) = 7.9 After 14 days at 54±2 ºC: pH (25ºC, 1% aqueous solution) = 7.4	
Storage stability test – **long term storage at ambient temperature**	Method 215/2013 OPPTS 830.6302, 830.6303 and 830.6304 CIPAC Method MT 75.3 CIPAC Method MT 191	0.01% w/w Imidacloprid Batch SW-B-5697 plastic syringe (HDPE and transparent polypropylene)	**Imidacloprid content** Initial: 0.010 ± 0.001 %w/w After 24 months: 0.010 ± 0.001 %w/w After 48 months: 0.010 ± 0.001 %w/w **Appearance/weight Change and compatibility of the packaging material** Initial: Colourless liquid (gel) with characteristic odour	S. Nichetti (2017) GLP-Study No. CH-217/2013

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			After 48 months Light yellow liquid (gel) with characteristic odour Weight change after 48 month: H1: -0.42% H2: -0.20% The container didn´t present any deformation in both bottom and lateral layers, or loss of sample and evident corrosion phenomena after 48 months storage. **pH** Initial: pH (25ºC, 1% aqueous solution) = 7.9 After 24 months: pH (25ºC, 1% aqueous solution) = 7.8 After 36 months: pH (25ºC, 1% aqueous solution) = 7.6 After 48 months: pH (25ºC, 1% aqueous solution) = 7.3	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	0.01% w/w Imidacloprid Batch SW-B-5697 100 mL test item was stored in a graduated glass centrifuge tube.	The test item did not show separation of solid or liquid material, nor changes in its physical state after 7 days at 0ºC	S. Nichetti (2013) GLP-Study No. CH-214/2013
Effects on content of the active substance and			Product is stored away from light	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
technical characteristics of the biocidal product - **light**				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			The results of the low temperature and accelerated storage stability tests show no effects of temperature and humidity. The product itself contains ca. 21 % water, thus no effects of humidity are expected.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			No reactivity towards package material	S. Nichetti (2017) GLP-Study No. CH-217/2013
Wettability			Ready-to-use solid Gel bait, not intended for use with water. Therefore the technical characteristics are waived (not applicable)	Waiving[9]
Suspensibility, spontaneity and dispersion stability				
Wet sieve analysis and dry sieve test				
Emulsifiability, re-emulsifiability and emulsion stability				
Disintegration time				
Particle size distribution, content of dust/fines, attrition, friability				

[9] Data waiving was acceptable (see complete justification(s)/annotation(s) in IUCLID dossier).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Persistent foaming				
Flowability/Pourability/Dust ability				
Burning rate — smoke generators				
Burning completeness — smoke generators				
Composition of smoke — smoke generators				
Spraying pattern — aerosols				
Physical compatibility			The product is ready to use and it is not intended to be used in combination with any other product.	Waiving[9]
Chemical compatibility				
Degree of dissolution and dilution stability			Ready-to-use solid Gel bait, not intended for use with water. Therefore the technical characteristics are waived (not applicable)	Waiving[9]
Surface tension			Product is a GL. Data requirement for liquid preparations, additionally measurement is limited to aqueous solutions with a dynamic viscosity <200mPa*s.	Waiving[9]
Viscosity	OECD 114 CIPAC method MT 192	0.01% w/w Imidacloprid Batch SW-B-5697	**Dynamic viscosity** At 20ºC: (60 – 10 rpm) From 8197 cP to 19760 cP At 40ºC: (100 – 10 rpm) From 4097 cP to 13340 cP	S. Nichetti (2013) GLP-Study No. CH-214/2013

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Kinematic viscosity At 20ºC: (60 – 10 rpm) From 6211 cP to 15139 cP At 40ºC: (100 – 10 rpm) From 3139 cP to 10221 cP Imidacloprid 0.01% gel is not a Newtonian fluid and its dynamic viscosity changes with the shear rate.	

Table 6

Conclusion on the physical, chemical and technical properties
The biocidal product Imidasect Ants is a colourless gel with a slight characteristic smell. Technical properties have not been determined, as it is a ready to use product without intention to spray it or to use it with other products. The pH of the product is 7.9 and it is not a Newtonian fluid. The storage stability data low temperature, accelerated (54°C/2 weeks) and longterm storage (48 months) test show no significant changes in active substance content and for Appearance/weight Change and compatibility of the packaging material.

3.3 Physical hazards and respective characteristics

Table 7: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	Justification for Non-Submission: EU Method A.14	-		Not explosive The product comprises 0.01 % Imidacloprid, which might be explosive based on its inherent structural properties. According to the CAR Imidacloprid is not explosive while it might be explosive according to the CLH report. A DSC study showed no exothermic decomposition up to 300 °C. Further, none of the other ingredients contained in the Gel formulation is expected to have explosive properties. Therefore, "Imidacloprid Gel 0.01 %" is not expected to have explosive properties	Doc III-B 3.2 (Sharda Worldwide Exports Pvt. Ltd.), Azeema, G. B. (2021) Report No.: 9269/2021
Flammable gases				Hazard class not applicable. Imidasect Ants is a gel respectively liquid.	
Flammable aerosols				Hazard class not applicable. Imidasect Ants does not get packaged or transported as an aerosol.	
Oxidising gases				Hazard class not applicable. Imidasect Ants is a gel respectively liquid	
Gases under pressure				Hazard class not applicable. Imidasect Ants is a gel respectively liquid.	
Flammable liquids	EU Method A.9, Regulation (EC) No 440/2008	0.01% w/w Imidacloprid Batch SW-B-5697		The sample did not show the typical flammability phenomena up to 64°C. The pilot flame was extinguished at this temperature.	Mazzei N. (2013) Report no.: 201302498

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
	(EN ISO 3680:2005)				
Flammable solids	Flammability upon ignition (solids, gases): Justification for Non-Submission: EU Method A.10, A.11			Not required as the product is a liquid.	Expert judgement by Federal Institute for Materials Research and Testing (BAM), Division 2.2
Self-reactive substances and mixtures	DSC Study according to OECD method 113 utilizing 5 mg urea as reference sample	0.01% w/w Imidacloprid Batch SCL-58863	Thermal decomposition energy below 300 J/g up to 300 °C	Not self-reactive. A DSC study was provided in which urea was utilized as reference sample. Since the tested sample of „Imidsect Ants" comprises solely 0.01 % of Imidacloprid and in addition to that it showed no exothermic peak and a higher endothermic peak (compared to urea, which is not a self-reactive substance) the product was classified as not self-reactive.	Azeema, G. B. (2021) Report No.: 9269/2021
Pyrophoric liquids				Due to known experience Imidsasect Ants is expected to have no pyrophoric properties.	
Pyrophoric solids				Hazard class not applicable. Imidasect Ants is a gel respectively liquid.	
Self-heating substances and mixtures				Imidasect Ants is a gel respectively a liquid. As the test method requested in CLP regulation is not considered for liquids, no test is requested.	
Substances and mixtures which in contact with	Flammability in contact with water:			It is not expected that the product is flammable in contact with water because the product does not contains metals or metalloids and the use	Doc III-B 3.3 (Sharda

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
water emit flammable gases	Justification for Non-Submission: EU Method A.12			experience shows that the product does not react with water.	Worldwide Exports Pvt. Ltd
Oxidising liquids	Justification for Non-Submission: EU Method A.17	-		The test substance does not contain any other ingredients which may indicate oxidising properties on combustible material. Therefore, " Imidasect Ants " is not expected to have oxidising properties	Doc III-B 3.3 (Sharda Worldwide Exports Pvt. Ltd.)
Oxidising solids	UN Test O.1 (in Part III of the UN-MTC) UN Test O.3 (in Part III of the UN-MTC)			Hazard class not applicable. Imidasect Ants is a gel respectively liquid.	
Organic peroxides				None of the ingredients contained in the Gel formulation is expected an organic peroxide. Therefore, "Imidacloprid Gel 0.01 %" is not expected to be an organic peroxide.	
Corrosive to metals	UN Test C.1 (in Part III of the UN-MTC, 37.4)	0.01% w/w Imidacloprid Batch 211701	Corrosion rate: 6.25 mm/year (= 15.5 % mass loss within 8 days) Types of material: Aluminium, type: 7075 T6 F53 Steel, type: S235JR+CR (1.0037 resp. St 37.2)	Not corrosive. Mass loss: 0.004 % within 8 days No localised corrosion was detected. Type of material: Aluminium, type: 7075 T6 F53 Mass loss: 0.173 % within 8 days No localised corrosion was detected. Type of material: Steel, type: S235JR+CR (1.0037 resp. St 37.2)	Petryka,M. (2021), Report No.: BC 19/21

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Auto-ignition temperature (liquids and gases)	EU Method A.15, Regulation (EC) No 440/2008 (ASTM E 659	0.01% w/w Imidaclopri d Batch SW-B-5697		The auto-ignition temperature is 409°C	Nichetti S. (2013) Final Report CH-2013/2013
Relative self-ignition temperature for solids				Hazard class not applicable. Imidasect Ants is a gel respectively liquid.	
Dust explosion hazard				Hazard class not applicable. Imidasect Ants is a gel respectively liquid.	

Table 8

Conclusion on the physical hazards and respective characteristics
The product comprises 0.01 % Imidacloprid, which might be explosive or self-reactive based on its inherent structural properties. According to the CAR Imidacloprid is not explosive while it mitght be explosive according to the CLH report. A DSC study showed no exothermic decomposition up to 300 °C for Imidsect Ants. Further, none of the other ingredients contained in the Gel formulation is expected to have explosive or self-reactive properties and the product comprises solely 0.01 % of Imidacloprid, why a possible explosive eorself-reactive property is further reduced. Therefore, "Imidasect Ants" is expected neither to be explosive nor to be self-reactive. Imidasect Ants is a non-flammable product, since it did not show the typical flammability phenomena up to 64°C. It also does not contain any other ingredients which may indicate oxidising properties on combustible material. Therefore, it is not expected to have oxidising properties. The product is classified as not being an organic peroxide, since none of the ingredients contained in the Gel formulation fulfuls the criteria for organic peroxides. Based on corrosion studies the product is not corrosive. The auto-ignition temperature of Imidasect Ants is 409°C.

Methods for detection and identificationThe determination of the active substance in Imidasect Ants was done with weighing about 1000 mg of the test item into a 20 mL conical flask, adding 9 mL of methanol and 1.00 mL of the diluted internal standard solution (100 µg/mL).
Place into an ultrasonic bath for 15 minutes, filter using syringe filter at 0.45 µm and inject 10 µL into the HPLC to determine the peak areas.

Table 9

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R²)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Active substance in the formulation	HPLC/UV using an internal standard	No interferences detected comparing chromatograms of solvent wash, Imidacloprid reference material, Ethyl paraben internal standard, Imidacloprid test substance, Placebo and test item solutions	5.97 – 13.93 µg/mL (r^2 > 0.999);N = 5; y = 1443637x - 44754	n=2 75% (0.081mg) 100% (0.104mg) 125% (0.144mg)	101.1 - 101.3 98.42-98.45 108.9-109.0	101.2 98.4 109.0 (total mean 102.9)	0.12	N/A	Nichetti,S. (2013), Study number CH – 215/2013

The precision (repeatability) was performed by six determinations of the test item.
The relative standard deviation was 0.51% for Imidacloprid and the Horwitz RSDr was 5.37 at a Imidacloprid concentration of 0.010% w/w. Since the relative standard deviation was lower than the Horwitz RSDr, the repeatability test for this active ingredient was acceptable.

Table 10

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	Imidacloprid	0.016 mg/kg	PNECsoil of 15.75 µg/kg ww based on NOEC earthworm reproduction, AF 10 CAR PT18, Doc I, 2.2.2.2
Drinking water	Imidacloprid	0.1 µg/L	minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	Imidacloprid	0.174 µg/L	PNECwater based on EC_{10} *Chironomus*, AF 5 CAR PT18, Doc I, 2.2.2.2
		0.0048 µg/L [1]	PNECwater based on EC_{10} *Caenis horaria*: 0.024 µg/L, AF 5, revised AR for PT18, 07/2015, chapter 2.2.2.2
Air	Imidacloprid	18 µg/m³	$AEL_{long\ term}$: 0.06 mg/kg bw/d, CAR PT 18, LoEP
Animal and human body fluids and tissues	no relevant residues expected	- [2]	CAR PT18, LoEP
Food of plant origin	no relevant residues expected		CAR PT18, Doc I, 2.1.1
Food of animal origin	no relevant residues expected		CAR PT18, Doc I, 2.1.1

[1] This limit was not considered in the assessment but will be considered for the renewal of the active substance.
[2] In the RAC opinion of 13.06.2019 classification of imidacloprid as Acute tox. 3 is proposed. If this classification gets into force, analytical methods for body fluids and tissues will be needed.

Table 11

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Imidacloprid	HPLC-UV, LiChrospher 60 RP select B column, 270 nm HPLC-UV, LiChrospher 100 CN column, 270 nm	no interfering substances	3 – 1019 µg/L R^2 0.99992	0.03 µg/L / 5 0.3 µg/L / 5 0.03 µg/L / 5 0.3 µg/L / 5	88 – 97 93 – 99 97 – 102 92 – 97	93 96 100 95	4.3 3.1 2.0 2.1	0.03 µg/L	CAR, doc IIIA 4.2.3/01, Sommer, 1999
Imidacloprid	LC-MS/MS, LiChrospher 60 RP Select B, Imidacloprid: m/z 256→209	no interfering substances	solvent: 5 – 50 ng/mL (it corresponds to 0.1 – 1.0 µg/L); R^2 0.99135 matrix: 0.5 – 5.0 µg/L; R^2 0.99902	0.1 µg/L / 3 0.2 µg/L / 3 0.5 µg/L / 3 (all in triplicate)	90–100 100-115 96-104	93 108 99	6.2 7.1 4.2	0.1 µg/L	CAR, doc IIIA 4.2.3/02, Billesbach *et al.*, 1996
Imidacloprid	HPLC-UV, LiChrospher 60 RP select B column, 270 nm	chromatograms demonstrate that the blanks are distinctly below 30 % of the LOQ	0.05 - 2 µg/L (concentration volume 50 mL) 0.1 - 10 µg/L concentration volume 10 mL	0.05 µg/L / 6 1.0 µg/L / 6	-	112 100	4 3	0.05 µg/L	CAR, doc IIIA 4.2.3/03, Koenig, 1996

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Imidacloprid	LC-MS/MS, Inertsil-ODS-3, ESI+, m/z 256→209, 256→84	blanks are distinctly below 30 % of the LOQ	0.02 – 5 ng/mL it corresponds to 0.02 – 6 µg/L 1st transition R^2 : 0.995 2nd transition R^2 : 0.997	m/z 256→209 0.1 µg/L /5 1 µg/L /5 m/z 256→84 0.1 µg/L /5 1 µg/L /5	91 – 106 95 - 108 77 – 99 95 - 110	99 100 89 102	6 5 10 5	0.1 µg/L	Krainz, 2008

Table 12

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Imidacloprid	HPLC-UV, LiChrospher 60 RP select B column, 270 nm HPLC-UV, Zorbax SB CN column, 270 nm	no interfering substances	0.05 – 2.45 µg/mL R^2 1.0000	0.01 mg/kg / 10 0.1 mg/kg / 10 0.01 mg/kg / 10 0.1 mg/kg / 10	87 - 109 86 – 97 81 –93 82 – 91	101 94 89 88	6.6 3.6 4.3 3.3	0.01 mg/kg	CAR, doc IIIA 4.2.1/03, Schramel, 1999
Imidacloprid	LC-MS/MS, LiChrospher 60 RP Select B, Imidacloprid: m/z 256→175	no interfering substances	2.5 – 100 µg/L R^2 : 0.9973 and 0.9998 in both soils	Soil Höfchen 0.005 mg/kg /5 0.05 mg/kg /5 BBA 2.2 soil 0.005 mg/kg /4 0.05 mg/kg /5	 92 – 104 85 – 93 97 – 114 89 - 95	 101 89 108 93	 4.8 3.4 7.0 2.8	0.005 mg/kg	CAR, doc IIIA 4.2.1/01, Schramel, 2001
Imidacloprid	LC-MS/MS, Inertsil- ODS-3, ESI+, m/z 256→209, 256→84	blanks are distinctly below 30 % of the LOQ	0.1 – 10 ng/mL it corresponds to 0.0025 – 0.25 mg/kg 1st transition R^2 : 0.998 2nd	sandy loam m/z 256→209 0.005 mg/kg /5 0.05 mg/kg /5 m/z 256→84 0.005 mg/kg /5 0.05 mg/kg /5	 97 – 116 100 – 113 105 –	 105 106 109 107	 7 5 3 6	0.005 mg/kg	Krainz, 2008

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
			transition R^2 : 0.998		113 101 - 114				

Table 13:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Imidacloprid	HPLC-UV, LiChrospher 60 RP select B column, 270 nm	chromatograms demonstrate that the blanks are distinctly below 30 % of the LOQ	0.09 – 1.16 mg/L, R^2 1.0000 0.8 – 10 mg/L, R^2 0.99989	Adsorber: Tenax 5 µg/m³ / 4 40 µg/m³ / 4 2000 µg/m³ / 4 Adsorber: XAD-2 5 µg/m³ / 4 40 µg/m³ / 4 2000 µg/m³ / 4	 103-107 100-102 99-102 103-106 98-101 101-105	 105 101 101 104 101 103	 4 4 4 4 4 4	5 µg/m³	CAR, doc IIIA 4.2.2/01, 4.2.2/02 Riegner, 1992; Riegner, 1993
Imidacloprid	HPLC-UV, Zorbax SB-CN column, 270 nm	no data	0.11 – 1.07 mg/L	5 µg/m³	101	-	-	5 µg/m³	CAR, doc IIIA 4.2.2/03, Hellpointner, 1999

Table 14

Analytical methods for surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Imidacloprid	HPLC-UV, LiChrospher 60 RP select B column, 270 nm HPLC-UV, LiChrospher 100 CN column, 270 nm	no interfering substances	3 – 1019 µg/L R^2 0.99992	0.03 µg/L / 5 0.3 µg/L / 5 0.03 µg/L / 5 0.3 µg/L / 5	101–118 80 – 97 72 –82 79 – 96	110 91 76 87	5.5 7.7 5.3 6.9	0.03 µg/L	CAR, doc IIIA 4.2.3/01, Sommer, 1999
Imidacloprid	LC-MS/MS, Inertsil-ODS-3, ESI+, m/z 256→209, 256→84	blanks are distinctly below 30 % of the LOQ	0.02 – 5 ng/mL it corresponds to 0.02 – 6 µg/L 1st transition R^2 : 0.999 2nd transition R^2 : 0.999	m/z 256→209 0.1 µg/L /5 1 µg/L /5 m/z 256→84 0.1 µg/L /5 1 µg/L /5	91 – 107 91 - 106 89 – 111 91 - 108	97 100 99 101	7 6 8 7	0.1 µg/L	Krainz, 2008

Table 15

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.2.2. Air Since the active substance is not volatile and no aerosols are to be expected, an analytical method for air is not necessary. 2. 5.2.4. Body fluids and tissues 3. 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant[10]
Justification	See justification(s)/annotation(s) in IUCLID dossier No relevant residues are expected in body fluids and tissues and in food of plant or animal origin.

Table 16

Conclusion on the methods for detection and identification
The methods provided regarding the residues of the active substances Imidacloprid were acceptable. Methods regarding residues of substances of concern were not necessary. Please note the footnotes to Table 10 (Relevant residue definitions for monitoring and levels for which compliance is required) concerning analytical methods for surface water and body fluids and tissues.

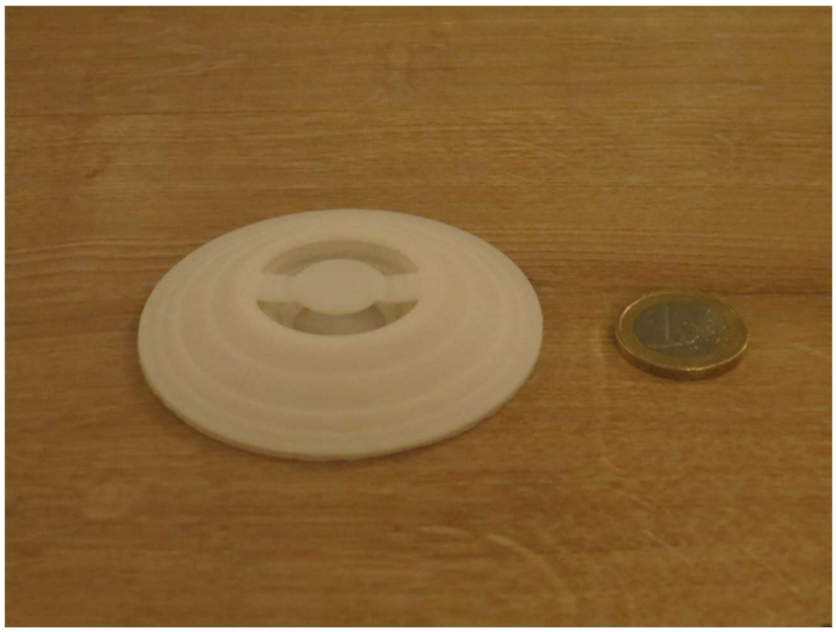
[10] Not necessary if neither the active substance nor the material treated with it come into contact with food- producing animals, food of plant and animal origin or feeding stuffs

3.4 Efficacy against target organisms

3.4.1 Function and field of use

Main Group 03: Pest Control
Product type 18: Insecticides, acaricides and products to control other arthropods

The biocidal product “Imidasect Ants” is a gel formulation with the insecticidal active substance Imidacloprid (0.01%), intended to be used as oral bait against eggs, larvae, nymphs, pupae and adults of Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*) indoors and outdoors as open gel application or in bait trays (Picture 1). The intended application rate for the application method “open gel application” is 0.2 – 0.4g b.p./m² or 0.2 g/m for indoor use and 0.2 g b.p./nest entry or ant trail or 0.2 g b.p./m building perimeter for outdoor use. In bait trays max. 0.35 g b.p./m² is intended to be applied for indoor use and max. 0.23 g b.p./m building perimeter for outdoor use.
The product is intended to be used by non-professional (use #1) and professional users (use #2).
The submitted studies are suitable to support the claim “kills adults of Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*) as open gel application and bait tray in indoor and outdoor environments”. The product can be used continuously for 2 months without replacing opened bait trays or unconsumed open gel bait. As the product contains a preservative a shelf life of two years is supported, even if no studies with an aged product have been submitted.
Major change in 2022: New studies demonstrated the efficacy against adult Black garden ants (*Lasius niger*) and the efficacy of the 48 months aged product against all three target organisms. Therefore, adult Black garden ants (*Lasius niger*) can be authorized as target organism and the shelf life can be elongated to 48 months.



Picture 1 Open bait tray

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

The product “Imidasect Ants” is intended to be used to kill eggs, larvae, nymphs, pupae and adults of Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*) in indoor and outdoor (health protection) environments.
Major change in 2022: The product is also intended to be used to kill adult Black garden ants (*Lasius niger*).

3.4.3 Effects on target organisms, including unacceptable suffering

Knockdown and kill.

3.4.4 Mode of action, including time delay

Imidacloprid is a neonicotinoid which acts on the central nervous system of insects by blockage of the nicotinergic neuronal pathway. This disturbance of the transmission of stimuli leads to paralysis and subsequent death of the target organisms. Imidacloprid acts as a contact insecticide as well as after ingestion.

3.4.5 Efficacy data

In accordance with the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.2.3) the applicant submitted laboratory studies (Heaven 2013a; Jadhav 2021a, b), a simulated-use test (Heaven 2013b) and field studies (Kinsey 2016; Suryawanshi 2021a, b, c) with the product “Imidasect Ants” as open gel application or in bait trays against Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*) (study summaries see Table 17).

<u>Laboratory trials:</u>
The laboratory test by Heaven (2013a) demonstrated 90.9% mortality 59 days after application of the open gel against *L. humile* and 99.6% mortality 28 days after product application against *M. pharaonis*. Mortality in the untreated controls was 14.2% for *L. humile* and 12.7% *M. pharaonis*.

A laboratory test by Jadhav (2021a) demonstrated 100% mortality with the fresh gel against *L. humile* and *M. pharaonis* after an exposure period of 28 days. With the 8 weeks opened gel bait the mortality was 94.7% against *L. humile* and 95% against *M. pharaonis* after an exposure period of 28 days. Mortality in the untreated controls was for both ant species ≤ 6.3% at the end of the exposure period.
A second laboratory test by Jadhav (2021b) demonstrated 100% mortality with the fresh bait trays against *L. humile* and *M. pharaonis* after an exposure period of 28 days. With the 8 weeks opened bait trays the mortality was 95.3% against *L. humile* and 97% against *M. pharaonis* after an exposure period of 28 days. Mortality in the untreated controls was for both ant species ≤ 5.3% at the end of the exposure period.
These laboratory tests are valid and sufficiently prove the efficacy (mortality > 95%; Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.3.1)) of the fresh and 8 weeks opened product “Imidasect Ants” applied as open gel and in bait trays against both ant species. The tests showed no difference in the palatability/mortality between both application methods (open gel and bait tray), demonstrating that the gel in the bait trays is easily found by the insects and the bait tray does not influence the accessibility of the gel for the ants as the bait trays provide enough space for ants to access. Ants lay olfactory trails to inform their conspecifics of food sources, and they will do so in the presence or absence of a bait tray. Therefore, the presence or absence of a bait tray does not have important implicaitons on the uptake rate. Technically, the bait tray provides a surface for placing the bait gel, so that the user does not have to place it directly on the floor or wall.

Simulated-use test:

The simulated-use test by Heaven (2013b) cannot be evaluated, due to very high control mortalities.
In accordance with the Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.2.3) “simulated-use tests can be waived if a robust field trial is submitted”.

Field studies:

Open gel application in indoor environments

The study by Kinsey (2016) was conducted with *M. pharaonis* in apartments and the open gel was applied in doses of 0.2 g/m². A population reduction of 100% was demonstrated in 2 out of 3 replicates beginning 4 weeks after product application and up to 6 weeks. In the 3rd replicate the population reduction was only 75% and 90% after 4 and 6 weeks after product application, respectively.
In a second study by Suryawanshi (2021a) the product was applied also as open gel (dosage: 0.2 g/m²) in houses in India infested with *L. humile* or *M. pharaonis*. With *L. humile* a population reduction of ≥ 90% was demonstrated in all 3 replicates beginning 1 week after product application and up to the end of the observation period after 4 weeks. For *M. pharaonis* a population reduction of ≥ 90% was demonstrated in all 3 replicates beginning 2 weeks after product application and up to 4 weeks after product application.
These field tests are valid and sufficiently prove the efficacy (population reduction > 90%; Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.3.1)) of the product against both ant species as open gel application in indoor environments.

Open gel application in outdoor environments

In the study by Suryawanshi (2021b) the product was also applied as open gel (dosage: 0.2 g/m²) under outdoor conditions in India infested with *L. humile* or *M. pharaonis*. With *L. humile* a population reduction of ≥ 90% was demonstrated in all 3 replicates beginning 2 weeks after product application and up to the end of the observation period after 4 weeks. For *M. pharaonis* a population reduction of ≥ 90% was demonstrated in all 3 replicates beginning 1 week after product application and up to 4 weeks after product application.

This field test is valid and sufficiently prove the efficacy (population reduction > 90%; Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.3.1)) of the product against both ant species as open gel application in outdoor environments.

Application in bait trays in indoor environments

In the study by Suryawanshi (2021c) the product was applied in trays (1 tray/7 m² loaded with 1.4 g gel) in houses in India infested with *L. humile* or *M. pharaonis*. With *L. humile* a population reduction of ≥ 90% was demonstrated in 2 out of 3 replicates beginning 3 weeks after product application and up to the end of the observation period after 4 weeks. In the third replicate the population reduction was 88.1% and 89.6% after 3 and 4 weeks, respectively. The population reduction in the untreated controls was ≤23.2%. For *M. pharaonis* a population reduction of ≥ 90% was demonstrated in all 3 replicates beginning 3 weeks after product application and up to 4 weeks after product application. The population reduction in the untreated controls was ≤43.1% with *M. pharaonis.*

This field test proves a population reduction > 90% in accordance with the Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.3.1), but the mortality in the untreated controls is very high and therefore the efficacy cannot be evaluated.

However, the laboratory tests demonstrated sufficient palatability/mortality for both application methods (open gel and bait tray) and the efficacy of the product applied as open gel in indoor and outdoor environments, was sufficiently demonstrated. Instead of a bait box/station with a lid as protection against environmental conditions like rain, sunlight, desiccation and dirt, the bait tray is a flat dish without a lid with a gel droplet in the middle. Technically, the tray just provides a surface/substrate for placing the bait gel, so that the user does not have to place the gel directly on the floor or wall. Therefore, both the open gel and the gel in a bait tray are exposed in the same way to environmental conditions (rain, sunlight, desiccation and dirt).

Therefore, the overall data package is suitable to authorize the application in bait trays in indoor environments.

Application in bait trays in outdoor environments

In the study by Kinsey (2016) the product was tested in bait boxes in doses of 0.2 g/m² against *L. humile* in outdoor environments. A population reduction of ≥ 95.6% was demonstrated in all 3 replicates 1 week after product application up to 4 weeks.

A field test with *M. pharaonis* and product application in bait trays in outdoor environments has not been provided. However, the laboratory tests demonstrated sufficient palatability/mortality for both application methods (open gel and bait tray) and the efficacy of the product applied as open gel in indoor and outdoor environments was sufficiently demonstrated. Instead of a bait box/station with a lid as protection against environmental conditions like rain, sunlight, desiccation and dirt, the bait tray is a flat dish without a lid with a gel droplet in the middle. Technically, the tray just provides a surface/substrate for placing the bait gel, so that the user does not have to place the gel directly on the floor or wall. Therefore, both the open gel and the gel in a bait tray are exposed in the same way to environmental conditions (rain, sunlight, desiccation and dirt).

Therefore, the overall data package is suitable to authorize the application in bait trays in outdoor environments.

Conclusion:

The efficacy of the product “Imidasect Ants” was not proven against ant nests, as laboratory studies were only conducted with adults and in the field studies mortality of queens and brood was not investigated. Therefore, only adults can be claimed as developmental stage.

Consequently, the submitted studies are suitable to support the claim “kills adults of Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*) as open gel application and bait tray in indoor and outdoor environments”. The product can be used continuously for 2 months without replacing opened bait trays or unconsumed open gel bait. As the product contains a preservative a shelf life of two years is supported, even if no studies with an aged product have been submitted.

Major change in 2022

Addition of the target organism adult Black garden ants (Lasius niger):

As part of the first authorisation and the renewal of the product, the applicant has already submitted laboratory studies (Heaven 2013a; Serrano 2016; Jadhav 2021a, b), a simulated-use test (Heaven 2013b) and field studies (Serrano 2015; Kinsey 2016; Suryawanshi 2021 b, c) with Black garden ants (*Lasius niger*), but the data package was not sufficient to authorize this target organism. Therefore, the applicant submitted two new field studies (Suryawanshi 2023; Yadav 2023) with Black garden ants (*Lasius niger*).

Laboratory tests:

The laboratory test by Heaven (2013a) demonstrated 93.4% mortality 28 days after application of the open gel against *L. niger*. However, due to the high mortality (15.1%) in the untreated controls at the end of the test period this test cannot be evaluated.

The laboratory test by Serrano (2016) demonstrated 100% mortality 14 days after application of bait trays against *L. niger*. Mortality in the untreated controls was 4.3% at the end of the test period.

A laboratory test by Jadhav (2021a) demonstrated 100% and 95.3% mortality after an exposure period of 28 days with the fresh and the 8 weeks opened gel bait, respectively. Mortality in the untreated controls was ≤ 6% at the end of the test period.

A second laboratory test by Jadhav (2021b) demonstrated 98.3% and 95% mortality after an exposure period of 28 days with the fresh and the 8 weeks opened bait trays. Mortality in the untreated controls was ≤ 2.3% at the end of the test period.

The laboratory tests by Serrano (2016) and Jadhav (2021a, b) are valid and sufficiently prove the efficacy (mortality > 95%; Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.3.1)) of the fresh and 8 weeks opened product "Imidasect Ants" applied as open gel and in bait trays against adult Black garden ants (*Lasius niger*). The tests showed no difference in the palatability/mortality between both application methods (open gel and bait tray).

Simulated-use test:

The simulated-use test by Heaven (2013b) cannot be evaluated, due to very high control mortalities.

In accordance with the Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.2.3) "simulated-use tests can be waived if a robust field trial is submitted".

Field trials:

The study by Serrano (2015) was conducted with the product applied as open gel (dosage: 0.2 g/per nest entry) in outdoor environments (terraces, pavements, gardens) in France against *Lasius niger*. A population reduction of ≥90% was demonstrated in 4 out of 5 replicates 28 days after product application. In the 5th replicate the population reduction was 90.6% 21 days after product application, but only 88.9% 28 days after product application. Mean population reduction in the untreated controls was 9.2% after 28 days.

In the study by Kinsey (2016) the product was applied as open gel (0.2 g/m²) at day 1, 5, 12 and 25 against *L. niger* in outdoor environments. The population reduction was 86.7 ± 10.2% and 93.3 ± 5.1% 32 and 35 days after product application, respectively.

In the study by Suryawanshi (2021b) the product was also applied as open gel (dosage: 0.2 g/m²) in outdoor paved areas in India infested with *L. niger*. A population reduction of ≥ 96.6% was demonstrated in all 3 replicates beginning 2 weeks after product application and up to the end of the observation period after 4 weeks. However, the population reduction in the untreated controls was up to 33.6% and therefore the efficacy of the product cannot be evaluated.

In the study by Suryawanshi (2021c) the product was applied in trays (1 tray/7 m² loaded with 1.4 g gel) in houses in India infested with *L. niger*. A population reduction of ≥ 91.5% was demonstrated in all 3 replicates at the end of the observation period after 4 weeks. However, the population reduction in the untreated controls was up to 39.1% and therefore the efficacy of the product cannot be evaluated.

In the study by Suryawanshi (2023a) the product was applied as open gel (dosage: 0.2 g/m²) in houses in India infested with *L. niger*. A population reduction of ≥ 95.3% was demonstrated in all 3 replicates beginning 1 week after product application and up to the end of the observation period after 4 weeks. The population reduction in the untreated controls was ≤10.7%.

In the study by Yadav (2023) the product was applied in trays (1 tray/7 m² loaded with 1.4 g gel) in houses in India infested with *L. niger*. A population reduction of ≥ 93.8% was demonstrated in all 3 replicates beginning 2 weeks after product application and up to the end of the observation period after 4 weeks. The population reduction in the untreated controls was ≤9.9%.
Due to very high control mortalities the field tests by Suryawanshi (2021b, c) cannot be evaluated, and the study by Kinsey (2016) is not valid as the product was re-applied which does not correspond with the intended use. However, the field tests by Serrano (2015), Suryawanshi (2023a) and Yadav (2023) are valid and sufficiently prove the efficacy (population reduction > 90%; Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.3.1)) of the fresh product “Imidasect Ants” applied as open gel under indoor and outdoor environments and in bait trays in indoor conditions against adult Black garden ants (*Lasius niger*). A field test with *L. niger* and product application in bait trays in outdoor environments has not been provided. However, the laboratory tests demonstrated sufficient palatability/mortality for both application methods (open gel and bait tray) and the efficacy of the product applied as open gel in indoor and outdoor environments was sufficiently demonstrated. Instead of a bait box/station with a lid as protection against environmental conditions like rain, sunlight, desiccation and dirt, the bait tray is a flat dish without a lid with a gel droplet in the middle. Technically, the tray just provides a surface/substrate for placing the bait gel, so that the user does not have to place the gel directly on the floor or wall. Therefore, both the open gel and the gel in a bait tray are exposed in the same way to environmental conditions (rain, sunlight, desiccation and dirt).
Therefore, the overall data package is suitable to authorize the application in bait trays in outdoor environments.

Conclusion: the overall data package is suitable to support the claim “kills adults of Black garden ants (*Lasius niger*) as open gel application and bait tray in indoor and outdoor environments”. The product can be used continuously for 2 months without replacing opened bait trays or unconsumed open gel bait.

Elongation of shelf life from 24 to 48 months:
The applicant submitted two new field studies (Suryawanshi 2023b, c) with Black garden ants (*Lasius niger*), Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*) and the 48 months aged product “Imidasect Ants”.
Both field tests are valid and sufficiently prove the efficacy (population reduction > 90%; Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.3.1)) of the 48 months old product “Imidasect Ants” against all three ant species. Therefore, a shelf life of 48 months can be authorized.

Table 17

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT18	indoor outdoor	Imidasect Ants (0.01% Imidacloprid); fresh	*Monomorium pharaonis, Linepithema humile, Lasius niger*	Laboratory test with open gel application	Choice trial: - plastic arena: 17 x 11.5 x 5 cm - dosage: 1 drop (0.2 g) per arena - test individuals: approx 300 ants (plus brood and queens) - competition food: sugar cube - acclimatisation: 7 days - starvation: 4 days - 4 replicates per species - temperature: 24 – 26.7°C - rel. humidity: 29.3 - 48.5% - efficacy parameter: number of ants at bait and sugar cube	*Linepithema humile* 90.9% mortality after 59 d control: 14.2% *Monomorium pharaonis* 99.6% mortality after 28 d control: 12.7% *Lasius niger* 93.4% mortality after 28 d control: 15.1% *evaluation: reliability index (RI) = 2* *- suitable to prove the palatability/efficacy against* Monomorium pharaonis *with the fresh product* *- not suitable to prove the efficacy against* Lasius niger *(mortality <95%; high mortality in control)*	Heaven (2013a) Study Code: 13/141
PT18	indoor outdoor	Imidasect Ants Trap (0.01% Imidacloprid); fresh	*Lasius niger*	Laboratory test with bait trays	Choice trial: - glass arena: 50 x 40 x 40 cm - dosage: 1 bait tray per arena - test individuals: 500 ± 20 workers	100% population reduction after 14 days in all replicates control: 4.3% mean population reduction after 4 weeks	Serrano (2016) Study No: 2126c/0816

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					- competition food: 2% sugar solution - starvation: no - 4 replicates - temperature: 25 ± 1°C - rel. humidity: 65 ± 4% - acclimatisation: 7 days - efficacy parameter: number of ants	*evaluation: RI = 2* *- suitable to prove the efficacy against* Lasius niger *with the fresh product* *- information if the construction/appearance of the bait trays used in the test are identical to the authorized bait trays is missing in the study report*	
PT18	indoor outdoor	Imidasect ants (Imidacloprid 0.01%) bait gel, fresh and 8 weeks aged under ambient conditions	*Monomorium pharaonis, Linepithema humile, Lasius niger;* adult	Laboratory test with open gel application	Choice trial: - vivarium: 60 x 40 x 15 cm with alternative food (suger granules) and water - dosage per arena: 0.2g gel - test individuals: 100 ants per replicate - 3 replicates per species and treatment (fresh/ aged) - temperature: 25.2 - 27.2°C - rel. humidity: 67 - 76% - assessment intervals: 1, 3, 7, 14, 21 and 28 days - untreated controls: n=3 per species	*Linepithema humile* fresh bait: 100% mortality after 28 d 8 weeks aged bait: 94.7% mortality after 28 d control: ≤3.7% mortality *Monomorium pharaonis* fresh bait: 100% mortality after 28 d 8 weeks aged bait: 95% mortality after 28 d control: ≤6.3% mortality *Lasius niger* fresh bait: 100% mortality after 28 d 8 weeks aged bait: 95.3% mortality after 28 d	Jadhav (2021a) Study Code: 368KAMG4906/R0

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						control: ≤6% mortality *evaluation: RI = 1* *- suitable to prove the palatability/efficacy against* Linepithema humile, Monomorium pharaonis *and* Lasius niger *with the fresh and 8 weeks opened product*	
PT 18	indoor outdoor	Imidasect ants (Imidacloprid 0.01%) gel traps loaded with 1.4 g gel, fresh and 8 weeks aged under ambient conditions	*Monomorium pharaonis, Linepithema humile, Lasius niger;* adult	Laboratory test with with bait trays	Choice trial: - vivarium: 60 x 40 x 15 cm with alternative food (suger granules) and water - dosage per arena: 1 trap with 1.4g bait gel - test individuals: 100 ants per replicate - 3 replicates per species and treatment (fresh/ aged) - temperature: 25.3 – 27.3°C - rel. humidity: 68 - 75% - assesment intervals: 1, 3, 7, 14, 21 and 28 days - untreated controls: n=3 per species	*Linepithema humile* fresh bait: 100% mortality after 28 d 8 weeks aged bait: 95.3% mortality after 28 d control: ≤3.7% mortality *Monomorium pharaonis* fresh bait: 100% mortality after 28 d 8 weeks aged bait: 97% mortality after 28 d control: ≤5.3% mortality *Lasius niger* fresh bait: 98.3% mortality after 28 d 8 weeks aged bait: 95% mortality after 28 d control: ≤2.3% mortality	Jadhav (2021b) Study Code: 368KAMG4909/R0

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						evaluation: RI = 1 *- suitable to prove the palatability/efficacy against* Linepithema humile, Monomorium pharaonis *and* Lasius niger *with the fresh and 8 weeks opened product*	
PT18	indoor outdoor	Imidasect Ants Trap (0.01% Imidacloprid); fresh	*Monomorium pharaonis, Linepithema humile, Lasius niger*	Simulated-use test with with bait trays	Choice trial: - plastic arena: 30 x 20 x 21 cm - dosage: 1 bait tray (0.4 g gel) per arena - test individuals: approx 200 ants (plus brood and queens) - competition food: sugar cube - acclimatisation: 7 days - starvation: 4 days - 5 replicates per species - temperature: 23.4 – 28.6°C - rel. humidity: 33.6 – 70.3% - efficacy parameter: number of ants at bait and sugar cube	*Linepithema humile* 64.9% mortality after 45 d control: 56.0% *Monomorium pharaonis 88.9*% mortality after 45 d control: 56.6% *Lasius niger* 94.8% mortality after 28 d control: 28.5% *evaluation: RI = 3* *- mortalities in untreated controls very high*	Heaven (2013b) Study Code: 13/288
PT18	indoor outdoor	Imidasect Ants (0.01% Imidacloprid); fresh	*Lasius niger;* whole nests	Field test with open gel application	- nests in outdoor environments (terraces, pavements, gardens) in France - dosage: 1 drop (0.2 g) per nest entry	95% mean population reduction after 28 days (88.9%, 90.2%, 96.0%, 100.0%, 100.0%);	Serrano (2015) Report No: 2008/1015R

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					- 5 replicates - efficacy parameter: number of ants within 5 min; after 4 weeks nests were opened	2 replicates with 2 and 3 nymphs/ cocoons; 3 replicates with no nymphs/ cocoons control: 9.2% (mean) population reduction after 4 weeks *evaluation: RI = 1* *- suitable to prove the efficacy against* Lasius niger	
PT18	indoor outdoor	Imidasect Ants (0.01% Imidacloprid); fresh	*Monomorium pharaonis, Linepithema humile, Lasius niger*; whole nests	Field test	- *Linepithema humile* nests in outdoor environments in Spain; application 0.2 g/m² in bait boxes - *Monomorium pharaonis* nests in indoor environments (apartments) in Czech Republic; application 0.2 g/m² as open gel - *Lasius niger* nests in outdoor environments in UK; application 0.2 g/m² as open gel, at day 1, 5, 12 and 25 - 3 replicates per species - efficacy parameter: number of *Monomorium pharaonis, Linepithema humile* individuals in monitoring stations; counting of *Lasius niger* around the nest *Lasius niger Monomorium pharaonis, Linepithema humile*	*Linepithema humile* population reduction 1 up to 4 weeks after application: ≥95.6% in all replicates *Monomorium pharaonis* population reduction 4 and 6 weeks after application: 100% in 2 replicates; replicate 1: 75% (4 weeks) and 90% (6 weeks) *Lasius niger* population reduction after 32 days: 86.7 ± 10.2%; after 35 days: 93.3 ± 5.1% *evaluation: RI = 1* *- suitable to prove the efficacy against* Linepithema humile *and* Monomorium pharaonis	Kinsey (2016) Study Code 14/364

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						- not suitable to prove the efficacy against Lasius niger *(re-application; population reduction <90%)* *- inclusion of untreated controls is preferable but not mandatory in accordance with the Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.4.2.2)*	
PT18	indoor outdoor	Imidasect ants (Imidacloprid 0.01%) gel; fresh	*Monomorium pharaonis, Linepithema humile*	Field test with open gel application	- indoor environments (houses) in India - dosage: 0.2 g/m² on/next to ant trails - 3 replicates per species - temperature: 26.1 - 28.6°C - rel. humidity: 60 - 77% - efficacy parameter: number of ants (pre-treatment and at assessment intervals) - assessment intervals: 1, 7, 14, 21 and 28 days - untreated controls: n=3 per species	*Linepithema humile* population reduction 1 up to 4 weeks after application: ≥91.8% in all replicates *Monomorium pharaonis* population reduction 2 up to 4 weeks after application: ≥91.1% in all replicates *evaluation: RI = 1* *- suitable to prove the efficacy against Linepithema humile and Monomorium pharaonis with open gel application indoors*	Suryawanshi (2021a) Study Code: 368KAMG4907/R0
PT18	indoor outdoor	Imidasect ants (Imidacloprid 0.01%) gel; fresh	*Monomorium pharaonis, Linepithema humile, Lasius niger*	Field test with open gel application	- outdoor paved areas in India - dosage: 0.2 g/m² on/next to ant trails (protected from rain fall) - 3 replicates per species	*Linepithema humile* population reduction 2 up to 4 weeks after application: ≥95.4% in all replicates	Suryawanshi (2021b) Study Code: 368KAMG4908/R0

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					- temperature: 26.4 - 28.7°C - rel. humidity: 60 - 77% - efficacy parameter: number of ants (pre-treatment and at assessment intervals) - assessment intervals: 1, 7, 14, 21 and 28 days - untreated controls: n=3 per species	*Monomorium pharaonis* population reduction 1 up to 4 weeks after application: ≥93.9% in all replicates *Lasius niger* population reduction 2 up to 4 weeks after application: ≥96.6% in all replicates; controls: ≤33.6% *evaluation: RI = 1* *- suitable to prove the efficacy against Linepithema humile and Monomorium pharaonis with open gel application outdoors* *- not suitable to prove the efficacy against* Lasius niger *(very high mortalities in untreated controls)*	
PT18	indoor outdoor	Imidasect ants (Imidacloprid 0.01%) gel traps loaded with 1.4 g gel; fresh	*Monomorium pharaonis, Linepithema humile, Lasius niger*	Field test with gel application in bait trays	- indoor environments (houses) in India - dosage: 1 tray/7 m^2 on/next to ant trails - 3 replicates per species - temperature: 25.1 - 28.5°C - rel. humidity: 69 - 75% - efficacy parameter: number of ants (pre-treatment and at assessment intervals) - assessment intervals: 1, 7, 14, 21 and 28 days	*Linepithema humile* population reduction 3 up to 4 weeks after application: ≥91.7% in 2 replicates; replicat 3: 88.1% and 89.6% population reduction in controls: ≤23.2% *Monomorium pharaonis* population reduction 1 up to 2 weeks after application: ≥93.2% in 2 replicates; replicat 2: 86.7%	Suryawanshi (2021c) Study Code: 368KAMG4910/R0

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					- untreated controls: n=3 per species	population reduction 3 up to 4 weeks after application: ≥94.7% in all replicates population reduction in controls: ≤43.1% *Lasius niger* population reduction 1 up to 3 weeks after application: 72.6-94.4% population reduction 4 weeks after application: ≥91.5% in all replicates population reduction in controls: ≤39.1% *evaluation: RI = 3* *- mortalities in untreated controls very high*	
PT18	indoor outdoor	Imidasect ants (Imidacloprid 0.01%) gel; fresh	*Lasius niger*	Field test with open gel application	- indoor environments (houses) in India - dosage: 0.2 g/m² next to ant trails - 3 replicates - temperature: 25.8 - 28.3°C - rel. humidity: 59 - 74% - efficacy parameter: number of ants (pre-treatment and at assessment intervals) - assessment intervals: 1, 7, 14, 21 and 28 days	population reduction 1 up to 4 weeks after application: ≥95.3% in all replicates population reduction in controls: ≤10.7% *evaluation: RI = 1* *- suitable to prove the efficacy against* Lasius niger *with open gel application indoors*	Suryawanshi (2023a) Study Code: 368AAPN8251/R0

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
					- untreated controls: n=3		
PT18	indoor outdoor	Imidasect ants (Imidacloprid 0.01%) gel traps loaded with 1.4 g gel; fresh	*Lasius niger*	Field test with gel application in bait trays	- indoor environments (houses) in India - dosage: 1 tray/7 m^2 next to ant trails - 3 replicates - temperature: 26.1 - 27.6°C - rel. humidity: 60 - 72% - efficacy parameter: number of ants (pre-treatment and at assessment intervals) - assessment intervals: 1, 7, 14, 21 and 28 days - untreated controls: n=3	population reduction 2 up to 4 weeks after application: ≥93.8% in all replicates population reduction in controls: ≤9.9% *evaluation: RI = 1* *- suitable to prove the efficacy against* Lasius niger *with bait trays indoors*	Yadav (2023) Study Code: 368AAPN8251/R1
PT18	indoor outdoor	Imidasect ants (Imidacloprid 0.01%) gel; 48 months old	*Monomorium pharaonis, Linepithema humile, Lasius niger*	Field test with open gel application	- outdoor paved areas in India - dosage: 0.2 g/m² next to ant trails - 3 replicates per species - temperature: 26.2 - 28.5°C - rel. humidity: 59 - 76% - efficacy parameter: number of ants (pre-treatment and at assessment intervals) - assessment intervals: 1, 7, 14, 21 and 28 days - untreated controls: n=3 per species	*Linepithema humile* population reduction 2 up to 4 weeks after application: ≥96.5% in all replicates *Monomorium pharaonis* population reduction 1 up to 4 weeks after application: ≥96.3% in all replicates *Lasius niger* population reduction 2 up to 4 weeks after application: ≥98.2% in all replicates	Suryawanshi (2023b) Study Code: 368BAPN8328/R0

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						population reduction in controls for all 3 ant species: ≤10% *evaluation: RI = 1* *- suitable to prove the efficacy against* Linepithema humile, Monomorium pharaonis *and* Lasius niger *with open gel application outdoors after storage of 48 months*	
PT18	indoor outdoor	Imidasect ants (Imidacloprid 0.01%) gel traps loaded with 1.4 g gel; 48 months old	*Monomorium pharaonis, Linepithema humile, Lasius niger*	Field test with gel application in bait trays	- indoor environments (houses) in India - dosage: 1 tray/7 m^2 next to ant trails - 3 replicates per species - temperature: 25.0 - 28.3°C - rel. humidity: 59 - 73% - efficacy parameter: number of ants (pre-treatment and at assessment intervals) - assessment intervals: 1, 7, 14, 21 and 28 days - untreated controls: n=3 per species	*Linepithema humile* population reduction 1 week after application: ≥92.1% in all replicates *Monomorium pharaonis* population reduction 1 up to 4 weeks after application: ≥90.5% in all replicates *Lasius niger* population reduction 3 up to 4 weeks after application: ≥90.3% in all replicates population reduction in controls for all 3 ant species: ≤10% *evaluation: RI = 1* *- suitable to prove the efficacy against* Linepithema humile,	Suryawanshi (2023c) Study Code: 368BAPN8328/R1

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
						Monomorium pharaonis *and* Lasius niger *with bait trays indoor after storage of 48 months*	

3.4.6 Occurrence of resistance and resistance management

As described in the CAR for Imidacloprid, resistance to this active substance has been shown to be associated with point mutations in nAChR subunits (in grasshoppers) or an increased expression of genes coding for detoxification systems (in potato beetles). However, no resistance to Imidacloprid has been reported in ants so far.

The following general resistance management measures are proposed:

- Use products at recommended doses and intervals.
- Do not use neonicotinoids for follow-up treatment where resistance reduces effectiveness.
- Monitor problematic pest populations in order to detect first shifts in sensitivity.
- In order to avoid the occurrence of resistance to any active ingredient, products with different modes of action should be used in alternation and the frequent repeated use of the same active substance should be avoided.
- In the case of reduced efficacy or suspected development of resistance, the use of the product has to be discontinued immediately and a professional pest control operator needs to be contacted.
- The use of biocidal products can be combined with other sanitation measures.
- Products should always be used in accordance with label recommendations.

3.4.7 Known limitations

No limitations and no undesirable or unintended side-effects have been observed during the efficacy studies.

The successful use of ant baits in the field depends on the state of the surrounding location. Cracks and crevices or other accessible openings create opportunities for these insects to re-enter treated areas from the outside, misleadingly indicating treatment failure. The possibility of re-infestation needs to be taken into account when planning a treatment against ants, and additional measures should be taken, such as the sealing off of walls, etc.

3.4.8 Evaluation of the label claims

The submitted studies are suitable to support the claim “kills adults of Pharaoh ants (*Monomorium pharaonis*), Argentine ants (*Linepithema humile*) and Black garden ants (*Lasius niger*) as open gel application and bait tray in indoor and outdoor environments”. The product can be used continuously for 2 months without replacing opened bait trays or unconsumed open gel bait. A shelf life of 48 months has been demonstrated for all three ant species.

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

The biocidal product is not intended to be used with other products including other biocidal products.

3.4.10 Data waiving and conclusion

Table 18

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 19

Conclusion on the efficacy
The submitted studies are suitable to support the claim “kills adults of Pharaoh ants (*Monomorium pharaonis*), Argentine ants (*Linepithema humile*) and Black garden ants (*Lasius niger*) as open gel application and bait tray in indoor and outdoor environments”. The product can be used continuously for 2 months without replacing opened bait trays or unconsumed open gel bait. Shelf life: 4 years

3.5 Risk assessment for human health

3.5.1 Assessment of effects of the active substance on human health

Table 20

Imidacloprid	Value	Study	Safety factor
AEL long-term	0.06 mg/kg bw/d	2-yr rat Eiben, R.; Kaliner, G. (1991 a and b)	100
AEL medium-term	0.2 mg/kg bw/d	2-gen.rat, supported by 90-d dog and developmental tox. rabbit Suter, P.; Biedermann, K.; Luetkemeier, H.; Wilson, J. T.; Terrier, C. (1990); Ruf, J.; Sander, E. (1990); Becker, H.; Vogel, W.; Terrier, C. (1988b)	100
AEL acute	0.4 mg/kg bw/d	Acute neurotoxicity rat supported by 28-d dog (acute effects) Sheets, L. P.; Hamilton, B. F. (1994a); Bloch, I. et al. 1987 (PPP-evaluation)	100

Table 21

Imidacloprid	Value	Reference
Inhalative absorption	100 %[1]	Default value / Assessment Report
Oral absorption	100 %[1]	Default value / Assessment Report
Dermal absorption	Refer to chapter 3.5.2.7 information on dermal absorption	

[1] Assessment Report (RMS DE (2011; rev 2015)

3.5.2 Assessment of effects of the product on human health

The toxicology of the biocidal product Imidasect Ants was examined appropriately in line with standard requirements and first authorisation has been granted in 2016 according to Article 19 of Regulation (EU) 528/2012. The biocidal product consists primarily of components of low toxicity. No studies with the biocidal product have been submitted by the applicant for first authorisation or renewal. However, acute toxicological studies with a biocidal product containing 2.15 % Imidacloprid have shown low oral and

dermal toxicity and no irritation to skin and eye and were considered a worst-case formulation, suitable to extrapolate the results to the biocidal product Imidasect Ants.
Post-authorisation a co-formulant has been exchanged in 2018. This minor change did not affect the outcome of human health assessment because the previous and newly added substances are comparable regarding their composition and toxicological properties. Since the basic composition of the biocidal product and its conditions of use remain the same, the initial assessment from first authorisation of the biocidal product is still valid, with the exception of dermal absorption. For the sake of completeness, the previous human health assessment from Annex IIIB has been transferred into the new format of the Product Assessment Report. Dermal absorption has been re-assessed in accordance with EFSA Guidance on Dermal Absorption (2017).

3.5.2.1 Skin corrosion and irritation

Table 22

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle(s), Dose levels, Duration(s) of exposure**	**Results11**	**Remarks (e.g. major deviations)**	**Reference**
OECD 404, METHOD B4 (EC) No. 440/2008 GLP: yes Reliability: 1	Rabbit New Zealand White (Substrain: Hsdlf: NZW) Males 3/group No controls	Imidacloprid 2.15 % gel No vehicle 0.5 ml applied for 4 h Semiocclusive 2.5 cm x 2.5 cm cotton gauze patch 72h post-exposure period Examination of primary irritation 0 h, 1 h, 24 h, 48 h and 72 h after patch removal Observation of reversibility of skin reactions on day 7	Average score (24 h/48 h/72 h) Erythema: Animal 1: 1 (1/1/1) Animal 2: 0.3 (1/0/0) Animal 3: 0.3 (1/0/0) Oedema: Animal 1: 0 (0/0/0) Animal 2: 0 (0/0/0) Animal 3: 0 (0/0/0) effects completely reversible after 48h – day 7 No corrosive effects were noted normal gain in bodyweight	Acceptable	Bradshaw, J. (2013) Project Number: 41204551

11 Average score (from findings at 24, 48 & 72h) for erythema and oedema for each animal/observations and time point of onset, reversibility (14 d); other adverse local / systemic effects, histopathological findings

Table 23

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to the skin.
Justification for the value/conclusion	Acute toxicity studies with the biocidal product Imidasect Ants are not available. Studies have been performed with the biocidal product Imidasect containing 2.15 % (w/w) Imidacloprid, representing a worst-case gel formulation. The main components beside the active substance, are identical in both formulations and of low toxicity. Due to their low concentrations and based on the available toxicological data, other components are not expected to have an outcome on the toxicity of the biocidal product. Therefore, the tests results can be extrapolated to the biocidal product Imidasect Ants, containing 0.01% (w/w) Imidacloprid. Hence, based on the results of the *in vivo* study and the criteria for classification as irritant or corrosive to the skin according to Regulation (EC) No 1272/2008 (section 3.2.2.1. Classification based on standard animal test data) the biocidal product is not classified as irritant or corrosive.
Classification of the product according to CLP	Classification for skin corrosion and irritation is not required.

3.5.2.2 Eye irritation

Table 24

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance,Dose levels, Duration of exposure**	**Results Average score (24, 48, 72h)/ observations and time point of onset, reversibility**	**Remarks (e.g. major deviations)**	**Reference**
OECD 405, METHOD B5 (EC) No. 440/2008 GLP: yes Reliability: 1	Rabbit New Zealand White (Substrain: Hsdlf: NZW) Males 3/group Untreated left eye as control	Imidacloprid 2.15 % gel No vehicle 0.1 ml applied for 1sec. 72 h post-exposure period Examination, 0 h, 1 h, 24 h, 48 h and 72 h after application Observation of	Average score (24 h/48 h/72 h) Corneal opacity: Animal 1: 0 (0/0/0) Animal 2: 0 (0/0/0) Animal 3: 0 (0/0/0) Iris: Animal 1: 0 (0/0/0) Animal 2: 0 (0/0/0) Animal 3: 0 (0/0/0) Conjunctivae Redness: Animal 1: 0.6 (1/1/0) Animal 2: 0.6 (1/1/0) Animal 3: 0.6 (1/1/0) Conjunctivae Chemosis: Animal 1: 0.6 (1/1/0)	Acceptable	Bradshaw, J. (2013) Project Number: 41204552

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance,Dose levels, Duration of exposure**	**Results Average score (24, 48, 72h)/ observations and time point of onset, reversibility**	**Remarks (e.g. major deviations)**	**Reference**
		reversibility on day 7	Animal 2: 0 (0/0/0) Animal 3: 0.6 (1/1/0) Conjunctivae Discharge: Animal 1: 0 (0/0/0) Animal 2: 0 (0/0/0) Animal 3: 0 (0/0/0) effects completely reversible after 72 h normal gain in bodyweight		

Table 25

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to the eyes.
Justification for the value/conclusion	Acute toxicity studies with the biocidal product Imidasect Ants are not available. Studies have been performed with the biocidal product Imidasect containing 2.15 % (w/w) Imidacloprid, representing a worst-case gel formulation. The main components beside the active substance, are identical in both formulations and of low toxicity. Due to their low concentrations and based on the available toxicological data, other components are not expected to have an outcome on the toxicity of the biocidal product. Therefore, the tests results can be extrapolated to the biocidal product Imidasect Ants, containing 0.01 % (w/w) Imidacloprid. Hence, based on the results of the *in vivo* study and the criteria for classification as irritant or corrosive to the eye according to Regulation (EC) No 1272/2008 (section 3.2.2.1. Classification based on standard animal test data) the biocidal product is not classified as irritant or corrosive.
Classification of the product according to CLP	Classification for eye irritation is not required.

3.5.2.3 Respiratory tract irritation

Table 26

Data waiving was acceptable for the following information requirements	
Information requirement	8.10. Other tests
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008.

Table 27

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain components classified for respiratory irritation in relevant concentrations.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.5.2.4 Skin sensitisation

Table 28

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure (topical/intradermal, if relevant)**	**Results (EC_3-value or proportion of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)**	**Remarks (e.g. major deviations)**	**Reference**
LLNA OECD 429, METHOD B.42 (EC) No. 440/2008 GLP: yes Reliability: 3	Mouse CBA/Ca (Sub-strain: CBA/CaOlaHsd) Female 4/group 4/control	Imidacloprid 2.15 % gel Vehicle: ethanol/distilled water 7:3 dose levels 10 %, 5 % and 2.5 %	Preliminary screening: 10 % No local skin irritation days 1-6 No increase in ear	Not acceptable An appropriate justification for dose selection was not given. A maximum dose of 10 % was selected. According to the guideline the	Bradshaw, J. (2013) Project Number: 41204553

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure (topical/intradermal, if relevant)**	**Results (EC_3-value or proportion of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)**	**Remarks (e.g. major deviations)**	**Reference**
		Induction: topical, daily application of 50 µl (25 µl per ear) Challenge: Injection of 250 µl of PBS containing 3H-methyl thymidine in tail vein on day 6 (total of 20µCi each mouse) Observation: Day 1-3: twice daily Day 4-6: daily	thickness days 1-6 For dilutions of 2.5, 5, and 10 % the stimulation index was below 3 No deaths and no signs of systemic toxicity	highest concentration should maximise exposure while avoiding systemic toxicity and/or excessive local skin irritation. A pre-test conducted with a 10 % dilution of the biocidal product did not show any acute or irritating effect. However, from the results of the other acute toxicity and irritation studies it must be concluded that a 10 % dilution does not represent the maximum dose without acute toxic or irritating effects. Therefore, the dose selection is considered not appropriate. A final decision on the skin-sensitising properties of the biocidal product is not possible.	

Table 29

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	Acute toxicity studies with the biocidal product Imidasect Ants are not available. Studies have been performed with the biocidal product Imidasect containing 2.15 % (w/w) Imidacloprid, representing a worst-case gel formulation. The main components beside the active substance, are identical in both formulations and of low toxicity. Due to their low concentrations and based on the available toxicological data, other components are not expected to have an outcome on the toxicity of the biocidal product. Therefore, the tests results can be extrapolated to the biocidal product Imidasect Ants, containing 0.01 % (w/w) Imidacloprid. However, based on the low test concentration in the submitted *in-vivo* study, a final decision on the skin-sensitising properties is not possible and classification has to be derived from the toxicological properties of the single components. The biocidal product contains several co-formulants classified for skin sensitisation. However, their concentrations are below their specific limits for classification. Hence, classification for skin sensitisation according to the Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Classification for skin sensitisation is not required

3.5.2.5 Respiratory sensitisation (ADS)

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or the components are not available.

Table 31

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain any components that are known to have respiratory tract sensitising properties. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Classification for respiratory tract sensitisation is not required.

3.5.2.6 Acute toxicity

3.5.2.6.1 Acute toxicity by oral route

Table 32

Summary table of animal studies on acute oral toxicity						
Method Guideline **GLP status, Reliability**	**Species, Strain, Sex, No/group**	**Test substance** **Dose levelsType of administration *(gavage, in diet, other)***	**Signs of toxicity *(nature, onset, duration, severity, reversibility)***	**Value LD_{50}**	**Remarks *(e.g. major deviations)***	**Reference**
OECD 423, METHOD B1 (EC) No. 440/2008 GLP: yes Reliability: 1	Wistar rat (Sub-strain: HsdHanTM: Wist or RccHanTM: Wist) Female 3/group No controls	Imidacloprid 2.15 % gel Vehicle: distilled water dose level 2000 mg/kg bodyweight (200mg/ml) Gavage (10 ml/kg) Observation: 0.5, 1, 2 and 4 h after dosing, Daily for 14 days	no deaths no signs of systemic toxicity normal gain in bodyweight no abnormalities at necropsy	LD_{50} > 2000 mg/kg bw	Acceptable	Bradshaw, J. (2013) Project Number: 41204548

Table 33

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} oral > 2000 mg/kg bw Not acutely toxic via the oral route.
Justification for the selected value	Acute toxicity studies with the biocidal product Imidasect Ants are not available. Studies have been performed with the biocidal product Imidasect containing 2.15 % (w/w) Imidacloprid, representing a worst-case gel formulation. The main components beside the active substance, are identical in both formulations and of low toxicity. Due to their low concentrations and based on the available toxicological data, other components are not expected to have an outcome on the toxicity of the biocidal product. Therefore, the tests results can be extrapolated to the biocidal product Imidasect Ants, containing 0.01% (w/w) Imidacloprid. Hence, based on the results of the *in vivo* study and the criteria for classification as acutely toxic according to Regulation (EC) No 1272/2008 (section 3.1.2. Criteria for classification of substances as acutely toxic), the biocidal product does not require classification.
Classification of the product according to CLP	Classification for acute oral toxicity is not required.

3.5.2.6.2 Acute toxicity by inhalation

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	According to the Biocide Regulation (EC) No 528/2012 and the corresponding Guidance on Information Requirements (2013) an acute toxicity study by inhalation is not required. In addition, the biocidal product consists primarily of components of low toxicity. The acute inhalation toxicity of the active substance have been investigated appropriately (LC_{50} (dust): > 5.323 mg/L, vapour pressure (20 °C): 4 x 10^{-10} Pa). Sufficient data for all other co-formulants are available and the corresponding properties of the biocidal product can be deduced from the single components. The applicant tried to perform an approriate study with the biocidal product Imidasect, containing 2.15 % (w/w) Imidacloprid, but failed in the production of an appropriate dust (Griffiths, D.R., 2013, Project Number: 41204549). Thus, further testing is not required.

Table 35

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on the inhalation LC_{50} available for the single components the inhalation LC_{50} of the biocidal product is estimated as > 5 mg/L.
Classification of the product according to CLP	Classification for acute inhalation toxicity is not required.

3.5.2.6.3 Acute toxicity by dermal route

Table 36

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area,**	**Signs of toxicity (nature, onset, duration, severity, reversibility)**	**LD_{50}**	**Remarks (e.g. major deviations)**	**Reference**
OECD 402, METHOD B3 (EC) No. 440/2008 GLP: yes Reliability: 1	Wistar rat (Sub-strain: HsdHanTM: Wist or RccHanTM: Wist) Male 5/group Female 5/group No controls	Imidacloprid 2.15 % gel No vehicle dose level 2000 mg/kg bodyweight 24 h exposure Semi-occluded dermal application approx. 10 % of total body surface area Observation: 0.5, 1, 2 and 4 h after dosing, Daily for 14 days	no deaths no signs of systemic toxicity no signs of dermal irritation normal gain in bodyweight (except for 1 male and all females during first week) no abnormalities at necropsy	LD_{50} > 2000 mg/kg bw	Acceptable	Bradshaw, J. (2013) Project Number: 41204550

Table 37

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} dermal > 2000 mg/kg bw Not acutely toxic via the dermal route.
Justification for the selected value	Acute toxicity studies with the biocidal product Imidasect Ants are not available. Studies have been performed with the biocidal product Imidasect containing 2.15% (w/w) Imidacloprid, representing a worst-case gel formulation. The main components beside the active substance, are identical in both formulations and of low toxicity. Due to their low concentrations and based on the available toxicological data, other components are not expected to have an outcome on the toxicity of the biocidal product. Therefore, the tests results can be extrapolated to the biocidal product Imidasect Ants, containing 0.01% (w/w) Imidacloprid.

Value used in the Risk Assessment – Acute dermal toxicity	
	Hence, based on the results of the *in vivo* study and the criteria for classification as acutely toxic according to Regulation (EC) No 1272/2008 (section 3.1.2. Criteria for classification of substances as acutely toxic), the biocidal product does not require classification.
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.5.2.7 Information on dermal absorption

Table 38

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	No dermal absorption study has been submitted by the applicant. For first authorisation of the biocidal product Imidasect Ants, the application of the dermal absorption values from the Imidacloprid CAR (DE, 2011), derived for the formulation Confidor OD 200, have been considered acceptable.. However, since there is no information on the identity of Confidor OD 200 available, similarity of formulations could not be compared and applicability of this value for the biocidal product Imidasect Ants could not be assessed in accordance with EFSA Guidance on Dermal Absorption (2017). In the absence of reliable dermal absorption data, default values according to EFSA Guidance on Dermal Absorption (2017) are to be applied.

Table 39

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	Imidacloprid All scenarios
Value(s)	70 %
Justification for the selected value(s)	Default according to EFSA Guidance on Dermal Absorption (2017).

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

Not relevant

3.5.2.9 Available toxicological data relating to a mixture

Not relevant

3.5.2.10 Other

Not available

3.5.2.11 Summary of effects assessment

Table 40

Endpoint	Brief description
Skin corrosion and irritation	Based on the extrapolation of the results of an *in vivo* study. Not classified for skin irritation or corrosion.
Eye irritation	Based on the extrapolation of the results of an *in vivo* study. Not classified for eye irritation.
Respiratory tract irritation	Based on the intrinsic properties of single components. Not irritating to the respiratory tract (not classified).
Skin sensitisation	Based on the intrinsic properties of single components. Not skin-sensitising (not classified).
Respiratory sensitization (ADS)	Based on the intrinsic properties of single components. Not sensitising to the respiratory tract (not classified).
Acute toxicity by oral route	Based on the extrapolation of the results of an *in vivo* study. Oral LD_{50} > 2000 mg/kg bw. Not classified for acute oral toxicity.
Acute toxicity by inhalation	Inhalation LC_{50} calculated from information on the ingredients: > 5.0 mg/L. Not classified for acute inhalation toxicity.
Acute toxicity by dermal route	Based on the extrapolation of the results of an *in vivo* study. Dermal LD_{50} > 2000 mg/kg bw. Not classified for acute dermal toxicity.
Information on dermal absorption	Imidacloprid: 70 % Default according to EFSA Guidance on Dermal Absorption (2017).
Available toxicological data relating to non-active substance(s)	Not relevant
Available toxicological data relating to a mixture	Not relevant
Other relevant information	Not relevant

3.5.3 Exposure assessment

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

Table 41

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	N.a.	N.a.	No	No	N.a.	N.a.
Dermal	No	Yes	Yes	No	No	Yes	N.a.
Oral	No	N.a.	N.a.	No	No	Yes	N.a.

List of scenarios

Table 42

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	Application with a cartridge gun	Primary exposure of workers resulting from gel spot application using a cartridge gun or similar device and disposal of the equipment. Secondary exposure of a professional bystander is not expected.	Professionals
2	Ready-to-use bait station	Primary exposure of workers resulting from distribution rtu-bait stations and collection of bait residues. Secondary exposure of a professional bystander is not expected.	Professionals
3	Adult - Placing and disposing of baits	Primary exposure, chronic Dermal contact of adult to the bait during application and disposal of the biocidal product and cleaning of equipment	Non-professional
4	Toddler - Ingestion and mouthing of bait	Secondary exposure, acute Dermal and oral contact of toddlers to bait containing an aversive agent a) Ingestion of bait in one bait tray (1400 mg) b) Ingestion of a gel bait drop (200 mg) c) Transient mouthing of bait (10 mg)	General public

3.5.3.1.1 Professional exposure

Imidasect Ants is a ready-to-use insecticide to control ants. It is applied by a cartridge gun or via ready-to-use bait stations. It contains the a.s. “Imidacloprid” (CAS-No.: 138261-41-3, 0.01 % (w/w)).

The biocidal product is marketed in the following packages:

- Cartridge (HDPE and transparent polypropylene): 30 g, 35 g, 50 g, 75 g, 100 g
- Bait tray (HDPE and transparent polypropylene): 0.75 g, 1 g, 1.2 g, 1.4 g
- Ampoule (HDPE): 5 mL
- Dropper (HDPE): 4 mL, 10 mL

The exposure to the a.s. is assessed separately for the different application techniques and will thus be described in individual subsections of the current section. It is usually based on the harmonised document “Biocides Human Health Exposure Methodology” (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.
In Annex 4.2.1, the details of the exposure calculations to the a.s. for the professional user are laid out.

- **Scenario 1 – Application with a cartridge gun**

Table 43

Description of Scenario 1: Application with a cartridge gun		
Imidasect Ants is a ready-to-use insecticide that is applied as gel spot or thin gel bead to cracks and crevices or to surfaces in and around buildings. The gel bait is provided in pre-filled and sealed cartridges, ampoules or droppers. Handling of the disposable ampoules and the resealable droppers is comparable to exposure via the use of cartridges. Here, the use of cartidges is assessed. Prior to use, any sealing caps are removed, the nozzle is installed and if necessary the gel cartridges are loaded into specialised dosing guns. The gel applicator is designed such that depending on the nozzle diameter a defined amount of product is released per spot. During the application phase a number of gel spots are distributed in a relatively small well-defined area. Imidasect Ants is a ready-to-use product and thus no (re-)filling occurs. *Dermal exposure* During the application process, exposure to skin is expected to occur only through transfer of gel residues from the nozzle to the hands of the operator especially when opening and/or sealing partially used cartridges and syringes. The spot application together with the gel formulation avoids dermal exposure to the operator via splashes or drift during application. In the *Biocides Human Health Exposure Methodology Document Version 1 (October 2015)* no suitable model is available to assess the described exposure situation. The assessment performed for the first authorisation is still valid and is in line with HEAdhoc Recommendation No. 6 (Version 4). As a reasonable worst case scenario, the assessment of dermal exposure is based on the estimation that a cylindrical spot of gel of a certain length and diameter is transferred to the hands each time the cartridge is opened or sealed. The mass of the product on the hands can then be calculated from the volume of the product on the hands (being equivalent to the length of product times the spot area) per opening and closing action multiplied by a representative number of opening and closing cycles and the density of the product. Since the b.p. is a ready-to-use product, no mixing and loading phase is calculated. Additionally, as a rare event, it is expected that the professional user gets into contact with the product residues during cleaning. Due to the small amount of product applied per spot, it is assumed that the contact of the b.p. to the hands might not occur more than once per day. Thus for the post-application phase, the calculation is performed analogous to the application phase but only one contact is taken into account. *Exposure by inhalation* Due to the non-volatile nature and the gel formulation of the b.p. exposure to aerosols or vapour is not expected for all phases of the application.		
	Parameters	Value
Tier 1	Concentration of the a.s. Imidacloprid in the b.p.	0.01 % (w/w)
	Density of the b.p.	1.3052 g/cm³ (20 °C)
	Length of bead transferred to hands	0.5 cm
	Diameter of the bead transferred to hands	0.158 cm
	Frequency of occurrence (application and post-application)	11

Calculations for Scenario 1

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 72.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.2.1 of this PAR.
For risk characterisation, see chapter 3.5.4.6.

- **Scenario 2 – Ready-to-use bait station**

Table 71

Description of Scenario 2: Ready-to-use bait station		
Imidasect Ants is a ready-to-use insecticide bait that is supplied in a plastic bait tray. The b.p. is formulated in a bait matrix as a gel. The ready-to-use bait stations are distributed indoors / outdoors in proximity to insect nests or directly onto insect trails. The bait stations themselves are sealed plastic containers. They are placed in such a way that the entrance/entrances of the bait stations point/s upwards or horizontal or slantwise. Prior to placement, the professional user removes a protective foil by cutting along a dotted line printed on the exterior of the bait station. A sticky pad on the back of the plastic container ensures that the bait station remains in a fixed position. After successful eradication of the target organisms, the bait stations are collected and disposed. *Dermal exposure* The design of the bait station prevents users from coming into direct contact with the gel containing the a.s. Exposure to skin is only expected to occur infrequently during opening of the bait stations. As a rare event, it is expected that the contact of the b.p. to the hands might not occur more than once per day, even if a higher number of applied bait is taken into account. In the *Biocides Human Health Exposure Methodology Document Version 1 (October 2015)* no suitable model is mentioned to assess the described exposure situation. The assessment performed for the first authorisation is still valid and is in line with HEAdhoc Recommendation No. 6 (Version 4).The b.p. is assumed to be distributed evenly within a bait station. As a reasonable worst case scenario, the potential exposure to the hands is assessed taking into account the amount of b.p. in each bait station, the fraction of b.p. that is accessible to the hands and the transfer efficiency of the b.p., e.g. that fraction of the accessible b.p. which might be transferred to the hands. Since the biocidal product is a ready-to-use product, no mixing and loading phase is assumed. For removal and disposal of the bait stations, it appears reasonable to assume that a small contamination of the bait stations could occur by insects taking the substance out of the bait stations. However, exposure resulting from removing and disposing of lightly contaminated bait stations is assumed to be substantially lower than the exposure resulting from opening them. Thus, exposure from removal and disposal is covered by the worst case assumption made for assessing application of the bait stations. *Exposure by inhalation* Due to the non-volatile nature and the packaging of the b.p. inhalation exposure to aerosols or vapour is not expected for all phases of the application.		
	Parameters	Value
Tier 1	Concentration of the a.s. Imidacloprid in the b.p.	0.01 % (w/w)
	Amount of b.p. per bait station	1.40 g
	Fraction of b.p. accessible to hands	25 %
	Transfer efficiency	50 %

Calculations for Scenario 2

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 72.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.2.1 of this PAR.
For risk characterisation, see chapter 3.5.4.6.

- **Summary of professional exposure**

The scenarios described here include all phases of application (mixing and loading, application and post-application). Therefore, the values in the following table are combined exposure values of all phases.

Table 72

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.			
Exposure scenario	**Tier/PPE**	**a.s. 1: Imidacloprid**	
		Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**
Scenario 1: Application with a cartridge gun	Tier 1: no PPE	Not expected	1.41×10^{-2}
	Tier 2: Protective gloves (EN 374)	Not expected	1.41×10^{-3}
Scenario 2: Ready-to-use bait station	Tier 1: no PPE	Not expected	2.28×10^{-2}
	Tier 2: Protective gloves (EN 374)	Not expected	2.28×10^{-3}

According to the calculation performed in Tier 1, additional protective equipment is not necessary; a risk for professional users is unlikely (for details see chapter 3.5.4.6).

3.5.3.1.2 Non-professional exposure

For non-professional users, the biocidal product Imidasect Ants has previously been approved for application in bait trays (maximum content: 1.4 g), with ampoules (maximum content: 5 mL), droppers (maximum content: 10 mL) or with syringes (maximum content: 15 g). Upon first authorisation, the applicant proposed to adopt primary exposure as assessed in the CAR for the syringe gel spot application of Imidacloprid GL 2.15 by professional users. This proposal was supported with some amendments. For renewal of product authorisation, no changes in the use conditions of the biocidal product Imidasect Ants have been submitted by the applicant. Therefore, exposure by spot application of a gel paste with a syringe or cartridge still represents a worst-case scenario also for the application with bait trays, as well as for ampoules and droppers.

Ampoules are intended for single use only. Droppers are re-sealable, but not intended to be re-sealed. Furthermore, droppers have a smaller opening (1.4 mm vs. 1.58 mm) and therefore it is not expected to

result in higher exposure than syringes and cartridges. Hence, the previous exposure assessment is still valid. For a detailed justification please refer to the previous PAR (DE, 2016) with the initial assessment. However, due to re-evaluation of the dermal absorption of the biocidal product, a default value of 70 %, in accordance with EFSA Guidance on Dermal Absorption (2017), has to be applied now. Exposure calculations have been revised accordingly.

The biocidal product Imidasect Ants contains a co-fomulant, which is currently assessed as an active substance for several product types. However, at the time of renewal no draft final CAR for one of the assessed product types is available, the co-formulant is not yet considered a substance of concern and therefore not included in the exposure and risk assessment of the biocidal product Imidasect Ants. For details see Chapter 5.1.

- **Scenario [3]**

Table 44

Description of Scenario [3]

Primary exposure - Placing and disposing of baits (adult).

The biocidal product Imidasect Ants is formulated as a gel and packed in syringes designed for the controlled placement of the bait. Using a suitable gel applicator the product is dispensed as spots to surfaces in identified target areas. For non-professional users, the maximum application rate is 0.4 g b.p./m^2, whereas one drop of gel equals 0.2 g of biocidal product. According to the assessment for professional use in the CAR, the maximum duration of application is 30 min and the frequency of application is 3 days per week, visiting 5 to 10 sites per day. For non-professional users the applicant proposed max. 12 applications per year, whereas the biocidal product can be used continuously for 2 - 3 months without replacing opened bait trays or unconsumed baits. In the absence of information on the seasonal distribution of the applications, chronic exposure is assumed. In accordance with the CAR, it is assumed that each time when sealing or opening the cartridge a string of 0.5 cm of gel will be transferred to the hand. Considering a diameter of the gel string of 0.158 cm (inner diameter of the syringe hole), a total volume of 0.009803 cm^3 of gel is transferred to the hand during sealing or opening of the cartridge. This corresponds to 12.795 mg gel per sealing and opening, taking into account the specific weight of 1.3052 g/cm^3. The amount of 12.795 mg gel corresponds to 0.00128 mg active substance per one opening or one sealing of the cartridge. In the CAR, 5 times of opening and 5 times of sealing per day are assessed. This is considered reasonable, as for treatment of one site only one opening and sealing is necessary and visiting of 5 sites per day is plausible (assuming 30 minutes treatment with gel). Assuming a dermal absorption of 70 % (EFSA 2017), the corresponding potential hand exposure from application of the biocidal product can be calculated as shown below.

According to the CAR, cleaning of the application equipment is not required, since the biocidal product is a ready-to-use product, intended to be disposed after use. Nevertheless, as a 'worst-case' it is assumed that the potential dermal exposure is equivalent to one opening of a cartridge. Thus, the corresponding potential hand exposure from cleaning can be calculated as shown below.

According to the CAR, for the disposal of old gel baits it is assumed that the total amount of the applied spots (5000 mg) may be removed in one day. The dislodgeable fraction is 1 % (CAR). Thus, the corresponding potential hand exposure from disposal can be calculated as shown below.

Oral primary exposure of a non-professional adult user is not expected, if the biocidal product is used as intended and the instructions of use are followed.

Inhalation exposure is considered not relevant due to the type of application and the low vapour pressure of the a. s. Imidacloprid (9 x 10^{-10} Pa, 25 °C).

	Parameters	Value
Tier 1	Length (L) of gel string (Applicant, CAR 2011)	0.5 cm
	Diameter / radius (r) of gel string (Applicant, CAR 2011)	0.158 / 0.079 cm
	Resulting volume (V) = π x r^2 x L	9.803 x 10^{-3} cm^3
	Density (d) (Applicant)	1.3052 g/cm^3
	Amount b.p. transferred to hands per opening or sealing = V x d	12.795 mg
	Concentration (c) a.s. (Applicant)	0.0 1% (w/w)
	Amount a.s. transferred to hands per opening or sealing = amount b.p. x c	0.00128 mg
	Number of openings and sealings (Applicant, CAR 2011)	10 (Application) 1 (Cleaning)

	Dermal absorption (Default, EFSA Guidance on Dermal Absorption 2017)	70 %
	Body weight adult (HEAdhoc Recommendation 14)	60 kg
	Total amount of spots applied per application (CAR 2011)	5000 mg
	Dislodgeable fraction (CAR 2011)	1 %

Calculations for Scenario [3]

Application (Placing of bait)

Systemic dermal exposure = a.s. on hands x number of openings x dermal absorption / bw
= 0.00128 mg x 10 x 70 % / 60 kg
= 0.000149 mg/kg bw/d

Cleaning

Systemic dermal exposure = a.s. on hands x number of openings x dermal absorption / bw
= 0.00128 mg x 1 x 70 % / 60 kg
= 0.0000149 mg/kg bw/d

Disposal of old gel baits

Systemic dermal exposure = applied amount of the b.p. x concentration a.s. in b.p. x dislodgeable fraction x dermal absorption / bw
= 5000 mg x 0.01 % x 1 % x 70 % / 60 kg
= 0.0000583 mg/kg bw/d

Total systemic dermal exposure: 0.000222 mg/kg bw/d

Total systemic exposure: 0.000222 mg/kg bw/d

Table 45

Summary table: systemic exposure from non-professional uses[12]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3] –Placing and disposing of baits (adult)	1	-	0.000222	-	0.000222

- **Combined scenarios**

Not relevant.

3.5.3.1.3 Secondary exposure of the general public

- **Scenario [4]**

Table 46

Description of Scenario [4]		
Secondary exposure – Ingestion and mouthing of bait (toddler). The biocidal product Imidasect Ants is formulated as a gel and packed in syringes (maximum content: 15 g), bait trays (maximum content: 1.4 g), ampoules and droppers. For secondary exposure it is assumed that a toddler gets in contact to the biocidal product in the bait tray or to spots placed on the ground. For the application with bait tray it is acknowledged that this type of exposure is unlikely, if the biocidal product is enclosed in a bait tray, which can only be opened with strong force. For the spot application by syringes or cartridges, such an exposure is not unlikely if the application site of the biocidal product is easily accessible for toddlers. However, exposure could be sufficiently reduced by a corresponding additional labelling advising to place gel spots inaccessible for toddlers if a risk is identified. Therefore, exposure is considered to be accidental and short-term (acute). This scenario also covers exposure of toddlers to insects contaminated with the biocidal product. It is assumed that the exposure scenario transient mouthing reflects this kind of exposure. It is noted that the Consexpo Fact Sheet “Pest Control Products” considers this type of exposure as negligible. The following scenarios are considered for calculation: a) Ingestion of bait in one bait tray. It is assumed that a toddler ingests the amount of one bait tray, 1400 mg respectively. b) Ingestion of a gel bait drop. It is assumed that a toddler ingests the amount of one drop of gel bait, which equals 200 mg of biocidal product. c) Transient mouthing of bait with aversive agent. It is assumed that the amount ingested by a toddler is only 10 mg, since the biocidal product contains a taste-aversive agent (TNsG on Human Exposure Part 3, 2002). As a worst-case assumption, it is considered that 100 % of the dermal exposure concentration is ingested. Thus, the potential systemic oral exposure can be calculated as shown below. Inhalation exposure is considered not relevant due to the type of application and the low vapour pressure of the a. s. Imidacloprid (9 x 10^{-10} Pa, 25 °C). Dermal exposure (touching of the bait before ingestions) is covered by the oral exposure assessment, as the dermal absorption is lower than the oral absorption.		
	Parameters	Value
Tier 1	Concentration (c) a.s. (Applicant)	0.01 % (w/w)
	Oral absorption (Default, CAR 2011)	100 %
	Body weight toddler (HEAdhoc Recommendation 14)	10 kg
	Amount of bait in one bait tray (Applicant)	1400 mg
	Weight of one gel bait drop (Applicant, CAR 2011)	200 mg
	Amount of bait for transient mouthing (TNsG on Human Exposure Part 3, 2002)	10 mg

Calculations for Scenario [4a] - Ingestion of bait in one bait tray

Systemic oral exposure = amount ingested x concentration a.s. in b.p. x oral absorption / bw

= 1400 mg x 0.01 % x 100 % / 10 kg

= 0.014 mg/kg bw

Total systemic exposure: 0.014 mg/kg bw

Calculations for Scenario [4b] - Ingestion of a gel bait drop [13]

Systemic oral exposure = amount ingested x concentration a.s. in b.p. x oral absorption / bw

= 200 mg x 0.01 % x 100 % / 10 kg

= 0.002 mg/kg bw

Total systemic exposure: 0.002 mg/kg bw

Calculations for Scenario [4c] - Transient mouthing of bait [14]

Systemic oral exposure = amount ingested x concentration a.s. in b.p. x oral absorption / bw

= 10 mg x 0.01 % x 100 % / 10 kg

= 0.0001 mg/kg bw

Total systemic exposure: 0.0001 mg/kg bw

Table 47

Summary table: systemic exposure of the general public [15]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4a] – Ingestion of bait in one bait tray (toddler)	1	-	-	0.014	0.014
Scenario [4b] - Ingestion of a gel bait drop (toddler)	1	-	-	0.002	0.002
Scenario [4c] – Transient mouthing of bait (toddler)	1	-	-	0.0001	0.0001

- **Combined scenarios**

Not relevant.

3.5.3.2 Dietary exposure

Table 48

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	Imidacloprid
Type of formulation	ready-to-use gel - gel bait from a syringe (non-professional user), cartridge (professional user), ampoule or dropper) - bait application in bait trays
Substance(s) of concern	none
Field(s) of use	indoor use in domestic premises (including kitchens), food handling places, public buildings outdoor use around buildings
Target organism(s)	Pharaoh ants (*Monomorium pharaonis)*, Argentine ants (*Linepithema humile),* adults
Application rate(s) and frequency	Located application of gel drops with a diameter of about 1 cm (approximately 0.2 g biocidal product corresponding to 0.02 mg a.s.): - Where ants are present gel is placed in drops near ant trails, tunnel openings and nests. - When presence or activity of ants is suspected or ants are detected sporadically gel is used in a bait box. - Open application- indoor: 0.2-0.4 g/m²; 0.2 g/m - Open application- outdoor: 0.2 g/lair entry or foraging trial; 0.2g/m building perimeter - Bait tray-indoor: max. 0.35g/m² - Bait tray-outdoor: max. 0.23 g /m building perimeter Repeat as necessary, 1 week interval between applications Maximum of 12 applications per year.
Category(ies) of users	Professional and non-professional users
Waiting periods after treatment	/
Further information	The intended use excludes contamination of food based on label restrictions: Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets. Do not store near food, drink and animal feeding stuff.

Conclusion

The Imidacloprid-containing biocidal product is to be used for the control of insect pests by application of gel bait that does not come in direct contact with food, feed stuff or livestock animals.

Contact with food or feed is not expected. No further data are required concerning the residue behaviour. The intended uses are not relevant in terms of consumer health protection.

Contact with food or feed is avoided by applying appropriate risk mitigation measures:

- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets. (General)
- Do not store near food, drink and animal feeding stuff. (Conditions of storage)

3.5.3.2.1.1 Information of non-biocidal use of the active substance

- Information on the residue definitions is provided in chapter 3.5.4.2 (Maximum residue limits or equivalent).

Table 49

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant Protection Products	Insecticide used in various plant protection products. (currently not approved under Reg. (EC) No 1107/2009)	MRLs are set for all products of plant and animal origin as listed in Reg (EU) No 491/2014 (to be updated soon according to SANTE/10118/2020 (not yet applicable)) Toxicological reference values*: ADI 0.06 mg/kg bw/day ARfD 0.08 mg/kg bw.

*Source Dir 08/116

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

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.5.3.4 Summary of exposure assessment

Table 50

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
Scenario 1: Application with a cartridge gun	Professionals	Tier 1: none	1.64×10^{-4} mg a.s./kg bw/day
Scenario 2: Ready-to-use bait station	Professionals	Tier 1: none	2.66×10^{-4} mg a.s./kg bw/day
Scenario [3] –Placing and disposing of baits (adult)	Non-professional	1	0.000222
Scenario [4a] – Ingestion of bait in one bait tray (toddler)	General public	1	0.014
Scenario [4b] - Ingestion of a gel bait drop (toddler)	General public	1	0.002
Scenario [4c] – Transient mouthing of bait (toddler)	General public	1	0.0001

3.5.4 Risk characterisation for human health

3.5.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report as in Table 20 and Table 21 of Section 3.5.1 Assessment of effects of the active substance on human health.

3.5.4.2 Maximum residue limits or equivalent

Residue definitions

Table 51

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL	Reg (EU) No 491/2014	Products of animal origin	0.05* - 0.3 mg/kg
MRL	Reg (EU) No 491/2014 (to be updated soon according to SANTE/10118/2020 (not yet applicable))	Products of plant origin	Reg (EU) No 491/2014 0.05* - 10 mg/kg SANTE/10118/2020 0.01* - 15 mg/kg

*lower limit of analytical detection

3.5.4.3 Specific reference value for groundwater

No specific reference values for ground water were derived.

3.5.4.4 Endocrine disrupting properties

In the active substance evaluation (2011), Imidacloprid has not been assessed for potential endocrine disrupting properties. However, based on the available information and according to the SVHC-candidate list and the ED-list, there are no indications for endocrine disrupting properties of the active substance. No co-formulant of the biocidal product Imidasect Ants was identified as an ED in accordance with Article 57(f) and Article 59 (1) REACH or in any EU decision. There is no data indicating that any co-formulant of the biocidal product may have endocrine disrupting properties based on the existing knowledge and the available scientific information from ECHA databases. Therefore, the co-formulants are not considered to have endocrine disrupting properties.

3.5.4.5 Risk for industrial users

No industrial applications are intended.

3.5.4.6 Risk for professional users

The occupational risk assessment for the biocidal product Imidasect Ants takes into account systemic effects of the active substance Imidacloprid.

The occupational risk assessment for systemic effects of the active substance Imidacloprid is based on the internal reference value (AEL). This reference value is compared with the estimated total uptake of Imidasect.

An occupational risk assessment for local effects is not neccessary for this product as it is not classified for human health hazards.

Systemic effects

Active substance Imidacloprid

The primary toxic effect of the active substance Imidacloprid is an increased incidence of mineralisation in the colloid of the thyroid gland follicles. The risk characterisation for systemic effects of Imidacloprid is performed with the AEL approach that compares total internal body burden (total uptake) with the reference value (AEL). The quantitative risk characterisation for professional users takes into account dermal exposure to Imidacloprid resulting from use of the biocidal product Imidasect Ants. The inhalative exposure of Imidacloprid is not taken into account in the quantitative assessment with AEL as inhalation of the gel product is not expected.

Details of risk characterisation

Reference value

As systemic reference value the $AEL_{long\text{-}term}$ of 0.06 mg Imidacloprid/kg bw/d is used.

Calculation of total uptake and AEL exhaustion (%)

For dermal route 70 % is assumed as default absorption for the active substance Imidacloprid.

Inhalative exposure is not considered because it is assumed that no contact with the product Imidasect via inhalation occurs.

The dermal uptake referring to the active substance Imidacloprid that results from use of the biocidal product Imidasect Ants is determined according to the following equation:

Dermal uptake (mg/kg bw/d) = dermal exposure to Imidacloprid (mg/kg bw/d) x 70 % dermal absorption / 100%

The total uptake is compared to the reference value. AEL exhaustion is expressed as percentage (%) value.

A risk for professional users referring to the active substance Imidacloprid resulting from the use of the biocidal product Imidasect Ants is unlikely, if the AEL exhaustion for each scenario is below the value of 100 %. Table 52 gives a detailed overview of the risk assessment results referring to the active substance Imidacloprid. It is noted that for clarity reasons all values are rounded to two significant places. However, the underlying calculations are based on unrounded values.

As shown in Table 93, for the scenarios 'Application with a cartridge gun' and 'Ready-to-use bait station' a risk for the professional user is unlikely already in Tier 1.

Table 52**: Overview of detailed risk assessment results referring to the active substance Imidacloprid in the biocidal product Imidasect Ants**

Scenario		**$AEL_{long-term}$** mg/kg bw/d	**Estimated inhalation uptake** mg/kg bw/d	**Inhalation uptake / AEL** %	**Estimated dermal uptake** mg/kg bw/d	**Dermal uptake / AEL** %	**Estimated total uptake** mg/kg bw/d	**Estimated total uptake / AEL** AEL exhaustion %	**Acceptable** (yes/no)
Application with a cartridge gun	Tier 1	0.06	not expected	-	$1.647x10^{-4}$	0.27	$1.64x10^{-4}$	0.27	yes
Ready-to-use bait station	Tier 1	0.06	not expected	-	$2.66x10^{-4}$	0.44	$2.66x10^{-4}$	0.44	yes

Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product Imidasect Ants is unlikely for the intended uses 'Application with a cartridge gun' and 'Ready-to-use bait station'. RMM described in chapter 2.5.2 have to be taken into account in order to ensure a safe use of the biocidal product Imidasect Ants.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.5.4.7 Risk for non-professional users

Table 53: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [3] – Placing and disposing of baits (adult)	1	6	0.06	0.000222	0.37	yes

- **Local effects**

Not relevant.

Conclusion

No risk has been identified for non-professional users if the biocidal product is used as intended. Hence, exposure of non-professional users to the biocidal product Imidasect Ants, containing 0.01 % (w/w) Imidacloprid, is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

3.5.4.8 Risk for the general public

Table 54: Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario [4a] – Ingestion of bait in one bait tray (toddler)	1	40	0.4	0.014	3.5	yes
Scenario [4b] - Ingestion of a gel bait drop (toddler)	1	40	0.4	0.002	0.5	yes
Scenario [4c] – Transient mouthing of bait (toddler)	1	40	0.4	0.0001	0.025	yes

- **Local effects**

Not relevant.

Conclusion

Exposure of the general public to the biocidal product Imidasect Ants, containing 0.01 % (w/w) Imidacloprid, is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.
No risk has been identified for toddlers accidentally ingesting small amounts or higher amounts of the gel bait and by exposure to insects contaminated with the biocidal product.

3.5.4.9 Risk for consumers via residues in food

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not required as the product contains only the active substance Imidacloprid and no substances of concern.

3.5.4.11 Summary of risk characterisation

3.5.4.11.1 Summary of risk characterisation for industrial user

No industrial applications are intended.

3.5.4.11.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product Imidasect Ants is unlikely for the intended uses ‘Application with a cartridge gun‘ and ‘Ready-to-use bait station’ (Table 52). RMM described in chapter 2.5.2 have to be taken into account in order to ensure a safe use of the biocidal product Imidasect Ants.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.5.4.11.3 Summary of risk characterisation for non-professional user

Table 55

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
Scenario [3] –Placing and disposing of baits (adult) Tier 1	0.06	0.000222	0.37	yes

3.5.4.11.4 Summary of risk characterisation for indirect exposure

Table 56

Scenario, Tier	Relevant reference value	Estimated uptake mg/kg bw/d	Estimated uptake/reference value (%)	Acceptable (yes/no)
Scenario [4a] – Ingestion of bait in one bait tray (toddler) Tier 1	0.4	0.014	3.5	yes
Scenario [4b] - Ingestion of a gel bait drop (toddler) Tier 1	0.4	0.002	0.5	yes
Scenario [4c] – Transient mouthing of bait (toddler) Tier 1	0.4	0.0001	0.025	yes

3.6 Risk assessment for animal health

The biocidal product Imidasect Ants is applied indoors and outdoors around buildings as open application of gel bait spots or in bait trays. Hence, exposure of pets and other domestic animals to the biocidal product cannot be excluded. As a worst-case, the exposure and risk assessment for the general public (toddler) can be adopted for animals. Since no risk has been identified for the general public, exposure of pets and other domestic animals to the biocidal product Imidasect Ants, containing 0.01 % (w/w) Imidacloprid, is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

3.7 Risk assessment for the environment

3.7.1 General information

The biocidal product Imidasect Ants contains no substance of concern for the environment. Consequently, the environmental risk assessment for this product is based on the active substance Imidacloprid (see Assessment Report Imidacloprid PT 18, 18 February 2011 and CAR Imidacloprid (Bayer Environmental Science, RMS Germany; February 2011)).

3.7.2 Effects assessment

The applicant has a full letter of access to the data from the active substance dossier. In addition, further effect data for several aquatic and terrestrial endpoints were delivered (see DOC IIIA of 3rd party dossier).

3.7.2.1 Mixture toxicity

Not required, since the product contains only one active substance and no substance of concern for the environment.

3.7.2.2 Aquatic compartment (including sediment and STP)

The effect values for the aquatic compartment delivered by the applicant Sharda are nearly identical to the effect values in the active substance dossier for Annex I inclusion. Therefore, these new data would not influence the effects assessment for surface water and sediment.

However, new information on the effect of Imidacloprid to mayfly nymphs became available in 2013 in the form of a publication.[16] The authors performed short and long-term toxicity tests with 10 (short-term) and 7 (long-term) aquatic invertebrate species from different taxonomic groups. In the acute tests 96h-EC_{50} values for the 10 test species range from 1.02 – 119 µg/L for the endpoint immobilization. Most sensitive species were *Cloeon dipterum* (1.02 µg/L), *Caenis horaria* (1.77 µg/L) and Limnephilidae (1.79 µg/L). Least sensitive were *Chaoborus obscuripes* (284 µg/L) and *Asellus aquaticus* (119 µg/L). In the long-term tests 28d-EC_{10} values (immobilization) for the 7 tested species were in the range of 0.024 – 4.57 µg/L. Again, the mayflies *Cloeon dipterum* (28d-EC_{10} = 0.033 µg/L) and *Caenis horaria* 28d-EC_{10} = 0.024 µg/L) were most sensitive.

[16] Roessink et al. (2013): "The neonicotinoid Imidacloprid shows high chronic toxicity to mayfly nymphs;" (Environmental Toxicology and Chemistry, Vol 32, No. 5, pp 1096-1100); https://doi.org/10.1002/etc.2201|

The long-term effect values found for *Cloeon dipterum* and *Caenis horaria* are a factor of about 30 below the lowest available effect value in the CAR of 0.87 µg/L (*Chironomus riparius*) and even lower than the $PNEC_{water}$ derived in the CAR (0.174 µg/L). That means that the PNEC derived in the CAR may underestimate the risk caused by Imidacloprid. A discussion on the use of the new information for a revision of the environmental effects assessment for Imidacloprid was held at TM III/13 with the result that the data by Roessink et al. should be considered for the effect assessment. At the Biocides Working Group Meeting IV - 2014 in September 2014 it was agreed to derive a new $PNEC_{water}$ for Imidacloprid from the lowest long-term effect value for *Caenis horaria* by applying an assessment factor of 5. Therefore:

$PNEC_{water}$ =0.024 µg/L / 5 = 0.0048 µg/L = 4.8 ng/L.

The newly derived $PNEC_{water}$ also influences the assessment for the sediment compartment, as the $PNEC_{sediment}$ is derived from the $PNEC_{water}$ using equilibrium partitioning method. Using a $K_{susp\text{-}water}$ of 6.3 and a RHO_{susp} of 1150 kg/m³ results in a **$PNEC_{sediment}$ of 26 ng/kg ww.**

In the CAR and assessment report for Imidacloprid a $PNEC_{stp}$ of 100 mg/L was derived for sewage treatment plants from a standard activated sludge respiration inhibition test with sludge from domestic sewage treatment plant in which a NOEC equal to 5,600 mg/L and an EC_{50} > 10,000 mg/L was determined.
Within product authorisation for the product Imidasect Ants new information compared to the CAR has been provided in a 3rd party dossier. In the first study (= key study CAR), the effect of Imidacloprid on aerobic biological sewage treatment processes was assessed by determining respiration inhibition of the microorganisms present in activated sludge (acc. to OECD 209). The EC_{50} was calculated to be >10 000 mg a.s./L (nominal) and the NOEC was determined to be 5600 mg a.s./L (nominal). In the second test submitted on the respiration inhibition of activated sludge also conducted according to OECD 209 (Doc IIIA 7.4.1.4*)*, both, EC_{50} and NOEC were determined to be 10,000 mg a.s/L (nominal). Thus, in both submitted studies, no inhibitory effects in the tested concentrations were detected.
According to the Guidance on the BPR, Volume IV, Part B, Infobox Nr. 7, p. 127 (ECHA, April 2015) if no inhibition is observed for active substances tested at concentrations exceeding their water solubility, the NOEC is now set equal to the water solubility which is subsequently used to derive the $PNEC_{stp}$. This results in a NOEC of 613 mg/L for the active substance Imidacloprid, since in both tests concentrations higher than the water solubility were used.
With a NOEC value of 613 mg/L derived from the two studies available both conducted according to OECD 209, the **$PNEC_{stp}$ amounts to 61.3 mg/L**.

3.7.2.3 Terrestrial compartment (including groundwater)

For the terrestrial compartment the applicant Sharda provided new effect data for *Folsomia candida* (effects on reproduction) as well as tests on nitrogen and carbon mineralisation. These effect values are in the same range as the already available effect values from the active substance dossier. As the $PNEC_{soil}$ in the active substance dossier is based on the NOEC from an earthworm reproduction study (56d-NOEC > 0.178 mg/kg dw) and no more sensitive effect values were delivered, the $PNEC_{soil}$ from the active substance dossier for Annex I inclusion is still valid.

Therefore, **$PNEC_{soil}$ is 15.75 µg/kg ww.**

Imidacloprid was shown to be highly toxic to bees both by oral and contact exposure. The 48 hour LD50 for oral toxicity was 0.0037 µg/bee. For contact toxicity a LD50 of 0.081 µg/bee was found. No guidance is currently available to assess the risk for bees and other pollinators.

3.7.2.4 Atmosphere

In view of the limited volatility of Imidacloprid (vapour pressure $4 \cdot 10^{-10}$ Pa at 20°C) emissions to air are expected to be not significant in relation to the intended use pattern. Furthermore, accumulation of Imidacloprid in the air is not expected since the half-life in troposphere was estimated to be 2.54 hours.

3.7.2.5 Non-compartment specific effects

Due to the low bioaccumulation potential, no assessment for secondary poisoning for fish or worm eating birds and mammals is necessary.
However, secondary poisoning via feeding of contaminated insects is possible from the outdoor use of the product Imidasect Ants.
From a bird reproduction study a **$PNEC_{oral,bird}$ of 4.2 mg/kg food** was derived.
For mammals a **$PNEC_{oral,mammal}$ of 8.3 mg/kg food** was derived from a rat 2-generation-reproduction study.

3.7.2.6 Summary of effects assessment

Table 57

Summary table on calculated PNEC values	
Compartment	**PNEC**
Surface water	4.8 ng/L
Sediment	26 ng/kg ww
STP	61.3 mg/L
Soil	15.75 µg/kg ww
Food-chain bird	4.2 mg/kg food
Food-chain mammal	8.3 mg/kg food

3.7.3 Fate and behaviour

Biodegradation

Based on the results from a new study on ready biodegradability according to OECD 301 A (Doc IIIA 7.1.1.2.1), Imidacloprid is classified as not readily biodegradable. Results from higher tier simulation studies for both water/ sediment systems and soil are available in the resp. CAR and AR. In the water/sediment systems a geometric mean DT_{50} of 185.4 d was determined (n=3, 12 °C), whereas for the soil field studies a geometric mean DT_{50} value of 135.1 days was calculated (n=14, 12 °C). The degradation rate constant in soil k_{bio_soil} is $5.13 \cdot 10^{-3}$ d^{-1}. For elimination estimations in sewage treatment plants a rate constant of 0 h^{-1} was used.

Abiotic Degradation

Imidacloprid is stable to hydrolysis at pH 5 and 7 and shows slight hydrolysis at pH 9. Therefore, hydrolysis is not considered to be a significant degradation route at environmentally relevant temperature and pH. A study on photolysis in water shows that Imidacloprid is rapidly photolytically degraded either in pure water or buffered solution (pH 7) with half-lives < 1 day in spring and summer.

Distribution in soil

In the context of the initial authorisation, the applicant provided new information about the sorption behaviour of the a.s. in 4 different soils (Doc IIIA A.7.1.3). The study showed that the a.s. can be classified as being highly mobile in soils with Ka_{oc} of 54.8 – 61.4 cm^3 g^{-1}. The RefMS considers the study reliable with only minor deficits. Therefore, for environmental exposure assessment, both studies (3rd party dossier and active substance dossier) were considered.. A mean organic carbon-water partitioning coefficient was calculated considering 4 soils of the 3rd party dossier (with Ka_{oc} of 54.8 – 61.4 cm^3 g^{-1}) and 12 soils from the active substance dossiers (with Ka_{oc} of 121 – 411 mL g^{-1}), respectively. A mean

Ka_{oc} of **186.6 mL g^{-1}** was calculated and considered for environmental exposure assessment. This organic carbon-water partitioning coefficient indicates a moderately mobility of the a.s. in soils.

Distribution in STP

The distribution of Imidacloprid in the sewage treatment plant is calculated using the SimpleTreat 4.0-model with the following release fractions: to air 0.0 %, to water 97.64 %, to sludge 2.36 % and the degraded fraction is 0.0 %. Imidacloprid is not biodegradable and for that reason the degradation rate constant in sewage treatment plant is k_{STP}= 0 h^{-1} (BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.4, table 4).

Bioconcentration

The calculated bioconcentration factor in fish is 0.61 and the estimation on terrestrial bioconcentration leads to a value of 0.88 for earthworm.

3.7.4 Exposure assessment

3.7.4.1 General information

The biocidal product (b.p.) Imidasect Ants is a ready-to-use insecticidal gel formulation containing 0.01 % (w/w) of the active substance Imidacloprid. The b.p. is to be used to control ants (Pharaoh ants, *Monomorium pharaonis,* Argentine ants, *Linepithema humile* and Black garden ants (*Lasius niger*)*)* in and around domestic premises (including kitchens), food handling places (handling, processing, storage preparation) and public or commercial buildings including hospital wards, hotels, public baths, municipal buildings, churches, halls, community centres, cinemas, etc.). Imidasect Ants is intended to be used indoors and outdoors by professionals and by non-professionals. For the biocidal product four different application patterns are foreseen. An environmental exposure assessment including further descriptions of the intended uses for these entire application patterns is described separately in the subsequent paragraphs:

(1) Indoor use in bait trays in private houses and commercial buildings (chapter 3.7.4.3)
(2) Indoor use as gel in private houses and commercial buildings (chapter 3.7.4.4)
(3) Outdoor use in bait trays around private houses and commercial buildings (chapter 3.7.4.5)
(4) Outdoor use as gel in private houses and commercial buildings (chapter 3.7.4.6)

The predicted environmental concentrations (PECs) for each compartment are assessed applying the Guidance BPR, IV, B+C (2017) chapter 2.3.8 and the emission scenario description is based on the Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD ESD PT 18 No. 18, 2008).

Table 58

Assessed PT	PT 18
Assessed scenarios	(1) Indoor use in bait trays in private houses and larger buildings (2) Indoor use as gel in private houses and larger buildings (3) Outdoor use in bait trays around private houses and larger buildings (4) Outdoor use as gel in private houses and larger buildings
ESD(s) used	Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD ESD PT 18 No. 18, 2008)
Approach	(1) Average consumption-based approach (2) Average consumption-based approach (3) Average consumption-based approach (4) Average consumption-based approach
Distribution in the environment	Calculations are based on - Emission Scenario Document (ESD) PT 18 No 18 (2008) - Guidance on the BPR, Vol. IV, Part B+C (2017) - the Technical Agreements on Biocides (TAB), v. 2.1 (2019)
Groundwater simulation	Yes Refined groundwater assessment was performed using FOCUS PEARL v.4.4.4
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes Service life: No
Remarks	

3.7.4.2 Fate and distribution in exposed environmental compartments

The following compartments might be exposed by application of the product Imidasect Ants:

Table 59

Identification of relevant receiving compartments based on the exposure pathway				
	STP	**Surface water and Sediment**	**Soil and Groundwater**	**Air**
Indoor use, bait tray	negligible	negligible	negligible	not relevant
Indoor use, gel application	yes	yes	yes	not relevant
Outdoor use, bait tray	yes	yes	yes	not relevant
Outdoor use, gel application	yes	yes	yes	not relevant

Parameters which describe the fate and distribution of Imidacloprid in the environment are summarised inTable 60. The partitioning coefficient for the aquatic and terrestrial compartment, which are relevant for the environmental emission estimation and exposure assessment are based on these input values.

Table 60

Input parameters (only set values) for calculating the fate and distribution in the environment of Imidacloprid			
Input	Value	Unit	Remarks
Molecular weight	255.7	g/mol	
Melting point	144.0	°C	
Boiling point	Not applicable	°C	Decomposition
Vapour pressure (at 12° C)	2.225×10^{-10}	Pa	1.0×10^{-9} is used as the lowest possible value in SimpleTreat
Water solubility (at 12° C)	545.14	mg/L	
Log Octanol/water partition coefficient	0.57	Log 10	Demin. Water, 21 °C
Organic carbon/water partition coefficient (Koc)	186.6	L/kg	Mean value (substance approval + 3rd party dossier)
Soil water partition coefficient	5.799	m^3/m^3	
Suspended matter-water partition coefficient	5.566	m^3/m^3	
Henry's Law Constant (at 12° C)	1.044×10^{-10}	Pa x m^3/mol	1.0×10^{-9} is used as the lowest possible value in SimpleTreat
Biodegradability	Not readily biodegradable		

Input parameters (only set values) for calculating the fate and distribution in the environment of Imidacloprid			
Input	Value	Unit	Remarks
Rate constant for STP	0	h^{-1}	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.4, table 4
DT_{50} for degradation in soil	135.1	d (at 12ºC)	Soil field studies, used acc. to CAR Imidacloprid (2016)

3.7.4.3 Indoor use in bait trays in private houses and commercial buildings

Imidasect Ants may be applied in ready-to-use bait trays in places where ants can appear. The bait tray is activated by replacing a covering sticker which seals the opening of the bait tray. A maximum application dose of 0.35 g b.p./ m² per treatment is envisaged. That means based on a maximum package size of 1.4 g in one bait tray, 1 bait tray can be placed each 4 m². Bait trays are removed when plague ceases or is eliminated. Imidasect Ants can be used continuously for 2-3 months without replacing opened and unconsumed baits. If the product is consumed beforehand, the treatment can be repeated every four weeks with a maximum of 12 applications per year.

The OECD ESD PT18 No. 18 (2008) specifies that emissions to the environment during the use of solid baits and gels deployed in bait trays are negligible during the service life stage. Therefore, from the indoor use of the biocidal product Imidasect Ants in bait trays, neither direct nor indirect emission to the aquatic or terrestrial environment can be expected. Thus, the exposure of STP, of surface water or sediment and of soils or groundwater can be regarded as negligible from the indoor use of the product Imidasect Ants in bait trays. Consequently, an environmental exposure assessment for this use pattern is not performed.

3.7.4.4 Indoor use as gel in private houses and commercial buildings

Imidasect Ants is formulated as ready-to-use product (RTU) and is applied as gel drops directly to the target surface such as hidden areas, places with difficult access or directly into foraging trails. The use of Imidasect Ants can be repeated when all gel is consumed by the insects or at maximum every four weeks (maximum of 12 applications per year).

3.7.4.4.1 Release estimation for indoor gel application

Due to the proposed use pattern of the b.p., the application mode can be described as treatment on surfaces not regularly cleaned, where the default surface area of barrier treatment was used in combination with the cleaning efficiency for gel applications on surfaces (TAB, ENV 149) as agreed at the CG-50 meeting in February 2022. Environmental exposure may arise due to wet cleaning of the target

areas after application of the biocidal product with subsequent release of the waste water to the STP system. A release and exposure estimation for mixing and loading steps is unnecessary as the b.p. is furnished as RTU product.

The release to the environment is assessed by the emission scenario described in chapter 3.3.2 of OECD ESD No. 18 (2008) under consideration of TAB entry ENV 144 (TAB database, status July 2021).

Release during application step

Following the agreement during the commenting period, the ERA was revised using the default surface area of barrier treatment according to ENV 142 in TAB (status July 2021), i.e. default target areas of 5.9 m^2 and 27 m^2 are considered in private houses and commercial buildings, respectively. An application rate of 1 gel drop/m^2 is envisaged. Whereas each gel drop contains 0.2 g of the biocidal gel formulation. Therefore, an application rate of 0.2 $g.m^{-2}$ b.p. is assumed for environmental release estimation.

An application frequency of 1 application per day in household/commercial building is considered as given by ESD PT 18 (OECD, 2008). Moreover, the ESD PT 18 states that no release to air and to the applicator can be expected due to the use of gel insecticides. Thus, the fraction emitted to the target surface is 100%.

The application of the b.p. in a typical scenario results in a release of Imidacloprid to the target surface of 1.18×10^{-7} kg $kg.d^{-1}$ in private houses and 5.4×10^{-7} kg d^{-1} in commercial buildings. Input values as well as the calculated emission rates are summarised in Table 61.

Table 61: Emission scenario for indoor application of Imidasect Ants during application step

Determinants of the emission scenario	Value
Quantity of b.p. applied [Qb.p.]	0.2 $g.spot^{-1}$
Application rate of the b.p. [APPb.p.]	1 $spot.m^{-2}$
Fraction of a.s. in the product [Fa.i.]	0.0001
Quantity of a.i. applied [Qa.s.]	2.0 x 10^{-5} $g.m^{-2}$
Area treated with the product [AREAtreated] - household - com. building	 5.9 m^2 27 m^2
Number of applications per day per household [Nappl, building]	1 d^{-1}
Fraction emitted to air [Fapplication, air]	0.0
Fraction emitted to treated area [Fapplication, treated area]	1.0
Fraction emitted to applicator [Fapplication, applicator]	0.0
Emission rates due to application of Imidasect Ants in households	
Local emission rate to air Eapplication, air = Nappl, building x Fapplication, air x Qa.s. x AREAtreated	0.0 $kg.d^{-1}$
Local emission rate to treated area Eapplication, floor = Nappl, building x Fapplication, floor x Qa.s. x AREAtreated	1.18 x 10^{-7} kg d^{-1}
Local emission rate to applicator Eapplication, applicator = Nappl, building x Fapplication, applicator x Qa.s. x AREAtreated	0.0 $kg.d^{-1}$
Emission rates to due to application of Imidasect Ants in larger buildings	
Local emission rate to air Eapplication, air = Nappl, building x Fapplication, air x Qa.s. x AREAtreated	0.0 $kg.d^{-1}$
Local emission rate to treated area Eapplication, floor = Nappl, building x Fapplication, floor x Qa.s. x AREAtreated	5.4 x 10^{-7} kg d^{-1}
Local emission rate to applicator Eapplication, applicator = Nappl, building x Fapplication, applicator x Qa.s. x AREAtreated	0.0 $kg.d^{-1}$

Release estimation of the b.p. during cleaning step

Considering the gel application of b.p. in the above mentioned areas, it might be realistic that residues of Imidasect Ants could be removed by dry cleaning methods. However, the exposure pathway of solid waste to municipal landfill will not be further evaluated.

For wet cleaning, a cleaning efficiency of 25 % is considered according to the conclusions at CG-50 in February 2022. The input and output values for Imidasect Ants are summarised in Table 62. The local emission rates to floor as further required input values are taken from results in Table 61.

Table 62: Emission scenario for indoor application of Imidasect Ants during cleaning step

Determinants of the emission scenario	Value
Fraction emitted to air	0
Cleaning efficiency [F_{CE}]	0.25
Fraction emitted during cleaning step	
Fraction emitted to waste water from applicator - washable coveralls [$F_{applicator, ww}$]	1
Fraction emitted to waste water during cleaning step [$F_{floor, ww}$]	1
Fraction emitted to waste from applicator - disposable coveralls [$F_{applicator, w}$]	0
Fraction emitted to waste during [$F_{floor, w}$]	0
Emission rates	
Local emission rate to air [$E_{cleaning, air}$]	0 $g.d^{-1}$
Local emission rate to waste water during cleaning step from treated area $E_{floor, ww} = E_{application, floor} \times F_{floor, ww} \times F_{CE}$ - households - commercial buildings	 2.95×10^{-8} kg d^{-1} 1.35×10^{-7} kg d^{-1}

Release estimation to sewage treatment plant

It is supposed that residues removed through wet cleaning may potentially be emitted to the sewer and subsequently to the sewage treatment plant (STP). According to the ESD No. 18 (2008) the STP is considered as one of the main “receiving compartment” in which insecticides will be released through wet cleaning events. In Europe, estimates of potential exposures resulting from STPs are carried out according to the Guidance on BPR, Vol. IV, Parts B+C (Version 2.0, 2017). According to this, the further receiving environmental compartments are surface water and sediment (after STP), soil and groundwater (from sludge application), and the outdoor air.

The water releases per day E_{ww_sim} from households and commercial buildings were summed up to perform a cumulative assessment. The input values for determining releases to STP in the course of spot treatment into cracks and crevices as well as the calculated emission rates are summarised in Table 63.

According to ESD PT 18 (2008) 4000 public buildings and 300 commercial building are connected to one STP. Furthermore, a simultaneity factor (F_{sim}) was implemented in the ESD PT18 that considers the simultaneity of treatments by the houses connected to the STP. Outgoing from a maximum application of 12 times per year a simultaneity factor of 1.386% (F_{sim} = 0.01386) was applied.

The application of the b.p. in a typical scenario results in release of **2.20×10^{-6} kg d^{-1}** Imidacloprid to STP.

Table 63: Cumulative and simultaneous emission scenario for indoor application of Imidasect Ants during cleaning step

Input	Value
Number of houses connected to STP [N_{houses}] - private houses - commercial buildings	 4000 300
Simultaneity factor indoor [F_{Sim}]	0.01386
Output	
Simultaneous emission to waste water during cleaning step: $E_{ww\_sim} = E_{floor,\ ww} \times N_{houses} \times F_{Sim}$ - households - commercial buildings	 1.64×10^{-6} kg d^{-1} 5.61×10^{-7} kg d^{-1}
Cumulative emission to waste water:	**2.20×10^{-6} kg.d^{-1}**

3.7.4.4.2 Estimation of Predicted Environmental Concentrations for the aquatic compartment (incl. sediment)

According to the intended use of Imidasect Ants, indirect emission to surface water and sediment via output of the effluent from STP occurs. The predicted environmental concentrations for STP, surface water and sediment are estimated as follows:

PEC_{STP} (=$Clocal_{inf}$) and $Clocal_{eff}$ according to equation 35, 36 and 41, chapter 2.3.6.7, GD on BPR Vol. IV, Parts B+C (2017),
$PEClocal_{surfacewater}$ according to equation 51, chapter 2.3.7.3, GD on BPR Vol. IV, Parts B+C (2017),
$PEClocal_{sediment}$ according to equation 53, chapter 2.3.7.4, GD on BPR Vol. IV, Parts B+C (2017).

The results are summarised in Table 64.

Table 64: Summary of STP influent ($Clocal_{inf}$) and effluent ($Clocal_{eff}$), PEC_{STP}, $PEClocal_{surface\ water}$ and $PEClocal_{sediment}$

$Clocal_{inf}$ [µg.L^{-1}]	$Clocal_{eff}$ [µg.L^{-1}]	PEC_{STP} [µg.L^{-1}]	$PEClocal_{surface\ water}$ [µg.L^{-1}]	$PEClocal_{sediment}$ [µg.kg^{-1}]
1.098×10^{-3}	1.072×10^{-3}	1.098×10^{-3}	1.072×10^{-4}	5.189×10^{-4}

3.7.4.4.3 Estimation of Predicted Environmental Concentrations for the terrestrial compartment

The application of sludge from the STP onto agricultural and grassland soil provokes an indirect emission to soil, as well as the leaching of a.s. through soil following sludge application causes indirect emission to groundwater. The PEC_{soil} is estimated according to equation 69, chapter 2.3.7.5, GD on BPR Vol. IV, Parts B+C (2017). Additionally, the estimation of the local PECs for the terrestrial compartment includes also groundwater. The $PEC_{groundwater}$ is calculated according to equation 71, chapter 2.3.7.6, GD on BPR

Vol. IV, Parts B+C (2017) as a first worst-case estimation. Table 65 indicates the PEC in soil and groundwater for Imidacloprid according to the application scenario.

Table 65: Summary of C_{sludge}, $PEClocal_{soil}$ and $PEClocal_{groundwater}$

C_{Sludge} [µg.kg^{-1}]	$PEClocal_{soil}$ [µg.kg^{-1}]	$PEClocal_{groundwater}$ [µg.L^{-1}]
6.6 x 10^{-2}	1.03 x 10^{-4}	2.08 x 10^{-5}

3.7.4.4.4 Estimation of Predicted Environmental Concentrations for the atmosphere

In view of the limited volatility of Imidacloprid (vapour pressure $4 \cdot 10^{-10}$ Pa at 20°C) emissions to air are expected to be not significant in relation to the intended use pattern.

3.7.4.4.5 Estimation Predicted Environmental Concentrations for primary and secondary poisoning

Primary poisoning of non-target animals is excluded according to the design of the b.p. Due to the low bioaccumulation potential of Imidacloprid the assessment of secondary poisoning according to the GD on BPR, Vol. IV, Parts B+C (2017), chapter 3.9.3 is not required. Furthermore, secondary poisoning due to the potential exposure of vertebrates (i.e. birds or mammals) consuming contaminated insects or taking their food (ref. to chapter 5 in ESD PT18 No. 18 (2008)) is excluded because of the indoor use of Imidasect Ants.

3.7.4.5 Outdoor use in bait trays around private houses and commercial buildings

Imidasect Ants may be applied in ready-to-use bait trays in places where ants can appear. The bait tray is activated by replacing a covering sticker which seals the opening of the bait trays. Typically bait trays are removed when plague ceases or is eliminated. Imidasect Ants can be used continuously for 2 - 3 months without replacing opened and unconsumed baits. If the product is consumed beforehand, the treatment can be repeated every four weeks (maximum of 12 applications per year).

3.7.4.5.1 Release estimation for outdoor bait trays

According to ESD PT 18 No. 18 (2008), the only possible emission route from the outdoor use of bait trays is when the bait box is flooded or by insect dispersion. As the biocidal product is furnished as a gel formulation, a dispersion of the product into the environment by insects is considered unlikely due to the consistency of the biocide. Therefore, only the emission scenario due to flooding is included in the presented environmental exposure and risk assessment.

Due to the proposed use pattern of the b.p., the application mode can be described as spot application. Environmental exposure may arise following flooding from a rain event. These emissions may enter directly into the surrounding soil of the bait trays or will be released to a STP system with subsequent indirect release to the environmental compartments surface water, sediment, soil (via sludge application) and groundwater. It is presumed, that outdoor areas of private houses, such as gardens, terraces and balconies, are not connected to an STP system. Therefore, release to STP is only considered for the use of Imidasect Ants around larger buildings. Moreover, a release and exposure estimation for mixing and loading steps is unnecessary as the b.p. is furnished as RTU product.

Estimation of releases from b.p. applications on paved and unpaved surfaces

1) Paved surfaces

The input values for determining the releases from b.p. applications on paved surfaces in the course of treatment around larger buildings and private houses, respectively, as well as the calculated emission rates are summarised in Table 66. An application rate of 0.23 $g.m^{-1}$ Imidasect Ants per building perimeter is envisaged.

According to ESD PT18 No. 18 (2008) and TAB v. 2.1 (ENV 159) for outdoor applications of insecticides around larger buildings, a default perimeter of 100 m is proposed with a perimeter width of 0.5 m. Considering an application rate of 0.23 $g.m^{-1}$, this leads to an area of 0.5 m^2 which is exposed directly to 0.23 g Imidasect Ants or an application rate of 0.46 $g.m^{-2}$, respectively.

In case of a treatment on paved surfaces around private houses the terrace scenario should be used according to TAB v. 2.1 (ENV 154 and ENV 159). The bait trays will be placed on the terrace as barrier in parallel to the private house over a length of 6 m (default value in terrace scenario) considering an application rate of 0.23 $g.m^{-1}$. According to the model to be applied, this leads to an overall application rate of 1.38 g b.p. on a terrace of domestic area of private houses.

The ESD PT 18 (2008) indicates that about 80 % of the insecticidal product deposits in bait trays outdoors are consumed by the target insects whereas 20 % remain in the bait tray and can be emitted into the environment due to a flooding case. Thus, the fraction emitted to paved surfaces is 20 %.

The application of the b.p. in an outdoor larger building scenario results in a release to paved soil surfaces of **4.6×10^{-4} g** Imidacloprid per perimenter (100 m). In case of application of the b.p. around private houses, the model of terrace scenario leads to calculated releases of **2.76×10^{-5} g** Imidacloprid to surrounding receiving soil area.

2) Unpaved surfaces

For releases due to b.p. applications on unpaved soil, the same assumptions for both, larger buildings and private houses, can be made: an application rate of 0.23 g b.p. per m² has to be considered.

For unpaved surfaces, the local emission of b.p. results in **4.6 x 10^{-6} g** Imidacloprid per 0.5 m².

Table 66: Emission scenario for outdoor application of Imidasect Ants during application step – release to paved and unpaved surfaces

Determinants of the emission scenario according to chapter 4.4.5, OECD ESD PT18 No.18 (2008)	**Value**
Amount of product used at each filling in the control operation [$Q_{b.p.}$]	0.23 g/m
Fraction of a.s. in the product [$F_{a.i.}$]	0.0001
Quantity of a.s. applied [$Q_{a.s.}$]	2.3 x 10^{-5} g
Number of application [N_{appl}]	1
Number of application sites per m [N_{sites}]	1
Fraction of a.s. emitted to soil during outdoor bait application [$F_{spot,bait}$]	0.2
Treated perimeter around larger buildings [$PERIMETER_{treated}$]	100 m
Default treated length for terrace scenario at private houses [$LENGTH_{treated\_hh}$]	6 m
Output	
Local direct emission rate to paved surfaces - larger buildings $E_{spot,\ lb} = Q_{b.p} \times F_{a.i} \times PERIMETER_{treated} \times N_{appl} \times F_{spot,soil}$	4.6 x 10^{-4} g
Local direct emission rate to receiving soil area (terrace scenario private houses (paved surfaces)) $E_{spot,\ soil\_terrace} = Q_{b.p} \times F_{a.i} \times LENGTH_{treated\_hh} \times N_{appl} \times F_{spot,soil}$	2.76 x 10^{-5} g
Local emission rate to unpaved soil surfaces (private houses and larger buildings) $E_{spot,\ soil} = Q_{b.p} \times F_{a.i} \times N_{sites} \times N_{appl} \times F_{spot,soil}$	4.6 x 10^{-6} g

Estimation of release to sewage treatment plants

In frame of BPR, estimates of potential exposures resulting from STPs are carried out according to the Guidance on BPR, Vol. IV, Parts B+C (Version 2.0, 2017). According to this, the further receiving environmental compartments are surface water and sediment (after STP), soil and groundwater (from sludge application), and the outdoor air.

The input values for determining releases to STP in the course of spot application as well as the calculated emission rates are summarised in Table 67. Outgoing from a maximum application of 12 times per year a simultaneity factor of 1.386% (F_{sim} = 0.01386) was applied.

The application of the b.p. in a typical scenario around commercial buildings results in a simultaneous release of **1.91 x 10^{-3} g.d^{-1}** Imidacloprid to the STP.

Table 67: Emission scenario for outdoor application of Imidasect Ants during application step – release to STP

Determinants of the emission scenario	Value
Local direct emission rate to paved surfaces - larger buildings $E_{spot, lb}$	4.6 x 10^{-4} g.d^{-1}
Number of larger buildings connected to STP [N_{lb}] - larger buildings	300
Simultaneity factor outdoor [F_{Sim}]	0.01386
Output	
Simultaneous emission to STP: $E_{water\_sim\_lb} = E_{spot, lb} \times N_{lb} \times F_{sim}$	1.91 x 10^{-3} g.d^{-1}

3.7.4.5.2 Estimation of Predicted Environmental Concentrations for the aquatic compartment (incl. sediment)

The estimation of the local PECs for the aquatic compartment includes PECs for surface water and sediment:

- $PEC_{surfacewater}$ according to equation 51;
- $PEC_{local\_sediment}$ according to equation 53, chapter 2.3.7.4, Guidance BPR Vol. IV Part B+C (2017).

For the estimation of the local PEC for the STP, $Clocal_{inf}$ should be used due to the intermittent application pattern:

- PEC_{STP} (= $Clocal_{inf}$) according to equation 42, chapter 2.3.6.7, Guidance on the BPR, Vol. IV, Part B+C (2017);
- $Clocal_{inf}$ according to equation 42, chapter 2.3.6.7, Guidance on the BPR, Vol. IV, Part B+C (2017).

The results are summarised in Table 68.

Table 68: Summary of STP influent ($Clocal_{inf}$) and effluent ($Clocal_{eff}$), PEC_{STP}, $PEClocal_{surface\ water}$ and $PEClocal_{sediment}$

$Clocal_{inf}$ [µg.L^{-1}]	$Clocal_{eff}$ [µg.L^{-1}]	PEC_{STP} [µg.L^{-1}]	$PEClocal_{surface\ water}$ [µg.L^{-1}]	$PEClocal_{sediment}$ [µg.kg^{-1}]
9.56 x 10^{-4}	9.34 x 10^{-4}	9.56 x 10^{-4}	9.34 x 10^{-5}	4.51 x 10^{-4}

3.7.4.5.3 Estimation of Predicted Environmental Concentrations for the terrestrial compartment

The terrestrial compartment may be exposed either directly after release of the a.s. to the surrounding soil of the bait trays or indirectly after release of the a.s. to the STP following sludge application to agricultural soil.

1) Direct exposure to paved surfaces

The predicted environmental concentration in soil (PEC_{soil}) is estimated on the assumptions according to TAB v. 2.1 (ENV 154). The receiving area of a terrace is set to 8.5 m² and the soil depth is 0.5 m. Using equation no. 60 of the ESD PT18 No. 18 (2008), the application of the b.p. in a typical scenario results in a direct local emission of 2.76 x 10^{-5} g Imidacloprid to soil (refer to Table 66). The input parameters for calculating PEC_{soil} are summarised in Table 69.

The estimation of the local PECs for the terrestrial compartment includes also the groundwater. The $PEC_{groundwater}$ is calculated according to equation 70 in the Guidance on the BPR, Vol. IV, Part B+C (2017) as a first worst-case estimation. Table 69 indicates the PEC in groundwater for Imidacloprid according to the application scenario.

Table 69: $PEC_{soil,direct}$ of Imidasect Ants during application step – direct release to paved surfaces

Determinants of the emission scenario according to chapter 4.4.5, OECD ESD PT18 No.18 (2008)	**Value**
Local direct emission rate to soil [$E_{spot,\ soil}$]	2.76 x 10^{-5} g
Area directly exposed to insecticide [$AREA_{exposed}$]	8.5 m²
Depth of exposed soil [$DEPTH_{soil}$]	0.5 m
Density of exposed soil [RHO_{soil}]	1700 kg.m^{-3}
Soil-water partition coefficient [$K_{soil\text{-}water}$]	5.799 m³.m^{-3}
Output	
Local concentration in soil due to direct release after a campaign: $C_{spot,soil} = \frac{E_{spot,\ soil}}{AREA_{exposed} \times DEPTH_{soil} \times RHO_{soil}}$	3.82 x 10^{-6} mg.kg^{-1}
Predicted environmental concentration in soil [PEC_{soil}]	**3.82 x 10^{-3} µg.kg^{-1}**
Local concentration in groundwater due to direct release after a campaign: $PEClocal_{soil,porew} = \frac{PEC_{soil} \times RHO_{soil}}{K_{soil\text{-}water}}$	1.12 x 10^{-3} µg.L^{-1}
Predicted environmental concentration in groundwater [PEC_{gw}]	**1.12 x 10^{-3} µg.L^{-1}**

The PEC in groundwater from application of Imidasect Ants in bait trays around buildings on paved surfaces does not exceed the trigger value of 0.1 µg.L^{-1} of the groundwater Directive.

2) Direct exposure to unpaved surfaces

The predicted environmental concentration in soil (PEC_{soil}) is estimated on the basis of equation no. 60 of the ESD PT18 No. 18 (2008). The application of the b.p. in a typical scenario results in a direct local emission of 4.60 x 10^{-6} g Imidacloprid per 0.5 m² of soil (refer to Table 66). The soil depth to be considered according to ESD PT 18 (2008) is 0.5 m, leading to a soil volume of 0.25 m³. The input parameters for calculating PEC_{soil} are summarised in Table 70.

The estimation of the local PECs for the terrestrial compartment includes also the groundwater. The $PEC_{groundwater}$ is calculated according to equation 70 in the Guidance on the BPR, Vol. IV, Part B+C (2017) as a first worst-case estimation. Table 70 indicates the PEC in groundwater for Imidacloprid according to the application scenario.

Table 70: $PEC_{soil,direct}$ of Imidasect Ants during application step – direct release to unpaved surfaces

Determinants of the emission scenario according to chapter 4.4.5, OECD ESD PT18 No.18 (2008)	**Value**
Local direct emission rate to soil [$E_{spot,\ soil}$]	4.6 x 10^{-6} g
Area directly exposed to insecticide [$AREA_{exposed}$]	0.5 m²
Depth of exposed soil [$DEPTH_{soil}$]	0.5 m
Density of exposed soil [RHO_{soil}]	1700 kg.m^{-3}
Soil-water partition coefficient [$K_{soil\text{-}water}$]	5.799 m³.m^{-3}
Output	
Local concentration in soil due to direct release after a campaign: $C_{spot,soil} = \frac{E_{spot,\ soil}}{AREA_{exposed} \times DEPTH_{soil} \times RHO_{soil}}$	1.08 x 10^{-5} mg.kg^{-1}
Predicted environmental concentration in soil [PEC_{soil}]	**1.08 x 10^{-2} µg.kg^{-1}**
Local concentration in groundwater due to direct release after a campaign: $PEClocal_{soil,porew} = \frac{PEC_{soil} \times RHO_{soil}}{K_{soil\text{-}water}}$	3.17 x 10^{-3} µg.L^{-1}
Predicted environmental concentration in groundwater [PEC_{gw}]	**3.17 x 10^{-3} µg.L^{-1}**

The PEC in groundwater from application of Imidasect Ants in bait trays around buildings on unpaved surfaces does not exceed the trigger value of 0.1 µg.L^{-1} of the groundwater Directive.

Indirect exposure (larger buildings)

The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater:

- PEC_{local_soil} according to equation 69, chapter 2.3.7.5, Guidance on the BPR, Vol. IV, Part B+C (2017);
- $PEC_{local\_groundwater}$ according to equation 71, chapter 2.3.7.6, Guidance on the BPR, Vol. IV, Part B+C (2017) as a first worst-case estimation.

Table 70 indicates the PEC in soil and groundwater for Imidacloprid according to the application scenario.

Table 71: Summary of C_{sludge}, $PEClocal_{soil}$ and $PEClocal_{groundwater}$ for indirect release to soil via sludge application

C_{sludge} [µg.kg^{-1}]	$PEClocal_{soil}$ [µg.kg^{-1}]	$PEClocal_{groundwater}$ [µg.L^{-1}]
5.71 x 10^{-2}	8.91 x 10^{-5}	1.8 x 10^{-5}

The PEC in groundwater resulting from the indirect release of Imidacloprid to soil via sludge application does not exceed the trigger value of 0.1 µg.L^{-1} of the groundwater Directive.

3.7.4.5.4 Estimation of Predicted Environmental Concentrations for the atmosphere

In view of the limited volatility of Imidacloprid (vapour pressure 4 x10^{-10} Pa at 20°C) emissions to air are expected to be not significant in relation to the intended use pattern.

3.7.4.5.5 Estimation Predicted Environmental Concentrations for primary and secondary poisoning

Primary poisoning of birds and mammals is not considered relevant for the case of insecticide treatment with Imidasect Ants as the OECD ESD PT 18 No.18 indicates that there is no risk of direct uptake from bait trays.

The OECD ESD PT18 (2008) states that the most important route of exposure for secondary poisoning is the intake of contaminated feed. The risk of secondary poisoning is considered at the local scale. Non-target animals (birds and mammals) have potentially a risk of secondary poisoning in the following ways: (1) by consumption of worms from contaminated soil, (2) by consumption of contaminated vegetation and (3) through eating treated insects that have ingested the poison.

The estimated theoretical exposure (ETE) will be calculated for indicator species among mammals and birds, and ETE corresponds to the PEC_{oral} per day. The ETE is used for the risk assessment. In consideration of the intended use of the product Imidasect Ants in bait trays as well as the realistic

emission path of the a.s. into the environment (here: soil compartment) the assessment of secondary poisoning via consumption of contaminated insects is carried out (i.e. calculation of ETE for (3)). Calculations for the consumption of worms from contaminated soil are considered unrealistic due to the low bioaccumulation potential of Imidacloprid. A risk for secondary poisoning by consumption of contaminated vegetation is only applicable for spray application of insecticides. The procedure for ETE calculation is described in chapter 5.2.3.4 of OECD ESD PT18 (2008). The relevant input parameters are presented in Table 72. The values taken from the pick lists of the ESD PT18 (2008; Table 5.2-5, 5.2-7) are not repeated here.

Table 72: Parameters used for estimation of daily uptake of a compound

Determinants of the emission scenario according to chapter 5.2.3.4, ESD PT18 No. 18 (2008)	**Value**
Application rate of a.s. [T_{appl}]	9.2 x 10^{-9} kg·m^{-2}
Avoidance factor [*AV*]	1
Fraction of diet obtained in treated area [*PT*]	1
Fraction of food type in diet [*PD*]	1

The values of the expected daily uptake ETE for assessment of secondary poisoning via consumption of contaminated insects (acute and short term) for selected indicator species are shown in Table 73.

Table 73: Expected daily uptake (ETE) of Imidacloprid for selected indicator species following application of Imidasect Ants around private houses and commercial buildings

Species		**ETEinsect [µg.(kg.d)$^{-1}$]**	
		Acute	**Short term**
Pipistrelle	***Pipistrellus pipistrellus***	**8.81 x 10^{-5}**	**3.21 x 10^{-5}**
Shrew	*Sorex araneus*	8.11 x 10^{-5}	3.00 x 10^{-5}
Hedgehog	*Erinaceus europaeus*	2.02 x 10^{-5}	7.34 x 10^{-5}
Badger	*Meles meles*	1.05 x 10^{-5}	3.82 x 10^{-5}
Tree sparrow	***Passer domesticus***	**3.91 x 10^{-4}**	**2.18 x 10^{-4}**
Blackbird	*Turdus merula*	9.93 x 10^{-5}	3.62 x 10^{-5}
Black-billed Magpie	*Pica pica*	5.29 x 10^{-5}	1.93 x 10^{-5}

The maximum values of expected daily uptake of Imidacloprid via contaminated insects are calculated for pipistrelle (mammals) and tree sparrow (birds) for acute and for short-term (poisoning) situations.

3.7.4.6 Outdoor use as gel around private houses and commercial buildings

Imidasect Ants may be applied as gel drops directly into foraging trails or as insecticidal barrier around private or commercial buildings. The application should only be conducted on paved surfaces (not applied on bare soil). The use of Imidasect Ants can be repeated when all gel is consumed by the insects or at maximum every four weeks (maximum of 12 applications per year).

3.7.4.6.1 Release estimation for outdoor gel application

Due to the proposed use pattern of the b.p., the application mode can be described as spot application. Environmental exposure may arise following flooding from a rain event. These emissions may enter directly into the surrounding soil of the application spot or will be released to a STP system with subsequent indirect release to the environmental compartments surface water, sediment, soil (via sludge application) and groundwater. It is presumed, that outdoor areas of private houses, such as gardens, terraces and balconies, are not connected to an STP system. Therefore, release to STP is only considered for the use of Imidasect Ants around commercial buildings. Moreover, a release and exposure estimation for mixing and loading steps is unnecessary as the b.p. is furnished as RTU product. The release to the environment is assessed by the emission scenario described in chapter 3.3.2 of OECD ESD No. 18 (2008).

Estimation of releases from b.p. applications on paved surfaces

The input values for determining the releases from b.p. applications on paved surfaces in the course of spot application around larger buildings and private houses, respectively, as well as the calculated emission rates are summarised in Table 74.

According to ESD PT18 No. 18 (2008) for outdoor applications of insecticides around commercial buildings, a default perimeter of 100 m is proposed with a perimeter width of 0.5 m. Considering an application rate of 0.2 $g.m^{-1}$ an area of 0.5 m^2 is directly exposed to 0.2 g Imidasect Ants, which results in an application rate of 0.4 $g.m^{-2}$. In case of spot application on paved surfaces around private houses the terrace scenario should be used according to TAB v. 2.1 (ENV 154 and ENV 159). For outdoor gel application of the b.p., a typical application rate of 1 drop per m is envisaged, each drop containing 0.2 g of the biocidal product. The gel will be dropped on the terrace as barrier in parallel to the private house over a length of 6 m (default value in terrace scenario). According to the model to be applied, this leads to an overall application rate of 1.2 g b.p. on a terrace of domestic area of private houses.

The ESD PT 18 (2008) indicates that about 90% of the insecticidal products deposits to the treated spot can be released to the environment, either directly or through ultimate release after target insect death. Thus, the fraction emitted to paved surfaces is 90%.

The application of the b.p. in an outdoor larger building scenario results in a release to paved soil surfaces (total perimeter) of **1.8 x 10^{-3} g** Imidacloprid per 0.5 m². In case of application of the b.p. around private houses, the model of terrace scenario leads to calculated releases of **1.08 x 10^{-4} g** Imidacloprid to surrounding receiving soil area.

Table 74: Emission scenario for outdoor spot application of Imidasect Ants during application step – direct release to soil

Determinants of the emission scenario according to chapter 4.4.5, OECD ESD PT18 No.18 (2008)	**Value**
Amount of product used at each filling in the control operation [$Q_{b.p.}$]	0.2 g/m
Fraction of a.s. in the product [$F_{a.i.}$]	0.0001
Quantity of a.s. applied [$Q_{a.s.}$]	2 x 10^{-5} g
Number of application [N_{appl}]	1
Number of application sites per m [N_{sites}]	1
Fraction of a.s. emitted to soil during outdoor bait application [$F_{spot,bait}$]	0.9
Treated perimeter around larger buildings [$PERIMETER_{treated}$]	100 m
Default treated length for terrace scenario at private houses [$LENGTH_{treated\_hh}$]	6 m
Output	
Local direct emission rate to paved surfaces - larger buildings $E_{spot,\ lb} = Q_{b.p} \times F_{a.i} \times PERIMETER_{treated} \times N_{appl} \times F_{spot,soil}$	1.8 x 10^{-3} g
Local direct emission rate to receiving soil area (terrace scenario private houses (paved surfaces)) $E_{spot,\ soil\_terrace} = Q_{b.p} \times F_{a.i} \times LENGTH_{treated\_hh} \times N_{appl} \times F_{spot,soil}$	1.08 x 10^{-4} g

Estimation of release to sewage treatment plants

In Europe, estimates of potential exposures resulting from STPs are carried out according to the Guidance on BPR, Vol. IV, Parts B+C (Version 2.0, 2017). According to this, the further receiving environmental compartments are surface water and sediment (after STP), soil and groundwater (from sludge application), and the outdoor air.

The input values for determining releases to STP in the course of spot application as well as the calculated emission rates are summarised in Table 75. Outgoing from a maximum application of 12 times per year a simultaneity factor of 1.386% (F_{sim} = 0.01386) was applied.

The application of the b.p. in a typical scenario around commercial buildings results in a simultaneous release of **7.48 x 10^{-3} g.d^{-1}** Imidacloprid to the STP.

Table 75: Emission scenario for outdoor spot application of Imidasect Ants during application step – release to STP

Determinants of the emission scenario	Value
Local direct emission rate to paved surfaces - larger buildings $E_{spot, lb}$	1.8×10^{-3} g.d^{-1}
Number of larger buildings connected to STP [N_{lb}] - larger buildings	300
Simultaneity factor outdoor [F_{Sim}]	0.01386
Output	
Simultaneous emission to STP: $E_{water\_sim\_lb} = E_{spot, lb} \times N_{lb} \times F_{sim}$	7.48×10^{-3} g.d^{-1}

3.7.4.6.2 Estimation of Predicted Environmental Concentrations for the aquatic compartment (incl. sediment)

The estimation of the local PECs for the aquatic compartment includes PECs for surface water and sediment:

- $PEC_{surfacewater}$ according to equation 51;
- $PEC_{local\_sediment}$ according to equation 53, chapter 2.3.7.4, Guidance BPR Vol. IV Part B+C (2017).

For the estimation of the local PEC for the STP, $Clocal_{inf}$ should be used due to the intermittent application pattern:

- PEC_{STP} (= $Clocal_{inf}$) according to equation 42, chapter 2.3.6.7, Guidance on the BPR, Vol. IV, Part B+C (2017);
- $Clocal_{inf}$ according to equation 42, chapter 2.3.6.7, Guidance on the BPR, Vol. IV, Part B+C (2017).

The results are summarised in Table 76.

Table 76: Summary of STP influent ($Clocal_{inf}$) and effluent ($Clocal_{eff}$), PEC_{STP}, $PEClocal_{surface\ water}$ and $PEClocal_{sediment}$

$Clocal_{inf}$ [µg.L^{-1}]	$Clocal_{eff}$ [µg.L^{-1}]	PEC_{STP} [µg.L^{-1}]	$PEClocal_{surface\ water}$ [µg.L^{-1}]	$PEClocal_{sediment}$ [µg.kg^{-1}]
3.74×10^{-3}	3.65×10^{-3}	3.74×10^{-3}	3.65×10^{-4}	1.77×10^{-3}

3.7.4.6.3 Estimation of Predicted Environmental Concentrations for the terrestrial compartment

The terrestrial compartment may be exposed either directly after release of the a.s. to the surrounding soil of the spot application or indirectly after release of the a.s. to the STP following sludge application to agricultural soil.

Direct exposure to paved surfaces

The predicted environmental concentration in soil (PEC_{soil}) is estimated on the assumptions according to TAB v. 2.1 (ENV 154). The receiving area of a terrace is set to 8.5 m² and the soil depth is 0.5 m. Using equation no. 60 of the ESD PT18 No. 18 (2008), the application of the b.p. in a typical scenario results in a direct local emission of 1.08 x 10^{-4} g.d^{-1} Imidacloprid per 0.5 m² of soil (refer to Table 66). The input parameters for calculating PEC_{soil} are summarised Table 77.

The estimation of the local PECs for the terrestrial compartment includes also the groundwater. The $PEC_{groundwater}$ is calculated according to equation 70 in the Guidance on the BPR, Vol. IV, Part B+C (2017) as a first worst-case estimation. Table 77 indicates the PEC in groundwater for Imidacloprid according to the application scenario.

Table 77: $PEC_{soil,direct}$ of Imidasect Ants during application step – direct release to paved surfaces

Determinants of the emission scenario according to chapter 4.4.5, OECD ESD PT18 No.18 (2008)	**Value**
Local direct emission rate to soil [$E_{spot,\ soil}$]	1.08 x 10^{-4} g
Area directly exposed to insecticide [$AREA_{exposed}$]	8.5 m²
Depth of exposed soil [$DEPTH_{soil}$]	0.5 m
Density of exposed soil [RHO_{soil}]	1700 kg.m^{-3}
Soil-water partition coefficient [$K_{soil\text{-}water}$]	5.799 m^3.m^{-3}
Output	
Local concentration in soil due to direct release after a campaign: $C_{spot,soil} = \frac{E_{spot,\ soil}}{AREA_{exposed} \times DEPTH_{soil} \times RHO_{soil}}$	1.49 x 10^{-5} mg.kg^{-1}
Predicted environmental concentration in soil [PEC_{soil}]	**1.49 x 10^{-2} µg.kg^{-1}**
Local concentration in groundwater due to direct release after a campaign: $PEClocal_{soil,porew} = \frac{PEC_{soil} \times RHO_{soil}}{K_{soil\text{-}water}}$	4.38 x 10^{-6} µg.L^{-1}
Predicted environmental concentration in groundwater [PEC_{gw}]	**4.38 x 10^{-3} µg.L^{-1}**

The PEC in groundwater from application of Imidasect Ants as gel application around buildings on paved surfaces does not exceed the trigger value of 0.1 µg.L-1 of the groundwater Directive.

Indirect exposure (larger buildings)

The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater:

- PEC_{local_soil} according to equation 69, chapter 2.3.7.5, Guidance on the BPR, Vol. IV, Part B+C (2017);
- $PEC_{local\_groundwater}$ according to equation 71, chapter 2.3.7.6, Guidance on the BPR, Vol. IV, Part B+C (2017) as a first worst-case estimation.

Table 70 indicates the PEC in soil and groundwater for Imidacloprid according to the application scenario.

Table 78: Summary of C_{sludge}, $PEClocal_{soil}$ and $PEClocal_{groundwater}$ for indirect release to soil via sludge application

C_{sludge} [µg.kg^{-1}]	$PEClocal_{soil}$ [µg.kg^{-1}]	$PEClocal_{groundwater}$ [µg.L^{-1}]
2.23 x 10^{-1}	3.49 x 10^{-4}	7.03 x 10^{-5}

The PEC in groundwater resulting from the indirect release of Imidacloprid to soil via sludge application does not exceed the trigger value of 0.1 µg.L^{-1} of the groundwater Directive.

3.7.4.6.4 Estimation Predicted Environmental Concentrations for primary and secondary poisoning

Primary poisoning of birds and mammals is not considered relevant for the case of insecticide treatment with Imidasect Ants as the OECD ESD PT 18 No.18 indicates that there is no risk of direct uptake from bait trays.

The OECD ESD PT18 (2008) states that the most important route of exposure for secondary poisoning is the intake of contaminated feed. The risk of secondary poisoning is considered at the local scale. Non-target animals (birds and mammals) have potentially a risk of secondary poisoning in the following ways: (1) by consumption of worms from contaminated soil, (2) by consumption of contaminated vegetation and (3) through eating treated insects that have ingested the poison.

The estimated theoretical exposure (ETE) will be calculated for indicator species among mammals and birds, and ETE corresponds to the PEC_{oral} per day. The ETE is used for the risk assessment. In consideration of the intended use of the product Imidasect Ants in bait trays as well as the realistic emission path of the a.s. into the environment (here: soil compartment) the assessment of secondary poisoning via consumption of contaminated insects is carried out (i.e. calculation of ETE for (3)). Calculations for the consumption of worms from contaminated soil are considered unrealistic due to the low bioaccumulation potential of Imidacloprid. A risk for secondary poisoning by consumption of

contaminated vegetation is only applicable for spray application of insecticides. The procedure for ETE calculation is described in chapter 5.2.3.4 of OECD ESD PT18 (2008). The relevant input parameters are presented in Table 79. The values taken from the pick lists of the ESD PT18 (2008; Table 5.2-5, 5.2-7) are not repeated here.

Table 79: Parameters used for estimation of daily uptake of a compound

Determinants of the emission scenario according to chapter 5.2.3.4, ESD PT18 No. 18 (2008)	**Value**
Application rate of a.s. [T_{appl}]	3.6 x 10^{-8} kg·m^{-2}
Avoidance factor [*AV*]	1
Fraction of diet obtained in treated area [*PT*]	1
Fraction of food type in diet [*PD*]	1

The values of the expected daily uptake ETE for assessment of secondary poisoning via consumption of contaminated insects (acute and short term) for selected indicator species are shown in Table 80

Table 80: Expected daily uptake (ETE) of Imidacloprid for selected indicator species following application of Imidasect Ants around private houses and commercial buildings

Species		**ETEinsect [µg.(kg.d)$^{-1}$]**	
		Acute	**Short term**
Pipistrelle	***Pipistrellus pipistrellus***	**3.45 x 10^{-4}**	**1.26 x 10^{-4}**
Shrew	*Sorex araneus*	3.18 x 10^{-4}	1.16 x 10^{-4}
Hedgehog	*Erinaceus europaeus*	7.89 x 10^{-5}	2.87 x 10^{-5}
Badger	*Meles meles*	4.10 x 10^{-5}	1.49 x 10^{-5}
Tree sparrow	***Passer domesticus***	**1.53 x 10^{-3}**	**8.54 x 10^{-4}**
Blackbird	*Turdus merula*	3.89 x 10^{-4}	1.42 x 10^{-4}
Black-billed Magpie	*Pica pica*	2.07 x 10^{-4}	7.54 x 10^{-5}

The maximum values of expected daily uptake of Imidacloprid via contaminated insects are calculated for pipistrelle (mammals) and tree sparrow (birds) for acute and for short-term (poisoning) situations.

3.7.4.7 Calculated PEC values

Table 81

	PEC_{STP} [µg·l^{-1}]	PEC_{water} [µg·l^{-1}]	PEC_{sed} [µg·kg^{-1}]	$PECIocal_{soil}$ [µg·kg^{-1}]	PEC_{GW} [µg·kg^{-1}]
Indoor use, bait tray	Not calculated				
Indoor use, gel application	1.10 x 10^{-3}	1.07 x 10^{-4}	5.19 x 10^{-4}	1.03 x 10^{-4}	2.08 x 10^{-5}
Outdoor use, bait tray	9.56 x 10^{-4}	9.34 x 10^{-5}	4.51 x 10^{-4}	direct release paved surfaces: 3.82 x 10^{-3} unpaved surfaces: 1.08 x 10^{-2} indirect release 8.91 x 10^{-5}	direct release paved surfaces: 1.12 x 10^{-3} unpaved surfaces: 3.17 x 10^{-3} indirect release 1.80 x 10^{-5}
Outdoor use, gel application	3.65 x 10^{-3}	3.65 x 10^{-4}	1.77 x 10^{-3}	direct release paved surfaces: 1.49 x 10^{-2} Indirect release 3.49 x 10^{-4}	direct release paved surfaces: 4.38 x 10^{-3} indirect release 7.03 x 10^{-5}

3.7.5 Risk characterisation

For the biocidal Product Imidasect Ants, four different use patterns were applied for. An environmental risk characterisation for these use patterns is described separately in the following paragraphs.

3.7.5.1 Indoor use in bait trays in private houses and commercial buildings

The OECD ESD PT18 No. 18 (2008) specifies that emissions to the environment during the use of solid baits and gels deployed in bait trays are negligible during the service life stage. Therefore, from the indoor use of the biocidal product Imidasect Ants in bait trays, neither direct nor indirect emission to the aquatic or terrestrial environment can be expected. Therefore, it can be concluded that no unacceptable risk arises from the indoor use of Imidasect Ants in bait trays.

3.7.5.2 Indoor use as gel in private houses and commercial buildings

Environmental releases may arise due to wet cleaning of the target surface after application of the biocidal product with subsequent release of the waste water to the STP system.

3.7.5.2.1 Sewage treatment plant

Table 82: PEC / PNEC ratio for sewage treatment plant

Compartment	PEC [mg/L]	PNEC [mg/L]	PEC / PNEC
Sewage treatment plant (STP)	1.10×10^{-6}	61.3	1.79×10^{-8}

Conclusion: A PEC/PNEC ratio of 1.79×10^{-8} was derived. Therefore, an unacceptable risk for sewage treatment plants from the indoor use of Imidasect Ants as gel in private houses and commercial buildings is not to be expected.

3.7.5.2.2 Aquatic compartment (incl. Sediment)

Table 83: PEC / PNEC ratio for the aquatic compartment (surface water and sediment)

compartment	PEC	PNEC	PEC / PNEC
Surface water	1.07×10^{-4} µg/L	4.8×10^{-3}µg/L	2.23×10^{-2}
Sediment	5.19×10^{-4} µg/kg ww	2.6×10^{-2} µg/kg ww	2.00×10^{-2}

Conclusion: A PEC/PNEC ratio for surface waters of 2.23×10^{-2} and for sediment of 2.00×10^{-2} was derived. Therefore, it can be concluded that the indoor use of Imidasect Ants as gel in private houses and commercial buildings does not pose an unacceptable risk for surface water and sediment.

3.7.5.2.3 Terrestrial compartment

Application of sewage sludge on agricultural and grassland soil leads to an indirect contamination of the soil compartment and the groundwater.

Soil

Table 84: PEC / PNEC ratio for the terrestrial compartment (soil)

Compartment	PEC [µg/kg]	PNEC [µg/kg]	PEC / PNEC
Soil	1.03×10^{-4}	15.75	6.54×10^{-6}

Conclusion A PEC/PNEC ratio for soil of 6.54×10^{-6} was derived. Therefore, it can be concluded that the indoor use of Imidasect Ants as gel does not pose an unacceptable risk for the soil compartment.

Groundwater

Conclusion: For groundwater a concentration of 2.08×10^{-5}µg/L was predicted. According to Directive 98/83/EC the limit value for pesticides in groundwater is 0.1 µg/L and must not be exceeded by the estimated PEC. As the $PEC_{groundwater}$ is well below the given limit value of 0.1 µg/L, no unacceptable risk to groundwater is expected.

3.7.5.2.4 Air compartment

The vapour pressure of the active substance Imidacloprid is very low (4×10^{-10} Pa at 20 °C) and therefore the concentration in indoor air is expected to be low. Furthermore, the indoor and outdoor air exchange is negligible.

3.7.5.3 Outdoor use in bait tray around private houses and larger buildings

According to OECD ESD No. 18 for PT18 emissions to the environment from bait trays may occur by flooding due to a rain event and by insect dispersion. Only release by flooding is considered as the biocidal product is a gel formulation.

Two exposure models are calculated: 1) a release to the sewage treatment plant and subsequently to surface water, sediment and soil (including groundwater) and 2) a direct release to the soil compartment including groundwater.

3.7.5.3.1 Sewage treatment plant

Table 85: PEC/PNEC ratio for sewage treatment plant

Compartment	PEC [mg/L]	PNEC [mg/L]	PEC / PNEC
Sewage treatment plant (STP)	9.56×10^{-7}	61.3	1.52×10^{-8}

Conclusion: A PEC/PNEC ratio of 1.52×10^{-8} was derived. Therefore, it can be concluded that no unacceptable risk for the sewage treatment plant arises from the outdoor use of Imidasect Ants in bait trays.

3.7.5.3.2 Aquatic compartment (incl. Sediment)

Table 86: PEC/PNEC ratio for the aquatic compartment (surface water and sediment)

compartment	PEC	PNEC	PEC / PNEC
Surface water	9.34×10^{-5} µg/L	4.8×10^{-3} µg/L	1.95×10^{-2}
Sediment	4.51×10^{-4} µg/kg	2.6×10^{-2} µg/kg	1.73×10^{-2}

Conclusion: A PEC/PNEC ratio for surface waters of 1.95×10^{-2} and for sediment of 1.73×10^{-2} was derived. Therefore, no unacceptable risk for surface water and sediment due to the outdoor use of the biocidal product Imidasect Ants in bait trays is to be expected by flooding from rain events.

3.7.5.3.3 Terrestrial compartment

The terrestrial compartment may be exposed either directly after release of the a.s. to the surrounding soil of the bait tray or indirectly after release of the a.s. to the STP following by sludge application to agricultural soil.

Direct Release

Direct release to the soil compartment occurs to paved and unpaved surfaces.

Soil

Table 87: PEC / PNEC ratio for the terrestrial compartment (soil)

Compartment	PEC [µg/kg]	PNEC [µg/kg]	PEC / PNEC
Soil – paved surfaces	3.82×10^{-3}	15.75	2.43×10^{-4}
Soil – unpaved surfaces	1.08×10^{-2}	15.75	6.86×10^{-4}

Conclusion For direct release to soil PEC/PNEC ratios of 2.43×10^{-4} for paved surfaces and 6.86×10^{-4} for unpaved surfaces were derived. Therefore, it can be concluded that no unacceptable risk to the soil compartment results from the direct release on both, paved and unpaved surfaces from the outdoor use in bait trays.

Indirect Release

Soil

Table 88: PEC / PNEC ratio for the terrestrial compartment (soil)

Compartment	PEC [µg/kg]	PNEC [µg/kg]	PEC / PNEC
Soil	8.91×10^{-5}	15.75	5.66×10^{-6}

Conclusion A PEC/PNEC ratio for soil of 5.66×10^{-6} was derived. Therefore, it can be concluded that no unacceptable risk to the soil compartment results from the indirect release via sludge application from the outdoor use in bait trays.

Groundwater

In line with the risk assessment for the soil compartment, risk characterisation for groundwater was done under consideration of direct releases to soil on paved and unpaved surfaces as well as for the indirect release via sludge application.

Direct Release

Conclusion: The predicted groundwater concentrations of 1.12×10^{-3} µg/L and 3.17×10^{-3}, respectively, are clearly below the limit concentration of 0.1 µg/L from directive 98/83/EC. Thus, no unacceptable risk to groundwater is expected from the direct release on paved and unpaved surfaces in relation to the outdoor use of Imidasect Ants in bait trays.

Indirect Release

Conclusion: The predicted groundwater concentration of 1.8 x 10^{-5} µg/L is clearly below the limit concentration of 0.1 µg/L from directive 98/83/EC. Thus, no unacceptable risk to groundwater is expected from the indirect release via sludge application in relation to the outdoor use of Imidasect Ants in bait trays.

3.7.5.3.4 Air compartment

In view of the limited volatility of Imidacloprid (vapour pressure 4 x 10^{-10} Pa at 20°C) emissions to air are expected to be not significant in relation to the intended use pattern.

3.7.5.4 Outdoor use as gel around private houses and commercial buildings

Environmental releases may arise due to flooding from a rain event. Two exposure models are calculated: 1) a release to the sewage treatment plant and subsequently to surface water, sediment and soil (including groundwater) and 2) a direct release to the soil compartment including groundwater.

3.7.5.4.1 Sewage treatment plant

Table 89: PEC / PNEC ratio for sewage treatment plant

Compartment	PEC [mg/L]	PNEC [mg/L]	PEC / PNEC
Sewage treatment plant (STP)	3.65 x 10^{-6}	61.3	5.95 x 10^{-8}

Conclusion: A PEC/PNEC ratio of 5.95 x 10^{-8} was derived. Therefore, it can be concluded that no unacceptable risk for the sewage treatment plant arises from the outdoor use of Imidasect Ants as gel.

3.7.5.4.2 Aquatic compartment (incl. Sediment)

Table 90: PEC / PNEC ratio for the aquatic compartment (surface water and sediment)

compartment	PEC	PNEC	PEC / PNEC
Surface water	3.65 x 10^{-4} µg/L	4.8 x 10^{-3} µg/L	7.6 x 10^{-2}
Sediment	1.77 x 10^{-3} µg/kg	2.6 x 10^{-2} µg/kg	6.81 x 10^{-2}

Conclusion: A PEC/PNEC ratio for surface waters of 7.60 x 10^{-2} and for sediment of 6.81 x 10^{-2} was derived. Therefore, no unacceptable risk for surface water and sediment due to the outdoor use of the biocidal product Imidasect Ants as gel is to be expected by flooding from rain events

3.7.5.4.3 Terrestrial compartment

The terrestrial compartment may be exposed either directly to the surrounding soil or indirectly after release of the a.s. to the STP following by sludge application to agricultural soil.

Direct Release

Direct release to the soil compartment occurs to paved surfaces.

Soil

Table 91: PEC / PNEC ratio for the terrestrial compartment (soil)

Compartment	PEC [µg/kg]	PNEC [µg/kg]	PEC / PNEC
Soil – paved surfaces	1.49 x 10^{-2}	15.75	9.46 x 10^{-4}

Conclusion For direct release to soil a PEC/PNEC ratio of 9.46 x 10^{-4} for paved surfaces was derived. Therefore, it can be concluded that no unacceptable risk to the soil compartment results from the direct release on paved surfaces from the outdoor use as gel around private houses and commercial buildings.

Indirect Release

Soil

Table 92: PEC / PNEC ratio for the terrestrial compartment (soil)

Compartment	PEC [µg/kg]	PNEC [µg/kg]	PEC / PNEC
Soil	3.49 x 10^{-4}	15.75	2.22 x 10^{-5}

Conclusion A PEC/PNEC ratio for soil of 2.22 x 10^{-5} was derived. Therefore, it can be concluded that no unacceptable risk to the soil compartment results from the indirect release via sludge application from the outdoor use as gel around commercial buildings.

Groundwater

In line with the risk assessment for the soil compartment, risk characterisation for groundwater was done under consideration of direct releases to soil on paved surfaces as well as for the indirect release via sludge application.

Direct Release

Conclusion: The predicted groundwater concentrations of 4.38 x 10^{-3} µg/L is clearly below the limit concentration of 0.1 µg/L from directive 98/83/EC. Thus, no unacceptable risk to groundwater is expected from the direct release on paved surfaces in relation to the outdoor use of Imidasect Ants as gel around private houses and commercial buildings.

Indirect Release

Conclusion: The predicted groundwater concentration of 7.03 x 10^{-5} µg/L is clearly below the limit concentration of 0.1 µg/L from directive 98/83/EC. Thus, no unacceptable risk to groundwater is expected from the indirect release via sludge application in relation to the outdoor use of Imidasect Ants as gel around commercial buildings.

3.7.5.4.4 Air compartment

In view of the limited volatility of Imidacloprid (vapour pressure 4 x 10^{-10} Pa at 20°C) emissions to air are expected to be not significant in relation to the intended use pattern.

3.7.5.5 Non-compartment specific

Non-target animals (birds and mammals) have potentially a risk for secondary poisoning by consumption of treated insects that have taken up the b.p.. Therefore, a risk characterisation for secondary poisoning of birds and mammals is necessary. As the outdoor use as gel around private houses and commercial buildings resulted in the highest PEC_{oral} values, the risk characterisation performed for this scenario covers also the risk for the outdoor application in bait trays.

Table 93: PEC/PNEC ratio for secondary poisoning of birds and mammals following application of Imidasect Ants around private houses and commercial buildings

exposure scenario	PEC_{oral} [mg·kg^{-1}]	$PNEC_{oral}$ [mg·kg$^{-1}_{feed}$]	PEC/PNEC
birds feeding on insects (acute)	1.53 x 10^{-6}	4.2	3.64 x 10^{-7}
birds feeding on insects (short-term)	8.54 x 10^{-7}	4.2	2.03 x 10^{-7}
mammals feeding on insects (acute)	3.45 x 10^{-7}	8.3	4.16 x 10^{-8}

mammals feeding on insects (short-term)	1.26 x 10^{-7}	8.3	1.52 x 10^{-8}

Conclusion: As a first tier characterisation of possible risks due to secondary poisoning of birds and mammals feeding on contaminated insects (acute and short-term) all risk quotients are far below 1. Therefore, it can be concluded that there is no unacceptable risk for secondary poisoning of birds and mammals from the outdoor use of Imidasect Ants as gel application and in bait trays around buildings.

3.7.5.6 PBT assessment

The assessment of the PBT criteria for the active substance Imidacloprid is adapted from the respective AR (Imidacloprid: DE, rev. 2015), which considered the specifications according to Annex XIII of the REACH regulation EC/1907/2006.

- **P/vP**

  Apart from the submission of a test on ready biodegradability in which Imidacloprid is confirmed to be not readily biodegradable, no new information compared to the CAR has been provided within product authorisation for the product Imidasect Ants. Therefore, the assessment of the P-/vP-criterion as stated in the CAR and assessment report is still valid.
  In an aquatic laboratory study under aerobic conditions a DT_{50} of 331 days (20 °C, in the dark) was measured for Imidacloprid. Converted to 12 °C average EU outdoor temperature the half-life amounts to 628 days. For the water phase in two water/sediment systems DT_{50} values of 31.6 and 242 days at 12 °C (corresponding to 14.2 and 108.7 days at 22 °C) were determined. The geometric mean DT_{50} for total system of all water/sediment-studies amounts to 185.4 d at 12 °C (n=3). From four aerobic laboratory degradation studies in soil a geometric mean DT_{50}-value of 295 days at 12 °C (corresponding to 156 days at 20 °C) was derived. Although field studies are in principle not appropriate for assessment of persistency criteria, the results of fourteen field studies in soil representative for northern as well as southern Europe resulted in an averaged DT_{50}-value of 135 days at 12 °C average EU outdoor temperature and 100 % field capacity (n=14) and reached maximum half-lives of 184.5 and 337.9 days thus confirming the high persistency of Imidacloprid. From these data Imidacloprid can definitely be considered to fulfil the P- as well as the vP-criterion.

- **B/vB**

  The calculated bioconcentration factor in fish is 0.61 and the estimation on terrestrial bioconcentration leads to a value of 0.88 for earthworm. Therefore, neither the B- nor the vB-criterion is fulfilled.

- **T**

28d-EC_{10} (equivalent to NOEC) for chironomids (*Chironomus riparius*), is 0.87 µg/L after 28 days. For the most sensitive species, *Caenis horaria*, the 28d-EC_{10} is 0.024 µg/L. Therefore, the T criterion is complied.
Even though the P- and the T-criteria are fulfilled, the active substance Imidacloprid is neither PBT - nor vP/vB - candidate as the B-criterion is not fulfilled.

3.7.5.7 Endocrine disrupting properties

Active substance
According to the CAR for Imidacloprid (eCA: DE, 2015), there are no indications for endocrine disrupting properties of this active substance on environmental non-target organisms. However, a comprehensive ED-assessment for the active substance according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage. This statement is also valid for the other biocidal active substances which are contained as co-formulants in the product.

Biocidal Product
The full composition of the product and a detailed ED-assessment of the co-formulants is contained in the confidential Annex (Section 5). There are no indications that a non-active substance of the product may have endocrine disrupting properties on environmental non-target organisms based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation, the community rolling action plan (CoRAP) or the activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards or ECHA's endocrine disruptor assessment list . For none of the co-formulants indications on potential ED effects on environmental non-target organisms were found in scientific literature.

3.7.5.8 Summary of risk characterisation

The biocidal product Imidasect Ants contains no substance of concern for the environment. Therefore, the risk assessment is based on the active substance Imidacloprid.

An environmental risk assessment was performed for the intended use of the biocidal product Imidasect Ants. Four different use patterns were considered: indoor use in bait trays, indoor use as gel application, outdoor use around private houses and commercial buildings in bait trays and outdoor use around private houses and commercial buildings as gel application.

The risk assessment shows, that all four use patterns do not result in an unacceptable risk for any of the environmental compartments considered.

3.8 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.9 Comparative assessment

3.9.1 Background

The product Imidasect Ants contains the active substance Imidacloprid, which meets the criteria for substitution under Article 10 of the Biocides Regulation (EU) No 528/2012[17] (BPR). Imidacloprid is considered to be very persistent (vP) and toxic (T) but not bioaccumulative (B) and therefore meets two of the criteria for being PBT. Therefore, in line with Article 23 (1) of the BPR the German CA has conducted a comparative assessment for the product Imidasect Ants according to the "Technical Guidance Note on comparative assessment of biocidal products" as agreed upon by the Member States on the 55th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 (document: CA-May-15-Doc-4.3a-Final-TNG on comparative assessment.doc).

The German CA used the information on biocidal products provided by the ECHA[18] for this comparative assessment. The database last updated on 08.06.2021 contained information on 5143 biocidal products.

3.9.2 Application administrative details

Procedure: Renewal of National Authorisation (NA-RNL)
Purpose: Renewal of authorisation
Case Number in R4BP: BC-RL056233-32
Evaluating Competent Authority: Germany (BAuA)
Applicant: Sharda Europe B.V.B.A
(Prospective) Authorisation holder: Sharda Cropchem España S.L.

3.9.3 Administrative information of the BP

Trade name: Imidasect Ants
Product type: 18 (Insecticide)
Active substance: Imidacloprid (CAS-Nr.: 138261-41-3)

[17] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
[18] https://echa.europa.eu/de/information-on-chemicals/biocidal-products

3.9.4 Intended use(s) for the relevant BP in the application

The biocidal product Imidasect Ants is an insecticide (PT18) which contains the active substance Imidacloprid. The product is to be used indoors and outdoors by non-professionals and professionals to control Tropical ants (Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*)).

Table 94 lists the intended uses of the biocidal product, which determines the focus of the comparative assessment.

Table 94: Intended use(s) of the biocidal product

Product type(s)	Insecticide (PT 18)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including, where relevant) development stage)	Tropical ants (Pharaoh ants (*Monomorium pharaonis*); Argentine ants (*Linepithema humile*)) (eggs; larvae; nymphs; pupae; imagines, adults)
Field(s) of use	Indoors, outdoors
Application method(s)	Open application Bait application in bait trays
Category(ies) of users	Non-professional; professional

The Imidasect Ants gel is placed on the market as a ready-to-use product and applied openly or in bait trays.
It is effective against Tropical ants (Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*)).
The active substance Imidacloprid exerts its insecticidal effect by causing a blockage in the nicotinergic neuronal pathway. As a result acetylcholine accumulates, resulting in paralysis, and eventually death of the insect.

3.9.5 Mapping of existing alternatives to the relevant BP

Identified eligible alternative BPs

The information on biocidal products provided by the ECHA[19] was used for this comparative assessment.
The database last updated on 08.06.2021 contained information on 5143 biocidal products.
Out of these 377 are authorised for use as an insecticide (Product type 18).

[19] https://echa.europa.eu/de/information-on-chemicals/biocidal-products

10 of these are authorised for use against Tropical ants (Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*)).

These biocidal products are based on the following active substances:

1) S-Methoprene
2) Indoxacarb (enantiomeric reaction mass S:R 75:25)
3) 1R-trans phenothrin
4) Imidacloprid
5) Fipronil

Fipronil 1R-trans phenothrin are themselves candidates for substitution.

Accordingly, the only alternative products for the control of Tropical ants (Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*)) are based on:

1) S-Methoprene
2) Indoxacarb (enantiomeric reaction mass S:R 75:25)

However, in Germany only the products based on Indoxacarb (enantiomeric reaction mass S:R 75:25) are authorised for both indoor and outdoor use.
Table 95 lists the mode of action of the remaining active substances and the risk of resistance development.

Table 95: Mode of action and risk of resistance development for PT18 (Insecticide)

Active Substance	Mode of action	Resistance reported
Imidacloprid	Imidacloprid is a neonicotinoid which acts on the central nervous system of insects by blockage of the nicotinergic neuronal pathway. This disturbance of the transmission of stimuli leads to paralysis and subsequent death of the target organisms. Imidacloprid acts as a contact insecticide as well as after ingestion (see chapter 3.4.4).	Yes
Indoxacarb	Indoxacarb is a pro-insecticide – it is not toxic to insects until it goes through an activation process. Upon ingestion by the insect, the indoxacarb is rapidly converted to DPX-JT333 by enzymatic cleavage of the N-carbomethoxy group in the insect mid-gut. DPX-JT333 binds to the sodium channels within the insect, thus blocking sodium movement into the cell, resulting in mild convulsions, paralysis and ultimately death. Belongs to class of pyrazolinelike insecticide.	Yes

Identified eligible non-chemical alternatives

Not relevant in the screening phase

3.9.6 Screening phase

Description of the assessment of the adequate chemical diversity in authorised BPs to minimise the occurrence of resistance and conclusion.

Chemical diversity

In accordance with Article 23 (3) (b) of the BPR, the German CA has checked whether the chemical diversity of the available active substances within the identified alternative biocidal products can be considered as adequate to minimise the occurrence of resistance in the target harmful organisms (i.e. cockroaches).

Resistance management

Whereas the development of resistance to Imidacloprid in ants is a possibility, no cases have been reported so far. However, it is important to control the efficacy in the field. In cases where the population has not been reduced after 4 weeks and the bait has been taken up, the development of resistance should be suspected. A change to another product with an active substance with a different mode of action is then recommended.

Therefore, chemical diversity of the active substances, which exert their activity based on different mode of actions, is highly important to minimise the occurrence of resistance in the target organisms. In the guidance for comparative assessment it is stated that as a general rule, at least three different active substances - mode of action combinations should remain available through authorised biocidal products for a given use in order to consider that the chemical diversity is adequate.

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

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

Conclusion of the screening phase

Stop comparative assessment. The German CA concludes that without Imidacloprid based products there is not an adequate chemical diversity, taking into account the potential for resistance development in Tropical ants (Pharaoh ants (*Monomorium pharaonis*) and Argentine ants (*Linepithema humile*)).

The comparative assessment is finalised at this stage. The product Imidasect Ants is authorised for a period not exceeding 5 years in accordance with Article 23 (6) BPR.

4 Annexes

4.1 List of studies for the biocidal product

Table 96

Author(s)	Year and Report date	Annex III requirement	Title and Report number	Source (where different from company) and Study sponsor
S. Nichetti	*2013*	*3.1 (BPD)*	*Imidacloprid 0.01% Gel: Determination of the Accelerated Storage Stability and Corrosion Characteristics*	*Sharda Worldwide Exports Pvt. Ltd.*
S. Nichetti	*2017*	*3.1*	*Imidacloprid 0.01% Gel: Four Years Storage Stability and Corrosion Characteristics* *Report no. CH – 217/2013*	*Sharda Cropchem Limited, Domnic Holm, 29th Road, Bandra (West), Mumbai 400050 – (India)*
S.Nichetti	*2017*	*3.2*	*Imidacloprid 0.01% Gel: Four Years Storage Stability and Corrosion Characteristics* *Report no. CH - 217/2013*	*Sharda Cropchem Limited, Domnic Holm, 29th Road, Bandra (West), Mumbai 400050 – (India)*
Nichetti, S.	*2013*	*3.4 (BPD)*	*Imidacloprid 0.01% Gel: Determination of the Auto Ignition Temperature*	*Sharda Worldwide Exports Pvt. Ltd.*
Nichetti, S.	*2013*	*3.4 (BPD)*	*Determination of the Flash Point on the Sample Imidacloprid 0,01% Gel*	*Sharda Worldwide Exports Pvt. Ltd.*
S. Nichetti	*2017*	*3.4.1*	*Imidacloprid 0.01% Gel: Four Years Storage Stability and Corrosion Characteristics* *Report no. CH - 217/2013*	*Sharda Cropchem Limited, Domnic Holm, 29th Road, Bandra (West), Mumbai 400050 – (India)*
S. Nichetti	*2017*	*3.4.1*	*Imidacloprid 0.01% Gel: Four Years Storage Stability and Corrosion Characteristics* *Report no. CH - 217/2013*	*Sharda Cropchem Limited, Domnic Holm, 29th Road, Bandra (West), Mumbai 400050 – (India)*
S. Nichetti	*2017*	*3.4.1*	*Imidacloprid 0.01% Gel: Four Years Storage Stability and Corrosion Characteristics* *Report no. CH - 217/2013*	*Sharda Cropchem Limited, Domnic Holm, 29th Road, Bandra (West), Mumbai 400050 – (India)*

Nichetti, S.	*2013*	*3.5 (BPD)*	*Imidacloprid 0.01% Gel: Determination of the Accelerated Storage Stability and Corrosion Characteristics*	*Sharda Worldwide Exports Pvt. Ltd.*
Nichetti, S.	*2013*	*3.6 (BPD)*	*Imidacloprid 0.01% Gel: Determination of the Relative Density*	*Sharda Worldwide Exports Pvt. Ltd.*
Nichetti, S.	*2013*	*3.7 (BPD)*	*Imidacloprid 0.01% Gel: Determination of the Accelerated Storage Stability and Corrosion Characteristics*	*Sharda Worldwide Exports Pvt. Ltd.*
Nichetti, S.	*2013*	*3.7 (BPD)*	*Imidacloprid 0.01% Gel: Two Years Storage Stability and Corrosion Characteristics*	*Sharda Worldwide Exports Pvt. Ltd.*
Nichetti, S.	*2015*	*3.7 (BPD)*	*Imidacloprid 0.01% Gel: Four Years Storage Stability and Corrosion Characteristics*	*Sharda Worldwide Exports Pvt. Ltd.*
Woolley, A.J.	*2013*	*3.10 (BPD)*	*Imidacloprid 0.01% Gel: Determination of the Viscosity*	*Sharda Worldwide Exports Pvt. Ltd.*
Nichetti, S.	*2013*	*4.1 (BPD)*	*Imidacloprid 0.01% GEL: Validation of the analytical method for the determination of the active ingredient content*	*Sharda Worldwide Exports Pvt. Ltd.*
Azeema, G.	*2021*	*4.8*	*Thermal Reactions of IMIDASECT ANTS (Imidacloprid 0.01% Gel) (DSC Analysis)* No report number provided	*SHARDA CROPCHEM LIMITED Prime Business Park, Dashrathlal Joshi Road, Vile Parle (West) Mumbai - 400 056, India.*
Petryka, M.	*2021*	*4.16*	*IMIDASECT ANTS Test for determination the corrosive properties to metals* *Report no. BC-19/21*	*Sharda Cropchem Limited 2nd Floor, Prime Business Park Dashrathal Joshi Road, Vile Parle (West), Mumbai 400056, India*
Heaven, H.	*2013*	*5.10 (BPD)*	*Laboratory bioassay to determine the efficacy of one bait against pharaoh ants, Monomorium pharaonis, argentine ants, Linepithema humile and black ants, Lasius niger*	*Sharda Worldwide Exports Pvt. Ltd.*
Heaven, H.	2015	5.10 *(BPD)*	Field trial to determine the efficacy of Imidacloprid 0.01% gel against three ant species	Sharda Worldwide Exports Pvt. Ltd.
Heaven, H.	2013	5.10 *(BPD)*	Simulated use of bioassay to determine the efficacy of Imidacloprd 0.01 ant bait stations against pharaoh ants, Monomorium pharaonis,	Sharda Worldwide Exports Pvt. Ltd.

			argentine ants, Linepithema humile and black ants, Lasius niger.	
Anonymous	2013	6.1.1 *(BPD)*	Imidacloprid 2.15% gel Acute Oral Toxicity Study in the Rat – Acute Toxic Class Method (OECD 423, EC METHOD B1 tris, US EPA OPPTS 870.1100, JMAFF)	Sharda Worldwide Exports Pvt. Ltd
Anonymous	2013	6.1.2 *(BPD)*	Imidacloprid 2.15% gel: Determination of Acute Dermal Toxicity (limit test) in the rat (OECD 404, EC METHOD B4, JMAFF, JMHW EPA OPPTS 870.2500)	Sharda Worldwide Exports Pvt. Ltd
Anonymous	2013	6.1.3 *(BPD)*	Imidacloprid 2.15% gel: Acute inhalation toxicity (nose only) study in the rat (OECD 436)	Sharda Worldwide Exports Pvt. Ltd
Anonymous	2013	6.2 *(BPD)*	Imidacloprid 2.15% gel: Determination of Acute Dermal Irritation Potential (OECD 404, EC METHOD B4, JMAFF, JMHW EPA OPPTS 870.2500)	Sharda Worldwide Exports Pvt. Ltd
Anonymous	2013	6.2 *(BPD)*	Imidacloprid 2.15% gel: Determination of Acute Eye Irritation Potential (OECD 405, EC METHOD B5, JMAFF, JMHW EPA OPPTS 870.2400)	Sharda Worldwide Exports Pvt. Ltd
Anonymous	2013	6.3 *(BPD)*	Imidacloprid 2.15% gel: Local Lymph Node Assay in the Mouse – Pooled Method (OECD 429, EC METHOD B42)	Sharda Worldwide Exports Pvt. Ltd
B.Serrano	*2015*	*6.7*	*Field assessment of the efficacy of an insecticidal treatment against ants* *Report no. 2008-IMIDASECTANTS001-FIELD/1015R*	*Sharda Cropchem Limited, Domnic Holm, 29th Road, Bandra (West), Mumbai - 400 050*
B.Serrano	*2016*	*6.7*	*IMIDASECT ANTS TRAP - Laboratory testing of insecticide ant bait box* *Report no. 2126c/0816R*	*Sharda Cropchem Limited, Domnic Holm, 29th Road, Bandra (West), Mumbai - 400 050*
R. Kinsey	*2016*	*6.7*	*Field trial to determine the efficacy of Imidacloprid 0.01% gel against three ant species* No report number provided	*Sharda Cropchem Ltd, Domnic Holm, 29th Road, Bandra (West) Mumbai - 400 050 India*
Suryawanshi, S.	*2021*	*6.7*	*Field efficacy of Imidacloprid 0.01% Bait Gel against two species of ants (M. pharaonis and Linepithema*	*Sharda Cropchem Ltd. 2nd Floor, Prime Business Park, Dashrathlal Jshi Road, Vile Parle (E), Mumbai 400056,*

			humile) under field conditions applied indoor. No report number provided	*Maharashtra, India.*
Suryawanshi, S.	*2021*	*6.7*	*Field efficacy of Imidacloprid 0.01% Bait Gel against three species of ants (L. niger, M. pharaonis and L. humile).* *Report no. 368KAMG4908/R0*	*Sharda Cropchem Ltd. 2nd Floor, Prime Business Park, Dashrathlal Jshi Road, Vile Parle (E), Mumbai 400056, Maharashtra, India.*
Suryawanshi, S.	*2021*	*6.7*	*Field efficacy of Imidacloprid 0.01% bait gel against three species of ants (L. niger, M. pharaonis and L. humile) applied in traps* *Report no. 368KAMG4910/R0*	*Sharda Cropchem Ltd. 2nd Floor, Prime Business Park, Dashrathlal Jshi Road, Vile Parle (E), Mumbai 400056, Maharashtra, India.*
Jadhav, T.	*2021*	*6.7*	*Study of palatability of Imidacloprid 0.01% bait gel against Lasius niger, Monomorium pharaonis and Linepithema humile* *Report no. 368KAMG4906/R0*	*Sharda Cropchem Ltd. 2nd Floor, Prime Business Park, Dashrathlal Jshi Road, Vile Parle (E), Mumbai 400056, Maharashtra, India.*
Jadhav, T	*2021*	*6.7*	*Study of palatability of Imidacloprid 0.01% bait gel against Lasius niger, Monomorium pharaonis and Linepithema humile in bait traps* *Report no. 368KAMG4909/R0*	*Sharda Cropchem Ltd. 2nd Floor, Prime Business Park, Dashrathlal Jshi Road, Vile Parle (E), Mumbai 400056, Maharashtra, India.*
Suryawanshi, S.	*2023*	*6.7*	*FIeld efficacy of Imidasect ants (Imidacloprid 0.01%-48 months old sample) Bait gel against three species of ants (L. Niger, M.Pharaonis and L. Humile.* *Study No.: 368BAPN8328/R0*	*Sharda Cropchem Limited, 2nd floor, Prime Business Park*
Suryawanshi, S.	*2023*	*6.7*	*Indoor conditions Field efficacy of Imidasect ants (Imidacloprid 0.01%-48 months old sample) bait gel in bait traps against three species of ants (L. niger, M. pharaonis and L. humile)* *Study No.: 368BAPN8328/R1*	*Sharda Cropchem Limited, 2nd floor, Prime Business Park*
Suryawanshi, S.	*2023*	*6.7*	*Field efficacy of Imidasect ants (Imidacloprid 0.01%) bait gel against Lasius niger under field conditions applied indoor.* *Study No.: 368AAPN8251/R0*	*Sharda Cropchem Limited, 2nd floor, Prime Business Park*
Yadav, A.	*2023*	*6.7*	*Field efficacy study of Imidasect ants (Imidacloprid 0.01%) bait gel applied in traps against Lasius niger under indoor conditions*	*Sharda Cropchem Limited, 2nd floor, Prime Business Park*

4.2 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.2.1 Safety for professional users

Exposure assessment

Output tables from environmental exposure assessment tools