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	SOFAST
Product type(s):	18 (Insecticides, acaricides and products to control other arthropods)
Active ingredient(s):	Imidacloprid; Cis-tricos-9-ene
Case No. in R4BP	BC-LS052997-00 (Major change) BC-XV010731-14 (initial assessment)
Asset No. in R4BP	DE-0008815-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/18.00007 710-05-18-00007-00-01-00-0000
Date	02.07.2021 (Major change) 29.09.2017 (initial assessment)

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1 Conclusion

The product SOFAST consists of water-dispersable granules with the active substances imidacloprid and cis-tricos-9-ene. It is used as an insecticide (product-type 18) for the control of houseflies and stable flies.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled for professional users. The authorised uses are:

- Indoor use (industrial or commercial premises, households, private and public areas) dispersed granules (painted on cardboards only) and of granular bait in shallow disposable dishes.
- Indoor use (livestock facilities) dispersed granules (painted on cardboards only) and of granular bait in bait stations (use against stable flies only).

The environmental risk assessment (see chapter 3.7) of the intended uses has shown unacceptable risks for the aquatic compartment (surface water and sediment). The non-professional user cannot follow the extensive risk mitigation measures, which are necessary to ensure a safe use of the biocidal product. Hence, the intended uses for the non-professional user cannot be authorised.

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[2] 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 lowest available effect value for the aquatic compartment in the amended List of Endpoints, resulting in a lower PENCaqua for the active substance imidacloprid as agreed at the BPC-WG

[1] 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.
[2] 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.

ENV IV in September 2014 and adopted at the 11th meeting of the Biocidal Products Committee (BPC) in June 2015.

3. The conclusions and recommendations of the Austrian Assessment Report for the approval of the active substance cis-tricos-9-ene including the “elements to be taken into account by Member States when authorising products” as requested by the Austrian CA.
4. The specific provisions from the Inclusion Directive for the active substance imidacloprid (Commission Directive 2011/69/EU).
5. The specific provisions from the Inclusion Directive for the active substance cis-tricos-9-ene (Commission Directive 2012/38/EU).

Approval of the active substances

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.
- 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.

The active substance cis-tricos-9-ene is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as outdoor use and exposure of food or feed, were excluded. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where 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.
- For products containing cis-tricos-9-ene that may lead to residues in food or feed, Member States shall verify the need to set new or to amend 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 product SOFAST consists of water-dispersable granules and contains the active substances imidacloprid and cis-tricos-9-ene.

No substance of concern has been identified.

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

Physical, chemical and technical properties

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

Physical hazards and respective characteristics

Physical-chemical hazard(s) were not identified (please find more information in chapter 3.2).

Methods for detection and identification

Information on the analytical methods for the active substances is provided in chapter 3.3 and in annex 4.3. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

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

Risk assessment for human health

Since no substance of concern has been identified the human health risk assessment for this product is based on the active substances imidacloprid and cis-tricos-9-ene.

A human health risk assessment has been carried out for for all intended uses. The human health risk assessment has been carried out for both active substances for non-professional as well as professional use of the product (see chapter 3.5).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to non-professional, professional users, bystanders and residents. Regarding non-professional and professional users' health protection, there are no objections against the intended uses if the directions for use according to chapter 2.5 and in addition chapter 3.5.3 for spray- and brush treatment are followed.

Risk assessment for the environment

Since no substance of concern has been identified the risk assessment for the environment for this product is based on the active substances imidacloprid and cis-tricos-9-ene.

A risk assessment for the environment has been carried out for all intended uses (see chapter 3.1).
Based on the risk assessment (see chapter 3.7) it is unlikely that the intended use(s) by the professional user cause any unacceptable risk for the environment if the directions for use according to chapter 2.5 and the risk mitigation measures according to chapter 3.7.3.6 are followed.
The non-professional user cannot follow the extensive risk mitigation measures, which are necessary to ensure a safe use of the biocidal product. Hence, the intended uses for the non-professional user cannot be authorised. The bait application by professional users and painting by professional users - with the BP being applied on disposable cardboards and with disposable clothes worn by the applicator - can be authorised.

Comparative Assessment

Since the active substance Imidacloprid has been identified as a candidate for substitution (see also chapter 2.2.4 (Candidate(s) for substitution)) a comparative assessment has been necessary (see chapter 3.9 (Comparative assessment)). The corresponding Comparative Assessment Report was forwarded to ECHA on 29.09.2017.
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

SOFAST

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	EKOPREVENT KFT Komló u. 10. 1222 Budapest Hungary

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 Shijizhuang China

Active substance	*cis*-tricos-9-ene (Muscalure)
Name of manufacturer	Denka International Holding B.V.
Address of manufacturer	Hanzeweg 1 NL-3771 NG Barneveld Netherlands
Location of manufacturing sites	Hanzeweg 1 NL-3771 NG Barneveld Netherlands

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Imidacloprid	(2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine	Active substance	138261-41-3	428-040-8	0.52
cis-tricos-9-ene (Muscalure)	(Z)-Tricos-9-en	Active substance	27519-02-4	248-505-7	0.10

- The product contains a bittering agent.

- Information on the full composition is provided in the confidential[3] annex (see chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

- Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

  Yes ☐

  No ☒

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

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?
    - **Imidacloprid**

Yes ☐

No ☒ (The technical equivalence of the active substance Imidacloprid from the new source was established by the German CA in August 2013, see Technical Equivalence Report)

- **cis-tricos-9-ene (Muscalure)**

Yes ☒

No ☐

2.2.3 Information on the substance(s) of concern

No substance of concern was identified.

2.2.4 Candidate(s) for substitution

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

- Imidacloprid

The following criteria for substitution are met:

- Very persistent
- Toxic

2.2.5 Type of formulation

Water-dispersable granules

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[4]

The current harmonised classification of the active substance imidacloprid is based on Commission Regulation (EU) No. 790/2009 (1st ATP)[5]. While no M-factors are given in the 1st ATP, the most recent effect data from the publication Roessink *et al.* (2013) and the following M factors derived (M100 (acute) and M1000 (chronic)) were considered for the assessment.

Next to imidacloprid, the biocidal product contains 0.1% of the active substance *cis*-tricos-9-ene (muscalure). For *cis*-tricos-9-ene the harmonized classification is based on Commission Regulation (EU) No. 605/2014 (6th ATP)[5].

The classification of the biocidal product SOFAST regarding the environment is solely based on the classification of the active substance imidacloprid as H400 and H410 with M-factor 100 (acute) and 1000 (chronic). With an active substance content of 0.52%, the classification of the biocidal product results in H400 and H410.
A classification regarding human health or physico-chemical properties is not required.
However, labelling with a supplemental hazard statement is required. Based on the concentration of the active substance cis-tricos-9-ene (Muscalure) in the biocidal product the additional labelling EUH208 is required according to Regulation (EC) No 1272/2008.
Besides the active substances, no other components affect the classification of the product.

4 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.
5 See: https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database

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”)	
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 cis-Tricos-9-ene. May produce an allergic reaction.
Supplemental label elements	-	None
Precautionary statements	P273	“Avoid release to the environment”
	P391	“Collect spillage”
	P501	“Dispose of contents/containers according to national legislation”

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.4 and 2.5.

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[6]

2.4.1 Use 1 appropriate for authorisation – Professional use: painting on cardboards

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Flies –Muscidae (imagines; adults)
Field(s) of use	Indoor use (industrial/commercial premises; households/ private areas; public areas)
Application method(s)	Painting on cardboards
Application rate(s) and frequency	In order to treat a room/building with a floor surface of 100 m^2 200 g of the product are dispersed in 150mL water and applied to cardboard sheets with a total surface of 1m^2. The cardboard sheets are then distributed in the area to be treated. Up to 6 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	10g bag HDPE 10g, 50g, 100g bottle HDPE or PP 300g, 350g bottle HDPE 1kg, 2kg bucket PP or Polyester with LDPE sealing film in a cardboard case 50g, 300g, 1kg, 2kg can PP or Polyester with LDPE sealing film in a cardboard case 1kg, 2kg complex bag (foil of complex material made of LDPE + polypropylene or polyester or paper)

2.4.1.1 Use-specific instructions for use

1) Mix well before application.
2) Use the dispersion within 8 hours after mixing.
3) Place cardboards where flies prefer to rest.
4) Check the cardboards every week and renew the application when there is no product or the cardboards are covered with dirt.

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

2.4.1.2 Use-specific risk mitigation measures

1) Apply only on non-absorbent cardboards which are then to be fixed to walls or ceilings where flies prefer to rest.
2) The area, where mixing/loading and the application to cardboards take place, must be covered with a disposable plastic sheet in order to avoid contamination of adjacent surfaces and floor.
3) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
4) For the mixing/loading and the application step the applicator must wear disposable clothes (e.g. paper smocks, aprons, overall) to avoid emissions to the sewer system due to washing of contaminated clothes.
5) Do not let the product or its residues or painting sludge enter soil, water courses or the sewer systems.
6) When applying the product on cardboards leave an untreated area around the edge.
7) When fixing the treated cardboards to walls or ceilings or collecting them for disposal touch only the untreated area around the edge.
8) Do not clean the cardboards.

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

None

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

Disposal of contaminated plastic sheets, disposable clothes and cardboards after use and all other waste (brush cleaning water, material used for spill cleaning, etc…) to residual waste as specified by the local disposer.

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

None

2.4.2 Use 2 appropriate for authorisation – Professional use: bait application in disposable shallow dishes

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Flies –Muscidae (imagines; adults)
Field(s) of use	Indoor use (industrial/commercial premises; households/ private areas; public areas)
Application method(s)	Bait application
Application rate(s) and frequency	20g for 10m^2 floor area to be treated; one bait point (disposable shallow dishes) per 10m^2 floor area. Up to 6 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	10g bag HDPE 10g bottle HDPE or PP 50g, 100g bottle HDPE or PP with dosing spoon/beaker 300g, 350g bottle HDPE with dosing spoon/beaker 1kg, 2kg bucket PP or Polyester with LDPE sealing film in a cardboard case with dosing spoon/beaker 50g, 300g, 1kg, 2kg can PP or Polyester with LDPE sealing film in a cardboard case with dosing spoon/beaker 1kg, 2kg complex bag (foil of complex material made of LDPE + polypropylene or polyester or paper) with dosing spoon/beaker

2.4.2.1 Use-specific instructions for use

1) Place granules in disposable shallow dishes avoiding the formation of piles.
2) Use the included dosing spoon/beaker when measuring the granules.
3) Create bait points with 20g granules every 10m², only up high (shelves, ledges, walls).
4) It is advisable to moisten the granules for greater efficiency.
5) Check bait points every 2 to 3 days.
6) Remove application when the granules are covered with dust.

2.4.2.2 Use-specific risk mitigation measures

1) For professional use only. The people responsible for cleaning the treated areas are to be instructed by the professional user on the following Risk Mitigation Measures (2 - 6)) to ensure that the product does not reach the sewer system. 2) Use only disposable shallow dishes and the dosing spoon to place the granular bait. 3) Product spills, residues and dead flies must be collected immediately by dry cleaning methods only (i.e. brush, vacuum cleaner or disposable cloth) with subsequent disposal via solid waste. 4) Do not wet wash the surfaces contaminated with the product or its residues or use disposable wet wipes with subsequent disposal via solid waste. 5) Ensure that spills from the application devices are avoided by un-intentional movement of the product through e.g. wind, humans or larger animals. 6) Do not wet clean the dosing spoon and the disposable shallow dishes. 7) Collect product residues, product spills and all other waste for disposal in accordance with local requirement after treatment. 8) Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.

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

None

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

None

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

None

2.4.3 Use 3 appropriate for authorisation – Professional use in livestock facilities: painting on cardboards

Product Type(s)	18

Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Flies –Muscidae (imagines; adults)
Field(s) of use	Indoor use (livestock facilities)
Application method(s)	Painting on cardboards
Application rate(s) and frequency	In order to treat a room/building with a floor surface of 100 m^2 200 g of the product are dispersed in 150mL water and applied to cardboard sheets with a total surface of 1m^2. The cardboard sheets are then distributed in the area to be treated. Up to 6 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	10g bag HDPE 10g, 50g, 100g bottle HDPE or PP 300g, 350g bottle HDPE 1kg, 2kg bucket PP or Polyester with LDPE sealing film in a cardboard case 50g, 300g, 1kg, 2kg can PP or Polyester with LDPE sealing film in a cardboard case 1kg, 2kg complex bag (foil of complex material made of LDPE + polypropylene or polyester or paper)

2.4.3.1 Use-specific instructions for use

1) Mix well before application.
2) Use the dispersion within 8 hours after mixing.
3) Place cardboards where flies prefer to rest.
4) Check the cardboards every week and renew the application when there is no product or the cardboards are covered with dirt.
5) It is recommendable to complement the treatment in livestock facilities with a larvicide product.

2.4.3.2 Use-specific risk mitigation measures

1) Apply only on non-absorbent cardboards which are then to be fixed to walls or ceilings where flies prefer to rest.
2) The area, where mixing/loading and the application to cardboards take place, must be covered with a disposable plastic sheet in order to avoid contamination of adjacent surfaces and floor.

3) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). 4) For the mixing/loading and the application step the applicator must wear disposable clothes (e.g. paper smocks, aprons, overall) to avoid emissions to the sewer system due to washing of contaminated clothes. 5) Do not let the product or its residues or painting sludge enter soil, water courses or the sewer systems. 6) When applying the product on cardboards leave an untreated area around the edge. 7) When fixing the treated cardboards to walls or ceilings or collecting them for disposal touch only the untreated area around the edge. 8) Do not clean the cardboards. 9) Remove all pieces of treated cardboards before cleaning and/or disinfectant events in livestock facilities. 10) Place cardboards treated with biocidal product out of reach of livestock animals. 11) Do not apply the biocidal product directly on manure/slurry.

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

None

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

Disposal of contaminated plastic sheets, disposable clothes and cardboards after use and all other waste (brush cleaning water, material used for spill cleaning, etc…) to residual waste as specified by the local disposer.

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

None

2.4.4 Use 4 appropriate for authorisation – Professional use in livestock facilities: bait application in bait stations

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Stable flies (*Stomoxys calcitrans*) (imagines; adults)
Field(s) of use	Indoor use (livestock facilities)
Application method(s)	Bait application
Application rate(s) and frequency	20g for 10m^2 floor area to be treated; One bait station per 10m^2 floor area. Up to 6 applications per year.
Category(ies) of users	Professional
Pack sizes and packaging material	10g bag HDPE 10g bottle HDPE or PP 50g, 100g bottle HDPE or PP with dosing spoon/beaker 300g, 350g bottle HDPE with dosing spoon/beaker 1kg, 2kg bucket PP or Polyester with LDPE sealing film in a cardboard case with dosing spoon/beaker 50g, 300g, 1kg, 2kg can PP or Polyester with LDPE sealing film in a cardboard case with dosing spoon/beaker 1kg, 2kg complex bag (foil of complex material made of LDPE + polypropylene or polyester or paper) with dosing spoon/beaker

2.4.4.1 Use-specific instructions for use

1) Use the included dosing spoon/beaker when measuring the granules.
2) Place bait stations with 20g granules every 10m², only up high (shelves, ledges, walls).
3) It is advisable to moisten the granules for greater efficiency.
4) Check bait stations every 2 to 3 days.
5) Remove application when the granules are covered with dust.
6) It is recommendable to complement the treatment in livestock facilities with a larvicide product.

2.4.4.2 Use-specific risk mitigation measures

1) Apply only in recommended bait stations (specific for flies). Use the dosing spoon to place the granular bait.
2) Do not wet clean the dosing spoon and the bait stations.

3) Place bait stations out of reach of livestock animals. 4) Do not apply the biocidal product directly on manure/slurry. 5) Remove all bait stations before cleaning and/or disinfectant events in livestock facilities.

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

None

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

None

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

None

2.5 General directions for use[7]

2.5.1 Instructions for use

1) Start treatment at the beginning of fly season to prevent massive proliferation. 2) Avoid continuous use of the product. 3) Alternate products containing active substances with different mode of action (to remove resistant individuals from the population). 4) Inform the authorisation holder if the treatment is ineffective. 5) This biocidal product contains the active substance Imidacloprid which is dangerous to bees.

2.5.2 Risk mitigation measures

1) Always read the label or leaflet before use and follow all the instructions provided.

7 [Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.]

2) 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.
3) Keep out of reach of children, pets and livestock.
4) Bait points and stations shall be out of reach of children, pets and livestock.
5) Clean up spills of the biocidal product immediately.
6) Avoid any unnecessary contact to the product. Misuse may cause health damage
7) Do not empty into drains.
8) Do not let the product, product waste or washing water from cleaning equipment (e.g. mugs, brush) enter into water courses or the sewer system.
9) The product can be applied in the presence of animals, if contact with the biocidal product is avoided.

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

Basic first aid measures:

1) If medical advice is needed, have product container or label at hand.
2) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
3) IF ON SKIN: Wash with plenty of soap and water.
4) IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
5) IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.

Medical advice for doctors and sanitary staff:

6) Symptomatic and supportive treatment

2.5.4 Instructions for safe disposal of the product and its packaging

1) Keep only in original container.
2) Do not mix with other wastes.
3) Residues of the biocidal product and all other contaminated waste (e.g. washing water from cleaning equipment (e.g. mugs, brush), material to collect product spills, dead flies) must be disposed off in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations.
4) Containers containing residues of the product have to be handled accordingly:

- European waste catalogue (EWC) Waste code 15 01 10*: packaging containing residues of or contaminated by dangerous substances
- European waste catalogue (EWC) Waste code 20 01 19*: pesticides

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

1) Shelf-life: 12 months
2) Protect from sunlight
3) Keep away from food, drinks and feeding stuff.

2.5.6 Other information

The product contains a bittering agent.

2.6 Packaging

Table 3

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
Bag	10g	HDPE	-	Non-professional, professional	Yes
Bottle	10g, 50g, 100g,	HDPE or PP			
Bottle	300g, 350g	HDPE			
Bucket	1kg	PP or Polyester with LDPE sealing film in a cardboard case			
Bucket	2kg			Professional	
Can	50g, 300g, 1kg			Non-professional, professional	
Can	2kg			Professional	
Complex Bag	1kg	Foil of complex material made of LDPE + polypropylene or polyester or paper		Non-professional, professional	
Complex Bag	2kg			Professional	

Dosing system:

For exact measuring, also to avoid misuse by over- or underdosing, the larger packaging types (50 g – 2 kg) will include a dosing spoon/beaker.

Maximum packsize for the non-professional user:

In order to adapt the package size for the non-professional user to the application rate, frequency and shelf life of the product, the pack size for non-professional users is limited to 1 kg.

With a shelf life of one year, max. 6 applications per year and an application rate of 200 g/100 m^2 an average household (130 m^2 flat (according to agreed assessment scenario)) would need a maximum of 1560 g product/year. Taking into account the classification of the product as H400/H410 this means that approximately 25% of the 2 kg pack would automatically turn into hazardous waste. This is considered as a disproportionate discrepancy that should be avoided in order to reduce the probability of improper disposal and misuse by overdosing.

3 Assessment of the product

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

3.1.1 Intended use 1 – Non-professional: spraying

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Flies – *Muscidae* (imagines; adults)
Field(s) of use	Indoor use (industrial/commercial premises; households/ private areas; public areas; animal housing
Application method(s)	Surface spraying
Application rate(s) and frequency	200g dissolved in 200mL water; applied to an effective surface of 1m^2 per 100m^2 floor surface to be treated.
Category(ies) of users	Non-professional
Pack sizes and packaging material	10g bag 10g, 50g, 100g, 300g, 350g bottle 1kg, 2kg bucket 50g, 300g, 1kg, 2kg can 1kg, 2kg complex bag

3.1.2 Intended use 2 – Non-professional: painting

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Flies – *Muscidae* (imagines; adults)
Field(s) of use	Indoor use (industrial/commercial premises; households/ private areas; public areas; animal housing

Application method(s)	Painting
Application rate(s) and frequency	200g dissolved in 150mL water; applied to an effective surface of 1m^2 per 100m^2 floor surface to be treated.
Category(ies) of users	Non-professional
Pack sizes and packaging material	10g bag 10g, 50g, 100g, 300g, 350g bottle 1kg, 2kg bucket 50g, 300g, 1kg, 2kg can 1kg, 2kg complex bag

3.1.3 Intended use 3 – Non-professional: bait application

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Flies – *Muscidae* (imagines; adults)
Field(s) of use	Indoor use (industrial/commercial premises; households/ private areas; public areas; animal housing
Application method(s)	Bait application
Application rate(s) and frequency	200g for 100m^2 floor area to be treateds; one bait point (cup, shallow dishes, bowl or bait station) per 10m^2 floor area.
Category(ies) of users	Non-professional
Pack sizes and packaging material	10g bag 10g, 50g, 100g, 300g, 350g bottle 1kg, 2kg bucket 50g, 300g, 1kg, 2kg can 1kg, 2kg complex bag

3.1.4 Intended use 4 – Professional: spraying

Product Type(s)	18

Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Flies – *Muscidae* (imagines; adults)
Field(s) of use	Indoor use (industrial/commercial premises; households/ private areas; public areas; animal housing
Application method(s)	Surface spraying
Application rate(s) and frequency	200g dissolved in 200mL water; applied to an effective surface of 1m^2 per 100m^2 floor surface to be treated.
Category(ies) of users	Professional
Pack sizes and packaging material	10g bag 10g, 50g, 100g, 300g, 350g bottle 1kg, 2kg bucket 50g, 300g, 1kg, 2kg can 1kg, 2kg complex bag

3.1.5 Intended use 5 – Professional: painting

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Flies – *Muscidae* (imagines; adults)
Field(s) of use	Indoor use (industrial/commercial premises; households/ private areas; public areas; animal housing
Application method(s)	Painting
Application rate(s) and frequency	200g dissolved in 150mL water; applied to an effective surface of 1m^2 per 100m^2 floor surface to be treated.
Category(ies) of users	Professional
Pack sizes and packaging material	10g bag 10g, 50g, 100g, 300g, 350g bottle

	1kg, 2kg bucket 50g, 300g, 1kg, 2kg can 1kg, 2kg complex bag

3.1.6 Intended use 6 – Professional: bait application

Product Type(s)	18
Where relevant, an exact description of the use	Insecticide
Target organism(s) (including development stage)	Flies – *Muscidae* (imagines; adults)
Field(s) of use	Indoor use (industrial/commercial premises; households/ private areas; public areas; animal housing
Application method(s)	Bait application
Application rate(s) and frequency	200g for 100m^2 floor area to be treated; one bait point (cup, shallow dishes, bowl or bait station) per 10m^2 floor area.
Category(ies) of users	Professional
Pack sizes and packaging material	10g bag 10g, 50g, 100g, 300g, 350g bottle 1kg, 2kg bucket 50g, 300g, 1kg, 2kg can 1kg, 2kg complex bag

3.2 Physicochemical properties

Table 4: Physical, chemical and technical properties of the Biocidal product

	Method	Purity/ Specification	Results	Reference
Physical state and nature	Visual. EPA 830.6303	Sofast; 0.483% w/w Imidacloprid 0.0284% w/w *cis*-tricos-9-ene (Muscalure) Batch SW-B-0520	Granules	D. Norris (2013)
	Visual. EPA 830.6303	Sofast; Batch SC-6354-B	cylindrical granules	I. Al Amin (2015)
Colour	Visual EPA 830.6302	Sofast; 0.483% w/w Imidacloprid 0.0284% w/w *cis*-tricos-9-ene (Muscalure) Batch SW-B-0520	White	D. Norris (2013)
	Visual EPA 830.6302	Sofast; Batch SC-6354-B	white	I. Al Amin (2015)
Odour	Olfactory EPA 830.6304	Sofast; 0.483% w/w Imidacloprid 0.0284% w/w *cis*-tricos-9-ene (Muscalure) Batch SW-B-0520	Very faint sweet odour	D. Norris (2013)
	Olfactory EPA 830.6304	Sofast; Batch SC-6354-B	characteristic odour	I. Al Amin (2015)
Explosive properties	EU Method A.14, Regulation (EC) No 440/2008	0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	In the test explosive transformation of Imidacloprid 0.5% + Tricosene 0.1 % GR has been not recognized. Imidacloprid 0.5% + Tricosene 0.1 % GR does not have explosive properties	T. Salacinski (2014) Study code: BW-19/14

	Method	Purity/ Specification	Results	Reference
			according to the criteria of EEC A.14 method.	
Oxidizing properties	EU Method A.17, Regulation (EC) No 440/2008	0.483% w/w Imidacloprid Batch SW-B-0520	Granule formulation labelled with Batch No. SW-B-0520 did not react and therefore is considered not highly oxidising	D. Norris (2013) Study no: DNA2047
	UN Test O.1, (in Part III of the UN MTC)	0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	Average burning time (s:) > 300 Imidacloprid 0.5% + Tricosene 0.1 % GR is not an oxidizing substance.	J. Szczygielska (2015) Study no: BC-48/14
Flash point	study scientifically unjustified		Waiver: SOFAST is a granular bait insecticide. Therefore, testing can be waived.	BAM 2.2 (2016)
Auto flammability	Relative Self-ignition temperature for solids EU Method A.16, Regulation (EC) No 440/2008	0.483% w/w Imidacloprid Batch SW-B-0520	The sample did not auto ignition below 170°C then it melted and left the cube.	D. Norris (2013) Study no: DNA2047
	Self-heating substances or mixtures UN Test N.4 (in Part III of the UN MTC)	0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	Oven temperature (°C): 140 ± 2 Volume of the test sample [cm^3]: 1000 Maximum temperature of sample during determination time (°C): 136.1 Imidacloprid 0.5% + Tricosene 0.1 % GR is not a self-heating substance.	J. Szczygielska (2015) Study no: BC-48/14
Other indications of flammability	Flammability upon ignition (solids) EU Method A.10, Regulation (EC) No 440/2008	0.483% w/w Imidacloprid Batch SW-B-0520	The sample ignition but it extinguished after 5 seconds. The flame did not propagate along 200 mm train. According to the results obtained in	D. Norris (2013) Study no: DNA2047

	Method	Purity/ Specification	Results	Reference
			this test, Granule formulation labelled with Batch No. SW-B-0520 is considered not highly flammable.	
	UN Test N.1 (in Part III of the UN MTC)	0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	Due to the fact that the combustion does not propagate along 200 mm of the train the result is negative. Imidacloprid 0.5% + Tricosene 0.1 % GR is not flammable substance .	J. Szczygielska (2015) Study no: BC-48/14
	Flammability in contact with water study scientifically not necessary		Waiver: The study does not need to be conducted because the product is known to be soluble in water to form a stable mixture.:	BAM 2.2 (2016)
Acidity / Alkalinity	CIPAC Method MT 75.3	Sofast; 0.483% w/w Imidacloprid 0.0284% w/w *cis*-tricos-9-ene (Muscalure) Batch SW-B-0520	pH= 6.92 at 1% dilution (20 ºC) (pre-storage sample) pH= 6.94 at 1% dilution (20 ºC) (post-storage sample after 14 days at 54ºC) Remarks: pH of distilled water used for 1% aqueous solution preparation was 6.81	D. Norris (2013)
	CIPAC Method MT 75.3	Sofast; Batch SC-6354-B	pH= 6.53 at 1% dilution (20 ºC) (pre-storage sample) pH= 6.16 at 1% dilution (20 ºC) (post-storage sample after 14 days at 54ºC)	I. Al Amin (2015)

	Method	Purity/ Specification	Results	Reference
Relative density / bulk density	CIPAC Method MT 159	Sofast; 0.483% w/w Imidacloprid 0.0284% w/w *cis*-tricos-9-ene (Muscalure) Batch SW-B-0520	Tap Density: 0.6871 g/mL Pour Density: 0.6448 g/mL	D. Norris (2013)
	CIPAC Method MT 159	Sofast; Batch SC-6354-B	Tap Density: 0.60 g/mL Pour Density: 0.56 g/mL	I. Al Amin (2015)
Storage stability – stability and shelf life			**Accelerated Storage:**	
	EPA 830.6302, EPA 830.6303 and EPA 830.6304	Sofast; 0.4835% w/w Imidacloprid 0.0284% w/w *cis*-tricos-9-ene (Muscalure) Batch SW-B-0520	**Accelerated Storage (14 days at 54ºC):** - Appearance/weight change (colour, physical state): **Initial:** Weight of a.s. Imidacloprid: 0.483% w/w Weight of a.s. (Z)-9-Tricosene: 0.0284% w/w Colour: white Physical state: granules Odour: very faint sweet **After 14 days at 54±2 ºC:** Weight of a.s. Imidacloprid: 0.477%w/w (-1.24%) Weight of a.s (Z)-9-Tricosene: 0.0264% w/w (-7.04%) Colour: white Physical state: granules Odour: very faint sweet Remarks: ▫ The test item is physically stable during storage at 54 ± 2ºC for 14	D. Norris (2013)

	Method	Purity/ Specification	Results	Reference
			days. There was no significant change in the pH of the neat formulation or a 1% aqueous solution of the test item during storage.	
	Visual Inspection. EPA 830.6302, EPA 830.6303 and EPA 830.6304	Sofast; Batch SC-6354-B	**Accelerated Storage:** **14 days at 54±2 ºC** Appearance/weight change (colour, physical state): ▫ **Initial:** Weight of a.s. Imidacloprid: 0.478% w/w Weight of a.s. (Z)-9-Tricosene: 0.097% w/w Colour: white Physical state: Cylindrical granules Odour: Characteristic ▫ **After 14 days at 54±2 ºC:** Weight of a.s. Imidacloprid: 0.447%w/w (-6.49%) Weight of a.s (Z)-9-Tricosene: 0.094% w/w (-3.09%) Colour: white Physical state: Cylindrical granules Odour: Characteristic Remarks: The test item is physically stable during storage at 54 ± 2ºC for 14 days. There was no significant change in the pH of the neat formulation or a 1% aqueous	I. Al Amin (2015)

	Method	Purity/ Specification	Results	Reference
			solution of the test item during storage. The concentrations of active substances could not be fully validated; therefore, the given data are only considered as additional data.	
			Long term storage test: The applicant states that "*The formulation is expected to be stable for two years […].*" No long-term storage stability test or corresponding interim reports have been submitted. The applicant started a long term storage test on Batch SW-B-0520. Since this product batch contains a distinct lower concentration of *cis*-tricos-9-ene, the applicant was informed that the corresponding study could not be used to evaluate the shelf life of the product. A new study plan was submitted by the applicant based on batch SC-6354-B. For this batch the concentrations of active substances could not be fully validated; therefore, the applicant was informed that the corresponding study could not be used to evaluate the shelf life of the product Sofast. Due to the advanced stage of the evalatuation process a new long-term storage test could not be conducted. Resulting from this, the shelf-life of the product was estimated based on the results of the accelerated storage stability tests. Since there is a certain	

	Method	Purity/ Specification	Results	Reference
			loss of the active substance contents during the accelerated storage at 54 ± 2ºC for 14 days and because of the aspect that the content of Muscalure in the tested batch Batch SW-B-0520 is lower than in the actual product Sofast and that the contents of the active substances in the tested Batch SC-6354-B could not be fully validated, the estimation of the shelf-life is restricted. Based on the given data we assess a shelf-life of 12 months. Additionally a two year storage stablity has to be submitted post autorisation.	
Effects of temperature		No data available	**Low temperatures:** Test item is a solid. No phase change is expected when temperature is lowered to 0 ºC and no changes in the properties are expected	
Effects of light		Not relevant	Product is stored away from light	
Reactivity towards container material			The data about all the packaging materials are sufficient.	
Technical characteristics in dependence of the formulation type	CIPAC Method MT 53.3.1	Sofast; 0.478% w/w Imidacloprid 0.097% w/w *cis*-tricos-9-ene (Muscalure) Batch SC-6354-B	<u>Wettability:</u> ▫ Wetting time at t=0: 19 s ▫ Wetting time at t=14 at 54 ± 2ºC: 19 s	I. Al Amin (2015)
	CIPAC Method MT 184	Sofast; Batch SC-6354-B	<u>Suspensibility:</u> ▫ Suspensibility at t=0: 100.29% in 1% solution ▫ Suspensibility at t=14 days at 54 ± 2ºC: 100.16% in 1% solution	I. Al Amin (2015)

	Method	Purity/ Specification	Results	Reference
			Wet sieve analysis: Not relevant. The product is a granular formulation.	
			Emulsifiability: Not relevant. The product is a granular formulation.	
			Disintegration time: Not relevant. The product is a granular formulation.	
	CIPAC Method MT 178	Sofast; 0. 483% w/w Imidacloprid 0.0284% w/w *cis*-tricos-9-ene (Muscalure) Batch SW-B-0520	Attrition/friability of granules; integrity of tablets: Mean attrition resistance of test item is 99.54% (pre-storage sample) and 99.05% (post storage sample after 2 weeks at 54 ºC)	D. Norris (2013)
		Sofast; Batch SC-6354-B	Attrition/friability of granules; integrity of tablets: ▫ Mean attrition resistance at t=0: 99.21% of initial material ▫ Mean attrition resistance at t=14 days at 54 ± 2ºC: 98.94% of initial material	I. Al Amin (2015)
			Persistence of foaming: Not relevant. The product is a granular formulation.	
	CIPAC Method MT 172	Sofast; 0. 483% w/w Imidacloprid 0.0284% w/w *cis*-tricos-9-ene (Muscalure) Batch SW-B-0520	Flowability/Pourability: Test item had clumped together after 14 day storage but easily passed through a 4.75 mm sieve after 5 taps.	D. Norris (2013)
		Sofast; Batch SC-6354-B	Flowability/Pourability:	I. Al Amin (2015)

	Method	Purity/ Specification	Results	Reference
			The granules of the preparation flow completely through a 4.75 mm sieve.	
	CIPAC Method MT 171	Sofast; 0. 483% w/w Imidacloprid 0.0284% w/w *cis*-tricos-9-ene (Muscalure) Batch SW-B-0520	<u>Dustability:</u> Pre-storage sample of test item produced 0.15 mg of dust and is considered nearly dust free. Post-accelerated storage sample produced 0.20 mg of dust and is also considered nearly dust free.	D. Norris (2013)
		Sofast; Batch SC-6354-B	<u>Dustability:</u> Dust content before and after accelerated storage (14 days 54ºC) is 0% (0.00 mg)	I. Al Amin (2015)
Compatibility with other products			The product will not be used in combination with any other product.	
Surface tension			Not relevant. The product is a granular formulation.	
Viscosity			Not relevant. The product is a granular formulation.	
Particle size distribution	CIPAC Method MT 170	Sofast; 0.478% w/w Imidacloprid 0.097% w/w *cis*-tricos-9-ene (Muscalure) Batch SC-6354-B	<u>Particle size distribution at t=0:</u> ≥ 2 mm: 0% ≥ 1 mm and < 2 mm: 92.88% ≥ 500 µm and < 1 mm: 3.88% ≥ 250 µm and < 500 µm: 0.63% ≥ 125 µm and < 250 µm: 0.74% ≥ 75 µm and < 125 µm: 0.71% ≥ 45 µm and < 75 µm: 0.68% < 45 µm: 0.50% <u>Particle size distribution at t=14 days after accelerated storage:</u> ≥ 2 mm: 0% ≥ 1 mm and < 2 mm: 85.53% ≥ 500 µm and < 1 mm: 8.21% ≥ 250 µm and < 500 µm: 2.81%	I. Al Amin (2015)

	Method	Purity/ Specification	Results	Reference
			≥ 125 µm and < 250 µm: 1.37% ≥ 75 µm and < 125 µm: 0.94% ≥ 45 µm and < 75 µm: 0.73% < 45 µm: 0.43%	

The active substances Imidacloprid and cis-tricos-9-ene do not exhibit any hazardous physico-chemical properties. The substances are not highly flammable. They do not show any explosive or oxidising properties. Therefore the active substances should not be classified based on its physico-chemical properties.

The product is not expected to be highly flammable or have any explosive or oxidizing properties. The non-active ingredients of the formulated product are largely feed-/food grademateriales or other substances not expected to be hazardous, therefore there is no risk expected from the formulated product with regards to the physico-chemical properties.

Remark:

For the tested Batch SC-6354-B the applicant determined the following active substances contents:

0.478% w/w Imidacloprid 0.097% w/w *cis*-tricos-9-ene (Muscalure)

These values could not be fully validated. For further explanation please refer to Doc IIIB 4.1-3 and Doc IIIB 4.1-4.

Table 5

Conclusion on the physical, chemical and technical properties
The data provided by the applicant was acceptable. However, additionally a two year storage stablity has to be submitted post autorisation.

3.3 Methods for detection and identification

Table 6

	Principle of method
Technical active substance as manufactured:	Imidacloprid: Methods: HPLC and LC-MS **Preparation of Standard Stock Solution of Imidacloprid** A quantity of 10.13 mg imidacloprid reference standard (99.90% purity) was weighed into a volumetric flask of 10 mL capacity, contents were dissolved in 5.0 mL acetonitrile and the volume was made up to the mark with acetonitrile (imidacloprid standard stock solution A, concentration 1011.99 ppm). A volume of 1.0 mL standard stock solution A was transferred into a volumetric flask of l0 mL capacity and volume was made up to the mark with mobile phase (standard solution F, concentration 101.20 ppm) for HPLC and LC-MS analysis. **Preparation of Standard Mixture Solution of Imidacloprid and Associated Impurities (IMP-A, IMP-B, IMP-C and IMP-D).** A volume of 0.5 mL standard stock solutions, A, B, C, D and E (imidacloprid, IMP-A, IMPB, IMP-C and IMP-D), respectively were transferred into a volumetric flask of l0 mL capacity and the volume was made up to the mark with mobile phase (standard mixture solution K). **Preparation of Sample Solution for Characterization and Specificity** Different quantities viz., 20.15, 20.22, 20.32, 20.17 and 20.27 mg test substance from Batch Nos.SWEPL-036, SWEPL-086, SWEPL-l22, SWEPL-l71 and SWEPL-201, respectively were weighed into separate volumetric flasks of 10 mL capacity, dissolved in 5.0 mL mobile phase and the volume was made up to the mark with mobile phase. **LC-MS and HPLC Analytical Conditions** The above prepared standard solution F(imidacloprid), standard solution G [IMP-A], standard solution H [IMP-B], standard solution I [IMP-C], standard solution J [IMP-D] and standard mixture solution K, mobile phase, acetonitrile (solvent used for solution preparation) and sample solutions were injected onto LC-MS (for characterization) and HPLC (for specificity) of imidacloprid and associated impurities based on retention time, elution pattern and mass using following LC/MS and HPLC parameters **LC-MS Parameters** Instrument: LC-MSD SL (Agilent - 1100 Series)

	Column: Zorbax, C-18 [150 mm x 4.6 mm (i.d.), 5.0 flm particle size] Wave length: 252nm Mobile Phase: Solvent A, Acetonitrile : Solvent B, 0.5% Formic acid in water (30:70, v/v) Flow rate: 0.5 mL/minute Injection Volume: 10.0 µL Solution A: Acetonitrile SolutionB: 0.5% Formic Acid in water **Mass Parameters** Mass Range: 100 to 500 m/z Dry Gas Flow Rate: 12.0 L/minute Dry Gas Temp.: 350 ºC Nebulizer Pressure: 50 psi Fragmentor Voltage: 100 - 125 Volts (negative) Quadra pole Temp: 100 º C Capillary Voltage: 4000 Volts (positive and negative) Retention Time (Approx): Imidacloprid: 7.132 minute IMP-A: 3.024 minute IMP-B: 13.854 minute IMP-C: 16.517 minute IMP-D: 4.319 minute **HPLC Parameters** Instrument: HPLC (Agilent 1100 series with PDA detector) Column: X-Terra, C-8, [150 mm x 4.6 mm (i.d.), 5µm particle size] Wave length: 252nm Mobile Phase : Solvent A, Acetonitrile: Solvent B, 0.5% Formic Acid in Water (30 : 70, v/v) Flow Rate: 1.0 mL / minute Injection Volume: 20µL Retention Time (Approx): Imidacloprid: 3.465 minute IMP-A: 1.800 minute IMP-B: 5.468 minute IMP-C: 6.213 minute IMP-D: 2.389 minute **Quantitation by HPLC**

	Preparation of Imidacloprid Standard Solution Standard solution F prepared for specificity was used for quantitation. **Preparation of Imidacloprid Sample Solutions for A.I. Content Determination** The known quantities (Refer Table 7 of 5-batch report) of test substance from each of the production batches [viz., SWEPL-036, SWEPL-086, SWEPL-122, SWEPL-I71 and SWEPL-201] were weighed in triplicate into separate volumetric flasks of 10 mL capacity, 5.0 mL mobile phase was added to dissolve the material and the volume was made up to the mark with mobile phase. One mL of each solution prepared above was transferred into separate volumetric flask of 10 mL capacity and volume was made up to the mark with mobile phase (working solution). **HPLC Analytical Conditions** The above prepared standard solutions of imidacloprid and associated impurities and test substance sample solutions were injected onto a High Perfomance Liquid Chromatography (HPLC) using the following validated parameters: Instrument: HPLC (Agilent 1100 series with PDA detector) Column: X-Terra, C-8, [150 mm x 4.6 mm (i.d.), 5µm particle size] Wave length: 252nm Mobile Phase : Solvent A, Acetonitrile: Solvent B, 0.5% Formic Acid in Water (30 : 70, v/v) Flow Rate: 1.0 mL / minute Injection Volume: 20µL Retention Time (Approx): Imidacloprid: 3.487 minute IMP-A: 1.807 minute IMP-B: 5.483 minute IMP-C: 6.227 minute IMP-D: 2.398 minute
	<u>*cis*-tricos-9-ene (Muscalure):</u> GC-FID **Separation method** Gas chromatography: DB-1 100%-dimethylpolysiloxane column, nitrogen carrier gas, temperature programmed elution from 115°C to 250°C **Detector** Flame ionization detector

	GC-FID method for the quantitation of Z-9-tricosene in muscalure technical. Muscalure is dissolved in hexane to an accurate concentration of ca 2.5 mg/mL and analyzed directly, using dipropylphthalate as internal standard, on DB-1 column.
Impurities in technical active substance:	Impurities in Imidacloprid as technical material: Methods: HPLC and HPLC-MS **Preparation of Standard Stock Solution of N-Nitroimidazolidin-2-emine [IMP-A]** A quantity of 10.17 mg N-Nitroimidazolidin-2-emine reference standard [IMP-A] (99.0% purity) was weighed into a volumetric flask of 10 mL capacity, contents were dissolved in 5.0 mL acetonitrile and the volume was made up to the mark with acetonitrile (IMP-A standard stock solution B, concentration 1006.83 ppm). A volume of 1.0 mL standard stock solution (IMP-A) was transferred into a volumetric flask of 10 mL capacity and volume was made upto the mark with mobile phase (standard solution G, concentration 100.68 ppm) for HPLC and LC-MS analysis. **Preparation of Standard Stock Solution of Dimer of imidacloprid [IMP-B]** A quantity of 10.15 mg Dimer of imidacloprid reference standard [IMP-B] (98.95% purity) was weighed into a volumetric flask of 10 mL capacity. Contents were dissolved in 5.0 mL acetonitrile and the volume was made up to the mark with acetonitrile (IMP-B standard stock solution C, concentration 1004.34 ppm). A volume of 1.0 mL standard stock solution C (IMP-B) was transferred into a volumetric flask of 10 mL capacity and volume was made up to the mark with mobile phase (standard solution H, concentration 100.43 ppm) for HPLC and LC-MS analysis. **Preparation of Standard Stock Solution of 1-[(5,6.dichloro-3-pyridinyl)methyl]-4,5-dihydro-N-nitro-1H-imidazol-2-amine [IMP-C]** A quantity of 10.28 mg 1-[(5,6-dich1oro-3-pyridinyl)methyl]-4,5-dihydro-N-nitro-1H-imidazol-2-amine reference standard [IMP-C] (97.91% purity) was weighed into a volumetric flask of 10 mL capacity, contents were dissolved in 5.0 mL acetonitrile and the volume was made up to the mark with acetonitrile (IMP-C standard stock solution D, concentration 1006.51 ppm). A volume of 1.0 mL standard stock solution D (IMP-C) was transferred into a volumetric flask of 10 mL capacity and volume was made up to the mark with mobile phase (standard solution I, concentration 100.65 ppm) for HPLC and LC-MS analysis.. **Preparation of Standard Stock Solution of Nitroso imidacloprid [IMP-D]** A quantity of 10.22 mg Nitroso imidacloprid reference standard [IMP-D] (98.77% purity) was weighed into a volumetric flask of 10 mL capacity, contents were dissolved in 5.0 mL acetonitrile and the volume was made up to the mark with acetonitrile (IMP-D standard stock solution E, concentration 1009.43 ppm). A volume of 1.0 mL standard stock solution E (IMP-D) was transferred into a volumetric flask of 10 mL capacity and volume was made up to mark with mobile phase (standard solution J, concentration 100.94 ppm) for HPLC and LC-MS analysis.

	Preparation of Standard Mixture Solution of Associated Impurities (IMP-A, IMP-B, IMP-C and IMP-D) A volume of 1.0, 0.6, 0.1 and 0.1 mL standard solutions, G, H, I and J (IMP-A, IMP-B, IMP-C and IMP-D), respectively were transferred into a volumetric flask of 10 mL capacity and the volume was made up to the mark with mobile phase (standard solution L). **Preparation of Imidacloprid Sample Solutions for Associated Impurities Content Determination** The known quantities (Refer Tables 8 to 11in 5-batch report) of test substance from each of the production batches [viz., SWEPL-036, SWEPL-086, SWEPL-I22, SWEPL-I71 and SWEPL-201] were weighed in triplicate into separate volumetric flasks of 10 mL capacity, 5.0 mL mobile phase was added to dissolve the material and the volume was made up to the mark with mobile phase (working solution). **LC-MS and HPLC Analytical Conditions** Same conditions used as for quantitation of the active.
	Impurities in cis-tricos-9-ene (Muscalure) as technical material: The method used to carry out 5-batch analyses was validated with respect to determination of significant impurities in technical grade Muscalure. Information on the analysis of the active substance's impurities is confidential, since it may reveal the possible method of manufacturing. The corresponding data are provided in the confidential annex of the Dossier for cis-tricos-9-ene (Muscalure).
active substance in the formulation:	Imidacloprid in the biocidal product: HPLC-DAD **Separation method** HPLC System: High performance liquid chromatograph (Agilent 1100 series) equipped with gradient pump, auto sampler, thermostatted column and reprocessing data software. **HPLC Column:** Column: Intersil ODS-3, 250 mm x 4.6 mm Mode: Isocratic Packing: ODS-3, 5µm Eluent: 33% methanol : 67% water, adjusted to pH 3 with H_3PO_4 Flow rate. 1.0 ml/min Data collection: Chemstation Injection volumne: 10 µl Retention time: Approximately 13.7-14.2 min

	Detector Agilent 1100 Diode Array Detector Wavelenght: 225 nm **Internal Standard** Imidacloprid, Purity: 99.9 % **Interfering substance(s)** No interfering peaks were detected
	Tricosene in the biocidal product: GC-UV/Vis **Separation method** Instrument: Agilent GC-MDS instrument 2 Column: RH-1701 (30 m x 0.32 mm x 1.0 µm) Temperatures: ▫ Column 80ºC (2 min), then 12ºC/min to 310ºC (hold for 5 min) ▫ Injector: 250ºC Carrier gas: Helium Data collection: Chemstation Retention time: Approximately 16.1-16.2 min **Detector** Detector: Thermo Nicolet IR100 FTIR Sim: 83, 97, 111 and 322 amu. Scanning: 50-550 amu (Impurity Spectral Analysis) Wavelenght: 225 nm **Internal Standard** Tricosene, analytical standard, Purity: 98.1% **Interfering substance(s)** No interfering peaks were detected

Table 7

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		
Active substance Imidacloprid	HPLC-DAD	was verified by analysing a sample of Solvent Blank, Formulation blank, Imidacloprid reference standard, Pre Storage Sample (DNA2047/I), Post Storage Sample (DNA2047/2) and Impurity reference standard. In addition the identity of the active substance was confirmed by comparison of the UV-spectra and LC-MS spectra of the reference item solutions with the UV-spectra of and LC-MS spectra the sample solutions.	0.0005mg/ml to 0.5mg/ml mg reference item/L; R^2 = 1.000	0.0005 mg /ml. (n=5) 0.05 mg /ml. (n=5) (0.05 mg/mL equates to 0.5 %w/w in formulation)	101.7% - 102.5 %	102%	0.2278	LOQ = 0.0005 mg /ml.	D. Norris (2013)
Active substance cis tricosene	GC-UV/Vis	was verified by analysing a sample of Solvent Blank, Formulation blank, Imidacloprid reference standard, Pre Storage Sample, Post Storage Sample and (Z)-9-Tricosene reference standard using the GC-MSD method. In addition the identity of the active substance was confirmed by comparison of the UV-spectra and GC-MS spectra of the reference item solutions with the UV-spectra	0.0001 mg/ml to 0.1 mg/ml mg reference item/L; R^2 = 0.9971	0.0001 mg /ml. (n=5) 0.01 mg /ml. (n=5)	95.11 % - 99.62%	96.89%	2.211	LOQ = 0.0001 mg /ml.	D. Norris (2013)

		of and GC-MS spectra the sample solutions.							

Available analytical methods for residues of the active substances imidacloprid and cis-tricos-9-ene are summarized in chapter 4.3 (Analytical methods residues – active substance). The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.
Other toxicologically and ecotoxicologically relevant components of the biocidal product do not exist. Therefore, further methods for residues are not needed.

Based on the results presented in chapter 4.3 (Analytical methods residues – active substance) sufficiently validated residue analytical methods for imidacloprid in soil, drinking water, surface water and air are available. For determination of residues of imidacloprid in food of animal origin sufficiently validated analytical methods are available from EU assessment as plant protection product.
Residue analytical methods for cis-tricos-9-ene are not available. For the environmental media soil and water residue analytical methods are not required.
Residue analytical methods for cis-tricos-9-ene in air are not available.

3.4 Efficacy against target organisms

3.4.1 Function and field of use

The product “Sofast” is an insecticide and contains 0.5% Imidacloprid as well as 0.1% cis-tricos-9-ene as an attractant.

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

The product is an insecticide designed to control Houseflies (*Musca domestica*) and Stable flies (*Stomoxys calcitrans*). It is designed for indoor use, including households, industrial and commercial premises and livestock facilities. The applications applied for are

a) scattering of granules onto shelves and ledges,
b) use in bait stations (only livestock facilities),
c) dispersion of the granules in water and spraying of the solution onto walls and other surfaces,
d) dispersion of the granules and painting of the solution onto walls and other surfaces.

3.4.3 Effects on target organisms, including unacceptable suffering

Knockdown and kill.

3.4.4 Mode of action, including time delay

Imidacloprid is a neonicotinoid and belongs to the 4A group of insecticides according to the IRAC classification scheme. These act as nicotinic acetylcholine receptor agonists. Neonicotinoids bind to the nicotinic acetylcholine receptors of cells. Ultimately, this blockage causes paralysis and death of the insect. Imidasect acts as a contact insecticide as well as upon ingestion.

3.4.5 Efficacy data

The applicant conducted a simulated-use-trial, which proved the efficacy of the product “Sofast” for indoor use (Lüpkes, 2013). The study was conducted in 20 m³ rooms with *M. domestica* and *S. calcitrans*. Four replicates were performed per species and per application method. The results are summarised in Table 8. This study is suitable as proof of efficacy for indoor use in private houses, and industrial and commercial premises.

In order to allow the authorisation also for use in livestock facilities, two field trials with *M. domestica* and *S. calcitrans* were performed. In the first trial (Heaven, 2015), the product was applied by diluting the granules and spraying or painting the solution onto walls on three different sites. The results of this field trial are not suitable to prove the efficacy of the product and are summarised in Table 8.
In the second trial (Heaven, 2015), the product was applied by scattering of the granules onto shelves and ledges on three different sites. The results of this field trial are not suitable to prove the efficacy of the product and are summarised in Table 8.
In order to allow the authorisation for use in livestock facilities another field trial with *M. domestica* and *S. calcitrans* was performed (Angayarkanni 2019). The product was applied by paint application on cardboards and by granular bait application in trays. A population reduction of at least 80% after 21 days was demonstrated against *M. domestica* and *S. calcitrans* for both application methods. The results of this field trial are suitable to prove the efficacy of “Sofast” for the application methods “Painting on cardboards” and “Bait application in disposable shallow dishes”. However, due to environmental risks the application in disposable shallow dishes in livestock facilites is not suitable only the use of bait stations would be acceptable.
In accordance with the TNsG (2016, chapter 13.2) the “study results of … field trials should demonstrate the efficacy of the product based on the submitted label claim”. Therefore, the applicant submitted subsequently field trials in livestock facilities with *M. domestica* (Raut 2020; Study 368EAMG3968/RO) and *S. calcitrans* (Raut 2020; Study 368EAMG3969/RO) with the product “Sofast” applied in bait stations. After an exposure period of 4 weeks the population reduction was 85.3%, 76.2% and 75.4% for *Musca domestica*. Consequently, only in 1 of 3 livestock facilities a sufficient population reduction of >80% was recorded. For *Stomoxys calcitrans* the population reduction in all 3 livestock facilities was >80%. In accordance with the TNsG (2016, chapter 13.2.1) for a general claim against flies in livestock facilities and animal housings both the housefly (*Musca domestica*) and the stable fly (*Stomoxys calcitrans*) should be tested. As the efficacy was not proven against *Musca domestica*, when the granular product was used in bait stations, a general claim against “flies” cannot be authorised. However, a claim against stable flies (*Stomoxys calcitrans*) only is acceptable for use of bait stations in livestock facilities.

In summary, the semi-field trial showed good efficacy of the product when used indoors (households etc.). The efficacy of “Sofast” against flies in livestock facilities was also demonstrated for the application methods “Painting on cardboards” and “Bait application in disposable shallow dishes”, but the application “Bait application in disposable shallow dishes” cannot be claimed due to environmental risks. For the application method “Bait application in bait stations” in livestock facilities only the target organism “stable flies (*Stomoxys calcitrans*)” can be claimed, a general claim against “flies” can not be authorised, as the efficacy for this application method was only proven against stable flies (*Stomoxys calcitrans*), but not for houseflies (*Musca domestica*).

Table 8

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**
Insecticide: Killing of adult flies.	Indoor use, including households, industrial and commercial premises and livestock facilities	Sofast (Imidacloprid 0.5%)	*M. domestica*, *S. calcitrans*	Simulated-use-trial with three different application forms: 1. Bait scattered and moistened, 2. Bait dissolved and painted, 3. Bait dissolved and sprayed	20m³ test rooms, 4 replicates per fly species per application method; Dosage: equivalent to 200g per 100m² (as claimed on the label); exposure time of 24 h.	1. Scattered Bait *M. domestica*: 85% knockdown (kd) at 8h, 97% kd at 24h *S. calcitrans*: 86% kd at 8h, 100% kd at 24h 2. Painted *M. domestica*: 93% kd at 8h, 99% kd at 24h *S. calcitrans*: 84% kd at 8h, 99% kd at 24h 3. Sprayed *M. domestica*: 92% kd at 8h, 98% kd at 24h *S. calcitrans*: 88% kd at 8h, 96% kd at 24h	Doc IIIB 5.10-1 Lüpkes, K.-H., 2013: Efficacy of a fly bait granule product against House flies and Stable flies
Insecticide: Killing of adult flies.	Indoor use, including households, industrial and commercial premises and livestock facilities	Sofast (Imidacloprid 0.5%)	*M. domestica*, *S. calcitrans*	Field trial	Livestock facilities; 3 replicates per fly species; Dosage: 200g product diluted in 200ml H_2O painted on 1m² of wall per 100m² floor surface; infestation level scoring with sticky traps; exposure time of up to 30 d	Reduction % on day 30: for *M. domestica* on the 3 sites: 2.4, 81.5 and 0.9%; control: 28.9%. For S. *calcitrans* on the 3 sites: 13.6, 57.1 and 96.3%; control: 80.7%	Doc IIIB 5.10-2 Heaven, H., 2015: Field trials to determine the efficacy of Imidacloprid 0.5% + Tricosene 0.1% GR (Sofast) against houseflies and stable flies

Insecticide: Killing of adult flies.	Indoor use, including households, industrial and commercial premises and livestock facilities	Sofast (Imidacloprid 0.5%)	*M. domestica*, *S. calcitrans*	Field trial	3 replicates in 3 different livestock facilities, both species were present; Dosage: 10g product per 5m² of floor surface; infestation level scoring with sticky traps, and counting of dead flies found near the baits; exposure time: 30d	Reduction % on day 30: for *M. domestica* on the 3 sites: 48.2, 88.8 and 65.3%; control: 67.9%. For S. *calcitrans* on the 3 sites: 82.1, 51.8 and 19%; control: 19.6%	Doc IIIB 5.10-3 Heaven, H., 2015: Field trials to determine the efficacy of Imidacloprid 0.5% + Tricosene 0.1% GR (Sofast) against houseflies and stable flies
Insecticide: Killing of adult flies.	Indoor use, including households, industrial and commercial premises and livestock facilities	Sofast (Imidacloprid 0.5% + Tricosene 0.1% GR)	*M. domestica*, *S. calcitrans*	Field trial in cattle sheds in India With two application methods: 1. Painting on cardboards, 2. Bait application	Livestock facilities; 3 replicates per field site; Dosage Painting on cardboards: 200g product diluted in 200ml H_2O painted on 1m² of panels per 100m² floor surface; Dosage Bait application: 200g product for 100m² in trays or swallow dishes; premonitoring Assessment on day 2,4,7,14 and 21	Painting on cardboards Reduction % for *M. domestica*: 40, 51, 56, 75, 87% for 2, 4, 7, 14 and 21 days Reduction % for *S. calcitrans*: 49, 51, 64, 71 and 80 % for 2, 4, 7, 14 and 21 days Bait application Reduction % for *M. domestica:* 48, 58, 61, 71, 85% for 2, 4, 7, 14 and 21 days Reduction % for *S. calcitrans:* 64, 72, 77, 86, 91% for 2, 4, 7, 14 and 21 days	Angayarkanni 2019 (Study 4518/2018): Efficacy assessment of Imidacloprid 0.5% + Tricosene 0.1% GR under field conditions against flies (house fly & *Stomoxy calcitrans*)
Insecticide: Killing of adult flies.	Indoor use, including households, industrial and commercial premises and	Sofast (Imidacloprid 0.5% + Tricosene 0.1% GR) granular product in bait station	*M. domestica*	Field trial in cattle sheds (approx. 200 m² each) in India	Livestock facilities; 3 replicates (3 controls); Dosage: Bait station with 2 g granular product/m² Premonitoring: on day 0 with sticky traps	Premonitoring count: 57 to 156 flies/shed population reduction after 4	Raut 2020 (Study 368EAMG3968/RO): Bioefficacy & Persistency of Sofast (Bait Box with Imidacloprid 0.5% + cis-Tricosene 0.1%) against House Fly

	livestock facilities				Assessment: weekly up to 4 weeks	weeks: 85.3%, 76.2% and 75.4% control: population growth of 18.4% after 4 weeks	
Insecticide: Killing of adult flies.	Indoor use, including households, industrial and commercial premises and livestock facilities	Sofast (Imidacloprid 0.5% + Tricosene 0.1% GR) granular product in bait station	*S. calcitrans*	Field trial in cattle sheds (approx. 240 m² each) in India	Livestock facilities; 3 replicates (3 controls); Dosage: Bait station with 2 g granular product/m² Premonitoring: on day 0 with sticky traps Assessment: weekly up to 4 weeks	Premonitoring count: 91 to 377 flies/shed population reduction after 4 weeks: 91.4%, 93.9% and 89.4% control: population reduction of 5.2% after 4 weeks	Raut 2020 (Study 368EAMG3969/RO): Bioefficacy & Persistency of Sofast (Bait Box with Imidacloprid 0.5% + cis-Tricosene 0.1%) against Stable Fly

3.4.6 Occurrence of resistance and resistance management

Resistance of flies against Imidacloprid has been reported from various countries, including Germany (Jandowsky et al., 2009, Kaufman et al., 2010, Memmi, 2010, Khan et al., 2013). In cases where the population has not been reduced and the bait has been taken up, the development of resistance should be suspected. A change to another product with an active substance with a different mode of action is then recommended. 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. It is recommendable to complement the treatment in livestock facilities with a larvicide product.

3.4.7 Known limitations

Not known.

3.4.8 Evaluation of the label claims

Sofast is a granular bait insecticide against flies. It is suitable to treat fly populations indoors in industrial/commercial premises, households, private and public areas applied by “Painting on cardboards” and “Bait application in disposable shallow dishes”.
For use in livestock facilities the application method “Painting on cardboards” can be authorised against “flies”, whereas for the application method “Bait application in bait stations” only the target organism “stable flies (*Stomoxys calcitrans*)” can be claimed, a general claim against “flies” cannot be authorised. The application method “Bait application in disposable shallow dishes” cannot be claimed due to environmental risks.

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

N.a.

3.4.10 Data waiving and conclusion

The efficacy of the product has been documented for fly populations in indoor environments (industrial/commercial premises, households, private and public areas) applied by “Painting on cardboards” and “Bait application in disposable shallow dishes”.

For use in livestock facilities the application method “Painting on cardboards” can be authorised against “flies”, whereas for the application method “Bait application in bait stations” only the target organism “stable flies (*Stomoxys calcitrans*)” can be claimed, a general claim against “flies” cannot be authorised. The application method “Bait application in disposable shallow dishes” cannot be claimed due to environmental risks.

As the product does not contain a preservative a shelf life of 12 months can be claimed.

3.5 Risk assessment for human health

3.5.1 Hazard potential

3.5.1.1 Toxicology of the active substance

The toxicology of the active substances imidacloprid (CAS-No. 138261-41-3) and cis-tricos-9-en (CAS No. 27519-02-4) were examined extensively according to standard requirements. The results of the toxicological assessments can be found in the respective CAR

Imidacloprid is of moderate acute toxicity. With regard to acute local effects, imidacloprid is neither irritant to skin nor eyes. The evaluation of the active substance has indicated that imidacloprid has no carcinogenic and genotoxic potential and is not sensitising. No substance-related fertility or developmental impairment was noted in the reproduction toxicity studies.
Acceptable exposure levels for acute, medium- and long-term exposure could be derived for imidacloprid.

Cis-tricos-9-ene is of low acute oral, dermal and inhalation toxicity, no skin and minimal eye irritation (no classification) was reported. Cis-tricos-9-ene has a skin sensitizing potential and classification with Skin sens. 1; H317 *May cause an allergic skin reaction* is proposed. No repeated dose studies, no long-term and no reproductive toxicity studies were submitted. Because cis-tricos-9-ene has no structural alerts for specific toxic effects, waiving was accepted. Genotoxicity was negative (bacterial mutation tests and an in vitro chromosomal aberration test). Acceptable exposure levels for acute, medium- and long-term exposure could be derived for cis-tricos-9-ene. No studies of metabolism and kinetics of cis-Tricos-9-en were submitted or evaluated; waiving was accepted because the available information on the toxicology of cis-tricos-9-ene does not give rise to concern for human health.

The threshold limits and labelling regarding human health risks listed in Annex 4.4 „Toxicology and metabolism" must be taken into consideration.

3.5.1.2 Toxicology of the substance(s) of concern

No substance of concern could be identified in the biocidal product.

3.5.1.3 Toxicology of the biocidal product

The toxicology of the biocidal product SOFAST was examined appropriately according to standard requirements. The product was not in the EU-review program for inclusion of the active substance in Annex I of Directive 98/8/EC or in the positive list of approved active substances of Regulation (EU) 528/2012, respectively.

The biocidal product consists primarily of components of low toxicity. Studies with the biocidal product have shown that it is of low oral, dermal and acute inhalation toxicity and not skin and eye irritating or skin-sensitising. The biocidal product has to be labelled with EUH208 due to sensitising properties of the active substance *cis*-tricos-9-ene.
The basis for the health assessment of the biocidal product is laid out in chapter 4.5 “Toxicology – biocidal product”.

3.5.2 Exposure

“SOFAST” is a granular bait insecticide containing imidacloprid (CAS 138261-41-3, pure: 970 g/kg; 0.52 % (w/w)) and cis-tricos-9-ene (CAS 27519-02-4, pure: 801 g/kg; 0.1% (w/w)) as active substances.
The following exposure assessment is valid for the product SOFAST. SOFAST is a white solid product consisting of water dispersible granules used as insecticide. It is applied after dispersion by spraying and brushing or application of the granular bait itself

3.5.2.1 Exposure of professional users

The biocidal product is marketed in different package sizes (see chapter 2.6).
The exposure to the active substances is assessed separately for the different application techniques and will thus be described in individual subsections of the current section. It’ s usually based on the harmonized document “Biocides Human Health Exposure methodology (October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdHoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG2007.
In chapter 4.6: Safety for professional operators the details of the exposure calculations to the active substances (a.s.) for the professional user are laid out.
The biocidal product SOFAST is applied indoors in household, commercial and public areas and in livestock facilities. The product is applied at a rate of 200 grams of product per 100 m^2 of floor surface. For spray and paint applications, the application shall be performed on an effective surface of 1 m^2 per 100 m^2 floor surface.

Primary exposure of professionals

Spray treatment

SOFAST consists of solid granules which have to be dispersed in water prior to application. Subsequently, the application solution (50% (w/w) SOFAST) is sprayed with low spraying pressure (1-3 bar) using hand held and/or hand held powered equipment.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

During the application process exposure via skin seems likely, mainly due to the deposition of the generated droplets on the work clothing and the hands of the operator. For the application method of manual spraying the dermal exposure is assessed using “Spraying model 1” (Technical Notes for Guidance (TNsG) on Human Exposure). The model is based on measurement data collected during spraying with hand-held spraying device and low spraying pressure (1-3 bar) and provides data of potential body and potential/actual hand exposure (measurements of hand exposure outside/inside gloves). The model covers spray application indoors and outdoors, in overhead and downward direction and relates to insecticide application. It already contains the mixing and loading phase. Therefore, a separate calculation for this phase has not been performed.

In addition, exposure of hands during cleaning of the equipment has to be considered, although it represents a minor part of the total dermal exposure. This post-application phase is assessed using the indicative values given by *Marquart et al*. for cleaning of spray guns.

Exposure by inhalation

Exposure to aerosols occurs during the application phase (spraying) and is calculated for both a.s. using the values from “Spraying model 1”.
In addition, inhalation exposure to vapour is calculated for the volatile active substance cis-tricos-9-ene using the consumer exposure model ConsExpo. It is negligible (several order of magnitude lower than aerosol exposure) comparing to the aerosol part because of the low vapour pressure and is not provided in the PAR, but is available on request.

Summary of exposure assessment

The results of the calculation for potential / actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 9: Results of exposure calculation (spray treatment) (for risk characterisation, see chapter 3.5: Risk assessment for human health and chapter 4.6 Safety for professional operators. Due to the identified risk in Tier 1, a refined exposure assessment is performed. For Tier 2 the following safety measures are taken into account: protective gloves and protective coverall.

Table 9: Results of exposure calculation (spray treatment)

	Tier 1		Tier 2	
a.s.	total potential inhalation [mg/m3]	total potential dermal exposure [mg/day]	total actual inhalation [mg/m3] 1)	total actual dermal exposure [mg/day]
Imidacloprid	0.068	104.58	0.068	7.64
Cis-tricos-9-ene	0.013	20.11	0.013	1.47

1) same value as potential inhalation exposure since no RPE or LEV is assumed

Brush treatment

SOFAST consists of solid granules which have to be dispersed in water prior to brush application. Subsequently, the application solution (57.14% (w/w) SOFAST) is applied using hand held equipment such as brush or roller.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

Due to the process of dilution: For the manual mixing and loading phase exposure to hands is expected. The hands are predominantly exposed to dust during filling of the granules into a vessel. Thus, the calculation is based on the generic exposure figures of Model 5 (pouring into a portable receiving vessel) of the TNsG Human Exposure User Guidance 2002 for mixing/loading granules into knapsack type application equipment.

For the application phase no appropriate exposure model for professional brushing is available, therefore the dermal exposure is assessed using the Consumer product painting Model 3 of the *TNsG Human Exposure to Biocidal Products* (Part 2, p. 202). The model describes brush painting of sheds and fences by non-professionals. Taking into account a similar kind of treated surfaces and assuming that professional users have more experience in brush treatment than non-professionals, the assessment may represent a worst-case calculation. For potential body as well as hand exposure the 75th percentile values are chosen due to the moderate uncertainty of the data (TNsG Human Exposure User Guidance 2002, p. 29). During the application phase body and hands are exposed. The application process significantly contributes to the total dermal exposure. Additionally, exposure of hands during cleaning of the brush is considered, although it represents a minor part of the total dermal exposure. As a worst case assumption this post-application phase is calculated on the basis of a Human Exposure Expert Group opinion (HEEG, endorsed TM III 2010) dealing with washing paint out of a brush.

Exposure by inhalation

Exposure to aerosols during the post-application phase is not expected, but has been calculated for the mixing and loading as well as application phase. The assessment is based on the same models chosen to assess the dermal exposure.
In addition, inhalation exposure to vapour is calculated for the volatile active substance cis-tricos-9-ene using the consumer exposure model ConsExpo. It is negligible (several order of magnitude lower than aerosol exposure) comparing to the aerosol part because of the low vapour pressure and is not provided in the PAR, but is available on request.

Summary of exposure assessment

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 10: Results of exposure calculation (brush treatment) (for risk characterisation, see chapter 3.5: Risk assessment for human health and chapter 4.6 Safety for professional operators). Due to the identified risk in Tier 1, a refined exposure assessment is performed. For Tier 2 the following safety measure is taken into account: protective gloves.

Table 10: Results of exposure calculation (brush treatment)

	Tier 1		Tier 2	
a.s.	total potential inhalation [mg/day]	total potential dermal exposure [mg/day]	total actual inhalation [mg/day][1)]	total actual dermal exposure [mg/day]
Imidacloprid	0.013	14.33	0.013	8.27
Cis-tricos-9-ene	3.96 x 10-$^{-3}$	2.75	3.96 x 10^{-3}	1.59

[1)] same value as potential inhalation exposure since no RPE or LEV is assumed

Application of granular bait

SOFAST consists of solid granules which can be applied as ready to use bait in shallow dishes, bowls or bait stations. The stations containing 20 g of product should be placed every 10 m². Main potential exposure to the product is during loading recipients where the product is placed in and during disposal of the product after use (both dermal and inhalation routes are considered during these stages).

Dermal exposure

Exposure to skin is considered to occur during application and post-application phase.

For the application phase exposure to hands is expected. The hands are predominantly exposed to dust during filling of the granules in shallow dishes, bowls or bait stations. Thus, the calculation is based on the "Mixing and loading model 5" of the TNsG Human Exposure User Guidance 2002, p. 25 (granule formulation, pouring into a fixed receiving vessel).

The post–application phase is assessed by expert judgement, taking into account that half of the applied biocidal product is consumed.

Exposure by inhalation

Exposure to dust during the application and post-application phase is calculated. The assessment is based on the same models chosen to assess the dermal exposure. In addition, inhalation exposure to vapour is calculated for the volatile active substance cis-tricos-9-ene using the consumer exposure model ConsExpo. It is negligible (several order of magnitude lower than aerosol exposure) comparing to the aerosol part because of the low vapour pressure and is not provided in the PAR, but is available on request.

Summary of exposure assessment

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in **Table 11**. Due to the risk assessment (for risk characterisation, see chapter 3.5: Risk assessment for human health and chapter 4.6 Safety for professional operators) no refinement of the exposure assessment is necessary (Tier 2).

Table 11: Results of exposure calculation (application of granular bait)

	Tier 1		Tier 2[1)]	
a.s.	total potential inhalation [mg/day]	total potential dermal exposure [mg/day]	total actual inhalation [mg/day][2)]	total actual dermal exposure [mg/day]
Imidacloprid	8.99×10^{-4}	4.27	8.99×10^{-4}	0.43
Cis-tricos-9-ene	0.024	0.82	0.024	0.08

1) according to risk assessment: not necessary

2) same value as potential inhalation exposure since no RPE or LEV is assumed

Secondary exposure of professionals

Secondary exposure of workers due to treated surfaces cannot be excluded. Especially if the biocidal product is applied to cardboard by spray and brush treatment it is estimated that dermal contact is possible when it is fixed to walls or ceilings as well as when it is collected for disposal. Based on the calculation that 10 mg imidacloprid / m2 and 2 mg cis-tricos-9-ene / m2 are used and the assumption that the palms of both hands (410 cm^2) could be exposed the resulting potential dermal exposure is 0.41 mg imidacloprid / day and 0.08 mg cis-tricos-9-ene / day, respectively. Compared to primary exposure it represents only a small part of the exposure. The contact is estimated to be incidental and can be minimised by additional risk mitigation measures:

Application by spray and brush treatment on cardboard should be carried out leaving an untreated area around the edge.

When treated cardboard is fixed to walls (or ceilings) or is collected for disposal only the untreated area around the edge should be touched.

3.5.2.2 Exposure of non-professional users and the general public

Exposure scenarios for intended uses	
Primary exposure Medium-term	1.) Placing and disposal of the biocidal product in cups 2.) Application by brushing a) Mixing and loading (dermal, inhalation) b) Application (dermal, inhalation) c) Cleaning (dermal) 3.) Application by spraying a) Mixing and loading (dermal, inhalation) b) Application (dermal, inhalation, oral) c) Cleaning (dermal)
Secondary exposure Medium-term	Re-entry adults (dermal, inhalation) Re-entry toddlers (dermal, inhalation, oral) Re-entry children (dermal, inhalation, oral)

In addition, a reverse reference scenario for children (toddlers) ingesting the biocidal product accidentally is included in chapter 4.7: Safety for non-professional operators and the general public.

Table 12: Primary exposure of non-professional users to imidacloprid

Primary exposure scenario	Systemic Exposure (mg/kg bw [/d])			
	inhalation	dermal	oral	total
Placing and disposal of pellets in cups	0.000556	5.86 x 10^{-6}	-	0.000562
Brushing Mixing & loading Application Cleaning	 0.000556 4.80 x 10^{-9} -	 2.93 x 10^{-7} 0.00686 0.00050	 - - -	0.00792
Spraying Mixing & loading Application Cleaning	 0.000556 0.000211 -	 2.93 x 10^{-7} 0.0110 0.00050	 0.00130 -	0.0136

Table 13: Secondary exposure of the general public to imidacloprid

Secondary exposure scenario	Systemic Exposure (mg/kg bw [/d])			
	inhalation	dermal	oral	total
Adults, re-entry, stay in treated areas	0.0164	-	-	0.0164
Toddlers, stay in treated areas	-	0.0612	0.00768	0.138
Children, stay in treated areas	-	0.0256	0.0285	0.0541

Table 14: Primary exposure of non-professional users to *cis*-tricos-9-ene

Primary exposure scenario	Systemic Exposure (mg/kg bw [/d])			
	inhalation	dermal	oral	total
Placing and disposal of pellets in cups	0.000246	1.10 x 10^{-5}	-	0.000257
Brushing Mixing & loading Application Cleaning	 0.0002460.000137 -	 5.49 x 10^{-7} 0.0135 0.00099	 - - -	0.0148
Spraying Mixing & loading Application Cleaning	 0.000246 4.59 x 10^{-5} 5.74 x 10^{-5} -	 5.49 x 10^{-7} 0.0206 0.00099	 - 0.000288 -	0.0222

Table 15: Secondary exposure of the general public to *cis*-tricos-9-ene

Secondary exposure scenarios	Systemic Exposure (mg/kg bw [/d])			
	inhalation	dermal	oral	total
Adults, re-entry, stay in treated areas	0.00366	0.0307	-	0.0344
Toddlers, stay in treated areas	0.00688	0.115	0.0156	0.137
Children, stay in treated areas	0.00506	0.0480	0.00569	0.0588

In chapter 4.7: Safety for non-professional operators and the general public, the results of the exposure calculations for the active substances for the non-professional user and the general public are laid out.

3.5.2.3 Exposure to residues in food

For applications of SOFAST in industrial/commercial premises, households/private areas, as well as public areas contact with food or feed has been excluded via label restrictions. Therefore no residue assessment is conducted for these intended uses.

For applications of SOFAST in livestock facilities a residue assessment according to Guidance on Estimating Livestock Exposure (Guidance on BPR (2015), Vol. III, Parts B+C, Section 6) has been conducted as described in detail in Annex 4.8 “Residue behaviour”. In brief, oral exposure through intake of dead insects (chicken) and inhalation exposure (cattle, pig, chicken) were identified as relevant scenarios. All other livestock exposure scenarios were excluded via label restrictions.

A summary of the assessment is given in the following tables:

Table 16 Summary: Livestock exposure Imidacloprid

Summary: Livestock exposure (mg imidacloprid/kg bw/d)							
	Beef cattle	**Dairy cattle**	**Calf**	**Pig**	**Broiler chicken**	**Laying hen**	**Remarks**
Oral exposure							
Tier 1: Oral (ingestion of dead insects)	n.a.	n.a.	n.a.	n.a.	0.1029	0.0921	External exposure estimate (mg/kg bw/d)[a]
Tier 2 Oral (metabolism study)	n.a.	n.a.	n.a.	n.a.	meat[b] 0.0028 fat[b] 0.0038 liver[c] 0.0309 kidney[c] 0.0309	meat[b] 0.0028 fat[b] 0.0038 liver[c] 0.0276 kidney[c] 0.0276 eggs[b] 0.0046	Internal exposure estimate (mg/kg)[b,c]
Inhalative exposure							
Tier 1: Inhalative (SVC model)	9.29×10^{-9}	8.86×10^{-9}	1.16×10^{-8}	fattening 1.30×10^{-8} breeding 1.07×10^{-8}	1.09×10^{-8}	9.78×10^{-8}	External exposure estimate (mg/kg bw/d)[a]
Conclusion Refinement of the critical scenarios identified in Tier 1 shows that relevant residues of imidacloprid in livestock animal tissues from the intended uses of SOFAST in animal facilities are not expected. Residues in poultry edible tissues and eggs do not exceed the current MRLs of 0.05* mg imidacloprid/kg.							

[a] calculation of estimated external livestock exposure acc. to Guidance on BPR, Vol III Parts B+C, section 6 (see Annex 4.8)
[b] Internal exposure based on extrapolation from results of metabolism study (see Annex 4.8)
[c] value calculated from estimated external livestock exposure and transfer factor (see Annex 4.8)

Table 17 Summary: Livestock exposure Cis-tricos-9-ene

Summary: Livestock exposure (mg cis-tricos-9ene/kg bw/d)							
	Beef cattle	**Dairy cattle**	**Calf**	**Pig**	**Broiler chicken**	**Laying hen**	
Oral exposure							
Tier 1: Oral (ingestion of dead insects)	n.a.	n.a.	n.a.	n.a.	0.0206	0.0184	External exposure estimate (mg/kg bw/d)[a]
Tier 2: Oral (ingestion of dead insects)	n.a.	n.a.	n.a.	n.a.	0.0043	0.0039	Internal exposure estimate (mg/kg bw/d)[b]
Inhalative exposure							
Tier 1: Inhalative (SVC model)	0.8475	0.8084	1.059	fattening 1.187 breeding 0.9779	0.9971	0.8921	External exposure estimate (mg/kg bw/d)[a]
Tier 2: Inhalative (ConsExpo)	0.00050	0.00102	0.000675	fattening 0.00176 breeding (individual) 0.00151 breeding (group) 0.00193	free range, litter floor 0.00059 free range. grating floor 0.00059 parent broilers in rearing 0.00059	battery 0.000476 free range, litter floor 0.00186 free range. grating floor 0.000845	Internal exposure estimate (mg/kg bw/d)[b,c]
Conclusion Refinement of the critical scenarios identified in Tier 1 shows that based on label restrictions and additional information on the LD_{50} of imidacloprid relevant residues of cis-tricos-9-ene in livestock animal tissues from the intended uses of SOFAST in animal facilities are not expected. Residues livestock edible tissues do not exceed the default MRLs of 0.01* mg/kg that applies for cis-tricos-9-ene.							

[a] calculation of estimated external livestock exposure acc. to Guidance on BPR, Vol III Parts B+C, section 6 (see Annex 4.8)
[b] Internal exposure based on assumptions supported by literature data (see Annex 4.8)
[c] Internal exposure based on calculation with ConsExpo model (see Annex 4.8)

3.5.3 Risk Characterisation

Exposure of professional users to biocidal products generally takes place via the inhalation and/or dermal route and is usually assessed by means of external inhalation and/or dermal exposure values. For many substances (both active substances and substances of concern) external reference values such as occupational exposure levels (OELs) are available. By contrast, internal or systemic reference values

normally exist for active substances only. Therefore, external reference values will preferably be the basis for the risk characterisation of biocidal products as chemical mixtures. In case only internal or systemic reference values are available, they will be converted to external reference values in order to allow for a comparison with external exposure values.

For detailed calculations for the biocidal product SOFAST see chapters 4.6: Safety for professional operators and 4.7: Safety for non-professional operators and the general public.

3.5.3.1 Risk for Professional Users

Based on the risk assessment of both active substances imidacloprid and cis-tricos-9-ene via inhalation and dermal route, a risk for professional users resulting from the intended uses with the biocidal product SOFAST is unlikely. Regarding occupational safety, there are no objections against the intended uses taking into account the provisions described below:

The following personal risk mitigation measures shall be applied (for use by professional users) for spray treatment and brush treatment unless they can be replaced by technical and/or organisational measures:

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- For spray treatment, in addition to chemical resistant gloves, a protective coverall (at least type 4, EN 14605).
- Application by spray and brush treatment on cardboard should be carried out leaving an untreated area around the edge.
- When treated cardboard is fixed to walls (or ceilings) or is collected for disposal only the untreated area around the edge should be touched.

Imidacloprid:

Based on the risk assessment of imidacloprid via inhalation and dermal route, a risk for professional users resulting from all intended uses spray treatment, brush treatment and application of granular bait is unlikely.

The quantitative risk characterisation which is presented in this PAR takes into account on the one hand dermal exposure to imidacloprid and on the other hand inhalation exposure to imidacloprid resulting from use of the biocidal product SOFAST. For the active substance the corresponding airborne concentrations are compared with the $AEL_{long\text{-}term}$ which is converted to external reference values.

Table 18 gives an overview of the considered scenarios and of the risk characterisation results referring to imidacloprid for the biocidal product SOFAST. It is noted, that the risk indices (RI) are each rounded up or down to one decimal in this table. For detailed calculations and risk indices for the different scenarios see chapter 4.6.

Table 18: Overview of risk characterisation results referring to imidacloprid for use of the biocidal product SOFAST.

Intended use	TIER 1		TIER 2	
	concern	RI	concern	RI
spray treatment	**yes**	2.5	**no**	0.4
brush treatment	**no**	0.3	**no**	0.2
application of granular bait	**no**	0.1	**no**	0.01

Cis-tricos-9-ene:

Based on the risk assessment of cis-tricos-9-ene via inhalation and dermal route, a risk for professional users resulting from all intended uses spray treatment, brush treatment and application of granular bait is unlikely.

The quantitative risk characterisation which is presented in this PAR takes into account on the one hand dermal exposure to cis-tricos-9-ene and on the other hand inhalation exposure to cis-tricos-9-ene resulting from use of the biocidal product SOFAST. For the active substance the corresponding airborne concentrations are compared with the $AEL_{long\text{-}term}$ which is converted to external reference values.

Table 19 gives an overview of the considered scenarios and of the risk characterisation results referring to cis-tricos-9-ene for the biocidal product SOFAST. It is noted, that the risk indices (RI) are each rounded up or down to one decimal in this table. For detailed calculations and risk indices for the different scenarios see chapter 4.6.

Table 19: Overview of risk characterisation results referring to cis-tricos-9-ene for use of the biocidal product SOFAST.

Intended use	TIER 1		TIER 2	
	concern	RI	concern	RI
spray treatment	**yes**	10.6	**no**	0.9
brush treatment	**yes**	1.4	**no**	0.8
application of granular bait	**no**	0.4	**no**	0.1

In summary, a risk for professional users resulting from the uses of the biocidal product SOFAST is unlikely since the risk characterisation consistently yields total risk indices of less than 1 at least after TIER 2 consideration. Risk reduction measures according to chapter 2.5 have to be taken into account in order to ensure safe use of the biocidal product SOFAST. The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.5.3.2 Risk for non-professional users and the general public

Exposure of non-professional users and the general public to the biocidal product SOFAST containing 0.5 % (w/w) imidacloprid and 0.1 % (w/w) *cis*-tricos-9-ene as active substances is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.
This also applies to pets.

No risk has been identified for non-professional users if the biocidal product is used as intended.
A risk has been identified for adults, children and pets by unintentional secondary exposure nearby treated surfaces. It is expected that this risk can be managed by additional risk mitigation measures (e.g. application inaccessble for children and pets; decontamination procedures in the surrounding of treated surfaces).
Applying a reverse reference scenario concerns by exposure to imidacloprid and *cis*-tricos-9-ene have been identified for toddlers and pets, which ingest the biocidal product unintentionally, particularly in the pure granular form. Therefore, access of children and pets to the bait have to be avoided. Spills have to be cleaned up immediately.

Table 20: Risk characterisation for primary exposure of non-professional users to imidacloprid

Primary exposure scenario	Systemic Exposure (mg/kg bw [/d])				Relevant AEL / NOAEL (mg/kg bw [/d])	AF/ ref. MoE	% AEL	MoE
	inhalation	dermal	oral	total				
Placing and disposal of pellets in cups	0.000556	5.86 x 10^{-6}	-	0.000562	$AEL_{med.-term}$ 0.2 $NOAEL_{med.-t.}$ 20	100	0.3	35587
Brushing Mixing & loading Application Cleaning	0.000556 4.80 x 10^{-9} -	2.93 x 10^{-7} 0.00686 0.00050	- - -	0.00792			4.0	2525

Spraying Mixing & loading Application Cleaning	0.000556-0.000211 - 	2.93 x 10^{-7} 0.0110 0.00050	0.00130 -	0.0136			6.8	1471

Table 21: Risk characterisation for secondary exposure of the general public to imidacloprid

Secondary exposure scenario	Systemic Exposure (mg/kg bw [/d])				Relevant AEL / NOAEL (mg/kg bw [/d])	AF/ ref. MoE	% AEL	MoE
	inhalation	dermal	oral	total				
Adults, re-entry, stay in treated areas	0.0164	-	-	0.0164	$AEL_{med.-term}$ 0.2 $NOAEL_{med.-t.}$ 20	100	8.2	1220
Toddlers, stay in treated	-	0.0612	0.00768	0.138			69	145
Children, stay in treated areas	-	0.0256	0.0285	0.0541			27	370

Table 22: Risk characterisation for primary exposure of non-professional users to *cis*-tricos-9-ene

Primary exposure scenario	Systemic Exposure (mg/kg bw [/d])				Relevant AEL / NOAEL (mg/kg bw [/d])	AF/ ref. MoE	% AEL	MoE
	inhalation	dermal	oral	total				
Placing and disposal of pellets in cups	0.000246	1.10 x 10^{-5}	-	0.000257	$AEL_{med.-term}$ > 0.024 $NOAEL_{med.-t.}$ not available	n.a.	1.1	n.a.
Brushing Mixing & loading Application Cleaning	0.0002460.000137 -	5.49 x 10^{-7} 0.0135 0.00099	- - -	0.0148			62	n.a.
Spraying Mixing & loading Application Cleaning	0.000246 4.59 x 10^{-5} 5.74 x 10^{-5} -	5.49 x 10^{-7} 0.0206 0.00099	- 0.000288 -	0.0222			92	n.a.

Table 23: Risk characterisation for secondary exposure of the general public to *cis*-tricos-9-ene

Secondary exposure scenarios	Systemic Exposure (mg/kg bw [/d])				Relevant AEL / NOAEL (mg/kg bw [/d])	AF/ ref. MoE	% AEL [1)]	MoE
	inhalation	dermal	oral	total				
Adults, re-entry, stay in treated areas	0.00366	0.0307	-	0.0344	$AEL_{med.-term}$ > 0.024 $NOAEL_{med.-t.}$ not available (AEL_{acute}: 0.57)	n.a.	143 (6)	n.a.
Toddlers, stay in treated areas	0.00688	0.115	0.0156	0.137			573 (24)	n.a.
Children, stay in treated areas	0.00506	0.0480	0.00569	0.0588			245 (10)	n.a.

[1)] in brackets: percentage of AEL_{acute}.

It is acknowledged that the use of the $AEL_{medium-term}$ in this case might be very conservative, particulary for adults, which are often aware of touching such surfaces. Based on the surface which is treated (1 m^2 wall per 100 m^2 floor) daily contact to contaminations on the ground or even to the treated wall is unlikely. Thus, intermittent exposure over the summer season is more realistic. However, for intermittent exposure neither reference values nor an appropriate guidance for exposure and risk assessment is available. Comparing the estimated daily exposure with the AEL_{acute} (resulting in acceptable exposure levels) is also not appropriate since no detailed information on exposure frequency is available. In this light, risk mitigation measures, which can reduce the load on contaminated surfaces around the application sites (e.g. by wiping of these surfaces by the user after application) are considered realistic to reduce exposure to acceptable levels.

It is assumed that for the user of this biocidal product this post application task (decontamination) is covered by the exposure scenario cleaning.

Reverse reference scenario for toddlers 'Oral ingestion of the biocidal product'

No exposure model exists for the scenario of a toddler ingesting orally pure granules or application dilutions in water. Since the biocidal product is applied in private households it cannot be generally excluded even if an aversive agent to minimise such an exposure is added. Therefore, a reverse reference scenario is calculated.

Based on the concentration of the active substances imidacloprid (0.5 %, w/w) and *cis*-tricos-9-ene (0.1 %, w/w) in the biocidal product, a body weight of 10 kg and the AEL_{acute} of 0.4 mg/kg bw and 0.57 mg/kg bw, respectively, the maximum acceptable dose can be calculated:

Imidacloprid: 800 mg biocidal product

cis-Tricos-9-ene: 5700 mg biocidal product

One teaspoon counts for approximately 5 g of the biocidal product. Thus, regarding imidacloprid the acceptable amount, which can be ingested by a toddler, is 6.25-fold lower than this simplified unit. Although an aversive agent has been added, the ingestion of such an amount is not unlikely if an infant has access to cups filled with biocidal product or to freshly prepared dilutions.
Thus, next to the addition of an aversive agent further risk mitigation measures to prevent unintended access of toddlers to the biocidal product are required.

3.5.3.3 Risk for consumers via residues

Uses in industrial/commercial, households/private areas and public areas
Contact with food, feed or livestock animals is avoided by applying appropriate risk mitigation measures. Consequently imidacloprid and cis-tricos-9-ene residues in food are not expected and a risk for consumers via residues in food is excluded.

Uses in animal facilities
Based on the results of the external livestock exposure estimate (see Annex 4.8 Residue behaviour) transfer of relevant residues into animal edible tissues is not expected and residues of imidacloprid and cis-tricos-9-ene in food of animal origin above the existing MRLs according to Regulation (EU) No. 396/2005 are not expected.
A risk for consumers via residues of imidacloprid and cis-tricos-9-ene in food of animal origin is not expected, provided that appropriate risk mitigation measures are observed.

The following risk mitigation measures are proposed:

- 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.
- The product can be applied in the presence of animals, if contact with the biocidal product is avoided.
- Place cardboards treated with biocidal product out of reach of livestock animals.
- Place bait stations out of reach of livestock animals.
- Do not apply the biocidal product directly on manure/slurry.

3.6 Risk assessment for animal health

Exposure of non-professional users and the general public to the biocidal product SOFAST containing 0.5 % (w/w) imidacloprid and 0.1 % (w/w) *cis*-tricos-9-ene as active substances is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.
This also applies to pets and livestock animals, given that the biocidal product is placed out of reach of those. Due to the allocated RMM, direct contact of livestock animals with the product will be excluded.

Hence, dermal and oral exposure is not relevant, with the exception of chicken potentially feeding on dead insects. Furthermore, as shown in section 4.8, the maximum external inhalation exposure of livestock animals is calculated for laying hens with only 9.78×10^{-8} mg imidacloprid/kg bw/d and can therefore be considered to have very minor impact on total exposure. Hence, the estimates of external livestock exposure assessment of broiler chicken (0.1029 mg/kg bw/d) and laying hens (0.0921mg/kg bw/d) mostly result from oral exposure, calculated in the scenario “ingestion of dead insects”.

Although these external exposure values are exceeding the human $AEL_{long\text{-}term}$ of 0.06 mg/kg bw/d for imidacloprid, DE considers the exposure of livestock animals and poultry in particular as acceptable for the following reasons:

Due to uncertainties in the allometric scaling, there is currently no consensus on safety factors for interspecies differences of domestic and farm animals in the EU for biocides RA, in particular when considering the existing remaining sources of the toxicokinetic differences between relevant animal species. Hence, DE prefers a stepwise approach. In a first step, the total internal dose received by the animal is compared to the AEL of the active substance for human health. If the estimated total doses in livestock exceeds the AEL, than a Margin of Exposure (MoE) assessment should be performed. Here, the MoE between the estimated total doses in chicken and the NOAEL of 6 mg/kg bw/d, obtained in a 2-year toxicity study in rats, will be 58 for broiler chicken and 65 for laying hens, which is considered acceptable according to the EFSA guidance document on risk assessment for birds and mammals (EFSA, 2009).

In addition, the scenario “ingestion of dead insects” includes very conservative assumptions. A refinement of the oral exposure estimates results in calculated internal residues in liver or kidney of up to 0.0309 mg imidacloprid/kg bw/d in broiler chicken and 0.0276 mg imidacloprid/kg bw/d in laying hens. When assuming that these values reflect the maximum available systemic dose, no unacceptable health risk is to be expected, since the human $AEL_{long\text{-}term}$ of 0.06 mg/kg bw/d for imidacloprid will not be exceeded.

3.7 Risk assessment for the environment

3.7.1 Environmental effects assessment

The biocidal product SOFAST contains two active substances, imidacloprid and *cis*-tricos-9-ene (muscalure). Therefore, both active substances have normally to be considered for the environmental effects assessment.
However, for *cis*-tricos-9-ene no PNECs were derived in the CAR based on intended indoor use of the representative product and the fact, that the substance is a pheromone with a highly target-specific mode of action. The available aquatic ecotoxicity studies with fish and daphnids indicate that no toxic effects up to and above the water solubility limit of *cis*-tricos-9-ene occur.
As the product SOFAST is intended to be used exclusively indoors and the concentration of *cis*-tricos-9-ene in the product is 5 times lower than the concentration of imidacloprid, the effects assessment for the product SOFAST is confined to the active substance imidacloprid.

Imidacloprid:
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 the 3rd party dossier).

3.7.1.1 Aquatic effects assessment

Imidacloprid:
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.[8] 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).

[8] 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 equilibrium partitioning method. Using a $K_{susp\text{-}water}$ of 6.3 and a RHO_{susp} of 1150 kg/m³ results in a **$PNEC_{sediment}$ of 26 ng/kg ww.**

In the CAR and assessment report for imidacloprid a $PNEC_{stp}$ of 100 mg/L was derived for sewage treatment plants from a standard activated sludge respiration inhibition test with sludge from domestic sewage treatment plant in which a NOEC equal to 5,600 mg/L and a EC50 > 10,000 mg/L were determined.

Within product authorisation for the product SOFAST new information compared to the CAR has been provided. In a test submitted on the respiration inhibition of activated sludge also conducted according to OECD 209 (Doc IIIA 7.4.1.4*)*, the NOEC was determined to be 10 000 mg a.s/L.

According to the Guidance on the BPR, Volume IV, Part B, Infobox Nr. 7, p. 127 (ECHA, April 2015) if no inhibition is observed for active substances tested at concentrations exceeding their water solubility, the NOEC is now set equal to the water solubility which is subsequently used to derive the $PNEC_{stp}$. This results in a NOEC of 613 mg/L for the active substance imidacloprid, since in both tests concentrations higher than the water solubility were used.

With a NOEC value of 613 mg/L derived from the two studies available both conducted according to OECD 209, the **$PNEC_{stp}$ amounts to 61.3 mg/L**

3.7.1.2 Terrestrial effects assessment

Imidacloprid:

For the terrestrial compartment the applicant Sharda provided new effect values for *Folsomia candida* (effects on reproduction) as well as tests on nitrogen and carbon mineralisation. These effect values are also 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.**

3.7.1.3 Non compartment specific effects relevant to the food chain (primary and secondary poisoning)

Imidacloprid:
Due to the low bioaccumulation potential no assessment for secondary poisoning for fish or worm eating birds and mammals is necessary.

3.7.2 Environmental exposure assessment

The biocidal product (b.p.) SOFAST is an insecticidal granular formulation containing 0.5% w/w Imidacloprid and 0.1% w/w *cis*-tricos-9-ene. SOFAST is applied indoors in households, commercial and public areas. The product is either applied as water based solution by spaying or brushing or as ready to use granular bait by private users or professionals:

Spraying: 200 g of the b.p. is dissolved in 200 ml water to be applied with pressure pumps. The solution obtained should stand at least 15 minutes before application and should only be applied 7-8 hours maximum after its preparation. The b.p. should be applied on non-porous surfaces where flies usually lay such as walls, window sills, pipes, joists. An effective application surface of 1 m^2 is foreseen to treat floor surface of 100 m².

Brushing: 200 g of the b.p. is dissolved in 150 ml of water to be applied with paintbrushes or brushes. The solution obtained should stand at least 20 minutes before application and should only be applied 7-8 hours maximum after its preparation. The b.p. should be applied on non-porous surfaces where flies usually such as walls, window sills, pipes, joists An effective application surface of 1 m^2 is foreseen to treat floor surface of 100 m².

Granular bait: The b.p. should be placed in cups, shallow dishes, bowls or bait stations with an application rate of 20 g b.p. every 10 m².The bait should be placed preferably in sheltered areas.

The predicted environmental concentrations (PECs) for each compartment relevant for insecticide applications in households are assessed applying the Guidance on BPR Vol. IV ENV Part B Risk

Assessment (a.s.) (April, 2015) 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).

As a major change the addition of professional use in animal housing premises against flies (adults) by painting on cardboards and as granular bait was applied for by the applicant.

Painting on cardboards: A rate of 200 g of the b. p. is diluted in 150 mL of water to be applied by painting on cardboards with a total surface of 1 m^2 for treating 100 m^2 floor area. The treated cardboards should then be placed in areas where flies prefer to rest. The maximum application frequency is indicated as 6 times per year.

Granular bait: A rate of 20 g of the b.p. is applied in disposable shallow dishes or bait station for treating 10 m^2 floor area. Again, the maximum application frequenciy is indicated as 6 times per year.

The predicted environmental concentrations (PECs) for each compartment relevant for insecticide applications in animal housings are assessed applying the Guidance on BPR Vol. IV ENV Part B+C Risk Assessment (a.s.) (October 2017) chapter 2.3.8 and the emission scenario description is based on the Emission Scenario Document for Insecticides for Stables and Manure Storage Systems (OECD ESD PT 18 No.14, 2006).

The applicant has a full letter of access to the data from the active substance dossier for both active substances. In addition, for the active substance imidacloprid, further environmental fate data were delivered from the applicant (see DOC IIIA of the 3rd party dossier). These data were evaluated by RefMS and considered for the environmental exposure estimation of SOFAST if the new data were considered as being reliable. The following endpoints are considered:

Imidacloprid

- **Water solubility:**
  The applicant has provided new data on water solubility of the a.s. Solubility in demineralised water at 20°C and pH 7 of 614 mg/L is given.

- **Vapour pressure:**

  Imidacloprid is not considered to be volatile (vapour pressure $4 \cdot 10^{-10}$ Pa at 20°C). The Henry's constant is $1.677 \cdot 10^{-10}$ $Pa \cdot m^3$ Mol^{-1} at 20°C. Therefore, imidacloprid has a low potential of volatilizing from water.

- **Biodegradation:**

  Based on the results from a new study on ready biodegradability (Doc IIIA 7.1.1.2.1) performed according to OECD 301A, imidacloprid attained 0% degradation after 28 days and is therefore confirmed to be 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 DT50 of 185.4 d was determined with a mineralisation rate of max. 2%, in the soil simulation studies the geometric mean DT50 value was 295 days. The degradation rate constant in soil k_{bio_soil} is $5.13 \cdot 10^{-3}$ d^{-1}.

- **Distribution in soil:**

  The applicant provided new information about the sorption behavior of the a.s. in 4 different soils (Doc IIIA A.7.1.3). The study showed that the a.s. can be classified as being highly mobile in soils with Ka_{oc} of 54.8 – 61.4 cm^3 g^{-1}. The RefMS considers the study reliable with only minor deficits. Therefore, for environmental exposure assessment, both studies (3rd party dossier and active substance dossier) were considered. A mean organic carbon-water partitioning coefficient was calculated considering 4 soils of the 3rd party dossier and 12 soils from the active substance dossiers (with Ka_{oc} of 121 – 411 mL g^{-1}), respectively. A mean Ka_{oc} of **186.6 mL g^{-1}** was calculated and considered for environmental exposure assessment. This organic carbon-water partitioning coefficient indicates a moderately mobility of the a.s. in soils.

- **Distribution in STP:**

  The distribution of imidacloprid in the sewage treatment plant is calculated using the SimpleTreat 3.0-model with the following release fractions: to air 0.0 %, to water 97.7 %, to sludge 2.3 % and the degraded fraction is 0.0 %. Imidacloprid is not biodegradable and for that reason the degradation rate constant in sewage treatment plant is k_{STP}= 0 h^{-1} (Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015), chapter 2.3.6.4, table 6).

- **Bioaccumulation:**

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

***cis*-tricos-9-ene**

- **Water solubility:**
  The water solubility is <7 x 10^{-6} g/L (at pH 4, 7 or 10; 20°C).
- **Vapour pressure:**
  The vapor pressure of the active substance is 6.4 x 10^{-2} Pa at 20°C and 0.119 Pa at 25°C; the calculated Henry's law constant is 2.95 x 103 Pa x m^3/mol.
- **Biodegradation**
  Based on model estimations on ready biodegradability and on its role in intraspecies communication it can be concluded that cis-tricos-9-ene will dissipate in environmental compartments due to biodegradation. However, in absence of substance specific data, a degradation rate constant in soil of $6.93 \cdot 10^{-7}$ d^{-1} (100000 d) was considered for environmental exposure assessment.
- **Distribution in soil:**
  A modelled log Koc of 6.7 was considered for environmental exposure assessment, indicating strong adsorption onto soil.
- **Distribution in STP:**
  The distribution of cis-tricos-9-ene in the sewage treatment plant is calculated using the SimpleTreat 3.0-model with the following release fractions: to air 8.7 %, to water 6.5 %, to sludge 83.2 % and the degraded fraction is 1.7 %. Cis-tricos-9-ene is classified as readily biodegradable based on QSAR estimation. However, due to the uncertainties of QSAR estimations and in order to be conservative, the degradation rate constant in sewage treatment plant is set to k_{STP}= 0.3 h^{-1} (Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015), chapter 2.3.6.4, table 6).

3.7.2.1 Indoor use as granular bait in private houses and commercial buildings

During the first version of the product assessment report from 17.01.2017, the RefMS considered the application of the b.p. SOFAST as granular bait in disposable cups, shallow dishes and bowls as equivalent to the placing in bait stations. For the later application pattern, the OECD ESD PT18 No. 18 (2008) specifies that emissions to the environment during the use of solid baits and gels deployed in bait stations are negligible during the service life stage. Consequently, an quantitative exposure assessment has not been performed.

During the mutual recognition of the authorization of the biocidal product SOFAST, UK CA has remarked strong doubts in the above mentioned assumption of negligible environmental emissions. To account for UK CAs concern the RefMS has conducted an quantitative exposure assessment. In

absence of an agreed environmental exposure scenario for a comparable product, the RefMS proposes the following exposure scenario:

Release during mixing and loading

In case of the application as granular bait, the mixing and loading step would be equivalent to the filling of the b.p. into the disposable shallow dishes. Minor losses during this use step would be possible. However, as no agreed emission scenario for this kind of application exist, RefMS did not account for this emissions separately but rather included this pathway into the application step.

Release during application

The product SOFAST is applied in disposable shallow dishes with an application rate of 2 g x m^{-2} (20g of product per cup and 1 cup for 10m^2 room surface) on a general surface area of 130m^2 (household) and 609m^2 (larger building). As a first assumption, 100% of the product reaches the area around the application site due to any kind of spills, either during the preparation or application phase. These areas may be e.g. windowsills, sideboards or ledges and are subject to wet cleaning. The contaminated area is according to TAB (September 2015) reduced by a factor of 0.296, taking the wet cleaning zone of a house into account.

Table 24: Emission scenario for indoor granule application in disposable cups of SOFAST during application step

Determinants of the emission scenario	Value	
	Imidacloprid	cis-tricos-9-ene
Quantity of b.p. applied [$Q_{b.p.}$]	2 g.m^{-2}	
Fraction of a.s. in the product [$F_{a.s.}$]	0.005	0.001
Quantity of a.s. applied [$Q_{a.s.}$]	0.01 g.m^2	0.002 g.m^2
Area treated with the product [$AREA_{treated}$] *- household* *- com. building*	 1.3 m^2 6.09 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 applicator [$F_{application, applicator}$]	0.0	
Fraction emitted to floor [$F_{application, floor}$]	1.0	
Wet cleaning zone correction factor [$F_{wet\ cleaning}$]	0.294	
Emission rates due to application of SOFAST in households		
Local emission rate to “wet cleaning zone” floor $E_{application, floor} = N_{appl, building} \times F_{application, floor} \times Q_{a.s.} \times AREA_{treated} \times F_{wet\ cleaning}$	3.82 x 10^{-4} kg.d^{-1}	7.64 x 10^{-5} kg.d^{-1}
Emission rates to due to application of SOFAST in commercial buildings		
Local emission rate to “wet cleaning zone” floor	1.79 x 10^{-3} kg.d^{-1}	3.58 x 10^{-4} kg.d^{-1}

$E_{application, treated\ area}$ = $N_{appl, building} \times F_{application, floor} \times Q_{a.s.} \times AREA_{treated} \times F_{wet\ cleaning}$		

In absence of appropriate default values, a cleaning efficiency of 3% was considered realistic to quantify the amount of a.s. taken up by the cleaning water. The cleaning efficacy was lowered to account for the fact that only minor losses of the product can be expected during the use phase of the product. The factor is in line with assumptions for a crack and crevice application made to an area not subject to routine wet cleaning and was proposed by UK CA. It should be noted, that the worst-case assumption of 100% release to the floor **in combination** with the low cleaning efficacy of 3% leads to a realistic estimation of emissions to the environment of 3%, covering any kind of loss due to spills, either during application or preparation.

[The applicant proposed during the commenting phase of the mutual recognition the "powder scenario" as an appropriate approach for the assessment of the environmental exposure - with additional refinement of selected input parameters. Although the RefMS could accept to apply the powder scenario in general, RefMs disagreed with some of the proposed input parameters by the applicant. For transparency, the differences between the powder scenario as RefMS would consider to be appropriate and the above described approach are briefly described here. In the powder scenario, an release factor to floor/ wet cleaning areas of 0.19 (0.18 for application and 0.01 for preparation) is proposed. Considering a corresponding cleaning efficacy of 50% for powder applications would lead to an overall emission of the product to the floor/wet cleaning area of 8.5% - instead of 3% as in the above described scenario. The RefMS decided to keep the scenario that was agreed during the referral of disagreement from UK instead of the powder scenario as discussed by the applicant – which would however not change the outcome of the risk assessment.]

Table 25: Emission scenario for indoor granule application of SOFAST in disposable cups during the cleaning step

Determinants of the emission scenario	Value	
	Imidacloprid	cis-tricos-9-ene
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 cleaning step [$F_{floor, ww}$]	1	
Fraction emitted to waste from applicator - disposable coveralls [$F_{applicator, w}$]	0	
Fraction emitted to waste during [$F_{floor, w}$]	0	
Emission rates		
Local emission rate to air	0 $kg.d^{-1}$	
Local emission rate to waste water during cleaning step from **applicator**	0 $kg.d^{-1}$	
Local emission rate to waste water during cleaning step from **floor and treated area** $E_{floor/treated\ area, ww}$ = $(E_{prep, floor} + E_{application, floor} + E_{application, treated\ area}) \times F_{floor, ww} \times F_{CE}$		
- households	1.15 x 10^{-5} $kg.d^{-1}$	2.30 x 10^{-6} $kg.d^{-1}$
- commercial buildings	5.37 x 10^{-5} $kg.d^{-1}$	1.07 x 10^{-5} $kg.d^{-1}$

Release estimation to sewage treatment plant

It is supposed that residues removed through wet cleaning may potentially be emitted to the sewer and subsequently to the sewage treatment plant (STP). According to the ESD No. 18 (2008) the STP is considered as one of the main “receiving 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 BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015). According to this, the further receiving environmental compartments are surface water and sediment (after STP), soil and groundwater (from sludge application), and the outdoor air.

The water releases per day E_{ww_sim} from households and commercial buildings were summed up to perform a cumulative assessment. The input values for determining releases to STP in the course of the application of SOFAST in disposable shallow dishes as well as the calculated emission rates are summarised in Table 26.

According to ESD PT 18 (2008) and to TAB version 1.2 (2016) 4000 public buildings and 300 commercial building are connected to one STP. Furthermore, a simultaneity factor (F_{sim}) was implemented in the ESD PT18 that considers the simultaneity of treatments by the houses and commercial buildings connected to the STP. For indoor applications, the ESD presumes per default a daily application of the biocidal products, leading to a simultaneity factor of 5.5% (F_{sim} = 0.055). However, according to the intended use of SOFAST, a maximum of 6 applications per year is assumed. Therefore, the simultaneity factor is calculated without taking into account the frequency of insecticide used on a daily, weekly and monthly basis:

$$F_{sim} = \frac{1.9 \times 32.15 + 0.54 \times 37.82}{100} = 0.82\%$$

The application of the b.p. in a typical scenario results in release of **5.08 x 10^{-4} kg d^{-1}** imidacloprid and **1.02 x 10^{-4} kg d^{-1}** cis-tricos-9-ene to STP.

Table 26: Cumulative and simultaneous emission scenario for indoor granule application of SOFAST in disposable cups during cleaning step.

Input	**Value**	
	Imidacloprid	**cis-tricos-9-ene**
Number of houses connected to STP [N_{houses}]		
- private houses	4000	
- commercial buildings	300	
Simultaneity factor indoor [F_{Sim}]	0.0082	
Output		
Simultaneous emission to waste water during cleaning step: $E_{ww\_sim} = (E_{floor/treated\ area,\ ww} + E_{applicator,\ ww}) \times N_{houses} \times F_{Sim}$		
- households	1.32 x 10^{-4} kg.d^{-1}	2.64 x 10^{-5} kg.d^{-1}
- commercial buildings	3.76 x 10^{-4} kg.d^{-1}	7.52 x 10^{-5} kg.d^{-1}
Cumulative emission to waste water:	**5.08 x 10^{-4} kg.d^{-1}**	**1.02 x 10^{-4} kg.d^{-1}**

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

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

PEC_{STP} (=$Clocal_{inf}$) and $Clocal_{eff}$ according to equation 32, 33 and 39, chapter 2.3.7.1, Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015),
$PEClocal_{surfacewater}$ according to equation 48, chapter 2.3.8.3, Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015),
$PEClocal_{sediment}$ according to equation 50, chapter 2.3.8.4, Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015).

The results are summarised in Table 27.

Table 27: Summary of STP influent (Clocalinf) and effluent (Clocaleff), PECSTP, PEClocalsurface water and PEClocalsediment.

	$Clocal_{inf}$ [µg.L^{-1}]	**$Clocal_{eff}$** [µg.L^{-1}]	**PEC_{STP}** [µg.L^{-1}]	**$PEClocal_{surface\ water}$** [µg.$L^{-1}$]	**$PEClocal_{sediment}$** [µg.kg^{-1}]
Imidacloprid	2.54×10^{-1}	2.48×10^{-1}	2.54×10^{-1}	2.48×10^{-2}	1.20×10^{-4}
cis-tricos-9-ene	5.08×10^{-2}	3.30×10^{-3}	5.08×10^{-2}	3.88×10^{-5}	1.87×10^{-7}

3.7.2.1.2 Estimation of Predicted Environmental Concentrations for the terrestrial compartment

The application of sludge from the STP onto agricultural and grassland soil provokes an indirect emission to soil, as well as the leaching of a.s. through soil following sludge application causes indirect emission to groundwater. The PEC_{soil} is estimated according to equation 66, chapter 2.3.8.5, Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015). Additionally, the estimation of the local PECs for the terrestrial compartment includes also groundwater. The $PEC_{groundwater}$ is calculated according to equation 68, chapter 2.3.8.6, Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015) as a first worst-case estimation. Table 28 indicates the PEC in soil and groundwater for imidacloprid according to the application scenario.

Table 28: Summary of Csludge, PEClocalsoil and PEClocalgroundwater

	C_{Sludge} [µg.kg^{-1}]	$PEClocal_{soil}$ [µg.kg^{-1}]	$PEClocal_{Groudwater}$ [µg.L^{-1}]
Imidacloprid	1.58 x 10^{-2}	2.46 x 10^{-5}	4.96 x 10^{-3}
cis-tricos-9-ene	1.20 x 10^{1}	1.71 x 10^{-3}	1.94 x 10^{-5}

3.7.2.2 Spraying or brushing indoors in household, commercial and public areas

3.7.2.2.1 Release estimation

SOFAST should be applied on non-porous surfaces where flies usually lay such as walls, window sills, pipes, joists. SOFAST is formulated as granules and has to be diluted in water before application. Due to the proposed use pattern of the b.p., the application mode can be described as target spot application. Environmental exposure may arise either due to washing of contaminated clothes from the applicator or due to wet cleaning of the treated surface and its surrounding floor surface. Both pathway will subsequent lead to release of contaminated waste water to the STP system.

The release to the environment is assessed by the emission scenario described in chapter 3.3.1 of OECD ESD No. 18 (2008). The OECD ESD No. 18 (2008) has no specific scenario for applications by brushing. The RefMS is of the opinion, that the scenario for spray applications is suitable to cover possible release for brushing applications. Therefore, an environmental exposure assessment is only conducted for spray application.

Release during mixing and loading

The input values for determining releases to the environment during the preparation step SOFAST as well as the calculated emission rates are summarised in Table 29. An application rate of 200 g of product per 100 m^2 of floor surface to be applied on an effective surface of 1 m^2 per 100 m^2 floor surface is envisaged. According to TAB (September 2015) the surface area of a standard house and of commercial buildings is set to 130 m^2 and 609 m², leading to an effective target surface of 1.3 m² and 6.09 m², respectively. The number of preparation steps per day is set to 1 for private households and 3 for larger buildings, as given by ESD PT 18 (OECD, 2008). The ESD PT 18 (OECD, 2008) defines emission factor to the floor depending on the design of the containers where the spray broth is prepared in (ESD PT 18 (OECD, 2008); Table 3.2-3). For an unspecific container with a volume of 1 liter, which is the smallest available container that is sufficiently big enough to prepare the needed spray broth, an emission for the general public of 0.1% is proposed. For release estimation to the applicator, an emission of 0.12% is proposed. Moreover, the ESD PT 18 states that no release to air can be expected.

Table 29: Emission scenario for indoor spot application of SOFAST during mixing and loading step

Determinants of the emission scenario	Value	
	Imidacloprid	cis-tricos-9-ene
Quantity of b.p. applied [$Q_{b.p.}$]	200 $g.m^{-2}$	
Fraction of a.s. in the product [$F_{a.s.}$]	0.005	0.001
Quantity of a.s. applied [$Q_{a.s.}$]	1 $g.m^2$	0.2 $g.m^2$
Area treated with the product [$AREA_{treated}$] *- household* *- com. building*	 1.3 m^2 6.09 m^2	
Number of preparations per day [$N_{appl, building}$] *- household* *- com. building*	 1 d^{-1} 3 d^{-1}	
Fraction emitted to air [$F_{prep, air}$]	0	
Fraction emitted to applicator [$F_{prep, applicator}$]	0.0012	
Fraction emitted to floor [$F_{prep, floor}$]	0.001	
Emission rates due to mixing and loading of SOFAST in households		
Local emission rate to air $E_{prep, air} = N_{prep, building} \times F_{prep, air} \times Q_{a.s.} \times AREA_{treated}$	0 $kg.d^{-1}$	0 $kg.d^{-1}$
Local emission rate to floor $E_{prep, floor} = N_{prep, building} \times F_{prep, floor} \times Q_{a.s.} \times AREA_{treated}$	1.30 x 10^{-6} $kg.d^{-1}$	2.60 x 10^{-7} $kg.d^{-1}$
Local emission rate to applicator $E_{prep, applicator} = N_{prep, building} \times F_{prep, applicator} \times Q_{a.s.} \times AREA_{treated}$	1.56 x 10^{-6} $kg.d^{-1}$	3.12 x 10^{-7} $kg.d^{-1}$
Emission rates to due to mixing and loading of SOFAST in commercial buildings		
Local emission rate to air $E_{prep, air} = N_{prep, building} \times F_{prep, air} \times Q_{a.s.} \times AREA_{treated}$	0 $kg.d^{-1}$	0 $kg.d^{-1}$
Local emission rate to floor $E_{prep, floor} = N_{prep, building} \times F_{prep, floor} \times Q_{a.s.} \times AREA_{treated}$	1.83 x 10^{-5} $kg.d^{-1}$	3.65 x 10^{-6} $kg.d^{-1}$
Local emission rate to applicator $E_{prep, applicator} = N_{prep, building} \times F_{prep, applicator} \times Q_{a.s.} \times AREA_{treated}$	2.19 x 10^{-5} $kg.d^{-1}$	4.38 x 10^{-6} $kg.d^{-1}$

Release during application

The input values for determining releases to the environment during application of SOFAST as well as the calculated emission rates are summarised in Table 30. Application rates and relevant treated areas are described in the subparagraph above. An application frequency of 1 application per day in households is proposed by ESD PT 18 (OECD, 2008). For commercial buildings, the application frequency is set as data requirement. In view of the intended use of the b.p., RefMS has set the application frequency equally to 1 application per day. Moreover, the ESD PT 18 (OECD, 2008) states that 85% of the emissions are

released to the target surface, 11% reach the surrounding floor surface and 2% of the emission release to the applicator and the air, respectively.

The wet cleaning zone in a house is 38.5 m² resulting in a correction factor of 0.294 (38.5 m² / 131 m² = 0.294) according to TAB (September 2015). Assuming that only releases to the wet cleaning zone of a house may contribute to emissions to the environment via wet cleaning processes with subsequent release to the sewage treatment plant, this correction factor was applied to releases to the floor. This implies, that only in wet cleaning rooms (kitchen and bathroom) releases to the surrounding floor of the target surface will reach the sewage treatment plant. For release estimation of the target surface, the wet cleaning zone correction was not applied, as wet cleaning operations of these surfaces cannot be excluded, even though these areas may not be located in the wet cleaning area of a house/commercial building.

Table 30: Emission scenario for indoor spot application of SOFAST during application step

Determinants of the emission scenario	Value	
	Imidacloprid	cis-tricos-9-ene
Quantity of b.p. applied [$Q_{b.p.}$]	200 g.m^{-2}	
Fraction of a.s. in the product [$F_{a.s.}$]	0.005	0.001
Quantity of a.s. applied [$Q_{a.s.}$]	1 g.m²	0.2 g.m²
Area treated with the product [$AREA_{treated}$] *- household* *- com. building*	 1.3 m^2 6.09 m^2	
Number of applications per day per household [$N_{appl, building}$]	1 d^{-1}	
Fraction emitted to air [$F_{application, air}$]	0.02	
Fraction emitted to treated area [$F_{application, treated area}$]	0.85	
Fraction emitted to applicator [$F_{application, applicator}$]	0.02	
Fraction emitted to floor [$F_{application, floor}$]	0.11	
Wet cleaning zone correction factor [$F_{wet cleaning}$]	0.294	
Emission rates due to application of SOFAST in households		
Local emission rate to air $E_{application, air} = N_{appl, building} \times F_{application, air} \times Q_{a.s.} \times AREA_{treated}$	2.60 x 10^{-5} kg.d^{-1}	5.20 x 10^{-6} kg.d^{-1}
Local emission rate to “wet cleaning zone” floor $E_{application, floor} = N_{appl, building} \times F_{application, floor} \times Q_{a.s.} \times AREA_{treated} \times F_{wet cleaning}$	4.20 x 10^{-5} kg.d^{-1}	8.41 x 10^{-6} kg.d^{-1}
Local emission rate to treated area $E_{application, treated area} = N_{appl, building} \times F_{application, treated area} \times Q_{a.s.} \times AREA_{treated}$	1.11 x 10^{-3} kg.d^{-1}	2.21 x 10^{-4} kg.d^{-1}
Local emission rate to applicator $E_{application, applicator} = N_{appl, building} \times F_{application, applicator} \times Q_{a.s.} \times AREA_{treated}$	2.60 x 10^{-5} kg.d^{-1}	5.20 x 10^{-6} kg.d^{-1}
Emission rates to due to application of SOFAST in commercial buildings		
Local emission rate to air	1.22 x 10^{-4} kg.d^{-1}	2.44 x 10^{-5} kg.d^{-1}

$E_{application, air} = N_{appl, building} \times F_{application, air} \times Q_{a.s.} \times AREA_{treated}$		
Local emission rate to "wet cleaning zone" floor $E_{application, treated area} =$ $N_{appl, building} \times F_{application, floor} \times Q_{a.s.} \times AREA_{treated} \times F_{wet cleaning}$	1.97×10^{-4} kg.d^{-1}	3.94×10^{-5} kg.d^{-1}
Local emission rate to treated area $E_{application, floor} = N_{appl, building} \times F_{application, treated area} \times Q_{a.s.} \times AREA_{treated}$	5.18×10^{-3} kg.d^{-1}	1.04×10^{-3} kg.d^{-1}
Local emission rate to applicator $E_{application, applicator} = N_{appl, building} \times F_{application, applicator} \times Q_{a.s.} \times AREA_{treated}$	1.22×10^{-4} kg.d^{-1}	2.44×10^{-5} 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 target spot application pattern the application and cleaning steps take place at the same day. Two cleaning methods are considered: dry cleaning by vacuum/broom and disposable clothes of the applicator resulting in emission to solid wastes, 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 application of b.p. in the above mentioned areas, it might be realistic that residues of SOFAST 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 surfaces, a default cleaning efficiency of 50 % is proposed. However, in view of the envisaged target areas such as walls, window sills, pipes or joists, RefMS considers a cleaning efficiency of 50 % will overestimated environmental releases as most of these areas will likely not be cleaned highly frequented. Therefore, a cleaning efficacy of 25%, as proposed for cleaning processes for spray applications into crack & crevices, has been considered for release estimation. The input and output values for SOFAST are summarised in Table 31. The local emission rates to floor as further required input values are taken from results in Table 29 and Table 30.

Table 31: Emission scenario for indoor spot application of SOFAST during cleaning step

Determinants of the emission scenario	Value	
	Imidacloprid	**cis-tricos-9-ene**
Fraction emitted to air	0	
Cleaning efficiency [F_{CE}]	0.25	
Fraction emitted during cleaning step		
Fraction emitted to waste water from applicator - washable coveralls [$F_{applicator, ww}$]	1	
Fraction emitted to waste water during cleaning step [$F_{floor, ww}$]	1	
Fraction emitted to waste from applicator - disposable coveralls [$F_{applicator, w}$]	0	
Fraction emitted to waste during [$F_{floor, w}$]	0	
Emission rates		
Local emission rate to air [$E_{cleaning, air}$]	0 $kg.d^{-1}$	
Local emission rate to waste water during cleaning step from **applicator** $E_{applicator, ww}$ = ($E_{prep, applicator}$ + $E_{application, applicator}$) × $F_{applicator, ww}$		
- households	2.76 x 10^{-5} $kg.d^{-1}$	5.51 x 10^{-6} $kg.d^{-1}$
- commercial buildings	1.44 x 10^{-4} $kg.d^{-1}$	2.87 x 10^{-5} $kg.d^{-1}$
Local emission rate to waste water during cleaning step from **floor and treated area** $E_{floor/treated area, ww}$ = ($E_{prep, floor}$ + $E_{application, floor}$ + $E_{application, treated area}$) × $F_{floor, ww}$ × F_{CE}		
- households	2.87 x 10^{-4} $kg.d^{-1}$	5.74 x 10^{-5} $kg.d^{-1}$
- commercial buildings	1.35 x 10^{-3} $kg.d^{-1}$	2.70 x 10^{-4} $kg.d^{-1}$

Release estimation to sewage treatment plant

It is supposed that residues removed through wet cleaning may potentially be emitted to the sewer and subsequently to the sewage treatment plant (STP). According to the ESD No. 18 (2008) the STP is considered as one of the main “receiving compartment” in which insecticides will be released through wet cleaning events. In Europe, estimates of potential exposures resulting from STPs are carried out according to the Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015). According to this, the further receiving environmental compartments are surface water and sediment (after STP), soil and groundwater (from sludge application), and the outdoor air.

The water releases per day E_{ww_sim} from households and commercial buildings were summed up to perform a cumulative assessment. The input values for determining releases to STP in the course of spot application as well as the calculated emission rates are summarised in Table 32.

According to ESD PT 18 (2008) 4000 public buildings and 300 commercial building are connected to one STP. Furthermore, a simultaneity factor (F_{sim}) was implemented in the ESD PT18 that considers the simultaneity of treatments by the houses connected to the STP. For indoor applications, the ESD presumes per default a daily application of the biocidal products, leading to a simultaneity factor of 5.5% (F_{sim} = 0.055). However, according to the intended use of SOFAST, a maximum of 6 applications per year is assumed. Therefore, the simultaneity factor is calculated without taking into account the frequency of insecticide used on a daily, weekly and monthly basis:

$$F_{sim} = \frac{1.9 \times 32.15 + 0.54 \times 37.82}{100} = 0.82\%$$

The application of the b.p. in a typical scenario results in release of **1.40 x 10^{-2} kg.d^{-1}** imidacloprid and **2.80 x 10^{-3} kg d^{-1}** cis-tricos-9-ene to STP.

Table 32: Cumulative and simultanous emission scenario for indoor spot application of SOFAST during cleaning step

Input	**Value**	
	Imidacloprid	**cis-tricos-9-ene**
Number of houses connected to STP [N_{houses}] - private houses - commercial buildings	4000 300	
Simultaneity factor indoor [F_{Sim}]	0.0082	
Output		
Simultaneous emission to waste water during cleaning step: $E_{ww\_sim} = (E_{floor/treated\ area,\ ww} + E_{applicator,\ ww}) \times N_{houses} \times F_{Sim}$		
- households	1.03 x 10^{-2} kg.d^{-1}	2.06 x 10^{-3} kg.d^{-1}
- commercial buildings	3.67 x 10^{-3} kg.d^{-1}	7.34 x 10^{-4} kg.d^{-1}
Cumulative emission to waste water:	**1.40 x 10^{-2} kg.d^{-1}**	**2.80 x 10^{-3} kg.d^{-1}**

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

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

PEC_{STP} (=$Clocal_{inf}$) and $Clocal_{eff}$ according to equation 32, 33 and 39, chapter 2.3.7.1, Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015),
$PEClocal_{surfacewater}$ according to equation 48, chapter 2.3.8.3, Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015),
$PEClocal_{sediment}$ according to equation 50, chapter 2.3.8.4, Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015).

The results are summarised in Table 33.

Table 33: 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}]
Imidacloprid	6.99 x 10^{0}	6.83 x 10^{0}	6.99 x 10^{0}	6.83 x 10^{-1}	3.30 x 10^{0}
cis-tricos-9-ene	1.40 x 10^{-0}	9.09 x 10^{-2}	1.40 x 10^{-0}	1.07 x 10^{-3}	5.16 x 10^{-3}

3.7.2.2.3 Estimation of Predicted Environmental Concentrations for the terrestrial compartment

The application of sludge from the STP onto agricultural and grassland soil provokes an indirect emission to soil, as well as the leaching of a.s. through soil following sludge application causes indirect emission to groundwater. The PEC_{soil} is estimated according to equation 66, chapter 2.3.8.5, Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015). Additionally, the estimation of the local PECs for the terrestrial compartment includes also groundwater. The $PEC_{groundwater}$ is calculated according to equation 68, chapter 2.3.8.6, Guidance on BPR Vol. IV ENV Part B Risk Assessment (a.s.) (April, 2015) as a first worst-case estimation. Table 34 indicates the PEC in soil and groundwater for imidacloprid according to the application scenario.

Table 34: Summary of C_{sludge}, $PEClocal_{soil}$ and $PEClocal_{groundwater}$

	C_{Sludge} [µg.kg^{-1}]	$PEClocal_{soil}$ [µg.kg^{-1}]	$PEClocal_{Groudwater}$ [µg.L^{-1}]
Imidacloprid	4.33 x 10^{-1}	6.77 x 10^{-1}	1.36 x 10^{-1}
cis-tricos-9-ene	3.28 x 10^{3}	4.72 x 10^{1}	5.33 x 10^{-4}

3.7.2.3 Professional application in livestock facilities by painting on cardboards

3.7.2.3.1 Release estimation

Beside the application in private houses and commercial buildings the procuct SOFAST is also applied for insecticide treatment in animal housings. One of the intended application techniques is painting on cardborads. SOFAST is used indoor and applied on non-absorbent cardboards by painting against flies (adults). Treated cardboards are placed in areas where flies prefer to rest. An application rate of 200 g of product diluted in 150 ml of water for treating 100 m^2 is intended. SOFAST contains 0.5% imidacloprid and 0.1% cis-tricos-9-ene, therefore, the typical application rate per surface unit is 10.0 mg imidacloprid/m^2 and 2.0 mg cis-tricos-9-ene/m^2.

During product application the cardboards are laying on an area covered with a disposable plastic sheet in order to prevent contamination of adjacent stable floor. The product should be applied with a disposable brush and the person who is applying the product should wear a disposable coverall to avoid emissions to the sewer system when washing contaminated clothing. After a drying period, the cardboards will then be fixed in different places where flies prefer to rest. These restrictions insure, that there are negligible emissions to the environment. As only negligible emissions to relevant environmental compartments are to be expected during this specific use of the b.p., an exposure assessment for this lifecycle step is not necessary. Hence, neither environmental emission estimation has been performed nor PECs have been calculated.

Potentially emitted volatilised components of the biocidal product might be expected (cis-tricos-9-ene), however, relevant concentrations are not realistic, as in an open stable air exchange is thinning down the amount volatilised and cis-tricos-9-ene is rapidly eliminated by photo-oxidative reactions. Data on this are available from the AR. Cis-tricos-9-ene, volatilised from the product, decomposes by photooxidation with half-lives of 4.7 hours by OH-radicals and of 2.1 hours by ozone radicals. Because of degradation and physico-chemical properties no effects on the atmospheric environment are likely.

After use, the cardboards/strips are to be disposed in accordance with the regulations for waste removal (waste incineration plant).

3.7.2.4 Professional application in livestock facilities by bait application

The second intended application technique applied for in animal housings is the insecticide application as granular solid bait in disposable shallow dishes. In contrast to the insecticide treatment in private houses and commercial buildings, the environmental assessment for the biocidal product SOFAST is solely based on the neonicotinoid imidacloprid for the following reasons:
According to the assessment report of Austria (2012), cis-tricos-9-ene is a sex pheromone released by flies to attract male and female adults of the species *Musca domestica* and only limited information is available for this a.s. However, based on the available information the substance should be regarded as an intended endocrine disruptor. Nonetheless, the available data also indicate that *cis*-tricos-9-ene has a highly target-specific mode of action and only a low (eco)toxicity in non-target organisms. The available aquatic ecotoxicity studies with fish and daphnids show no toxic effects up to and above the water solubility limit of *cis*-tricos-9-ene. Furthermore, cis-tricos-9-ene is readily biodegradable and has a high vapour pressure and acts by slowly vaporising, resulting in a low steady state indoor air concentration.
Due to the above reasons and the fact that the product SOFAST is intended to be used exclusively indoors it is reasonable to assume, that any hazard or risk for environmental non-target organisms will be driven by the application of the neonicotinoid imidachloprid. Therefore, the active substance cis-tricos-9-ene is not further considered for the environmental assessment of the product SOFAST regarding the application in animal housings.

3.7.2.4.1 Release estimation

The product specific input parameters which are relevant for the environmental emission estimation and exposure assessment are summarised in Table 35.

Table 35

Determinants of the emission scenario according to chapter 5 in OECD ESD PT 18 No.14 (2006)		**Value**
Type of housing (for application *m* of the notification) *cat-subcat (i1)*		1 – 18
Type of disinfectant *bioctype (i2)*		1 (insecticides against flies)
Type of application n *appway (i3)*		5 (bait)
Type of manure storage *manstore (i4)*		1 – 3 (all waste streams)
Input		
Maximum immission standards	- for nitrogen on grassland	170 $kg.ha^{-1}.yr^{-1}$
	- for nitrogen on arable land	170 $kg.ha^{-1}.yr^{-1}$

Determinants of the emission scenario according to chapter 5 in OECD ESD PT 18 No.14 (2006)		Value
Number of repeated treatments prescribed		Max. 6 applications
Period between biocide treatments		35 d
Number of land application	- on grassland	4 yr^{-1}
	- on arable land	1 yr^{-1}
Manure storage time	- grassland	53 d
	- arable land	212 d
Content of active ingredient in formulation		0.52 % w/w
Quantity of active ingredient per m²		10.4 $mg.m^{-2}$
Output		
Number of biocide application during manure storage period for application	- on grassland (ref. to intermediate calculations ESD No. 14, p. 55)	1.5
	- on arable land	6

Furthermore, the floor area according to table 5.2 and the fraction of a.s. released to the relevant stream due to bait application according to table 5.4 (both ESD PT 18 No. 14) were used.
Using the above-mentioned input parameters, the following PEC_{soil} for grassland and arable land (after 10 consecutive years, degradation in soil considered) were calculated. For some poultry stables, combined release of slurry/manure and waste water to agricultural soil is possible (relevant for i1=8,11,12,16-18). As these values represent the worst-case compared to the values for releases of only slurry/manure, only those worst-case values are presented in the subsequent Table 36.

Table 36

PEC_{soil} [mg/kg] for grassland and arable land after 10 years of consecutive manure application (degradation considered) for indoor b.p. application in baits								
Grassland								
i1=1	i1=2	i1=3	i1=4	i1=5	i1=6	i1=7	i1=8	i1=9
7.00E-4	2.08E-4	0.002	0.001	0.002	0.001	3.59E-4	4.00E-4	4.00E-4
i1=10	i1=11	i1=12	i1=13	i1=14	i1=15	i1=16	i1=17	i1=18
4.00E-4	0.002	7.22E-4	7.53E-4	3.79E-4	8.23E-4	0.001	0.001	0.001
Arable land								
i1=1	i1=2	i1=3	i1=4	i1=5	i1=6	i1=7	i1=8	i1=9

2.93E-4	8.71E-4	7.12E-4	5.06E-4	6.42E-4	4.18E-4	1.50E-4	1.67E-4	1.67E-4
i1=10	i1=11	i1=12	i1=13	i1=14	i1=15	i1=16	i1=17	i1=18
1.67E-4	7.09E-4	3.02E-4	3.15E-4	1.59E-4	3.44E-4	5.86E-4	6.19E-4	4.40E-4

For releases to STP, the following $Elocal_{water}$ for the relevant animal (sub)categories were calculated:

Table 37

$Elocal_{water}$ [kg/d] for indoor b.p. application in baits					
i1=8	i1=11	i1=12	i1=16	i1=17	i1=18
0.004	0.007	0.005	0.016	0.009	0.012

3.7.2.4.2 Environmental exposure assessment for bait application

In the subsequent chapter, the environmental exposure assessment is presented for the worst-case animal (sub)categories. For cattle, the animal (sub)categorie ‘veal calves’ represents the worst-case. For pigs and poultry, the worst-case animal (sub)categories are ‘sows in groups’ and ‘laying hens in free range with litter floor’, respectively. For the release pathway via STP, the animal (sub)category ‘turkeys’ represents the worst-case.

Table 38: Environmental exposure assessment of the terrestrial compartment after slurry/manure application onto agricultural soils

Predicted environmental concentrations (PECs) for releases via slurry/manure in terrestrial environment for the worst-case animals i1=3 'veal calves', i1=5 'sows in groups' and i1=11 `laying hens, free range with litter floor'						
Cat - subcat	**Index** i1	**Waste stream**	**PEC_{soil}**		**$PEC_{groundwater}$**	
			arable land	grassland	arable land	grassland
			[mg.kg^{-1}]		**[µg.L^{-1}]**	
Veal calves	3	Slurry	7.12E-4	0.002	0.209	0.499
Sows in groups	5	Slurry	6.42E-4	0.002	0.188	0.450
Laying hens, free range with litter floor	11	Manure + waste water	7.09E-4	0.002	0.208	0.497

The grassland scenario represents the worst-case scenario for the estimated PECs on the basis of nitrogen immission standard. The calculated results of $PEC_{groundwater}$ for a.s. imidacloprid exceed the maximum permissible concentration in groundwater of 0.1 µg/L (generic trigger value for a.s. in biocides and their relevant metabolites, degradation and reaction products according to Council Directives 2006/118/EC and 98/83/EC).

Table 39: Environmental exposure assessment of the aquatic compartment after slurry/manure application onto agricultural soils (run-off and drainage)

Predicted environmental concentrations (PECs) for releases via slurry/manure in aquatic environment for the worst-case animals i1=3 'veal calves', i1=5 'sows in groups' and i1=11 `laying hens in free range with litter floor'						
Cat - subcat	**Index** i1	**Waste stream**	**$PEC_{surface\ water}$**		**$PEC_{sediment}$**	
			arable land	grassland	arable land	grassland
			[$mg.L^{-1}$]		**[$mg.kg^{-1}_{ww}$]**	
Veal calves	3	Slurry	2.09E-5	4.99E-5	1.01E-4	2.42E-4
Sows in groups	5	Slurry	1.88E-5	4.50E-5	9.10E-5	2.18E-4
Laying hens in free range with litter floor	11	Manure + waste water	2.08E-5	4.97E-5	1.01E-4	2.41E-4

Again, the grassland scenario represents the worst-case scenario for the estimated PECs.

Table 40: Environmental exposure assessment of the terrestrial compartment after sewage sludge application onto agricultural soils

Predicted environmental concentrations (PECs) for releases via sewage sludge in terrestrial environment for the worst-case animal i1=16 'turkeys'			
Cat - subcat	**Index** i1	**$PECIocal_{soil}$** [$mg.kg^{-1}$]	**$PECIocal_{groundwater}$** [$\mu g.L^{-1}$]
Turkeys	16	8.10E-4 *	0.150

* In case of the release pathway via STP $PECIocal_{soil}$ is derived as $PEC_{initial}$ instead as PEC_{TWA} as the relevant PNEC is a $PNEC_{initial}$.

The calculated result of $PEC_{groundwater}$ for imidacloprid exceed the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 2006/118/EC and 98/83/EC).

Environmental exposure assessment of the aquatic compartment after release **via STP**

The distribution in STP was re-calculated using SimpleTreat 4.0. The fraction to water and sewage sludge are 97.64 % and 2.36 %, respectively. The fraction emitted to air is negligible and 0 % of the a.s. is degraded in STP.

Table 41

Predicted environmental concentrations (PECs) for releases via STP in aquatic environment for the worst-case animal i1=16 'turkeys'				
Cat - subcat	**Index** i1	**PEC_{STP}** [$mg.L^{-1}$]	**$PECIocal_{surface\_water}$** [$mg.L^{-1}$]	**$PECIocal_{sediment}$** [$mg.kg^{-1}_{ww}$]
Turkeys	16	0.008	7.81E-4	0.004

3.7.3 Environmental risk characterisation

The biocidal product SOFAST is foreseen to be applied indoors in household, commercial and public areas by non-professional or professional users. The application methods are spraying or brushing of the biocidal product on non-porous surfaces where flies usually lay such as walls, window sills, pipes, joists. Additionally, an open bait application as granules in disposable shallow dishes is foreseen.

For the indoor application of the biocidal product SOFAST as a granulated bait in disposable shallow dishes a quantitative risk assessment was done considering 3% release of the b.p. to the sewer system (see 3.7.2.1 for details).

As the OECD ESD No. 18 (2008) has no specific scenario for applications by brushing, the RefMS is of the opinion, that the scenario for spray applications is suitable to cover possible release for brushing applications. Therefore, the environmental exposure assessment was only conducted for spray application for releases during mixing and loading, application and during cleaning (for details see chapter 3.7.2.2). The environmental risk characterisation for these use patterns is described in the following paragraphs. No differentiation is made between application by non-professionals and professionals, as the same application rate is used.

For *cis*-tricos-9-ene no PNECs were derived in the CAR based on intended indoor use of the representative product and the fact, that the substance is a pheromone with a highly target-specific mode of action. The available aquatic ecotoxicity studies with fish and daphnids indicate that no toxic effects up to and above the water solubility limit of cis-tricos-9-en occur.

As the product SOFAST is intended to be used exclusively indoors and the concentration of *cis*-tricos-9-ene in the product is 5 times lower than the concentration of imidacloprid, the effects assessment for the product SOFAST is confined to the active substance imidacloprid. Therefore, the environmental risk assessment only considers the active substance imidacloprid.

3.7.3.1 Indoor use as granular bait in private houses and commercial buildings

For the indoor application of the biocidal product SOFAST as a granulated bait in disposable shallow dishes a quantitative risk assessment was done considering 3% release of the b.p. to the sewer system (see 3.7.2.1 for details). The further receiving environmental compartments are surface water and sediment (after STP), soil and groundwater (from sludge application) and the outdoor air.

3.7.3.1.1 Sewage treatment plant

Table 42: PEC/PNEC ratio for sewage treatment plant

Compartment	PEC [µg/L]	PNEC [µg/L]	PEC/PNEC
Sewage treatment plant (STP)	2.54×10^{-1}	6.13×10^{4}	0.000002

Conclusion: A PEC/PNEC ratio of 0.000002 was derived for the sewage treatment plant. As this is well below the trigger value of 1, an unacceptable risk for the sewage treatment plant from the indoor use of the b.p. as a granular bait in disposable cups, bowls is not to be expected.

3.7.3.1.2 Aquatic compartment (incl. sediment)

Table 43: PEC/PNEC ratio for the aquatic compartment (surface water and sediment)

Compartment	PEC	PNEC	PEC/PNEC
Surface water	2.48×10^{-2} µg/L	4.80×10^{-3} µg/L	**5.172**
Sediment	1.2×10^{-4} mg/kg	2.63×10^{-5} mg/kg	**4.559**

Conclusion: A PEC/PNEC ratio of 5.172 for surface water and 4.559 for sediment was derived. Both ratios exceed the trigger value of 1. Therefore, there is an unacceptable risk for surface water and sediment from the intended use of the biocidal product SOFAST as a granular bait in disposable cups, bowls.

3.7.3.1.3 Terrestrial compartment

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

Table 44: PEC/PNEC ratio for the terrestrial compartment (soil)

Compartment	PEC [mg/kg]	PNEC [mg/kg]	PEC/PNEC
Soil	2.46 x 10^{-5}	1.58 x 10^{-2}	0.002

Conclusion: A PEC/PNEC ratio of 0.002 was derived for the soil compartment. As this is below the trigger value of 1, an unacceptable risk for the soil compartment is not to be expected.

Table 45: PEC/PNEC ratio for the terrestrial compartment (groundwater)

Compartment	PEC [µg/L]	Limit value* [µg/L]
Groundwater	4.96 x 10^{-3}	0.1

*limit value for pesticides in groundwater according to directive 98/83/EC

Conclusion: For groundwater a concentration of 4.96 x 10^{-3} 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. The $PEC_{groundwater}$ is below the given limit value of 0.1 µg/L, therefore an unacceptable risk to groundwater is not to be expected.

3.7.3.1.4 Air compartment

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

3.7.3.1.5 Secondary Poisoning

Due to the low bioaccumulation potential no assessment for secondary poisoning for fish or worm eating birds and mammals is necessary.

3.7.3.2 Spraying or brushing indoors in household, commercial and public areas

Environmental exposure of the biocidal product may arise either due to washing of contaminated clothes from the applicator or due to wet cleaning of the treated surface and its surrounding floor surface. Both pathway will subsequently lead to release of contaminated waste water to the STP system.

3.7.3.2.1 Sewage treatment plant

Table 46: PEC/PNEC ratio for sewage treatment plant

Compartment	PEC [µg/L]	PNEC [µg/L]	PEC/PNEC
Sewage treatment plant (STP)	6.99×10^{0}	6.13×10^{4}	0.00011

Conclusion: A PEC/PNEC ratio of 0.00011 was derived for the sewage treatment plant. As this is well below the trigger value of 1, an unacceptable risk for the sewage treatment plant from the indoor use by spraying or brushing of the biocidal product SOFAST is not to be expected.

3.7.3.2.2 Aquatic compartment (incl. sediment)

Table 47: PEC/PNEC ratio for the aquatic compartment (surface water and sediment)

Compartment	PEC	PNEC	PEC/PNEC
Surface water	6.83×10^{-1} µg/L	4.80×10^{-3} µg/L	**142.3**
Sediment	3.3×10^{-3} mg/kg	2.63×10^{-5} mg/kg	**125.5**

Conclusion: A PEC/PNEC ratio of 142.3 for surface water and 125.5 for sediment was derived. Both ratios exceed the trigger value of 1. Therefore, there is an unacceptable risk for surface water and sediment from the intended use of the biocidal product SOFAST.

3.7.3.2.3 Terrestrial compartment

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

Table 48: PEC/PNEC ratio for the terrestrial compartment (soil)

Compartment	PEC [mg/kg]	PNEC [mg/kg]	PEC/PNEC
Soil	6.77×10^{-4}	1.58×10^{-2}	0.043

Conclusion: A PEC/PNEC ratio of 0.043 was derived for the soil compartment. As this is below the trigger value of 1, an unacceptable risk for the soil compartment is not to be expected.

Table 49: PEC/PNEC ratio for the terrestrial compartment (groundwater)

Compartment	PEC [µg/L]	Limit value* [µg/L]
Groundwater	1.36×10^{-1}	0.1

*limit value for pesticides in groundwater according to directive 98/83/EC

Conclusion: For groundwater a concentration of 1.36×10^{-1} 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. The $PEC_{groundwater}$ is slightly above the given limit value of 0.1 µg/L, therefore an unacceptable risk to groundwater cannot be excluded.

3.7.3.2.4 Air compartment

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

3.7.3.2.5 Secondary Poisoning

Due to the low bioaccumulation potential no assessment for secondary poisoning for fish or worm eating birds and mammals is necessary.

3.7.3.3 Professional application in livestock facilities by painting on cardboards

Negligible exposure is expected when the product SOFAST is used in livestock facilities by painting on cardboards due to extensive risk mitigation measures (for details, please see chapter 3.7.3.6). Therefore, no PECs were derived and a quantitative risk characterisation is not presented. For details, see chapter 3.7.2.3.

3.7.3.4 Professional bait application in livestock facilities

For the indoor application of the biocidal product SOFAST in livestock facilities as a granulated bait in disposable shallow dishes a quantitative risk assessment was done. For details for the environmental exposure assessment, please see chapter 3.7.2.4.

In the subsequent chapter, the environmental risk assessment is presented for the worst-case animal (sub)categories. For cattle, the animal (sub)category ‘veal calves’ represents the worst-case. For pigs and poultry, the worst-case animal (sub)categories are ‘sows in groups’ and ‘laying hens in free range with

litter floor', respectively. For the release pathway via STP, the animal (sub)category 'turkeys' represents the worst-case.

3.7.3.4.1 Aquatic compartment after release via STP

Table 50: PEC/PNEC ratios for releases via STP in aquatic environment for the worst-case animal (sub)category i1=16 'turkeys'

Compartment	PEC	PNEC	PEC/PNEC
Sewage treatment plant (STP)	0.008 mg/L	61.30 mg/L	1.305E-04
Surface Water	7.809E-04 mg/L	4.800E-06 mg/L	**162.7**
Sediment	0.004 mg/kg ww	2.600E-05 mg/kg ww	**153.9**

Conclusion: The PEC/PNEC ratios for releases via STP for the worst-case animal (sub)category "turkeys" is above 1 for surface water and sediment, indicating unacceptable risks from the use of the product SOFAST for these environmental compartments (see Table 50). The risk quotient for STP is below the trigger value of 1, indicating acceptable risk for STP microorganisms.

Table 51 and Table 52 show the risk quotients for the aquatic compartment (surface water and sediment) after slurry/manure application onto agricultural soils and emission to the aquatic compartment by run-off and/or drainage. Predicted environmental concentrations (PECs) were calculated for the worst-case animal (sub)categories i1=3 'veal calves', i1=5 'sows in groups' and i1=11 `laying hens in free range with litter floor' (for details see chapter 3.7.3.4).

Table 51: PEC/PNEC ratios for surface water after slurry/manure application to agricultural soil

Animal (sub)categories (worst case)	$PNEC_{surface\ water}$ [mg/L]	$PEC_{surface\ water}$ [mg/L]		PEC/PNEC	
		arable land	grassland	arable land	grassland
Veal calves	4.800E-06	2.086E-05	4.991E-05	**4.346**	**10.40**
Sows in groups		1.881E-05	4.500E-05	**3.919**	**9.375**
Laying hens in free range with litter floor		2.078E-05	4.971E-05	**4.329**	**10.36**

Table 52: PEC/PNEC ratios for sediment after slurry/manure application to agricultural soil

Animal (sub)categories (worst case)	$PNEC_{sediment}$ [mg/kg ww]	$PEC_{sediment}$ [mg/kg ww]		PEC/PNEC	
		arable land	grassland	arable land	grassland
Veal calves	2.600E-05	1.010E-04	2.416E-04	**3.885**	**9.292**
Sows in groups		9.104E-05	2.178E-04	**3.502**	**8.377**
Laying hens in free range with litter floor		1.006E-04	2.406E-04	**3.869**	**9.254**

Conclusion: The risk quotients for the worst case animal categories for both arable and grass land are above 1, indicating an unacceptable risk for the aquatic compartment after slurry/manure application to agricultural soil and subsequent run off/drainage to the aquatic compartment. To account for the unacceptable risk, appropriate risk mitigation measures are presented in chapter 3.7.3.6, leading to negligible exposure of the environment. Therefore, refinement of the PEC calculations was not necessary.

3.7.3.4.2 Terrestrial compartment

Table 53 and Table 54 give the risk quotients for the terrestrial compartment (soil and groundwater) after slurry/manure application onto agricultural soils. Predicted environmental concentrations (PECs) for releases via slurry/manure were calculated for the worst-case animals i1=3 ‘veal calves’, i1=5 ‘sows in groups’ and i1=11 `laying hens in free range with litter floor’ (for details see chapter 3.7.3.4). For groundwater, the predicted environmental concentrations are compared to the generic trigger value for

a.s. in biocides and their relevant metabolites, degradation and reaction products according to Council Directives 2006/118/EC and 98/83/EC of 0.1 µg/L.

Table 53: PEC/PNEC ratios for the terrestrial compartment (soil) for releases via slurry/manure for the worst case categories

Animal (sub)categories (worst case)	$PNEC_{soil}$ [mg/kg ww]	PEC_{soil} [mg/kg]		PEC/PNEC	
		arable land	grassland	arable land	grassland
Veal calves	0.016	7.119E-04	0.002	0.045	0.125
Sows in groups		6.418E-04	0.002	0.040	0.125
Laying hens in free range with litter floor		7.091E-04	0.002	0.044	0.125

Conclusion: The risk quotients for the soil compartment are below 1 for the worst case animal categoeries, indicationg acceptable risk for the terrestrial compartment after slurry/manure application to agricultural soil.

Table 54: Risk chracterisation for groundwater after releases via slurry/manure for the worst case categories

Animal (sub)categories (worst case)	Generic trigger value [µg/L]	PEC_{GW} [µg/L]	
		arable land	grassland
Veal calves	0.1	**0.209**	**0.499**
Sows in groups		**0.188**	**0.450**
Laying hens in free range with litter floor		**0.208**	**0.497**

Conclusion: The predicted environmental concentrations for groundwater after slurry/manure application to agriculatural soil all above the trigger value of 0.1 µg/L. To account for the unacceptable risk, appropriate risk mitigation measures are presented in chapter 3.7.3.6, leading to negligible exposure to the environment. Therefore, refinement of the PEC calculations was not necessary.

Emissions to agricultural soil and groundwater can also occur after sewage sludge application to agricultural soil. The risk characterisation was done for the worst case animal category i1=16 “turkeys” and is summarized in Table 55 below.

Table 55: PEC/PNEC ratios for the terrestrial compartment (soil and groundwater) after sewage sludge application onto agricultural soil

Animal categories (worst case)	$PNEC_{soil}$ [mg/kg ww]	$PEClocal_{soil}$ [$mg.kg^{-1}$]	PEC/PNEC	Generic trigger value [µg/L]	$PEClocal_{GW}$ [$\mu g.L^{-1}$]
turkeys	0.016	8.099E-04	0.051	0.1	**0.150**

Conclusion: Acceptable risk was shown after the application of sewage sludge to agriculatural soil. The predicted environmental concentration for groundwater exceeds the trigger value of 0.1 µg/L, indicationg an unacceptable risk for groundwater.

3.7.3.4.3 Overall conclusion for the environmental risk assessment for the bailt application in livestock facilities

Unacceptable risks for the aquatic compartment and groundwater needs to be addressed in order to guarantee a safe use of the product SOFAST in livestock facilities when used as granular bait. Therefore, to ensure negligible exposure to the environment, the use of granular bait (use 4) is restricted to specific bait stations for flies when used in livestock facilities, in addition to further RMMs to avoid emissions to the environment (for details, please see chapter 3.7.3.6).

3.7.3.5 PBT assessment

Imidacloprid:

P-/vP-Criterion:

Apart from the submission of a test on ready biodegradabilty 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-Criterion:
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-Criterion:
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.

Conclusion: 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.

cis-Tricos-9-ene (muscalure):

According to the final assessment report for the active substance *cis*-tricos-9-ene (see chapter 2.1.6.2 of the AR), the PBT status is as follows:

P-/vP-Criterion:
There are no indications that *cis*-tricos-9-ene is persistent in environmental compartments. Model estimations suggest that *cis*-tricos-9-ene is degradable in environmental matrices by either abiotic or biotic processes. The P-criterion is not met.

B-/vB-Criterion:
Log BCFfish ≥2.9
The B-criterion is probably met though it is unlikely that *cis*-tricos-9-ene will bioaccumulate in aquatic species.

T-Criterion:

Based on acute toxicity data on fish and daphnids no indication exists that the chronic NOEC of *cis*-tricos-9-ene is <0.01 mg/L.
No specific tests for potential endocrine disruption and carcinogenicity were carried out.
From the available genotoxicity studies and consideration of potential effects and exposure there is no concern for endocrine disruption or for CMR effects. The T-criterion is therefore not met.

Conclusion: *cis*-tricos-9-ene does not meet the PBT criteria.

3.7.3.6 Overall conclusion of the evaluation

The biocidal product SOFAST contains no substance of concern for the environment. For the active substance *cis*-tricos-9-ene no PNECs were derived (see chapter 3.7.1: Environmental effects assessment for details).Thus, the risk assessment is based solely on the active substance imidacloprid.

An environmental risk assessment was performed for the intended uses (indoor use (industrial/commercial premises, households/ private areas, public areas and livestock facilities by painting on cardboards (use 1) or bait application (use 2)). As the OECD ESD No. 18 (2008) has no specific scenario for applications by brushing, the RefMS is of the opinion, that the scenario for spray applications is suitable to cover possible release for brushing applications. Therefore, the environmental exposure assessment was only conducted for spray application for releases during mixing and loading, application and during cleaning. For the use as a granulated bait, negligible releases to the environment are expected and therefore no PECs were derived and no risk characterisation conducted.

For the use by spraying and brushing in households/commercial premises, no unacceptable risks are to be expected for the sewage treatment plant and the soil compartment. However, both for surface water and the sediment the PEC/PNEC ratio exceeds the trigger value of 1 (PEC/PNEC = 142.3 for surface water; PEC/PNEC = 125.5 for sediment). For the groundwater, the limit value of 0.1 µg/L is slightly exceeded by the $PEC_{groundwater}$ of 1.36×10^{-1} µg/L. **Therefore, there is an unacceptable risk for surface water, sediment and groundwater due to indirect release of the biocidal product SOFAST.**

As already mentioned, environmental exposure of the biocidal product may arise either due to washing of contaminated clothes from the applicator or due to wet cleaning of the treated surface and its surrounding floor surface. Both pathways will subsequently lead to release of contaminated waste water to the STP system. Therefore, if these emissions to the sewer system are prevented, the risk for the environment would be acceptable.

When commenting on the German draft PAR the applicant suggested restricting the use to “painting” by professionals only since these users would be able to follow RMMs in order to actually prevent emissions

to the sewer system. Furthermore the applicant suggested to wear disposable clothes and to cover the area where application takes place by a plastic sheet. eCA DE additionally considers it necessary to restrict the application of the biocidal product to disposable cardboards instead of directly on walls.

Consequently, the eCA DE considers the following risk mitigation measures necessary for **painting by professionals** industrial/commercial premises, households/ private areas, public areas:

1. Apply only on non-absorbent cardboards which are then to be fixed to walls or ceilings where flies prefer to rest.
2. The area, where mixing/loading and the application to cardboards take place, must be covered with a disposable plastic sheet in order to avoid contamination of adjacent surfaces and floor.
3. For the mixing/loading and the application step the applicator must wear disposable clothes (e.g. paper smocks, aprons, overall) to avoid emissions to the sewer system due to washing of contaminated clothes.
4. Do not let the product or its residues or painting sludge enter soil, water courses or the sewer systems.
5. Do not clean the cardboards.
6. Disposal of contaminated plastic sheets, disposable clothes and cardboards after use to residual waste as specified by the regional disposer.

As a major change to the authorisation of the product SOFAST in households/private and commercial areas, the use in livestock facilities was applied for and evaluated. For use 3 (painting of the dissolved granules) the product is applied on cardboards. Extensive risk mitigation measures ensure negligible exposure (for details, please see chapter 3.7.3.6), therefore a risk characterisation for this use was waived. Risk mitigation for the use of the product on cardboards in livestock facilities

For painting on cardboards by professionals:

a) Remove all pieces of treated cardboards before cleaning and/or disinfectant events in livestock facilities.
b) Do not apply the biocidal product directly on manure/slurry.

Contrary to “painting” an application on cardboards by “spraying” is considered as neither applicable nor practicable.

For the use of the biocidal product SOFAST as granulated bait in disposable shallow dishes indoors in private houses/commercial premises, unacceptable risks to the aquatic environment (surface water and sediment) were predicted. During the referral for the b.p. SOFAST, the following risk mitigation measures were adopted for the use of the b.p. as granulated bait indoor in disposable shallow dishes to account for the calculated unacceptable risk for the environment. As these measures are extensive, RefMS DE

suggested to restrict the use of the b.p. as granular bait to the professional user, which was accepted during referral.

1) For professional use only. The people responsible for cleaning the treated areas are to be instructed by the professional user on the following Risk Mitigation Measures to ensure that the product does not reach the sewer system.
2) For use in households/commercial premices: Use only disposable devices and the dosing spoon to place the granular bait.
3) Product spills, residues and dead flies must be collected immediately by dry cleaning methods only (i.e. brush, vacuum cleaner or disposable cloth) with subsequent disposal via solid waste.
4) Do not wet wash the surfaces contaminated with the product or its residues or use disposable wet wipes with subsequent disposal via solid waste.
5) Ensure that spills from the application devices are avoided by un-intentional movement of the product through e.g. wind, humans or larger animals.
6) Do not wet clean the dosing spoon and the disposable devices.

For use of granular bait in livestock facilities in disposable shallow dishes, unacceptable risks were shown for the aquatic compartment and for groundwater. Therefore, the use of granular bait in livestock facilities is restricted to specific bait stations for flies. The following RMM are necessary:

For use as granular bait by professionals:

1. Apply only in recommended bait stations (specific for flies). Use the dosing spoon to place the granular bait.
2. Do not wet clean the dosing spoon and the bait stations.
3. Remove all bait stations before cleaning and/or disinfectant events in livestock facilities.
4. Do not apply the biocidal product directly on manure/slurry.

3.8 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.9 Comparative assessment

3.9.1 Background

The product SOFAST contains the two active substances cis-tricos-9-ene and imidacloprid.
While the active substance cis-triscos-9-ene does not meet the criteria for substitution under Article 10 of the Biocides Regulation (EU) No 528/2012[9] (BPR), the active substance imidacloprid does meet the criteria for substitution.
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 SOFAST 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).

For this comparative assessment the German CA used the list of biocidal products authorised in the European Union for PT18 maintained by ECHA (in the version of 28.11.2016).
In accordance with the Technical Guidance Note on comparative assessment of biocidal products (CA-May-15-Doc-4.3a-final) the biocidal product SOFAST was only compared to the alternative biocidal products authorised in Germany as the R4BP3 is not yet populated with searchable SPCs and no search tool has yet been provided by ECHA.

3.9.2 Application administrative details

Procedure: National Authorisation (NA)
Purpose: Authorisation
Case Number in R4BP: BC-XV010731-14
Evaluating Competent Authority: Germany (BAuA)
Applicant: Sharda Europe B.V.B.A.
(Prospective) Authorisation holder: Sharda Europe B.V.B.A.

[9] 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.

3.9.3 Administrative information of the BP

Trade name: SOFAST
Product type: 18 (Insecticide)
Active substances: Imidacloprid (CAS-Nr.: 138261-41-3); cis-tricos-9-ene (CAS-Nr.: 27519-02-4);

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

The product SOFAST is an insecticide (product-type 18) with the active substances imidacloprid and cis-tricos-9-ene. It consists of granules. It is used indoors by non-professionals (in households and private areas) and professionals (in industrial or commercial premises, households, private and public areas) for the control of houseflies and stable flies.
Table 56 lists the intended uses of the biocidal product appropriate for authoristation determining the focus of the comparative assessment.

Table 56: Intended uses appropriate for authorisation of the biocidal product

Use 1: Non-professional use: bait application

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 flies
Target organism (including, where relevant) development stage)	Flies – *Muscidae* (imagines; adults)
Field(s) of use	Indoor use (households/ private areas)
Application method(s)	Bait application
Category(ies) of users	Non-professional

Use 2: Professional use: bait application and painting on cardboards

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 flies
Target organism (including, where relevant) development stage)	Flies – *Muscidae* (imagines; adults)
Field(s) of use	Indoor use (industrial/commercial premises; households/ private areas; public areas, livestock facilities)
Application method(s)	Bait application, painting on cardboards

Category(ies) of users	Professional

The product SOFAST will be placed on the market as granules (ready to use). It has to be applied in cups, shallow dishes, bowls or bait stationsor to be painted on cardboards.
It is effective against flies (houseflies (*Musca domestica*) and stable flies (*Stomoxys calcitrans*)).
The active substance imidacloprid exerts its insecticidal effect by causing a blockage in the nicotinergic neuronal pathway. As a result acetylcholine accumulates resulting in paralysis and eventually death of the insect.

3.9.5 Mapping of existing alternatives to the relevant BP in Germany

Identified eligible alternative BPs[10]

According to the information available in the list of authorised biocidal products (on 28.11.2016) maintained by the ECHA, there are about 388 biocidal products authorised under product type 18 (insecticides) of the Biocidal Products Directive and Biocidal Products Regulations (including mutual recognitions and same product authorisations).
These are based on fifteen active substances: Abamectin, aluminium phosphide releasing phosphine, bacillus thuringiensis[11], bacillus thuringiensis[12], carbon dioxide, deltamethrin, dinotefuran, Fipronil, imidacloprid, indoxacarb, magnesium phosphide releasing phosphine, metoflutrin, nitrogen, spinosad, sulfuryl difluoride.

No products containing abamectin, dinotefuran, metoflutrin or bacillus thuringiensis[12] have yet been authorised in Germany.

Fipronil and spinosad are themselves candidates for substitution but in addition to being toxic they are considered as “persistent” while imidacloprid is considered as very persistent.

Products based on carbon dioxide, magnesium phosphide releasing phosphine, nitrogen, aluminium phosphide releasing phosphine and sulfuryl difluoride are fumigation products.

[10] In accordance with the Technical Guidance Note on comparative assessment of biocidal products (CA-May-15-Doc-4.3a-final) the biocidal product Imidasect Ants was only compared to the alternative biocidal products authorised in Germany as the R4BP3 is not yet populated with searchable SPCs and no search tool has been provided by ECHA yet.
[11] subsp. Israelensis Serotype H-14 Strain AM 65-52
[12] subsp. Israelensis Strain SA3A

In Germany, the magnesium phosphide releasing phosphine, aluminium phosphide releasing phosphine and sulfuryl difluoride containing products are only authorised for use by trained professionals.[13]
In Germany, also the two products containing carbon dioxide or nitrogen are only authorised for use by trained professionals.
Since the product SOFAST is intended for non-professional and (non-trained) professional use, all the fumigation products are not considered as eligible alternative products and are therefore not included in this comparative assessment.

In Germany, the products containing indoxacarb or Fipronil are only authorised for the control of ants or cockroaches.
In Germany, products containing Bacillus thuringiensis[11] are authorised for the control of mosquitoes; the control of flies (larvae) is only authorised for the trained professional user.

Accordingly, the only remaining alternative products for the control of flies in Germany are imidacloprid, spinosad and deltamethrin containing products.
Table 56 lists the mode of action of the remaining active substances and the risk of resistance development.

Table 57: Mode of action and risk of resistance development for PT18 insecticides

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 upon ingestion.	Yes
Spinosad	Spinosad is a contact and stomach poison, which has an effect on the insect nervous system. The spinosyns and spinosoids have a novel mode of action, primarily targeting binding sites on nicotinic acetylcholine receptors (nAChRs) of the insect nervous system. Spinosoid binding leads to disruption of acetylcholine neurotransmission. Spinosad also has secondary effects as a ɣ-	Yes

[13] Application only by persons owning a certificate of competence for fumigation pursuant to Annex I No. 4.3 of German Hazardous Substances Ordinance (GefStoffV).

	amino-butyric acid (GABA) neurotransmitter agonist. Spinosad kills insects via hyperexcitation of the insect nervous system.	
Deltamethrin	Deltamethrin is a pyrethroid insecticide acting on harmful organisms by contact and ingestion. It expresses a strong knock-down effect. Pyrethroids impair ion transport 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.	Yes

Identified eligible non-chemical alternatives

Not relevant in the screening phase

3.9.6 Screening phase

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

Chemical diversity

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

Resistance management

Resistance of flies against imidacloprid has been reported from various countries, including Germany. However, resistance has also been reported for the only remaining alternative products for the control of flies in Germany with the active sunbstances spinosad or deltamethrin.

The chemical diversity of the active substances exerting 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.
Therefore, it is concluded that if imidacloprid containing products were substituted, this would not leave an adequate chemical diversity to control the risk of further resistance formation.

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 flies.

The comparative assessment is finalised at this stage. The product SOFAST 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 58

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
IIIB, 3.1.1	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 3.1.2	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 3.1.3	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 3.2	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 3.3	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 3.4	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o	Norris, D	2013	Sharda Worldwide	Yes

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
	Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.			Exports Pvt. Ltd.	
IIIB, 3.5	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 3.6	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 3.7	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 3.10	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 4.1 (Imidacloprid)	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 4.1 (cis-tricos-9-ene)	Determination of Physico-Chemical Studies including Storage Stability and Shelf Life Specification Data for a Granule Formulation containing 0.5°/o Imidacloprid stored at 54° C± 2° C for 2 weeks with associated validation, in compliance with Good Laboratory Practice.	Norris, D	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 4.1	Imidacloprid 0.5% + tricosene 0.1% GR. Stage Ia: Active ingredients content evaluation of the initial preparation and after accelerated storage	Al Amin, I.	2015	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 4.1	Imidacloprid 0.5% + tricosene 0.1% GR. Method development and validation for determination of the content of active substances in the formulation	Woloszynowska, M	2015	Sharda Worldwide Exports Pvt. Ltd.	Yes

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
IIIB, 5.10	Efficacy of a fly bait granule product against House flies and Stable flie	K-H. Lüpkes	2013	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 5.10	Field trials to determine the efficacy of Imidacloprid 0.5% + Tricosene 0.1% GR (SOFAST) against houseflies and stable flies 15/177	Heaven, H	2015	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 5.10	Field trials to determine the efficacy of Imidacloprid 0.5% + Tricosene 0.1% GR (SOFAST) against houseflies and stable flies 15/178	Heaven, H	2015	Sharda Worldwide Exports Pvt. Ltd.	Yes
IIIB, 6.1.1	Acute oral toxicity study of imidacloprid 0.5% GR in rats	Anonymous[14]	2014	Sharda Worldwide Exports Pvt. Ltd	Yes
IIIB, 6.1.2	Acute dermal toxicity study of imidacloprid 0.5% GR in rats	Anonymous[14]	2014	Sharda Worldwide Exports Pvt. Ltd	Yes
IIIB, 6.1.3	Acute inhalation toxicity study of imidacloprid 0.5% GR in rats	Anonymous[14]	2014	Sharda Worldwide Exports Pvt. Ltd	Yes
IIIB, 6.2.1	Acute dermal irritation study of imidacloprid 0.5% GR in rabbits	Anonymous[14]	2014	Sharda Worldwide Exports Pvt. Ltd	Yes
IIIB, 6.2.2	Acute eyel irritation study of imidacloprid 0.5% GR in rabbits	Anonymous[14]	2014	Sharda Worldwide	Yes

[14] Study with vertebrates. Please, refer to the study summaries (DocIIIB, 6.1, 6.2 and 6.3 files) for the name of the author(s).

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
				Exports Pvt. Ltd	
IIIB, 6.3	Skin snesitisation study of imidacloprid 0.5% GR in guinea pigs	Anonymous[14]	2014	Sharda Worldwide Exports Pvt. Ltd	Yes

4.2 List of studies for the active substance(s)

4.2.1 Imidacloprid

- The applicant has access to the data from the active substance approval for the active substance imidacloprid (see chapter 4.2.2.1 for details).
- The applicant provided its own dossier on the active substance imidacloprid (see chapter 4.2.1.2 for details).

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[15]) of the active substance imidacloprid for use in insecticides (PT18). Please, refer to the corresponding Assessment Report for a reference list.

4.2.1.2 List of studies 3rd party dossier

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
A3.1.1, A3.1.3, A3.2, A3.3.1, A3.3.2, A3.3.3, A3.5, A3.6, A3.7, A3.9, A3.11, A3.13, A3.16, A3.18	Final Report: Determination of Physical and Chemical Properties of Imidacloprid technical, Anadiag S.A., Study No. A6002, GLP, (Un)	Wasser C	2006	Sharda Worldwide Exports Pvt. Ltd	Y

15 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
A3.1.2, A3.3.1, A3.3.2, A3.3.3	Final Report: Imidacloprid Technical 98%: Determination of the Boiling Point/ Boiling Range and the Determination of Color, Physical State and Odor, RCC Ltd, Report No. B71572, GLP, (Un)	Franke J	2008a	Sharda Worldwide Exports Pvt. Ltd	Y
A3.2.1, A3.10	Imidacloprid: Determination of Thermal Stability and Stability in Air and Calculation of Henry's Law Constant, Harlan Laboratories Ltd., Report No. 41205295, GLP, (Un)	O'Connor BJ	2013	Sharda Worldwide Exports Pvt. Ltd	Y
A3.4	Final Report: Imidacloprid Technical 98%: Determination of Spectra, RCC Ltd, Report No. B71583, GLP, (Un)	Franke J	2008b	Sharda Worldwide Exports Pvt. Ltd	Y
A3.15	Final Report: Imidacloprid Technical: Determination of Explosive Properties, SafePharm Laboratories Ltd, Study No. 2530/0014, GLP, (Un)	Tremain S	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A3.17	Final Report: Reaction with packing material of Imidacloprid Technical, Microquim S.A., Report No. FOBR-6111, GLP, (Un)	Karothy L	2007	Sharda Worldwide Exports Pvt. Ltd	Y
A4.1	Final Report: Preliminary analyses of five representative production batches of imidacloprid technical grade active ingredient (TGAI) to determine % imidacloprid and to quantify its associated impurities, Jai Research Foundation, Study No. 5830, GLP, (Un)	Desai H	2006a	Sharda Worldwide Exports Pvt. Ltd	Y
A4.1	Final Report: Validation of analytical methods for the determination of imidacloprid active ingredient and its associated impurities by HPLC. Annex 3, Jai Research Foundation, Study No. 5830, GLP, (Un)	Desai H	2006b	Sharda Worldwide Exports Pvt. Ltd	Y
A4.2(a)	Final Report: Imidacloprid (Technical 98% min) – Validation of a Residue Analytical Method for the Determination of Imidacloprid in Soil, RCC Ltd, Report No. B71616, GLP, (Un)	Krainz A	2008a	Sharda Worldwide Exports Pvt. Ltd	Y

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
A4.2(c)	Final Report: Imidacloprid (Technical 98% min) – Validation of a Residue Analytical Method for the Determination of Imidacloprid in Drinking and Surface Water, RCC Ltd, Report No. B71627, GLP, (Un)	Krainz A	2008a	Sharda Worldwide Exports Pvt. Ltd	Y
A5	Interim report: Laboratory bioassay to determine the efficacy of one bait against pharaoh ants, Monomorium pharaonis, argentine ants, Linepithema humile and black ants, Lasius niger, i2LResearch Ltd, Report No. 13-141, (Un)	Heaven H	2013	Sharda Worldwide Exports Pvt. Ltd	Y
A5	Efficacy of a fly bait granule product against House flies and Stable flies. BioGenius GmbH, Report no. BIO39a-13, (Un)	Lupkes K-H	2013a	Sharda Worldwide Exports Pvt. Ltd	Y
A5	Final interim report: Efficacy of a fly bait granule product against House flies and Stable flies. BioGenius GmbH, Report no. BIO044b-13, (Un)	Lupkes K-H	2013b	Sharda Worldwide Exports Pvt. Ltd	Y
A5	Final Report: Efficacy of a cockroach gel against cockroaches, BioGenius GmbH, Report No. BIO147-12, (Un)	Radecki C	2012	Sharda Worldwide Exports Pvt. Ltd	Y
A6.1.1	Final Report: Acute Oral Toxicity Study of Imidacloprid Technical in Rats, Jai Research Foundation, Report No. 5792, GLP, (Un)	Mukherjee A	2006a	Sharda Worldwide Exports Pvt. Ltd	Y
A6.1.2	Final Report: Acute Dermal Toxicity Study of Imidacloprid Technical in Rats, Jai Research Foundation, Report No. 5793, GLP, (Un)	Mukherjee A	2006b	Sharda Worldwide Exports Pvt. Ltd	Y
A6.1.3	Final Report: Acute Inhalation Toxicity Study of Imidacloprid Technical in Rats, Jai Research Foundation, Report No. 5797, GLP, (Un)	Mukherjee A	2006c	Sharda Worldwide Exports Pvt. Ltd	Y
A6.1.4i	Final Report: Acute Dermal Irritation Study of Imidacloprid Technical in Rabbits, Jai Research Foundation, Report No. 5794, GLP, (Un)	Mukherjee A	2006d	Sharda Worldwide	Y

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
				Exports Pvt. Ltd	
A6.1.4ii	Final Report: Acute Eye Irritation Study of Imidacloprid Technical in Rabbits, Jai Research Foundation, Report No. 5795, GLP, (Un)	Mukherjee A	2006e	Sharda Worldwide Exports Pvt. Ltd	Y
A6.1.5	Final Report: Skin Sensitisation Study of Imidacloprid Technical in Guinea Pigs (Guinea Pig Maximisation Test), Jai Research Foundation, Report No. 5796, GLP, (Un)	Mukherjee A	2006f	Sharda Worldwide Exports Pvt. Ltd	Y
A6.6.1	Final Report: Bacterial Reverse Mutation Test of Imidacloprid Technical using Salmonella Typhimurium, Jai Research Foundation, Report No. 6816, GLP, (Un)	Nagane RM	2007	Sharda Worldwide Exports Pvt. Ltd	Y
A6.6.1[16]	Title: Predictions for Rodent Toxicity Imidacloprid and Impurity Test facility: Harlan Laboratories Ltd. Project Number: C70338 GLP (UN)	Bachmann, C.	2009	Sharda Worldwide Exports Pvt. Ltd	Y
A6.6.1[16]	Title: Salmonella Typhimurium and escheria coli reverse mutation assay with 1,3-Bis[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine Test facility: Harlan Laboratories Ltd. Project Number: 1305200 GLP (UN)	Sokolowski, A.	2010	Sharda Worldwide Exports Pvt. Ltd	Y
A6.6.2	Final Report: Imidacloprid: Chromosome Aberration Test in Human Lymphocytes in vitro, Harlan Laboratories Ltd., Report No. 41205297, GLP, (Un)	Morris A and Bowles A	2013	Sharda Worldwide Exports Pvt. Ltd	Y

[16] Provided by the applicant for assessment of technical equivalence of active substance only (see Technical Equivalence Report by German CA attached to corresponding assets) – a study summary (DocIII file) does not exist.

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
A6.6.3	Final Report: Imidacloprid: L5178Y Mouse Lymphoma Assay, Harlan Laboratories Ltd., Report No. 41205298, GLP, (Un)	Anonymous [17]	2013	Sharda Worldwide Exports Pvt. Ltd	Y
A6.6.4	Final Report: Micronucleus Test of Imidacloprid Technical in Mice, Jai Research Foundation, Report No. 7168, GLP, (Un)	Anonymous [17]	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A6.12.2	Final Report: Assessment Report: Imidacloprid Product Type 18	BAuA	2011	n/a	N
A7.1.1.1.1	Final Report: Imidacloprid: Determination of the Effects of Industrial Processing and/or Household Preparation, SafePharm Laboratories Ltd, Study No. 2530/0008, GLP, (Un)	O'Connor BJ and Woolley SM	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A7.1.1.1.2	Imidacloprid: Aqueous Photolysis and Determination of the Quantum Yield of [14C] Imidacloprid, Harlan Laboratories Ltd., Report No. D65784, GLP, (Un)	Wehrhan A	2013	Sharda Worldwide Exports Pvt. Ltd	Y
A7.1.1.2.1	Final Report: Imidacloprid: Assessment of Ready Biodegradability; DOC Die-Away Test, Harlan Laboratories Ltd., Report No. 41205301, GLP, (Un)	Bayliss C	2013	Sharda Worldwide Exports Pvt. Ltd	Y
A7.1.3	Final Report: 14C-Imidacloprid: Adsorption and desorption in soils, Harlan Laboratories Ltd., Study No. 2530/0005, GLP, (Un)	Roulstone PM	2009	Sharda Worldwide Exports Pvt. Ltd	Y
A7.3.1	Final Report: Imidacloprid: Estimation of degradation by photooxidation in air, Harlan Laboratories Ltd., Report No. B90797-A, (Un)	Gurney A	2009	Sharda Worldwide Exports Pvt. Ltd	Y
A7.4.1.2	Final Report: Imidacloprid: Daphnia sp., 48-hour Acute Immobilisation Test, Harlan Laboratories Ltd., Report No. 41205302, GLP, (Un)	Parr S	2013	Sharda Worldwide	Y

[17] Study with vertebrates. Please, refer to the study summaries (DocIII files) for the name of the author(s).

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
				Exports Pvt. Ltd	
A7.4.1.3(1)	Final Report: Imidacloprid technical - Toxicity to Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum) in a 72-hour algal growth inhibition test, RCC Ltd, Report No. B72044, GLP, (Un)	Bätscher R	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A7.4.1.3(2)	Imidacloprid: Algal Growth Inhibition Test, Harlan Laboratories Ltd., Report No. 41205303, GLP, (Un)	Vryenhoef H	2013a	Sharda Worldwide Exports Pvt. Ltd	Y
A7.4.1.3(3)	Imidacloprid: Algal Growth Inhibition Test, Harlan Laboratories Ltd., Report No. 41301697, GLP, (Un)	Vryenhoef H	2013b	Sharda Worldwide Exports Pvt. Ltd	Y
A7.4.1.4	Final Report: Imidacloprid technical: Toxicity to activated sludge in a respiration inhibition test , RCC Ltd, Report No. B71932, GLP, (Un)	Seyfried B	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A7.4.3(1)	Final Report: Imidacloprid - Biological Effects and Fate in Outdoor Mesocosm Ponds, Harlan Laboratories Ltd., Report No. B72325, GLP, (Un)	Memmert U	2009c	Sharda Worldwide Exports Pvt. Ltd	Y
A7.4.3(2)	Final Report: Imidacloprid technical: effects on the development of sediment-dwelling larvae of Chironomus riparius in a water-sediment system, Harlan Laboratories Ltd., Report No. B72180, GLP, (Un)	Memmert U	2009b	Sharda Worldwide Exports Pvt. Ltd	Y
A7.4.3(3)	Final Report: Imidacloprid technical - Acute toxicity to first-instar larvae of Chironomus riparius, RCC Ltd, Report No. B72123, GLP, (Un)	Memmert U	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A7.4.3(4)	Final Report: Toxicity of Imidacloprid technical to the freshwater crustacean Gammarus in a water-sediment system, Harlan Laboratories Ltd., Report No. B72303, GLP, (Un)	Memmert U	2009a	Sharda Worldwide Exports Pvt. Ltd	Y

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
A7.5.1.1(1), A7.5.1.1(2)	Final Report: Imidacloprid 20% SL - Effects on the activity of soil microflora (Nitrogen and carbon transformation tests), BioChem agrar, Report No. 08 10 48 006 C/N, GLP, (Un)	Schulz L	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.1.3(1)	Final Report: Terrestrial (non-target) plant test with Imidacloprid 20 % SL: Seedling emergence and seedling growth test, BioChem agrar, Report No. 08 10 48 501 S, (Un)	Friedrich S	2009a	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.1.3(2)	Final Report: Terrestrial (non-target) plant test with Imidacloprid 20 % SL: Vegetative Vigour Test, BioChem agrar, Report No. 08 10 48 502 S, (Un)	Friedrich S	2009b	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.2.1	Final Report: Imidacloprid technical - Effects on reproduction of the springtail Folsomia candida (Collembola), Harlan Laboratories Ltd., Report No. B71976, GLP, (Un)	Schmidt T	2009a	Sharda Worldwide Exports Pvt. Ltd	Y
A 7.5.3.1.1	Final Report: Avian Acute Oral Toxicity Test with Imidacloprid 600FS in Japanese Quail (Coturnix coturnix japonica), Bioagri Laboratorios, Report no. RF-A00827.302.013.12., GLP, (Un)	Anonymous [17]	2012	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.4.1(1)	Final Report: Imidacloprid 20% SL – Acute oral and contact toxicity to the honey bee (Apis mellifera L.) in the laboratory, eurofins-GAB GmbH, Report No. S08-02153, GLP, (Un)	Kling A	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.4.1(2)	Final Report: Imidacloprid 20% SL – A Semi-field Study to Evaluate Effects on the Honey Bee (Apis mellifera; Hymenoptera, Apidae) in Apple Orchard in Spain 2008, eurofins-GAB GmbH, Report No. S08-00382, GLP, (Un)	Bocksch S	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.4.1(3)	Final Report: Imidacloprid 20% SL– Toxicity to adults of the parasitoid wasp Aphidius rhopalosiphi (Hymenoptera: Braconidae) under extended conditions in the laboratory, Harlan Laboratories Ltd., Report No. B71785, GLP, (Un)	Schmidt T	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.4.1(4)	Final Report: Imidacloprid 20% SL– Effects of Fresh and Aged Residues to Adults of the Parasitoid Wasp Aphidius rhopalosiphi (Hymenoptera:	Jeker L	2009a	Sharda Worldwide	Y

Document III Section No / Reference No	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Unpublished	Author(s)	Year	Owner	Data Protection Claimed (Yes/No)
	Braconidae) under Extended Laboratory Conditions, Harlan Laboratories Ltd., Report No. B71897, GLP, (Un)			Exports Pvt. Ltd	
A7.5.4.1(5)	Final Report: Imidacloprid 20% SL– Toxicity to Adults of the Parasitoid Wasp Aphidius rhopalosiphi (Hymenoptera: Braconidae) Under Semi - Field Conditions, Harlan Laboratories Ltd., Report No. B71910, GLP, (Un)	Jeker L	2009b	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.4.1(6)	Final Report: Imidacloprid 20% SL: Toxicity to the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) under extended laboratory conditions, RCC Ltd, Report No. B71763, GLP, (Un)	Jeker L	2008	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.4.1(7)	Final Report: Imidacloprid 20% SL: Effects of Fresh and Aged Residues to the Predatory Mite Typhlodromus pyri (Acari: Phytoseiidae) under Extended Laboratory Conditions , Harlan Laboratories Ltd., Report No. B71886, GLP, (Un)	Jeker L	2009c	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.4.1(8)	Final Report: Imidacloprid 20% SL– Toxicity to adults of the ground beetle species Poecilus cupreus (Coleoptera: Carabidae) under extended laboratory conditions, Harlan Laboratories Ltd., Report No. B71864, GLP, (Un)	Schmidt T	2009b	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.4.1(9)	Final Report: Imidacloprid 20% SL– Acute effects of repeated spray application to adults of the ground beetle species Poecilus cupreus (Coleoptera: Carabidae) under semi-field conditions, Harlan Laboratories Ltd., Report No. B71921, GLP, (Un)	Schmidt T	2009c	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.4.1(10)	Final Report: Imidacloprid 20% SL: Toxicity to larvae of the seven-spotted ladybird Coccinella septempunctata (Coleoptera: Coccinellidae) under extended laboratory conditions, Harlan Laboratories Ltd., Report No. B71807, GLP, (Un)	Jeker L	2009d	Sharda Worldwide Exports Pvt. Ltd	Y
A7.5.4.1(11)	Final Report: Imidacloprid 20% SL - Toxicity to larvae of the green lacewing Chrysoperla carnea (Neuroptera: Chrysopidae) under extended laboratory conditions, Harlan Laboratories Ltd., Report No. B71831, GLP, (Un)	Schmidt T	2009d	Sharda Worldwide Exports Pvt. Ltd	Y

4.2.1.3 Values from list of endpoints and 3rd party dossier

Comparison of
values from agreed list of endpoints and from 3rd party dossier

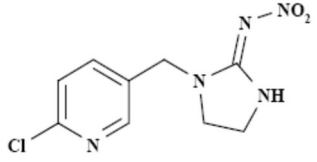
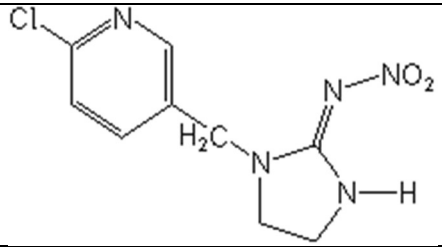
Chapter 1: Identity, Physical and Chemical Properties, Further Information, and Proposed Classification and Labelling

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**[1]
Active substance (ISO Common Name)	Imidacloprid	Imidacloprid
Function (*e.g.* fungicide)	Insecticide	Insecticide

Rapporteur Member State	Germany	Germany

[1] Imidacloprid Dossier submitted by the applicant "Sharda B.V.B.A" in Germany (1. R4BP2: 2013/29078/6824/DE/APP/10334 (R4BP3 BC-VS010393-20); German reference number: 5.0-710 05/18.00006; 2. R4BP2 2013/29078/6822/DE/APP/10327 (R4BP3 BC-XV010731-14); German reference number: 5.0-710 05/18.00007; 3. R4BP2: 2013/29078/6820/DE/APP/10318 (R4BP3 BC-DL010811-54); German reference number: 5.0-710 05/18.00008; 4. R4BP2: 2013/29078/6818/DE/APP/10305 (R4BP3 BC-MF010412-63); German reference number: 5.0-710 05/18.00009)

Identity (Annex IIA, point II.)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Chemical name (IUPAC)	((2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine	(2E)-1-[(6-chloropyridin-3-yl)methyl]-Nnitroimidazolidin-2-imine
Chemical name (CA)	2-imidazolidinimine, 1-[(6-chloro-3-pyridinyl)methyl]-*N*-nitro-, (2*E*)-	2-Imidazolidinimine, 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-, (2E)-
CAS-No	138261-41-3	138261-41-3
EC No	ELINCS: 428-040-8	428-040-8
Other substance No	CIPAC: 582 Manufacturer's development code number NTN 33893	Not available
Minimum purity of the active substance as manufactured (g/kg or g/l)	970 g/kg	980 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	See confidential data and information folder under Doc IIIA for impurities	See TER
Molecular formula	$C_9H_{10}ClN_5O_2$	$C_9H_{10}ClN_5O_2$
Molecular mass	255.7 g/mol	255.7 g/mol
Structural formula	 only E-isomer	

Physical and chemical properties (Annex IIA, point III., unless otherwise indicated)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Melting point (state purity)	144 °C (99.9 %)	Melting at 143 °C under decomposition
Boiling point (state purity)	not applicable (decomposition)	Melting at 143 °C under decomposition
Temperature of decomposition	>200 °C	143 °C
Appearance (state purity)	Colorless crystal (99.8 %) to cream colored powder (98.5 %)	White powder (97.95%) to white to yellowish powder containing black particles (98%)
Relative density (state purity)	D^{23}_4 = 1.54	d^{20}_4 = 1.517, (97.95%)
Surface tension	72.20 mN/m at 20 °C (c = 458.91 mg/L)	49.6 mN/m at 25 °C (saturated aqueous solution)
Vapour pressure (in Pa, state temperature)	4 x 10^{-10} Pa at 20 °C 9 x 10^{-10} Pa at 25 °C	LoA provided.[19]
Henry's law constant (Pa m^3 mol^{-1})	1.7 x 10^{-10} Pa m^3 mol^{-1} (20 °C)	calculated: 3.77 x 10^{-10} Pa m^3/mole
Solubility in water (g/l or mg/l, state temperature)	613 mg/L in demineralised water at 20 °C	614 mg/L in purified water at 25 °C
	pH5: independent of pH	pH4: 640 mg/L at 25 °C
	pH9: independent of pH	pH7: 636 mg/L at 25 °C
	pH7:	pH9: 639 mg/L at 25 °C
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	at 20 °C **Solvent** **Solubility** *n*-Hexane < 100 mg/L Toluene 690 mg/L Dichloromethane 67000 mg/L 2-Propanol 2300 mg/L	at 25 °C **Solvent** **Solubility** n-heptane: 2.0E-04 g/L xylene: 0.36 g/L 1,2-dichloroethane: 28.9 g/L methanol: 8.20 g/L

	Acetone 50000 mg/L Ethylacetate 6700 mg/L Acetonitrile 50000 mg/L DMSO >200000 mg/L DMF >200000 mg/L	acetone: 42.2 g/L ethyl acetate: 6.82 g/L octanol: 0.81 g/L
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	no solvents used in biocidal products	Not required according to the TNsG on Data Requirements, because the a.s. as manufactured does not contain any organic solvent.
Partition coefficient (log P_{OW}) (state temperature)	pH 5:independent of pH	
	pH 9:independent of pH	
	pH 7: log $P_{O/W}$ = 0.57 (demin. water) at 21 °C	log Pow = 0.61 ± 0.01 temperature: 21 °C pH: 5.3
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH 5: stable at 25 °C	pH 4: no degradation
	pH 7: stable at 25 °C	pH 5: no degradation
	pH 9: DT50 approx. 1 year at 25 °C DT50 2.75 years (calculation to EU outdoor Temperature at 12 °C)	pH 6: no degradation
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	It is not possible to specify a pK value of the test substance in pure aqueous system.	It is not possible to specify a pK value of the test substance in pure aqueous system
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	**λ_{max} [nm]** **ε** 212 13346 270 22054	**λ_{max} [nm]** **ε [L/cm.mol]** 269 22400 (pH 7.1, log ε: 4.35) 269 21700 (pH 1.1, log ε: 4.34) 269 18401 (pH 13.0, log ε: 4.26)

Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	pH 7: 30 - 50° latitude (calculation) DT50 experimental: 57 min, DT50 calculated: 0.2 - 1.6 days (spring, summer) 1.4 - 16 days (fall, winter)	Half-Life DT50: 0.2d (experimental)* Half-Life DT50: 0.5d (experimental)** Half-Life DT50: 0.4d (experimental)*** * Continuous irradiation ** Natural summer sunlight at 50°N *** Natural summer sunlight at 30-40°N
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	Φ = 0.0142 (highly pure water, 25 °C)	Φ = 0.0123 (buffer solution pH 7, 25 °C)
Flammability	Not highly flammable	Not highly flammable
Explosive properties	Not explosive	No explosive properties

Classification and proposed labelling (Annex IIA, point IX.)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
with regard to physical/chemical data	none	none
with regard to toxicological data	Xn, R22*	Xn, R22 Warning Acute Tox. 4; H302 (Harmful if shallowed)
with regard to fate and behaviour data	none	none
with regard to ecotoxicological data	N, R50, R53	N, R50/53 according to 67/548/EEC as stated in (EC) No 790/2009 (1st ATP to (EC) No 1272/2008) Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) according to CLP as stated in (EC) No 790/2009 (1st ATP to (EC) No 1272/2008)

* The question of whether the LD_{50} in mice (which would result in a more severe classification, i. e. R25) should be used for C & L regarding acute toxicity has been discussed at TMII09. In the view of the RMS, a uniform basis should be selected when classifying/labelling chemical substances, i.e. acute toxicity should always be classified/labelled based on rat studies, when available. While no consensus between MS could be reached, it was nevertheless decided by TMII09, that both LD_{50} values should be given, but the question of C & L of Imidacloprid for acute toxicity should be left to the RAC at EChA.

Chapter 2: Methods of Analysis

Analytical methods for the active substance

	Value from Assessment Report (18.02.2011)	Value from assessment of 3rd party dossier
Technical active substance (principle of method) (Annex IIA, point 4.1)	HPLC	HPLC and LC-MS analysis
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	HPLC	HPLC and LC-MS analysis

Analytical methods for residues

	Value from Assessment Report (18.02.2011)	Value from assessment of 3rd party dossier
Soil (principle of method and LOQ) (Annex IIA, point 4.2)	residue definition: imidacloprid LC-MS/MS LOQ: 0.005 mg/kg HPLC-UV LOQ: 0.01 mg/kg	Residue definition: Imidacloprid LC-MS/MS; Inertsil ODS-3 column, ESI+, m/z 256→209, 256→84 LOQ: 0.005 mg/kg (LUFA soil 2.3)
Air (principle of method and LOQ) (Annex IIA, point 4.2)	residue definition: imidacloprid HPLC-UV LOQ: 5 µg/m³	Residue definition: Imidacloprid HPLC-UV LOQ: 5 µg/m³ (Waiver, LoA from Bayer)
Water (principle of method and LOQ) (Annex IIA, point 4.2)	residue definition: imidacloprid HPLC-UV LOQ: 0.03 µg/L (for drinking and surface water) LC-MS/MS LOQ: 0.1 µg/L (for surface water)	Residue definition: Imidacloprid LC-MS/MS; Inertsil ODS-3 column, ESI+, m/z 256→209, 256→84 LOQ: 0.1 µg/L (drinking water, surface water)

	HPLC-UV LOQ: 0.05 µg/L (for drinking water)	
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	not necessary	Not necessary
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	not necessary	Not necessary
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	not necessary	Not necessary

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Rate and extent of oral absorption:	Rapid and extensive: > 90 % based on urinary (56 %) and biliary (35 %) excretion	LoA provided.[19]
Rate and extent of dermal absorption:	0.3 % for concentrate and ca. 8 % in dilution, based on human *in vitro* study with a formulation of imidacloprid in oil	LoA provided.[19]
Distribution:	Widely distributed, sum of residues in tissue after 48 h < 1 % of dose, highest in liver, kidney, lung, and skin	LoA provided.[19]
Potential for accumulation:	No potential for accumulation	LoA provided.[19]
Rate and extent of excretion:	> 95 % within 48 h, mainly via urine	LoA provided.[19]
Metabolism	Extensively metabolised (at least 16 different metabolites), ca. 10-15 % parent excreted unchanged *Major metabolic pathways*: oxidative cleavage between methylene group and imidazolidine moiety; hydroxylation of imidazolidine ring in position 4 or 5 and subsequent elimination to yield a C-C double bond	LoA provided.[19]

[19] The 3rd party dossier contained no data regarding this end point. However, since the applicant provided a LoA to the dossier submitted by "Bayer" for annex I inclusion the data from the left column can be used for the assessment.

Toxicologically significant metabolite	No specific concern, but information given only for some metabolites (cf. "Other Studies" section)	LoA provided.[19]

Acute toxicity (Annex IIA, point 6.1)

between 300 and < 2000 mg/bw (Mukherjee A (2006a)	380-650 mg/kg bw **R22***	between 300 and < 2000 mg/bw (Mukherjee A (2006a)
-	131/168 MG/KG BW (M/F)	-
> 2000 mg/kg bw (Mukherjee A (2006b)	> 5000 MG/KG BW	> 2000 mg/kg bw (Mukherjee A (2006b)
Dust Aerosol > 0.438 mg/L air (maximum achievable concentration, 4 h, nose only) (Mukherjee A (2006c)	Aerosol > 0.069 mg/L, Dust > 5.323 mg/L (4 h, nose-only, max. attainable concentrations.)	Dust Aerosol > 0.438 mg/L air (maximum achievable concentration, 4 h, nose only) (Mukherjee A (2006c)
Non-irritant (Mukherjee A (2006d)	Non-irritant	Non-irritant (Mukherjee A (2006d)
Non-irritant (Mukherjee A (2006e)	Non-irritant	Non-irritant (Mukherjee A (2006e)
Non-sensitising (M+K) (Mukherjee A (2006f)	Non-sensitising (M+K)	Non-sensitising (M+K) (Mukherjee A (2006f)

Repeated dose toxicity (Annex IIA, point 6.3)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Species/target/critical effect	Rat: Decreased body weight gain; hepatotoxicity, thyroid mineralisation (long-term) Dog: Decreased body weight gain; tremor (at higher doses) Mouse: Hepatotoxicity, decreased body weight gain	LoA provided.[19]
Relevant medium-term oral NOAEL	90-d neurotoxicity rat: 9.3 mg/kg bw/d 90-d dog: 23.5 mg/kg bw/d	LoA provided.[19]

* The question of whether the LD_{50} in mice (which would result in a more severe classification, i. e. R25) should be used for C & L regarding acute toxicity has been discussed at TMII09. In the view of the RMS, a uniform basis should be selected when classifying/labelling chemical substances, i.e. acute toxicity should always be classified/labelled based on rat studies, when available. While no consensus between MS could be reached, it was nevertheless decided by TMII09, that both LD_{50} values should be given, but the question of C & L of Imidacloprid for acute toxicity should be left to the RAC at EChA.

Relevant long-term oral NOAEL	2-yr rat: 5.7 mg/kg bw/d 1-yr dog: 41 mg/kg bw/d 2-yr mouse: 208 mg/kg bw/d	LoA provided.[19]
Relevant dermal NOAEL	21-d rabbit: 1000 mg/kg bw/d	LoA provided.[19]
Relevant inhalation NOAEL	28-d rat: 0.03 mg/L air (8.2 mg/kg bw/d)	LoA provided.[19]

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Genotoxicity (Annex IIA, point 6.6)	Imidacloprid is unlikely to be genotoxic in humans	Based on the studies submitted imidacloprid is unlikely to be genotoxic (Nagane RM (2007), Morris A and Bowles A (2013), Brown R (2013), Nagane RM (2008)

Carcinogenicity (Annex IIA, point 6.4)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Species/type of tumour	None	LoA provided.[19]
lowest dose with tumours	Not applicable	LoA provided.[19]

Reproductive toxicity (Annex IIA, point 6.8)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Species/ Reproduction target/critical effect	<u>Parental</u> Decreased food consumption and body weight gain <u>Reproduction</u> No effect	LoA provided.[19]

	Offspring Decreased body weight gain and birth weight	
Relevant parental NOAEL	20 mg/kg bw/d	LoA provided.[19]
Relevant reproductive NOAEL	50 mg/kg bw/d	LoA provided.[19]
Relevant offspring NOAEL	20 mg/kg bw/d	LoA provided.[19]

Developmental toxicity (Annex IIA, point 6.8)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Species/ Developmental target / critical effect	Maternal Decreased body weight gain, reduced food consumption (rat) Foetuses Rat: No adverse effects up to highest dose tested Rabbit: Decreased body weight, ret. ossification	LoA provided.[19]
Relevant maternal NOAEL	Rat: 30 mg/kg bw/d Rabbit: 24 mg/kg bw/d	LoA provided.[19]
Relevant developmental NOAEL	Rat: 100 mg/kg bw/d Rabbit: 24 mg/kg bw/d	LoA provided.[19]

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Species/ target/critical effect	Tremor, decreased motor/locomotor activity No evidence of developmental neurotoxicity	LoA provided.[19]
Relevant NOAEL for neurotoxicity	Acute, rat: 42 mg/kg bw/d 13-wk, rat: 196 mg/kg bw/d (highest dose level tested) Dev., rat: 30 mg/kg bw/d	LoA provided.[19]
Relevant developmental NOAEL	Not applicable	LoA provided.[19]

Other toxicological studies (Annex IIIA, VI/XI)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Studies on metabolites:	<u>Imidacloprid-nitrosimine</u> LD_{50} (rat) = 1980/3560 mg/kg bw (M/F), LD_{50}(mouse) = 200-300 mg/kg bw 12-wk rat: NOAEL = 13 mg/kg bw/d based on haematology/clinical chemistry findings Standard battery of in vitro and in vivo genotoxicity tests: unlikely to be genotoxic <u>Imidacloprid-urea</u> LD_{50} = 4080/1820 mg/kg bw (M/F), neg. in the Ames test <u>Imidacloprid-desnitro</u> LD_{50} = 300/280 mg/kg/bw (M/F), neg. in the Ames test <u>Imidacloprid-olefine</u> LD_{50} = 3500/1100 mg/kg bw (M/F), neg. in the Ames test	LoA provided.[19]

Medical data (Annex IIA, point 6.9)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Medical surveillance data on manufacturing plant personnel	No adverse health effects reported.	No adverse health effects reported
Intoxication case reports	Ingestion of 200 mg in 4-yr old child without adverse effects; two suicidal fatalities reported in a second case report	Two suicidal fatalities reported (Proença, P. et al. (2005))

	Value from Assessment Report (18.02.2011)			**Value from assessment of 3rd party dossier**		
Summary (Annex IIA, point 6.10)	Value	Study	Safety factor	Value	Study	Safety factor
AEL_{acute}*	0.4 mg/kg bw	Rat, acute neurotoxicity, supported by dog, 28-d (acute effects)	100	LoA provided.[19]		
$AEL_{medium\text{-}term}$*	0.2 mg/kg bw/d	Rat, 2-gen., supported by dog, 90-d and rabbit, develop-mental)	100	LoA provided.[19]		
$AEL_{long\text{-}term}$*	0.06 mg/kg bw/d	Rat, 2-yr	100	LoA provided.[19]		
Drinking water limit	Not allocated			Not allocated		

* AEL: Systemic (= Internal) Acceptable Exposure Level

Acceptable exposure scenarios (including method of calculation)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Professional users		See PAR for corresponding products to be authorised.
Production of active substance:	Not assessed by the rapporteur under the requirements of the BPD	See PAR for corresponding products to be authorised.
Formulation of biocidal product	Not assessed by the rapporteur under the requirements of the BPD	See PAR for corresponding products to be authorised.
Intended uses: Application of Imidacloprid granules	Ready for use granules with 0.5 % active substance	See PAR for corresponding products to be authorised.

Mixing & loading: No mixing & loading, ready for use product **Application:** Placing 2 kg b.p. in dishes in a 1000 m^2 stable floor. Form of exposure: dust of granules (0.5 % a.s.) Duration: 120 min Frequency: 8 days per year (farmer), 90 days per year (pest control operator) Model: TNsG Human Exposure Model 5 Mixing & loading (Part 2, p.137) **Post-application:** collection of 1 kg b.p. Form of exposure: dust of granules (0.5 % a.s.) Duration: 120 min. Frequency: 8 days per year (farmer), 90 days per year (pest control operator) Model: TNsG Human Exposure Model 5 Mixing & loading (Part 2, p.137)	Potential inhalation exposure (all phases): Potential dermal exposure (all phases):	0.0006 mg/person/day The respective air concentration (mg/m^3) is not given and cannot be calculated because essential parameters, such as sampling time etc are missing. The resulting value in mg/person/day is therefore taken forward for risk assessment concerning inhalation. 0.049 mg/person/day	See PAR for corresponding products to be authorised.
Intended uses: Brushing of diluted Imidacloprid granules	Granules with 0.5 % active substance diluted with water to 0.33 % a.s. bait paste		See PAR for corresponding products to be authorised.

Mixing & loading: Preparation of bait paste, filling of granules and dilution with water, stirring Form of exposure: dust of granules (0.5 % a.s.) Duration: 15 min Frequency: 8 days per year (farmer), 90 days per year (pest control operator) Model: TNsG Human Exposure Model 5 Mixing & loading (Part 2, p.137) **Application:** Brushing of bait paste Form of exposure: liquid (0.33 % a.s.) Duration: 120 min Frequency: 8 days per year (farmer), 90 days per year (pest control operator) Model: Model 3 (Consumer product painting) TNsG Human Exposure (Part 2, p. 202) **Post-application:** Cleaning of application equipment Form of exposure: liquid (0.33 % a.s.) Duration: 5 min. Frequency: 8 days per year (farmer), 90 days per year (pest control operator) Model: Cleaning of a brush is not covered by any of the proposed models in the TNsG Human Exposure. Calculations are based on an	Potential inhalation exposure (all phases) Potential dermal exposure (all phases)	0.0004 mg/person/day 11.1 mg/person/day	See PAR for corresponding products to be authorised.

approach by the Competent Authority of Finland used in the CA Report for Tolylfluanid (PT 8).			
Intended uses: Application of Imidacloprid gel	Ready for use gel with 2.15 % active substance		
Mixing & loading: No mixing & loading, ready for use product **Application:** Spot application using a suitable gel applicator Form of exposure: liquid (2.15 % a.s.) Duration: 30 min per site, 5 sites per day Frequency: 5 opening and 5 sealing operations of cartridge per day Model (dermal): Expert judgment assuming the transfer of 0.5 cm gel string to the hand per opening or sealing **Post-application:** Handling of empty cartridge Form of exposure: liquid (2.15 % a.s.) Duration: 5 min. Frequency: 1 event per day Model (dermal): Expert judgment assuming the transfer of 0.5 cm gel string to the hand per event	Potential inhalation exposure (all phases) Potential dermal exposure (all phases)	Negligible 1.1 mg/person/day	See PAR for corresponding products to be authorised.
Secondary exposure	Typical work in animal housing (e.g cleaning)		
Typical work in animal housing	Potential inhalation exposure	Negligible	See PAR for corresponding products to be authorised.

Form of exposure: Active substance stick to dust Model (dermal): Expert judgment based on the calculation that 10 mg a.s./m^2 is used and that the palms of both hands (420 cm^2) are exposed	Potential dermal exposure	0.42 mg/person/day	
Non-professional users	Non-professional use is not intended.		See PAR for corresponding products to be authorised.
Indirect exposure as a result of use	<u>Imidacloprid GL 2.15:</u> Acute exposure (dermal absorption 8%) to adults removing old baits, basing on simplified assumptions: 0.0086 mg/kg bw (2.2% of AEL-S_{acute}) Acute exposure (oral, dermal) exposure to children by uptake of dried baits, basing on simplified worst case assumptions: oral: 0.215 mg/kg bw (54% of AEL-S_{acute}) <u>Imidacloprid GR 0.5:</u> Acute exposure (dermal absorption: 8%) to adults by contact to treated walls, basing on simplified assumptions: 0.000224 mg/kg bw/d (0.1% of AEL-S_{acute}) Acute exposure (dermal, oral) to children by contact to treated walls, basing on simplified worst case assumptions: oral: 0.005333 mg imidacloprid/kg bw (1.3% of AEL-S_{acute})		See PAR for corresponding products to be authorised.

	dermal: 0.000427 mg imidacloprid/kg bw (0.1% of AEL-S_{acute}) total: 0.00576 mg imidacloprid/kg bw (1.4% of AEL-S_{acute})	

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 5 (298 K): stable	pH 5 (90°C): stable
	pH 7 (298 K): stable	pH 6 (100°C): stable
	pH 9 (298 K): DT50: 355 days (285 K): DT50: 2.75 years (calculation to EU outdoor temperature)	pH 7 (120°C): stable
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Half-life: 57 min (experimental) GC-solar: 0.15 to 0.32 d (spring and summer); 0.25 - 6.12 d (fall and winter) as function of latitude Frank&Kloeppfer: 0.2 - 1.6 d (spring and summer); 1.4 - 16 d (fall) Metabolites (results are an aggregate of 3 studies): 17.2 % imidacloprid guanidine eq. NTN33893-desnitro eq. NTN38014; 9.8 % 1-[(6-chloro-3-pyridinyl)methyl]-2-imidazolidone eq. NTN33893-urea eq. NTN33519 12.6 % NTN33893-desnitro-olefine 15 % 6-chloropicolyl-guanidine eq. NTN 33893-ring-open guanidine and 6-chloro-nicotinic acid	Half-Life DT50: 0.2d (experimental)* Half-Life DT50: 0.5d (experimental)** Half-Life DT50: 0.4d (experimental)*** * Continuous irradiation ** Natural summer sunlight at 50°N *** Natural summer sunlight at 30-40°N Metabolites: • 4 major metabolites (>10%) • M4 and M5 reached 16% and 28% between 1 and 3 days of constant irradiation and decreased from that time point to 8.9% and 9.8% after 15 days of constant irradiation. • The metabolites M1 and M7 kept increasing during the study up to mean concentrations of 30% and 17%, respectively.

		• None of the metabolites have been identified
Readily biodegradable (yes/no)	no	no
Biodegradation in seawater	Not relevant for intended use	LoA provided.[19]
Non-extractable residues	Aerobic at 22 ± 1°C in the dark, 30 d: 8.2 % after 30 days, max. 9.7 % (day 21) Aerobic at 22 ± 1°C in the dark, 92 d, two systems: 66.3 % after 92 days (max.) 15.4 % after 92 days (max.) Anaerobic at 22 ± 1°C in the dark, 358 d: 16.0 % after 120 days, max. 22.6 % (day 358)	LoA provided.[19]
Distribution in water / sediment systems (active substance)	Aerobic at 22 ± 1°C in the dark, 30 d, silty clay : Water: max. 90.7 % (day 0); decline to 64 % (day 30) Sediment: max. 23.5 % (day 7); 20.4 % after 30 days DT_{50} (dissipation) = > 30 d (water) DT_{50} = 129 d (entire system) Converted to average EU outdoor temperature of 12°C: DT_{50} (dissipation, 12°C) = > 67 d (water) DT_{50} (12°C) = 287 d (entire system) Mineralisation: 0.7 % after 30d (max.) Aerobic at 22 ± 1°C in the dark, 92 d, two systems (a, loamy silt, b loamy sand): Distribution Water:	LoA provided.[19]

	max. 78.5 % (day 0); decline to 5.1 % (day 92) max. 90.3 % (day 0); decline to 52.8 % (day 92) Sediment: max. 31.9 % (day 14); 6.6 % after 92 days max. 10.3 % (day 60); 8.9 % after 92 days DT_{50} a) DT_{50} (dissipation) = 14.2 d (water) DT_{50} (dissipation) = 35.7 d (sediment) DT_{50} = 30 d (entire system) b) DT_{50} (dissipation) = 108.7 d (water) DT_{50} = 149.7 d (entire system) Converted to average EU outdoor temperature of 12°C: a) DT_{50} (dissipation, 12°C) = > 31.6 d (water) DT_{50} (dissipation, 12°C) = 79.4 d (sediment) DT_{50} (12°C) = 66.8 d (entire system) b) DT_{50} (dissipation, 12°C) = 242 d (water) DT_{50} (12°C) = 333.2 d (entire system) Mineralisation: 1.4 % after 92 days (max.) 2.0 % after 92 days (max.) **Geometric mean DT_{50} (n=3):** **entire system** = **83.3 days** at 22°C, corresponding to 185.4 days at 12°C average EU outdoor temperature	

	<u>Anaerobic at 22 ± 1°C in the dark, 358 d:, silt loam</u> Distribution Water: max. 93.4 % (day 0); decline to 3 % (day 120); 0.1 % after 358 days Sediment: max. 18.7 % (day 14); 1.7 % after 120 days; 0.1 % after 358 days DT_{50} DT_{50} (dissipation) = not determined in water DT_{50} = 36 d (entire system) Converted to average EU outdoor temperature of 12°C: DT_{50} (12°C) = 80 d (entire system) Mineralisation < 0.1 % after 120 days; max. 0.2 % after 358 days <u>Aerobic at 20°C in the dark, 366 d, open water system:</u> Water: max. 97 % (day 0); decline to 65.4 and 47.8 % (days 91 and 366) DT_{50} (dissipation) = 331 d (water) Converted to average EU outdoor temperature of 12°C: DT_{50} (dissipation, 12°C) = 628 d (water) Mineralisation: 0.7 % and 1.0 % after 92 days, max. 4.3 % after 366 days	
Distribution in water / sediment systems (metabolites)	<u>Aerobic at 22 ± 1°C in the dark, 30 d:</u>	LoA provided.[19]

	No metabolites > 10 % detected, four minor metabolites (< 3 %) identified <u>Aerobic at 22 ± 1°C in the dark, 92 d, two systems (a, b):</u> a) NTN33893-desnitro: 12.3% total system (water 6.0% and sediment 6.3%) after 92 days b) No metabolites > 10 % detected, three minor metabolites identified <u>Anaerobic at 22 ± 1°C in the dark, 358 d:</u> NTN33893-desnitro in water and sediment phase Water: max. 20% after 60 days Sediment: max. 51.5% after 249 days Total system: max. 66% after 249 days <u>Aerobic at 20°C in the dark, 366 d, open water system:</u> NTN33893-desnitro in water phase Water: 14.8 % after 92 days, max. 26.4 % after 274 days, 19.2 % after 366 days	

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Mineralization (aerobic)	After 100 days: sandy loam (a): 2.7% Silt soil: 6.4% loamy sand 10.0% sandy loam (b): 16.6% after 91 days, 20.3% after 126 days, sandy loam (a): 4.9% after 366 days	LoA provided.[19]
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): 106 – 193 days (n=4) Geometric mean: 156 days (n=4) Soil type DT_{50} kinetic Loamy sand 154 1st oder silt soil 193 1st oder sandy loam 186 1st oder sandy loam 106 1st oder **Standardised to FOCUS kinetics (20°C, 100% FC): geo, mean: 117.7 days (n=4)** Converted to average EU outdoor temperature of **12°C:** **DT_{50}: 201-366 days, geo. mean: 295 days (n=4)** DT_{90lab} (20°C, aerobic): n/a DT_{50lab} (10°C, aerobic): 233-425 days (n=4) Geometric mean: 343 days (n=4)	LoA provided.[19]

	DT_{50lab} (20°C, anaerobic): not determined	LoA provided.[19]
	degradation in the saturated zone: n/a	LoA provided.[19]
Field studies (state location, range or median with number of measurements)	DT_{50f}: Northern Europe DT_{50f} (in days) Investigated: imidacloprid Germany / soil / best fit / 1st order / r^2 Swisttal Hohn / silt loam / 173 / 208 / 0.92 Swisttal Hohn / silt loam / 140 / 185 / 0.88 Burscheid-Höfchen / silt loam / 62 / 104 / 0.88 Burscheid-Höfchen / silt loam / 79 / 131 / 0.61 Kirchlauter / sandy loam / 142 / 178 / 0.82 Kirchlauter / sandy loam / 180 / 216 / 0.85 Worms / loam / 151 / 197 / 0.50 Worms / loam / 196 / 228 / 0.74 Laacher Hof / sandy loam / 119 / 152 / 0.81 Laacher Hof / sandy loam / 160 / 186 / 0.86 median (d) / 147 / 186 Range: 104-228 d (n=10) Geometric mean: 174 d (n=10) Southern Europe Investigated: Confidor 200 SL soil / best fit / 1st order France / silty loam / 63 d [1] / 111 Italy / silty clay / 183 d [2] / 288 Italy / loamy sand / 28 d [1] / 40 Spain / silty clay loam / 77 d [1] / 116 geometric mean / 71 d / 110 d [1] square root 1st order square root 1.5st order	LoA provided.[19]

	Range: 40-288 d (n=4) Geometric mean: 110 d Total geometric mean for Europe: 153 d (n=14) Normalised to FOCUS reference conditions (20°C, 100% FC): normalised values according to FOCUS location — DT_{50} (d) Kirchlauter-Pettstadt 85.8 Swisstal-Hohn 89.8 Höfchen 50.6 Worms-Heppenheim 94.3 Laacher Hof 86.0 Kirchlauter-Pettstadt 70.8 Swisstal-Hohn 98.2 Höfchen 41.0 Worms-Heppenheim 82.0 Laacher Hof 71.6 Bagnolo di Nogarole Rocca 179.8 St. Etienne du Gres 65.7 Ca Degli Oppi, Italy 27.0 Castellarnau 58.5 median 76.8 geometric mean 71.9 Range: 27.1-179.8 d (n=14) Converted to average EU outdoor temperature of 12°C: DT_{50}: range 50.9-337.9 days (n=14); **geometric mean: 135.1 days (n=14; 12°C, 100% FC)**	
		LoA provided.[19]

	DT_{90f}: DT_{90f} : investigated: Confidor 200 SL NE soil 1st order sandy loam 717*) sandy loam 591*) silt loam 614*) silt loam 690*) silt loam 435*) silt loam 345 loam 757*) loam 654*) sandy loam 618*) sandy loam 504*) geometric mean 578 d	
Anaerobic degradation	n/a	LoA provided.[19]
Soil photolysis	n/a	n/a
Non-extractable residues	Laboratory soil degradation studies 16.6% (sandy loam) – 25% (sandy loam) after 100 days (n=4) sandy loam: 26.9% after 91 days, 28.1% after 126 days, sandy loam: 23% after 366 days sandy loam: 39.5% after 366 days	LoA provided.[19]
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	No metabolites > 10% In total nine minor metabolites were found. Maximum fraction: NTN33893-olefine (1.8 % TAR after 100 d), NTN33893-ring-open-nitroguanidine (max. 3.4 % TAR after 77 d)	LoA provided.[19]

	NTN33893-desnitro (4,3 % TAR after 201 d).	
Soil accumulation and plateau concentration	Not required	Not required

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Arithmetic mean: 2.32 mL/g, 3.18 mL/g 230 mL/g, 277 mL/g no pH-dependence	Arithmetic mean: 2.05 cm^3/g, 7.4 cm^3/g 186.6 cm^3/g, 534.9 cm^3/g no pH-dependence

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Direct photolysis in air	-	-
Quantum yield of direct photolysis	-	-
Photo-oxidative degradation in air	Theoretical estimation according to Atkinson, using US EPA AOPWIN, version 1.87. DT_{50}: 2.54 h 24-hours-mean concentration: 5×10^5 OH radicals/cm^3	Theoretical estimation according to Atkinson, using US EPA AOPWIN, version 1.91. DT_{50}: 2.54 h 24-hours-mean concentration: 5×10^5 OH radicals/cm^3
Volatilization	No data supplied, not required	No data supplied, not required

Monitoring data, if available (Annex VI, para. 44)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Soil (indicate location and type of study)	None available	None available
Surface water (indicate location and type of study)	None available	None available

<table>
<tr><td>Ground water (indicate location and type of study)</td><td>Germany, groundwater monitoring programme
Data from 4 Federal States
<table><tr><th></th><th colspan="5">number</th></tr><tr><th></th><th>total</th><th><LOQ</th><th>≤0.1</th><th>>0.1-1.0</th><th>>1.0 µg/L</th></tr><tr><td>2000</td><td>9</td><td>9</td><td>0</td><td>0</td><td>0</td></tr><tr><td>2001</td><td>23</td><td>22</td><td>1</td><td>0</td><td>0</td></tr><tr><td>2002</td><td>279</td><td>278</td><td>1</td><td>0</td><td>0</td></tr><tr><td>total</td><td>627</td><td>625</td><td>2</td><td>0</td><td>0</td></tr></table></td><td>LoA provided.[19]</td></tr>
<tr><td>Air (indicate location and type of study)</td><td>None available</td><td>None available</td></tr>
</table>

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

			Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Species	Time-scale	Endpoint	Toxicity	Toxicity
Fish				
Oncorhynchus mykiss	96 h	mortality	LC_{50} = 211 mg/l	LoA provided.[19]
Oncorhynchus mykiss	91 d	time to hatch	NOEC = 9.02 mg/l	LoA provided.[19]
Invertebrates				
Daphnia magna	48 h	immobility	EC_{50} = 85 mg/l	EC_{50} > 100 mg/L
Chironomus riparius	24 h	mortality	LC_{50} = 0.055 mg/l	LC50 = 0.05 mg/L
Daphnia magna	21 d	reproduction	NOEC =1.8 mg/l	LoA provided.[19]
Cloeon dipterum	96 h	immobility	EC_{50} = 1.02 µg/L	-
Caenis horaria	96 h	immobility	EC_{50} = 1.77 µg/L	-
Chironomus riparius	28d	development, emergence	EC_{10} = 2.09 µg/l (nominal conc.) EC_{10} = 0.87 µg/l (mean measured conc.); this value was used for the effects assessment	NOEC = 2.0 µg/L (nominal) NOEC = 0.78 µg/L (mean measured conc.)

Cloeon dipterum	28 d	immobility	EC_{10} = 0.033 µg/L	-
Caenis horaria	28 d	immobility	EC_{10} = 0.024 µg/L	-
Gammarus fossarum	28 d	Survival, behaviour		NOEC = 0.032 mg/L (nominal) NOEC = 0.017 mg/L (mean measured conc.)
Metabolite Imidacloprid, desnitro: *Hyalella azteca*	96 h	mortality	LC_{50} = 51.8 mg/l	LoA provided.[19]
Metabolite Imidacloprid, desnitro: *Chironomus riparius*	28 d	development, emergence	EC_{10} = 27 mg/l (nominal conc.) EC_{10} = 9.45 mg/l (mean measured conc.)	LoA provided.[19]
Algae				
Selenastrum capricornutum	72 h	Growth rate inhibition	E_rC_{50} > 100 mg/l NOEC < 100 mg/l	E_rC_{50} > 100 mg/L NOE_rC = 8.9 mg/L

Microorganisms				
Activated sludge from sewage treatment plant (treating predominantly domestic sewage)	3 h stat.	respiration inhibition	EC_{50} > 10000 mg/L (nominal) NOEC = 5600 mg/L (nominal)	EC_{50} > 10000 mg/l (nominal) NOEC = 10000 mg/l (nominal)
Freshwater species community				
Sediment dwelling organisms, phytoplankton and zooplankton	26 weeks	mesocosm	NOEC = 0.6 µg/l (nominal)	77d NOEC <0.5 µg/L (nominal)

Effects on earthworms or other soil non-target organisms

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Acute toxicity to earthworms (Annex IIIA, point XIII.3.2)	*Eisenia fetida*: LC_{50} (14 d) = 10.7 mg/kg dw	LoA provided.[19]
Reproductive toxicity to earthworms (Annex IIIA, point XIII.3.2)	*Eisenia fetida*: NOEC (56 d) ≥ 0.178 mg/kg dw	LoA provided.[19]
Long-term toxicity to other soil non-target macroorganisms	*Folsomia candida*: NOEC (28 d) = 0.3 mg/kg dw (mortality) NOEC (28 d) = 1.25 mg/kg dw (reproduction) *Hypoaspis aculeifer* : NOEC (14-23 d) ≥ 2.66 mg/kg dw* (mortality and reproduction)	*Folsomia candida:* *NOEC (28 d) = 1.25 mg/kg dw (mortality and reproduction)*

*assuming a soil depth of 3 mm and a soil density of 1500 kg/m³ for dry soil

Effects on soil micro-organisms (Annex IIA, point 7.4)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Nitrogen mineralization	NOEC = 2.7 mg/ kg dw	NOEC ≥ 3.5 mg/kg dw
Carbon mineralization	NOEC = 2.67 mg/ kg dw	NOEC ≥ 3.5 mg/kg dw

Effects on terrestrial vertebrates

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	See chapter 3 (LOEP)	See chapter 3 (LOEP)
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	*Coturnix japonica*: LD_{50} = 31 mg/kg bw	*Coturnix japonica*: LD_{50} (females)= 759 mg/kg bw
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	*Coturnix japonica:* LC_{50} (5d) = 392 mg/kg food	LoA provided.[19]
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	*Colinus virginianus :* NOEC (20 week) = 126 mg/kg food	LoA provided.[19]

Effects on terrestrial plants

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Acute toxicity to plants (3 species)	EC_{50} (14 d) > 100 mg/kg dw (emergence, growth) NOEC (14 d) = 10 mg/kg dw (emergence, growth)	EC50 (21 d) ≥ 1000 g/ha (corresponding to ≥ 0.66 mg/kg dw) NOEC (21 d) ≥ 1000 g/ha (corresponding to ≥ 0.66 mg/kg dw)

Effects on honeybees (Annex IIIA, point XIII.3.1)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Acute oral toxicity	LD_{50} (48 h) = 0.0037 µg/bee	LD50 (96 h) > 0.333 µg/bee
Acute contact toxicity	LD_{50} (48 h) = 0.081 µg/bee	LD50 (96 h) = 0.3 µg/bee

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Acute oral toxicity	Not relevant to biocidal product	Not relevant for biocidal product
Acute contact toxicity	Not relevant to biocidal product	Not relevant for biocidal product
Acute toxicity to…	Not relevant to biocidal product	Not relevant for biocidal product

Bioconcentration (Annex IIA, point 7.5)

	Value from Assessment Report (18.02.2011)	**Value from assessment of 3rd party dossier**
Bioconcentration factor (BCF)	estimated on basis of log P_{ow} = 0.57 according to TGD: BCF_{fish} = 0.61 (equation 74) $BCF_{earthworm}$ = 0.88 (equation 82d)	estimated on basis of log P_{ow} = 0.61 according to TGD: BCF_{fish} = 0.65 (equation 74) $BCF_{earthworm}$ = 0.88 (equation 82d)
Depuration time(DT_{50}) (DT_{90})	n/a	n/a
Level of metabolites (%) in organisms accounting for > 10 % of residues	n/a	n/a

4.2.2 Cis-Tricos-9-ene

The applicant has access to the data from the active substance approval (see chapter 4.2.2.1 for details).

4.2.2.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[20]) of the active substance cis-tricos-9-ene (PT19). Please, refer to the corresponding Assessment Report for a reference list.

20 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

4.3 Analytical methods residues – active substance

4.3.1 Imidacloprid

Imidacloprid

Matrix, action levels, relevant residue and reference

matrix	limit	relevant residue	reference or comment
plant products		no relevant residues expected	AR for PT 18, chapter 2.1.1 (overall summary and conclusion),
food of animal origin		no relevant residues expected	AR for PT 18, chapter 2.1.1 (overall summary and conclusion),
meat	0.05 mg/kg	imidacloprid	Regulation (EU) No. 491/2014, annex IIIA
milk	0.1 mg/kg		
fat	0.05 mg/kg		
eggs	0.05 mg/kg		
liver/kidney	0.05 mg/kg		
soil	0.05 mg/kg	imidacloprid	common limit
drinking water	0.1 µg/L	imidacloprid	minimal requirement of the Drinking Water Act (Trinkwasser-VO).
surface water	0.6 µg/L	imidacloprid	NOEC sediment dwelling organisms: 0.6 µg/L, AR for PT 18, list of endpoints,
	0.024 µg/L [1]		EC_{10} *Caenis horaria*, Roessink et. al., Environ. Toxicol. Chem. 32, 2013.
air	18 µg/m³	imidacloprid	$AEL_{long\ term}$: 0.06 mg/kg bw/d, AR for PT18, list of endpoints,
body fluids / tissues		not residue relevant	not classified as toxic or very toxic AR for PT18, list of endpoints,

[1] Agreed chronic endpoint according to discussion on BPC WG-ENV (IV/2014)

Methods suitable for the determination of residues (monitoring methods)

matrix	primary method	confirmatory method	independent laboratory validation	reference
plant products	not required	not required	not required	AR for PT 18, chapter 2.1.1 (overall summary and conclusion).
food of animal origin	available	available	available	DAR, addendum 2, Schöning, 2005, Lakaschus, 2005
soil	available	available	generally not required	Krainz, 2008
air	available	available	generally not required	CAR, doc IIIA 4.2.2./02, Riegner, 1993 CAR, doc IIIA 4.2.2/03, Hellpointner, 1999,

matrix	primary method	confirmatory method	independent laboratory validation	reference
drinking water	available	available	generally not required	Krainz, 2008
surface water	available	available	generally not required	Krainz, 2008
body tissues	not required	not required	generally not required	AR for PT 18, chapter 2.1.1 (overall summary and conclusion)
body fluids	not required	not required	generally not required	AR for PT 18, chapter 2.1.1 (overall summary and conclusion)

Methods for products of plant origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Not necessary, no residues expected from the intended use					

Methods for foodstuffs of animal origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
DAR; addendum 2, Schöning, 2005	meat, fat, liver, kidney, eggs milk	0.03 0.01	LC-MS/MS, Luna C18, m/z 256→175 / 256→209 for imidacloprid	confirmation included	Bayer CropScience AG
DAR; addendum 2, Lakaschus, 2005	meat, eggs milk	0.03 0.01	LC-MS/MS, Luna C18, m/z 256→175 / 256→209 for imidacloprid	confirmation included, ILV of	Bayer CropScience AG

Methods for soil

reference	LOQ (mg/kg)	principle	comment	owner
Krainz, 2008	0.005	LC-MS/MS, Inertsil-ODS-3, ESI+, m/z 256→209, 256→84	confirmation included	Sharda Europe
CAR, doc IIIA 4.2.1/01, Schramel, 2001	0.005	LC-MS/MS, LiChrospher 60 RP select B column, ESI+, m/z 256→175	no confirmation included	Bayer AG
CAR, doc IIIA 4.2.1/03, Schramel, 1999	0.01	HPLC-UV, LiChrospher 60 RP select B column, 270 nm	confirmation by Zorbax SB-CN column included	Bayer AG

Methods for drinking water and surface water

reference	matrix	LOQ (µg/L)	principle	comment	owner
Krainz, 2008	drinking water surface water	0.1	LC-MS/MS, Inertsil-ODS-3, ESI+, m/z 256→209, 256→84	confirmation included, LOQ not sufficient for chronic endpoint of 0.024 µg/L	Sharda Europe
CAR, doc IIIA 4.2.3/03, Koenig, 1996	drinking water	0.05	HPLC-UV, LiChrospher 60 RP select B column, 270 nm	no confirmation included	Bayer AG
CAR, doc IIIA 4.2.3/02, Billesbach, 1996	ground water	0.1	LC-MS/MS, LiChrospher 60 RP select B column, ESI+, m/z 256→209	only for confirmation, not sufficient for chronic endpoint of 0.024 µg/L	Bayer AG
CAR; doc IIIA 4.2.3/01, Sommer	drinking water surface water	0.03	HPLC-UV, LiChrospher 60 RP select B column, 270 nm	confirmation by LiChrospher 100 CN column included	Bayer AG

Methods for air

reference	LOQ ($µg/m^3$)	principle	comment	owner
CAR, doc IIIA 4.2.2./02, Riegner, 1993	5	HPLC-UV, LiChrospher 60 RP select B column, 270 nm		Bayer AG
CAR, doc IIIA 4.2.2/03, Hellpointner, 1999	5	HPLC-UV, Zorbax SB-CN, 270 nm	for confirmation	Bayer AG

Methods for body fluids/tissue

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Not necessary, not classified as toxic or very toxic					

Methods for non-active ingredients

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Not required, no relevant residues of non-active ingredient expected					

4.3.2 Cis-Tricos-9-ene

(Z)-9-Tricosene (cis-tricos-9-ene)

Matrix, action levels, relevant residue and reference

matrix	limit	relevant residue	reference or comment
plant products	0.01 mg/kg	(Z)-9-Tricosene [1)]	default MRL according to art. 18(1) (b), Reg. (EC) No. 396/2005
food of animal origin	0.01 mg/kg	(Z)-9-Tricosene [1)]	default MRL according to art. 18(1) (b), Reg. (EC) No. 396/2005
soil		No relevant residues expected	CAR, docI, chapter 2.1.1
drinking water		No relevant residues expected	CAR, docI, chapter 2.1.1
surface water		No relevant residues expected	CAR, docI, chapter 2.1.1
air	7 µg/m³	(Z)-9-Tricosene	$AEL_{medium\text{-}term}$: >0.024 mg/kg bw/d, CAR, docI, list of endpoints
body fluids / tissues		not residue relevant	not classified as toxic or very toxic

[1)] According to Guidance for waiving of data requirements for pheromones for inclusion in Annex I/IA of directive 98/8/EG required, if a MRL/Tolerance is required.

Methods suitable for the determination of residues (monitoring methods)

matrix	primary method	confirmatory method	independent laboratory validation	reference
plant products	missing [1]	missing [1]	missing [1]	CAR, docI, chapter 2.1.1
food of animal origin	missing [1]	missing [1]	missing [1]	CAR, docI, chapter 2.1.1
soil	not required	not required	generally not required	CAR, docI, list of endpoints
air	missing [2]	missing [2]	generally not required	CAR, docI, list of endpoints
drinking water	not required	not required	generally not required	CAR, docI, list of endpoints
surface water	not required	not required	generally not required	CAR, docI, list of endpoints
body tissues	not required	not required	generally not required	CAR, docI, list of endpoints
body fluids	not required	not required	generally not required	CAR, docI, list of endpoints

[1)] According to Guidance for waiving of data requirements for pheromones for inclusion in Annex I/IA of directive 98/8/EG required, if a MRL/Tolerance is required
[2] Requirement of BAuA, FB4 because of spray application

Methods for products of plant origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Relevant residues are not expected for intended use because no application on food or feed of plant origin.					

Methods for foodstuffs of animal origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
No methods available					

Methods for soil

reference	LOQ (mg/kg)	principle	comment	owner
Not required according to Guidance for waiving of data requirements for pheromones				

Methods for drinking water and surface water

reference	matrix	LOQ (µg/L)	principle	comment	owner
Not required according to Guidance for waiving of data requirements for pheromones					

Methods for air

reference	LOQ ($\mu g/m^3$)	principle	comment	owner
Missing, waiver not acceptable because vapour pressure > 0.01 Pa				

Methods for body fluids/tissue

reference	matrix	LOQ (mg/kg)	principle	comment	owner
Not required according to Guidance for waiving of data requirements for pheromones					

4.4 Toxicology and metabolism –active substance

4.4.1 Imidacloprid

Threshold Limits and other Values for Human Health Risk Assessment

Summary		
	Value	Study
AEL long-term	0.06 mg/kg bw/d	Assessment Report (RMS DE (2011))
AEL medium-term	0.2 mg/kg bw/d	Assessment Report (RMS DE (2011))
AEL acute	0.4 mg/kg bw/d	Assessment Report (RMS DE (2011))
Inhalative absorption	100 %	Default value / Assessment Report (RMS DE (2011))
Oral absorption	> 90 %	Assessment Report (RMS DE (2011))
Dermal absorption	Confidor OD 200: 0.3 % for the concentrate (200 g/L; applied volume 10 µl/cm^2) and 8 % for the dilutions in water (0.7 and 0.07 g/L; applied volume 10 µl/cm^2) based on *in vitro* human skin study [1)]	Assessment Report (RMS DE (2011)) EFSA Scientific Report (2008) 148, 1-120
	formulations with > 5 % active ingredient: 25 % formulations with ≤ 5 % active ingredient: 75 %	Default values (EFSA Guidance on Dermal Absorption, 2012)

[1)] With respect to the composition the biocidal product SOFAST is comparable to the biocidal product Imidacloprid GR 0.5, which was assessed in the CAR for Annex I inclusion. The concentration of imidacloprid in the biocidal product SOFAST is equal to its concentration in Imidacloprid GR 0.5. In contrast to the GR 0.5 from the CAR, the biocidal product contains also 0.1% cis-tricos-9-ene and small amounts of a flavouring agent. It is not expected that these changes has an impact on dermal absorption. Thus, despite this differences in the composition, the dermal absorption of SOFAST should also be comparable to Imidacloprid GR 0.5. According to the CAR the dermal absorption value derived for the dilution of Confidor OD 200 can also be used for the biocidal product Imidacloprid GR 0.5. Thus, it is also applicable for the biocidal product SOFAST and the corresponding in-use dilutions. Therefore, the dermal absorption value for the tested dilutions of Confidor OD 200 resulting in a dermal absorption value of 8 % is applied for the biocidal product SOFAST. The dermal absorption value of 0.3 % for the concentrate of Confidor OD 200 cannot be used for the assessment of the concentrated biocidal product since both formulations are not comparable. The active substance concentration is 0.5 % in the bio-cidal product SOFAST and appr. 20 % in the test formulation Confidor OD 200. Due to the fact that percentage dermal absorption is in-versely related to the active substance concentration in most cases (also proven with the test results with concentrate and dilution of Confidor OD 200) read-across with the dermal absorption value of the concentrated test formulation is not applicable for SOFAST (concentrate). In addition, almost all co-formulants and the formulation type are dif-ferent.

Classification	
Current, with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008	Warning Acute Tox. 4; H302 (Harmful if shallowed)

Classification	
Proposed, with regard to toxicological data according to the criteria in Reg. 1272/2008 based on Assessment Report (RMS DE (2011))	Warning Acute Tox. 4; H302 (Harmful if shallowed)

4.4.2 Cis-Tricos-9-en (Muscalure)

Threshold Limits and other Values for Human Health Risk Assessment

Summary		
	Value	Study
AEL long-term	> 0.024 mg/kg bw/d	Assessment Report (RMS AT (2012))
AEL medium-term	> 0.024 mg/kg bw/d	Assessment Report (RMS AT (2012))
AEL acute	> 0.57 mg/kg bw/d	Assessment Report (RMS AT (2012))
Inhalative absorption	100 %	Default value / Assessment Report (RMS AT (2012))
Oral absorption	100 %	Default value / Assessment Report (RMS AT (2012))
Dermal absorption	formulations with > 5 % active ingredient: 25 % formulations with ≤ 5 % active ingredient: 75 % [1)]	Default values (EFSA Guidance on Dermal Absorption, 2012)

[1)] Based on the concentration of the active substance in the biocidal product and in accordance to the EFSA Guidance on Dermal Absorption (2012) a dermal absorption of 75 % is assumed for exposure and risk assessment of SOFAST.

Classification	
Current, with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008	None
Proposed, with regard to toxicological data according to the criteria in Reg. 1272/2008 based on Assessment Report (RMS AT (2012))	Warning Skin Sens. 1 H317: May cause an allergic skin reaction

4.5 Toxicology – biocidal product

General information	
Formulation Type	Water-dispersable granules
Active substance (incl. content)	imidacloprid (CAS No. 138261-41-3; 0.52 %, w/w) *cis*-tricos-9-ene (Muscalure, CAS No. 27519-02-4; 0.1 %, w/w)
Category	Insecticide (PT18)

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD_{50} oral (OECD 423)	> 2000 mg/kg bw Anonymus (2014)[1)]
Rat LD_{50} dermal (OECD 402)	> 2000 mg/kg bw Anonymus (2014)[1)]
Rat LC_{50} inhalation (OECD 403)	> 2.311 mg/L (highest attainable concentration, nose-only) Anonymus (2014)[1)]
Skin irritation (OECD 404)	Non-irritant Anonymus (2014)[1)]
Eye irritation (OECD 405)	Non-irritant Anonymus (2014)[1)]
Skin sensitisation (OECD 406, GPMT)	Non-sensitising Anonymus (2014)[1)]

[1)] Study was performed with Imidacloprid GR 0.5. This formulation is identical to the biocidal product SOFAST; Study with vertebrates. Please, refer to the study summaries (DocIIIB, 6.1, 6.2 and 6.3 files) for the name of the author(s).

Additional relevant toxicological information (e.g. Annex IIIB, point 6.5, 6.7)		
Short-term toxicity studies	No study submitted	
Toxicological data on active substance (relevant for classification, not tested with the preparation)	*cis*-tricos-9-ene (muscalure, 0.1 %, w/w) H317 [1)] (≥ 0.1 % for EUH208)[2)]	EUH208
Toxicological data on non-active substance (relevant for classification/labelling, not tested with the preparation)	None	
Further toxicological information	No data – not required	

[1)] According to AT CAR and the SDS submitted by the applicant.
[2)] According to Regulation (EC) No 1272/2008.

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Regulation (EC) No 1272/2008	EUH208 'Contains *cis*-tricos-9-ene. May produce an allergic reaction.'

4.6 Safety for professional operators

Exposure assessment

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Primary exposure of professionals

Scenario **Spray treatment**

Application number **004**

Details of exposure assessment

The following parameters have been used for calculation:

formulation type	water dispersible granules (WDG)
concentration imidacloprid (a.s. 1) in b.p.	0.52 % (w/w)
concentration cis-tricos-9-ene (a.s. 2) in b.p.	0.10 % (w/w)
concentration b.p. in application solution	50.00 % (w/w)
density of product	0.6448 g/cm^3
density of application solution[1)]	1.22 g/cm^3
factor for respiratory protection	1 (no RPE is assumed)
penetration of coverall	10% (type 4, i.e. protection 90%)
penetration of protective gloves	10% (i.e. protection 90%)

References

1) Handbook of Chemistry and physics 60th ed D-270: d (48 (w/w) saccharose-solution)
2) TNsG Human Exposure (HE) 2002, part 2, chapter 3.2/18.01: 120 min
3) Spraying Model 1 (1-3bar), TNsG Human exposure User Guidance 2002
4) Marquart, H., Warren, N., Laitinen, J., van Hemmen, J. Default values for assessment of potential dermal exposure of the hands to industrial chemicals in the scope of regulatory risk assessments; Ann.Occup.hyg., Vol.50, pp.469-489, 2006

Table 59 and

Table 60 give an overview of the exposure assessment and the used calculation. For the calculation unrounded values are used according to the excel-format, even if rounded values are shown in the tables.

Table 59: Exposure assessment - a.s. no. 1: imidacloprid

INHALATION EXPOSURE	TIER 1		INHALATION EXPOSURE	TIER 2	
Application (incl. Mixing & Loading)			**Application (incl. Mixing & Loading)**		
Concentration a.s.	0.26%		Potential inhalation exposure a.s.	0.27040	mg/m³
Duration 2)	120	min	Protection factor	1	
Indicative value (75th percentile) 3)	104	mg/m³	Actual inhalation exposure a.s.	0.27040	mg/m³
Potential inhalation exposure a.s.	0.27040	mg/m³	8 h TWA	0.06760	mg/m³
8 h TWA	0.06760	mg/m³			
Post-Application	not expected		**Post-Application**	not expected	
All phases			**All phases**		
Total potential inhalation exposure a.s. (8h TWA)	0.068	mg/m³	Total actual inhalation exposure a.s. (8h TWA)	0.068	mg/m³
DERMAL EXPOSURE	**TIER 1**		**DERMAL EXPOSURE**	**TIER 2**	
Application (incl. Mixing & Loading)			**Application (incl. Mixing & Loading)**		
Concentration a.s.	0.26%		Actual hand exposure (product) 3)	10.7	mg b.p./ min
Duration 2)	120	min	Actual hand exposure a.s.	3.3	mg a.s.
Frequency	daily		Potential body exposure a.s.	28.70	mg a.s.
Potential hand exposure (product) 3)	181	mg b.p./ min	RMM: protective coverall	10%	
Potential hand exposure a.s.	56.47	mg a.s.	Actual body exposure a.s.	2.87	mg a.s.
Potential body exposure (product) 3)	92	mg b.p./ min			
Potential body exposure a.s.	28.70	mg a.s.			
Total potential dermal exposure a.s.	85.18	mg a.s.	Total actual dermal exposure a.s.	6.21	mg a.s.
Post-Application			**Post-Application**		
Concentration a.s.	0.26%		Potential dermal exposure a.s.	0.55	mg a.s.
Indicative value / potential hand exposure (product) 4)	210	mg b.p.	RMM: protective gloves	10%	
Potential hand exposure a.s.	0.55	mg a.s.	Actual hand exposure a.s.	0.05	mg a.s.
Total potential dermal exposure a.s.	0.55	mg a.s.	Total actual dermal exposure a.s.	0.05	mg a.s.
All phases			**All phases**		
Total potential dermal exposure all phases a.s.	85.7	mg a.s.	Total actual dermal exposure all phases a.s.	6.26	mg a.s.
Total potential dermal exposure all phases a.s. - corrected with density 1)	104.58	mg a.s.	Total potential dermal exposure all phases a.s. - corrected with density1)	7.64	mg a.s.

Table 60: Exposure assessment - a.s. no. 2: cis-tricos-9-ene

INHALATION EXPOSURE	TIER 1		INHALATION EXPOSURE	TIER 2	
Application (incl. Mixing & Loading)			**Application (incl. Mixing & Loading)**		
Concentration a.s.	0.05%		Potential inhalation exposure a.s.	0.05200	mg/m³
Duration 2)	120	min	Protection factor	1	
Indicative value (75th percentile) 3)	104	mg/m³	Actual inhalation exposure a.s.	0.05200	mg/m³
Potential inhalation exposure a.s.	0.0520	mg/m³	8 h TWA	0.01300	mg/m³
8 h TWA	0.0130	mg/m³			
Post-Application	not expected		**Post-Application**	not expected	
All phases			**All phases**		
Total potential inhalation exposure a.s. (8h TWA)	0.013	mg/m³	Total actual inhalation exposure a.s. (8h TWA)	0.013	mg/m³
DERMAL EXPOSURE	**TIER 1**		**DERMAL EXPOSURE**	**TIER 2**	
Application (incl. Mixing & Loading)			**Application (incl. Mixing & Loading)**		
Concentration a.s.	0.05%		Actual hand exposure (product) 3)	10.7	mg b.p./ min
Duration 2)	120	min	Actual hand exposure a.s.	0.64	mg a.s.
Frequency	daily		Potential body exposure a.s.	5.52	mg a.s.
Potential hand exposure (product) 3)	181	mg b.p./ min	RMM: protective coverall	10%	
Potential hand exposure a.s.	10.86	mg a.s.	Actual body exposure a.s.	0.55	mg a.s.
Potential body exposure (product) 3)	92	mg b.p./ min			
Potential body exposure a.s.	5.52	mg a.s.			
Total potential dermal exposure a.s.	16.38	mg a.s.	Total actual dermal exposure a.s.	1.19	mg a.s.
Post-Application			**Post-Application**		
Concentration a.s.	0.05%		Potential dermal exposure a.s.	0.11	mg a.s.
Indicative value / potential hand exposure (product) 4)	210	mg b.p.	RMM: protective gloves	10%	
Potential hand exposure a.s.	0.11	mg a.s.	Actual hand exposure a.s.	1.05E-02	mg a.s.
Total potential dermal exposure a.s.	0.11	mg a.s.	Total actual dermal exposure a.s.	1.05E-02	mg a.s.
All phases			**All phases**		
Total potential dermal exposure all phases a.s.	16.49	mg a.s.	Total actual dermal exposure all phases a.s.	1.20	mg a.s.
Total potential dermal exposure all phases a.s. - corrected with density 1)	20.11	mg a.s.	Total potential dermal exposure all phases a.s. - corrected with density1)	1.47	mg a.s.

Scenario **Brush treatment**

Application number **005**

Details of exposure assessment

The following parameters have been used for calculation:

formulation type	water dispersable granules (WDG)
concentration imidacloprid (a.s. 1) in b.p.	0.52 % (w/w)
concentration cis-tricos-9-ene (a.s. 2) in b.p.	0.10 % (w/w)
concentration b.p. in application solution	57.14 % (w/w)
density of product	0.6448 g/cm^3
amount of b.p. / 100 m^2	0.200 kg
applied b.p per day[1)]	3.200 kg
density of application solution[2)]	1.26 g/cm^3
factor for respiratory protection	1 (no RPE is assumed)
penetration of protective gloves	10% (i.e. protection 90%)

References

1) about 16 * 1 m2 treated area (120 min / 7.6 min/m2)
2) Handbook of Chemistry and physics 60th ed D-270: d (54 (w/w) saccharose-solution)
3) Mixing and loading model 5, TNsG Human Exposure User Guidance 2002
4) TNsG Human Exposure (HE), part 2, chapter 3.2/18.01: 120 min
5) Consumer product painting model 3, indoor value, TNsG
6) Human Exposure Expert Group (HEEG) opinion on Exposure model Primary exposure scenario - washing out of a brush which has been used to apply a paint, 2010

Table 61 and
Table **61** give an overview of the exposure assessment and the used calculation. For the calculation unrounded values are used according to the excel-format, even if rounded values are shown in the tables.

Table 61: Exposure assessment - a.s. no. 1: imidacloprid

INHALATION EXPOSURE	**TIER 1**		**INHALATION EXPOSURE**	**TIER 2**	
Mixing & Loading			**Mixing & Loading**		
Concentration a.s.	0.52%		Potential inhalation exposure a.s.	0.00060	mg a.s.
Duration	15	min	Protection factor	1	
Indicative value per operation 3)	0.036	mg a.s. / kg a.s.	Actual inhalation exposure a.s.	0.00060	mg a.s.
Potential inhalation exposure a.s.	0.00060	mg a.s.			
Application			**Application**		
Concentration a.s.	0.30%		Potential inhalation exposure a.s.	0.00484	mg/m³
Duration 4)	120	min	Protection factor	1	
Indicative value (50th percentile) 5)	1.63	mg/m³	Actual inhalation exposure a.s.	0.00484	mg/m³
Potential inhalation exposure a.s.	0.00484	mg/m³	8 h TWA	0.00121	mg/m³
8 h TWA	0.00121	mg/m³			
Post-Application	not expected, no aerosol		**Post-Application**	not expected, no aerosol	
All phases			**All phases**		

Annexes

Total potential inhalation exposure a.s.	0.013	mg a.s.	Total actual inhalation exposure a.s.	0.013	mg a.s.
DERMAL EXPOSURE	**TIER 1**		**DERMAL EXPOSURE**	**TIER 2**	
Mixing & Loading			**Mixing & Loading**		
Concentration a.s.	0.52%		Potential hand exposure a.s.	2.85	mg a.s.
Number of pourings (loadings)	1		RMM: protective gloves	10%	
Indicative value -potential hand exposure (product) 3)	171	mg a.s. / kg a.s.	Actual hand exposure a.s.	0.28	mg a.s.
Potential hand exposure a.s.	2.85	mg a.s.	Total actual dermal exposure a.s.	0.28	mg a.s.
Application			**Application**		
Concentration a.s.	0.30%		Potential hand exposure a.s.	2.11	mg a.s.
Duration4)	120	min	RMM: protective gloves	10%	
Indicative value - hand 5)	5.91	mg/min	Actual hand exposure a.s.	0.21	mg a.s.
Indicative value - body 5)	16.9	mg/min	Potential body exposure a.s.	6.03	mg a.s.
Potential hand exposure (product)	709.20	mg	RMM: protective coverall	100%	
Potential hand exposure a.s.	2.11	mg a.s.	Actual body exposure a.s.	6.03	mg a.s.
Potential body exposure (product)	2028.00	mg			
Potential body exposure a.s.	6.03	mg a.s.			
Total potential dermal exposure a.s.	8.13	mg a.s.	Total actual dermal exposure a.s.	6.24	mg a.s.
Post-Application			**Post-Application**		
Concentration a.s.	0.30%		Potential hand exposure a.s.	0.39	mg a.s.
Residues in brush 6)	25	ml	RMM: protective gloves	10%	
Product on skin after 3 washings 6)	131.56	mg b.p.	Actual hand exposure a.s.	3.91E-02	mg a.s.
Potential hand exposure a.s.	0.39	mg a.s.			
Total potential dermal exposure a.s.	0.39	mg a.s.	Total actual dermal exposure a.s.	3.91E-02	mg a.s.
All phases			**All phases**		
Total potential dermal exposure all phases a.s.	11.37	mg a.s.	Total actual dermal exposure all phases a.s.	6.56	mg a.s.
Total potential dermal exposure all phases a.s. - corrected with density 5)	14.33	mg a.s.	Total potential dermal exposure all phases a.s. - corrected with density	8.27	mg a.s.

Table 62: Exposure assessment - a.s. no. 2: cis-tricos-9-ene

INHALATION EXPOSURE	**TIER 1**		**INHALATION EXPOSURE**	**TIER 2**	
Mixing & Loading			**Mixing & Loading**		
Concentration a.s.	0.10%		Potential inhalation exposure a.s.	1.15E-04	mg a.s.
Duration	15	min	Protection factor	1	
Indicative value per operation 3)	0.036	mg a.s. / kg a.s.	Actual inhalation exposure a.s.	$1.15x10^{-4}$	mg a.s.
Potential inhalation exposure a.s.	$1.15x10^{-4}$	mg a.s.			
Application			**Application**		
Concentration a.s.	0.057%		Potential inhalation exposure a.s.	0.00093	mg/m³
Duration 4)	120	min	Protection factor	1	
Indicative value (50th percentile) 5)	1.63	mg/m³	Actual inhalation exposure a.s.	0.00093	mg/m³
Potential inhalation exposure a.s.	0.00093	mg/m³	8 h TWA	$2.33x10^{-4}$	mg/m³

8 h TWA	$2.33x10^{-4}$	mg/m³			
Post-Application	not expected, no aerosol		**Post-Application**	not expected	
ConsExpo concentration a.s. vapour part	$1.52x\ 10^{-4}$	mg/m³	**ConsExpo concentration a.s. vapour part**	$1.52x\ 10^{-4}$	mg/m³
			Protection factor	1	
			Actual inhalation exposure a.s.	$1.52x10^{-4}$	mg/m³
All phases including ConsExpo calc.			**All phases including ConsExpo calc.**		
Total potential inhalation exposure a.s.	$3.96x10^{-3}$	mg a.s.	Total actual inhalation exposure a.s. including vapour part (ConsExpo)	$3.96x10^{-3}$	mg a.s.
DERMAL EXPOSURE	**TIER 1**		**DERMAL EXPOSURE**	**TIER 2**	
Mixing & Loading			**Mixing & Loading**		
Concentration a.s.	0.10%		Potential hand exposure a.s.	0.55	mg a.s.
Number of pourings (loadings)	1		RMM: protective gloves	10%	
Indicative value -potential hand exposure (product) 3)	171	mg a.s. / kg a.s.	Actual hand exposure a.s.	$5.47x10^{-2}$	mg a.s.
Potential hand exposure a.s.	0.55	mg a.s.	Total actual dermal exposure a.s.	$5.\ 47x10^{-2}$	mg a.s.
Application			**Application**		
Concentration a.s.	0.057%		Potential hand exposure a.s.	0.41	mg a.s.
Duration4)	120	min	RMM: protective gloves	10%	
Indicative value - hand 5)	5.91	mg/min	Actual hand exposure a.s.	$4.05x10^{-2}$	mg a.s.
Indicative value - body 5)	16.9	mg/min	Potential body exposure a.s.	1.16	mg a.s.
Potential hand exposure (product)	709.20	mg	RMM: protective coverall	100%	
Potential hand exposure a.s.	0.41	mg a.s.	Actual body exposure a.s.	1.16	mg a.s.
Potential body exposure (product)	2028.00	mg			
Potential body exposure a.s.	1.16	mg a.s.			
Total potential dermal exposure a.s.	1.56	mg a.s.	Total actual dermal exposure a.s.	1.20	mg a.s.
Post-Application			**Post-Application**		
Concentration a.s.	0.057%		Potential hand exposure a.s.	$7.52x10^{-2}$	mg a.s.
Residues in brush 6)	25	ml	RMM: protective gloves	10%	
Product on skin after 3 washings 6)	131.56	mg b.p.	Actual hand exposure a.s.	$7.52x10^{-3}$	mg a.s.
Potential hand exposure a.s.	$7.52x10^{-2}$	mg a.s.			
Total potential dermal exposure a.s.	$7.52x10^{-2}$	mg a.s.	Total actual dermal exposure a.s.	$7.5x10^{-3}$	mg a.s.
All phases			**All phases**		
Total potential dermal exposure all phases a.s.	2.19	mg a.s.	Total actual dermal exposure all phases a.s.	1.26	mg a.s.
Total potential dermal exposure all phases a.s. - corrected with density 1)	2.75	mg a.s.	Total potential dermal exposure all phases a.s. - corrected with density1)	1.59	mg a.s.

Parameter for ConsExpo concentration a.s. - vapour part:

Compound name :	Cis-tricos-9-ene
CAS number :	27519-02-4
molecular weight	323 g/mol
vapour pressure	0.064 Pascal

Inhalation model: Exposure to vapour : evaporation		
weight fraction compound	0.057	%
exposure duration	8	minute
room volume	8	m3
ventilation rate	0	1/hr
applied amount	350	gram
release area	1	m2
application duration	8	minute
mol weight matrix	39	g/mol
mass transfer rate	2080	m/min
inhalation mean concentration 8 h TWA:	1.52×10^{-4}	mg/m3

Scenario **Application of granular bait**

Application number **006**

Details of exposure assessment

The following parameters have been used for calculation:

formulation type	water dispersable granules (WDG)
concentration imidacloprid (a.s. 1) in b.p.	0.52 % (w/w)
concentration cis-tricos-9-ene (a.s. 2) in b.p.	0.10 % (w/w)
amount of b.p. / 100 m2	0.200 kg
amount of b.p. per day (worst case)	3.200 kg
factor for respiratory protection	1 (no RPE is assumed)
penetration of protective gloves	10% (i.e. protection 90%)

References

1) Mixing and loading model 5, TNsG Human Exposure User Guidance 2002, p. 25 (granule formulation, pouring into portable receiving vessel)TNsG Human Exposure (HE), part 2, chapter 3.2/18.01: 120 min
2) expert judgement, half of the applied biocidal product is consumed

Table 5 and 6 give an overview of the exposure assessment and the used calculation. For the calculation unrounded values are used according to the excel-format, even if rounded values are shown in the tables.

Table 63: Exposure assessment - a.s. no. 1: imidacloprid

INHALATION EXPOSURE	TIER 1		INHALATION EXPOSURE	TIER 2	
Mixing & Loading	ready to use product, no M&L		**Mixing & Loading**	ready to use product, no M&L	
Application			**Application**		
Concentration a.s.	0.52%		Potential inhalation exposure a.s.	0.00060	mg a.s /day
Amount per day and floor area	0.01664	kg a.s./day	Protection factor	1	
Indicative value (75th percentile) 1)	0.036	mg a.s./kg a.s.	Actual inhalation exposure a.s.	0.00060	mg a.s /day
Potential inhalation exposure a.s.	0.00060	mg a.s /day			
Post-Application			**Post-Application**		
Concentration a.s.	0.52%		Potential inhalation exposure a.s.	0.00030	mg a.s /day
Amount per day and floor area 2)	0.00832	kg a.s./day	Protection factor	1	
Indicative value (75th percentile) 1)	0.036	mg a.s./kg a.s.	Actual inhalation exposure a.s.	0.00030	mg a.s /day
Potential inhalation exposure a.s.	0.00030	mg a.s /person/day			
All phases			**All phases**		
Total potential inhalation exposure a.s.	$8.99x10^{-4}$	mg a.s /day	Total actual inhalation exposure a.s.	$8.99x10^{-4}$	mg a.s /day
DERMAL EXPOSURE	**TIER 1**		**DERMAL EXPOSURE**	**TIER 2**	
Mixing & Loading	ready to use product, no M&L		**Mixing & Loading**	ready to use product, no M&L	
Application			**Application**		
Concentration a.s.	0.52%		Potential hand exposure a.s.	2.85	mg a.s /day
Amount per day and floor area	0.01664	kg a.s./day	RMM: protective gloves	10%	
Indicative value (75th percentile) hands1)	171	mg a.s./kg a.s.	Actual hand exposure a.s.	0.28	mg a.s /day
Potential hand exposure a.s.	2.85	mg a.s /day			
Total potential dermal exposure a.s.	2.85	mg a.s /day	Total actual dermal exposure a.s.	0.28	mg a.s /day
Post-Application			**Post-Application**		
Concentration a.s.	0.52%		Potential hand exposure a.s.	1.42	mg a.s /day
Amount per day and floor area 2)	0.00832	kg a.s./day	RMM: protective gloves	10%	
Indicative value (75th percentile) hands 1)	171	mg a.s./kg a.s.	Actual hand exposure a.s.	0.14	mg a.s /day
Potential hand exposure a.s.	1.42	mg a.s /day			
Total potential dermal exposure a.s.	1.42	mg a.s /day	Total actual dermal exposure a.s.	0.14	mg a.s /day
All phases			**All phases**		
Total potential dermal exposure all phases a.s.	4.27	mg a.s /day	Total actual dermal exposure all phases a.s.	0.43	mg a.s /day

Table 64: Exposure assessment - a.s. no. 2: cis-tricos-9-ene

INHALATION EXPOSURE	TIER 1		INHALATION EXPOSURE	TIER 2	
Mixing & Loading	ready to use product, no M&L		**Mixing & Loading**	ready to use product, no M&L	
Application			**Application**		
Concentration a.s.	0.10%		Potential inhalation exposure a.s.	0.00012	mg a.s /day
Amount per day and floor area	0.0032	kg a.s./day	Protection factor	1	
Indicative value (75th percentile) 1)	0.036	mg a.s./kg a.s.	Actual inhalation exposure a.s.	0.00012	mg a.s /day
Potential inhalation exposure a.s.	0.00012	mg a.s /day			
Post-Application			**Post-Application**		
Concentration a.s.	0.10%		Potential inhalation exposure a.s.	0.00006	mg a.s /day
Amount per day and floor area 2)	0.0016	kg a.s./day	Protection factor	1	
Indicative value (75th percentile) 1)	0.036	mg a.s./kg a.s.	Actual inhalation exposure a.s.	0.00006	mg a.s /day
Potential inhalation exposure a.s.	0.00006	mg a.s /day			
ConsExpo concentration a.s. vapour part	$2.43x10^{-3}$	mg/m³	**ConsExpo concentration a.s. vapour part**	$2.43x10^{-3}$	mg/m³
			Protection factor	1	
			Actual inhalation exposure a.s.	$2.43x10^{-3}$	mg/m³
All phases including ConsExpo cal.			**All phases phases including ConsExpo cal.**		
Total potential inhalation exposure a.s.	0.024	mg a.s /day	Total actual inhalation exposure a.s.	0.024	mg a.s /day
DERMAL EXPOSURE	**TIER 1**		**DERMAL EXPOSURE**	**TIER 2**	
Mixing & Loading	ready to use product, no M&L		**Mixing & Loading**	ready to use product, no M&L	
Application			**Application**		
Concentration a.s.	0.10%		Potential hand exposure a.s.	0.55	mg a.s /day
Amount per day and floor area	0.0032	kg a.s./day	RMM: protective gloves	10%	
Indicative value (75th percentile) hands 1)	171	mg a.s./kg a.s.	Actual hand exposure a.s.	0.05	mg a.s /day
Potential hand exposure a.s.	0.55	mg a.s /day			
Total potential dermal exposure a.s.	0.55	mg a.s /day	Total actual dermal exposure a.s.	0.05	mg a.s /day
Post-Application			**Post-Application**		
Concentration a.s.	0.10%		Potential hand exposure a.s.	0.27	mg a.s /day
Amount per day and floor area 2)	0.0016	kg a.s./day	RMM: protective gloves	10%	
Indicative value (75th percentile) 1)	171	mg a.s./kg a.s.	Actual hand exposure a.s.	0.03	mg a.s /day
Potential hand exposure a.s.	0.27	mg a.s /day			

Total potential dermal exposure a.s.	0.27 mg a.s /day	Total actual dermal exposure a.s.	0.03 mg a.s /day
All phases		**All phases**	
Total potential dermal exposure all phases a.s.	0.82 mg a.s /day	Total actual dermal exposure all phases a.s.	0.08 mg a.s /day

Parameter for ConsExpo concentration a.s. - vapour part:

Compound name :	Cis-tricos-9-ene
CAS number :	27519-02-4
molecular weight	323 g/mol
vapour pressure	0.064 Pascal

Inhalation model: Exposure to vapour : evaporation		
weight fraction compound	0.10	%
exposure duration	8	minute
room volume	8	m3
ventilation rate	0	1/hr
applied amount	200	gram
release area	16	m2
application duration	8	minute
mol weight matrix	357	g/mol
mass transfer rate	2080	m/min
inhalation mean concentration 8 h TWA:	2.43×10^{-3}	mg/m3

Details of risk characterisation – imidacloprid

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to imidacloprid from the biocidal product SOFAST, inhalation exposure to imidacloprid is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ (0.06 mg/kg bw/d) of imidacloprid is used. Since this systemic reference value is to be compared with external inhalation exposure concentrations of imidacloprid, the corresponding $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) according to the equation:

> RV_{inhal} (in mg/m^3) = $AEL_{long\text{-}term}$ of imidacloprid (in mg/kg bw/d) x 60 kg / 10 m^3 x100 % / %-inhalation absorption

This external inhalation reference value (RV_{inhal}) is directly compared with airborne concentrations of imidacloprid. By this means RV_{inhal} equivalent to 0.36 mg/m^3 is calculated for imidacloprid.

For the purpose of risk characterisation resulting from dermal exposure of professional users to imidacloprid from the biocidal product SOFAST, dermal exposure to imidacloprid is assessed. For this, the internal reference value $AEL_{long\text{-}term}$ (0.06 mg/kg bw/d) of imidacloprid is used. Since this systemic reference value is to be compared with external dermal exposure concentrations of imidacloprid, the corresponding $AEL_{long\text{-}term}$ is converted to an external dermal reference value (RV_{derm}) according to the equation:

RV_{derm} (in mg/kg) = $AEL_{long\text{-}term}$ of imidacloprid (in mg/kg bw/d) / %-dermal absorption x 100 %

By this means, RV_{derm} equivalent to 0.75 mg/kg bw/d is calculated for imidacloprid.

Absorption by inhalation

As default an inhalation absorption rate of 100 % is assumed for the active substance imidacloprid.

Dermal absorption rate

A value equivalent to 8 % is used as dermal absorption rate for dilutions of imidacloprid in water. For the concentrate a value equivalent to 0.3 % is used. These values are taken from the assessment report (RMS DE (2011)).

Calculation of risk quotient RQ_{inhal}, risk quotient RQ_{derm} and the substance specific RI

The risk quotient for the inhalation route (RQ_{inhal}) referring to the active substance imidacloprid resulting from use of the biocidal product SOFAST is determined according to the equation:

RQ_{inhal} = inhalation exposure to imidacloprid (in mg/m^3) / RV_{inhal} of imidacloprid (in mg/m^3).

The risk quotient for the dermal route (RQ_{derm}) referring to the active substance imidacloprid resulting from use of the biocidal product SOFAST is determined according to the equation:

RQ_{derm} = dermal exposure to imidacloprid (in mg/kg) / RV_{derm} of imidacloprid (in mg/kg).

Dermal exposure to imidacloprid given in mg/kg is calculated from dermal exposure to imidacloprid in mg/person through division by 60 kg/person.

The summation of both RQs for a substance within a scenario gives the corresponding substance specific risk index (RI).

Table 40 gives a detailed overview of the risk assessment results referring to the active substance imidacloprid for the biocidal product SOFAST. It is noted that for clarity reasons exposure values, risk quotients and risk indices are rounded to two decimal places in Table 65. However, the underlying calculations are based on unrounded exposure values.

Table 65: Overview of detailed risk assessment results referring to the active substance imidacloprid for the biocidal product SOFAST

RV_{inhal}: reference value for the inhalation route

Scenario		inhalation external			dermal external				RI
		potential/ actual exposure	RV_{inhal}	RQ_{inhal}	potential/ actual exposure		RV_{derm}	RQ_{derm}	
		mg/m³	mg/m³		mg/person	mg/kg			
Spray treatment	Tier 1	0.07	0.36	0.19	104.58	1.74	0.75	2.32	2.51
	Tier 2	0.07	0.36	0.19	7.64	0.13	0.75	0.17	0.36
Brush treatment	Tier 1	$1.27x10^{-3}$	0.36	$3.53x10^{-3}$	14.33	0.24	0.75	0.32	0.32
	Tier 2	$1.27x10^{-3}$	0.36	$3.53x10^{-3}$	8.27	0.14	0.75	0.18	0.19
Application of granular bait	Tier 1	$8.99x10^{-5}$	0.36	$2.50x10^{-4}$	4.27	0.07	0.75	0.09	0.10
	Tier 2	$8.99x10^{-5}$	0.36	$2.50x10^{-4}$	0.43	0.01	0.75	0.01	0.01

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI: substance specific risk index

Conclusion and risk assessment – imidacloprid

A risk for professional users referring to the active substance imidacloprid resulting from the use of the biocidal product SOFAST is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in table 40, the scenarios brush treatment and application of granular bait yield RIs of less than 1 already in TIER 1 with indices of 0.32 and 0.10, respectively. By contrast, the RI of the scenario spray treatment exceeds the value equivalent to 1 after TIER 1 consideration with an index of 2.51. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenario. However, when risk reduction measures are implemented the risk characterisation results consistently yield RI of less than 1 in TIER 2:

- spray treatment: RI of 0.36

In summary, a risk for professional users referring to the active substance imidacloprid resulting from all considered scenarios is unlikely since the respective risk characterisation consistently yields total risk indices of less than 1 at least after TIER 2 consideration. Risk reduction measures have to be taken into account in order to ensure safe use of the biocidal product SOFAST.

Details of risk characterisation – cis-tricos-9-ene

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to cis-tricos-9-ene from the biocidal product SOFAST, inhalation exposure to cis-tricos-9-ene is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ (0.024 mg/kg bw/d) of cis-tricos-9-ene is used. Since this

systemic reference value is to be compared with external inhalation exposure concentrations of cis-tricos-9-ene, the corresponding $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) according to the equation:

> RV_{inhal} (in mg/m³) = $AEL_{long\text{-}term}$ of cis-tricos-9-ene (in mg/kg bw/d) x 60 kg / 10 m³ x100 % / %-inhalation absorption

This external inhalation reference value (RV_{inhal}) is directly compared with airborne concentrations of cis-tricos-9-ene. By this means RV_{inhal} equivalent to 0.14 mg/m³ is calculated for cis-tricos-9-ene.

For the purpose of risk characterisation resulting from dermal exposure of professional users to cis-tricos-9-ene from the biocidal product SOFAST, dermal exposure to cis-tricos-9-ene is assessed. For this, the internal reference value $AEL_{long\text{-}term}$ (0.024 mg/kg bw/d) of cis-tricos-9-ene is used. Since this systemic reference value is to be compared with external dermal exposure concentrations of cis-tricos-9-ene, the corresponding $AEL_{long\text{-}term}$ is converted to an external dermal reference value (RV_{derm}) according to the equation:

RV_{derm} (in mg/kg) = $AEL_{long\text{-}term}$ of cis-tricos-9-ene (in mg/kg bw/d) / %-dermal absorption x 100 %

By this means, RV_{derm} equivalent to 0.03 mg/kg bw/d is calculated for cis-tricos-9-ene.

Absorption by inhalation

As default an inhalation absorption rate of 100 % is assumed for the active substance cis-tricos-9-ene.

Dermal absorption rate

Default values according to the EFSA Guidance are used in the risk characterisation for professional users. The value equivalent to 75 % is used as dermal absorption rate for formulations with ≤ 5 % cis-tricos-9-ene. Formulations with > 5 % cis-tricos-9-ene are assessed by using the default dermal absorption rate of 25 %.

Calculation of risk quotient RQ_{inhal}, risk quotient RQ_{derm} and the substance specific RI

The risk quotient for the inhalation route (RQ_{inhal}) referring to the active substance cis-tricos-9-ene resulting from use of the biocidal product SOFAST is determined according to the equation:

RQ_{inhal} = inhalation exposure to cis-tricos-9-ene (in mg/m^3) / RV_{inhal} of cis-tricos-9-ene (in mg/m^3).

The risk quotient for the dermal route (RQ_{derm}) referring to the active substance cis-tricos-9-ene resulting from use of the biocidal product SOFAST is determined according to the equation:

RQ_{derm} = dermal exposure to cis-tricos-9-ene (in mg/kg) / RV_{derm} of cis-tricos-9-ene (in mg/kg).

Dermal exposure to cis-tricos-9-ene given in mg/kg is calculated from dermal exposure to cis-tricos-9-ene in mg/person through division by 60 kg/person.

The summation of both RQs for a substance within a scenario gives the corresponding substance specific risk index (RI).

Table 66 gives a detailed overview of the risk assessment results referring to the active substance cis-tricos-9-ene for the biocidal product SOFAST. It is noted that for clarity reasons exposure values, risk quotients and risk indices are rounded to two decimal places in Table 66. However, the underlying calculations are based on unrounded exposure values.

Table 66: Overview of detailed risk assessment results referring to the active substance cis-tricos-9-ene for the biocidal product SOFAST

Scenario		inhalation external			dermal external				RI
		potential/ actual exposure	RV_{inhal}	RQ_{inhal}	potential/ actual exposure		RV_{derm}	RQ_{derm}	
		mg/m^3	mg/m^3		mg/person	mg/kg			
Spray treatment	Tier 1	0.01	0.14	0.09	20.11	0.34	0.03	10.47	10.57
	Tier 2	0.01	0.14	0.09	1.47	0.02	0.03	0.77	0.86
Brush treatment	Tier 1	$3.96x10^{-4}$	0.14	$2.75x10^{-3}$	2.75	0.05	0.03	1.43	1.44
	Tier 2	$3.96x10^{-4}$	0.14	$2.75x10^{-3}$	1.59	0.03	0.03	0.83	0.83
Application of granular bait	Tier 1	$2.45x10^{-3}$	0.14	0.02	0.82	0.01	0.03	0.43	0.44
	Tier 2	$2.45x10^{-3}$	0.14	0.02	0.08	$1.37x10^{-3}$	0.03	0.04	0.06

RV_{inhal}: reference value for the inhalation route

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI: substance specific risk index

Conclusion and risk assessment – cis-tricos-9-ene

A risk for professional users referring to the active substance cis-tricos-9-ene resulting from the use of the biocidal product SOFAST is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in table 41, scenario application of granular bait yields a RI of less than 1 already in TIER 1 with an index of 0.44. By contrast, the RI of the scenarios spray treatment and brush treatment exceed the value equivalent to 1 after TIER 1 consideration with indices of 10.57 and 1.44, respectively. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenarios. However, when risk reduction measures are implemented the risk characterisation results consistently yield RI of less than 1 in TIER 2:

- spray treatment: RI of 0.86
- brush treatment: RI of 0.0.83

In summary, a risk for professional users referring to the active substance cis-tricos-9-ene resulting from all considered scenarios is unlikely since the respective risk characterisation consistently yields total risk indices of less than 1 at least after TIER 2 consideration. Risk reduction measures have to be taken into account in order to ensure safe use of the biocidal product SOFAST.

Overall conclusion and risk assessment

In summary, a risk for professional users resulting from the uses of the biocidal product SOFAST is unlikely since the risk characterisation consistently yields total risk indices of less than 1 at least after TIER 2 consideration. Risk reduction measures according to chapter 2.9 have to be taken into account in order to ensure safe use of the biocidal product SOFAST. The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

4.7 Safety for non-professional operators and the general public

General information	
Formulation Type	Water-dispersable granules [1)]
Active substance (incl. content)	imidacloprid (CAS No. 138261-41-3; 0.5 %, w/w) *cis*-tricos-9-ene (Muscalure, CAS No. 27519-02-4; 0.1 %, w/w)
Category	Insecticide (PT18)

[1)] For application the granular product is placed in cups or it is diluted in water and applied by brushing or spraying

Conclusion

Exposure of non-professional users and the general public to the biocidal product SOFAST containing 0.5 % (w/w) imidacloprid and 0.1 % (w/w) *cis*-tricos-9-ene as active substances is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

This also applies to pets.

Exposure Assessment

Imidacloprid / *cis*-Tricos-9-ene	
Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Primary exposure Medium-term	1.) Placing and disposal of the biocidal product in cups 2.) Application by brushing a) Mixing and loading (dermal, inhalation) b) Application (dermal inhalation, oral) c) Cleaning (dermal) 2.) Application by spraying a) Mixing and loading (dermal, inhalation) b) Application (dermal, inhalation) c) Cleaning (dermal)
Secondary exposure Medium-term	Re-entry adults (dermal, inhalation) Re-entry toddlers (dermal, inhalation, oral) Re-entry children (dermal, inhalation, oral)

Details for the exposure estimates

General Parameters	Value	Reference
Imidacloprid		
AEL_{acute}	0.4 mg/kg bw	Section 4.4.1 based on CAR / AR (DE, 2011)
$AEL_{medium\text{-}term}$	0.2 mg/kg bw/d	Section 4.3.1 based on CAR / AR (DE, 2011)
$AEL_{long\text{-}term}$	0.06 mg/kg bw/d	Section 4.3.1 based on CAR / AR (DE, 2011)
Oral absorption	100 %	Section 4.3.1 based on CAR / AR (DE, 2011)
Dermal absorption	8 %	Section 4.3.1 based on CAR / AR (DE, 2011)
Vapour pressure	9.0×10^{-10} Pa (25°C)	CAR / AR (DE, 2011)
***cis*-Tricos-9-ene (Muscalure)**		
AEL_{acute}	> 0.57 mg/kg bw	Section 4.3.2 based on CAR / AR (AT, 2012)
$AEL_{medium\text{-}term}$	> 0.024 mg/kg bw/d	Section 4.3.2 based on CAR / AR (AT, 2012)
$AEL_{long\text{-}term}$	> 0.024 mg/kg bw/d	Section 4.3.2 based on CAR / AR (AT, 2012)
Oral absorption	100 %	Section 4.3.2 based on CAR / AR (AT, 2012)
Dermal absorption	75 %	Default, based on EFSA Guidance on Dermal Absorption (2012)
Vapour pressure	0.064 (20°C)	CAR / AR (AT, 2012)
General		
Body weight adult (non-professional user)	60 kg	Default, HEEG opinion, endorsed at TM II 2013
Body weight child	23.9 kg	Default, HEEG opinion, endorsed at TM II 2013
Body weight toddler	10 kg	Default, HEEG opinion, endorsed at TM II 2013

4.7.1 Imidacloprid

Primary exposure

According to the applicant the biocidal product SOFAST is applied indoors in households, commercial and public areas. The application frequency is 6 times per year. It is limited to the summer season when flies usually occur. Thus, medium-term exposure is assumed.

For spray and brush applicationby non-professional users one m^2 is treated with 200 g of the biocidal product. This treatment is effective for a total floor surface of 100 m^2. For spray application 200 g b.p. are dispersed in 200 mL water (concentration of the diluted biocidal product: 0.25 %). For brush application 200 g b.p. are dispersed in 150 mL water (concentration of the diluted biocidal product: 0.286 %). For application as a bait (placing in cups) 200 g of the biocidal product are placed per 100 m^2 in 10 portions.

1.) Placing of pellets in cups

Application and disposal

The pellets are placed in cups every 10 m^2. One cup is filled with 20 g/m^2. For a total surface of 100 m^2 10 cups have to be placed. Dermal exposure was assessed with Consexpo 4.1 using the model 'Mixing and loading, granules'. This model refers to the loading of a device for spraying. As a worst case it is assumed that each placing of a cup is equivalent to one loading process. Thus, the estimate for one application has to be multiplied by 10. The same model is used for disposal. Thus, the resulting exposure value is multiplied by 2.

Extract from the corresponding Consexpo report:

General exposure data

Application frequency	6 per year	(Applicant)
Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Dermal model: direct dermal contact with product: constant rate

Weight fraction compound	0.5 % imidacloprid
Exposed area	1948.8 cm^2 (Hand, lower arms, HEEG opinion, not relevant for the Consexpo model)
Contact rate	0.033 mg/min (Consexpo Pest Control Products Fact Sheet)
Release duration	80 s (Consexpo Pest Control Products Fact Sheet)

Uptake model: fraction

Uptake fraction (dermal abs.) 8 % (Refer to 'General parameters Imidacloprid' above)

Dermal: point estimates

Dermal external dose (1 x):	3.66 x 10^{-6} mg/kg bw/d
Dermal internal dose (1 x):	2.93 x 10^{-7} mg/kg bw/d
Dermal external dose (10 x):	3.66 x 10^{-5} mg/kg bw/d
Dermal internal dose (10 x):	2.93 x 10^{-6} mg/kg bw/d

Systemic dermal exposure 'Placing': 2.93 x 10^{-6} mg/kg bw/d
Systemic dermal exposure 'Placing' and 'Disposal': 5.86 x 10^{-6} mg/kg bw/d

Inhalation exposure is likely by inhalation of dust when the formulation is handled. It is assumed that a typical room of 50 m^3 poses a floor surface area of around 20 m^2. For this surface area 40 g of product are envisaged in the treatment. As proposed by the applicant the concentration in the inhaled air (C_{inh}) is calculated according to the following formula:

$$C_{inh} = \frac{Q_{prod} \times F_{AI}}{V_{room}} \times F_{inh}$$

Where
C_{inh} is the inhalation exposure
Q_{prod} is the amount of product used in the treatment (40 g)
F_{AI} is the fraction of active ingredient in the product (0.5 % imidacloprid)
F_{inh} is the dust inhalable fraction of the product (1 % dust fraction is assumed acc. to the applicant)
V_{room} is the volume of a typical room (50 m^3)

Inhalation exposure for the active substance contained in the product is:

C_{inh} (imidacloprid) = 0.04 mg/m^3

As proposed by the applicant for the calculation of the systemic exposures the following parameters have been considered:

Exposure time: 2 x 20 minutes (application and disposal)
Inhalation rate: 1.25 m^3/h
Inhalation absorption: 100 %
Body weight: 60 kg

Systemic inhalation exposure 'Placing' and 'Disposal': 5.56 x 10^{-4} mg/kg bw/d

Systemic exposure 'Placing/disposal of pellets in cups': 5.62 x 10^{-4} mg/kg bw/d

2.) Brushing

Mixing and loading

The biocidal product is solved in water before application. Exposure mainly occurs via the dermal route. Based on the particle size in the dust fraction, the attrition rate of the granular biocidal product, low vapour pressure and the short exposure time (compared to the application time) in case of imidacloprid inhalation exposure is considered low. However, as a worst case it is assumed that inhalation exposure as assessed for scenario 1 (Placing of pellets in cups – placing and disposal) represents a worst case assessment also for mixing and loading before brushing or spraying. Oral exposure is not expected.

Dermal exposure is assessed as described above for 'Placing of pellets in cups'

Extract from the corresponding Consexpo report:

General exposure data

Application frequency	6 per year	(Applicant)
Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Dermal model: direct dermal contact with product: constant rate

Weight fraction compound	0.5 % imidacloprid
Exposed area	1948.8 cm^2 (Hand, lower arms, HEEG opinion, not relevant for the Consexpo model)
Contact rate	0.033 mg/min (Consexpo Pest Control Products Fact Sheet)
Release duration	80 s (Consexpo Pest Control Products Fact Sheet)

Uptake model: fraction

Uptake fraction (dermal abs.)	8 % (Refer to 'General parameters Imidacloprid' above)

Dermal: point estimates

Dermal external dose:	3.66 x 10^{-6} mg/kg bw/d
Dermal internal dose:	2.93 x 10^{-7} mg/kg bw/d

Inhalation exposure as assessed for scenario 1

Systemic inhalation exposure 'Placing' and 'Disposal': 5.56 x 10^{-4} mg/kg bw/d

Systemic dermal exposure 'Mixing and loading': 2.93 x 10^{-7} mg/kg bw/d

Total systemic exposure 'Mixing and loading': 5.56 x 10^{-4} mg/kg bw/d

Systemic exposure 'Mixing and loading': 2.93 x 10^{-7} mg/kg bw/d

Application

The biocidal product is used as waterborne paint. Therefore, exposure is assessed in accordance to the 'Consexpo Paint Products Fact Sheet' (2007). Exposure is expected via the dermal and the inhalation route. Exposure is assessed with Consexpo 4.1 using the following models and parameters. For

penetration through clothing a factor of 100 % is assumed as a worst case. It is assumed that the non-professional user treats in maximum 2 m^2 per application. Since the treatment of a surface of 1 m^2 is effective for 100 m^2 floor, this is considered as a worst case for private housings. For release duration (application time) 60 min is assumed. Based on a study by Garrod et al. (Ann. Occup. Hyg. (2000) 44 (6): 421-426.) painting of wood preservatives last in maximum 14 min/m^2 (28 min for 2 m^2). Considering potential differences in the painting of wood preservatives and insecticides, 60 min is considered as a worst case.

Extract from the corresponding Consexpo report:

Compound

Vapour pressure	9.0 x 10^{-10} Pa	(Refer to parameters above)

General exposure data

Application frequency	6 per year	(Applicant)
Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Inhalation model: Exposure to vapour: constant rate

Weight fraction compound	0.286 % imidacloprid	(Diluted product, applicant)
Exposure duration	130 min	(Consexpo Paint Products Fact Sheet)
Room volume	58 m^3	(Applicant, worst case; based on the treated area, surface is bigger)
Ventilation rate	0.6 h^{-1}	(Consexpo Paint Products Fact Sheet)
Applied amount	700 g	(Applicant, 200 g b.p. per m^2, 400 g diluted with 300 g water)
Release area	2 m^2	(Applicant, expert judgement, see above)
Application duration	60 min	(Expert judgement, see above)
Mol weight matrix	205 g/mol	(Calculated from the main components of the mixture)
Mass transfer rate	2310 m/min	(Consexpo, Langmuir)

Uptake model: fraction

Uptake fraction (inhal. abs.)	100 %	(Refer to 'General parameters Imidacloprid' above)
Inhalation rate	32.9 m^3/d	(Consexpo default)

Dermal model: direct dermal contact with product: constant rate

Weight fraction compound	0.286 % imidacloprid	(Diluted product, applicant)
Exposed area	16600 cm^2	(Whole body, HEEG opinion, not relevant for the Consexpo model)
Contact rate	30 mg/min	(Consexpo Paint Products Fact Sheet, based on exposure data)
Release duration	60 min	(Expert judgement, see above)

Uptake model: fraction

Uptake fraction (dermal abs.)	8 %	(Refer to 'General parameters Imidacloprid' above)

Inhalation point estimates

Inhalation mean event concentration:	9.68 x 10^{-8} mg/m^3
Inhalation internal dose:	4.80 x 10^{-9} mg/kg bw/d

Dermal point estimates

Dermal external dose:	0.0858 mg/kg bw/d
Dermal internal dose:	0.00686 mg/kg bw/d

Systemic exposure 'Application': 0.00686 mg/kg bw/d

Post application exposure

Exposure may occur during the cleaning of brushes. For cleaning processes and in accordance to the ’HEEG opinion on Exposure model ‘Primary exposure scenario – washing out of a brush’, which has been used to apply a paint’ (2010, endorsed on TM III2010), dermal exposure is expected. It is assessed using the ‘General Exposure Calculator For Washing Out Of Brushes’, which is attached as an Excel document to the corresponding HEEG opinion. In this model cleaning the brush used for applying paint is done by repeated dipping and swilling it in a vessel containing an appropriate solvent. It represents a worst case for waterborne paints because for these paints, the brush will often be cleaned under a running tap; the running water washing both the paint from the brush and most contamination from the hands.

Activity and Parameters	No gloves	Units
Volume of brush	**200**	**mL**
Volume of paint remaining on brush after painting ($^1/_8$ of 200 ml = 25 ml)	25	mL
Density of paint	**1.00**	**g/mL**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	25.00	g
Concentration of a.s. in paint	**0.286**	**% w/w**
A. Weight of a.s. on brush after painting	71.4250	mg
B. Residues of a.s. on brush after 1st washing (10 % of A)	7.1425	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	64.2825	mg
C. Weight of a.s. squeezed out from brush onto cloth (50 % of B)	3.5713	mg
Cloth absorbs 90 % of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10 % of C)	0.3571	mg
Penetration of a.s. through gloves	**100**	**%**
Weight of a.s. on hand	0.3571	mg
Dermal absorption of a.s.	**8.00**	**%**
Weight of a.s. entering the body	0.0286	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	3.5713	mg
E. Residues of a.s. on brush after 2nd washing (10 % of D)	0.3571	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	3.2141	mg
F. Weight of a.s. squeezed out from brush onto cloth (50 % of E)	0.1786	mg
Cloth absorbs 90 % of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10 % of F)	0.0179	mg
Penetration of a.s. through gloves	100	%
Weight of a.s. on hand	0.0179	mg
Dermal absorption of a.s.	8.00	%
Weight of a.s. entering the body	0.00143	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (**E** – **F**)	0.1786	mg
H. Residues of a.s. on brush after 3rd washing (10 % of G)	0.0179	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	0.1607	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50 % of H)	0.0089	mg
Cloth absorbs 90 % of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10 % of I)	0.0009	mg
Penetration of **a.s.** through gloves	100	%
Weight of a.s. on hand	0.0009	mg
Dermal absorption of a.s.	8.00	%
Weight of a.s. entering the body	0.00007	mg
Total weight of a.s. entering the body	**0.0301**	**mg**
Body weight	**60**	**kg**
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE	**0.0005**	**mg a.s./kg bw**

Systemic (dermal) exposure 'Post-Application': **0.0005 mg/kg bw/d**

Total systemic exposure by 'Brushing'

Mixing and loading	5.56 x 10^{-4} mg/kg bw/d
Application	0.00686 mg/kg bw/d
Post application	0.0005 mg/kg bw/d
Total systemic exposure	**0.00792 mg/kg bw/d**

3.) Spray application

Mixing and loading

The biocidal product is solved in water and diluted two-fold before application. The exposure assessment for Mixing and Loading prior spray application is identical to those before brushing and can be adopted. For details refer to the corresponding assessment above.

Inhalation exposure as assessed for scenario 1

Systemic inhalation exposure 'Placing' and 'Disposal':	5.56×10^{-4} mg/kg bw/d
Systemic dermal exposure 'Mixing and loading':	2.93×10^{-7} mg/kg bw/d
Total systemic exposure 'Mixing and loading':	**5.56×10^{-4} mg/kg bw/d**

Application

The biocidal product is used as waterborne paint. Therefore, exposure is assessed in accordance to the 'Consexpo Paint Products Fact Sheet' (2007) using the product category 'spray painting' and the default product 'pneumatic spraying' with some adaptions to information by the applicant. Exposure is expected via the dermal and the inhalation route. Exposure is assessed with Consexpo 4.1 using the following models and parameters. For penetration through clothing a factor of 100 % is assumed as worst case. It is assumed that the non-professsional user treats in maximum 2 m^2 per application. Since the treatment of a surface of 1 m^2 is effective for 100 m^2 floor, this is considered as a worst case for private housings. For release duration (application time) a 15 min is assumed. For the treatment of 2 m^2, 800 mL (g) paint (200 g b.p. diluted with 200 mL water per m^2 treated surface) is required. Assuming a mass generation rate of 0.5 g/s (Consexpo Paint Products Fact Sheet) the non-professional user needs 26.7 min (rounded to 30 min) for this area.

Extract from the corresponding Consexpo report:

Compound

Molecular weight	256 g/mol	
Vapour pressure	9.0×10^{-10} Pa	(Refer to 'General parameters Imidacloprid' above)

General exposure data

Application frequency	6 per year	(Applicant)
Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Inhalation model: Exposure to spray

Weight fraction compound	0.25 % imidacloprid	(Diluted product, applicant)
Exposure duration	60 min	(Expert judgement, spray duration and time a user stay in room after treatment, e.g. for cleaning of equipment)
Room volume	58 m^3	(Worst case; based on the treated area, surface is bigger)
Ventilation rate	0.5 hr^{-1}	(Worst case)
Mass generation rate	0.5 g/s	(Consexpo Paint Products Fact Sheet)
Spray duration	30 min	(Expert judgement, based on mass generation rate and applied amount)
Airborne fraction	20 %	(Consexpo Paint Products Fact Sheet)
Weight fraction non-volatile	99.99 %	(Based on the identity and dilution)
Density non-volatile	1.8 g/cm3	(Consexpo Paint Products Fact Sheet, default for paints)
Room height	2. 5 m	(Consexpo Paint Products Fact Sheet)

Inhalation cut-off diameter 15 µm (Consexpo Paint Products Fact Sheet)
Non-respirable uptake fraction 100 % (Consexpo default)
Spraying away from exposed person

Uptake model: fraction

Uptake fraction (inhal. abs.) 100 % (Refer to 'General parameters Imidacloprid' above)
Inhalation rate 32.9 m^3/d (Consexpo default)

Dermal model: direct dermal contact with product: constant rate

Weight fraction compound 0.25 % imidacloprid (Diluted product, applicant)
Exposed area 16600 cm^2 (Total body, HEEG opinion, not relevant for the Consexpo model)
Contact rate 110 mg/min (Consexpo Paint Products Fact Sheet, based on exposure data)
Release duration 30 min (Expert judgement, based on mass generation rate and applied amount)

Uptake model: fraction

Uptake fraction (dermal abs.) 8 % (Refer to 'General parameters Imidacloprid' above)

Inhalation point estimates

Inhalation mean event concentration: 0.00920 mg/m^3
Inhalation internal dose: 0.000211mg/kg bw/d

Dermal point estimates

Dermal external dose: 0.138 mg/kg bw/d
Dermal internal dose: 0.0110 mg/kg bw/d

Oral non-respirable point estimates

Oral internal dose: 0.00130 mg/kg bw/d

Integrated point estimates

Total external dose: 0.139 mg/kg bw/d
Total internal dose: 0.0125 mg/kg bw/d

Systemic exposure 'Application': 0.0125 mg/kg bw/d

Post application exposure

The applicant did not provide information for the assessment of equipment cleaning. However, it is assumed that brush cleaning as assessed for brush application above represents also a worst case for cleaning of spray equipment, particularly since the concentration of the active in-use-dilution is 0.25 % instead of 0.286 %. Thus, the corresponding exposure assessment is adopted.

For the detailed calculation refer to the exposure assessment for brushing

Systemic exposure 'Post-Application':	**0.00050 mg/kg bw/d**
Total systemic exposure by 'Spraying'	
Mixing and loading	5.56×10^{-4} mg/kg bw/d
Application	0.0125 mg/kg bw/d
Post application	0.00050 mg/kg bw/d
Total systemic exposure	**0.0136 mg/kg bw/d**

Secondary exposure

Adults, re-entry

Secondary exposure of adults by re-entry to treated areas is assessed with Consexpo 4.1 based on the 'rubbing off model' for children and toddlers after spray application. For adults it is assumed that exposure is limited to the hand palms (exposed area: 410 cm^2). It is also expected that the dried active substance is 30 % dislodgeable (Biocides Human Health Exposure Methodology, 2015, page 171, Table: Transfer coefficients – Dislodgeable residues) on a small surface and is rubbed off by occasional hand contact (dislodgeable amount = 1.0 a.s. g/m^2 x 30 % = 0.3 g/m^2). The surface is assumed to be identical to the hand palms (rubbed surface: 410 cm^2). Oral exposure by hand-to-mouth contact is considered not relevant for adults. Exposure of adults might occur occasionally (in maximum daily) during the application season (summer). Thus, it is considered as medium-term exposure.

Extract from the corresponding Consexpo report:

Compound

Compound name:	Imidacloprid

General exposure data

Exposure frequency	1 per day	(Expert judgement, during summer season)
Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Dermal model: direct dermal contact with product: rubbing off

Weight fraction compound	100 % imidacloprid	(Calculation is based on the application rate of the a.s.)
Exposed area	410 cm^2	(Expert judgement, based on HEEG opinion, palm of both hands)
Transfer coefficient	0.6 m^2/h	(Consexpo Pest Control Products Fact Sheet/General Fact Sheet)
Rubbed surface	410 cm^2	(Expert judgement, based on HEEG opinion)
Release duration	60 min	(Consexpo Pest Control Products Fact Sheet)

Dislodgeable amount	0.3 g/m^2	(Expert judgement based on application rate a.s. and transfer coefficient according to Biocides Human Health Exposure Methodology, 2015)

Uptake model: fraction

Uptake fraction (dermal abs.)	8 %	(Refer to 'General parameters Imidacloprid' above)

Oral model: Oral exposure to product:

Not relevant

Dermal/integrated point estimates

Dermal external dose:	0.205 mg/kg bw/d
Dermal internal dose:	0.0164 mg/kg bw/d

Total systemic exposure **0.0164 mg/kg bw/d**

Toddlers, contact to residues on floors

Secondary exposure of toddlers may occur when they are crawling on floors near treated walls. The maximum application rate is 1.0 g imidacloprid/m^2. According the 'Consexpo Pest Control Products Fact Sheet' (2006) it is assumed that 15 % of the maximum amount applied on surface will be on the ground and that 30 % are dislodgeable (Biocides Human Health Exposure Methodology, 2015, page 171, Table: Transfer coefficients – Dislodgeable residues). Thus, an amount of 0.045 g imidacloprid/m^2 is expected. According to the 'Consexpo Pest Control Products Fact Sheet' (2006) the rubbed surface is 2 or 22 m^2 depending on the type of application. The surface for general surface application is 22 m^2 representing the area of an average living room. Since the biocidal product is applied directly on the wall and inhabited rooms usually are furniture near the wall it is expected that the relevant contaminated surface is considerably smaller. In addition, not the whole wall is treated but only a small proportion (1 m^2 wall for 100 m^2 floor). For application in inhabited areas where children/toddlers normally stay a surface of 1 m^2 is considered as realistic for such a contact.

Since the biocidal product is for use in households and public areas daily exposure during the summer season must be expected. Thus, medium-term exposure is assumed.

Extract from the corresponding Consexpo report:

Compound

Compound name:	Imidacloprid

General exposure data

Exposure frequency	1 per day	(expert judgement, during summer season)
Body weight	10 kg	(HEEG opinion)

Dermal model: direct dermal contact with product: rubbing off

Weight fraction compound 100 % imidacloprid (Calculation is based on the application rate of the a.s.)

Exposed area	1128 cm^2	(Expert judgement based on HEEG opinion, surface of hands, feet ½ of the legs)
Transfer coefficient	0.17 m^2/h	(Cohen-Hubal et al., Environ Health Perspect. 2006 Feb; 114(2): 264–269)
Rubbed surface	1 m^2	(Consexpo Pest Control Products Fact Sheet, explanation above)

Release duration	60 min	(Consexpo Pest Control Products Fact Sheet)
Dislodgeable amount	0.045 g/m^2	(Calculation based on Consexpo Pest Control Products Fact Sheet, application rate and transfer coefficient acc. to Biocides Human Health Exposure Methodology, 2015, see above)

Uptake model: fraction

Uptake fraction (dermal abs.)	8 %	(Refer to 'General parameters Imidacloprid' above)

Oral model: oral exposure to product: direct intake

Weight fraction compound 100 % imidacloprid (Estimate is based on the application rate a.s.)

Ingestion rate 0.768 mg (Calculation is based on the dermal external load as calculated by Consexpo for dermal point estimates, it is assumed that only hands are mouthed by toddlers (ingestion rate = 0.00677 mg/cm^2 x 230.4 cm^2 = 1.537 mg). It is also assumed that only 50 % of the dermal load is ingested orally.

Uptake model: fraction

Uptake fraction (oral abs.)	100 %	(Refer to 'General parameters Imidacloprid' above)

Dermal point estimates

Dermal load:	0.00677 mg/cm^2
Dermal external dose:	0.765 mg/kg bw/d
Dermal internal dose:	0.0612 mg/kg bw/d

Oral point estimates

Oral external dose:	0.0768 mg/kg bw/d
Oral internal dose:	0.0768 mg/kg bw/d

Integrated point estimates

Total external dose:	0.842 mg/kg bw/d
Total internal dose:	0.138mg/kg bw/d

Total systemic exposure **0.138 mg/kg bw/d**

Children (6 to 11 y), contact to residues on floors

Exposure of children is assessed similar to exposure of toddlers. The body weight and the exposed area of the body surface are adapted. Oral exposure cannot be generally excluded for children.

Extract from the corresponding Consexpo report:

Compound

Compound name: Imidacloprid

General exposure data

Exposure frequency	1 per day	(BfR proposal, during summer season)
Body weight	23.9 kg	(HEEG opinion)

Dermal model: direct dermal contact with product: rubbing off

Weight fraction compound	100 % imidacloprid	(Calculation is based on the application rate of the a.s.)
Exposed area	2403.5 cm^2	(Expert judgement based on HEEG opinion, surface of hands, feet ½ of the legs)
Transfer coefficient	0.17 m^2/h	(Cohen-Hubal et al., Environ Health Perspect. 2006 Feb; 114(2): 264–269)
Rubbed surface	1 m^2	(Proposal of the applicant, see above)
Release duration	60 min	(Consexpo Pest Control Products Fact Sheet)
Dislodgeable amount	0.045 g/m^2	(Calculation based on Consexpo Pest Control Products Fact Sheet, application rate and transfer coefficient acc. to Biocides Human Health Exposure Methodology, 2015, see above)

Uptake model: fraction

Uptake fraction (dermal abs.) 8 %	(Refer to 'General parameters Imidacloprid' above)

Oral model: oral exposure to product: direct intake

Weight fraction compound	1 fraction	(Estimate is based on the application rate a.s.)
Ingestion rate	0.682 mg	(Calculation is based on the dermal external load as calculated by Consexpo for dermal point estimates, it is assumed that only hands are mouthed by children (ingestion rate = 0.00319 mg/cm^2 x 427.8 cm^2 = 1.365 mg). It is also assumed that only 50 % of the dermal load is ingested orally.)

Uptake model: fraction

Uptake fraction (oral abs.) 100 %	(Refer to 'General parameters Imidacloprid' above)

Dermal point estimates

Dermal load:	0.00319 mg/cm^2
Dermal external dose:	0.320 mg/kg bw/d
Dermal internal dose:	0.0256 mg/kg bw/d

Oral point estimates

Oral external dose:	0.0285 mg/kg bw/d
Oral internal dose:	0.0285 mg/kg bw/d

Integrated point estimates

Total external dose:	0.349 mg/kg bw/d
Total internal dose:	0.0541 mg/kg bw/d

Total systemic exposure **0.0541 mg/kg bw/d**

Summary total systemic secondary exposure

Adults, re-entry, contact to residues	0.0164 mg/kg bw/d
Toddlers, contact to residues	0.138 mg/kg bw/d
Children, contact to residues	0.0541 mg/kg bw/d

4.7.2 *cis*-Tricos-9-ene (Muscalure)

Exposure assessment for *cis*-tricos-9-ene is comparable to the assessment of imidacloprid. Therefore only parameters, differing from the imidacloprid assessment are listed below. Explanations given for imidacloprid are usually also applicable to *cis*-tricos-9-ene. Main difference is the volatility of *cis*-tricos-9-

ene. Since *cis*-tricos-9-ene has a significantly higher vapour pressure, some major changes are required for assessment of inhalation exposure.

The application rate for non-professional users is 200 g of b.p. per m^2 (0.2 g *cis*-tricos-9-ene /m^2). The biocidal product shall be applied to an effective surface of 1 m^2 per 100 m^2 floor surface to be treated. For spray application 200 g b.p. are solved in 200 mL. For brushing 200 g b.p. are solved in 150 mL of water. These dilutions are sufficient to treat 1 m^2 effective for 100 m^2 of fly-resting surfaces.

Primary exposure

1.) Placing of pellets in cups

Application and disposal

The pellets are placed in cups every 10 m^2. Thus, one cup is filled with 20 g/m^2. For a total surface of 100 m^2 10 cups have to be placed. Dermal exposure was assessed with Consexpo 4.1 using the model 'Mixing and loading, granules' with the following parameters. This model refers to the loading of a device for spraying. As a worst case it is assumed that each placing of a cup is equivalent to one loading process. Thus, the estimate for one application has to be multiplied by 10. The same model is used for disposal. Thus, the resulting exposure value is multiplied by 2.

Extract from the corresponding Consexpo report:

General exposure data

Application frequency	6 per year	(Applicant)
Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Dermal model: direct dermal contact with product: constant rate

Weight fraction compound	0.1 %	*cis*-tricos-9-ene
Exposed area	1948.8 cm^2	(Hand, lower arms, HEEG opinion, not relevant for the Consexpo model)
Contact rate	0.033 mg/min	(Consexpo Pest Control Products Fact Sheet)
Release duration	80 s	(Consexpo Pest Control Products Fact Sheet)

Uptake model: fraction

Uptake fraction (dermal abs.)	75 %(Refer to 'General parameters *cis*-Tricos-9-ene' above)

Dermal: point estimates

Dermal external dose (1 x):	7.23×10^{-7}	mg/kg bw/d
Dermal internal dose (1 x):	5.49×10^{-7}	mg/kg bw/d
Dermal external dose (10 x):	7.23×10^{-6}	mg/kg bw/d
Dermal internal dose (10 x):	5.49×10^{-6}	mg/kg bw/d

Systemic dermal exposure 'Placing': 5.49×10^{-6} mg/kg bw/d
Systemic dermal exposure 'Placing' and 'Disposal': 1.10×10^{-5} mg/kg bw/d

Inhalation exposure is likely by inhalation of dust, when the formulations are handled. It is assumed that a typical room of 50 m^3 poses a floor surface area of around 20 m^2. For this surface area 40 g of product are envisaged in the treatment. As proposed by the applicant the concentration in the inhaled air (C_{inh}) is calculated according to the following formula:

$$C_{inh} = \frac{Q_{prod} \times F_{AI}}{V_{room}} \times F_{inh}$$

Where
C_{inh} is the inhalation exposure
Q_{prod} is the amount of product used in the treatment (40 g)
F_{AI} is the fraction of active ingredient in the product (0.1 % imidacloprid)
F_{inh} is the dust inhalable fraction of the product (1 % dust fraction is assumed)
V_{room} is the volume of a typical room (50 m^3)

Inhalation exposures for the active substances contained in the product are:

C_{inh} (*cis*-tricos-9-ene) = 0.008 mg/m^3

As proposed by the applicant for the calculation of the systemic exposures the following parameters have been considered:

Exposure time:	2 x 20 min (application and disposal)
Inhalation rate:	1.25 m^3/h
Inhalation absorption:	100 %
Body weight:	60 kg

Systemic inhalation exposure to dust: 0.000111 mg/kg bw/d

Due to the high vapour pressure of *cis*-tricos-9-ene secondary exposure to this compound is not limited to vapour but may also occur via evaporation. The same model as used for secondary exposure of adults (see section below) with a reduction of the exposure duration to 40 min can be applied. For details refer to this section.

Systemic inhalation exposure to vapour: 0.000135 mg/kg bw/d
Systemic inhalation exposure 'Placing' and 'Disposal': 0.000246 mg/kg bw/d
Systemic exposure 'Placing/disposal of pellets in cups': 0.000257 mg/kg bw/d

2.) Brushing

Mixing and loading

The biocidal product is solved in water before application. Exposure mainly occurs via the dermal route. Based on the particle size in dust fraction, the attrition rate of the granular biocidal product and the short exposure time inhalation exposure is considered low. However, as a worst case it is assumed that inhalation exposure as assessed for scenario 1 (Placing of pellets in cups – placing and disposal) including exposure from vapour represents a worst case assessment also for mixing and loading before brushing or spraying.Oral exposure is also not expected.

Dermal exposure was assessed with Consexpo 4.1 using the following models and parameters.

Extract from the corresponding Consexpo report (parameters identical to the corresponding imidacloprid exposure assessment are not listed):

General exposure data

Application frequency	6 per year	(Applicant)
Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Dermal model: direct dermal contact with product: constant rate

Weight fraction compound 0.1 % *cis*-tricos-9-ene

Uptake model: fraction

Uptake fraction (dermal abs.) 75 % (Refer to 'General parameters *cis*-tricos-9-ene' above)

Dermal: point estimates

Dermal external dose:	7.32×10^{-7}	mg/kg bw/d
Dermal internal dose:	5.49×10^{-7}	mg/kg bw/d

Inhalation exposure as assessed for scenario 1

Systemic inhalation exposure 'Placing' and 'Disposal': 2.46×10^{-4} mg/kg bw/d

Systemic dermal exposure 'Mixing and loading': 5.49×10^{-7} mg/kg bw/d

Total systemic exposure 'Mixing and loading': 2.46×10^{-4} mg/kg bw/d

Application

The biocidal product is used as waterborne paint. Therefore, exposure is assessed in accordance to the 'Consexpo Paint Products Fact Sheet' (2007). Exposure is expected via the dermal and the inhalation route. Exposure is assessed using Consexpo 4.1 using the following models and parameters. For penetration through clothing a factor of 100 % is assumed as worst case. In contrast to imidacloprid, inhalation exposure to vapour is assumed.

Extract from the corresponding Consexpo report:

Compound

Molecular weight	323 g/mol	
Vapour pressure	0.064 Pa	(Refer to 'General parameters *cis*-tricos-9-ene' above)

General exposure data

Application frequency	6 per year	(Applicant)
Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Inhalation model: Exposure to vapour: evaporation

Weight fraction compound 0.06 % *cis*-tricos-9-ene (Applicant, diluted product)

Exposure duration	132 min	(Consexpo Paint Products Fact Sheet)
Room volume	58 m^3	(Worst case; based on the treated area, surface is bigger)
Ventilation rate	0.6 h^{-1}	(Consexpo Paint Products Fact Sheet)
Applied amount	700 g	(Applicant, 200 g b.p. per m^2, 400 g diluted with 300 g water)
Release area	2 m^2	(Applicant, BfR proposal, caculated from applied amount see above section for imidacloprid exposure)
Application duration	60 min	(Expert judgement, see above section for imidacloprid exposure)
Mol weight matrix	205 g/mol	(Calculated from the main components of the mixture)
Mass transfer rate	2080 m/min	(Langmuir, Consexpo Paint Products Fact Sheet)

Uptake model: fraction

Uptake fraction (inhal. abs.) 100 % (Refer to 'General parameters *cis*-tricos-9-ene' above)

Dermal model: direct dermal contact with product: constant rate

Weight fraction compound 0.06 % *cis*-tricos-9-ene (Applicant, diluted product)

Contact rate 30 mg/min (Consexpo Paint Products Fact Sheet, based on exposure data)

Uptake model: fraction

Uptake fraction (dermal abs.) 75 % (Refer to 'General parameters *cis*-tricos-9-ene' above)

Inhalation point estimates

Inhalation mean concentration on day of exposure: 0.000250 mg/m^3

Inhalation internal dose: 0.000137 mg/kg bw/d

Dermal point estimates

Dermal external dose: 0.0180mg/kg bw/d

Dermal internal dose: 0.0135 mg/kg bw/d

Systemic exposure 'Application': 0.0136 mg/kg bw/d

Post application

Exposure may occur during the cleaning of brushes. For details refer to the exposure assessment of imidacloprid. Calculation is identical except the concentration of the active substance (0.06 % instead of 0.286 %, w/w) and the dermal absorption value (75 % instead of 8 %).

Systemic exposure 'Post-Application': 0.00099 mg/kg bw/d

Total systemic exposure by 'Brushing'

Mixing and loading	2.46 x 10^{-4} mg/kg bw/d
Application	0.0136 mg/kg bw/d
Post application	0.00099 mg/kg bw/d
Total systemic exposure	**0.0148 mg/kg bw/d**

3.) Spray application

Mixing and Loading

The biocidal product is solved in water and diluted two-fold before application (1+1). The exposure assessment for Mixing and loading prior spray application is identical to those before brushing and can be adopted. For details refer to the corresponding assessment above.

Inhalation exposure as assessed for scenario 1

Systemic inhalation exposure ‘Placing’ and ‘Disposal’:	2.46×10^{-4} mg/kg bw/d
Systemic dermal exposure ‘Mixing and loading’:	5.49×10^{-7} mg/kg bw/d
Total systemic exposure ‘Mixing and loading’:	**2.46×10^{-4} mg/kg bw/d**

Application

The biocidal product is used as waterborne paint. Therefore, exposure is assessed in accordance to the "Consexpo Paint Products Fact Sheet" (2007). Exposure is expected via the dermal and the inhalation route. Exposure is assessed using Consexpo 4.1 with the following models and parameters. For penetration through clothing a factor of 100 % is assumed as a worst case.

Extract from the corresponding Consexpo report (most parameters identical to the corresponding imidacloprid exposure assessment are not listed):

Compound

Molecular weight	323 g/mol	
Vapour pressure	0.064 Pa	(Refer to 'General parameters *cis*-tricos-9-ene' above)

General exposure data

Application frequency	6 per year	(Applicant)
Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Inhalation model: Exposure to spray

Weight fraction compound	0.05 % *cis*-tricos-9-ene	(Applicant, diluted product)
Room volume	58 m^3	(Applicant, worst case; based on the treated area, surface is bigger)
Ventilation rate	0.6 h^{-1}	(Consexpo Paint Products Fact Sheet)

Uptake model: fraction

Uptake fraction (inhal. abs.)	100 %	(Refer to 'General parameters *cis*-tricos-9-ene' above)

Dermal model: direct dermal contact with product: constant rate

Weight fraction compound	0.05 % *cis*-tricos-9-ene	(Applicant, diluted product)

Uptake model: fraction

Uptake fraction (dermal Abs.)	75 %	(Refer to 'General parameters *cis*-tricos-9-ene' above)

Inhalation point estimates

Inhalation mean event concentration:	0.00201 mg/m^3
Inhalation internal dose:	4.59×10^{-5} mg/kg bw/d

Dermal: point estimates

Dermal external dose:	0.0275 mg/kg bw/d
Dermal internal dose:	0.0206 mg/kg bw/d

Oral non-respirable point estimates

Oral internal dose:	0.000288 mg/kg bw/d

Integrated (point estimates)

Total external dose:	0.0278 mg/kg bw/d
Total internal dose:	0.0209 mg/kg bw/d

The spray model assesses inhalation exposure to spray particles. However, *cis*-tricos-9-ene is volatile. Thus, exposure to vapour must also be considered. It is assessed using the Consexpo model (exposure to vapour: evaporation).

Extract from the corresponding Consexpo report:

Compound

Molecular weight	323 g/mol	
Vapour pressure	0.064 Pa	(Refer to 'General parameters *cis*-tricos-9-ene' above)

General exposure data

Application frequency	6 per year	(Applicant)
Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Inhalation model: Exposure to vapour: evaporation

Weight fraction compound 0.05 % *cis*-tricos-9-ene (Applicant, diluted product)

Exposure duration	60 min	(Consexpo Paint Products Fact Sheet)
Room volume	58 m^3	(Applicant, worst case; based on the treated area, surface is bigger)
Ventilation rate	0.6 h^{-1}	(Consexpo Paint Products Fact Sheet)
Applied amount	800 g	(Applicant, diluted biocidal product)
Release area	2 m^2	(Applicant, caculated from applied amount)
Application duration	30 min	(Expert judgement, based on mass generation rate and applied amount)
Mol weight matrix	205 g/mol	(Calculated from the main components of the mixture)
Mass transfer rate	2080 m/min	(Langmuir, Consexpo Paint Products Fact Sheet)

Uptake model: fraction

Uptake fraction (inhal. abs.)	100 %	(Refer to 'General parameters *cis*-tricos-9-ene' above)

Inhalation point estimates

Inhalation mean event concentration:	0.00251 mg/m^3
Inhalation internal dose:	5.74 x 10^{-5} mg/kg bw/d

Total systemic exposure 'Application': **0.0210 mg/kg bw/d**

Post application

Exposure may occur during the cleaning of the equipment. Since the concentration value for brushing is slightly higher this assessment is adopted for spray application. Thus, for details of the exposure assessment refer to 'Brushing' application.

Systemic exposure 'Post-Application': **0.00099 mg/kg bw/d**

Total systemic exposure by 'Spraying'	
Mixing and loading	2.46 x 10^{-4} mg/kg bw/d
Application	0.0210 mg/kg bw/d
Post application	0.00099 mg/kg bw/d
Total systemic exposure	**0.0222 mg/kg bw/d**

Secondary exposure

Adults, re-entry

Secondary exposure of adults by re-entry to treated areas is assessed with Consexpo 4.1 based on the rubbing off model for children and toddlers after spray application. For adults it is assumed that exposure is limited to the hand palms (exposed area: 410 cm^2). It is also expected that the dislodgeable active substance (30 %, Biocides Human Health Exposure Methodology, 2015, page 171, Table: Transfer coefficients – Dislodgeable residues) of a small surface is rubbed off by occasional hand contact (dislodgeable amount = 0.2 g a.s./m^2 x 30 % = 0.06 g a.s./m^2). This surface is assumed to be identical to the hand palms (rubbed surface: 410 cm^2). Oral exposure by hand-to mouth contact is considered not relevant for adults. Exposure of adults might occur occasionally during the application season (summer). Thus, it is considered as medium-term exposure. The assessment of dermal and oral exposure is comparable to imidacloprid. Only changed parameters are listed below. Based on the volatility of *cis*-tricos-9-ene also inhalation exposure has to be assessed. Inhalation exposure was assessed with Consexpo 4.1 assuming that a person stays in a treated room for 18 h. As a worst case, it is assumed that a person is exposed to the amount used for 2 m^2 (surface treated by non-professional users per application, refer to primary exposure) applied in one room. Assuming an application rate of 200 g/m^2 for the pure biocidal product 400 g are used for this room. It is expected that persons stay the most time of the day in this room (18 h). Note that the exposure time for dermal contact is shorter than for inhalation exposure since this contact will not occur permanently.

Extract from the corresponding Consexpo report:

Compound

Compound name:	*cis*-Tricos-9-ene	

General exposure data

Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Dermal model: direct dermal contact with product: rubbing off

Dislodgeable amount	0.006 g/m^2	(Calculation based on application rate and transfer coefficient acc. to Biocides Human Health Exposure Methodology, 2015, see above)

Uptake model: fraction

Uptake fraction (dermal Abs.)	75 %	(Refer to 'General parameters *cis*-tricos-9-ene' above)

Oral model: oral exposure to product: constant rate

Not relevant

Dermal/integrated: point estimates

dermal external dose:	0.0410 mg/kg bw/d
dermal internal dose:	0.0307 mg/kg bw/d

Inhalation exposure

Compound

Compound name:	*cis*-Tricos-9-ene	
Molecular weight	323 g/mol	
Vapour pressure	0.064 Pa	(Refer to 'General parameters *cis*-tricos-9-ene' above)

General exposure data

Body weight	60 kg	(HEEG opinion, refer also to 'General parameters' above)

Inhalation model: Exposure to vapour: evaporation

Weight fraction compound 0.1 % *cis*-tricos-9-ene (Active substance in the dried biocidal product)

Exposure duration	18 h	(See above)
Room volume	58 m^3	(Consexpo General Fact Sheet)
Ventilation rate	0.6 h^{-1}	(Consexpo Paint Products Fact Sheet)
Applied amount	400 g	(Total amount of the a.s. on 2 m^2, see above)
Release area	2 m^2	(See above)
Application duration	24 h	(Time interval the a.s. evaporate)
Molecular Weight matrix	342 g	(Saccharose)
Mass transfer rate	2080 m/min	(Consexpo, Langmuir)

Uptake model: fraction

Uptake fraction (inhal. abs.) 100 % (Refer to 'General parameters *cis*-tricos-9-ene' above)

Inhalation point estimates

Inhalation mean event concentration:	0.00891 mg/m^3	
Inhalation internal dose:		0.00366 mg/kg bw/d

Integrated dermal/inhalation point estimates

Total external dose:	0.0447 mg/kg bw/d
Total internal dose:	0.0344 mg/kg bw/d

Total systemic exposure **0.0344 mg/kg bw/d**

Toddlers, contact to residues on floors

Secondary exposure to toddlers may occur when they are crawling on floors near treated walls. The maximum application rate is 0.2 g *cis*-tricos-9-ene/m^2. According the 'Consexpo Pest Control Products Fact Sheet' (2006) it is assumed that 15 % of the amount applied on surface will be on the ground and that 30 % are dislodgeable (Biocides Human Health Exposure Methodology, 2015, page 171, Table: Transfer coefficients – Dislodgeable residues). Thus, an amount of 0.009 g *cis*-tricos-9-ene/m^2 is expected. The assessment is comparable to imidacloprid. Only changed parameters are listed below. For other parameters refer to imidacloprid assessment.

Based on the volatility of *cis*-tricos-9-ene also inhalation exposure has to be assessed. Inhalation exposure was assessed with Consexpo 4.1. For additional parameters refer also to Secondary exposure, Adults, re-entry.

Note that the exposure time for dermal contact is shorter than for inhalation exposure since this contact will not occur permanently.

Extract from the corresponding Consexpo reports:

Compound

Compound name:	*cis*-Tricos-9-ene	

Dermal model: direct dermal contact with product: rubbing off

Dislodgeable amount	0.009 g/m^2	(Calculation based on Consexpo Pest Control Products Fact Sheet, application rate and transfer coefficient acc. to Biocides Human Health Exposure Methodology, 2015, see above)

Uptake model: fraction

Uptake fraction (dermal abs.)	75 %	(Refer to 'General parameters *cis*-tricos-9-ene' above)

Oral model: oral exposure to product: direct intake

Ingestion rate	0.156 mg	(Calculation is based on the external dermal load, for calculation details refer to the corresponding assessment for imidacloprid)

Uptake model: fraction

Uptake fraction (oral abs.)	100 %	(Refer to 'General parameters *cis*-tricos-9-ene' above)

Dermal point estimates

Dermal load:	0.00135 mg/cm^2
Dermal external dose:	0.153 mg/kg bw/d
Dermal internal dose:	0.115 mg/kg bw/d

Oral point estimates

Oral external dose:	0.0156 mg/kg bw/d
Oral internal dose:	0.0156 mg/kg bw/d

Integrated point estimates

Total external dose:	0.169 mg/kg bw/d
Total internal dose)	0.130 mg/kg bw/d

Inhalation exposure

Compound

Molecular weight	323 g/mol	
Vapour pressure	0.064 Pa	(Refer to 'General parameters *cis*-tricos-9-ene' above)

General exposure data

Body weight	10 kg	(HEEG opinion, refer also to 'General parameters' above)

Inhalation model: Exposure to vapour: evaporation

Weight fraction compound	0.1 % *cis*-tricos-9-ene	(Concentration of a.s. in the dried biocidal product)
Exposure duration	18 h	(See above)
Room volume	58 m^3	(Consexpo General Fact Sheet)
Ventilation rate	0.6 h^{-1}	(Consexpo Paint Products Fact Sheet)
Applied amount	400 g	(Total amount of the a.s. on 2 m^2, see above)
Release area	2 m^2	(See above)
Application duration	24 h	(Time interval the a.s. evaporate)
Molecular weight matrix	342 g	(Saccharose, predominat component of dried bait)
Mass transfer rate	2080 m/min	(Consexpo, Langmuir)

Uptake model: fraction

Uptake fraction (inhal. abs.)	100 %	(Refer to 'General parameters *cis*-tricos-9-ene' above)
Inhalation rate	10.3 m^3/d	(Consexpo default, toddler 10 kg, light exercise)

Inhalation point estimates

Inhalation mean event concentration:	0.00891 mg/m^3
Inhalation internal dose:	0.00688 mg/kg bw/d

Integrated dermal/oral/inhalation point estimates

Total external dose:	0.176 mg/kg bw/d
Total internal dose:	0.137 mg/kg bw/d

Total systemic exposure **0.137 mg/kg bw/d**

Children (6 to 11 y), contact to residues on floors

Exposure of children is assessed similar to exposure of toddlers. The body weight and the exposed area of the body surface are adapted. Oral exposure cannot be generally excluded for children. The assessment of dermal and oral exposure is comparable to imidacloprid. Only changed parameters are listed below. Inhalation exposure is assessed as proposed for toddlers taken into account other anthropometric data.

Extract from the corresponding Consexpo report:

Compound

Compound name: *cis*-Tricos-9-ene

Dermal model: direct dermal contact with product: rubbing off

Dislodgeable amount	0.009 g/m^2	(Calculation based on on Consexpo Pest Control Products Fact Sheet, application rate and transfer coefficient acc. to Biocides Human Health Exposure Methodology, 2015, see above)

Uptake model: fraction

Uptake fraction (dermal Abs.)	75 %	(Refer to 'General parameters *cis*-tricos-9-ene' above)

Oral model: oral exposure to product: direct intake

Ingestion rate	0.136 mg	(Calculation is based on the external dermal load, for calculation det ails refer to the corresponding assessment for imidacloprid)

Uptake model: fraction

Uptake fraction (oral abs.)	100 %	(Refer to 'General parameters *cis*-tricos-9-ene' above)

Dermal point estimates

Dermal load:	0.000637 mg/cm^2
Dermal external dose:	0.0640 mg/kg bw/d
Dermal internal dose:	0.0480 mg/kg bw/d

Oral point estimates

Oral external dose:	0.00569 mg/kg bw/d
Oral internal dose:	0.00569 mg/kg bw/d

Integrated dermal/oral point estimates

Total external dose:	0.0697 mg/kg bw/d
Total internal dose:	0.0537 mg/kg bw/d

Inhalation exposure

Compound

Molecular weight	323 g/mol	
Vapour pressure	0.064 Pa	(Refer to 'General parameters *cis*-tricos-9-ene' above)

General exposure data

Body weight	23.9 kg	(HEEG opinion, refer also to 'General parameters' above)

Inhalation model: Exposure to vapour: evaporation

Weight fraction compound	0.1 %	(Concentration a.s. in the dried biocidal product on the wall)
Exposure duration	18 h	(See above)
Room volume	58 m^3	(Consexpo General Fact Sheet)
Ventilation rate	0.6 h^{-1}	(Consexpo Paint Products Fact Sheet)
Applied amount	400 g	(See above, based on applicant's information)
Release area	2 m^2	(See above)
Application duration	24 h	(Time interval the a.s. evaporates)
Mol. weight matrix	342 g/mol	(Saccharose, predominat component of dried bait)
Mass transfer rate	2080 m/min	(Consexpo, Langmuir)

Uptake model: fraction

Uptake fraction (inhal. abs.)	100 %	(Refer to 'General parameters *cis*-tricos-9-ene' above)
Inhalation rate	18.1 m^3/d	(Consexpo default, child 23.9 kg, light exercise)

Inhalation point estimates

Inhalation mean event concentration:	0.00891 mg/m^3
Inhalation internal dose:	0.00506 mg/kg bw/d

Integrated dermal/oral/inhalation point estimates

Total external dose:	0.0748 mg/kg bw/d
Total internal dose:	0.0588 mg/kg bw/d

Total systemic exposure **0.0588 mg/kg bw/d**

Total systemic secondary exposure

Adults, re-entry, contact to residues	0.0344 mg/kg bw/d
Toddlers, contact to residues	0.137 mg/kg bw/d
Children, contact to residues	0.0588 mg/kg bw/d

Reverse reference scenario for toddlers 'Oral ingestion of the biocidal product'

No exposure model exists for the scenario of a toddler ingesting orally pure granules or application dilutions in water. Since the biocidal product is applied in private households in open portions of 10 g it cannot be generally excluded even if an aversive agent to minimise such an exposure is added. Therefore, a reverse reference scenario is calculated.

Based on the concentration of the active substances imidacloprid (0.5 %, w/w) and *cis*-tricos-9-ene (0.1 %, w/w) in the biocidal product, a body weight of 10 kg and the AEL_{acute} of 0.4 mg/kg bw and 0.57 mg/kg bw, respectively, the maximum acceptable dose can be calculated:

Imidacloprid:	800 mg biocidal product
cis-Tricos-9-ene:	5700 mg biocidal product

One teaspoon counts for approximately 5 g of the biocidal product. Thus, regarding imidacloprid the acceptable amount, which can be ingested by a toddler, is 6.25-fold lower than this simplified unit. Although an aversive agent has been added, the ingestion of such an amount is not unlikely if an infant has access to cups filled with biocidal product or to freshly prepared dilutions. Due to the high sugar content and the blue colour the biocidal product might be attractive for children.

Thus, next to the addition of an aversive agent further risk mitigation measures to prevent unintended access of toddlers to the biocidal product are required.

4.7.3 Risk characterisation

Imidacloprid:

Primary exposure scenario	Systemic Exposure (mg/kg bw [/d])				Relevant AEL / NOAEL (mg/kg bw [/d])	AF/ ref. MoE	% AEL	MoE
	inhalation	dermal	oral	total				
Placing and disposal of pellets in cups	0.000556	5.86×10^{-6}	-	0.000562	$AEL_{med.-term}$ 0.2 $NOAEL_{med.-t.}$ 20	100	0.3	35587
Brushing Mixing & loading Application Cleaning	0.000556 4.80×10^{-9} -	2.93×10^{-7} 0.00686 0.00050	- - -	0.00792			4.0	2525
Spraying Mixing&loading Application Cleaning	0.000556 0.000211 -	2.93×10^{-7} 0.0110 0.00050	0.00130 -	0.0136			6.8	1471

Secondary exposure scenario	Systemic Exposure (mg/kg bw [/d])				Relevant AEL / NOAEL (mg/kg bw [/d])	AF/ ref. MoE	% AEL	MoE
	inhalation	dermal	oral	total				
Adults, re-entry, stay in treated living areas	0.0164	-	-	0.0164	$AEL_{med.-term}$ 0.2 $NOAEL_{med.-t.}$ 20	100	8.2	1220
Toddlers, stay in treated living areas	-	0.0612	0.00768	0.138			69	145
Children, stay in treated living areas	-	0.0256	0.0285	0.0541			27	370

***cis*-Tricos-9-ene:**

Primary exposure scenario	Systemic Exposure (mg/kg bw [/d])				Relevant AEL / NOAEL (mg/kg bw [/d])	AF/ ref. MoE	% AEL	MoE
	inhalation	dermal	oral	total				
Placing and disposal of pellets in cups	0.000246	1.10×10^{-5}	-	0.000257	$AEL_{med.-term}$ > 0.024 $NOAEL_{med.-t.}$ not available	n.a.	1.1	n.a.
Brushing Mixing & loading Application Cleaning	0.0002460.000137 -	5.49×10^{-7} 0.0135 0.00099	- - -	0.0148			62	n.a.

Spraying Mixing & loading Application Cleaning	0.000246 4.59×10^{-5} 5.74×10^{-5} -	5.49×10^{-7} 0.0206 0.00099	- 0.000288 -	0.0222			92	n.a.

Secondary exposure scenarios	Systemic Exposure (mg/kg bw [/d])				Relevant AEL / NOAEL (mg/kg bw [/d])	AF/ ref. MoE	% AEL [1)]	MoE
	inhalation	dermal	oral	total				
Adults, re-entry, stay in treated areas	0.00366	0.0307	-	0.0344	$AEL_{med.-term}$ > 0.024 $NOAEL_{med.-t.}$ not available (AEL_{acute}: 0.57)	n.a.	143 (6)	n.a.
Toddlers, stay in treated areas	0.00688	0.115	0.0156	0.137			573 (24)	n.a.
Children, stay in treated areas	0.00506	0.0480	0.00569	0.0588			245 (10)	n.a.

[1)] in brackets: percentage of AEL_{acute}.

It is acknowledged that the use of the $AEL_{medium-term}$ in this case might be very conservative, particulary for adults, which are often aware of touching such surfaces. Based on the surface, which is treated (1 m^2 wall per 100 m^2 floor) daily contact to contaminations on the ground or even to the treated wall is unlikely. Thus, intermittent exposure over the summer season is more realistic. However, for intermittent exposure neither reference values nor an appropriate guidance for exposure and risk assessment is available. Comparing the estimated daily exposure with the AEL_{acute} (resulting in acceptable exposure levels) is also not appropriate since no detailed information on exposure frequency is available. In this light, risk mitigation measures, which can reduce the load on the contaminated surfaces near the application sites (e.g. by wiping of these surfaces by the user after application) are considered realistic to reduce exposure to acceptable levels.

It is assumed that for the user of this biocidal product this post application task (decontamination) is covered by the exposure scenario Cleaning.

4.8 Residue behaviour

1.1 Intended use

Intended uses of biocidal product SOFAST (as described in applicant´s PAR (22.07.2019))	
Active substance(s)	imidacloprid cis-tricos-9-ene
Type of formulation	water dispersible granules
Substance(s) of concern	none
Field(s) of use	Indoor use in industrial/commercial premises, households/ private areas, public areas and livestock facilities
Target organism(s)	Flies – Muscidae (imagines, adults)
Application rate(s) and frequency	Application of biocidal product during fly season (i.e. typically from April to October), depending on fly population pressure: max. 6 applications/year with intervals of 1 month <u>Ready-to-use granular bait</u> application of bait in disposable shallow dishes only up high (shelves, ledges, walls...) at a rate of 200 g biocidal product per 100 m^2 floor surface (corresponding to 10 mg imidacloprid and 2 mg cis-tricos-9-ene per m^2), one bait point (disposable shallow dishes or bait station) every 10 m^2 <u>Paint application on cardboards</u> aqueous solution of biocidal product (200 g biocidal product/150 ml) is painted onto an effective surface area of 1 m^2 per 100 m^2 floor surface of the treated room resulting in 2 g biocidal product/m^2 floor surface (corresponding to 10 mg imidacloprid and 2 mg cis-tricos-9-ene per m^2 floor surface)
Category(ies) of users	professional
Waiting periods after treatment	not applicable
Further information	<u>General RMMs proposed by applicant:</u> - Do not use directly on or near food, feed or drinks. - Do not use on surfaces or utensils likely to be in direct contact with food, feed or drinks. - Keep out of reach of children and animals. - Bait points shall be out of reach of children and animals. - Do not apply the biocidal product directly on manure/slurry. <u>RMMs for cardboard application proposed by applicant:</u> - The product can be applied in presence of animals if contact with paint can be avoided (application on cardboards). - Place cardboards out from the reach of animals or where food/feedstuff can be contaminated (application on cardboards).

1.2 Representative dietary exposure scenarios

Critical scenarios with respect to consumer dietary intake for the biocidal product SOFAST are presented in the following table. They have been selected based on the information on the intended uses given in the table above.
For applications of SOFAST in industrial/commercial premises and households/private areas as well as public areas, contact with food or feed has been excluded via label restrictions. Therefore no residue assessment is conducted for these intended uses.

Summary table of representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
Livestock exposure			
1.	animal husbandry	indoor application of bait in livestock animal facilities (either granular bait in bait stations or bait painted on cardboards)	livestock animals

Relevant scenarios for dietary risk assessment

- oral exposure through intake of dead insects (chicken)
- inhalation exposure (cattle, pig, chicken)

The following scenarios are excluded by risk mitigation measures:

- oral exposure by licking of treated surfaces (cattle, pig)
- oral exposure via uptake of feed contaminated in trough (cattle, pig, chicken)
- dermal exposure by rubbing against surfaces (cattle, pig)

1.3 Description of dietary exposure scenarios

In this section assumptions, default values and other relevant information are listed for the representative dietary exposure scenario identified above. The assessment follows the approach proposed in the Guidance on Estimating Livestock Exposure to Biocidal Active Substances (Guidance on BPR (2017), Vol. III, Parts B+C, section 6).

Values and assumptions applied in livestock exposure calculations		
Parameter	**Value**	**Reference**
Tier 1		
maximal application rate ($R_{appl.\ a.s.}$)	<u>concentration of active substances in biocidal product</u> 0.52 % imidacloprid (w/w) 0.1 % cis-tricos-9-ene (w/w) <u>application rate</u>: <u>Paint application on cardboards</u> aqueous solution of biocidal product (200 g biocidal product/150 ml) is painted onto an effective surface area of 1 m^2 per 100 m^2 floor surface of the treated room resulting in 2 g biocidal product/m^2 floor surface (corresponding to 10 mg imidacloprid and 2 mg cis-tricos-9-ene per m^2 floor surface) <u>Ready-to-use granular bait</u> application of bait in shallow dishes preferably up high (shelves, ledges, walls...) at a rate of 200 g biocidal product per 100 m^2 floor surface (corresponding to 10 mg imidacloprid and 2 mg	Product specific information

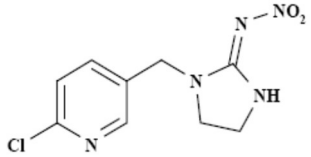
	cis-tricos-9-ene per m^2), one bait station is placed every 10 m^2	
vapour pressure (VP)	imidacloprid: 9 x 10^{-10} Pa (25°C = 298 K) cis-tricos-9-ene: 0.064 Pa (25°C = 298 K)	CAR, PT18, 2011, RMS: DE CAR, PT19, 2012, RMS: AT
representative animal species	beef and dairy cattle, pigs, broiler chicken, laying hen	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
animal body weight (bw $_{animal}$)	beef cattle: 500 kg dairy cattle: 650 kg calves: 200 kg fattening pigs: 100 kg breeding pigs: 260 kg broiler chicken: 1.7 kg laying hen: 1.9 kg	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
No. of animals per stable ($N_{animals}$)	beef cattle: 125 dairy cattle: 100 calves: 80 fattening pigs: 400 breeding pigs (individual&group housing): 132 broiler chicken (free range, litter floor): 20000 broiler chicken (parent broiler, free range, grating floor): 7000 broiler chicken (parent broiler chicken in rearing, free range, grating floor): 9000 laying hen (battery): 21000 laying hen (free range, litter floor): 10000 laying hen (free range, grating floor): 20000	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
treated surface area per stable ($A_{treated\ stable\ surface}$)	floor area per stable beef cattle: 370 m^2 dairy cattle: 1170 m^2 calves: 160 m^2 fattening pigs: 600 m^2 breeding pigs (individual housing): 560 m^2 breeding pigs (group housing): 710 m^2 broiler chicken (free range, litter floor): 1110 m^2 broiler chicken (parent broiler, free range, grating floor): 390 m^2 broiler chicken (parent broiler chicken in rearing, free range, grating floor): 500 m^2 laying hen (battery): 750 m^2 laying hen (free range, litter floor): 1430 m^2 laying hen (free range, grating floor): 1270 m^2	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
alveolar ventilation rate (AVR)	beef cattle: 51 m^3/d dairy cattle: 62 m^3/d calves: 25 m^3/d fattening pigs: 14 m^3/d breeding pigs: 30 m^3/d broiler chicken: 0.2 m^3/d laying hen: 0.2 m^3/d	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
gas constant (R)	8.31451 J/K mol	
molecular weight (MW)	imidacloprid: 255.7 g·mol $^{-1}$ cis-tricos-9-ene: 322.6 g·mol $^{-1}$	
Consumpt. a.s by flies	3.5 mg b.p./day	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017

N_{flies}	10 flies/day	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
Tier 2 (Refined realistic worst-case scenario)		
weight fraction substance (ConsExpo calculation)	imidacloprid 0.0052 cis-tricos-9-ene: 0.001 (fraction of active substance in biocidal product)	Product specific information
use frequency (ConsExpo calculation)	application frequency of biocidal product: up to 6 applications per year	Product specific information
Model (ConsExpo calculation)	exposure to vapour	ConsExpo Fact Sheet
Mode of release (ConsExpo calculation)	constant rate	ConsExpo Fact Sheet
exposure duration (ConsExpo calculation)	default: 24 h	ConsExpo Fact Sheet
product amount (ConsExpo calculation)	application rate: 2.0 g biocidal product/m^2 floor surface (corresponding to 10 mg imidacloprid and 2.0 mg cis-tricos-9-ene per m^2 floor surface). values for individual animal species (considering default stable size) beef cattle: 370 m^2 * 2.0 g/ m^2 = 740 g dairy cattle: 1170 m^2 * 2.0 g/ m^2 = 2340 g calves: 160 m^2 * 2.5 g/ m^2 = 320 g fattening pigs: 600 m^2 * 2.0 g/ m^2 = 1200 g breeding pigs (individual housing): 560 m^2 * 2.0 g/ m^2 = 1120 g breeding pigs (group housing): 710 m^2* 2.0 g/ m^2 = 1420 g broiler chicken (free range, litter floor): 1110 m^2 * 2.0 g/ m^2 = 2220 g broiler chicken (parent broiler, free range, grating floor): 390 m^2 * 2.0 g/ m^2 = 780 g broiler chicken (parent broiler chicken in rearing, free range, grating floor): 500 m^2 * 2.0 g/ m^2 = 1000 g laying hen (battery): 750 m^2 * 2.0 g/ m^2 = 1500 g laying hen (free range, litter floor): 1430 m^2 * 2.0 g/ m^2 = 2860 g laying hen (free range, grating floor): 1270 m^2 * 2.0 g/ m^2 = 2540 g	Product specific information and treated area acc to Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
room volume	beef cattle: 3063 m^3 dairy cattle: 9630 m^3 calves: 590 m^3 fattening pigs: 2110 m^3 breeding pigs (individual housing): 1960 m^3 breeding pigs (group housing): 2480 m^3 broiler chicken (free range, litter floor): 4170 m^3 broiler chicken (parent broiler, free range, grating floor): 1458 m^3 broiler chicken (parent broiler chicken in rearing, free range, grating floor): 1880 m^3	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017

	laying hen (battery): 2810 m^3 laying hen (free range, litter floor): 5360 m^3 laying hen (free range, grating floor): 4780 m^3	
room ventilation rate	beef cattle: 2 per h dairy cattle: 0.9 per h calves: 4.1 per h fattening pigs: 1.9 per h breeding pigs (individual housing): 3.5 per h breeding pigs (group housing): 2.8 per h broiler chicken : 4.3 per h laying hen (battery): 5.2 per h laying hen (free range, litter floor): 1.3 per h laying hen (free range, grating floor): 2.9 per h (winter season as worst case)	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
emission duration (ConsExpo calculation)	4 weeks (worst case estimate for time period during which the product is emitted in the stable.)	ConsExpo Fact Sheet
absorption fraction (ConsExpo calculation)	default: 100 %	ConsExpo Fact Sheet
alveolar ventilation rate (unit as applied in ConsExpo calculation)	beef cattle: 2110 L/h dairy cattle: 2589 L/h h calves: 1032 L/h fattening pigs: 601 L/h breeding pigs: 1267 L/h broiler chicken: 8.2 L/h laying hen: 8.9 L/h	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
Livestock exposure calculations		
Scenario	**Calculation of external livestock exposure**	**Reference**
Screening		
Surface treatment of animal housing (floor area)	$Exp_{ext.\ livestock} = (R_{appl.\ a.s.} \times A_{treated\ stable\ surface}) \div (N_{animals} \times bw_{animal})$	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
Realistic worst case		
Oral (ingestion of dead insects)	$Exp_{ext.\ livestock} = Consumpt._{a.s\ by\ flies.} \times N_{flies} \div bw_{animal}$	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
Inhalative (SVC model)	$Exp_{ext.\ livestock} = (VP \times MW) \div (R \times T) \times AVR \div bw_{animal}$	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017

2. Imidacloprid

2.1 General information

General information on the active substance imidacloprid	
Active substance (Common Name)	imidacloprid
CAS number	138261-41-3
Chemical structure	 only E-isomer

Molecular formular	$C_9H_{10}ClN_5O_2$
Molar mass	255.7 g/mol
Log $P_{o/w}$	pH 5: independent of pH pH 9: independent of pH pH 7: log $P_{O/W}$ = 0.57 (demin. water) at 21 °C
Active substance approval	PT: 18; RMS: DE
Restrictions from active substance approval	AR (2011) section 3.2 6. For products containing imidacloprid that may lead to residues in food or feed, Member States shall verify the need to set new and/or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 and/or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.
Current regulations on MRLs	Regulation (EC) No 491/2014

2.2 Non-biocidal use of imidacloprid

Summary table of other (non-biocidal) uses of imidacloprid			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products	Insecticide used in various plant protection products	MRLs for imidacloprid according to Regulation (EC) No 491/2014: (more information on residue definitions see below) for food of animal origin: Swine, bovine, sheep, goat, horses, other farm animals Muscle 0.1 mg/kg Fat 0.05* mg/kg Liver 0.3 mg/kg Kidney 0.3 mg/kg Edible offal 0.3 mg/kg Poultry (all tissues) 0.05* mg/kg Milk 0.1 mg/kg Bird eggs 0.05* mg/kg Various values for food of plant origin
2.	Veterinary medicinal products	Insecticide against lice and fleas (dogs, cats)	No MRLs available as no veterinary use on food-producing animals

* MRLs set at LOQ

2.3 Nature of residues (imidacloprid)

2.3.1 Stability and hydrolysis

Summary of information on stability and hydrolysis studies (imidacloprid)

	Conditions (Duration, Temperature, pH)	Reference
Hydrolytic stability	pH 5: stable at 25 °C pH 7: stable at 25 °C pH 9: DT50 approx. 1 year at 25 °C DT50 2.75 years (calculation to EU outdoor Temperature at 12 °C)	Imidacloprid, Assessment Report 2011, RMS: DE
Photolytic stability	pH 7: 30 - 50° latitude (calculation) DT50 experimental: 57 min, DT50 calculated: 0.2 - 1.6 days (spring, summer) 1.4 - 16 days (fall, winter)	Imidacloprid, Assessment Report 2011, RMS: DE

2.3.2 Metabolism in livestock

Summary of animal metabolism studies (imidacloprid)								
Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of sampling**	
Lactating ruminants	Goat	[pyridinyl-^{14}C-methylene] label	1	10	3	Milk	twice daily	CAR (2011), Doc IIIA 6.15.3/01 and 02
						Urine and faeces	24h, 48h, 50h	
						Tissues	50h (at sacrifice)	
Laying poultry	Hens	[pyridinyl-^{14}C-methylene] label	5	10	3	Eggs	24h, 48h	CAR (2011), Doc IIIA 6.15.3/03 and 04
						Excreta	24h, 48h, 50h	
						Tissues	50h	

Results of animal metabolism studies (imidacloprid)	
Animals covered	Lactating goats, laying hens
Time needed to reach a plateau concentration	No conclusion on milk and eggs based on the metabolism studies
Description of animal metabolism	Absorption, distribution and elimination of imidacloprid was a rather fast process in the investigated livestock species. Only an amount of 0.3 % of the administered dose was found in goat milk.

	The metabolism proceeds through several pathways, including hydroxylation of the imidazolidine ring, step-wise reduction and loss of the nitro group, opening and progressive degradation of the imidazolidine ring and cleavage of the methylene ring whereas the qualitative and quantitative composition of the metabolic spectrum varies among the animal species and tissues. Parent imidacloprid, 5-hydroxy-imidacloprid (M01) and imidacloprid-olefine (M06) formed the major part of the TRR in muscle, fat, milk, eggs and kidney. However, all metabolites identified contained the 6-chloropyridinyl moiety of imidacloprid and were identified as the moiety of toxicological significance.
Residues detected in edible tissues	(residues of parent imidacloprid only = DoR acc. to Reg (EU) 396/2005) Goat (CAR (2011), Doc IIIA 6.15.3/03 and 04) muscle 2.55 mg/kg, fat 1.39 mg/kg, kidney 0.838 mg/kg, milk 0.50 mg/kg Laying hens (CAR (2011), Doc IIIA 6.15.3/04) muscle 0.138 mg/kg, fat 0.191 mg/kg, eggs 0.023 mg/kg
Metabolism in rat and ruminant similar	yes
Fat soluble residue	no (log $P_{O/W}$ = 0.57, see AR (2011))

2.3.3 Conclusion and summary (imidacloprid)

Summary on the nature of residues (imidacloprid)	
Stability under standard hydrolysis conditions Processed commodities	a.s. is stable under standard hydrolysis conditions (room temperature, pH 5, 7, 9), conditions simulating food processing were not tested
Animal metabolism	analysed on lactating goat and laying hen (see above)
Existing plant residue definitions	from evaluation of plant protection products **Monitoring**: Currently: Parent compound imidacloprid only (according to Regulation (EC) No 396/2005) DE originally proposed "sum of imidacloprid, 5-hydroxy-imidacloprid and imidacloprid olefine, expressed as imidacloprid" for reasons of analytical feasibility. Re-analysis of field samples for these compounds, however, revealed a great variability of their individual fractions, making it difficult to derive conversion factors. The problem was presented by DE (RMS) to the experts of the PRIMA working group on 15/02/2011 but no final decision was made on the further strategy. New residue trials are currently conducted. EFSA also discussed to use the same DoR for monitoring as for risk assessment (EFSA's Conclusion on the peer review, 2008). **Risk assessment**: Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid (EFSA's Conclusion on the peer review, 2008).

	Conversion factors (monitoring to risk assessment): not concluded
Existing animal residue definitions	from evaluation of plant protection products **Monitoring**: Sum of imidacloprid and its metabolites imidacloprid-5-hydroxy (M01) and imidacloprid-olefine (M06), expressed as imidacloprid (It should be noted that according to Regulation (EC) No 396/2005 the DoR for animal commodities is currently restricted to imidacloprid.) **Risk assessment**: Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid (EFSA's Conclusion on the peer review, 2008). **Conversion factors** (monitoring to risk assessment): not concluded
Conclusion on degradation of active substance under use conditions	Degradation of imidacloprid under conditions of the intended biocidal use is not expected to deviate from the degradation reported for uses in plant protection products

2.4 Estimating Livestock Exposure to imidacloprid

2.4.1 Tier 1: External exposure assessment for livestock animals

External exposure assessment for livestock animals has been performed according to Guidance on Estimating Livestock Exposure to Biocidal Active Substances (Guidance on BPR (2017), Vol. III, Parts B+C, section 6). In Tier 1 external livestock exposure has been performed calculating the screening scenario as well as realistic worst case exposure scenarios. Default values and assumptions were applied as listed in the description of scenarios above. Results are reported for the representative animal species beef and dairy cattle, calf, pig, broiler chicken and laying hen.

Screening scenario: External Livestock exposure (mg imidacloprid/kg bw/d)							
	Beef cattle	**Dairy cattle**	**Calf**	**Pig**	**Broiler chicken**	**Laying hen**	
Screening	0.0592	0.1800	0.1000	fattening 0.1500 breeding (individual) 0.1632 breeding (group) 0.2069	free range, litter floor 0.3265 free range. grating floor 0.3277 parent broilers in rearing 0.3268	battery 0.1880 free range, litter floor 0.7526 free range. grating floor 0.3342	

Trigger value exceeded?	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Realistic worst-case scenarios: External Livestock exposure (mg imidacloprid/kg bw/d)							
	Beef cattle	**Dairy cattle**	**Calf**	**Pig**	**Broiler chicken**	**Laying hen**	
Tier 1 Oral (ingestion of dead insects)	n.a.	n.a.	n.a.	n.a.	0.1029	0.0921	
Tier 1 Inhalative (SVC model)	$9.29x10^{-9}$	$8.86x10^{-9}$	$1.16x10^{-8}$	fattening $1.30x10^{-8}$ breeding $1.07x10^{-8}$	$1.09x10^{-8}$	$9.78x10^{-8}$	
Sum	$9.29x10^{-9}$	$8.86x10^{-9}$	$1.16x10^{-8}$	fattening $1.30x10^{-8}$ breeding $1.07x10^{-8}$	0.1029	0.0921	
Trigger value exceeded?	No	No	No	No	Yes	Yes	

n.a.: not applicable

Conclusions on Tier 1 calculations of external livestock exposure for imidacloprid

The external exposure estimate for livestock animals using the screening scenarios show that the trigger value is exceeded for all animal species.

The calculation of realistic worst case scenarios identified the following critical scenario with external livestock exposure above the trigger value that requires further refinement:

- oral exposure scenario “ingestion of dead insects” for broiler chicken and laying hen

For all animal species, the calculation of inhalation exposure (SVC model) only resulted in a minor contribution to total external animal exposure due to low vapour pressure of imidacloprid. No further refinement is required.

2.4.2 Tier 2: Refined exposure estimate for livestock animals

According to the Guidance on Estimating Livestock Exposure to Biocidal Active Substances a Tier 2 refinement is performed for the critical exposure scenario “ingestion of dead insects” (for broiler chicken and laying hen) identified in Tier 1.

The “ingestion of dead insects” scenario applied in tier 1 considers daily uptake of 3.5 mg biocidal product per fly (based on sucrose uptake by flies) corresponding to 0.0182 mg imidacloprid/fly per day. Furthermore it is assumed that one chicken eats 10 flies per day resulting in a daily imidacloprid exposure of 0.182 mg imidacloprid/chicken.

Refined exposure estimate: Estimated internal exposure livestock exposure (mg imidacloprid /kg bw/d)							
Refinement of oral exposure - Metabolism studies with imidacloprid in laying hen described in the CAR (2011) reported residues of 0.138, 0.191, and 0.23 mg/kg imidacloprid in muscle, fat and eggs, respectively, following a daily exposure of 10 mg imidacloprid on 3 consecutive days. Considering the about 50-fold higher daily dosage in the metabolism study compared to the estimated imidacloprid uptake of 0.182 mg/chicken/day from (scenario "ingestion of dead insects") expected residues were extrapolated for **meat, fat and eggs**. - Residues in chicken **liver and kidney** were calculated from the maximal external oral exposure estimate for chicken (broiler chicken: 0.1029 mg/kg bw/d, laying hen: 0.0921mg/kg bw/d) and a transfer factor of 0.3 for liver and kidney (chosen as applicable for imidacloprid with an Log Po/w of 0.57)[a]							
	Beef cattle	**Dairy cattle**	**Calf**	**Pig**	**Broiler chicken**	**Laying hen**	
Tier 2 Oral (ingestion of dead insects)	n.a.	n.a.	n.a.	n.a.	meat [b] 0.0028 fat [b] 0.0038 liver [c] 0.0309 kidney [c] 0.0309	meat [b] 0.0028 fat [b] 0.0038 liver [c] 0.0276 kidney [c] 0.0276 eggs [b] 0.0046	
Conclusion The refinement of the **oral exposure** estimate for chicken ingesting dead insects results in estimated residues of imidacloprid up to a maximum of 0.0309 mg/kg bw/d which is below the current MRLs for chicken edible tissues set at the LOQ of 0.05* mg/kg.							

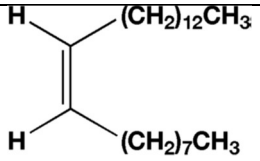
[a] Leeman et al. (2007): Transfer of chemicals from feed to animal products: the use of transfer factors in risk assessment. Food additives and contaminants; 24, 1-13

Conclusion on Tier 2 refinements of livestock exposure assessment for imidacloprid
Refinement of the critical scenarios identified in Tier 1 shows that relevant residues of imidacloprid in livestock animal tissues from the intended uses of SOFAST in animal facilities are not expected. Residues in poultry edible tissues and eggs do not exceed the current MRLs of 0.05* mg imidacloprid/kg.

3. Cis-tricos-9-ene

3.1 General information

General information on the active substance cis-tricos-9-ene	
Active substance (Common Name)	Muscalure (ESA name; there is no ISO common name for this substance)
CAS number	27519-02-4

Chemical structure	
Molecular formular	$C_{23}H_{46}$
Molar mass	322.6
Log Po/w	pH 4: >8.2 (20 °C) pH 7: >8.2 (20 °C) pH 10: >8.2 (20 °C) (no pH dependency expected)
Active substance approval	PT 19 (2012, RMS: AT)
Restrictions from active substance approval	CAR (2012) Doc I 3.3 c No dietary risk assessment was submitted by the applicant. Oral exposure estimates of farm animals result above the actually proposed dietary risk assessment trigger value of 0.004 mg/kg bw. Inhalative exposure of farm animals kept in stables / animal houses, where Denka Flylure is used as intended, was estimated only as Tier 1 without refinements and acceptable risk was only shown for cattle and pigs, not for poultry. No acceptable data on analytic methods and exposure of food/feeding stuff were provided. Therefore for products containing cis-tricos-9-ene that may lead to residues in food or feed, Member States shall verify the need to set new or to amend 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. In addition a refined risk assessment for farm animals and data on analytic methods of food/feeding stuff, as appropriate – may therefore be required at product authorisation stage.
Current regulations on MRLs	Active substance not approved for plant protection products: Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396 / 2005 applies.

3.2 Non-biocidal use of cis-tricos-9-ene

Naturally occurring pheromone (attractant) produced by flies and bees. No further information is available on non-biocidal uses.

3.3 Nature of residues (**cis-tricos-9-ene**)

3.3.1 Stability and hydrolysis

Summary of information on stability and hydrolysis studies (cis-tricos-9-ene)		
	Conditions (Duration, Temperature, pH)	**Reference**
Hydrolytic stability	not determined as muscalure does not contain hydrolysable functional groups	Cis-tricos-9-ene, Assessment Report 2012, RMS: AT
Photolytic stability	not determined	Cis-tricos-9-ene, Assessment Report 2012, RMS: AT

3.3.2 Metabolism in livestock

Information on metabolism of cis-tricos-9-ene in laboratory and livestock animals is not available as data has been waived (see CAR (2012) Doc IIA 3.1 for waiver according to Guidance for Waiving of Data Requirements for Pheromones for Inclusion in Annex I/IA of Directive 98/8/EC, 2005, Addendum to the Technical Notes on Data Requirements, ECB, 2008.).

It is assumed that cis-tricos-9-ene is fat soluble as a log $P_{O/W}$ above 8.2 has been reported in the CAR (2012).

3.3.3 Conclusion and summary (cis-tricos-9-ene)

Summary on nature of residues (cis-tricos-9-ene)	
Stability under standard hydrolysis conditions Processed commodities	stability under hydrolysis conditions was not determined
Animal metabolism	not determined
Existing plant residue definitions	not available
Existing animal residue definitions	not available
Conclusion on degradation of active substance under use conditions	no conclusion

3.4 Estimating Livestock Exposure to cis-tricos-9-ene

3.4.1 Tier 1: External exposure assessment for livestock animals

External exposure assessment for livestock animals has been performed according to Guidance on Estimating Livestock Exposure to Biocidal Active Substances. In Tier 1, external livestock exposure has been performed calculating the screening scenario as well as realistic worst case exposure scenarios. Default values and assumptions were applied as listed in the description of scenarios above. Results are reported for the representative animal species beef and dairy cattle, calf, pig, broiler chicken and laying hen.

Screening scenario: External Livestock exposure (mg cis-tricos-9-ene/kg bw/d)							
	Beef cattle	**Dairy cattle**	**Calf**	**Pig**	**Broiler chicken**	**Laying hen**	
Screening	0.0118	0.0360	0.0200	fattening 0.0300	free range, litter floor 0.0653	battery 0.0376	

				breeding (individual) 0.0326 breeding (group) 0.0414	free range. grating floor 0.0655 parent broilers in rearing 0.0654	free range. litter floor 0.1505 free range. grating floor 0.0668	
Trigger value exceeded?	Yes	Yes	Yes	Yes	Yes	Yes	

Realistic worst-case scenarios: External Livestock exposure (mg cis-tricos-9-ene/kg bw/d)							
	Beef cattle	**Dairy cattle**	**Calf**	**Pig**	**Broiler chicken**	**Laying hen**	
Tier 1 Oral (ingestion of dead insects)	n.a.	n.a.	n.a.	n.a.	0.0206	0.0184	
Tier 1 Inhalative (SVC model)	0.8475	0.8084	1.059	fattening 1.187 breeding 0.9779	0.9971	0.8921	
Sum	0.8475	0.8084	1.059	fattening 1.187 breeding 0.9779	1.0177	0.9105	
Trigger value exceeded?	Yes	Yes	Yes	Yes	Yes	Yes	

n.a.: not applicable

Conclusion on Tier 1 calculations of external livestock exposure for cis-tricos-9-ene:

The external exposure estimate for livestock animals using the screening scenarios and relevant realistic worst-case scenarios shows that the trigger value of 0.004 mg/kg bw/d is exceeded for all animal species. Therefore further refinement of the assessment is required.

3.4.2 Tier 2: Refined exposure estimate for livestock animals

Refinement of oral exposure scenario “ingestion of dead insects” for laying hen and broiler chicken

The “ingestion of dead insects” scenario applied in Tier 1 considers a daily uptake of 3.5 mg biocidal product per fly (based on sucrose uptake by flies) corresponding to 0.0035 mg cis-tricos-9-ene/fly per day. Furthermore it is assumed that one chicken eats 10 flies per day resulting in a daily exposure of 0.035 mg cis-tricos-9-ene/chicken.

As a Tier 2 refinement option the Guidance on Estimating Livestock Exposure to Biocidal Active Substances (Guidance on BPR, Vol III, Parts B+C, section 6) proposes to use LD_{50} values of the active substance to determine a more realistic concentration of the biocidal product in/on flies.

Refinement of inhalation exposure

In Tier 1 inhalation exposure of livestock animals has been estimated using the SVC model, which assumes as worst case that livestock animals are exposed to air containing cis-tricos-9-ene at its saturated vapor concentration (SVC).
As Tier 2 the estimation of inhalation exposure was refined using the ConsExpo 4.1 model "Inhalation: Exposure to vapour – constant rate" that considers more realistic conditions such as the applied amount of biocidal product, room volume and room ventilation rates.
Results of the calculations estimating inhalation exposure from treated surfaces are summarized in the table below.

Refined realistic worst-case scenario: External livestock exposure (mg cis-tricos-9-ene /kg bw/d)

Refinement of oral exposure
- Recalculation of the realistic worst-case estimate for the oral exposure scenario "dead insects" for chicken considering that one fly contains 740 ng cis-tricos-9-ene.
  Justification: An LD_{50} of imidacloprid in Musca domestica has been determined in the range of 2400 – 3700 ng/fly[a]. The LD_{50} level of 3700 ng imidacloprid/fly corresponds to 0.74 mg biocidal product SOFAST which also contains 740 ng cis-tricos-9-ene/fly[b]. It is considered acceptable to base the refinement on the LD_{50} levels of imidacloprid as the relative amount of cis-tricos-9-ene on treated surfaces compared to imidacloprid will rapidly decline due to the high volatility of the attractant.

Refinement of inhalation exposure
- Calculation of livestock animal exposure to cis-tricos-9-ene using the ConsExpo 4.1 inhalation model "Exposure to vapour – Constant rate".
- Default values as reported in section "Representative dietary exposure scenarios", table "Values and assumptions applied in livestock exposure calculations" above.
- ConsExpo reports for the individual animal species are reproduced at the end of the Annex Residue behaviour.

	Beef cattle	**Dairy cattle**	**Calf**	**Pig**	**Broiler chicken**	**Laying hen**	
Tier 2 Oral (ingestion of dead insects)	n.a.	n.a.	n.a.	n.a.	0.0043	0.0039	
Tier 2 Inhalative (Cons Expo 4.1)	0.00050	0.00102	0.000675	fattening 0.00176 breeding (individual) 0.00151 breeding (group) 0.00193	free range, litter floor 0.00059 free range. grating floor 0.00059 parent broilers in rearing 0.00059	battery 0.000476 free range, litter floor 0.00186 free range. grating floor 0.000845	
Sum	0.00050	0.00102	0.000675	fattening 0.00176 breeding (individual) 0.00151 breeding (group) 0.00193	free range, litter floor 0.00489 free range. grating floor 0.00489 parent broilers in rearing	battery 0.004376 free range, litter floor 0.00576 free range. grating floor 0.0004745	

					0.00489		
Trigger value exceeded?	No	No	No	No	see conclusion below	see conclusion below	

Conclusion

The refinement of the **oral exposure** estimate for chicken ingesting dead insects results in exposure values for cis-tricos-9-ene up to 0.00576 mg/kg bw/d. However, when deriving the overall trigger value of 0.004 mg/kg bw/d (for all animal species) for the Guidance on Estimating Livestock Exposure to Biocidal Active Substances the value derived for chicken as individual species was 0.0063 mg/kg bw/d. Therefore, the slight exceedance of the overall trigger value is considered acceptable and no further assessment of residues in chicken edible tissues needs to be performed.

The refinement of the **inhalation exposure** estimate for cis-tricos-9-ene results in exposure values well below the trigger value of 0.004 mg/kg bw/d in all livestock animals. Significant residues in livestock animals from inhalation exposure are not expected.

[a] LD_{50} of imidacloprid as published in Cross-Resistance to Imidacloprid in Strains of German Cockroach (*Blatella germanica*) and House Fly (*Musca domestica*), Wen Z and Scott JG, Pestic. Sci. (1997), 49, pp. 367-371. This value is in the same order of magnitude as the value used in the applicant´s dossier (average LC 95 of 243 ug/g = 2917 ng for a 12 fly based on data published in Monitoring permethrin and imidacloprid resistance in Indonesian house fly Musca domestica L. (Diptera: Muscidae), Kustiati et al., J. Entomol. (2016) 13 (1-2): 40-47.

[b] Note: The estimated uptake of 740 ng cis-tricos-9-ene/fly is below the maximum naturally occurring amount of up to 1500 ng/fly that has been detected in houseflies (Correlation of Housefly Sex Pheromone Production with Ovarian Development, Dillwith JW, Adams TS and Blomquist GJ, J. Insect Physiol (1983), Vol 29 No 5, pp. 377-386).

Conclusion on Tier 2 refinements of livestock exposure assessment for cis-tricos-9-ene

Refinement of the critical scenarios identified in Tier 1 shows that based on label restrictions and additional information on the LD_{50} of imidacloprid relevant residues of cis-tricos-9-ene in livestock animal tissues from the intended uses of SOFAST in animal facilities are not expected. Residues livestock edible tissues do not exceed the default MRLs of 0.01* mg/kg that applies for cis-tricos-9-ene.

4. Estimated dietary consumer exposure

Dietary consumer exposure to imidacloprid from the intended biocidal use is considered low compared to other non-biocidal uses. Dietary risk assessment has been performed based on existing MRLs for imidacloprid.

Summary of human dietary exposure for imidacloprid			
Chronic consumer exposure via food (mg a.s./kg bw)	**Estimated consumer exposure**	**Critical consumer group**	**Remarks**
MRLs acc. to Reg. (EU) No 491/2014	60 % of ADI	NL toddler	EFSA PRIMo rev 3.1* ADI: 0.06 mg/kg (Pesticide Web)

* Screenshot of the EFSA PRIMo calculation at the end of this annex

4.2 Cis-tricos-9-ene

Based on the residue assessment performed above relevant residues of cis-tricos-9-ene in food and feed are not expected. Dietary risk assessment has been performed based on the default MRL that is applicable for the cis-tricos-9-ene. As an ADI is not available for cis-tricos-9-ene the long-term AEL as reported in the CAR has been applied as toxicological reference value. This long-term AEL of 0.024 mg/kg bw/day is based on the “Threshold of Toxicological Concern” of 1800 µg/day (as supported e.g. by ILSI

2005, International Life Sciences Institute) and the long term intake rates of the structurally related higher-mono-alkenes (C17:1- C30:1) as natural food component (CAR (2012), Doc I 2.1.5.4).

Summary of human dietary exposure for cis-tricos-9-ene			
Chronic consumer exposure via food (mg a.s./kg bw)	**Estimated consumer exposure**	**Critical consumer group**	**Remarks**
Default MRL acc to Art 1881)(b) Reg. 396/2005	<0.1 % of long-term AEL	Uk adult	EFSA PRIMo rev 3.1* $AEL_{long\text{-}term}$: 0.024 mg/kg (CAR)

* Screenshot of the EFSA PRIMo calculation at the end of this annex

5. Overall conclusion on dietary exposure and risk assessment

The biocidal product is to be used as an insecticide against flies in industrial/commercial premises, households/private areas, public areas as well as livestock animal facilities.

For the intended **uses in industrial/commercial, households/private areas and public areas** contact with food, feed or livestock animals is avoided by applying appropriate risk mitigation measures. Consequently imidacloprid and cis-tricos-9-ene residues in food are not expected and a risk for consumers via residues in food is excluded.

For **uses in animal facilities** the results of the livestock exposure estimate indicate that transfer of relevant residues into animal edible tissues is not expected and residues of imidacloprid and cis-tricos-9-ene in food of animal origin above the existing MRLs according to Regulation (EU) No. 396/2005 are not expected.
A risk for consumers via residues of imidacloprid and cis-tricos-9-ene in food of animal origin is not expected, provided that appropriate risk mitigation measures are observed.

The following risk mitigation measures are proposed:

- 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.
- The product can be applied in the presence of animals, if contact with the biocidal product is avoided.
- Place cardboards (treated with biocidal product) or bait stations out of reach of livestock animals
- Do not apply the biocidal product directly on manure/slurry.

Appendix: Consexpo reports

ConsExpo 4.1 report

file name: beef cattle
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	500	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	3,06E3	m3
ventilation rate	2	1/hr
applied amount	740	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	2,11E3	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,00492	mg/m3
inhalation mean concentration on day of exposure:	0,00492	mg/m3
inhalation air concentration year average :	0,00492	mg/m3/day
inhalation acute (internal) dose :	0,000499	mg/kg
inhalation chronic (internal) dose :	0,000498	mg/kg/day

Integrated (point estimates)

total external dose:	0,000499	mg/kg
total acute dose (internal):	0,000499	mg/kg
total chronic dose (internal):	0,000498	mg/kg/day

ConsExpo 4.1 report

file name: dairy cattle
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	650	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	9,63E3	m3
ventilation rate	0,9	1/hr
applied amount	2,34E3	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	2,59E3	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,0107	mg/m3
inhalation mean concentration on day of exposure:	0,0107	mg/m3
inhalation air concentration year average :	0,0107	mg/m3/day
inhalation acute (internal) dose :	0,00102	mg/kg
inhalation chronic (internal) dose :	0,00102	mg/kg/day

Integrated (point estimates)

total external dose:	0,00102	mg/kg
total acute dose (internal):	0,00102	mg/kg
total chronic dose (internal):	0,00102	mg/kg/day

ConsExpo 4.1 report

file name: calf
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	200	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	590	m3
ventilation rate	4,1	1/hr
applied amount	320	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	1,03E3	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,00545	mg/m3
inhalation mean concentration on day of exposure:	0,00545	mg/m3
inhalation air concentration year average :	0,00545	mg/m3/day
inhalation acute (internal) dose :	0,000675	mg/kg
inhalation chronic (internal) dose :	0,000675	mg/kg/day

Integrated (point estimates)

total external dose:	0,000675	mg/kg
total acute dose (internal):	0,000675	mg/kg
total chronic dose (internal):	0,000675	mg/kg/day

ConsExpo 4.1 report

file name: fattening pigs
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	100	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	2,11E3	m3
ventilation rate	1,9	1/hr
applied amount	1,2E3	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	601	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,0122	mg/m3
inhalation mean concentration on day of exposure:	0,0122	mg/m3
inhalation air concentration year average :	0,0122	mg/m3/day
inhalation acute (internal) dose :	0,00176	mg/kg
inhalation chronic (internal) dose :	0,00176	mg/kg/day

Integrated (point estimates)

total external dose:	0,00176	mg/kg
total acute dose (internal):	0,00176	mg/kg
total chronic dose (internal):	0,00176	mg/kg/day

ConsExpo 4.1 report

file name: breeding pigs, individual housing
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	260	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	1,96E3	m3
ventilation rate	1,8	1/hr
applied amount	1,12E3	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	1,27E3	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,0129	mg/m3
inhalation mean concentration on day of exposure:	0,0129	mg/m3
inhalation air concentration year average :	0,0129	mg/m3/day
inhalation acute (internal) dose :	0,00151	mg/kg
inhalation chronic (internal) dose :	0,00151	mg/kg/day

Integrated (point estimates)

total external dose:	0,00151	mg/kg
total acute dose (internal):	0,00151	mg/kg
total chronic dose (internal):	0,00151	mg/kg/day

ConsExpo 4.1 report

file name: breeding pigs, group housing
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	260	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	2,48E3	m3
ventilation rate	1,4	1/hr
applied amount	1,42E3	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	1,27E3	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,0165	mg/m3
inhalation mean concentration on day of exposure:	0,0165	mg/m3
inhalation air concentration year average :	0,0165	mg/m3/day
inhalation acute (internal) dose :	0,00193	mg/kg
inhalation chronic (internal) dose :	0,00193	mg/kg/day

Integrated (point estimates)

total external dose:	0,00193	mg/kg
total acute dose (internal):	0,00193	mg/kg
total chronic dose (internal):	0,00193	mg/kg/day

ConsExpo 4.1 report

file name: broilers, free range, litter floor
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	1,7	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	4,17E3	m3
ventilation rate	4,3	1/hr
applied amount	2,22E3	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	8,2	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,0051	mg/m3
inhalation mean concentration on day of exposure:	0,0051	mg/m3
inhalation air concentration year average :	0,0051	mg/m3/day
inhalation acute (internal) dose :	0,000591	mg/kg
inhalation chronic (internal) dose :	0,00059	mg/kg/day

Integrated (point estimates)

total external dose:	0,000591	mg/kg
total acute dose (internal):	0,000591	mg/kg
total chronic dose (internal):	0,00059	mg/kg/day

ConsExpo 4.1 report

file name: broilers, free range, grating floor
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	1,7	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	1,46E3	m3
ventilation rate	4,3	1/hr
applied amount	780	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	8,2	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,00513	mg/m3
inhalation mean concentration on day of exposure:	0,00513	mg/m3
inhalation air concentration year average :	0,00513	mg/m3/day
inhalation acute (internal) dose :	0,000594	mg/kg
inhalation chronic (internal) dose :	0,000593	mg/kg/day

Integrated (point estimates)

total external dose:	0,000594	mg/kg
total acute dose (internal):	0,000594	mg/kg
total chronic dose (internal):	0,000593	mg/kg/day

ConsExpo 4.1 report

file name: broilers, parent broilers in rearing, free range, grating floor
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	1,7	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	1,88E3	m3
ventilation rate	4,3	1/hr
applied amount	1E3	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	8,2	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,0051	mg/m3
inhalation mean concentration on day of exposure:	0,0051	mg/m3
inhalation air concentration year average :	0,0051	mg/m3/day
inhalation acute (internal) dose :	0,00059	mg/kg
inhalation chronic (internal) dose :	0,00059	mg/kg/day

Integrated (point estimates)

total external dose:	0,00059	mg/kg
total acute dose (internal):	0,00059	mg/kg
total chronic dose (internal):	0,00059	mg/kg/day

ConsExpo 4.1 report

file name: laying hen, battery
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	1,9	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	2,81E3	m3
ventilation rate	5,2	1/hr
applied amount	1,5E3	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	8,9	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,00424	mg/m3
inhalation mean concentration on day of exposure:	0,00424	mg/m3
inhalation air concentration year average :	0,00424	mg/m3/day
inhalation acute (internal) dose :	0,000477	mg/kg
inhalation chronic (internal) dose :	0,000476	mg/kg/day

Integrated (point estimates)

total external dose:	0,000477	mg/kg
total acute dose (internal):	0,000477	mg/kg
total chronic dose (internal):	0,000476	mg/kg/day

ConsExpo 4.1 report

file name: laying hen, free range, litter floor
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	1,9	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	5,36E3	m3
ventilation rate	1,3	1/hr
applied amount	2,86E3	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	8,9	liter/h

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,0165	mg/m3
inhalation mean concentration on day of exposure:	0,0165	mg/m3
inhalation air concentration year average :	0,0165	mg/m3/day
inhalation acute (internal) dose :	0,00186	mg/kg
inhalation chronic (internal) dose :	0,00186	mg/kg/day

Integrated (point estimates)

total external dose:	0,00186	mg/kg
total acute dose (internal):	0,00186	mg/kg
total chronic dose (internal):	0,00186	mg/kg/day

ConsExpo 4.1 report

file name: laying hen, free range, grating floor
Report date: 08.01.2016

Product

SOFAST

Compound

Compound name :	cis-tricos-9-ene	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	365	1/year
body weight	1,9	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,001	fraction
exposure duration	24	hour
room volume	4,78E3	m3
ventilation rate	2,9	1/hr
applied amount	2,54E3	gram
release duration	24	hour

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	8,9	liter/h

Output

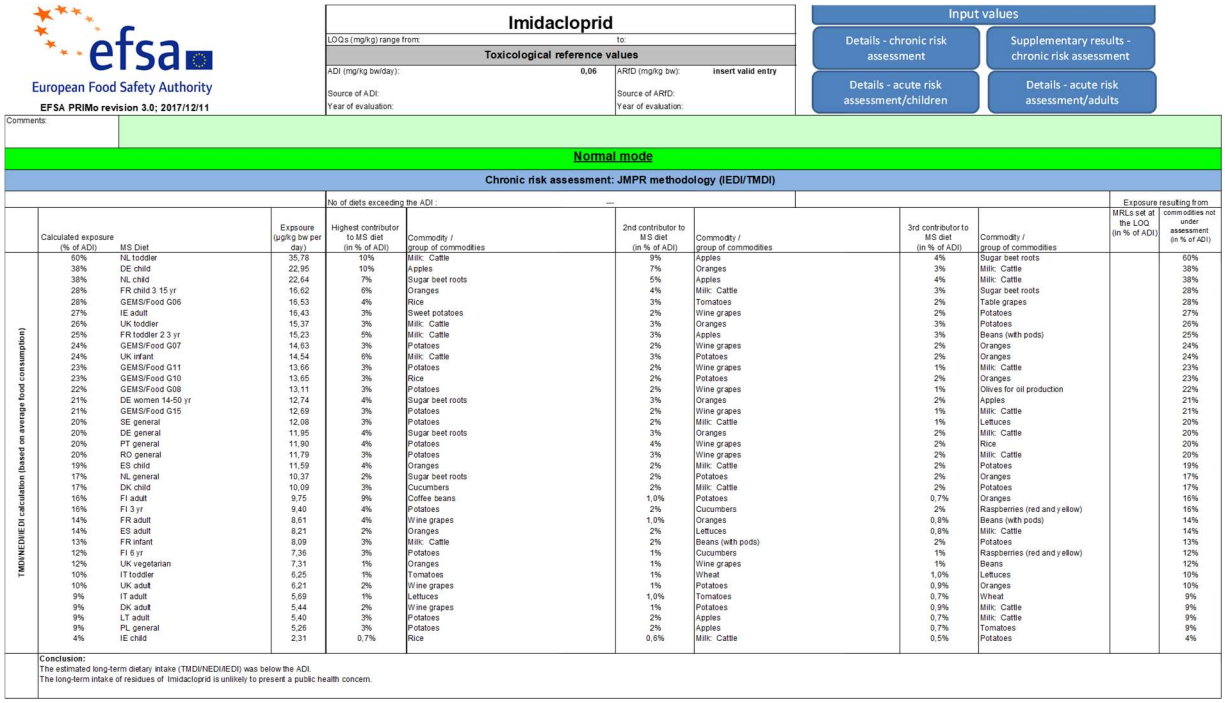
Inhalation (point estimates)

inhalation mean event concentration :	0,00752	mg/m3
inhalation mean concentration on day of exposure:	0,00752	mg/m3
inhalation air concentration year average :	0,00751	mg/m3/day
inhalation acute (internal) dose :	0,000845	mg/kg
inhalation chronic (internal) dose :	0,000845	mg/kg/day

Integrated (point estimates)

total external dose:	0,000845	mg/kg
total acute dose (internal):	0,000845	mg/kg
total chronic dose (internal):	0,000845	mg/kg/day

Appendix: Screenshots of TMDI calculation, based on PRIMo rev.3.1.



efsa European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Imidacloprid

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,06	ARfD (mg/kg bw):	insert valid entry
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values: Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

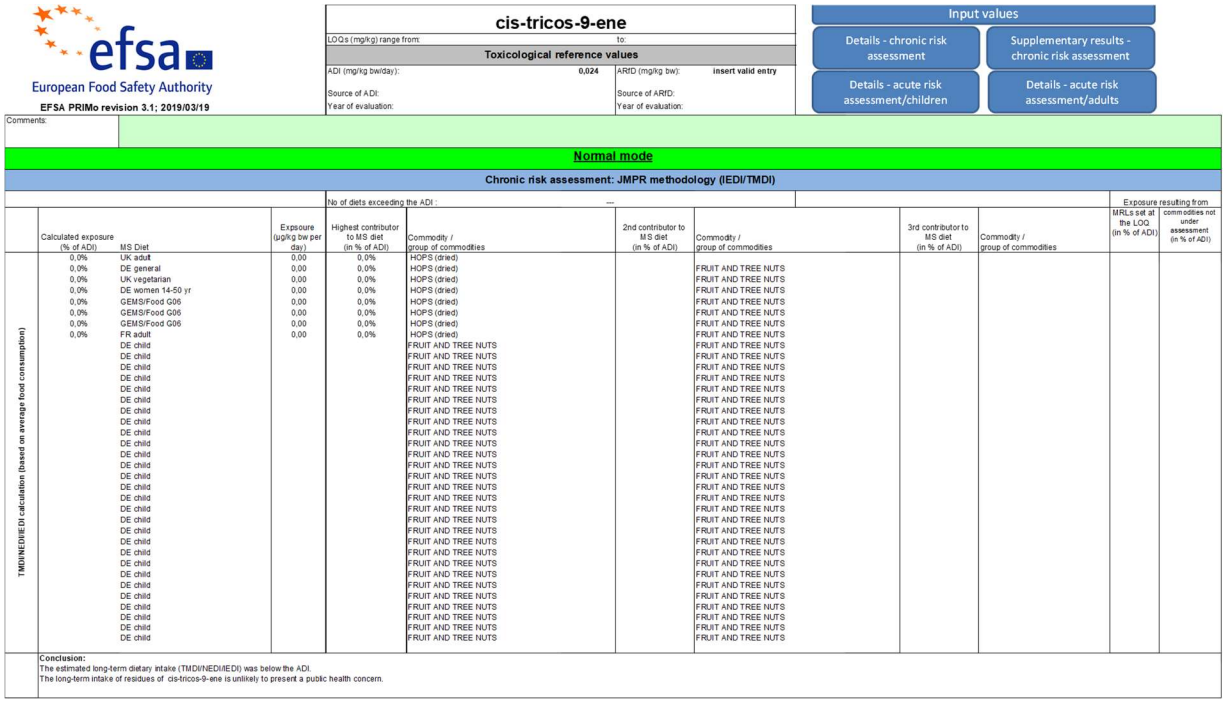
Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
60%	NL toddler	35,78	10%	Milk: Cattle	9%	Apples	4%	Sugar beet roots		60%
38%	DE child	22,95	10%	Apples	7%	Oranges	3%	Milk: Cattle		38%
38%	NL child	22,64	7%	Sugar beet roots	5%	Apples	4%	Milk: Cattle		38%
28%	FR child 3 15 yr	16,62	6%	Oranges	4%	Milk: Cattle	3%	Sugar beet roots		28%
28%	GEMS/Food G06	16,53	4%	Rice	3%	Tomatoes	2%	Table grapes		28%
27%	IE adult	16,43	3%	Sweet potatoes	2%	Wine grapes	2%	Potatoes		27%
26%	UK toddler	15,37	3%	Milk: Cattle	3%	Oranges	3%	Potatoes		26%
25%	FR toddler 2 3 yr	15,23	5%	Milk: Cattle	3%	Apples	3%	Beans (with pods)		25%
24%	GEMS/Food G07	14,63	3%	Potatoes	2%	Wine grapes	2%	Oranges		24%
24%	UK infant	14,54	6%	Milk: Cattle	3%	Potatoes	2%	Oranges		24%
23%	GEMS/Food G11	13,66	3%	Potatoes	2%	Wine grapes	1%	Milk: Cattle		23%
23%	GEMS/Food G10	13,65	3%	Rice	2%	Potatoes	2%	Oranges		23%
22%	GEMS/Food G08	13,11	3%	Potatoes	2%	Wine grapes	1%	Olives for oil production		22%
21%	DE women 14-50 yr	12,74	4%	Sugar beet roots	3%	Oranges	2%	Apples		21%
21%	GEMS/Food G15	12,69	3%	Potatoes	2%	Wine grapes	1%	Milk: Cattle		21%
20%	SE general	12,08	3%	Potatoes	2%	Milk: Cattle	1%	Lettuces		20%
20%	DE general	11,95	4%	Sugar beet roots	3%	Oranges	2%	Milk: Cattle		20%
20%	PT general	11,90	4%	Potatoes	4%	Wine grapes	2%	Rice		20%
20%	RO general	11,79	3%	Potatoes	3%	Wine grapes	2%	Milk: Cattle		20%
19%	ES child	11,59	4%	Oranges	2%	Milk: Cattle	2%	Potatoes		19%
17%	NL general	10,37	2%	Sugar beet roots	2%	Potatoes	2%	Oranges		17%
17%	DK child	10,09	3%	Cucumbers	2%	Milk: Cattle	2%	Potatoes		17%
16%	FI adult	9,75	9%	Coffee beans	1,0%	Potatoes	0,7%	Oranges		16%
16%	FI 3 yr	9,40	4%	Potatoes	2%	Cucumbers	2%	Raspberries (red and yellow)		16%
14%	FR adult	8,61	4%	Wine grapes	1,0%	Oranges	0,8%	Beans (with pods)		14%
14%	ES adult	8,21	2%	Oranges	2%	Lettuces	0,8%	Milk: Cattle		14%
13%	FR infant	8,09	3%	Milk: Cattle	2%	Beans (with pods)	2%	Potatoes		13%
12%	FI 6 yr	7,36	3%	Potatoes	1%	Cucumbers	1%	Raspberries (red and yellow)		12%
12%	UK vegetarian	7,31	1%	Oranges	1%	Wine grapes	1%	Beans		12%
10%	IT toddler	6,25	1%	Tomatoes	1%	Wheat	1,0%	Lettuces		10%
10%	UK adult	6,21	2%	Wine grapes	1%	Potatoes	0,9%	Oranges		10%
9%	IT adult	5,69	1%	Lettuces	1,0%	Tomatoes	0,7%	Wheat		9%
9%	DK adult	5,44	2%	Wine grapes	1%	Potatoes	0,9%	Milk: Cattle		9%
9%	LT adult	5,40	3%	Potatoes	2%	Apples	0,7%	Milk: Cattle		9%
9%	PL general	5,26	3%	Potatoes	2%	Apples	0,7%	Tomatoes		9%
4%	IE child	2,31	0,7%	Rice	0,6%	Milk: Cattle	0,5%	Potatoes		4%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Imidacloprid is unlikely to present a public health concern.



efsa European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

cis-tricos-9-ene

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,024	ARfD (mg/kg bw):	insert valid entry
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values: Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
0,0%	UK adult	0,00	0,0%	HOPS (dried)						
0,0%	DE general	0,00	0,0%	HOPS (dried)		FRUIT AND TREE NUTS				
0,0%	UK vegetarian	0,00	0,0%	HOPS (dried)		FRUIT AND TREE NUTS				
0,0%	DE women 14-50 yr	0,00	0,0%	HOPS (dried)		FRUIT AND TREE NUTS				
0,0%	GEMS/Food G06	0,00	0,0%	HOPS (dried)		FRUIT AND TREE NUTS				
0,0%	GEMS/Food G06	0,00	0,0%	HOPS (dried)		FRUIT AND TREE NUTS				
0,0%	GEMS/Food G06	0,00	0,0%	HOPS (dried)		FRUIT AND TREE NUTS				
0,0%	FR adult	0,00	0,0%	HOPS (dried)		FRUIT AND TREE NUTS				
	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				
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	DE child			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of cis-tricos-9-ene is unlikely to present a public health concern.