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
Product type(s):	18 (Insecticide)
Active ingredient(s):	Imidacloprid
Case No. in R4BP	BC-LJ056204-43
Asset No. in R4BP	DE-0008650-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/18.00009 710-05-18-00009-01-00
Date	14.12.2021

Tables of content

Changes history table

Application type	refMS/eCA	Case number in the refMS	Decision date[1]	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	DE	-	29.06.2016	Initial assessment and authorisationm under BPD 98/8/EG	-
NA-AAT	DE	BC-PV029023-22	09.02.2017	Amendment of authorisation after agreement in CG	-
NA-ADC	DE	BC-LS033868-06	21.09.2017	Addition of two trade names in DE	-
NA-AAT	DE	BC-EJ041807-39	02.08.2018	Post authorisation condition fulfilled – Efficacy studies added to PAR	-
NA-TRS	DE	BC-MH054165-42	08.10.2019	Change of authorisation holder in DE	-
NA-ADC	DE	BC-KX060094-15	10.07.2021	Addition of two product manufactures in DE	-
NA-AAT	DE	BC-XH066759-08	02.06.2021	Extension of authorisation validity until 31.12.2021	-
NA-RNL	DE	BC-LJ056204-43	14.12.2021	Renewal of the authorisation	-

[1] Date is entered when DE CA 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 with the active substance Imidacloprid (2.2 % w/w) is used as an Insecticide (product-type 18) for the control of cockroaches indoors and outdoors (use as a barrier around buildings at potential entry points).

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 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 0 (

Composition and formulation) and the confidential annex 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 3.5.

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).

A human health risk assessment has been carried out for non-professional and professional use of the product (see chapter 3.6) 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 and professional users, bystanders and residents. Regarding non-professional and 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).

A risk assessment for the environment has been carried out for non-professional and professional use of the product (see chapter 3.8) 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 to 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 3.10). The corresponding Comparative Assessment Report was forwarded to ECHA on 29.11.2021.
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

2.1.2 Manufacturer(s) of the product

Name of manufacturer	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 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, - Shijizhang 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	2.194 2.15 (pure)

- The product contains a bittering agent.
  - ➢ Information on the full composition is provided in the confidential[4] annex.
- Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☐
  No ☒
- 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 before product authorisation)

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. Therefore, no corresponding regulatory measures are required. In case a co-formulant is identified as ED in the future, the biocidal product family will be considered as ED and authorisation will have to be revised accordingly.

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

2.2.4 Information on the substance(s) of concern

In accordance to CA-Nov14-Doc.5.11 - SoC guidance_final, no substance of concern for human health was identified.

Please note, the co-formulant 1,2-benzisothiazol-3(2H)-one (CAS no. 2634-33-5) is currently under evaluation as a biocidal active substance. However, toxicological reference values have not yet been agreed on. Furthermore, its concentration in the biocidal product is below concentration limits for classification. Therefore, according to the Substances of Concern draft guidance this substance is currently not identified as substance of concern.

A further co-formulant, reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (CMIT:MIT; CAS no. 55965-84-9), is also a biocidal active substance in another PT. However, its concentration in the b.p. is < 0.1 % and therefore is not a SoC.

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

GD – Gel for direct application

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

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. 790/2009 (1st ATP)[5]. The substance is classified as Acute Tox. 3 (H301), Aquatic

[5] See: https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database

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 regarding the environment is solely based on the classification of the active substance Imidacloprid as H400 and H410 with M-factors 100 (acute) and 1000 (chronic). With an active substance content of 2.15 %, the classification of the biocidal product Imidasect results in H400 and H410.

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.
Labelling of the biocidal product with EUH208 is required, due to the sensitising co-formulant 1,2-benzisothiazol-3(2H)-one. For details please refer to the Confidential Annex.

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Aquatic acute 1	H400 (Very toxic to aquatic life)
Aquatic chronic 1	H410 (Very toxic to aquatic life with long-lasting effects)

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS09	
Signal word	-	Warning
Hazard statements	H410	Very toxic to aquatic life with long-lasting effects
Supplemental hazard information	EUH208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.
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

2.4.1 Use 1 appropriate for authorisation – indoor, application in cracks and crevices, German cockroach, professional

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blattella germanica,* German cockroach (nymphs, adults)
Field(s) of use	Indoor use
Application method(s)	Application in cracks and crevices
Application rate(s) and frequency	Low infestation rate 0.1g/m2; high infestation rate 0.2g/m2 1 drop of 0.1 g is equivalent to 5 mm diameter. Maximum of 6 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	Cartridge, Plastic (HDPE) , 30g; 35g, 50g, 100g

2.4.1.1 Use-specific instructions for use

1) 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, in all cracks and crevices that can be a harborage for cockroaches.
2) Do not expose bait drops to sunlight or heat source (i.e. radiator).
3) Do not apply on porous surfaces. In case where it is not possible apply the product on a plastic sheet.

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.4.2 Use 2 appropriate for authorisation – indoor, application in cracks and crevices, non-professional

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blattella germanica,* German cockroach (nymphs, adults) *Blatta orientalis*, Oriental cockroach (nymphs, adults)
Field(s) of use	Indoor use
Application method(s)	Application in cracks and crevices
Application rate(s) and frequency	Low infestation rate 0.2 g/m^2; high infestation rate 0.3 g/m^2 1 drop of 0.1 g is equivalent to 5 mm diameter. Maximum of 6 applications per year.
Category(ies) of users	General public (non-professional)

Pack sizes and packaging material	Syringe, Plastic (HDPE), 3g, 5g, 10g, 15g

2.4.2.1 Use-specific instructions for use

1) 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, in all cracks and crevices that can be a harbourage for cockroaches.
2) If a large number of cockroaches is visible or is suspected, refer to the application rate for “high infestation”. If only a few or individual cockroaches have been seen, refer to the application rate for “low infestation”.
3) Do not expose bait drops to sunlight or heat source (i.e. radiator).
4) Do not apply on porous surfaces. In case where it is not possible apply the product on a plastic sheet.

2.4.2.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.4.3 Use 3 appropriate for authorisation – indoor, application in cracks and crevices, Oriental cockroach, professional

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blatta orientalis*, Oriental cockroach (nymphs, adults)
Field(s) of use	Indoor use
Application method(s)	Application in cracks and crevices
Application rate(s) and frequency	Low infestation rate 0.2g/m2; high infestation rate 0.3g/m2 1 drop of 0.1 g is equivalent to 5 mm diameter. Maximum of 6 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	Cartridge, Plastic (HDPE), 30g; 35g, 50g, 100g

2.4.3.1 Use-specific instructions for use

1) 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, in all cracks and crevices that can be a harborage for cockroaches.
2) Do not expose bait drops to sunlight or heat source (i.e. radiator).
3) Do not apply on porous surfaces. In case where it is not possible apply the product on a plastic sheet.

2.4.3.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.4.4 Use 4 appropriate for authorisation – indoor, bait trays

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blattella germanica,* German cockroach (nymphs, adults) *Blatta orientalis*, Oriental cockroach (nymphs, adults)
Field(s) of use	Indoor use
Application method(s)	In bait trays
Application rate(s) and frequency	Low infestation rate 0.2g/m2 (one 0.75g bait tray per 4m2, one 1g bait tray per 5m2, one 1.2g bait tray per 6m2, one 1.4g bait tray per 7m2) High infestation rate 0.3g/m2 (one 0.75g bait tray per 2.5m2, one 1g bait tray per 3m2, one 1.2g bait tray per 4m2, one 1.4g bait tray per 5m2) Maximum of 6 applications per year
Category(ies) of users	General public (non-professional) Professional
Pack sizes and packaging material	Bait tray, Plastic (HDPE), 0.75g, 1g, 1.2g, 1.4g

2.4.4.1 Use-specific instructions for use

If a large number of cockroaches is visible or is suspected, refer to the application rate for “high infestation”. If only a few or individual cockroaches have been seen, refer to the application rate for “low infestation”.

2.4.4.2 Use-specific risk mitigation measures

1) The bait trays applied shall be tamper-resistant. 2) Do not force open the bait tray.

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.4.5 Use 5 appropriate for authorisation – outdoor, bait trays

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blattella germanica,* German cockroach (nymphs, adults) *Blatta orientalis*, Oriental cockroach (nymphs, adults)
Field(s) of use	Outdoor use as a barrier around buildings at potential entry points for cockroaches
Application method(s)	In bait trays
Application rate(s) and frequency	Overall 0.3 g/m perimeter (one 0.75 g bait tray per 2.5 m, one 1 g bait tray per 3 m, one 1.2 g bait tray per 4 m, one 1.4 g bait tray per 5 m) Maximum of 6 applications per year.
Category(ies) of users	General public (non-professional) Professional

Pack sizes and packaging material	bait tray, Plastic (HDPE) , 0.75g, 1g, 1.2g, 1.4g

2.4.5.1 Use-specific instructions for use

Apply bait trays only on hard surfaces such as terraces or patio.

2.4.5.2 Use-specific risk mitigation measures

1) The bait trays applied shall be tamper-resistant. 2) Do not force open the bait tray. 3) Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water. 4) Do not use the product where release to drains (sewers) cannot be prevented.

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.5 General directions for use

2.5.1 Instructions for use

1) Comply with the instructions for use.
2) Before treatment, remove all natural source of food for cockroaches (waste, food scraps ...) from the infested area to encourage the ingestion of the gel.
3) During inspections, check the treated area and if necessary, replace the gel used as cockroaches leave secretions and faeces to attract conspecifics.
4) Product can be used continuously for 3 months without replacing opened bait trays or unconsumed baits.
5) Inform the authorisation holder if the treatment is ineffective.
6) To protect birds, pets and mammals, dead cockroaches must be removed from the treated area on a daily basis.
7) Check the bait trays once a week.
8) If the infestation persists despite following the instructions on the label, contact a professional pest controller. Avoid continuous use of the product.
9) At the end of the treatment campaign, collect bait trays for disposal.

2.5.2 Risk mitigation measures

1) Keep out of reach of children.
2) Place the bait out of the reach of children, birds, pets, farm animals and other non-target animals.
3) Avoid release to the environment.
4) 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 animals.

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

1) If medical advice is needed, have product container or label at hand.
2) IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.
3) 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.

4) IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
5) IF INHALED: Not applicable.
6) This biocidal product contains Imidacloprid which is dangerous to bees.

2.5.4 Instructions for safe disposal of the product and its packaging

1) Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
2) Dispose of unused product, its packaging, the bait trays and all other waste (i.d. dead insects) in accordance with local regulations.
3) 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.Shelf-life 24 months
3) The product has to be stored away from light.

2.5.6 Other information

1) 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	Plastic (HDPE)	Transparent PP	Professional, non-professional	Yes
Cartridge	30g, 35g, 50g, 100g	Plastic (HDPE)	Transparent PP	Professional, non-professional	Yes
Bait tray	0.75g, 1g, 1.2g, 1.4g	Plastic (HDPE)	Transparent PP	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 – indoor, open application, German cockroach, non-professional

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blattella germanica* German cockroach nymphs, adults
Field(s) of use	Indoor use (Health protection)
Application method(s)	Application in cracks and crevices
Application rate(s) and frequency	Low infestation rate 0.1g/m2; high infestation rate 0.2g/m2 1 drop of 0.1 g is equivalent to 5 mm diameter. Maximum of 6 applications per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Syringe, Plastic (HDPE) , 3g, 5g, 10g, 15g

3.1.2 Intended use 2 – indoor, open application, German cockroach, professional

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blattella germanica* German cockroach nymphs, adults
Field(s) of use	Indoor use (Health protection)
Application method(s)	Application in cracks and crevices
Application rate(s) and frequency	Low infestation rate 0.1g/m2; high infestation rate 0.2g/m2 1 drop of 0.1 g is equivalent to 5 mm diameter. Maximum of 6 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	Cartridge, Plastic (HDPE) , 30g; 35g, 50g, 100g

3.1.3 Intended use 3 – indoor, open application, Oriental cockroach, non-professional

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blatta orientalis* Oriental cockroach nymphs, adults
Field(s) of use	Indoor use (Health protection)
Application method(s)	Application in cracks and crevices
Application rate(s) and frequency	Low infestation rate 0.2g/m2; high infestation rate 0.3g/m2 1 drop of 0.1 g is equivalent to 5 mm diameter. Maximum of 6 applications per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Syringe, Plastic (HDPE) , 3g, 5g, 10g, 15g

3.1.4 Intended use 4 – indoor, open application, Oriental cockroach, professional

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blatta orientalis* Oriental cockroach nymphs, adults
Field(s) of use	Indoor use (Health protection)
Application method(s)	Application in cracks and crevices
Application rate(s) and frequency	Low infestation rate 0.2g/m2; high infestation rate 0.3g/m2 1 drop of 0.1 g is equivalent to 5 mm diameter. Maximum of 6 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	Cartridge, Plastic (HDPE) , 30g; 35g, 50g, 100g

3.1.5 Intended use 5 – indoor, bait trays, German cockroach

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blattella germanica* German cockroach nymphs, adults
Field(s) of use	Indoor use (Health protection)
Application method(s)	In bait trays
Application rate(s) and frequency	Low infestation rate 0.1g/m2 (one 0.75g bait tray per 8m2, one 1g bait tray per 10m2, one 1.2g bait tray per 12m2, one 1.4g bait tray per 14m2) High infestation rate 0.2g/m2 (one 0.75g bait tray per 4m2, one 1g bait tray per 5m2, one 1.2g bait tray per 6m2, one 1.4g bait tray per 7m2) Maximum of 6 applications per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Bait tray, Plastic (HDPE) , 0.75g, 1g, 1.2g, 1.4g

3.1.6 Intended use 6 – indoor, bait trays, Oriental cockroach

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blatta orientalis* Oriental cockroach nymphs, adults
Field(s) of use	Indoor use (Health protection)
Application method(s)	In bait trays
Application rate(s) and frequency	Low infestation rate 0.2g/m2 (one 0.75g bait tray per 4m2, one 1g bait tray per 5m2, one 1.2g bait tray per 6m2, one 1.4g bait tray per 7m2) High infestation rate 0.3g/m2 (one 0.75g bait tray per 2.5m2, one 1g bait tray per 3m2, one 1.2g bait tray per 4m2, one 1.4g bait tray per 5m2) Maximum of 6 applications per year.
Category(ies) of users	General public (non-professional) Professional
Pack sizes and packaging material	bait tray, Plastic (HDPE) , 0.75g, 1g, 1.2g, 1.4g

3.1.7 Intended use 7 – outdoor, bait trays, German cockroach

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blattella germanica* German cockroach nymphs, adults
Field(s) of use	Outdoor use as a barrier around buildings at potential entry points for cockroaches (e.g. windows, doors, ventilation openings), (Health protection)
Application method(s)	In bait trays
Application rate(s) and frequency	Low infestation rate 0.1g/m2 (one 0.75g bait tray per 8m2, one 1g bait tray per 10m2, one 1.2g bait tray per 12m2, one 1.4g bait tray per 14m2) High infestation rate 0.2g/m2 (one 0.75g bait tray per 4m2, one 1g bait tray per 5m2, one 1.2g bait tray per 6m2, one 1.4g bait tray per 7m2) Maximum of 6 applications per year
Category(ies) of users	General public (non-professional) Professional
Pack sizes and packaging material	bait tray, Plastic (HDPE) , 0.75g, 1g, 1.2g, 1.4g

3.1.8 Intended use 8 – outdoor, bait trays, Oriental cockroach

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	*Blatta orientalis* Oriental cockroach nymphs, adults
Field(s) of use	Outdoor use as a barrier around buildings at potential entry points for cockroaches (e.g. windows, doors, ventilation openings), (Health protection)
Application method(s)	In bait trays
Application rate(s) and frequency	Low infestation rate 0.2g/m2 (one 0.75g bait tray per 4m2, one 1g bait tray per 5m2, one 1.2g bait tray per 6m2, one 1.4g bait tray per 7m2) High infestation rate 0.3g/m2 (one 0.75g bait tray per 2.5m2, one 1g bait tray per 3m2, one 1.2g bait tray per 4m2, one 1.4g bait tray per 5m2) Maximum of 6 applications per year.
Category(ies) of users	General public (non-professional) Professional

Pack sizes and packaging material	bait tray, Plastic (HDPE) , 0.75g, 1g, 1.2g, 1.4g

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	2.15% w/w Imidacloprid Batch 200183	Gel	A.J. Woolley (2013), Determination of physico-chemical properties Study number: 41204554
Colour at 20 °C and 101.3 kPa	Visual	2.15% w/w Imidacloprid Batch 200183	Brown opaque with white flecks	A.J. Woolley (2013), Determination of physico-chemical properties Study number: 41204554
Odour at 20 °C and 101.3 kPa	Olfactory	2.15% w/w Imidacloprid Batch 200183	Slight specific odour	MSDS Imidasect
Acidity / alkalinity	CIPAC Method MT 75.3	2.15% w/w Imidacloprid Batch 200183	Initial: pH= 5.92 7 days at 0 ± 2ºC: pH= 6.03	A.J. Woolley (2013), Determination of physico-chemical properties Study number: 41204554
Relative density / bulk density	OECD 109 Method EC A.3 CIPAC Method MT 3.2 Pyknometer method	2.15% w/w Imidacloprid Batch 200183	Mean density = 1.25 x 10^3 kg/m^3 (20ºC) D^{20}_4: 1.25	A.J. Woolley (2013), Determination of physico-chemical properties Study number: 41204554
Storage stability test – **accelerated storage**	CIPAC Method MT 75.3 CIPAC Method MT 191	2.15% w/w Imidacloprid Batch 200183 Storage in 40 ml white, translucent plastic syringe barrels with white, opaque plastic tips.	Initial: 1.88%w/w Brown gel with white flecks. pH (25ºC, 1% aqueous dispersion) 5.92.	A.J. Woolley (2013), Determination of Accelerated Storage Stability Study number: 41204557

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			14 days at 54±2 ºC: 1.83%w/w (decrease of 2.3 %) Brown gel with white flecks. pH (25ºC, 1% aqueous dispersion) 5.29. No signs of corrosion, degradation or leaking of the packaging material. The test item is physically stable to storage at 54 ± 2ºC for 14 days. There was no significant change in the pH of the neat formulation or a 1% aqueous dispersion of the test item during storage.	
Storage stability test – **long term storage at ambient temperature**		2.15% w/w Imidacloprid Batch 200183 Storage in 40 ml white, translucent plastic syringe barrels with white, opaque plastic tips.	Initial: 1.88%w/w Brown gel with white flecks. pH (25ºC, 1% aqueous dispersion) 5.92. 24 months at ambient temperature (25 ºC): 1.84%w/w (decrease of 2.1 %) Brown gel with white flecks. pH (25ºC, 1% aqueous dispersion) 5.45. weight loss: 0.225 %	A.J. Woolley (2013), Determination of Long-Term Storage Stability Study number: 41204556

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			No signs of corrosion, degradation or leaking of the packaging material. The formulation is expected to be stable for 2 years under the conditions of the test.	
Storage stability test – **low temperature stability test for liquids**	CIPAC Method MT 39.3	2.15% w/w Imidacloprid Batch 200183	Initial: Brown opaque gel with white flecks. 7 days at 0 ± 2ºC: Brown opaque gel with white flecks, with no separated material. The test item is physically stable to storage at 0 ± 2ºC for 7 days. There was no significant change in the pH of the neat formulation or a 1% aqueous dispersion of the test item during storage.	A.J. Woolley (2013), Determination of physico-chemical properties Study number: 41204554
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Product is stored away from light	Waiving[6]
Effects on content of the active substance and			No significant effects observed during long-term	

[6] 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
technical characteristics of the biocidal product – **temperature and humidity**			and accelarated storage tests.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Storage stability test – **long term storage at ambient temperature**: No signs of corrosion, degradation of the packaging material or leaking of the packaging.	A.J. Woolley (2013), Determination of Long-Term Storage Stability Study number: 41204556
Wettability			Not required as the product is a ready-to-use gel.	Waiving[6]
Suspensibility, spontaneity and dispersion stability			Not required as the product is a ready-to-use gel.	Waiving[6]
Wet sieve analysis and dry sieve test			Not required as the product is a ready-to-use gel.	Waiving[6]
Emulsifiability, re-emulsifiability and emulsion stability			Not required as the product is a ready-to-use gel.	Waiving[6]
Disintegration time			Not required as the product is a ready-to-use gel and not a tablet.	Waiving[6]
Particle size distribution, content of dust/fines, attrition, friability			Not required as the product is a ready-to-use gel and not a granule or powder.	Waiving[6]
Persistent foaming			Not required as the product is a ready-to-use gel and not applied in water for use.	Waiving[6]
Flowability/Pourability/Dustability			Not required as the product is a ready-to-use gel.	Waiving[6]

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Burning rate — smoke generators			Not required as the product is a ready-to-use gel.	Waiving[6]
Burning completeness — smoke generators			Not required as the product is a ready-to-use gel.	Waiving[6]
Composition of smoke — smoke generators			Not required as the product is a ready-to-use gel.	Waiving[6]
Spraying pattern — aerosols			Not required as the product is a ready-to-use gel without spray applications.	Waiving[6]
Physical compatibility			The product is ready-to-use and it is not intended to be used with any other product.	Waiving[6]
Chemical compatibility			The product is ready-to-use and it is not intended to be used with any other product.	Waiving[6]
Degree of dissolution and dilution stability			Not required as the product is a ready-to-use gel which is neither diluted nor dissolved.	Waiving[6]
Surface tension			Not required for a highly viscous gel.	Waiving[6]
Viscosity	OECD 114, Rotational viscometer	2.15% w/w Imidacloprid Batch 200183	At 20 ± 0.5°C: 2.26 x 10^6 mPa s At 40 ± 0.5°C: 1.29 x 10^6 mPa s	A.J. Woolley (2013), Determination of physico-chemical properties Study number: 41204554

Table 6

Conclusion on the physical, chemical and technical properties
Imidasect is a ready-to-use brown gel with white flecks. In addition, Imidasect is highly viscous. Based on the provided stability studies a shelf-life of 2 years can be granted. The data provided by the applicant was acceptable.

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	Screening method by DSC	2.15% Imidaclopird Gel Batch: 200183	2.6 mg sample heated from 25 to 500 °C (1 °C/min) in medium pressure crucible.	No significant exothermic reactions, decomposition energy <300 J/g. Based on the thermal behavior of the test item, the result for the explosive properties has been predicted negative. Not classified based on GHS/CLP criteria.	Woolley, A.J. (2013), Harlan Study number: 41204554Woolley, A.J. (2021), Expert Statement 41204554
Flammable gases				Hazard class not applicable. Imidsasect is a gel respectively liquid.	
Flammable aerosols				Hazard class not applicable. Imidsasect does not get packaged or transported as an aerosol.	
Oxidising gases				Hazard class not applicable. Imidsasect is a gel respectively liquid.	
Gases under pressure				Hazard class not applicable. Imidsasect is a gel respectively liquid.	
Flammable liquids	EU method, A.9 Regulation (EC) No 440/2008	2.15% Imidaclopird Gel Batch: 200183		The test item has been determined not to have a flash point below its boiling temperature (126 °C). (ISO 3679-2004, ASTM D-3278-89) Not classified based on GHS/CLP criteria.	Woolley, A.J. (2013), Harlan Study number: 41204554

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Flammable solids				Hazard class not applicable. Imidsasect is a gel respectively liquid.	
Self-reactive substances and mixtures	Screening method by DSC	2.15% Imidaclopird Gel Batch: 200183	2.6 mg sample heated from 25 to 500 °C (1 °C/min) in medium pressure crucible.	No significant exothermic reactions, decomposition energy <300 J/g. Based on the thermal behavior of the test item, the result for self-reactive properties has been predicted negative. Not classified based on GHS/CLP criteria.	Woolley, A.J. (2013), Harlan Study number: 41204554 Woolley, A.J. (2021), Expert Statement 41204554
Pyrophoric liquids				Due to known experience Imidsasect is expected to have no pyrophoric properties. Not classified based on GHS/CLP criteria.	
Pyrophoric solids				Hazard class not applicable. Imidsasect is a gel respectively liquid	
Self-heating substances and mixtures				Imidasect is a gel respectively a liquid. As the test method requested in CLP regulation is not considered for liquids, no test is requested. Not classified based on GHS/CLP criteria.	
Substances and mixtures which in contact with water emit flammable gases				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 experience shows that the product does not react with water. Not classified based on GHS/CLP criteria.	
Oxidising liquids	Expert statement	Imidaclopri d 2.15% Gel,		Based on the chemical structure of the active ingredients or other components in the test item formulation, the result for the oxidizing properties	Woolley, A.J. (2013), Harlan

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
		Batch No. 200183		has been predicted negative. The remaining components are either known to be non-oxidizing or are present in such small amounts as to have an insignificant effect. Not classified based on GHS/CLP criteria.	Study number: 41204554
Oxidising solids				Hazard class not applicable. Imidsasect is a gel respectively liquid.	
Organic peroxides				None of the ingredients contained in the Gel formulation is expected an organic peroxide. Therefore, "Imidacloprid Gel 2.15 %" is not expected to be an organic peroxide. Not classified based on GHS/CLP criteria.	
Corrosive to metals	UN method C.1	Imidacloprid 2.15% Gel, Batch No. 211601	Corrosion rate: 6.25 mm/year (= 15.5 % mass loss within 7 days) Aluminium type: 7075 T6 F53 Steel type: S235JR+CR (1.0037 resp. ST 37.2)	Not corrosive. Mass loss: 0.004 % within 7 days No localised corrosion was detected. Type of material: Aluminium, type: 7075 T6 F53 Mass loss: 0.140 % within 7 days No localised corrosion was detected. Type of material: Steel, type: S235JR+CR (1.0037 resp. St 37.2)	Petryka, M. (2021) Study No.: BC-20/21
Auto-ignition temperature (liquids and gases)	EU method, A.15 Regulation (EC) No 440/2008	Imidacloprid 2.15% Gel, Batch No. 200183		The test item has been determined to have an auto-ignition temperature of 404 ± 5 °C.	Woolley, A.J. (2013), Harlan Study number: 41204554

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Relative self-ignition temperature for solids				Hazard class not applicable. Imidsasect is a gel respectively liquid.	
Dust explosion hazard				Hazard class not applicable. Imidsasect Ants is a gel respectively liquid.	

Table 8

Conclusion on the physical hazards and respective characteristics
The product comprises 2.194 % 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 and decomposition energy <300 J/g. Therefore, "Imidasect" is expected neither to be explosive nor to be self-reactive. Imidasect is a non-flammable product, since it did not show the typical flammability phenomena up to 126°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 fulfils the criteria for organic peroxides. Based on corrosion studies the product is not corrosive. The auto-ignition temperature of Imidasect is 404°C.

3.4 Methods for detection and identification

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, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Imidacloprid	HPLC/UV determination at 260 nm	The specificity was confirmed by external standard and diode array deviation. There was no evidence of interfering peaks from the matrix blank at the retention times of the active ingredient.	2.04 – 50 mg L^{-1} (R^2 > 0.9996)	Level 1: 15.3 mg L^{-1} Level 2: 20.3 mg L^{-1} Level 3: 40.7 mg L^{-1} (2 measurements per Level, before fortification with active substance no active substane present) **Precision/ Repeatability:** Six replicate injections of an Imidacloprid standard solution (10 mg/L) were	100 – 101 99.2 – 101 99.1 – 99.3	100	0.962	8.67 × 10^{-2} mg L^{-1}	A. J. Woolley (2013), Study No.: 41204555

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, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				performed. An RSD of 0.969 was obtained.					

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	$PNEC_{soil}$ 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	$PNEC_{water}$ 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, R²)**	**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 R² 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); R² 0.99135 matrix: 0.5 – 5.0 µg/L; R² 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	105 106 109 107	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		105 – 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, R²)**	**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[7]
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.

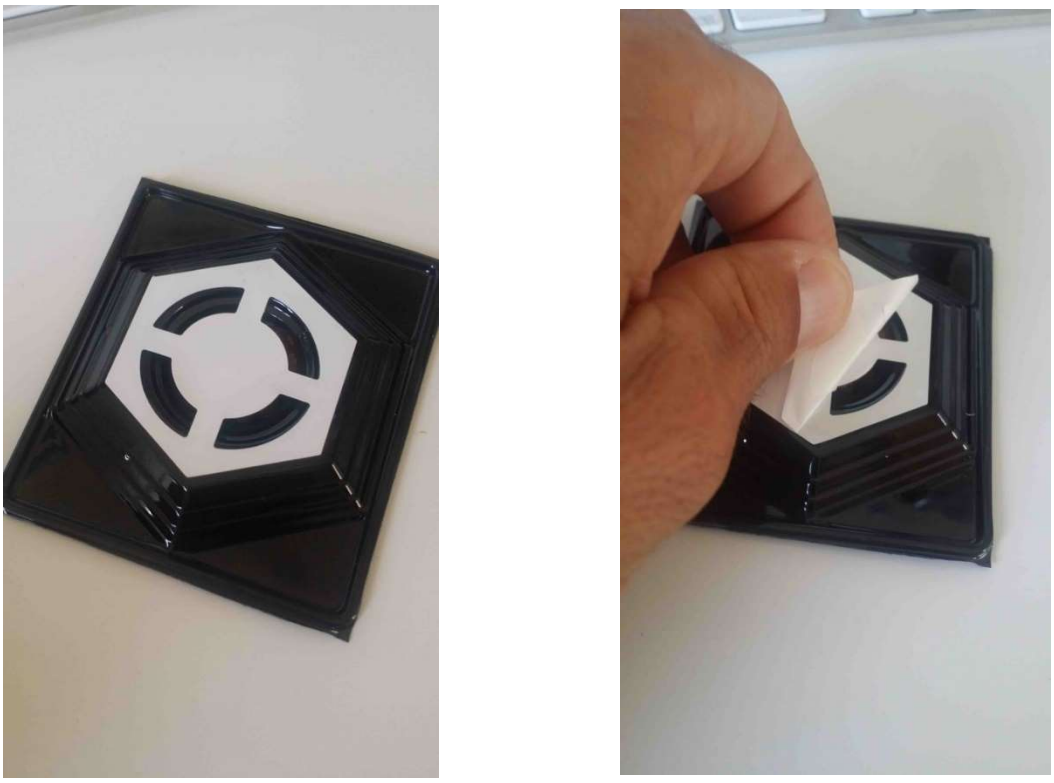
[7] Not necessary if neither the active substance nor the material treated with it come into contact with food-producing animals, food of plant and animal origin or feeding stuffs

3.5 Efficacy against target organisms

3.5.1 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” is a gel formulation with the insecticidal active substance Imidacloprid (2.15%), intended to be used against nymphs and adults of German cockroaches (*Blattella germanica*) and Oriental cockroaches (*Blatta orientalis*) indoors as open gel application or as bait tray (Picture 1) and outdoors exclusively in bait trays (Picture 1). The application rate for German cockroaches is 0.1 g/m² at low and 0.2 g/m² at high infestation rates and for Oriental cockroaches 0.2 g/m² at low and 0.3 g/m² at high infestation rates.
The submitted studies are suitable to prove the efficacy of the product “Imidasect” to support the claim “kill nymphs and adults of German cockroaches (*Blattella germanica*) and Oriental cockroaches (*Blatta orientalis*) as open gel application and bait tray in indoor environments and as bait tray in outdoor environments”. An effective application rate is 0.1 g/m² for low and 0.2 g/m² for high *B. germanica* infestation and 0.2 g/m² for low and 0.3 g/m² for high *B. orientalis* infestation rates. The product can be used continuously for 3 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.



Picture 1 Open bait tray

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

The product “Imidasect” is intended to be used to kill nymphs and adults of German cockroaches (*Blattella germanica*) and Oriental cockroaches (*Blatta orientalis*) in indoor (health protection) and outdoor environments.

3.5.3 Effects on target organisms, including unacceptable suffering

Knockdown and kill

3.5.4 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.

3.5.5 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 5.6.4.3.2.3) the applicant submitted laboratory (Radecki 2012; Serrano 2016; Tosky 2021a, b) and field studies (Heaven 2015; Serrano 2016; Yadav 2021a, b) with the product “Imidasect” as open gel application or bait tray against German cockroaches (*B. germanica*) and Oriental cockroaches (*B. orientalis*) (study summaries see Table 25).

The laboratory test by Radecki (2012) demonstrated a sufficient efficacy of the open gel application of 98% against *B. germanica* and of 93% *B. orientalis* after an exposure period of 14 days. Mortality in the untreated controls was for both cockroach species ≤ 2% at the end of the exposure period.
In the laboratory trial with the bait tray (Serrano 2016) a sufficient efficacy of 100% against *B. germanica* and *B. orientalis* was observed after an exposure period of 4 and 8 days, respectively. Mortality in the untreated controls was for both cockroach species ≤ 4% at the end of the exposure period.
A laboratory test by Tosky (2021a) demonstrated 100% mortality with the fresh gel and also 8 weeks opened gel bait against *B. germanica* and *B. orientalis* after an exposure period of 21 and 14 days, respectively. Mortality in the untreated controls was for both cockroach species ≤ 7.8% at the end of the exposure period.

A second laboratory test by Tosky (2021b) demonstrated 100% mortality with the fresh bait trays and also 8 weeks opened bait trays against *B. germanica* and *B. orientalis* after an exposure period of 21 and 10 days, respectively. Mortality in the untreated controls was for both cockroach species ≤ 7.8% at the end of the exposure period.

Three field tests were conducted in indoor environments:
In the study by Heaven (2015) the open gel was applied in apartments and restaurants with each a low and high infestation of *B. germanica* or *B. orientalis* in Spain. The gel was applied in doses of 0.1 g/m² for low and 0.2 g/m² for high *B. germanica* infestation and 0.2 g/m² for low and 0.3 g/m² for high *B. orientalis* infestation. A population reduction of ≥ 80% was demonstrated in all 3 replicates 2 weeks after product application against *B. germanica* and after 4 weeks against *B. orientalis*. At the end of the observation period (8 weeks after product application) for both species only in 2 out of 3 replicates a population reduction of ≥ 80% was observed due to re-infestation form neighbouring apartments and the sewerage, respectively.
The field test by Serrano (2016) was conducted in apartments and restaurants/bakeries in France infested with *B. germanica* or *B. orientalis* and the product was applied in bait trays. For both cockroach species a population reduction of ≥ 80% was demonstrated in all replicates 2 weeks after product application and up to the end of the observation period after 8 weeks.
In the study by Yadav (2021a) the product was also applied in bait trays in houses in India infested with *B. germanica* or *B. orientalis*. With *B. germanica* a population reduction of ≥ 80% was demonstrated in all 3 replicates beginning 2 weeks after product application and up to the end of the observation period after 8 weeks. For *B. orientalis* a population reduction of ≥ 80% was demonstrated in all 3 replicates beginning 2 weeks after product application and up to 6 weeks after product application. At the end of the observation period (8 weeks after product application) the population reduction ranged between 57.6 and 73.5% in all 3 replicates due to re-infestation.

One field study was conducted under outdoor conditions on balconies and/or terraces in India (Yadav 2021b) with bait trays against *B. germanica* or *B. orientalis*. For both cockroach species a population reduction of ≥ 80% was demonstrated in all 3 replicates beginning 1 week after product application and up to 4 weeks. However, with *B. germanica* 6 and 8 weeks after product application only in 1 out of 3 replicates a population reduction of ≥ 80% was observed due to re-infestation. With *B. orientalis* after 6 weeks in 2 out of 3 replicates a population reduction of ≥ 80% was demonstrated and at the end of the trial (8 weeks after product application) the population reduction ranged between 40.9 and 70.5% in all 3 replicates due to re-infestation.
Re-infestation from outside the treated area is a common and well-known problem in cockroach infestations in the field. The rise in population counts after the initial reduction in these replicates is not due to lack of efficacy of the product, but due to re-infestation.

In the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) (Version 3.0; April 2018; chapter 5.6.4.3.2.3 and 5.6.4.3.3.1) it is requested that bait products against cockroaches must be tested in laboratory (mortality > 95%), simulated-use (can be waived) and field test (population reduction > 80%). Due to the specificity of baits, only effects against species of cockroaches that have been tested in the field can be claimed on the product label. The palatability of the fresh and 8 weeks opened product “Imidasect” applied as open gel and in bait trays has been proven in laboratory tests against *B. germanica* and *B. orientalis*. The efficacy of the product “Imidasect” was also proven in the field for *B. germanica* and *B. orientalis* for open gel application and bait trays at an application rate of 0.1 g/m² for low and 0.2 g/m² for high *B. germanica* infestation and 0.2 g/m² for low and 0.3 g/m² for high *B. orientalis* infestation rates.

Consequently, the submitted studies are suitable to prove the efficacy of the product “Imidasect” to support the claim “kill nymphs and adults of German cockroaches (*Blattella germanica*) and Oriental cockroaches (*Blatta orientalis*) as open gel application and bait tray in indoor environments and as bait tray in outdoor environments”. An effective application rate is 0.1 g/m² for low and 0.2 g/m² for high *B. germanica* infestation and 0.2 g/m² for low and 0.3 g/m² for high *B. orientalis* infestation rates. The product can be used continuously for 3 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.

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	indoors outdoors	Imidasect Gel (2.15% Imidacloprid); fresh and 8 weeks aged	*Blattella germanica, Blatta orientalis;* nymphs (stage 3 to 4) and adults	Laboratory test with open gel application	Choice trial: - arena: 45 x 30 x 25 cm with hiding place and alternative food - dosage per arena: 0.1 g for *B. germanica* and 0.2 g for *B. orientalis* - 30 insects (10 males, 10 females, 10 nymphs) - 3 replicates per species - temperature: 26.5 - 29°C - rel. humidity: 66 - 79% - acclimatisation: 24 hours - assessment intervals: 1, 3, 7, 10, 14 , 21 and 28 days - untreated controls: n = 3 per species	*B. germanica*: fresh and 8 weeks aged bait: 100% mortality after 21 days control: ≤ 7.8% mortality *B. orientalis*: fresh and 8 weeks aged bait: 100% mortality after 14 days control: ≤ 7.8% mortality *evaluation: reliability index (RI): 1* *- suitable to prove the palatability/efficacy against* Blattella germanica *and* Blatta orientalis *with the fresh and 8 weeks opened product*	Tosky, J, 2021a
PT18	indoors outdoors	Imidasect Trap (2.15% Imidacloprid);	*Blattella germanica,*	Laboratory test with bait tray	Choice trial: - arena: 45 x 30 x 25 cm with hiding place and alternative food	*B. germanica*: fresh: 100% mortality after 14 days	Tosky, J, 2021b

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**
		loaded with 1.4 g gel; fresh and 8 weeks aged	*Blatta orientalis;* nymphs (stage 3 to 4) and adults		- dosage per arena: 1 bait tray - 30 insects (10 males, 10 females, 10 nymphs) - 3 replicates per species - temperature: 26.2 – 28.8°C - rel. humidity: 66 - 77% - acclimatisation: 24 hours - assessment intervals: 1, 3, 7, 10, 14 , 21 and 28 days - untreated controls: n = 3 per species	8 weeks aged bait: 100% mortality after 21 days control: ≤ 6.7% mortality *B. orientalis*: fresh: 100% mortality after 7 days 8 weeks aged bait: 100% mortality after 10 days control: ≤ 7.8% mortality *evaluation: RI: 1* *- suitable to prove the palatability/efficacy against* Blattella germanica *and* Blatta orientalis *with the fresh and 8 weeks opened product*	
PT18	indoors outdoors	Imidasect Gel (2.15% Imidacloprid)	*Blattella germanica, Blatta orientalis;*	Laboratory test with open gel application	Choice trial: - arena: cardboard 40 x 60 x 15 cm with hiding place - dosage per arena: 1 drop of the product (0.1 g)	*B. germanica*: 98% efficacy after 14 days control: 0% mortality	Radecki, C, 2012

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**
			nymphs (stage 3 to 4) and adults		- 20 insects (5 males, 5 females, 10 nymphs) - 3 replicates per species - temperature: 25 - 26°C - rel. humidity: 55 - 69% - starvation: no - acclimatisation: 24 hours - assessment intervals: 1, 3, 7, 10 and 14 days - untreated controls: n = 3 per species	*B. orientalis*: 93% efficacy after 14 days control: 2% mortality *evaluation: RI: 1* *- suitable to prove the palatability/efficacy against* Blattella germanica *and* Blatta orientalis	
PT18	indoors outdoors	Imidasect Trap (2.15% Imidacloprid); loaded with 1.4 g gel	*Blattella germanica, Blatta orientalis;* nymphs (stage 3 to 4) and adults	Laboratory test with bait tray	Choice trial: - arena: plastic 30 x 30 x 15 cm with hiding place - dosage per arena: 1 bait tray (1.4 g gel) - 30 insects (10 males, 10 females, 10 nymphs) - 4 replicates per species - temperature: 25 ± 1°C - rel. humidity: 65 ± 4% - starvation: no - acclimatisation: 24 hours - assessment intervals: everyday up to 12 days - untreated controls: n = 4 per species	*B. germanica*: 98% mortality after 3 days 100% mortality after 4 days control: 4% mortality after 12 days *B. orientalis*: 98% mortlity after 7 days 100% mortlity after 8 days control: 2% mortality after 12 days	Serrano, B, 2016

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* Blattella germanica *and* Blatta orientalis	
PT18	indoors outdoors	Imidasect Gel (2.15% Imidacloprid)	*Blattella germanica,* *Blatta orientalis;*	Field trial with open gel application indoors (in sheltered areas (corners, cracks, crevices, cable duct, along furniture pedestal))	- apartments and restaurants in Spain - dosage against *B. germanica*: 0.1 g/m² for low and 0.2 g/m² for high infestation - dosage against *B. orientalis*: 0.2 g/m² for low and 0.3 g/m² for high infestation - 3 replicates per species - pre-monitoring 2 days prior application with monitoring traps for 24 or 48 hours - assessment intervals: 2-weekly up to 8 weeks with monitoring traps - untreated controls: no	*B. germanica*: population reduction 2 weeks after application: ≥83.3% population reduction 8 weeks after application: 83.3%; 100%; 70.8% (re-infestation) *B. orientalis*: population reduction 4 weeks after application: ≥87.5% population reduction 8 weeks after application: 77.5% (re-infestation); 94.4%; 100% *evaluation: RI: 1* *- suitable to prove the efficacy against*	Heaven, H, 2015

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**
						Blattella germanica *and* Blatta orientalis *with the open gel application indoors*	
PT18	indoors outdoors	Imidasect Trap (2.15% Imidacloprid); loaded with 1.4 g gel	*Blattella germanica,* *Blatta orientalis;*	Field trial with bait tray indoors	- apartments and restaurants/bakeries in France - dosage: approx. 1 trap/8 m² (corresponding to 0.18 g gel/m²) - 5 replicates per species - pre-monitoring 14 and 7 days prior application with monitoring traps overnight - assessment: 1, 7, 14, 28 and 56 days after application with monitoring traps (for 24 hours) - untreated controls: n=5 per species	*B. germanica*: population reduction 2 weeks after application: ≥88% in all replicates population reduction 8 weeks after application: ≥86% in all replicates *B. orientalis*: population reduction 2 weeks after application: ≥80% in all replicates population reduction 8 weeks after application: ≥90% in all replicates *evaluation: RI: 1* *- suitable to prove the efficacy against* Blattella germanica	Serrano, B, 2016

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**
						and Blatta orientalis *with bait trays indoors*	
PT18	indoors outdoors	Imidasect Trap (2.15% Imidacloprid); loaded with 1.4 g gel	*Blattella germanica,* *Blatta orientalis;*	Field trial with bait tray indoors	- houses in India - dosage against *B. germanica*: 1 trap/14 m² (corresponding to 0.1 g gel/m²) - dosage against *B. orientalis*: 1 trap/7 m² (corresponding to 0.2 g gel/m²) - 3 replicates per species - pre-monitoring 2 days prior application with monitoring traps for 48 hours - assessment intervals: 1, 2, 4, 6 and 8 weeks with monitoring traps - untreated controls: n=3 per species	*B. germanica*: population reduction 2 weeks after application: ≥86.9% in all replicates population reduction 8 weeks after application: ≥87.9% in all replicates *B. orientalis*: population reduction 1 week after application: 100% in all replicates population reduction 6 weeks after application: ≥95.7% population reduction 8 weeks after application: 57.6 - 73.5% in all replicates due to re-infestation *evaluation: RI: 1*	Yadav, A, 2021a

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**
						- suitable to prove the efficacy against Blattella germanica *and* Blatta orientalis *with bait trays indoors*	
PT18	indoors outdoors	Imidasect Trap (2.15% Imidacloprid); loaded with 1.4 g gel	*Blattella germanica, Blatta orientalis;*	Field trial with bait tray outdoors	- outdoor area of houses (balcony and terrace) in India - dosage against *B. germanica*: 1 trap/14 m² (corresponding to 0.1 g gel/m²) - dosage against *B. orientalis*: 1 trap/7 m² (corresponding to 0.2 g gel/m²) - 3 replicates per species - pre-monitoring 2 days prior application with monitoring traps for 48 hours - assessment intervals: 1, 2, 4, 6 and 8 weeks with monitoring traps - untreated controls: n=3 per species	*B. germanica*: population reduction 1 week after application: ≥93.8% in all replicates population reduction 4 weeks after application: 100% in all replicates population reduction 6 and 8 weeks after application: ≥85.3% in 2 replicates; replikat 1: 75.2% and 72.6% due to re-infestation *B. orientalis*: population reduction 1 week after application: 100% in all replicates population reduction 4 weeks after application: 100% in all replicates	Yadav, A, 2021b

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 6 weeks after application: ≥80.0% in 2 replicates; replikat 3: 71.6% re-infestation population reduction 8 weeks after application: 40.9 – 70.5% in all replicates due to re-infestation *evaluation: RI: 1* *- suitable to prove the efficacy against* Blattella germanica *and* Blatta orientalis *with bait trays outdoors*	

3.5.6 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 cockroaches so far.

Cockroaches are known to be able to develop an aversive behaviour to oral baits, often referred to as “behavioural resistance”. This behaviour is mostly related to sugars present in the bait. If the application of a bait product is not efficiently reducing or eradicating the cockroach population, a different type of bait formulation or a different product type should be employed.

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.
- The use of biocidal products can be combined with other sanitation measures.
- Products should always be used in accordance with label recommendations.

3.5.7 Known limitations

Imidacloprid acts on nymphs and adults of cockroaches. The successful use of cockroach 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 cockroaches, and additional measures should be taken, such as the sealing off of walls, etc.

3.5.8 Evaluation of the label claims

The submitted studies are suitable to prove the efficacy of the product “Imidasect” to support the claim “kill nymphs and adults of German cockroaches (*Blattella germanica*) and Oriental cockroaches (*Blatta orientalis*) as open gel application and bait tray in indoor environments and as bait tray in outdoor environments”. An effective application rate is 0.1 g/m² for low and 0.2 g/m² for high *B. germanica* infestation and 0.2 g/m² for low and 0.3 g/m² for high *B. orientalis* infestation rates. The product can be used continuously for 3 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.

3.5.9 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.

3.5.10 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 prove the efficacy of the product “Imidasect” to support the claim “kill nymphs and adults of German cockroaches (*Blattella germanica*) and Oriental cockroaches (*Blatta orientalis*) as open gel application and bait tray in indoor environments and as bait tray in outdoor environments”. An effective application rate is 0.1 g/m² for low and 0.2 g/m² for high *B. germanica* infestation and 0.2 g/m² for low and 0.3 g/m² for high *B. orientalis* infestation rates. The product can be used continuously for 3 months without replacing opened bait trays or unconsumed open gel bait. Shelf life: 2 years

3.6 Risk assessment for human health

3.6.1 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
Oral absorption	100 %[1]	Default value
Dermal absorption	Refer to chapter 3.6.2.7 information on dermal absorption	

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

3.6.2 Assessment of effects of the product on human health

The toxicology of the biocidal product Imidasect 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. The applicant submitted toxicological studies. He confirmed that the test substance in these studies is identical to the biocidal product. These acute toxicological studies have shown that it is of low oral and dermal toxicity and not irritating to skin and eye. Upon renewal, no additional studies have been submitted by the applicant. Since the composition of the biocidal product and its conditions of use remain the same, the initial assessments of the studies submitted for first authorisation of the biocidal product are still valid, with the exception of

dermal absorption. For 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).

3.6.2.1 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**	**Results8**	**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 72 h 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 48 h – day 7 No corrosive effects were noted normal gain in bodyweight	Acceptable	Bradshaw, J. (2013) Project Number: 41204551

8 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	Based on the results of an *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).
Classification of the product according to CLP	Classification for skin corrosion and irritation is not required.

3.6.2.2 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, 1 h, 24 h, 48 h and 72 h after application Observation of reversibility on day 7	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) 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)	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**
			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	Based on the results of an *in vivo* study and the criteria for classification as irritant or corrosive to the eye according to Regulation (EC) No 1272/2008 (section 3.3.2.1. 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.

3.6.2.3 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.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.6.2.4 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 % 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	Preliminary screening: 10% No local skin irritation days 1-6 No increase in ear 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	Not acceptable An appropriate justification for dose selection was not given. A maximum dose of 10 % was selected. According to the guideline the 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.	Bradshaw, J. (2013) Project Number: 41204553

Table 29

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	Based on the low test concentration in the submitted *in-vivo* study, a final decision on the skin-sensitising properties of the biocidal product 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. Based on the content of the co-formulant 1,2-benzisothiazol-3(2H)-one, labelling with EUH208 is required. For details please refer to the Confidential Annex.
Classification of the product according to CLP	Classification for skin sensitisation is not required. Labelling with EUH208 (Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.) is required.

3.6.2.5 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.

3.6.2.6 Acute toxicity

3.6.2.6.1 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 levels** **Type 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 body weight (200 mg/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	Based on the results of an *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.

3.6.2.6.2 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 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.

3.6.2.6.3 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: Wistor 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	Based on the results of an *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).
Classification of the product according to CLP	Classification for acute dermal toxicity is not required.

3.6.2.7 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, the application of the dermal absorption values from the Imidacloprid CAR (DE, 2011), derived for the formulation Confidor OD 200, have been considered acceptable. Upon renewal of Imidasect product authorisation, the respective study from the CAR has been re-evaluated in accordance with EFSA Guidance on Dermal Absorption (2017) and a dermal absorption value of 14 % has been derived from the human skin samples treated with dilutions of the test substance containing 0.007-20 % Imidacloprid. 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 could not be assessed. 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).

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

Not relevant.

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

Not available.

3.6.2.11 Summary of effects assessment

Table 40

Endpoint	Brief description
Skin corrosion and irritation	Based on the results of an *in vivo* study. Not classified for skin irritation or corrosion.
Eye irritation	Based on 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), labelling with EUH208 for 1,2-Benzisothiazol-3(2H)-one is necessary.
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 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 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

3.6.3 Exposure assessment

3.6.3.1 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 (100 mg) c) Transient mouthing of bait (10 mg)	General public

3.6.3.1.1 Professional exposure

Imidasect is a ready-to-use insecticide to control cockroaches. It is applied by a cartridge gun, or via ready-to-use bait stations. It is contains the a.s. “Imidacloprid” (CAS-No.: 138261-41-3, 2.194 % (w/w)).

The biocidal product is marketed in the following packages:

- Cartridge, Plastic (HDPE); 30g, 35g, 50g, 100g
- Bait tray, Plastic (HDPE); 0.75g, 1g, 1.2g, 1.4g

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 harmonized 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 opinions/HEAdhoc recommendations (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**

Description

Imidasect is a ready-to-use insecticide which 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 or syringes. 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 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 or syringe 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.

Table 43

Details of Scenario 1	
Parameters	Value
Concentration of the a.s. Imidacloprid in the b.p.	2.194 % (w/w)
Density of the b.p.	1.25 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	10

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 45.
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 3.6.4.

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

Description

Imidasect is a ready-to-use insecticide bait which 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.

Table 44

Details of Scenario 2	
Parameters	Value
Concentration of the a.s. Imidacloprid in the b.p.	2.194 % (w/w)
Amount of b.p. per bait station	1.4 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 45
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 3.6.4.

- **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 45

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	**Estimated external dermal exposure [mg/day]**
Scenario 1: Application with a cartridge gun	Tier 1: none	Not expected	2.96
	Tier 2: Protective gloves (EN 374)	Not expected	0.30
Scenario 2: Ready-to-use bait station	Tier 1: none	Not expected	4.80
	Tier 2: Protective gloves (EN 374)	Not expected	0.48

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 3.6.4.6).

3.6.3.1.2 Non-professional exposure

For non-professional users, the biocidal product Imidasect has previously been approved for application in bait trays (maximum content: 1.4 g) 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 have been submitted by the applicant. Hence, 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. Therefore, 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.

- **Scenario [3]**

Table 46

Description of Scenario [3]

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

The biocidal product Imidasect 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 through a "gage needle" as spots to surfaces in identified target areas. For non-professional users, the maximum application rate is 0.3 g b.p./m^2, whereas one drop of gel equals 0.1 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. 6 applications per year. 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 cm3 of gel is transferred to the hand during sealing or opening of the cartridge. This corresponds to 12.254 mg gel per sealing and opening, taking into account the specific weight of 1.25 g/cm3. The amount of 12.254 mg gel corresponds to 0.26885 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)	1.25 g/cm^3
	Amount b.p. transferred to hands per opening or sealing = V x d	12.254 mg
	Concentration (c) a.s. (Applicant)	2.194 % (w/w)
	Amount a.s. transferred to hands per opening or sealing = amount b.p. x c	0.26885 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
= 0.26885 mg x 10 x 70 % / 60 kg
= 0.031366 mg/kg bw/d

Cleaning

Systemic dermal exposure = a.s. on hands x number of openings x dermal absorption / bw
= 0.26885 mg x 1 x 70 % / 60 kg
= 0.003137 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 2.194 % x 1% x 70 % / 60 kg
= 0.012798 mg/kg bw/d

Total systemic dermal exposure: 0.047301 mg/kg bw/d

Total systemic exposure: 0.047301 mg/kg bw/d

Table 47

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./kg bw/day)	**Estimated dermal uptake** (mg a.s /kg bw/day)	**Estimated oral uptake** (mg a.s./kg bw/day)	**Estimated total uptake** (mg a.s./kg bw/day)
Scenario [3] –Placing and disposing of baits (adult)	1	-	0.047301	-	0.047301

- **Combined scenarios**

Not relevant.

3.6.3.1.3 Secondary exposure of the general public

- **Scenario [4]**

Table 48

Description of Scenario [4]

Secondary exposure – Ingestion and mouthing of bait (toddler).

The biocidal product Imidasect is formulated as a gel and packed in syringes (maximum content: 15 g) or in bait trays (maximum content: 1.4 g). 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 100 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).

	Parameters[9]	Value
Tier 1	Concentration (c) a.s. (Applicant)	2.194 % (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)	100 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 2.194 % x 100% / 10 kg
= 3.0716 mg/kg bw

Total systemic exposure: 3.0716 mg/kg bw

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

Systemic oral exposure = amount ingested x concentration a.s. in b.p. x oral absorption / bw
= 100 mg x 2.194 % x 100 % / 10 kg
= 0.2194 mg/kg bw

Total systemic exposure: 0.2194 mg/kg bw

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

Systemic oral exposure = amount ingested x concentration a.s. in b.p. x oral absorption / bw
= 10 mg x 2.194 % x 100 % / 10 kg

= 0.02194 mg/kg bw

Total systemic exposure: 0.02194 mg/kg bw

Table 49

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./kg bw/day)	**Estimated dermal uptake** (mg a.s./kg bw/day)	**Estimated oral uptake** (mg a.s./kg bw/day)	**Estimated total uptake** (mg a.s./kg bw/day)
Scenario [4a] – Ingestion of bait in one bait tray (toddler)	1	-	-	3.0716	3.0716
Scenario [4b] - Ingestion of a gel bait drop (toddler)	1	-	-	0.2194	0.2194
Scenario [4c] – Transient mouthing of bait (toddler)	1	-	-	0.02194	0.02194

- **Combined scenarios**

Not relevant.

3.6.3.2 Dietary exposure

Table 50

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	Imidacloprid
Type of formulation	ready-to-use gel for non-professional users: gel in syringes, for professional users: gel in cartridges, - also available in bait boxes
Substance(s) of concern	none
Field(s) of use	- indoor use (in industrial/commercial facilities, in domestic/private premises (including kitchens), in public buildings) - outdoor use as barrier around buildings
Target organism(s)	German cockroaches (Blattella germanica), Oriental cockroaches (Blatta orientalis), in various development stages (nymphs, adults)
Application rate(s) and frequency	Located application of gel drops with a diameter of about 5 mm (approximately 0.1 g biocidal product per drop corresponding to 2.15 mg a.s.): Use against German cockroaches 1 (normal infestation level) or 2 (high infestation level) drops of gel per m² Use against Oriental cockroaches 2 (normal infestation level) or 3 (high infestation level) drops of gel per m² Biocidal product may also be applied in bait stations (Indoors: low infestation rate 0.2 g/m^2; high infestation rate 0.3 g/m^2; Outdoors: Overall amount of bait 0.15 g/m building perimeter (e.g. 7.5 g for 59 m building perimeter)) in places where cockroaches can appear. Treated area should be checked regularly and gel should be replaced if necessary.
Category(ies) of users	Non-professional user, professional user
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 animals. Do not store near food, drink and animal feeding stuff.

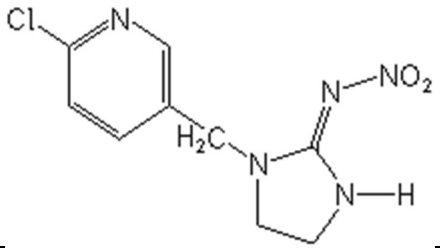
Conclusion

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, feedstuff 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 animals. (General)
- Do not store near food, drink and animal feeding stuff. (Conditions of storage)

3.6.3.2.1 General information on active substance(s)

Table 51

Active substance (Common Name)	Imidacloprid
CAS number	138261-41-3
Chemical structure	
Molecular formular	$C_9H_{10}ClN_5O_2$
Molar mass	255.7 g mol^{-1}
Log Po/w	0.57 at 21 °C
Active substance approval	PT: 18; RMS: DE
Restrictions	-
Current regulations on MRLs	-

3.6.3.2.1.1 Information of non-biocidal use of the active substance

Information on the residue definitions is provided in chapter 3.6.4.2 (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 21of Section 3.6.1 Assessment of effects of the active substance on human health.
Maximum residue limits or equivalent).

Table 52

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.	MRLs are set for all products of plant and animal origin as listed in Reg (EU) No 491/2014.

3.6.3.3 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.

3.6.3.4 Summary of exposure assessment

Table 53

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	0.03 mg a.s./kg bw/day
Scenario 2: Ready-to-use bait station	Professionals	Tier 1: none	0.06 mg a.s./kg bw/day
Scenario [3] –Placing and disposing of baits (adult)	Non-professional	1	0.047301 mg a.s /kg bw/day
Scenario [4a] – Ingestion of bait in one bait tray (toddler)	General public	1	3.0716 mg a.s /kg bw/day
Scenario [4b] - Ingestion of a gel bait drop (toddler)	General public	1	0.2194 mg a.s /kg bw/day
Scenario [4c] – Transient mouthing of bait (toddler)	General public	1	0.02194 mg a.s /kg bw/day

3.6.4 Risk characterisation for human health

3.6.4.1 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 21of Section 3.6.1 Assessment of effects of the active substance on human health.

3.6.4.2 Maximum residue limits or equivalent

Residue definitions

Table 54

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	Products of plant origin	0.05* - 10 mg/kg

*lower limit of analytical detection

3.6.4.3 Specific reference value for groundwater

No specific reference values for ground water were derived.

3.6.4.4 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. One of the co-formulants is currently included in the EU Community rolling action plan (CoRAP) and under investigation for potential endocrine disrupting properties. For details, refer to the Confidential Annex.
None of the other co-formulant of the biocidal product Imidasect 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.

3.6.4.5 Risk for industrial users

No industrial applications are intended.

3.6.4.6 Risk for professional users

The occupational risk assessment for the biocidal product Imidasect 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. 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 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 is unlikely, if the AEL exhaustion for each scenario is below the value of 100 %. Table 55 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 55, 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 55: Overview of detailed risk assessment results referring to the active substance Imidacloprid in the biocidal product Imidasect

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	-	0.03	58	0.03	58	Yes
Ready-to-use bait station	Tier 1	0.06	not expected	-	0.06	93	0.06	93	yes

Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product Imidasect is unlikely for the intended uses ‘Application with a cartridge gun‘ and ‘Ready-to-use bait station’. RMM described in chapter 2.5 have to be taken into account in order to ensure a safe use of the biocidal product Imidasect.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

For the components Kelzan XCD and Carbopol EZ 2 Polymer contained in the biocidal product the composition is not fully known. The risk assessment is based on the assumption that the biocidal product contains no further substances relevant for evaluation

3.6.4.7 Risk for non-professional users

Table 56: 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	0.047301	78.8	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, containing 2.194% (w/w) Imidacloprid, is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

3.6.4.8 Risk for the general public

Table 57: 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	3.0716	768	no
Scenario [4b] - Ingestion of a gel bait drop (toddler)	1	40	0.4	0.2194	55	yes
Scenario [4c] – Transient mouthing of bait (toddler)	1	40	0.4	0.02194	5.5	yes

- **Local effects**

Not relevant.

Conclusion

Exposure of the general public to the biocidal product Imidasect, containing 2.194 % (w/w) Imidacloprid, is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.
A risk has been identified for toddlers accidentally ingesting higher amounts of the gel bait. However, since the gel paste contains an aversive agent, is enclosed in a tamper-resistant bait tray and/or will be placed inaccessible for children, pets and other domestic animals, there is no concern against the intended use.
The consumption of one gel bait drop (0.1 g) will lead to an exposure of 0.2194 mg/kg bw (55% of AEL_{acute}). Thus, the consumption of two drops would lead to an exceedance of the AEL_{acute}. However, the consumption of more than one gel bait spot is considered unlikely for the following reasons: (1) Bait spots are hardly visible if dried, (2) the bait contains an aversive agent and (3) the bait is applied inaccessible for children. Even if non-professional users do not comply with the instructions for use this does not, in any case, affect the overall conclusion of a safe use, given that there are sufficient reasons, why an exposure is very unlikely.
No risk has been identified for toddlers, pets and other domestic animals by transient mouthing (ingesting small amounts of the biocidal product) and by exposure to insects contaminated with the biocidal product.
In conclusion, to ensure a safe use of the biocidal product Imidasect, the following risk mitigation measures and safety instruction are required:

- Keep out of reach of children.
- Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children.
- The bait trays applied shall be tamper-resistant. (only uses 5-8)
- Do not force open the bait tray. (only uses 5-8)

3.6.4.9 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.

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

Professional user

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.

3.6.4.11 Summary of risk characterisation

3.6.4.11.1 Summary of risk characterisation for industrial user

No industrial applications are intended.

3.6.4.11.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product Imidasect is unlikely for the intended uses ‘Application with a cartridge gun‘ and ‘Ready-to-use bait station’ (Table Table 55). RMM described in chapter 2.5 have to be taken into account in order to ensure a safe use of the biocidal product Imidasect.

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

3.6.4.11.3 Summary of risk characterisation for non-professional user

Table 58

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	0.047301	78.8	yes

3.6.4.11.4 Summary of risk characterisation for indirect exposure

Table 59

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	3.0716	768	no
Scenario [4b] - Ingestion of a gel bait drop (toddler) Tier 1	0.4	0.2194	55	yes
Scenario [4c] – Transient mouthing of bait (toddler) Tier 1	0.4	0.02194	5.5	yes

3.7 Risk assessment for animal health[10]

The biocidal product Imidasect 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, containing 2.194 % (w/w) Imidacloprid, is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

[10] Pets and domestic animals. Regarding wild animals, please refer to chapter 3.8

3.8 Risk assessment for the environment

3.8.1 General information

The biocidal product Imidasect 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)).

3.8.2 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).

3.8.2.1 Mixture toxicity

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

3.8.2.2 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.[11] 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).

[11] 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)

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.
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 the 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.**

For the product authorisation of the product Imidasect, two studies for the derivation of $PNEC_{STP}$ are considered since 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 acc. to OECD 209), 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. If no inhibition is observed for active substances tested at concentrations exceeding their water solubility, which is the case in both mentioned studies, the NOEC is set equal to the water solubility which is subsequently used to derive the $PNEC_{STP}$. (acc. to Guidance BPR, IV, B+C (2017), Infobox 7) This results in a NOEC of 613 mg/L for the active substance Imidacloprid and the **$PNEC_{STP}$ amounts to 61.3 mg/L**.

3.8.2.3 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.

3.8.2.4 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.

3.8.2.5 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.
From a bird reproduction study a **$PNEC_{oral,bird}$ of 4.2 mg/kg food** was derived.
For mammals a **PNECoral,mammal of 8.3 mg/kg food** was derived from a rat 2-generation-reproduction study.

3.8.2.6 Summary of effects assessment

Table 60

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

Summary table on calculated PNEC values	
Compartment	**PNEC**
Food-chain bird	4.2 mg/kg food
Food-chain mammal	8.3 mg/kg food

3.8.3 Fate and behaviour

Biodegradation

Based on the results from a study on ready biodegradability (acc. to OECD 301 A), 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[12] 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

According to the AR (rev. AR, 2015), an arithmetic mean Ka_{OC} of **230 mL/g** was calculated for Imidacloprid (n=12). Further information got available in frame of a 3rd party dossier. Taking into account the additional values (n=4), an arithmetic mean Ka_{OC} of **186.6 mL/g** was calculated and considered for environmental exposure assessment. This organic carbon-water partitioning coefficient indicates a moderately mobility of the a.s. in soils.

Bioconcentration

12 This value is in accordance with the LoEP, rev. AR for Imidacloprid, 2015. In the meanwhile, the Guidance BPR Vol. IV Part B+C (2017) states that “if up to three DT 50-values from different water-sediment or soil systems are available, the worst case value will be used […].”. Since this endpoint is not used in the environmental exposure assessment, it makes no difference at this point. However, in the context of the a.s. renewal, the value should be revised.

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

3.8.4 Exposure assessment

3.8.4.1 General information

The biocidal product Imidasect is a ready-to-use insecticidal gel formulation containing 2.194 % (w/w) of the active substance Imidacloprid (technical; pure a.s. content: 2.15 % w/w). The biocidal product is intended to be used indoors and outdoors by professionals and by non-professionals in non-food/feed areas, inside residential homes, commercial establishments and public buildings to control cockroaches.

Indoor application: Two different application patterns are foreseen for indoor application of the biocidal product. Firstly, Imidasect may be applied as gel drops directly to the target surface such as hidden areas or places with difficult access (crack and crevice). For gel application of the biocidal product, a typical application rate of 1 – 3 drops per m² is envisaged, each drop containing 0.1 g of the biocidal product. Secondly, Imidasect can be used in ready-to-use bait trays in places where cockroaches can appear. The bait tray consists of a cover and a base layer. The gel formulation is embedded in the inner cavity in the base and both parts of the bait tray are sealed together. The bait tray is activated by replacing a covering sticker which seals the opening of the bait tray. A twofold sticker is placed also underneath the base of the bait tray in order to ease the placement of the trap in vertical surfaces. A maximum application dose of 0.3 g/m² per treatment is envisaged. The applicant states a maximum of 6 applications per year.

Outdoor application: For outdoor treatment, the biocidal product Imidasect is only intended to be used in bait trays. The outdoor use is intended to avoid movement of the target organisms from possible outdoor infestation sources such as vents, air conditioner boxes, drains or house foundations into houses, industrial or commercial buildings (barrier treatment). A maximum application rate of 0.15 g Imidasect per meter building perimeter is foreseen. The purpose of the treatment is a curative treatment where cockroaches can appear. The applicant states a maximum of 6 applications per year.

For the biocidal product Imidasect three different application patterns are foreseen. An environmental exposure assessment for these entire application patterns is described separately in the subsequent paragraphs:

(1) Indoor use in bait trays in private houses and larger buildings (chapter **3.8.4.3**)
(2) Indoor use as gel in private houses and larger buildings (chapter **3.8.4.4**)

(3) Outdoor use in bait trays around private houses and larger buildings (chapter **3.8.4.5**)

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 61

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
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
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	

3.8.4.2 Fate and distribution in exposed environmental compartments

Parameters which describe the fate and distribution of Imidacloprid in the environment are summarised inTable 62. 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 62

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	°C	
Boiling point	Not applicable	°C	Decomposition
Vapour pressure (at 12° C)	2.225×10^{-10}	Pa	
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	Calculated
Biodegradability	Not readily biodegradable		
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)

Following compartments might be exposed by application of the product Imidasect:

Table 63

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

The distribution in the sewage treatment plant is calculated using SimpleTreat v. 4.0. This results in a release fraction to water of 97.64 % and to sludge of 2.36 %. The fraction degraded amounts to 0 % and the release fraction to air is negligible. Since the values for vapour pressure and Henry's law constant are too low for SimpleTreat v. 4.0 (see Table 62), the smallest possible value is entered for the calculations (1×10^{-9}).

3.8.4.3 Indoor use in bait trays in private houses and larger 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 in bait trays, neither direct nor indirect emissions to the aquatic or terrestrial environment can be expected. Thus, the exposure of STP, surface water or sediment and soils or groundwater can be regarded as negligible from the indoor use of the product Imidasect in bait tray. Consequently, an environmental exposure assessment for this use pattern is not performed.

3.8.4.4 Indoor use as gel (open application) in private houses and larger buildings

3.8.4.4.1 Release estimation for indoor gel application

Imidasect is formulated as ready-to-use product (RTU) and is applied as gel drops directly to the target surface such as hidden areas or places with difficult access. Due to the proposed use pattern of the b.p., the application mode can be described as barrier treatment in cracks and crevices. Environmental exposure 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. 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

The input values for determining releases to the environment in the course of the treatmentin cracks and crevices as well as the calculated emission rates are summarised in Table 64. An application rate of 1 – 3 gel drops/m² is envisaged for normal and high infestation, respectively. Each gel drop contains

0.1 g of the biocidal gel formulation. Thus, an application rate of 0.1 – 0.3 $g.m^{-2}$ b.p. is considered for environmental release estimation.
According to ESD PT 18 No. 18 (2008) and TAB ENV 142 (TAB database, status July 2021), for indoor treatment in cracks and crevices in private houses and larger buildings, default target areas of5.9 m^2 and27 m^2 are proposed, respectively. An application frequency of 1 application per day in household/larger 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, only the fraction emitted to the target surface has to be considered in the emission estimation of the application step. 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 0.0129 – 0.0388 $g.d^{-1}$ in private houses and 0.0592 – 0.178 $g.d^{-1}$ in larger buildings.

Table 64: Emission scenario for indoor spot application of Imidasect during application step

Determinants of the emission scenario	**Value**	
	Normal infestation	*High infestation*
Quantity of b.p. applied [$Q_{b.p.}$]	0.1 $g.spot^{-1}$	
Application rate of the b.p. [$APP_{b.p.}$]	1 $spot.m^{-2}$	3 $spots.m^{-2}$
Fraction of a.s. in the product [$F_{a.i.}$]	0.02194	
Quantity of a.i. applied [$Q_{a.s.}$]	0.002194 $g.m^{-2}$	0.006582 $g.m^{-2}$
Area treated with the product [$AREA_{treated}$] *- household* *- com. building*	5.9 m^2 27 m^2	
Number of applications per day per household [$N_{appl, building}$]	1 d^{-1}	
Fraction emitted to air [$F_{application, air}$]	0.0	
Fraction emitted to treated area [$F_{application, treated area}$]	1.0	
Fraction emitted to applicator [$F_{application, applicator}$]	0.0	
Emission rates due to application of Imidasect in households		
Local emission rate to air $E_{application, air} = N_{appl, building} \times F_{application, air} \times Q_{a.s.} \times AREA_{treated}$	0.0 $kg.d^{-1}$	
Local emission rate to treated area $E_{application, floor} = N_{appl, building} \times F_{application, floor} \times Q_{a.s.} \times AREA_{treated}$	1.29 x 10^{-2} $g.d^{-1}$	3.88 x 10^{-2} $g.d^{-1}$
Local emission rate to applicator $E_{application, applicator} = N_{appl, building} \times F_{application, applicator} \times Q_{a.s.} \times AREA_{treated}$	0.0 $kg.d^{-1}$	
Emission rates to due to application of Imidasect in larger buildings		
Local emission rate to air $E_{application, air} = N_{appl, building} \times F_{application, air} \times Q_{a.s.} \times AREA_{treated}$	0.0 $kg.d^{-1}$	
Local emission rate to treated area $E_{application, floor} = N_{appl, building} \times F_{application, floor} \times Q_{a.s.} \times AREA_{treated}$	5.92 x 10^{-2} $g.d^{-1}$	1.78 x 10^{-1} $g.d^{-1}$
Local emission rate to applicator $E_{application, applicator} = N_{appl, building} \times F_{application, applicator} \times Q_{a.s.} \times AREA_{treated}$	0.0 $kg.d^{-1}$	

Release estimation of the b.p. during cleaning step

According to the OECD ESD No. 18, it is assumed that for the considered application pattern the application and cleaning steps take place at the same day. Two cleaning methods are considered:

1. dry cleaning by vacuum/broom and disposable clothes of the applicator resulting in emission to solid wastes,
2. wet cleaning of washable surfaces and applying of washable coveralls resulting in emission to waste water.

In general, the cleaning step will therefore lead to releases either to solid wastes or to waste water. Considering the gel bait application of b.p. in the above-mentioned areas, it might be realistic that residues of Imidasect could be removed by dry cleaning methods. However, the exposure pathway of solid waste to municipal landfill will not be further evaluated.

Furthermore, according to the OECD ESD No. 18, for the envisaged application to target surface such as hidden areas or places with difficult access (crack and crevice), a cleaning efficiency of 3 % is considered. The input and output values for Imidasect are summarised in Table 65. The local emission rates to floor as further required input values are taken from results in Table 64.

Table 65: Emission scenario for indoor spot application of Imidasect during cleaning step

Determinants of the emission scenario	**Value**	
Fraction emitted to air	0	
Cleaning efficiency [F_{CE}]	0.03	
Fraction emitted during cleaning step		
Fraction emitted to waste water from applicator - washable coveralls [$F_{applicator, ww}$]	1	
Fraction emitted to waste water during wet cleaning step [$F_{floor, ww}$]	1	
Fraction emitted to waste from applicator - disposable coveralls [$F_{applicator, w}$]	0	
Fraction emitted to waste during wet cleaning step [$F_{floor, w}$]	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 $E_{floor, ww} = E_{application, floor} \times F_{floor, ww} \times F_{CE}$	*Emission rate [$g.d^{-1}$]*	
	Normal infestation	*High infestation*
- households	3.88×10^{-4}	1.17×10^{-3}
- larger buildings	1.78×10^{-3}	5.33×10^{-3}

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 compartments” 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 the BPR, Vol. IV, Part B+C (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 larger buildings were summed up to perform a cumulative assessment. The input values for determining releases to STP in the course of spot application into cracks and crevices as well as the calculated emission rates are summarised in Table 66. For environmental exposure estimation, only the high application rate is evaluated as worst-case scenario.

According to ESD PT 18 No. 18 (2008) and TAB v2.1 (ENV 140) 4000 public buildings and 300 larger 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. Since the intended use of Imidasect is foreseen with a maximum application frequency of 6 applications per year, the equation for F_{sim} is modified accordingly by omitting the respective summands for daily, weekly and monthly use.

$$F_{sim} = \frac{1.9 \times 32.15 + 0.54 \times 37.82}{100} = 0.815\%$$

The application of the b.p. in a typical scenario results in release of **5.10 x 10^{-2} g.d^{-1}** Imidacloprid to STP.

Table 66: Cumulative and simultaneous emission scenario for indoor spot application of Imidasect during cleaning step

Input	**Value**
Number of houses connected to STP [N_{houses}] - private houses - larger buildings	 4000 300
Simultaneity factor indoor [F_{Sim}]	0.00815
Output	
Simultaneous emission to waste water during cleaning step: $E_{ww\_sim} = E_{floor,\ ww} \times N_{houses} \times F_{Sim}$ - households - larger buildings	 3.80 x 10^{-2} g.d^{-1} 1.30 x 10^{-2} g.d^{-1}
Cumulative emission to waste water:	**5.10x 10^{-2} g.d^{-1}**

3.8.4.4.2 Estimation of Predicted Environmental Concentrations for the aquatic compartment and STP

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} (= $Clocal_{eff}$) according to equation 41, 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 67.

Table 67: Summary of the cumulative 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}]
2.55 x 10^{-2}	2.49 x 10^{-2}	2.49 x 10^{-2}	2.49 x 10^{-3}	1.21 x 10^{-2}

3.8.4.4.3 Estimation of Predicted Environmental Concentrations for the terrestrial compartment

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

Table 68: Summary of the cumulative C_{sludge}, $PECIocal_{soil}$ and $PECIocal_{groundwater}$

C_{sludge} [µg.kg^{-1}]	$PECIocal_{soil}$ [µg.kg^{-1}]	$PECIocal_{groundwater}$ [µg.L^{-1}]
1.523 x 10^{-0}	2.38 x 10^{-3}	4.79 x 10^{-4}

3.8.4.5 Outdoor use in bait trays around private houses and larger buildings

According to ESD PT 18 No. 18 (2008), the only possible emission routes from the outdoor use of bait trays are when the bait tray 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 environmental exposure and risk assessment.

3.8.4.5.1 Release estimation

The outdoor use of Imidasect in bait trays is intended to avoid movement of target organisms from possible outdoor infestation sources such as vents, air conditioner boxes, drains or house foundations into houses, industrial or larger buildings (barrier treatment). A maximum application rate of 0.15 g Imidasect per meter building perimeter is foreseen (i.e. high infestation rate). The purpose of the treatment is a curative treatment where cockroaches can appear. Typically, bait trays are removed when plague or source of cockroaches (nest) ceases or is eliminated. The applicant states a maximum of 6 applications per year.
Due to the proposed use pattern of the b.p., the application mode can be described as barrier treatment (described also as spot application in ESD PT 18 No. 18; p.128). Environmental exposure may arise following flooding from a rain event. These emissions may enter directly into the surrounding soil of the bait tray 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 a STP system. Therefore, release to STP is only considered for the use of Imidasect 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 a treatment around larger buildings and private houses, respectively, as well as the calculated emission rates are summarised in Table 69. An application rate of 0.15 g.m^{-1} Imidasect 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 0.15 g.m^{-1}, this leads to an area of 0.5 m² which is exposed directly to 0.15 g Imidasect or an application rate of 0.3 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 0.15 g.m^{-1}. According to the model to be applied, this leads to an overall application rate of 0.9 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 **6.58 x 10^{-2} g** Imidacloprid per m perimeter. In case of application of the b.p. around private houses, the model of terrace scenario leads to calculated releases of **3.95 x 10^{-3} 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 0.15 g b.p. per m perimeter has to be considered.

For unpaved surfaces, the local emission of b.p. results in **6.58 x 10^{-4} g** Imidacloprid per m perimeter.

Table 69: Emission scenario for outdoor spot application of Imidasect 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 [$Q_{b.p.}$]	0.15 g/m
Fraction of a.s. in the product [$F_{a.i.}$]	0.02149
Quantity of a.s. applied [$Q_{a.s.}$]	0.00329 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 $E_{spot,\ lb} = Q_{b.p} \times F_{a.i} \times PERIMETER_{treated} \times N_{appl} \times F_{spot,soil}$	6.58×10^{-2} g
Local direct emission rate to receiving soil area (terrace scenario private houses (paved surfaces)) $E_{spot,\ soil\_terrace} = Q_{b.p} \times F_{a.i} \times LENGTH_{treated\_hh} \times N_{appl} \times F_{spot,soil}$	3.95×10^{-3} g
Local emission rate to unpaved soil surfaces (private houses and larger buildings) $E_{spot,\ soil} = Q_{b.p} \times F_{a.i} \times N_{sites} \times N_{appl} \times F_{spot,soil}$	6.58×10^{-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 the BPR, Vol. IV, Part B+C (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 70.

According to ESD PT 18 No. 18 (2008) 300 larger buildings are connected to one STP. Furthermore, a simultaneity factor (F_{sim}) was implemented in the ESD PT 18 No. 18 that considers the simultaneity of treatments by the houses connected to the STP. Since the intended use of Imidasect is foreseen with a maximum application frequency of 6 applications per year, the equation for F_{sim} is modified accordingly by omitting the respective summands for daily, weekly and monthly use.

$$F_{sim} = \frac{1.9 \times 32.15 + 0.54 \times 37.82}{100} = 0.815\%$$

The application of the b.p. in a typical scenario around larger buildings results in a simultaneous release of **1.62×10^{-1} g.d^{-1}** Imidacloprid to the STP.

Table 70: Emission scenario for outdoor spot application of Imidasect during application step – release to STP

Determinants of the emission scenario	Value
Local direct emission rate to paved surfaces - larger buildings $E_{spot, lb}$	6.58 x 10^{-2} g.d^{-1}
Number of larger buidlings connected to STP [N_{lb}] - larger buildings	300
Simultaneity factor outdoor [F_{Sim}]	0.0082
Output	
Simultaneous emission to STP: $E_{water\_sim\_lb} = E_{spot, lb} \times N_{lb} \times F_{sim}$	1.62 x 10^{-1} g.d^{-1}

3.8.4.5.2 Estimation of Predicted Environmental Concentrations for the aquatic compartment and STP

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} (= $Clocal_{eff}$) according to equation 41, 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 71.

Table 71: 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}]
8.10 x 10^{-2}	7.91 x 10^{-2}	7.91 x 10^{-2}	7.90 x 10^{-3}	3.83 x 10^{-2}

3.8.4.5.3 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 tray 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 3.87 x 10^{-3} g.d^{-1} Imidacloprid per m perimeter (refer Table 69). The input parameters for calculating PEC_{soil} are summarised in Table 73.

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 73 indicates the PEC in groundwater for Imidacloprid according to the application scenario.

Table 72: $PEC_{soil,direct}$ of Imidasect 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 [$E_{spot,\ soil}$]	3.95 x 10^{-3} 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: $C_{spot,soil} = \frac{E_{spot,\ soil}}{AREA_{exposed} \times DEPTH_{soil} \times RHO_{soil}}$	5.47 x 10^{-4} mg.kg^{-1}
Predicted environmental concentration in soil [PEC_{soil}]	**5.47 x 10^{-1} µg.kg^{-1}**
Local concentration in groundwater due to direct release after a campaign: $PEClocal_{soil,porew} = \frac{PEC_{soil} \times RHO_{soil}}{K_{soil\text{-}water}}$	1.60 x 10^{-1} µg.L^{-1}
Predicted environmental concentration in groundwater [PEC_{gw}]	**1.60 x 10^{-1} µg.L^{-1}**

The PECs in groundwater from application of Imidasect in bait trays around buildings on paved surfaces exceed the trigger value of 0.1 µg.L^{-1} of the groundwater Directive. Since the predicted environmental concentration in groundwater due to releases on paved surfaces is below the calculated value for releases due to applications on unpaved soil, please see the subsequent chapter for more information on the refinement step with FOCUS PEARL (v. 4.4.4).

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 6.58 x 10^{-4} g Imidacloprid per 0.5 m² of soil (refer Table 69). 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 73.

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 73 indicates the PEC in groundwater for Imidacloprid according to the application scenario.

Table 73: $PEC_{soil,direct}$ of Imidasect 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 [$E_{spot,\ soil}$]	6.58 x 10^{-4} 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 m^3.m^{-3}
Output	
Local concentration in soil due to direct release after a campaign: $C_{spot,soil} = \frac{E_{spot,\ soil}}{AREA_{exposed} \times DEPTH_{soil} \times RHO_{soil}}$	1.55 x 10^{-3} mg.kg^{-1}
Predicted environmental concentration in soil [PEC_{soil}]	**1.55 x 10^{0} µg.kg^{-1}**
Local concentration in groundwater due to direct release after a campaign: $PEClocal_{soil,porew} = \frac{PEC_{soil} \times RHO_{soil}}{K_{soil\text{-}water}}$	4.54 x 10^{-1} µg.L^{-1}
Predicted environmental concentration in groundwater [PEC_{gw}]	**4.54 x 10^{-1} µg.L^{-1}**

The PECs in groundwater from application of Imidasect in bait trays around buildings on unpaved surfaces exceed the trigger value of 0.1 µg.L^{-1} of the groundwater Directive.

Therefore, a refinement of the groundwater assessment is necessary.
A refinement step, which leads to a more realistic estimation, is the use of a standard assessment tool to examine the potential mobility of Imidacloprid in soil and the leaching behaviour to groundwater. A scenario-based transport and fate simulation tool is provided by EU FOCUS models (e.g. PELMO and PEARL models). The simulation model FOCUS PEARL 4.4.4 is used for the refinement of $PEC_{groundwater}$. Calculations have been performed for all FOCUS scenarios by consideration of the input parameters in Table 74.

As a worst case assumption, the application rate of 0.15 g Imidasect per 0.5 m² is extrapolated to an application rate of 3000 g Imidasect per ha. Considering a concentration of the a.s. of 2.194 % (w/w), this leads to an application rate of 65.82 g a.s. per ha. The ESD PT 18 No. 18 (2008) indicates that about 80 % of the insecticidal products deposits in bait trays are consumed by the insects whereas 20 % remain in the bait tray and can be emitted into the environment. Thus, the fraction emitted to soil is 20 %, leading to a total release of13.16 g a.s. per ha and treatment. According to the indented use of Imidasect, a maximum of 6 applications per year is envisaged. This release is spread evenly throughout the year, starting on 1th January.

Table 74. Overview of the application rates and dosage for the model PEARL to estimate the leaching potential of Imidacloprid

Input parameter	Value
Application rate: Imidasect Imidacloprid **Fraction a.s. to soil (20%)**	 3.0 kg b.p./ha 65.82 g a.s./ha **13.16 g a.s./ha**
Application time	6 times per year (max): 1th January, 1th March, 1th May, 1th July, 1th September, 1th November
Crop type	grass/alfalfa
Application type	surface application
Plant uptake factor	0.0

The chemical parameters of Imidacloprid used for the FOCUS PEARL simulations are consistent with those described in chapter 0. For a number of input parameters which are required in the simulation models, substance specific data are not available. Thus, default values were used for the simulation. The selected input parameters are summarised in Table 75.

Table 75: Summary of chemical parameters of Imidacloprid used for FOCUS PEARL simulations

Input parameter	Value
Molar mass [g.mol^{-1}]	255.7
Saturated vapour pressure [Pa] at 285 K	2.225 x 10^{-10}
Solubility in water [mg.L^{-1}] at 285 K	545.14
Koc [L.kg^{-1}]	186.6
Kom (coeff. for sorption on organic matter) [L.kg^{-1}]	108.24
Freundlich Sorption Exponent [1/n]	0.8
Half-life [d] at 285 K	135.1
Molar activation energy [kJ.mol^{-1}]	65.4

The results of the groundwater modelling using FOCUS PEARL (v.4.4.4) are shown in Table 76 for all 9 representative locations (FOCUS Scenarios). The average concentration of Imidacloprid closest to the 80th percentile at 1 m soil depth is below the trigger value of 0.1 µg/L (Directive 2006/118/EC; Annex 1) for all FOCUS Scenarios. Since the PEC_{gw} value calculated for direct releases on unpaved soil is worst case compared to the PEC_{gw} value calculated for b.p. treatments on paved soils (terrace scenario), the refinement applies for both b.p. treatments, since modelling was based on the worst-case assumption.

Table 76: Predicted 80th percentile concentrations of Imidacloprid in the percolate at 1 m soil depth for the application of Imidasect in bait trays around buildings

Scenario	Concentration closest to the 80th percentile [µg L^{-1}]
Châteaudun	< 0.000001
Hamburg	< 0.000001
Jokioinen	< 0.000001
Kremsmuenster	< 0.000001
Okehampton	< 0.000001
Piacenza	< 0.000001
Porto	< 0.000001
Sevilla	< 0.000001
Thiva	< 0.000001

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

Table 77: 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}]
4.83 x 10^{0}	7.54 x 10^{-3}	1.52 x 10^{-3}

3.8.4.5.4 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 as the OECD ESD PT 18 No.18 indicates that there is no risk of direct uptake from bait trays.

The OECD ESD PT18 No. 18 (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 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 is 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 No. 18 (2008). The relevant input parameters are presented in
Table Table 78. The values taken from the pick lists of the ESD PT18 No. 18 (2008; Table 5.2-5, 5.2-7) are not repeated here.

Table 78: 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}]	$1.32 \cdot 10^{-6}$ 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 79.

Table 79: Expected daily uptake (ETE) of Imidacloprid for selected indicator species following application of Imidasect around private houses and larger buildings

Species		ETE_{insect} [µg.(kg.d)$^{-1}$]	
		Acute	**Short term**
Pipistrelle	*Pipistrellus pipistrellus*	**1.264 x 10^{-2}**	**4.59 x 10^{-3}**
Shrew	*Sorex araneus*	1.164 x 10^{-2}	4.23 x 10^{-3}
Hedgehog	*Erinaceus europaeus*	2.88 x 10^{-3}	1.05 x 10^{-3}
Badger	*Meles meles*	1.50 x 10^{-3}	5.46 x 10^{-4}
Tree sparrow	*Passer domesticus*	**5.60 x 10^{-2}**	**3.12 x 10^{-2}**
Blackbird	*Turdus merula*	1.42 x 10^{-2}	5.17 x 10^{-3}
Black-billed Magpie	*Pica pica*	7.57 E x 10^{-3}	2.76 x 10^{-3}

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.

3.8.4.6 Atmosphere

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

3.8.4.7 Aggregated exposure (combined for relevant emission sources)

An agreed guidance document for aggregated exposure assessment is not available, yet. Therefore, such an assessment was not conducted.

3.8.5 Risk characterisation

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

3.8.5.1 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 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 in bait trays.

3.8.5.2 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.

3.8.5.2.1 Sewage treatment plant

Table 80: PEC / PNEC ratio for sewage treatment plant

Compartment	PEC [mg/L]	PNEC [mg/L]	PEC / PNEC
Sewage treatment plant (STP)	2.49×10^{-5}	61.3	4.06×10^{-7}

Conclusion: A PEC/PNEC ratio of 4.06×10^{-7} was derived. Therefore, an unacceptable risk for sewage treatment plants from the indoor use of Imidasect as gel in private houses and commercial buildings is not to be expected.

3.8.5.2.2 Aquatic compartment (incl. Sediment)

Table 81: PEC / PNEC ratio for the aquatic compartment (surface water and sediment)

compartment	PEC	PNEC	PEC / PNEC
Surface water	2.49×10^{-3} µg/L	4.8×10^{-3} µg/L	0.52
Sediment	1.21×10^{-2} µg/kg ww	2.6×10^{-2} µg/kg ww	0.47

Conclusion: A PEC/PNEC ratio for surface water of 0.52 and for sediment of 0.47 was derived. Therefore, it can be concluded that the indoor use of Imidasect as gel in private houses and commercial buildings does not pose an unacceptable risk for surface water and sediment.

3.8.5.2.3 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 82: PEC / PNEC ratio for the terrestrial compartment (soil)

Compartment	PEC [µg/kg]	PNEC [µg/kg]	PEC / PNEC
Soil	2.38 x 10^{-3}	15.75	1.51 x10^{-4}

Conclusion A PEC/PNEC ratio for soil of 1.51 x 10^{-4} was derived. Therefore, it can be concluded that the indoor use of Imidasect as gel does not pose an unacceptable risk for the soil compartment.

Groundwater

Conclusion: For groundwater a concentration of 4.79 x 10^{-4} 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, there is no concern for groundwater.

3.8.5.2.4 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.

3.8.5.3 Outdoor use in bait trays 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.

3.8.5.3.1 Sewage treatment plant

Table 83: PEC / PNEC ratio for sewage treatment plant

Compartment	PEC [mg/L]	PNEC [mg/L]	PEC / PNEC
Sewage treatment plant (STP)	7.91 x 10^{-5}	61.3	1.29 x10^{-6}

Conclusion: A PEC/PNEC ratio of 1.29 x 10^{-6} was derived. Therefore, it can be concluded that no unacceptable risk for the sewage treatment plant arises from the outdoor use of Imidasect in bait trays.

3.8.5.3.2 Aquatic compartment (incl. Sediment)

Table 84: PEC / PNEC ratio for the aquatic compartment (surface water and sediment)

compartment	PEC	PNEC	PEC / PNEC
Surface water	7.90 x 10^{-3} µg/L	4.8x10^{-3} µg/L	**1.65**
Sediment	3.83 x 10^{-2} µg/kg	2.6 x 10^{-2} µg/kg	**1.47**

Conclusion: A PEC/PNEC ratio for surface water of 1.65 and for sediment of 1.47 was derived. Therefore, an **unacceptable risk for surface water and sediment** due to the outdoor use of the biocidal product Imidasect in bait trays is to be expected by flooding from rain events.

3.8.5.3.3 Terrestrial compartment

The terrestrial compartment may be exposed either directly after release of the a.s. to the surrounding soil of the bait tray by flooding from rain events 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 both to paved as well as unpaved surfaces. As the release to unpaved surfaces leads to higher PECs for both soil and groundwater, only this scenario is considered as worst case for the risk characterisation, as it covers also the release scenario to paved surfaces.

Soil

Table 85: PEC / PNEC ratio for the terrestrial compartment (soil)

Compartment	PEC [µg/kg]	PNEC [µg/kg]	PEC / PNEC
Soil	1.55	15.75	9.8 x10^{-2}

Conclusion: A PEC/PNEC ratio for soil of 9.8 x10^{-2} was 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.

Groundwater

Conclusion: For groundwater concentrations of **4.54 x 10^{-1} µg/L** (b.p. treatment on unpaved soil) and **1.60 x 10^{-1} µg/L** (b.p. treatment on paved soil – terrace scenario) were predicted, which exceed the limit value of 0.1 µg/L from directive 98/83/EC. Thus, a refinement of the groundwater assessment was performed for the worst case b.p. treatment on unpaved soil as the results also cover applications on paved soil. Using FOCUS PEARL simulation, the following values were determined:

Scenario	Concentration closest to the 80th percentile [µg L^{-1}]
Châteaudun	< 0.000001
Hamburg	< 0.000001
Jokioinen	< 0.000001
Kremsmuenster	< 0.000001
Okehampton	< 0.000001
Piacenza	< 0.000001
Porto	< 0.000001
Sevilla	< 0.000001
Thiva	< 0.000001

As all of the 9 representative locations from the FOCUS scenario are clearly below the limit concentration of 0.1 µg/L, no concern for groundwater is expected from the direct release on both paved and unpaved surfaces from the outdoor use in bait trays.

Indirect Release

Soil

Table 86: PEC / PNEC ratio for the terrestrial compartment (soil)

Compartment	PEC [µg/kg]	PNEC [µg/kg]	PEC / PNEC
Soil	7.54 x 10^{-3}	15.75	4.8 x 10^{-4}

Conclusion A PEC/PNEC ratio for soil of 4.8 x $10^{-4}$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

Conclusion: For groundwater a concentration of 1.52 x 10^{-3} µg/L was predicted, that is clearly below the limit concentration of 0.1 µg/L. Thus, no concern for groundwater is expected from the indirect release via sludge application from the outdoor use in bait trays.

3.8.5.3.4 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 air is expected to be low.

3.8.5.4 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.

Table 87: PEC/PNEC ratio for secondary poisoning of birds and mammals following application of Imidasect around private houses and commercial buildings

exposure scenario	PEC_{oral} [$mg \cdot kg^{-1}$]	$PNEC_{oral}$ [$mg \cdot kg^{-1}_{feed}$]	PEC/PNEC
birds feeding on insects (acute)	5.60×10^{-5}	4.2	$1.33 \cdot 10^{-5}$
birds feeding on insects (short-term)	3.12×10^{-5}	4.2	$7.43 \cdot 10^{-6}$
mammals feeding on insects (acute)	1.26×10^{-5}	8.3	$1.52 \cdot 10^{-6}$
mammals feeding on insects (short-term)	4.59×10^{-6}	8.3	$5.453 \cdot 10^{-7}$

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 in bait stations around buildings.

3.8.5.5 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. 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**

  The 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.

3.8.5.6 Endocrine disrupting properties

Active substance

According to the CAR for Imidacloprid, 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.

Biocidal Product

The full composition of the product as well as the results of the ED-assessment of the co-formulants are summarised in the confidential Annex (Section 5).

3.8.5.7 Summary of risk characterisation

The biocidal product Imidasect 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. Three different use patterns were considered: indoor use in bait trays, indoor use as open gel application and outdoor use in bait trays around private houses and commercial buildings.

The risk assessment shows, that the indoor use of the biocidal product Imidasect against cockroaches both in bait trays and as open gel application does not result in an unacceptable risk for any of the environmental compartments considered.

In case of outdoor use of the product Imidasect around private houses and commercial buildings in bait trays and assuming flooding of the product caused by rain events, an unacceptable risk for both surface water (PEC/PNEC 1.6) and sediment (PEC/PNEC 1.4) from indirect release via STP is identified. However, as the biocidal product is used in bait trays, releases to the environment are only assumed to occur by flooding from rain events. Thus, releases into the environment may significantly be reduced, if the bait trays are put in places where they are protected from rain events and consequently the unacceptable risks for the environmental compartments, which have been identified in the environmental risk assessment, can be reduced to an acceptable level. Therefore, the following risk mitigation measures should be clearly labelled on the product:

“Apply only in areas that are not liable to submersion or becoming wet, i.e. protected from rain, floods and cleaning water.“

“**Do not use the product where release to drains (sewers) cannot be prevented.”**

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

3.10.1 Background

The product Imidasect contains the active substance Imidacloprid, which meets the criteria for substitution under Article 10 of the Biocides Regulation (EU) No 528/2012[13] (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 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[14] for this comparative assessment. The database last updated on 08.06.2021 contained information on 5143 biocidal products.

3.10.2 Application administrative details

Procedure: Renewal of National Authorisation (NA-RNL)
Purpose: Renewal of authorisation
Case Number in R4BP: BC-LJ056204-43
Evaluating Competent Authority: Germany (BAuA)
Applicant: Sharda Europe B.V.B.A
(Prospective) Authorisation holder: Sharda Cropchem España S.L.

3.10.3 Administrative information of the BP

Trade name: Imidasect

[13] 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.
[14] https://echa.europa.eu/de/information-on-chemicals/biocidal-products

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

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

The biocidal product Imidasect 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 cockroaches.

Table 88 lists the intended uses of the biocidal product, which determines the focus of the comparative assessment.

Table 88: Intended use(s) of the biocidal product

Product type(s)	Insecticide (PT 18)
Where relevant, an exact description of the authorised use	This product can only be used for the control of cockroaches
Target organism (including, where relevant) development stage)	Small cockroaches (German cockroach) Big cockroaches (Oriental cockroach)
Field(s) of use	Indoors, outdoors
Application method(s)	Open application; in bait stations
Category(ies) of users	Non-professional; professional

The Imidasect gel is placed on the market as a ready-to-use product and applied openly (in form of small drops) or in bait stations.
It is effective against small cockroaches (German cockroach) and big cockroaches (Oriental cockroach).
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.

3.10.5 Mapping of existing alternatives to the relevant BP

Identified eligible alternative BPs

The information on biocidal products provided by the ECHA[15] 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).

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

33 of these are authorised for use against German and Brown banded cockroaches.

These biocidal products are based on the following active substances:

1) Deltamethrin
2) Indoxacarb (enantiomeric reaction mass S:R 75:25)
3) alpha-Cypermethrin
4) Dinotefuran
5) Etofenprox
6) Permethrin
7) Imidacloprid
8) Clothianidin
9) Fipronil
10) Pyriproxyfen
11) S-Methoprene
12) Hydrogen cyanide
13) Nitrogen
14) Carbon dioxide

Clothianidin and Fipronil are candidates for substitution themselves.
All products containing the active substances Pyriproxyfen or S-Methoprene contain Imidacloprid too.
Products based on Hydrogen cyanide, Nitrogen and Carbon dioxide are fumigation products with all their intrinsic hazards.
Accordingly, the only remaining alternative products for the control of cockroaches are based on:

1) Deltamethrin
2) Indoxacarb (enantiomeric reaction mass S:R 75:25)
3) alpha-Cypermethrin
4) Dinotefuran
5) Etofenprox
6) Permethrin

However, in Germany only the products based on Deltamethrin and Indoxacarb (enantiomeric reaction mass S:R 75:25) are authorised for both indoor and outdoor use.
Table 89 lists the mode of action of the remaining active substances and the risk of resistance development.

Table 89: 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 3.5.4).	Yes
Deltamethrin	Deltamethrin belongs to the family of pyrethroids and is a sodium channel modulator. Pyrethroids impair ion transport	Yes

	through the membrane of nerve axons, causing muscular paralysis in the insect; death seems to follow a nervous system impairment that occurs a few minutes to several hours after pesticide absorption. The primary site of activity of deltamethrin is the voltage sensitive sodium channel in nerve membrane. Deltamethrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyperexcitability. Deltamethrin acts primarily by contact but also by ingestion.	
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 pyrazoline-like insecticide.	Yes

Identified eligible non-chemical alternatives

Not relevant in the screening phase

3.10.6 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

The development of resistance to insecticides in cockroaches is increasing. Resistance to all the major groups of insecticides (pyrethroids, organochlorines, organophosphates and carbamates) have been reported in the USA. In the UK, cockroach resistance is known to the pyrethroids and organophosphates. The potential for resistance development in German cockroaches to abamectin and Imidacloprid has also been reported. Therefore, resistance management strategies should be used. Alternation or combination of insecticides having a different mode of action is 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 cockroaches.

The comparative assessment is finalised at this stage. The product Imidasect 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 90

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	4.16	IMIDASECT Test for determination the corrosive properties to metals. Report no. BC-20/21	Petryka, M.	2021	Sharda Cropchem Limited 2nd Floor, Prime Business Park Dashrathal Joshi Road, Vile Parle (West), Mumbai 400056, India
2	6.7	Study of palatability and mortality of IMIDASECT (Imidaclroprid 2.15%) bait gel against Blatella germanica and Blatta orientalis in bait traps. Report no. 368KAMG4902/R0	Tosky, J.	2021	Sharda Cropchem Ltd
3	6.7	Study of palatability and mortality of Imidacloprid 2.15% bait gel against Blattella germanica and Blatta orientalis in bait traps Report no. 368KAMG4902/R0	Tosky, Jophy	2021	Sharda Cropchem Ltd.
4	6.7	Study of palatability and mortality of IMIDASECT (Imidacloprid 2.15%) bait gel against Blattella germanica and Blatta orientalis Report no. 368KAMG4905/R0	Tosky, J.	2021	Sharda Cropchem Ltd.
5	6.7	Study of palatability and mortality of Imidacloprid 2.15% bait gel against Blattella germanica and Blatta orientalis Report no. 368KAMG4905/R0	Tosky, Jophy	2021	Sharda Cropchem Ltd
6	6.7	Field efficacy assessment of IMIDASECT (Imidacloprid 2.15%) bait gel against B. germanica and B. orientalis applied in bait traps	Yadav, A.	2021	Sharda Cropchem Ltd

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
		Report no. 368KAMG4903/R0			
7	6.7	Field efficacy assessment of Imidacloprid 2.15% bait gel against B. germanica and B. orientalis applied in bait traps. Report no. 368KAMG4903/R0	Yadav, Aviraj	2021	Sharda Cropchem Limited
8	6.7	Field efficacy assessment of IMIDASECT (Imidacloprid 2.15%) bait gel against B. germanica and B. orientalis in outdoor areas as bait traps Report no. 368KAMG4904/R0	Yadav, A.	2021	Sharda Cropchem Ltd.
9	6.7	Field efficacy assessment of Imidacloprid 2.15% bait gel against B. germanica and B. orientalis in outdoor areas as bait traps Report no. 368KAMG4904/R0	Yadav, Aviraj	2021	Sharda Cropchem Ltd
10	6.7	Evaluation of efficacy of cockroach gel Imidacloprid 2.15% (batch 200183). Method BioG B 950-01 Report no. BIO147-12	Radecki, C.	2012	SHARDA Worldwide Exports Pvt. Ltd.
11	6.7	Field trials to determine the efficacy of Imidacloprid 2.15% gel against two cockroach species Report no. 14/363	Heaven, H	2015	Sharda CropChem Ltd Domnic Holm, 29 th Road, Bandra (West) Mumbai - 400 050 India
12	6.7	FIELD TRIAL OF THE EFFICACY OF AN INSECTICIDAL BAIT TRAP TO CONTROL GERMAN AND ORIENTAL COCKROACHES Report no. 2126a/0816R	Serrano, B	2016	SHARDA CROPCHEM Ltd Dominc Holm, 29th Road Bandra (West), Mumbai 400050 INDIA
13	6.7	Laboratory trial of the efficacy of an insecticidal bait trap to control german and oriental cockroaches. Report no. 2126b/0816R	Serrano, B.	2016	SHARDA CROPCHEM Ltd Dominc Holm, 29th Road Bandra (West), Mumbai 400050 INDIA

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.xlsx