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 APPLICATION

(submitted by the competent authority)

SOFAST

Product type(s)

PT 18 (Insecticides, acaricides and products to control other arthropods)

Imidacloprid and Cis-tricos-9-ene as included in the Union list of approved active substances of Regulation (EU) No 528/2012

Case Number in R4BP: BC-DS072678-10

Competent Authority: DE (BAuA)

Date: 26.06.2024

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Changes history table

Application type	refMS /eCA	Case number in the refMS	Decision date[1]	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	DE	BC-XV010731-14	29.09.2017	First authorisation	-
NA-MAC	DE	BC-LS052997-00	02.07.2021	Mayor change (composition, storage stability, live stock facilities)	-
NA-RNL	DE	BC-DS072678-10	26.06.2024	First renewal of the authorisation	

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

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 by professional users.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19 (1) of Regulation (EU) No 528/2012 and therefore can be authorised for the use as an insecticide by professional users, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended uses of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

The biocidal product does not contain a non-active substance (so called "co-formulant") which is considered as a substance of concern.

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product contains the active substances imidacloprid and cis-tricos-9-ene, which have not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More information is available in section 2.7 of the PAR and in the Confidential annex.

The biocidal product contains Imidacloprid which meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: it meets two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006.
However, a comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 should be carried out only when the active substance is identified as meeting the substitution criteria in the renewal of approval Regulation in accordance with Article 10 (5) of the BPR (CA-June22-Doc.4.2[2]).

Therefore, a comparative assessment of the biocidal product is not required.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the Confidential annex. The manufacturer of the biocidal product is listed in section 1.3 of the SPC.

[2] The document is available in CIRCABC at https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/aa098b99-9f78-4606-b9e0-9275764168d2/details.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer of the active substance is listed in section 1.4 of the SPC.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of the active substance is available. More information on the analytical methods for the active substance(s) is available in section 3.4 of the PAR.

Methods for the detection of Imidacloprid in soil, air and water were provided and deemed acceptable at EU level.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against houseflies and stable flies for uses 1, 2 and 3. For use 4 the product has been shown to be efficacious only against stable flies. More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.

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.

Based on the risk assessment, it is unlikely that the intended use causes any unacceptable acute or chronic risk to professional users, professional bystanders and non-professional bystanders/general public, if the directions for use, as specified in the SPC, are followed.

Dietary risk assessment

For the use in industrial/commercial premises and households/private areas as well as public areas, contact with food or feed has been excluded via label restrictions.

For the use in livestock facilities the external exposure of livestock cannot be fully excluded by label restrictions. Therefore, a livestock exposure assessment and a dietary risk

assessment have been performed. More information is available in section 3.6.8.3 of the PAR.

Based on the assessment, a risk for consumers via dietary uptake of imidacloprid and cis-tricos-9-ene residues from the intended biocidal uses are not expected, if risk mitigation measures, as specified in the SPC, are followed.

Risk assessment for animal health

A risk assessment for animal health has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.7 of the PAR.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable risk for companion animals and livestock animals, if the directions for use, as specified in the SPC, are followed.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

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.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

Product type(s)	PT 18 (Insecticides, acaricides and products to control other arthropods)
Type(s) of formulation	WG Water dispersible granules

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number	Use description	PT	Target organisms	Application method	Application rate (min-max)	User category	Conclusion (eCA/ refMS)	Comment (eCA/refMS)
1	Professional use: brushing on cardboards	18	Flies – Muscidae (imagines; adults)	Brushing on cardboards	In order to treat a room/building with a floor surface of 100 m2 200 g of the product are dispersed in 150mL water and applied to cardboard sheets with a total surface of 1m2. The cardboard sheets are then distributed in the area to be treated. Up to 6 applications per year.	Professional	R	Additional RMM (human health and environment)
2	Professional use: bait application in disposable shallow dishes	18	Flies – Muscidae (imagines; adults)	Bait application	20g for 10m2 floor area to be treated; one bait point (disposable shallow dishes) per 10m2 floor area.	Professional	R	Additional RMM (human health and environment)

					Up to 6 applications per year.			
3	Professional use in livestock facilities: brushing on cardboards	18	Flies – Muscidae (imagines; adults)	Brushing on cardboards	In order to treat a room/building with a floor surface of 100 m2 200 g of the product are dispersed in 150mL water and applied to cardboard sheets with a total surface of 1m2. The cardboard sheets are then distributed in the area to be treated. Up to 6 applications per year.	Professional	R	Additional RMM (human health and environment)
4	Professional use in livestock facilities: bait application in bait stations	18	Stable flies (Stomoxys calcitrans) (imagines; adults)	Bait application	20g for 10m2 floor area to be treated; One bait station per 10m2 floor area. Up to 6 applications per year.	Professional	R	Additional RMM (human health and environment)

Codes for indicating the acceptability for each use

A	Acceptable

R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

2.3 Identity and composition

NA-APP
The identity and composition of the biocidal product are

identical ☐
not identical ☒

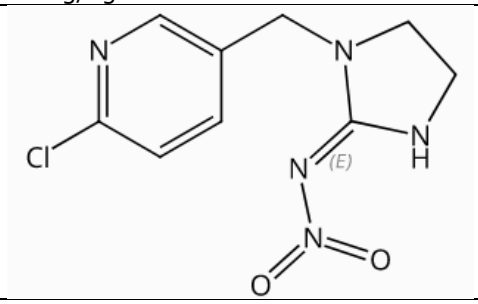
to the identity and composition of the product(s) evaluated in connection with the approval for listing of the active substances on the Union list of approved active substances under Regulation (EU) No 528/2012 .

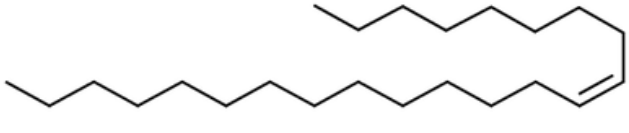
The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

According to the information provided the product contains nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.
For further information, please refer to the conf. annex of the PAR.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

Main constituent(s)	
Common name	Imidacloprid
Chemical name	(2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine
EC number	428-040-8
CAS number	138261-41-3
Index number in Annex VI of CLP	612-252-00-4
Minimum purity / content	970 g/kg
Structural formula	

Main constituent(s)	
Common name	*cis*-tricos-9-ene (Muscalure)
Chemical name	(Z)-Tricos-9-en
EC number	248-505-7
CAS number	27519-02-4
Index number in Annex VI of CLP	601-089-00-4
Minimum purity / content	801 g/kg
Structural formula	

2.5 Information on the source(s) of the active substance(s)

NA-APP

Is the source of Imidacloprid the same as the one evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☐ 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.)

Is the source of Muscalure the same as the one evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☒ Yes

☐ No

2.6 Candidate(s) for substitution

The following candidate for substitution has been identified:

- Imidacloprid

Imidacloprid does meet the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

Imidacloprid does meet the following criteria for substitution:

- it meets two of the criteria for being PBT

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

Active substance

The biocidal product contains the active substances Imidacloprid and cis-Tricos-9-ene (Muscalure), which have not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100. For details please see chapter 3.8.1.3 and the Confidential annex of the PAR.

Non-active substance

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product. For details please see chapter 3.8.1.3 and the Confidential annex of the PAR.

2.8 Classification and labelling

The current harmonised classification of the active substance **imidacloprid** (CAS-No. 138261-41-3) is based on Commission Regulation (EU) No. 790/2009 (1st ATP) and Commission Regulation (EU) No. 2021/849 605/2014 (17th ATP):
Acute tox. 3, H301
Aquatic acute Cat. 1 (H400) (M 100)
Aquatic chronic Cat. 1 (H410) (M 1000)

The current harmonised classification of the active substance **cis-tricos-9-ene** (CAS-No. 27519-02-4) is based on Commission Regulation (EU) No. 790/2009 (1st ATP) and Commission Regulation (EU) No. 605/2014 (6th ATP):
Skin sens. 1B, H317
cis-Tricos-9-ene is not classified for the environment.

Besides the active substances imidacloprid and cis-tricos-9-ene, the other components do not affect the classification and labelling of the biocidal product.

Classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is required.

Table 2.4 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	Aquatic acute Cat 1 (H400) Aquatic chronic Cat 1 (H410)	H410
Hazard Pictograms	 GHS09	 GHS09
Signal word(s)	Warning	Warning
Hazard statements	H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects	H410 Very toxic to aquatic life with long lasting effects
Precautionary statements*	P273 - Avoid release to the environment P391 – Collect spillage P501 - Dispose of contents/containers according to national legislation	P273 - Avoid release to the environment P391 – Collect spillage P501 - Dispose of contents/containers according to national legislation
Supplemental hazard statements	EUH208 - Contains cis- Tricos- 9 - ene (CAS No. 27519- 02- 4). May produce an allergic reaction.	
Notes	none	

2.9 Letter of access

Not relevant (no new data on the active substance was submitted).

2.10 Data submitted in relation to product authorisation

Not relevant (no new data on the active substance was submitted).

2.11 Similar conditions of use across the Union

Not relevant (national authorisation).

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
Bag	10g	HDPE	-	Professional	Yes
Bottle	10g, 50g, 100g,	HDPE or PP			Yes
Bottle	300g, 350g	HDPE			Yes
Bucket[3]	1kg	PP or Polyester with LDPE sealing film in a cardboard case			Yes
Bucket[4]	2kg				Yes
Can	50g, 300g, 1kg				Yes
Can	2kg				Yes
Complex Bag	1kg	Foil of complex material made of LDPE + polypropylene or polyester or paper			Yes
Complex Bag[4]	2kg				Yes

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.

[3] Secondary packaging for Complex Bag
[4] According to the applicant the layer of the packaging which is in direct contact with the biocidal product is PE.

3.2 Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa				
3.1.1.	Physical state at 20 °C and 101.3 kPa	Visual inspection. EPA 830.6303	Sofast; 0.4835% w/w Imidacloprid 0.0284% w/w Muscalure Batch SW-B-0520	Granules (solid)	DNAL – David Norris Analytical Laboratories Ltd.; Study No. DNA2047 (2013)
		Visual inspection. EPA 830.6303	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B;	Granules (solid)	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)
		Visual inspection. OCSPP 830.6303	Sofast; 0.50 % w/w imidacloprid 0.10 % w/w Muscalure Batch SCL-79304	Granules (solid)	Bioscience Research Foundation, Study No. 5015/2019 (2022)
3.1.2.	Colour at 20 °C and 101.3 kPa	Visual inspection. EPA 830.6302	Sofast; 0.4835% w/w Imidacloprid 0.0284% w/w Muscalure Batch SW-B-0520	white	DNAL – David Norris Analytical Laboratories Ltd.; Study No. DNA2047 (2013)
		Visual inspection. EPA 830.6302	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B;	white	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)
		Visual inspection. OCSPP 830.6302	Sofast; 0.50 % w/w imidacloprid	white	Bioscience Research Foundation, Study No. 5015/2019

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
			0.10 % w/w Muscalure Batch SCL-79304		(2022)
3.1.3.	Odour at 20 °C and 101.3 kPa	Olfactory inspection. EPA 830.6304	Sofast; 0.4835% w/w Imidacloprid 0.0284% w/w Muscalure Batch SW-B-0520	Very faint sweet odour	DNAL – David Norris Analytical Laboratories Ltd.; Study No. DNA2047 (2013)
		Olfactory inspection. EPA 830.6304	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B;	characteristic odour	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)
		Olfactory inspection. OCPSS 830.6304	Sofast; 0.50 % w/w imidacloprid 0.10 % w/w Muscalure Batch SCL-79304	Pungent odour	Bioscience Research Foundation, Study No. 5015/2019 (2022)
3.2.	Acidity, alkalinity and pH value	CIPAC Method MT 75.3	Sofast; 0.4835% w/w Imidacloprid 0.0284% w/w 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.	DNAL – David Norris Analytical Laboratories Ltd.; Study No. DNA2047 (2013)
		CIPAC Method MT 75.3	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene 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)	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.3.	Relative density / bulk density	CIPAC Method MT 159	Sofast; 0.4835% w/w Imidacloprid 0.0284% w/w Muscalure Batch SW-B-0520	Tap Density: 0.6871 g/mL Pour Density: 0.6448 g/mL	DNAL – David Norris Analytical Laboratories Ltd.; Study No. DNA2047 (2013)
		CIPAC Method MT 159	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	Tap Density: 0.60 g/mL Pour Density: 0.56 g/mL	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)
3.4.1.1.	Storage stability test – **accelerated storage**	EPA 830.6302, EPA 830.6303 and EPA 830.6304; CIPAC Method MT 75; CIPAC 58.2; HPLC-DAD	Sofast; 0.4835% w/w Imidacloprid 0.0284% w/w Muscalure Batch SW-B-0520	**Accelerated Storage (14 days at 54ºC)** (metal can with a white outer coating and a plastic pop lid)**:** **Content of a.s. Imidacloprid:** Initial: 0.483% w/w After storage: 0.477%w/w (-1.24%) **Content of a.s. (Z)-9-Tricosene:** Initial: 0.0284% w/w After storage: 0.0264%w/w (-7.0%) **Physical state:** Initial: granules After storage: granules **Colour:** Initial: white After storage: white **Odour:** Initial: very faint sweet After storage: very faint sweet **Sample weight:**	DNAL – David Norris Analytical Laboratories Ltd.; Study No. DNA2047 (2013)

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				Initial: 650.02 g After storage: 649.98 g (-0.0062%) **pH:** Initial: 6.92 at 1% dilution (20 °C) After storage: 6.94 at 1% dilution (20 °C) **Particle Size distribution (dry sieve):** Initial: • Granular material (collected on 850 – 250 µm test sieve): 98.03% • Dust fraction (through 250 µm and retained on 150 µm test sieve): 0.63% • Dust fraction (through 150 µm test sieve): 1.34% After storage: • Granular material (collected on 850 – 250 µm test sieve): 98.66% • Dust fraction (through 250 µm and retained on 150 µm test sieve): 0.71% • Dust fraction (through 150 µm test sieve): 0.63% Remarks: The test item is physically stable during storage at 54 ± 2ºC for 14 days.	
		EPA 830.6302, EPA 830.6303 and EPA 830.6304; CIPAC MT 75.3; CIPAC MT 184; CIPAC 47.2; CIPAC 170; CIPAC 53.3; CIPAC 178.2;	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	**Accelerated Storage (14 days at 54ºC) (glass beaker):** **Content of a.s. Imidacloprid:** Initial: 0.478% w/w After storage: 0.447%w/w (-6.49%) **Content of a.s. (Z)-9-Tricosene:** Initial: 0.097% w/w After storage: 0.094%w/w (-3.09%)	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		Karl Fischer CIPAC 171 CIPAC 174 CIPAC 172		**Physical state:** Initial: granules After storage: granules **Colour:** Initial: white After storage: white **Odour:** Initial: characteristic After storage: characteristic **pH:** Initial: 6.53 at 1% dilution (20 °C) After storage: 6.16 at 1% dilution (20 °C) **Bulk density:** Initial: • Pour density: 0.56 g/mL • Tap density: 0.60 g/mL After storage: • Pour density: 0.56 g/mL • Tap density: 0.60 g/mL **Persisting Foam (1% water suspension):** Initial: 0 mL foam after 10 s, 1min, 3 min and 12 min After storage: 0 mL foam after 10 s, 1min, 3 min and 12 min **Particle Size distribution (dry sieve):** Initial: ≥ 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%	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				≥ 45 µm and < 75 µm: 0.68% < 45 µm: 0.50% Particle size distribution after storage: ≥ 2 mm: 0% ≥ 1 mm and < 2 mm: 85.53% ≥ 500 µm and < 1 mm: 8.21% ≥ 250 µm and < 500 µm: 2.81% ≥ 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% **Wettability:** Initial: 19 s After storage: 22 s **Resistance to attrition:** Initial: 99.21% After storage: 98.94% **Moisture content:** Initial: 0.56% After storage: 0.298% **Dust content:** Initial: 0.0mg (0.0%) After storage: 0.0mg (0.0%) **Suspension stability:** Initial: 1 % water suspension 100.29 % After storage: 1 % water suspension 100.16 % **Dispersion stability:** Initial: 87.12 % After storage: 87.73 %	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				After storage 100% Flowability was determined. Remarks: The test item is physically stable during storage at 54 ± 2°C for 14 days. The contents of the active substances were not measured as part of the study; therefore, the given data are only considered for the assessment of the stability of the product for the physical, chemical and technical properties.	
		CIPAC MT 46.3	Sofast; Batch No.: 6900/004 0.5 % w/w Imidacloprid* (representative product; see remark and conf. Annex)	**Accelerated Storage (14 days at 54 °C)** (original PE container): **Weight of packaging:** Initial: 67.010 g After 2 weeks: 66.997 g (-0.019 %) **Apperance:** Initial: white, odouless, homogeneous granulated solid of cylindrical shape; 1 – 5 mm particle length; white in colour After 2 weeks: ivory white, slightly toasted cereal odour, homogeneous granulated solid of cylindrical shape; 1 – 5 mm particle length; ivory white in colour with some dark brown particles **pH (1 % w/v):** Initial: 6.30 After 2 weeks: 6.26	IDUQC LABORATORIOS (2023), Report No.: P-23-0288/S-23-0354
	*Remark by eCA DE: Although in the study report the content (Z)-9-Tricosene was not mentioned/addressed, the applicant clarified that the used product was a representative test material and submitted a CoA on the used batch 6900/004; the CoA can be found in the conf. Annex.				

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	SANCO 3030/99 rev. 4; CIPAC MT 166; a.s. content: GC-FID	Sofast; 0.50 % w/w imidacloprid 0.10 % w/w Muscalure Batch SCL-79304	**Long term storage, 24 months at 25±2°C (packaging: three layers film complex bag, Polyester 12µ + Polyester Metallic 12µ + PE 60µ)** **Content of a.s. Imidacloprid:** Initial: 0.500% w/w After 6 months: 0.494% w/w (-1.2%) After 12 months: 0.487% w/w (-2.6%) After 24 months: 0.483%w/w (-5.4%) **Content of a.s. (Z)-9-Tricosene:** Initial: 0.100% w/w After 6 months: 0.104% w/w (+4.0%) After 12 months: 0.102% w/w (+2.0%) After 24 months: 0.093%w/w (-7.0%) **Sample weight:** After 6 months: no change After 12 months: no change After 24 months: no change **Physical state (OCSPP 830.6303):** Initial: Granules (solid) After 6 months: Granules (solid) After 12 months: Granules (solid) After 24 months: Granules (solid) **Colour (OCSPP 830.6302):** Initial: white After 6 months: white After 12 months: white	Bioscience Research Foundation, Study No. 5015/2019 (2022)

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				After 24 months: white **Odour (OCSPP 830.6304):** Initial: pungent odour After 6 months: pungent odour After 12 months: pungent odour After 24 months: pungent odour **pH at 1% w/v dilution (25 ºC) (CIPAC MT 75.3) :** Initial: 4.16 After 6 months: 4.15 After 12 months: 4.14 After 24 months: 4.12 **Acidity (CIPAC MT 191):** Initial: 0.248% m/m After 6 months: 0.242% m/m After 12 months: 0.245% m/m After 24 months: 0.249% m/m **Wettability (CIPAC MT 53.3):** *With swiling, complete wetting:* Initial: 2 s After 6 months: 2 s After 12 months: 2 s After 24 months: 3 s *Without swiling, complete wetting:* Initial: 120 s After 6 months: 120 s After 12 months: 119 s	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				After 24 months: 120 s **Wet sieve test (CIPAC MT 185):** *% of sample passed through 75µm sieve* Initial: 99.942 After 6 months: 99.937 After 12 months: 99.940 After 24 months: 99.938 **Dispersibility (CIPAC MT 174):** Initial: 98.68% After 6 months: 98.67% After 12 months: 98.62% After 24 months: 98.54% **Suspensibility (CIPAC MT 184):** *0.5% solution:* Initial: 80.86% After 6 months: 80.22% After 12 months: 79.50% After 24 months: 77.82% *1% solution:* Initial: 93.71% After 6 months: 93.25% After 12 months: 91.33% After 24 months: 90.64% **Persisting Foam (1% w/v in water) (CIPAC MT 47.3):** Initial: 0 mL foam after 0 min, 1 min and 12 min	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				After 6 monthsl: 0 mL foam after 0 min, 1 min and 12 min After 12 months: 0 mL foam after 0 min, 1 min and 12 min After 24 months: 0 mL foam after 0 min, 1 min and 12 min **Dustiness (CIPAC MT 171):** Initial: 0.02% dust content After 6 months: 0.02% dust content After 12 months: 0.03% dust content After 24 months: 0.03% dust content **Attrition resistance (CIPAC MT 178.2):** Initial: 99.96% After 6 months: 99.96% After 12 months: 99.97% After 24 months: 99.97% .	
	Remark by eCA DE: Although in the study report the used packaging is described as "Aluminium bag", the applicant stated on our request that the used packaging was the original packaging which is a complex flexible packaging made of three layers (Polyester 12µ + Polyester Metallic 12µ + PE 60µ) which can also be used for pharmaceutical or foodstuff products and has high barrier properties to gas, water vapour and UV. (Further information can be found in the confidential annex). The applicant explained the error simply because of the appearance of the packaging. Further, the product was shown to be stable for 24 monhs. However, during RNL those cannot be assessed hence the afore granted shelf-life of 12 months is stated, instead.				
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	-	-	Waiving: The product is a solid. No phase change or changes in the properties are expected when temperature is lowered to 0 °C.	-
3.4.2.1.	Effects on content of the active substance and technical characteristics of the	-	-	Product has to be stored away from light. Please refer to the results of the storage stability tests. Remark by the eCA:	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
	biocidal product – **light**			Since the stability towards light was not sufficiently shown, the storage condition "Protect from light" will be added to the according sections and label claims.	
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Please refer to the results of the storage stability tests. Remark by the eCA: The stability towards elevated temperatures was shown during the accelerated storage studies at 54 °C. An impact of humidty was not addressed. Therefore the storage condition "Store in a dry place" will be added to the according sections and label claims.	-
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT 46.3 Accelerated aging in an oven at 54ºC +/- 2ºC for 2 weeks, (CIPAC Methodology MT 46.3), of an aliquot of the product in its original PE container in which the sample was received. _____ Sanco 3030/99 Rev. 4 and CIPAC MT 46.3		Storage stability test – accelerated storage Results: After the aging period: the container is stable without bulging, sinking or appreciable changes.	IDUQC Laboratorios P-23-0288/S-23-0354/1

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				Storage stability test – long-term storage at ambient temperature Results: The test was performed in the primary packaging (complex bag): No physical damages with no perforations, no darkening, no leakages and no rustiness. The plausibility of the studies is given by the worst-case assessment of the applicant. According to the applicant the layer of the packaging which is in direct contact with the biocidal product is PE.	Bioscience Research Foundation Study No: 5015/2019 (2022)
3.5.1.	Wettability	CIPAC Method MT 53.3.1	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	Wettability: ▫ Wetting time at t=0: 19 s ▫ Wetting time at t=14 at 54 ± 2ºC: 19 s	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)
		CIPAC MT 53.3	Sofast; 0.50 % w/w imidacloprid 0.10 % w/w Muscalure Batch SCL-79304	**Wettability (CIPAC MT 53.3):** *With swiling, complete wetting:* Initial: 2 s After 6 months: 2 s After 12 months: 2 s After 24 months: 3 s *Without swiling, complete wetting:* Initial: 120 s After 6 months: 120 s After 12 months: 119 s After 24 months: 120 s	Bioscience Research Foundation, Study No. 5015/2019 (2022)

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
eCA remark:		The results for wettability without swirling are outside the limit of 1min (see Guidance on BPR, Vol I, Parts A+B+C). The applicant submitted a statement clarifying that the long wetting time should be no problem during the uses a) Bait application and b) Painting on cardboards. Furthermore, as no further equipment (e.g. no spraying device of any type) is used, this should have no impact on the application of the product. To address this issue we will extend the information in the SPC under specific use instructions to"Mix well before application. Stir until homogenisation is achieved, approximately 2 minutes."			
3.5.2.	Suspensibility, spontaneity, and dispersion stability	CIPAC Method MT 184	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	Suspensibility: ▫ Suspensibility at t=0: 100.29% in 1% solution ▫ Suspensibility at t=14 days at 54 ± 2ºC: 100.16% in 1% solution	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)
		CIPAC MT 184	Sofast; 0.50 % w/w imidacloprid 0.10 % w/w Muscalure Batch SCL-79304	**Suspensibility (CIPAC MT 184):** *0.5% solution:* Initial: 80.86% After 6 months: 80.22% After 12 months: 79.50% After 24 months: 77.82% *1% solution:* Initial: 93.71% After 6 months: 93.25% After 12 months: 91.33% After 24 months: 90.64%	Bioscience Research Foundation, Study No. 5015/2019 (2022)
3.5.3.	Wet sieve analysis and dry sieve test	CIPAC MT 185	Sofast; 0.50 % w/w imidacloprid 0.10 % w/w Muscalure Batch SCL-79304	**Wet sieve test (CIPAC MT 185):** *% of sample passed through 75µm sieve* Initial: 99.942 After 6 months: 99.937 After 12 months: 99.940 After 24 months: 99.938	Bioscience Research Foundation, Study No. 5015/2019 (2022)
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not relevant for wettable granules.	-
3.5.5.	Disintegration time	-	-	Not relevant for wettable granules.	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	CIPAC Method MT 170	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	Particle size distribution at t=0: ≥ 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% Particle size distribution after 14 days at 54°C: ≥ 2 mm: 0% ≥ 1 mm and < 2 mm: 85.53% ≥ 500 µm and < 1 mm: 8.21% ≥ 250 µm and < 500 µm: 2.81% ≥ 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%	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)
3.5.7.	Persistent foaming	CIPAC MT 47.3	Sofast; 0.50 % w/w imidacloprid 0.10 % w/w Muscalure Batch SCL-79304	**Persisting Foam (1% w/v in water) (CIPAC MT 47.3):** Initial: 0 mL foam after 0 min, 1 min and 12 min After 6 months: 0 mL foam after 0 min, 1 min and 12 min After 12 months: 0 mL foam after 0 min, 1 min and 12 min After 24 months: 0 mL foam after 0 min, 1 min and 12 min	Bioscience Research Foundation, Study No. 5015/2019 (2022)
3.5.8.	Flowability/pourability/ dustability	CIPAC Method MT 172	Sofast; 0.4835% w/w Imidacloprid 0.0284% w/w 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.	DNAL – David Norris Analytical Laboratories Ltd.; Study No. DNA2047 (2013)

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		CIPAC Method MT 172	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	Flowability/Pourability: The granules of the preparation flow completely through a 4.75 mm sieve.	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)
		CIPAC Method MT 171	Sofast; 0.4835% w/w Imidacloprid 0.0284% w/w Muscalure Batch SW-B-0520	Dustability: 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.	DNAL – David Norris Analytical Laboratories Ltd.; Study No. DNA2047 (2013)
		CIPAC Method MT 171	Sofast; 0.52 % w/w Imidacloprid 0.1% w/w tricosene Batch SC-6354-B	Dustability: Dust content before and after accelerated storage (14 days 54ºC) is 0% (0.00 mg)	Institute of Industrial Organic Chemistry, Study No. BF-41/14 (2015)
		CIPAC Method MT 171	Sofast; 0.50 % w/w imidacloprid 0.10 % w/w Muscalure Batch SCL-79304	**Dustiness (CIPAC MT 171):** Initial: 0.02% dust content After 6 months: 0.02% dust content After 12 months: 0.03% dust content After 24 months: 0.03% dust content	Bioscience Research Foundation, Study No. 5015/2019 (2022)
3.5.9.	Burning rate — smoke generators	-	-	Not relevant for wettable granules. The product is not a smoke generator.	-
3.5.10.	Burning completeness — smoke generators	-	-	Not relevant for wettable granules. The product is not a smoke generator.	-
3.5.11.	Composition of smoke — smoke generators	-	-	Not relevant for wettable granules. The product is not a smoke generator.	-
3.5.12.	Spraying pattern — aerosols / spray	-	-	Not relevant for wettable granules.	-
3.6.1.	Physical compatibility	-	-	Not relevant, the product will not be used in combination with any other product.	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.6.2.	Chemical compatibility	-	-	Not relevant, the product will not be used in combination with any other product.	-
3.7.	Degree of dissolution and dilution stability	-	-	Not relevant for wettable granules.	-
3.8.	Surface tension	-	-	Not relevant for wettable granules.	-
3.9.	Viscosity	-	-	Not relevant for wettable granules.	-

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
SOFAST are white water dispersible granules (WG) with a characteristic odour. The submitted studies to determine the physical chemical properties and the technical characteristics have been performed in accordance with the current requirements and the results are deemed to be acceptable. For setting the shelf-life the requested new storage stability studies with correct (Z)-9-Tricosene content were submitted. However, the current accelerated study report does not determine the active substance contents within the study, but shows that all physical and technical characteristics are acceptable before and after storage. In contrast to this, the old accelerated study supports the result that the product is stable for 2 weeks at 54°C and shows that the active substance contents do not decrease by more than 10%. Therefore, we are of the opinion that no further study is needed and that it can be concluded that the product is stable 2 weeks at 54°C. The resistance towards humidity and light was not sufficiently shown why according label instructions will be added to the storage conditions. Based on the results of the new long term storage stability study a shelf-life of 12 months can be confirmed in accordance with the shelf-life of the first authorization (as submitted shelf life study would confirm 24 month shelf-life) **Implications for labelling:** Protect from direct light. Store in a dry place. Shelf-life: 12 months

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
4.1.	Explosives	EU Method A.14, Regulation (EC) No 440/2008	Sofast; Batch SC-6354-B Certificate of Analysis: 0.52 %w/w Imidacloprid; 0.1 %w/w Tricosene	Impact sensitivity: no reaction Friction sensitivity: no reaction Thermal sensitivity: confinement unchanged In the tests, explosive transformations of Sofast have not been recognized. The product "Sofast" does not have explosive properties according to the criteria of EEC A.14 method.	Institute of Industrial Organic Chemistry (2014) Study code: BW-19/14
4.2.	Flammable gases	-	-	Not relevant. The product is not a gas.	-
4.3.	Flammable aerosols	-	-	Not relevant. The product is not an aerosol.	-
4.4.	Oxidising gases	-	-	Not relevant. The product is not a gas.	-
4.5.	Gases under pressure	-	-	Not relevant. The product is not a gas.	-
4.6.	Flammable liquids	-	-	Not relevant. The product is not a liquid.	-
4.7.	Flammable solids	EU Method A.10, Regulation (EC) No 440/2008	Sofast; Batch SW-B-0520 Certificate of Analysis: 0.52 %w/w Imidacloprid; 0.1 %w/w Tricosene	The flame did not propagate along the sample train. The product "Sofast" is considered not highly flammable.	David Norris Analytical Laboratories Ltd. (2013) Study code: DNA2047
		UN Test Method N.1	Sofast; Batch SC-6354-B Certificate of	The sample ignites and the flame is propagated over a distance of 50, 60 and 70 mm of the train for each test. Application time of the ignition source: 30 s, 60 s, 120 s.	Institute of Industrial Organic Chemistry (2014) Study code: BC-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
			Analysis: 0.52 %w/w Imidacloprid; 0.1 %w/w Tricosene	Due to the fact that 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 according to test UN N.1 criteria.	48/14
4.8.	Self-reactive substances and mixtures	DSC Study In accordance with section 20.3.3.3 in the UN-MTC	Sofast; Batch 6900/004 Certificate of Analysis: 0.55 %w/w Imidacloprid* (representative product; see remark and conf. Annex)	Exothermal peak: 189.06 – 305.99 °C; 646.55 J/g Rupture of sealing disc observed at approx. 440 °C (above exothermal peak). No impact on results expected. Mass loss: 2.83 mg (of entire crucible; initially 4.10 mg sample tested) The exothermal decomposition energy was determined to be 646.55 J/g. This is above the threshold vaue of 300 J/g. Therefore, further tests were conducted.	IDUQC Laboratorios ALMABE (2023); Report No.: [P-23-0101/S-23-0121] (Rev 02)
		*Remark by eCA DE: Although in the (first) study report the content (Z)-9-Tricosene was not mentioned/addressed, the applicant clarified that the used product was a representative test material and submitted a CoA on the used batch 6900/004; the CoA can be found in the conf. Annex. The study report was revised accordingly. Therefore, the study was deemed acceptable.			
		UN test method H.4 (heat accumulation storage test)	Sofast; Batch 6900/004 Certificate of Analysis: 0.55 %w/w Imidacloprid* (representative product; see remark and conf. Annex)	The test item was observed to take 52.6 hours to reach a temperature 2 °C below the oven temperature (of 75 °C). Over the following 168 hours (7 days) the test item reached a maximum temperature of 73.8 °C. The test item did not reach a temperature of more than 6 °C above the oven temperature. Therefore, the SADT of the substance is >75 °C. The mixture is therefore exempt from classification as a self-reactive.	DEKRA UK Ltd. (2023), Report No.: GLP/3016013982
		*Remark by eCA DE: Although in the study report the content (Z)-9-Tricosene was not mentioned/addressed, the applicant			

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
		clarified that the used product was a representative test material and submitted a CoA on the used batch 6900/004; the CoA can be found in the conf. Annex. Therefore, the study was deemed acceptable.			
4.9.	Pyrophoric liquids	-	-	Not relevant. The product is not a liquid.	-
4.10.	Pyrophoric solids	-	-	According to the additional classification considerations in CLP Annex I, 2.10.4, the classification procedure for pyrophoric solids does not need to be applied when experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance or mixture is known to be stable at room temperature for prolonged periods of time (days). This is the case for the biocidal product Sofast, which is in the market for a long time and never showed these properties.	-
4.11.	Self-heating substances and mixtures	UN Test Method N.4	Sofast; Batch SC-6354-B Certificate of Analysis: 0.52 %w/w Imidacloprid; 0.1 %w/w Tricosene	Heating the sample in a container having a side of 100 mm at a temperature of 140 °C: Negative result; the temperature difference did not exceeded 60 °C. The product "Sofast" is not a self-heating mixture according to test UN N.4 criteria.	Institute of Industrial Organic Chemistry (2014) Study code: BC-48/14
4.12.	Substances and mixtures which in contact with water emit flammable gases	-	-	The study does not need to be conducted because the product is known to be soluble in water to form a stable mixture.	-
4.13.	Oxidising liquids	-	-	Not relevant. The product is not a liquid.	-
4.14.	Oxidising solids	EU Method A.17, Regulation (EC) No 440/2008	Sofast; Batch SW-B-0520; 0.4835% w/w Imidacloprid;	The material lit and burnt readily, and white smoke was produced. The sample did not react and no crackling or sparks were observed. According to the results the product "Sofast" is	David Norris Analytical Laboratories Ltd. (2013) Study code: DNA2047

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
			0.0284% w/w Muscalure	considered not highly oxidising.	
		UN Test Method O.1	Sofast; Batch SC-6354-B Certificate of Analysis: 0.52 %w/w Imidacloprid; 0.1 %w/w Tricosene	Negative result; the sample mixture (1:1 and 4:1 sample and cellulose) exhibited a mean burning time higher than the mean burning time of the reference mixture (3:7 potassium bromate and cellulose). According to test UN O.1 ”Sofast” is not considered as an oxidizing solid.	Institute of Industrial Organic Chemistry (2014) Study code: BC-48/14
4.15.	Organic peroxides	-	-	The study does not need to be conducted because the product does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	-
4.16.	Corrosive to metals	-	-	The study does not need to be conducted because there is no established suitable test method for solid substances.	-
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	-	-	Not relevant. The product is neither a liquid nor a gas.	-
4.17.2.	Relative self-ignition temperature for solids	EU Method A.16, Regulation (EC) No 440/2008	Sofast; Batch SW-B-0520; 0.4835% w/w Imidacloprid; 0.0284% w/w Muscalure	The sample did not self-ignite below 170 °C then it melted and left the cube. The product Sofast is not considered to self-ignite.	David Norris Analytical Laboratories Ltd. (2013) Study code: DNA2047
		UN Test Method N.4	Sofast; Batch SC-6354-B Certificate of Analysis: 0.52 %w/w	The preliminary results observed by UN test N.4 exclude self-heating of the mixture up to 400 °C. ”Sofast” is not a self-igniting mixture according to test UN N.4 criteria.	Institute of Industrial Organic Chemistry (2014) Study code: BC-48/14

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
			Imidacloprid; 0.1 %w/w Tricosene		
4.17.3.	Dust explosion hazard	Particle size distribution: SOP reference 224 Dust Explosibilty: VDi 2263 Dust explosion (Hartmann tube), MIE, MIT, LIT: BS EN ISO/IEC 80079-20-2 Explosion Severity, LOC, MEC: BS EN 14034-parts 1-4 (20 L sphere)	Sofast; Batch 6900/004 0.55 %w/w Imidacloprid* (representative product; see remark and conf. Annex)	Particle size distribution: D_{50} = 1 – 2 mm <500 µm: 0.5 % Moisture content (hand milled): 0.61 % w/w 1.23 % w/w **Dust Explosibilty:** The tested material has found to be an combustible dust. **Dust explosion risk:** Minimum Ignition Energy (MIE; with induction): 60 – 80 mJ Minimum (dust cloud) Igniton Temperature "MIT": 360 °C Layer (5 mm) Ignition Temperature "LIT": >400 °C Explosion Severity Maximum explosion pressure: p_{max} = 8.3 bar g K_{st} value: K_{st} = 158 bar·m/s St class: St 1 Limiting Oxygen Concentration "LOC": 11 % v/v Minimum Explosive Concentration "MEC": 90 g/m³	DEKRA UK Ltd. (2023), Report No.: S3016013705R1/2023, S3016014097R1/2023
		*Remark by eCA DE: Although in the study report the content (Z)-9-Tricosene was not mentioned/addressed, the applicant clarified that the used product was a representative test material and submitted a CoA on the used batch 6900/004; the CoA can be found in the conf. Annex. Therefore, the study was deemed acceptable.			

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is not classified for physical hazards.

3.4 Methods for detection and identification

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues
Principle of the method*:*
Imidacloprid in the biocidal product: HPLC-DAD [Analytical Laboratories Ltd.; Study No. DNA2047 (2013)] **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 [Analytical Laboratories Ltd.; Study No. DNA2047 (2013)]

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

Imidacloprid and Muscalure in the biocidal product:
GC-FID [Bioscience Research Foundation, Study No. 5015/2019 (2022)

Instrument name: GC Chromatography
Make: Shimadzu
Model: GC-2030 Nexis
Detector: FID
Column: (30 mm x 0.25 mm) ID: Rtx-5sil MS 0.25 µm
Injection-T: 280°C
Detector-T: 250°C
Injection volumne: 1 µl
Runtime: 32 min
Flow rate carrier gas: Nitrogen column flow 1.62 mL/min
Retention time: Approximately 24.9 min for Imidacloprid
Approximately 25.5 min for Muscalure

Analyte	Linearity	Specificity	Fortification range, level and	Recovery rate (%)	Precision (%)	Limit of Quantification	Reference

			number of measurements at each level							**LOQ** – *only for impurit(y/ies)*	
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		
Imidacloprid in the biocidal product: HPLC-DAD	0.0005 mg/mL to 0.5 mg/mL (mg reference item/mL); 6 concentrations; R^2 = 1.000	*was verified by analysing a sample of Solvent Blank, Formulation blank, Imidacloprid reference standard, Pre Storage Sample, Post accelerated Storage Sample 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.*	0.05 mg/mL	5	101.7 % - 102.5 %	102%	0.2278	0.05 mg/mL	6	-	Analytical Laboratories Ltd.; Study No. DNA2047 (2013)
Active substance cis-tricosene in the biocidal product: GC-UV/Vis	0.0001 mg/mL to 0.1 mg/mL (mg reference item/mL); 6 concentrations; R^2 = 0.9971	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	0.01 mg/mL	5	95.11 % - 99.62 %	96.89 %	2.211	0.003 mg/mL	6	-	Analytical Laboratories Ltd.; Study No. DNA2047 (2013)

		UV-spectra and GC-MS spectra of the reference item solutions with the UV-spectra of and GC-MS spectra the sample solutions.									
Imidacloprid in the biocidal product: GC-FID	4.0 mg/L – 30.0 mg/L; 6 concentrations; R^2 = 0.9998	No interference observed with peak of interest.	4.0 mg/L 10 mg/L 15 mg/L	3 3 3	99.40-100.09 % 99.64-99.98 % 100.74 - 101.43 %	99.68 99.82 101.08	0.360 0.174 0.341	5 mg/L	5 samples measured in duplicate	-	Bioscience Research Foundation, Study No. 5015/2019 (2022)
a.s. muscalure in the biocidal product: GC-FID	4.0 mg/L – 30.0 mg/L; 6 concentrations; R^2 = 0.9992	No interference observed with peak of interest.	4.0 mg/L 10 mg/L 15 mg/L	3 3 3	99.00-101.82 % 99.56-100.88 % 100.84 - 101.84 %	100.41 100.38 101.21	1.404 0.709 0.540	5 mg/L	5 samples measured in duplicate	-	Bioscience Research Foundation, Study No. 5015/2019 (2022)

Table 3.7 Analytical methods for air

For the active substances Imidacloprid (PT18) and Cis-tricos-9-ene (PT19), the applicant provided a letter of access (LoA) to the dossiers assessed for the approval (CAR) upon first authorisation (see chapter 2.9). In the PAR (for product authorisation), the applicant claims: "*Analytical methods for the detection of imidacloprid in air were provided and deemed acceptable at EU level. No other data is required*."

Table 3.8 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
Analytical methods for the determination of the active substances Imidacloprid (PT18) and Cis-tricos-9-ene (PT19) in the biocidal product are available. Specificity, linearity, accuracy and precision were checked and found acceptable. According to Guidance for waiving of data requirements for pheromones for inclusion in Annex I/IA of directive 98/8/EG analytical methods for cis-tricos-9-ene in soil, water and body fluids and tissues are not required. Methods for the detection of imidacloprid in soil, air and water were provided and deemed acceptable at EU level. During the next active substance renewal, the limit of 0.0048 µg/L based on PNECwater should be considered for the analytical methods for the determination of residues of imidacloprid in surface water. Methods for body fluids and tissues seemed to be not necessary as imidacloprid was not classified as toxic or very toxic. Since December 17th 2022, according to the 17th ATP of CLP-Regulation, imidacloprid is classified as Acute tox. 3. During the next active substance renewal, the need for analytical methods for body fluids and tissues according to this classification should be considered. Relevant residues are not expected in food/feed of plant and animal origin; therefore, analytical methods for the determination of active substances in food/feed of plant and animal origin are not required. Analytical methods for the determination of residues of substances of concern are not necessary.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

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

The product "Sofast" is an insecticide and contains 0.5% Imidacloprid as well as 0.1% cis-tricos-9-ene (Muscalure) as an attractant.
The product is intended to control adult flies (house flies (*Musca domestica*) and stable flies (*Stomoxys calcitrans*)) for indoor use by professionals. The applications intended for use are:

a) Use #1: dispersion of 200 g granules in 150 ml water and painting onto 1 m² cardboard sheets in industrial/commercial premises, households/private areas or public areas of 100 m² ground
b) Use #2: application of 20 g dry granules in one disposable shallow dish in industrial/commercial premises, households/private areas or public areas of 10 m² ground
c) Use #3: dispersion of 200 g granules in 150 ml water and painting onto 1 m² cardboard sheets in livestock facilities of 100 m² ground
d) Use #4: application of 20 g dry granules in one bait box in livestock facilities of 10 m² ground against stable flies (*Stomoxys calcitrans*) only

Based on the submitted efficacy studies, the product "Sofast" is suitable to treat fly populations indoors in industrial/commercial premises, households, private and public areas by "Dispersion of granules in water and painting on cardboards" and "Application of dry granules in disposable shallow dishes" (use #1 and #2).
For use in livestock facilities, the application method "Dispersion of granules in water and painting on cardboards" (use #3) can be authorised against "flies", whereas for the application method "Application of dry granules in bait boxes" (use #4) only the target organism "stable flies (*Stomoxys calcitrans*)" can be claimed, a general claim against "flies" cannot be authorised.
As the product "Sofast" does not contain a preservative only a shelf life of 12 months can be claimed.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

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. Imidacloprid acts as a contact insecticide as well as upon ingestion. The effect on the target organism is knockdown and kill.
Cis-tricos-9-ene (Muscalure) is produced by female house flies as component of the wax layer on the cuticle, together with a series of related compounds. It is the major component of the house fly aggregation pheromone and is attractive on flies of both sexes.

3.5.3 Efficacy data

Table 3.9 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
PT18; Indoor use, including households, industrial and commercial premises and livestock facilities; Use #1-4	Sofast (Imidacloprid 0.5%+ Tricosene 0.1%); fresh	*M. domestica*, *S. calcitrans*	Simulated-use-trial: - application methods: 1. scattered and moistened 2. dissolved and painted on cardboards 3. dissolved and sprayed on cardboards - dosage: equivalent to 200 g product per 100 m² (corresponding to the intended dosage) - test rooms: 20m³ with alternative food source (sugar water for house flies and for stable flies additional cattle blood) - temp: 21 – 24°C	1. Scattered and moistened dry granules *M. domestica*: 85% knockdown (kd) at 8 h, 97% mortality at 24 h *S. calcitrans*: 86% kd at 8h, 100% mortality at 24h 2. Painted *M. domestica*: 93% kd at 8 h, 99% mortality at 24 h *S. calcitrans*: 84% kd at 8 h, 99% mortality at 24 h 3. Sprayed *M. domestica*: 92% kd at 8 h, 98% mortality at 24 h *S. calcitrans*: 88% kd at 8 h, 96% mortality at 24 h untreated controls: <10% mortality at 24 h *evaluation: RI = 1* *- knockdown ≥80% and ≥90% mortality after 24 hours* *- suitable to prove the palatability/efficacy against* M. domestica *and* S. calcitrans *with the*	BioGenius GmbH; Study no: BIO39a-13	6.7-001/Efficacy of a fly bait granule product against house flies and Stable flies

			- rel. humidity: 30 – 56% - 100 adult flies per replicate - replicates: 4 per fly species and per application method (+ 4 untreated controls) - exposure time: 24 h	*fresh product applied as dry granules and painted/sprayed on cardboards in the intended dosage according to Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 3.0 April 2018; chapter 5.6.4.13*		
PT18; Indoor use, including households, industrial and commercial premises and livestock facilities; Use #1-4	Sofast (Imidacloprid 0.5% + Tricosene 0.1% GR, 0.1 % calcium propionate); fresh and 2 years old (aged under accelerated conditions: 54°C during 14 days)	*M. domestica, S. calcitrans*	Simulated use-trial: - application methods: 1. dry granules in petri dish and moistened 2. dissolved and painted on cardboards - dosage: equivalent to 200 g product per 100 m² (corresponding to the intended dosage) - test cage: 24 x 14 x 14 inches, food source (10% sucrose solution) - acclimatization period: 1 day - starvation: 4 h - temp:	<u>1. Dry granules in dishes, moistened</u> *M. domestica*: fresh product: 90% mortality (KT90) after 14.8 h, 100% mortality at 24 h aged product: KT90 after 15 h, 100% mortality at 24 h *S. calcitrans*: fresh product: KT90 after 13.5 h, 100% mortality at 24 h aged product: KT90 after 12.9 h, 100% mortality at 24 h untreated controls: 0% mortality at 24 h <u>2. Painted</u> *M. domestica*: fresh product: KT90 after 19.8 h, 100% mortality at 24 h aged product: KT90 after 19.7 h, 100% mortality at 24 h *S. calcitrans*: fresh product: KT90 after 20.3 h, 100% mortality at 24 h aged product: KT90 after 18.8 h, 100% mortality at 24 h	Lifescience Pvt. Ltd.; Study no: 368DALG2814/R0	6.7-007/Palatability trial against flies in livestock facilities (fresh and aged) 368DALG2814/R0 / To evaluate palatability of a bait product (Imidacloprid 0.5% + Tricosene 0.1% GR - SOFAST) fresh and aged under accelerated conditions, against housefly (Musca domestica) and stable fly (Stomoxys calcitrans).

			27 ± 2°C - rel. humidity: 50 – 90% - 50 adult flies per replicate - replicates: 5 per fly species and per application method (+ 5 untreated controls) - exposure time: 24 h	untreated controls: <10% mortality at 24 h *evaluation: RI = 3* *- knockdown ≥80% and ≥90% mortality after 24 hours* *- formulation of the test product not identidal to the formulation of "Sofast" under authorisation* *- not suitable to prove the palatability/efficacy against* M. domestica *and* S. calcitrans *with the fresh and aged product applied as dry granules and painted on cardboards in the intended dosage according to Guidance on the BPR Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 3.0 April 2018; chapter 5.6.4.13*		
PT18; Indoor use, including households, industrial and commercial premises and livestock facilities; Use #1-4	Sofast (Imidacloprid 0.5%+ Tricosene 0.1% GR); fresh	*M. domestica*, *S. calcitrans*	Field trial: - in livestock facilities in Spain - 3 replicates per fly species (+ 1 untreated control) - application method: dissolved and painted on walls or cardboards - dosage: 200 g product diluted in 200 ml water painted on 1 m² per 100 m² floor surface - infestation	population 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% *evaluation: RI = 3* *- population reduction ≥80% only in one of three sites* *- control mortality too high* *- painting directly on walls corresponds not to the intended use* *- not suitable to prove the efficacy against* M. domestica *and* S. calcitrans *with the fresh product applied painted on cardboards in the intended dosage according to TAB Efficacy Version 2.2; July 2020; chapter 18*	i2LResearch Ltd; Study no: 15/177	6.7-002/Field trials to determine the effciacy of Imdacloprid 0.5% + tricosene 0.1 % GR (SOFAST) against houseflies and stable flies

			level scoring with sticky traps - exposure time: 30 d			
PT18; Indoor use, including households, industrial and commercial premises and livestock facilities; Use #1-4	Sofast (Imidacloprid 0.5% + Tricosene 0.1% GR); fresh	*M. domestica*, *S. calcitrans*	Field trial: - in livestock facilities in Spain - 3 replicates per fly species (+ 1 untreated control) - application method: dry granules in shallow dishes, occasionally moistened - dosage: 10 g product per dish per 5 m² floor surface - infestation level scoring with sticky traps and counting of dead flies found near the baits - exposure time: 30 d	population 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% *evaluation: RI = 3* *- population reduction ≥80% only in one of three sites* *- control mortality too high* *- application of 10 g product per dish per 5 m2 corresponds not to the intended dosage of 20 g product in one dish per 10 m2 floor space* *- not suitable to prove the efficacy against* M. domestica *and* S. calcitrans *with the fresh product applied as dry granules according to TAB Efficacy Version 2.2; July 2020; chapter 18*	i2LResearch Ltd; Study no: 15/178	6.7-003/Field trials to determine the efficacy of Imidacloprid 0.5% + Tricosene 0.1% GR (SOFAST) against houseflies and stable flies
PT18; Indoor use, including households, industrial and commercial premises and livestock	Sofast (Imidacloprid 0.5% + Tricosene 0.1% GR); 1 year old	*M. domestica*, *S. calcitrans*	Field trial: - in 2 cattle sheds in India - 3 replicates per location and fly species (+ 3 untreated controls) - application methods:	<u>1. Painting</u> population reduction % for *M. domestica*: 40, 51, 56, 75, 87% for 2, 4, 7, 14 and 21 days population reduction % for *S. calcitrans*: 49, 51, 64, 71 and 80 % for 2, 4, 7, 14 and 21 days untreated controls: no population reduction	Bioscience Research Foundation; Study no: 4518/2018	6.7-004/ Field trial against flies in livestock facilities 4518/2018 / Efficacy assessment of Imidacloprid 0.5% + Tricosene 0.1% GR under field conditions against flies (House fly &

facilities; Use #1-4			1. dissolved and painted on cardboards 2. dry granules in shallow dishes - dosage: 1. 200 g product diluted in 200 ml water painted on 1 m² cardboard per 100 m² floor surface 2. 20 g product in one dish per 10 m² floor surface - infestation level scoring with sticky traps - exposure time: 21 d	<u>2. Dry granules in dishes:</u> population reduction % for *M. domestica:* 48, 58, 61, 71, 85% for 2, 4, 7, 14 and 21 days population reduction % for *S. calcitrans:* 64, 72, 77, 86, 91% for 2, 4, 7, 14 and 21 days untreated controls: no population reduction *evaluation: RI = 1* *- population reduction ≥80%* *- suitable to prove the efficacy against* M. domestica *and* S. calcitrans *with the 1 year old product applied as dry granules and painted on cardboards in the intended dosage according to TAB Efficacy Version 2.2; July 2020; chapter 18*		Stomoxys calcitrans)
PT18; Indoor use, including households, industrial and commercial premises and livestock facilities; Use #1-4	Sofast (Imidacloprid 0.5% + Tricosene 0.1% GR); 1 year old	*M. domestica*	Field trial: - in cattle sheds (approx. 200 m² each) in India - 3 replicates (+ 3 untreated controls) - application method: dry granules in bait box - dosage: 2 g product in one bait box per 1 m² floor surface	population reduction after 4 weeks: 85.3%, 76.2% and 75.4% untreated controls: population growth of 18.4% after 4 weeks *evaluation: RI = 3* *- population reduction ≥80% only in one of three sheds* *- not suitable to prove the efficacy against* M. domestica *with the 1 year old product applied as dry granules in bait boxes according to TAB Efficacy Version 2.2; July 2020; chapter 18*	Ross Lifescience Pvt. Ltd.; Study no: 368EAMG3968/RO	6.7-005/Field trial in livestock facilities 368EAMG3968/R0 / Bioefficacy & Persistency of Sofast (Bait Box with Imidacloprid 0.5% + cis-Tricos-9-ene 0.1% GR) against House fly

			- infestation level scoring with sticky traps - exposure time: 4 weeks			
PT18; Indoor use, including households, industrial and commercial premises and livestock facilities; Use #1-4	Sofast (Imidacloprid 0.5% + Tricosene 0.1% GR); 1 year old	*S. calcitrans*	Field trial: - in cattle sheds (approx. 240 m² each) in India - 3 replicates (+ 3 untreated controls) - application method: dry granules in bait box - dosage: 2 g product in one bait box per 1 m² floor surface - infestation level scoring with sticky traps - exposure time: 4 weeks	population reduction after 4 weeks: 91.4%, 93.9% and 89.4% untreated controls: population reduction of 5.2% after 4 weeks *evaluation: RI = 1* *- population reduction ≥80%* *- suitable to prove the efficacy against* S. calcitrans *with the 1 year old product applied as dry granules in bait boxes in the intended dosage according to TAB Efficacy Version 2.2; July 2020; chapter 18*	Lifescience Pvt. Ltd.; Study no: 368EAMG3969/RO	6.7-006/ Field trial in livestock facilities 368EAMG3969/R0 / Bio-efficacy & Persistency of Sofast (Bait Box with Imidacloprid 0.5% + cis-Tricos-9-ene 0.1% GR) against Stable Fly

3.5.4 Efficacy assessment

The efficacy evaluation of the renewal is based on the requirements of the Guidance on the Biocidal Products Regulation (BPR) (Volume II Efficacy - Assessment and Evaluation (Parts B+C); Version 3.0; April 2018; chapter 5.6.4.13) and the Technical Agreements for Biocides (TAB) Efficacy (EFF) Version 2.2; July 2020; chapter 4 and 18. As the Guidance on BPR does not contain requirements for bait products against flies in stables, the criteria for "products intended for use as general surface treatment, space treatment or vaporisers in stables and waste dumps" were used. Therefore, efficacy has to be demonstrated in a laboratory test (≥80% knockdown and ≥90% mortality after 24 hours) and a field test (≥80% population reduction).
For the renewal the applicant provided no new studies in addition to the studies, which were submitted within the first authorisation: two simulated-use tests and five field tests with the product "Sofast" (study summaries: Table 3.13).

A choice-laboratory test was not submitted. Instead a valid simulated-use trial was conducted in 20 m³ rooms with the fresh product with adult *M. domestica* and *S. calcitrans*, which had a free choice between an alternative food source and the product. The study showed a ≥80% knockdown and ≥90% mortality after 24 hours (in accordance with the Guidance on the (BPR) (Volume II Efficacy - Assessment and Evaluation (Parts B+C); Version 3.0; April 2018; chapter 5.6.4.13) for the fresh product applied as dry granules or dissolved in water and painted/sprayed on cardboards in the intended dosage. This test is suitable to demonstrate acceptable toxicity of the product in competition with the alternative food source under more realistic conditions than in a laboratory test. Therefore, a laboratory test is not necessary and can be waived in accordance with the Guidance on the (BPR) (Volume II Efficacy - Assessment and Evaluation (Parts B+C); Version 3.0; April 2018; chapter 5.6.4.1.3.3, when robust field studies are available.

A second simulated-use trial with a fresh and under accelerated conditions aged product, which contains 0.1% calcium propionate (CAS number: 4075-81-4) was conducted in cages with adult *M. domestica* and *S. calcitrans*, which had a free choice between an alternative food source and the product. The study showed a ≥80% knockdown and ≥90% mortality after 24 hours (in accordance with the Guidance on the (BPR) (Volume II Efficacy - Assessment and Evaluation (Parts B+C); Version 3.0; April 2018; chapter 5.6.4.13) for the fresh and two years aged product containing 0.1% calcium propionate (CAS number: 4075-81-4) as a preservative, when applied as dry granules or dissolved in water and painted on cardboards in the intended dosage. However, as the formulation of the test product (calcium propionate as a preservative) was not identical to the formulation of the product "Sofast", this study is not acceptable to prove the efficacy of the two years old product "Sofast". Consequently, as the product "Sofast" does not contain a preservative only a shelf life of 12 months can be claimed in accordance with the TAB Efficacy Version 2.2; July 2020; chapter 4.

In the field studies (study no: 15/178 and 15/177) the fresh product was applied by diluting the granules in water and painting the solution onto walls/cardboards and as dry granules in dishes, respectively. In both studies, only in 1 of the 3 treated sites a population reduction of >80% was demonstrated for *M. domestica* and *S. calcictrans*. Therefore, the results are not suitable to prove the efficacy of the product in accordance with the TAB Efficacy Version 2.2; July 2020; chapter 18.
In order to allow the authorisation for use in livestock facilities, another field trial with *M. domestica* and *S. calcitrans* was performed (Study no: 4518/2018). The one year old product was applied after dispersion in water by painting on cardboards and by dry granules in dishes, respectively. 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 "Dispersion of granules in water and painting on cardboards" (use #3) and "Application of dry granules in disposable shallow dishes" in accordance with the TAB Efficacy Version 2.2; July 2020; chapter 18.
In accordance with the Guidance on the (BPR) (Volume II Efficacy - Assessment and Evaluation (Parts B+C); Version 3.0; April 2018; chapter 5.6.4.13.2 the "study results of … field trials should demonstrate the efficacy of the product based on the submitted label claim". Therefore, the applicant submitted two field trials in livestock facilities with *M. domestica* (Study 368EAMG3968/RO) and *S. calcitrans* (Study 368EAMG3969/RO) with the one year old product "Sofast" applied in bait boxes. After an exposure period of 4 weeks, the population reduction was 85.3%, 76.2% and 75.4% for *M. domestica*. Consequently, only in 1 of 3 livestock facilities a sufficient population reduction of ≥80% was recorded. For *S. calcitrans* the population reduction in all 3 livestock facilities was ≥80%. In accordance with the Guidance on the Biocidal Products Regulation (BPR) (Volume II Efficacy - Assessment and Evaluation (Parts B+C); Version 3.0; April 2018; chapter 5.6.4.13.2.1 for a general claim against flies in livestock facilities and animal housings both the housefly (*M. domestica*) and the stable fly (*S. calcitrans*) should be tested. As the efficacy was not proven against *M. domestica*, when the granular product was used in bait boxes, a general claim against "flies" cannot be authorised. However, a claim against stable flies (*S. calcitrans*) in livestock facilities is acceptable for use of bait boxes.
In summary, the simulated-use trial by Lüpkes (2013) showed good efficacy of the product when used indoors (households etc.) when applied as dry granules in shallow dishes and painted on cardboards. The efficacy of "Sofast" against flies in livestock facilities was also demonstrated for the application methods "Dispersion of granules in water and painting on cardboards" and "Application of dry granules in disposable shallow dishes". For the application method "Application of dry granules in bait boxes" 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*).
As the product "Sofast" does not contain a preservative only a shelf life of 12 months can be claimed.

3.5.5 Conclusion on efficacy

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 by "Dispersion of granules in water and painting on cardboards" and "Application of dry granules in disposable shallow dishes" (use #1 and #2).
For use in livestock facilities, the application method "Dispersion of granules in water and painting on cardboards" (use #3) can be authorised against "flies", whereas for the application method "Application of dry granules in bait boxes" (use #4) only the target organism "stable flies (*Stomoxys calcitrans*)" can be claimed, a general claim against "flies" cannot be authorised. As the product "Sofast" does not contain a preservative only a shelf life of 12 months can be claimed.

3.5.6 Occurrence of resistance and resistance management

Resistance and cross-resistance against neonicotinoids (including Imidacloprid), a group of insecticides acting agonistically on insect nicotinic acetylcholine receptors (nAChRs), can occur in relevant susceptible pests in Europe. Resistance of flies against Imidacloprid has

been reported from various countries, including Germany (Jandowsky et al., 2010[5], Kaufman et al., 2010[6], Memmi, 2010[7], Khan et al., 2013[8]).
In general, precautions should be taken to reduce the possibility of insects developing resistance to neonicotinoid insecticides.
Resistance can occur very quickly in flies that have a short life and reproductive cycle. Therefore, a high effectiveness of the product is necessary to avoid resistance.
"Sofast" should only be used against adult flies and is not applicable for other stages (e.g. eggs, larvae and pupae).
The development of resistance to cis-tricos-9-ene (Muscalure) is highly unlikely considering that cis-tricos-9-ene is produced by the target organism itself, and plays such a large role in the propagation of the species.

In cases where the population has not been reduced although the bait has been taken up, the development of resistance should be suspected.
The following general resistance management measures are proposed:

- 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.
- The use of biocidal products in livestock facilities can be combined with other sanitation measures (e.g. frequent removal of dung) or non-chemical means of control (for example biological including the use of parasitoids) within an integrated fly control program.
- Fly infestation in animal housings can be estimated by monitoring methods (e.g. monitoring of (re)-appearance of larvae in the manure or adult fly population with glue strips) prior to chemical treatment.
- Products should always be used in accordance with label recommendations.

3.5.7 Known limitations

Not known.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

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

[5] Jandowsky, A., Clausen, P.-H., Schein, E., Bauer, B. 2010: Occurrence and distribution of insecticide resistance in house flies (Musca domestica) on dairy farms in Brandenburg, Germany; Praktische Tierarzt 91(7), pp. 590-598

[6] Kaufman, P.E., Nunez, S.C., Mann, R.S., Geden, C.J., Scharf, M.E. 2010:
Nicotinoid and pyrethroid insecticide resistance in houseflies (Diptera: Muscidae) collected from Florida dairies; Pest Management Science 66(3), pp. 290-294

[7] Memmi, B.K. 2010: Mortality and knockdown effects of imidacloprid and methomyl in house fly (Musca domestica L., Diptera: Muscidae) populations; Journal of Vector Ecology 35(1), pp. 144-148

[8] Khan, H.A.A., Shad, S.A., Akram, W. 2013: Resistance to new chemical insecticides in the house fly, Musca domestica L., from dairies in Punjab, Pakistan; Parasitology Research 112(5), pp. 2049-2054

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

The toxicology of the biocidal product SOFAST was examined appropriately in line with standard requirements. Studies with the biocidal product Imidacloprid GR 0.5 were presented. In contrast to the test substance Imidacloprid GR 0.5, the biocidal product SOFAST contains a different flavouring agent, which is not expected to have any impact on the toxicological risk assessment (detailed comparison in conf. annex of the PAR). Bridging is therefore acceptable. The biocidal product does not possess acute oral, inhalative or dermal toxicity and is not irritating nor sensitising to the skin and eye. The applicant provides no information on dermal absorption of the active substance cis-tricos-9-ene. For the active substance imidacloprid, the applicant refers to the dermal absorption study and the derived absorption value from the CAR (2011). However, this is not acceptable as re-evaluation of the study according the EFSA Guidance on Dermal Absorption (2017) is required. This refers particularly to an assessment regarding the similarity of the test substance and the biocidal product and the derivation of a dermal absorption value used for the human health exposure assessment. In the absence of this re-evaluation, default values have to be applied.

3.6.1.1 Skin corrosion and irritation

Table 3.10 Summary table of animal studies on skin corrosion/irritation

Summary table of animal studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
OECD 404, GLP compliant, 1 (reliable without restriction)	Rabbit, New Zealand White, males, 3 animals	Imidacloprid GR 0.5, Vehicle: distilled water, 500 mg of pulverised test substance were moistened with 0.5 mL distilled water; Exposure: 4 h; Post-exposure period: 24, 48,72 h	Mean of scores at 24, 48 and 72 h: erythema (0.33) and oedema (0.00) Below range classification, therefore non-irritant	-	[redacted] Study No.: 406-1-01-8869

Table 3.11 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation

Value/conclusion	Non-irritant
Justification for the value/conclusion	Study data with comparable biocidal product
Classification of the product according to CLP	Not classified according to CLP

3.6.1.2 Eye irritation

Table 3.12 Summary table of animal studies on serious eye damage and eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
OECD 405, GLP complaint, 1 (reliable without restriction)	Rabbit, New Zealand White, females, 3 animals	Imidacloprid GR 0.5, Rabbit Nº1: 55.32 mg Rabbit Nº2: 52.64 mg Rabbit Nº3: 54.48 mg; Exposure period: 1 h Postexposure period 72 h.	Mean scores at 24, 48 and 72 h: corneal opacity (0), iritis (0), conjunctival redness (0) and conjunctival chemosis (0)	-	[redacted] Study No.: 407-1-01-8870

Table 3.13 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Non-irritant to the eye
Justification for the value/conclusion	Study data with comparable biocidal product
Classification of the product according to CLP	Not classified according to CLP

3.6.1.3 Respiratory tract irritation

Table 3.14 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the conclusion	The biocidal product does not contain co-formulants classified for respiratory irritation.
Classification of the product according to CLP	No classification required.

Table 3.15 Data waiving

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

3.6.1.4 Skin sensitization

Table 3.16 Summary table of animal studies on skin sensitisation

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure***)*	**Results**	**Remarks**	**Reference**
OECD 406, GLP complaint, 1 (reliable without restriction)	Guinea pig, Cavia porcellus (Hartley), males and females, 10 control, 20 test group	Imidacloprid GR 0.5, dose of 5.0 % in distilled water intradermaly injected during induction exposure (day 0). Test item is non-irritant when applied topically. day 6: clipped site was applied with 0.5 ml 10 % (w/v) sodium lauryl sulphate in vaseline to augment the local skin irritation. An amount of 100 mg of pulverised test item and moistened with 0.2 ml of distilled water was selected for topical application during induction on day 7 and challenge exposure on day 21	Well-defined erythema (in 20/20 guinea pigs) and very slight oedema (in 11/20 guinea pigs) to slight oedema (in 9/20 guinea pigs) on day 1 Very slight erythema in 17/20 guinea pigs to well defined erythema in 3/20 guinea pigs and very slightly oedema in 10/20 guinea pigs on day 10 no positive skin response (visual observation) at 24 and 48 h post patch removal of the challenge exposure		[redacted] Study No.: 408-1-01-8871

Table 3.17 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitising
Justification for the value/conclusion	Study data with comparable biocidal product
Classification of the product according to CLP	Not classified according to CLP

3.6.1.5 Respiratory sensitization

Table 3.18 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Respiratory sensitisation is not assumed.
Justification for the value/conclusion	The biocidal product does not contain co-formulants classified for respiratory sensitisation.
Classification of the product according to CLP	No classification is required.

Table 3.19 Data waiving

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

3.6.1.6 Acute oral toxicity

Table 3.20 Summary table of animal studies on acute oral toxicity

Summary table of animal studies on acute oral toxicity						
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels, type of administration**	**Signs of toxicity**	**Value LD50**	**Remarks**	**Reference**
OECD 423, GLP complaint, 1 (reliable without restriction)	Rat, Wistar, female, 6 animals	Imidacloprid Gr 0.5 2000 mg/kg bw, gavage	No mortality, No clinical signs were observed on any animal No adverse clinical observations or macroscopic external or internal abnormalities at necropsy	>2000 mg/kg bw		[redacted] Study No.: 401-1-01-8866

Table 3.21 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD50 >2000 mg/kg bw
Justification for the selected value	Study data with comparable biocidal product
Classification of the product according to CLP	Not classified according to CLP

3.6.1.7 Acute inhalation toxicity

Table 3.22 Summary table of animal studies on acute inhalation toxicity

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, form and particle size (MMAD) Actual and nominal concentration, Type of administration**	**Signs of toxicity**	**LC50**	**Remarks**	**Reference**
OECD 403, GLP complaint, 1 (reliable without restriction)	Rat, Wistar, males and females, 3 animals per group	Imidacloprid Gr 0.5, MMAD: 3.3 µm with GSD of 2.77, maximum breathing zone concentration of 2.322 mg/L air, nose-only exposure	No mortality in rats for the maximum achievable breathing zone concentration No treatment-related clinical signs were observed No adverse clinical observations or macroscopic external or internal abnormalities at necropsy	>2.311 mg/L air	-	[redacted] Study No.: 405-1-01-8868

Table 3.23 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} > 2.311 mg/L air
Justification for the selected value	Study data with comparable biocidal product
Classification of the product according to CLP	Not classified according to CLP

3.6.1.8 Acute dermal toxicity

Table 3.24 Summary table of animal studies on acute dermal toxicity

Summary table of animal studies on acute dermal toxicity

Method, Guideline GLP status, Reliability	Species, strain, Sex, No/group	Test substance, Vehicle, Dose levels, Surface area	Signs of toxicity	LD50	Remarks	Reference
OECD 402, GLP complaint, 1 (reliable without restriction)	Rat, Wistar, males and females, 5 animals per group	Imidacloprid GR 0.5 vehicle: Distilled water, 440.0 to 563.4 mg of moisture test item with 0.2 ml of distilled water, 7x5 cm body surface clipped area (>10 % body surface area)	No treatment-related mortality, clinical signs, changes in body weight or necropsy findings when treated with 2000 mg/kg bw of test item	>2000 mg/kg bw	-	[redacted] Study No.: 403-1-01-8867

Table 3.25 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} > 2000 mg/kg bw
Justification for the selected value	Study data with comparable biocidal product
Classification of the product according to CLP	Not classified according to CLP

3.6.2 Information on dermal absorption

Table 3.26 Value(s) used in the Risk Assessment – Dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Imidacloprid and cis-tricos-9-ene All scenarios
Value(s)	50 %
Justification for the selected value(s)	Default according to EFSA Guidance on Dermal Absorption (2017).

Table 3.27 Data waiving

Data waiving	
Information requirement	8.6 Information on dermal absorption

Justification	No dermal absorption study with the product has been submitted by the applicant. For the first authorisation of the biocidal product SOFAST, the application of the dermal absorption values from the Imidacloprid CAR (DE, 2011), derived for the formulation Confidor OD 200, have been considered acceptable. Upon renewal of SOFAST product authorisation, the respective study from the CAR has been re-evaluated by the refMS in accordance with EFSA Guidance on Dermal Absorption (2017) with respect to the derivation of a dermal absorption value: A value of 14 % has been derived from the human skin samples treated with dilutions of the test substance containing 0.007 % imidacloprid. However, a comparison between the biocidal product SOFAST and the test formulation Confidor OD 200, confirming similarity of formulations in accordance to the EFSA Guidance on Dermal Absorption (2017) and applicability of this value for the biocidal product SOFAST was not provided by the applicant. In the absence of reliable dermal absorption data, default values according to EFSA Guidance on Dermal Absorption (2017) are to be applied for both active substances.

3.6.3 Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)). Consequently, only the active substances were addressed in the human health risk assessment.

3.6.4 Other

Not relevant.

3.6.4.1 Food and feeding stuffs studies

Not relevant.

3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Not relevant.

3.6.4.3 Other test(s) related to the exposure to humans

Not relevant.

3.6.5 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of (the) non-active substance(s), refer to the respective section of the confidential annex.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

Relevant guidance documents consulted for human health risk assessment

Please, consider chapter 4.4.2.

Relevant exposure models or exposure studies used for human health risk assessment
Secondary exposure of the general public was in the first line assessed using ConsExpo web. Secondary exposure of toddlers by oral uptake of granules was assessed with a reverse reference scenario.

Professional user:
The evaluation of this insecticide is based on Headhoc recommendation No. 6 - Methods and models (version 4).

For the volatile active substance *cis*-tricos-9-ene (CAS 27519-02-4), the exposure estimates are calculated by the model ConsExpo.

For the non-volatile active substance Imidacloprid (CAS 138261-41-3), the following models are used:

- For scenario 1 (painting on and handling of cardboards):
  - mixing and loading-phase (manual dissolving of granules): BfR-Study Agricultural Operator (AOEM),
  - application (painting on cardboards): TNsG "consumer product panting model 3" and
  - secondary exposure (handling of cardboards): model "Secondary exposure(Handling of processed cardboards)".
- For scenario 2 (pouring granules into trays, application phase): the model "TNsG-Spray&Dust2 hh flex duster".

Strategy for human health risk assessment
Based on the mode of action of the active substance, a systemic exposure and risk assessment is perfomed. Since the biocidal product is not classified for local effects and relevant local effects of the active substances are not described, only a quantitative assessment is required.

Professional user:

Systemic quantitative risk assessment for the active substances Imidacloprid and *cis*-tricos-9-ene via the dermal and inhalation route was performed with the respective AELlong-term of 0.06 mg/kg bw/d (Imidacloprid) and 0.024 mg/kg bw/d (*cis*-tricos-9-ene).

Additionally, a cumulative risk characterisation from combined exposure to the active substances Imidacloprid and *cis*-tricos-9-ene was performed.

Considerations on volatility of the active substance(s) and substance(s) of concern
The attractant *cis*-tricos-9-ene (CAS 27519-02-4) has a low vapour pressure of 0.064 Pa. Imidacloprid is non-volatile.

Strategy for livestock exposure and/or dietary risk assessment
For the use in industrial/commercial premises and households/private areas as well as public areas, contact with food or feed has been excluded via label restrictions. For the use in livestock facilities the external exposure of livestock cannot be fully excluded by label restrictions and a residue exposure assessment according to Guidance on Estimating Livestock Exposure (Guidance on BPR (2017), Vol. III, Parts B+C, Section 6) has been conducted as described in detail in 3.6.8.3.

Strategy for the assessment of substance(s) of concern
Not applicable for professional users since no substance of concern was identified.

Strategy for disinfectant by-products assessment
Not relevant

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

Table 3.28 Summary table: main paths of human exposure

Summary table: main paths of human exposure					
Exposure path	**Primary (direct) exposure**		**Secondary (indirect) exposure**		
	Professional users (including industrial users and trained professional users)	**Non-professional users**	**Professional users** (including industrial users and trained professional users)	**Non-professional bystanders/ General public**	**Via food**
Oral	n.a.	n.a	n.a.	Yes	Yes
Dermal	Yes	n.a	No	Yes	n.a
Inhalation	Yes	n.a	No	Yes	n.a.

3.6.6.3 List of exposure scenarios

The following list contains all scenarios for professional exposure assessed according to the "Biocides Human Health Exposure Methodology Document"[9] (parts regularly updated by HEAdhoc Recommendation No. 6).

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

[9] The document is available at https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure.

Table 3.29 Summary table: exposure scenarios

Summary table: exposure scenarios			
Scenario and task number	**Description of scenario and tasks**	**Use No.**	**Exposed group**
Primary exposure			
FB4_1a	Professional use: painting on cardboards		
FB4_1a-1	Mixing & Loading: dissolving granules (manual)	1 3	professional
FB4_1a-2	Application: Painting on cardboards (manual)	1 3	professional
FB4_1a-3	Post-Application: washing out the brush replaced by disposable brush (manual)	1 3	professional
FB4_2	Professional use: bait application in disposable shallow dishes		
FB4_2-1	No Mixing & Loading: not applicable	2 4	professional
FB4_2-2	Application: Pouring granules into trays (manual / with spoon or beaker)	2 4	professional
FB4_2-3	Post-Application: Disposing of granules (manual)	2 4	professional
Secondary exposure			
FB4_1b	Placing of cardboards		
FB4_1b-1	Mixing & Loading: not applicable	1 3	professional
FB4_1b-2	Application: Placing of cardboards (manual)	1 3	professional
FB4_1b-3	Post-Application: not applicable	1 3	professional
BfR 1-1	***Re-entry of adults***		General public
BfR 1-2	***Re-entry of children***		General public
BfR 1-3	***Re-entry of toddlers***		General public
BfR 2	***Oral uptake of granules by a toddler – reverse reference scenario***		General public
Combined primary and secondary exposure			
FB4_1c	Painting on cardboads and placing them	1 3	professional

3.6.6.4 Reference values to be used in risk characterisation

Table 3.30 Reference values to be used in risk characterisation

Imidacloprid

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	Assessment Report Report (RMS DE (2011; rev 2015)		100		0.4 mg/kg bw/d
AELmedium-term	Assessment Report Report (RMS DE (2011; rev 2015)		100		0.2 mg/kg bw/d
AELlong-term	Assessment Report Report (RMS DE (2011; rev 2015)			100	0.06 mg/kg bw/d
AECdermal				n.r.	
AECinhalation				n.r.	
ARfD	90-day dog (acute effects) supported by the developmental study in rabbit		100		0.08 mg/kg bw
ADI	Assessment Report Report (RMS DE (2011; rev 2015)		100		0.06 mg/kg bw/d

Cis-tricos-9-en

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
AELshort-term	Assessment Report Report (RMS AT (2012)				> 0.57 mg/kg bw/d
AELmedium-term	Assessment Report Report (RMS AT (2012)				> 0.024 mg/kg bw/d
AELlong-term	Assessment Report Report (RMS AT (2012)				> 0.024 mg/kg bw/d
AECdermal				n.r.	
AECinhalation				n.r.	
ARfD					

ADI					

3.6.6.5 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.6.6.6 Professional users (including industrial users and trained professional users)

Professional users of the insecticide are assumed to be farmers as well as pest controllers. The latter may use the product daily during the growing season in commercial and public areas and in livestock facilities.
Manufacturing of the product is not assessed under the Biocidal products regulation (EU) No. 528/2012 (BPR).

Scenario FB4-1a: Professional use - painting on cardboards

Description and input parameters

Table 3.31 Description and input parameters

Description of Scenario FB4_1a
Sofast consists of solid granules. 200 grams must be dispersed in water for the treatment of 100 m² of floor area. Then, the viscous application solution (57.14% (w/w) Sofast) is applied to cardboards of 1 m² using hand held equipment as a brush or roller. Dermal exposure Exposure of the hands is considered to occur during all phases of handling. For mixing and loading phase (dosing of granules and diluting, manually), the calculation is based on the BfR-Study Agricultural Operator (AOEM). During the application phase (painting on cardboards), hands and body are exposed. The TNsG "Consumer product panting Model 3" is used (as professional users should have more experience in brush treatment than non-professionals, the assessment may represent a worst-case calculation). For potential hands as well as body exposure, the 75th percentile values are chosen due to the moderate uncertainty of the data. As prescription of use of a disposable brush or roller is assumed, subsequent cleaning of the brush is omitted (HEEG 11). Furthermore, an untreated edge must be left on every board where it can be touched without exposure. For placing of cardboards around the room: see scenario 1b. Exposure by inhalation Exposure to aerosols has been calculated for mixing and loading as well as for the application phase. The assessment is based on the same models chosen for the dermal exposure. In addition, inhalation exposure to vapour is calculated for the volatile active substance *cis*-tricos-9-ene (despite of the low vapour pressure) by the consumer exposure model "ConsExpo".

Input parameters for Scenario FB4_1a			
Skin: exposure towards areosols via BfR-study and TNSG consumer painting Model 3			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Mixing & loading duration [min]	15	Applicant
	Number of events [1/day]	1	Applicant
	Frequency	daily	Applicant
	Application duration [min]	120	Headhoc 6, No. 50
	Number of events [1/day]	1	Applicant
	Frequency	daily	Applicant
	Room volume [m³]	80	Expert judgement
	Ventilation rate [h-1]	0.5	Worst case assumption
	Application temperature [°C]	20	Room temperature
Tier 2 / gloves and coverall (type 6).	protective gloves [%]	90	HEEG Opinion
	coverall type 6 (coated) [%]	90	HEEG Opinion
Respiratory tract: exposure to vapour (cis-tricos-9-ene) during application via ConsExpo.			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Exposure Duration [min]	120	Headhoc 6, No. 50
	Molecular weight matrix [g/mol]	39.1	Expert judgement
	Product amount [kg]	5.6	Applicant
	Weight Fraction [%]	0.06	Applicant
	Room Volume [m³]	80	Expert judgement
	Ventilation rate [changes / h]	0.5	Worst case assumption
	Vapour pressure [Pa]	0.064	CAR/AR, 2012
	Application temperature [°C]	20	Room temperature
	Molecular weight [g/mol]	323	CAR/AR, 2012
	Release Area [m²]	16	Applicant, expert judgement
	Mass Transfer Coefficient [m/h]	10	Expert judgement
	Application Duration [min]	120	Headhoc 6, No. 50
	Does area increase?	True	Expert judgement (source persists)
Tier 2 / *none*	-	-	-

Scenario FB4_1b: Placing of cardboards

Description and input parameters

Table 3.32 Description and input parameters

Description of Scenario FB4_1b
After brushing with the solution of dissolved granules (see scenario FB4_1a), the cardboards are distributed in the rooms to be treated. Dermal exposure Exposure of the hands is considered to occur incidentally, only, due to the untreated edge of each cardboard (once per day). Because of stickiness of the application solution (sugar in water), a transfer coefficient of 50% on the palms of both hands is assumed and multiplied by the amount of b.p. on this area. Exposure by inhalation is assumed to be negligible.

Input parameters for Scenario FB4_1b			
Skin: exposure of hands towards wet cardboards			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Exposed skin area [cm²]:	410	palms of both hands
	Application amount [g b.p./m²]:	200	Applicant
	Contaminated hand surface [%] (fingers):	33	Expert judgement*)
	Transfer coefficient [%]:	50	due to high stickiness of the sugar solution
Tier 2 (PPE)	protective gloves [%]	90	HEEG Opinion

*) Incidental exposure of fingers (33% of hands), only, during fixing to walls (or ceilings) or disposal, if a sufficiently wide margin is left free when painting the cardboard.

Scenario FB4_2: Professional use: bait application in disposable shallow dishes

Description and input parameters

Table 3.33 Description and input parameters

Description of Scenario FB4_2
Sofast consists of solid granules which can be applied as ready to use bait (RTU) in shallow dishes, bowls or bait stations. The dishes (containing 20 g of b.p.) should be placed every 10 m². Exposure to dust is assumed to occur during application and post-application (loading dishes and disposal of the product). Dermal exposure Hands are predominantly exposed to dust during pouring of the granules. The calculation is based on "Consumer product spraying and dusting model 2" from the TNsG. 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 slightly volatile active substance *cis*-tricos-9-ene (0.064 Pa) using the consumer exposure model ConsExpo.

Input parameters for Scenario FB4_2			
***Skin**: exposure towards dust via the model 'consumer spray&dust' 2 (TNsG).*			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Application duration [min]	120	Headhoc 6, No. 50
	Release area [m²]	1	Applicant, expert judgement
Tier 2[2]	protective gloves [%]	90	HEEG Opinion
***Respiratory tract**: exposure towards vapour (cis-tricos-9-ene, only) via ConsExpo.*			
	Parameters[1]	Value	Reference and justification[3]
Tier 1 (no PPE)	Exposure Duration [min]	120	Headhoc 6, No. 50
	Molecular weight matrix [g/mol]	345	Expert judgement
	Product amount [kg]	3	Based on 20g/10m³ (applicant), 1500 m² (Headhoc 6 No.54)
	Weight Fraction	0,10%	Applicant
	Room Volume [m³]	8	Expert judgement
	Ventilation rate [changes / h]	0,5	Worst case assumption
	Vapour pressure [Pa]	0,064	CAR/AR, 2012
	Application temperature [°C]	20	Room temperature
	Molecular weight [g/mol]	323	CAR/AR, 2012
	Release Area [m²]	1	Applicant, expert judgement
	Mass Transfer Coefficient [m/h]	10	Expert judgement
	Application Duration [min]	120	Headhoc 6, No. 50
	Does area increase?	False	Expert judgement
Tier 2	-	-	-

Outcome of systemic exposure and risk characterisation

Table 3.34 Summary table: estimated systemic exposure and risk characterisation for professional users for the active substance Imidacloprid

Summary table: estimated systemic exposure and risk characterisation for professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake a.s. Imidacloprid [mg/kg bw/day]**	**Estimated inhalation uptake a.s. Imidacloprid [mg/kg bw/day]**	**Estimated total uptake a.s. Imidacloprid [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.06 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario FB4_1a	1 / no PPE	n.a.	0.09	2.01×10^{-4}	0.09	147	no
	2 / gloves, coated coverall (type 6)	n.a.	8.79×10^{-3}	2.01×10^{-4}	8.99×10^{-3}	15	**yes**
Scenario FB4_1b	1 / no PPE	n.a.	0.04	not expected (no aerosol)	0.04	68	**yes**
	2 / gloves	n.a.	4.09×10^{-3}	not expected (no aerosol)	4.09×10^{-3}	6.8	yes
Scenario FB4_2	1 / no PPE	n.a.	0.03	not expected (no aerosol)	0.03	44	**yes**
	2 / gloves	n.a.	0.01	not expected (no aerosol)	0.01	23	yes

n.a.: not applicable for professional user
For output tables from exposure assessment (detailed exposure calculations), please refer to Appendix 4.1.1

Table 3.35 Summary table: estimated systemic exposure and risk characterisation for professional users for the active substance *cis*-tricos-9-ene

Summary table: estimated systemic exposure and risk characterisation for professional users							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake a.s. cis-tricos-9-ene [mg/kg bw/day]**	**Estimated inhalation uptake a.s. cis-tricos-9-ene [mg/kg bw/day]**	**Estimated total uptake a.s. cis-tricos-9-ene [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.024 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario FB4_1a	1 / no PPE	n.a.	0.02	4.70×10^{-5}	0.02	71	**yes**
	2 / gloves, coated coverall (type 6)	n.a.	1.69×10^{-3}	4.70×10^{-5}	1.74×10^{-3}	7.2	yes
Scenario FB4_1b	1 / no PPE	n.a.	7.86×10^{-3}	not expected (no aerosol)	7.86×10^{-3}	33	**yes**
	2 / gloves	n.a.	7.86×10^{-4}	not expected (no aerosol)	7.86×10^{-4}	3.27	yes
Scenario FB4_2	1 / no PPE	n.a.	5.04×10^{-3}	not expected (no aerosol)	5.04×10^{-3}	21	**yes**
	2 / gloves	n.a.	2.65×10^{-4}	not expected (no aerosol)	2.65×10^{-4}	11	yes

n.a.: not applicable for professional user

For output tables from exposure assessment (detailed exposure calculations), please refer to Appendix 4.1.1.

Combined scenarios

Outcome of combined systemic exposure and risk characterisation

Table 3.36 Summary table: combined systemic exposure and risk characterisation for professional users for the active substance Imidacloprid

Summary table: combined systemic exposure and risk characterisation for professional users							
Scenarios combined	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake a.s. Imidacloprid [mg/kg bw/day]**	**Estimated inhalation uptake a.s. Imidacloprid [mg/kg bw/day]**	**Estimated total uptake a.s. Imidacloprid [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.06 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario 4_1c (combined FB4_1a + Scenario FB4_1b)	1 / no PPE	n.a.	0.13	2.01×10^{-4}	0.13	215	No
	2 / (gloves, coated coverall type 6)	n.a.	0.01	2.01×10^{-4}	0.01	22	**yes**

n.a.: not applicable for professional user
For output tables from exposure assessment (detailed exposure calculations), please refer to Appendix 4.1.1.

Table 3.37 Summary table: combined systemic exposure and risk characterisation for professional users for the active substance *cis*-tricos-9-ene

Summary table: combined systemic exposure and risk characterisation for professional users							
Scenarios combined	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake a.s. cis-tricos-9-ene [mg/kg bw/day]**	**Estimated inhalation uptake a.s. cis-tricos-9-ene [mg/kg bw/day]**	**Estimated total uptake a.s. cis-tricos-9-ene [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.024 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario 4_1c (combined FB4_1a + Scenario FB4_1b)	1 / no PPE	n.a.	0.02	4.70×10^{-5}	0.02	103	No
	2 / (gloves, coated coverall type 6)	n.a.	2.48×10^{-3}	4.70×10^{-5}	2.52×10^{-3}	11	**yes**

n.a.: not applicable for professional user
For output tables from exposure assessment (detailed exposure calculations), please refer to Appendix 4.1.1.

Outcome of (semi-)**quantitative local exposure** and risk characterisation

Not applicable for professional user

Outcome of qualitative local risk assessment

Not applicable for professional user

Conclusion

Based on the systemic risk assessment of the active substances Imidacloprid and *cis*-tricos-9-ene via the inhalation and dermal route, a risk for professional users resulting from the use scenarios of the biocidal product SOFAST is unlikely at the latest after TIER 2 consideration.
For risk characterisation from combined exposure to the active substances within the biocidal product, please refer to chapter 3.6.10.
In summary, regarding occupational safety, there are no objections against the uses taking into account the provisions described in chapter 3.6.11 of this PAR.

3.6.6.7 Non-professional users

Not relevant. The biocidal product is for professional use only.

3.6.6.8 Secondary exposure to professional bystanders and non-professional bystanders/general public

Not applicable for professional users.

Scenario BfR 1-1: [Re-entry of adults]

Description and input parameters

Table 3.38 Description and input parameters for bystanders

Description of Scenario BfR 1-1
Re-entry of adults Secondary dermal exposure of adults by re-entry to treated areas is assessed with ConsExpo web based on the rubbing off model for children and toddlers after spray application. The corresponding reports are also filed in section 4.1.1. For adults it is assumed that exposure is limited to the hand palms (exposed area: 410 cm^2), when touching treated (dried) cardboards. It is also expected that the dislodgeable active substance (3 %, dried paint, HEADhoc recommendation No 15, 2017) of a small surface is rubbed off by occasional hand contact (application rate: 200 g product for 1 m^2 cardboard; dislodgeable amount: imidacloprid = 1.04 g a.s./m^2 x 3 % = 0.0312 g a.s./m^2, *cis*-tricos-9-ene = 0.2 g a.s./m^2 x 3 % = 0.006 g a.s./m^2). This surface is assumed to be identical to the hand palms (rubbed surface: 410 cm^2). Please note that direct contact to treated cardboards is not expected for children as cardboards have to be placed out of reach of children. Oral exposure by hand-to mouth contact is considered not relevant for adults. Dermal exposure is assessed for imidacloprid and *cis*-tricos-9-ene. Based on the volatility of *cis*-tricos-9-ene, also inhalation exposure has to be assessed for this active substance. For inhalation exposure it was assumed that a person stays in a treated room for 18 h. Based on the application rate of 200 g product for a room of 100 m^2 and a treated cardboard surface of 1 m^2 for such a room, it is assumed that a person is exposed to the amount used for 0.25 m^2 applied in one room of 25 m^2 with a volume of 58 m^3 (50 g product). Note that the exposure time for dermal contact is shorter than for inhalation exposure since this contact will not occur permanently. Exposure of adults might occur occasionally during the application season (summer) and is therefore considered as medium-term exposure.

Input parameters for Scenario BfR 1-1			
Dermal exposure			
	Parameters	Value	Reference and justification
Tier 1	Dermal model	Direct product contact – Rubbing off	ConsExpo web
	Weight fraction compound	100 %	Calculation is based on the application rate of the a.s.
	Exposed area	410 cm^2	Expert judgement, based on HEAdhoc Recommendation no. 14, 2017, palm of both hands, adult
	Transfer coefficient, adult	0.78 m^2/h	HEAdhoc Recommendation no. 12, 2016
	Rubbed surface	410 cm^2	Expert judgement, based on HEAdhoc Recommendation no. 14, 2017, palm of both hands
	Release duration	60 min	ConsExpo Pest Control Products Fact Sheet, 2006
	Dislodgeable amount Imidacloprid *cis*-tricos-9-ene	0.0312 g/m^2 0.006 g/m^2	Expert judgement based on application rate a.s. and transfer coefficient according to Biocides Human Health Exposure Methodology, 2015, see also above
	Dermal absorption (uptake fraction)	50 %	Default, EFSA Guidance on dermal absorption, 2017
	Exposure frequency	1/d	Expert judgement, during summer season
	Body weight, adult	60 kg	HEAdhoc Recommendation no. 14, 2017
Inhalation exposure			
	Parameters	Value	Reference and justification
Tier 1	Inhalation model	Exposure to vapour: evaporation	ConsExpo web
	Molecular weight	323 g/mol	CAR/AR, 2012
	Vapour pressure	0.064 Pa	CAR/AR, 2012
	Inhalation model	Exposure to vapour: evaporation	ConsExpo web
	Exposure duration	18 h	See above
	Room volume	58 m^3	ConsExpo General Fact Sheet, 2006
	Ventilation rate	0.6 h^{-1}	ConsExpo Paint Products Fact Sheet, 2007
	Applied amount	50 g	See above

	Release area	0.25 m^2	See above
	Application duration	24 h	Time interval the a.s. evaporates
	Molecular weight matrix	342 g	Saccharose
	Mass transfer rate	2080 m/min	ConsExpo, Langmuir
	Inhalation absorption (uptake fraction)	100 %	Default
	Inhalation rate, adult, long-term	16 m^3/d	HEAdhoc Recommendation no. 14, 2017

Imidacloprid
Dermal exposure: 0.011 mg/kg bw/d
Total exposure: 0.011 mg/kg bw/d

Cis-tricos-9-ene
Inhalation exposure: 0.0017 mg/kg bw/d
Dermal exposure: 0.0021 mg/kg bw/d
Total exposure: 0.0037 mg/kg bw/d

Scenario BfR 1-2 and 1-3: [Re-entry of children/toddlers]

Description and input parameters

Description of Scenario BfR 1-2 and 1-3
Re-entry of children and toddlers Secondary exposure of toddlers and children may occur when they are crawling on floors near walls where cardboards have been treated. Direct contact to treated cardboards is not expected. Based on the label instructions, they have to b placed out of reach of children. In addition, children will not be present during application. Therefore, exposure during application is not relevant. Exposure was assessed using ConsExpo web. The corresponding reports are also filed in section 4.1.1. The maximum application rate is 1.04 g imidacloprid/m^2 and 0.20 g *cis*-tricos-9-ene /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 3 % are dislodgeable (Dried paint, HEADhoc recommendation No 15, 2017). Thus, an amount of 0.00468 g imidacloprid/m^2 or 0.0009 g *cis*-tricosene/m^2 is expected. According to the 'ConsExpo Pest Control Products Fact Sheet' (2006) the rubbed surface for general surface application is 22 m^2 representing the area of an average living room. Since the biocidal product is applied on cardboards and the ground has to be covered by a foil or by paper to minimise exposure of the floor the contaminated surface is considerably smaller even if applied by spraying. 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 a realistic worst case for such a contact. Oral exposure might occur, when contaminated hands are mouthed or licked. Based on the dermal external load calculated by ConsExpo for dermal point estimates and the assumptions that only hands are mouthed and that only 50 % of the dermal load is ingested orally the total ingested amount can be estimated. Dermal and oral exposure is assessed for both imidacloprid and *cis*-tricos-9-ene. Based on the volatility of *cis*-tricos-9-ene also inhalation exposure has to be assessed for this active substance. For inhalation exposure it was assumed that a person stays in a treated room for 18 h. Based on the application rate of 200 g product for a room of 100 m^2 and a treated cardboard surface of 1 m^2 for such a room, it is assumed that a person is exposed to the amount used for 0.25 m^2 applied in one room of 25 m^2 with a volume of 58 m^3 (50 g product). Note that the exposure time for dermal contact is shorter than for inhalation exposure since this contact will not occur permanently. 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.

Input parameters for Scenario 1-2 and 1-3			
Dermal exposure			
	Parameters	Value	Reference and justification
Tier 1	Dermal model	Direct product contact – Rubbing off	ConsExpo web
	Weight fraction compound	100 %	Calculation is based on the application rate of the a.s.
	Exposed area, child (2-6 y) Exposed area, toddler	1658 cm^2 1128 cm^2	Expert judgement based on HEAdhoc Recommendation no. 14, 2017, surface of hands, feet, half of the legs
	Transfer coefficient, child (2-6 y) and toddler	0.2 m^2/h	HEAdhoc Recommendation no. 12, 2016
	Rubbed surface	1 m^2	Expert judgement, see above
	Release duration	60 min	ConsExpo Pest Control Products Fact Sheet, 2006
	Dislodgeable amount imidacloprid *cis*-tricos-9-ene	 0.00468 g/m^2 0.00090 g/m^2	Expert judgement based on application rate a.s. and transfer coefficient according to Biocides Human Health Exposure Methodology, 2015, see also above
	Dermal absorption (uptake fraction)	50 %	Default, EFSA Guidance on dermal absorption, 2017
	Exposure frequency	1/d	(Expert judgement, during summer season)
	Body weight, child (2-6 y) Body weight, toddler	15.6 kg 10 kg	HEAdhoc Recommendation no. 14, 2017
Oral exposure			
	Parameters	Value	Reference and justification
Tier 1	Oral model	Direct product contact – Direct oral intake	ConsExpo web
	Dermal load imidacloprid child (2-6 y) toddler *cis*-tricos-9-ene child (2-6 y) toddler	 0.00056 mg/cm^2 0.00083 mg/cm^2 0.00011 mg/cm^2 0.00016 mg/cm^2	Dermal exposure, ConsExpo Web
	Surface hands, child (2-6 y) surface hands, toddler	330.9 cm^2 230.4 cm^2	HEAdhoc Recommendation no. 14, 2017

	Dermal load on hands imidacloprid child (2-6 y) toddler *cis*-tricos-9-ene child (2-6 y) toddler	 0.18530 mg 0.19123 mg 0.03640 mg 0.03686 mg	Dermal load x surface hands
	Transfer hand to mouth	50 %	
	Amount ingested imidacloprid child (2-6 y) toddler *cis*-tricos-9-ene child (2-6 y) toddler	 0.09265 mg 0.09562 mg 0.01820 mg 0.01843 mg	Dermal load on hands x Transfer hand to mouth
	Oral absorption	100 %	Default
Inhalation exposure			
	Parameters	Value	Reference and justification
Tier 1	Inhalation model	Exposure to vapour: evaporation	ConsExpo web
	Molecular weight, *cis*-tricos-9-ene	323 g/mol	CAR/AR, 2012
	Vapour pressure, *cis*-tricos-9-ene	0.064 Pa	CAR/AR, 2012
	Exposure duration	18 h	See above
	Room volume	58 m^3	ConsExpo General Fact Sheet, 2006
	Ventilation rate	0.6 h^{-1}	ConsExpo Paint Products Fact Sheet, 2007
	Applied amount	50 g	See above
	Release area	0.25 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
	Inhalation absorption (uptake fraction)	100 %	Default
	Inhalation rate, child (2-6 y), long-term Inhalation rate, toddler, long-term	10.1 m^3/d 8 m^3/d	HEAdhoc Recommendation no. 14, 2017

Child (2-6 y)
Imidacloprid
Dermal exposure: 0.030 mg/kg bw/d
Oral exposure 0.006 mg/kg bw/d
Total exposure: 0.036 mg/kg bw/d

Cis-tricos-9-ene

Inhalation exposure: 0.0040 mg/kg bw/d
Dermal exposure: 0.0058 mg/kg bw/d
Oral exposure 0.0012 mg/kg bw/d
Total exposure: 0.0110 mg/kg bw/d

Toddler
Imidacloprid
Dermal exposure: 0.0468 mg/kg bw/d
Oral exposure 0.0096 mg/kg bw/d
Total exposure: 0.0564 mg/kg bw/d

Cis-tricos-9-ene
Inhalation exposure: 0.0050 mg/kg bw/d
Dermal exposure: 0.0090 mg/kg bw/d
Oral exposure 0.0018 mg/kg bw/d
Total exposure: 0.0158 mg/kg bw/d

Scenario BfR 2: [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 intended to be applied in private households and in other public areas accessible for the general public 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. Calculations are also filed in section 4.1.1.
Based on the concentration of the active substances imidacloprid (0.52 %, w/w) and *cis*-tricos-9-ene (0.1 %, w/w) in the biocidal product, a body weight of 10 kg, an oral absorption of 100 % and the AEL_{acute} of 0.4 mg/kg bw and 0.57 mg/kg bw, respectively, the maximum acceptable dose is calculated:

Imidacloprid: 769 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 6.5-fold lower than this simplified unit. Although an aversive agent has been added, the ingestion of such an amount is not unlikely if a toddler or child has access to cups filled with the biocidal product or 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 and other children to the biocidal product are required. The biocidal product regardless if applied on cardboards or in loose granular form has to be placed inaccessible for children.

Outcome of systemic exposure and risk characterisation

Table 3.39 Summary table: estimated systemic exposure and risk characterisation for non-professional bystanders/general public to imidacloprid

Summary table: estimated systemic exposure and risk characterisation for non-professional bystanders/general public							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.2 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario BfR 1-1	1	-	0.011	-	0.011	5.5	Yes
Scenario BfR 1-2	1	0.006	0.030	-	0.036	18.0	Yes
Scenario BfR 1-3	1	0.0096	0.0468	-	0.0564	28.2	Yes

Table 3.40 Summary table: estimated systemic exposure and risk characterisation for non-professional bystanders/general public to cis-tricos-9-ene

Summary table: estimated systemic exposure and risk characterisation for non-professional bystanders/general public							
Exposure scenario	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.024 mg/kg bw/d	**Acceptable (Yes/No)**
Scenario BfR 1-1	1	-	0.0021	0.0017	0.0037	15.4	Yes
Scenario BfR 1-2	1	0.0012	0.0058	0.0040	0.0110	45.8	Yes
Scenario BfR 1-3	1	0.0018	0.0090	0.0050	0.0158	65.8	Yes

Combined scenarios

Not relevant.

Outcome of (semi-)quantitative local exposure and risk characterisation

Not relevant.

Outcome of qualitative local risk assessment

Not relevant.

Conclusion

Secondary exposure of the general public
No risk has been identified for re-entry of adults to areas, where cardboards are placed.
Based on the risk assessment, exposure of children to the biocidal product and its active substances by contact with contaminated surfaces (scenarios 1-2 and 1-3) is considered acceptable if treated cardboards are placed out of reach of children. Consequently, the biocidal product has to be labelled accordingly for uses 1 and 3. Furthermore, the risk assessment is based on the assumption that children are not present during application (painting of cardboards). This has to be clearly indicated on the label.
Based on scenario 2, a risk for children by ingestion of the bait cannot be generally excluded. Consequently, for uses 2 and 4, the baits have to be placed inaccessible for children.

3.6.7 Monitoring data

Not relevant.

3.6.8 Dietary risk assessment

The imidacloprid and cis-tricos-9-ene-containing biocidal product SOFAST is intended to be used for the control of flies either as granular bait in bait stations (use 2 and 4) or as bait painted on cardboards (use 1 and 3). For the use in industrial/commercial premises and households/private areas as well as public areas, contact with food or feed has been excluded via label restrictions.

- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets. (General)
- Attach treated cardboards inaccessible for children, pets, livestock animals and other non-target animals. (Use 1 and 3)
- Place product out of the reach of children, birds, pets, farm animals and other non-target animals. (Use 2 and 4)
- Place product away from food, drink and feed, as well as from utensils or surfaces that have contact with these. (Use 2 and 4)
- Do not store near food, drink and feed. (General conditions of storage)

For the use in livestock facilities the external exposure of livestock cannot be fully excluded by label restrictions and a residue exposure assessment according to Guidance on Estimating Livestock Exposure (Guidance on BPR (2017), Vol. III, Parts B+C, Section 6) has been conducted as described in detail in 3.6.8.3.

3.6.8.1 Information of non-biocidal use of the active substance and residue definitions

Imidacloprid is currently not approved under Reg. (EC) No 1107/2009 as plant protection product (Expiration of approval: 01/12/2020). MRLs have been set for imidacloprid according to Reg. (EU) 2021/1881. Furthermore, imidacloprid is approved in veterinary medicinal products for the use as insecticide against lice and fleas.

(Z)-9-Tricosene (cis-tricos-9-ene, muscalure) is a naturally occurring pheromone produced by flies and bees. (Z)-9-Tricosene is not approved under Reg. (EC) No 1107/2009 as plant protection product but a default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396 / 2005 applies.

Table 3.41 Summary table of other (non-biocidal) uses

Summary table of other (non-biocidal) uses					
	Sector of use	**Residue definition**	**Sample matrix**	**Reference regulation**	**Reference**
1.	Plant protection products	Insecticide (currently not approved)	Imidacloprid	*Reg. (EU) 2020/1643 (Not approved under Reg. (EC) No 1107/2009)* *MRL:* Reg. (EU) 2021/1881	*https://eur-lex.europa.eu/eli/reg_impl/2020/1643/oj* *https://eur-lex.europa.eu/eli/reg/2021/1881/oj*
2.	Veterinary medicinal products	Insecticide against lice and fleas (dogs, cats, fin fish)	Imidacloprid	Use in cats and dogs: EMA/CVMP/523600/2021 Use in fin fish: EMA/CVMP/223046/2021	https://www.ema.europa.eu/en/documents/smop-initial/cvmp-summary-positive-opinion-imoxat_en.pdf https://www.ema.europa.eu/en/documents/mrl-report/imidacloprid-fin-fish-summary-report-committee-veterinary-medicinal-products_en.pdf
3.	Plant protection products	Not approved	(Z)-9-Tricosene (formerly Z-9-Tricosene)	Not approved under *under Reg. (EC) No 1107/2009* Default MRL: **Reg. 396/2005**	https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/1343 https://eur-lex.europa.eu/eli/reg/2005/396/oj

3.6.8.2 Nature of residues

Stability and hydrolysis

Table 42

Summary of information on stability and hydrolysis studies (imidacloprid)		
	Conditions (Duration, Temperature, pH)	**Reference**
Hydrolytic stability	Imidacloprid 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 for EU outdoor temperature of 12 °C) Cis-tricos-9-ene not determined as muscalure, does not contain hydrolysable functional groups	Imidacloprid, Assessment Report 2011, RMS: DE Cis-tricos-9-ene, Assessment Report 2012, RMS: AT

Photolytic stability	Imidacloprid 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) Cis-tricos-9-ene not determined	Imidacloprid, Assessment Report 2011, RMS: DE Cis-tricos-9-ene, Assessment Report 2012, RMS: AT

Metabolism in livestock

Four studies investigating the metabolism of imidacloprid in livestock animals, two in lactating goats and two in laying hens, have been evaluated in the imidacloprid CAR (2011, Doc IIIA 6.15.3/01-04).

Information on metabolism of cis-tricos-9-ene in laboratory and livestock animals is not available as studies have 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 $P_{O/W}$ >8.2 has been reported in the CAR (2012).

Table 43

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 hens	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 (highest residues)	(residues of parent imidacloprid only = DoR acc. to Reg (EU) 396/2005) Goat (CAR (2011), Doc IIIA 6.15.3/01 and 02) muscle 2.55 mg/kg, fat 1.39 mg/kg, kidney 0.838 mg/kg, liver 0.79 mg/kg, milk 0.50 mg/kg Laying hens (CAR (2011), Doc IIIA 6.15.3/03 and 04) muscle (breast+ thigh muscle) 0.575mg/kg, fat 0.49 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))

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**: Parent compound imidacloprid only (according to Regulation (EU) No 2021/1881) **Risk assessment**: Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid (EFSA Reasoned Opinion, EFSA Journal 2019;17(1):5570). **Conversion factors** (monitoring to risk assessment): not concluded
Existing animal residue definitions	From evaluation of plant protection products **Monitoring**: Parent compound imidacloprid only (according to Reg (EU) No. 2021/1881) **Risk assessment**: Sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety,

	expressed as imidacloprid (EFSA Reasoned Opinion, EFSA Journal 2019;17(1):5570). **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

3.6.8.3 Estimating livestock exposure to active substances used in biocidal products and Worst Case Consumer Exposure (WCCE)

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 (RWCE) scenarios.

Relevant RWCE scenarios for livestock exposure assessment:

- oral exposure via ingestion of dead insect (poultry)
- inhalation exposure (all livestock animals)

The following RWCE 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, poultry)
- dermal exposure by rubbing against surfaces (cattle, pig)

List of scenarios

Table 3.44 Summary table of main representative exposure scenarios

Summary table of main representative exposure scenarios			
Scenario number	Type of use[1]	Description of scenario	Subject of exposure[2]
DRA-[1]	Animal husbandry	Indoor application of bait in livestock animal facilities (either granular bait in bait stations or bait painted on cardboards)	Livestock animals

DRA-[1]: Indoor application of bait in livestock animal facilities

If not indicated otherwise input parameters are taken from the "Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017"

Table 3.45 Input parameters for DRA-[1]

Input parameters for DRA-[1]		
Scenario	**Parameters**	**Value**
TIER I (External exposure assessment for livestock animals)		
Screening	**Maximal application rate biocidal product ($R_{appl.\ bp}$)**	– Use #3 painting on cardboards: 200 g bp dispersed in 150 ml for 1 m² cardboards per 100 m² room (2 g bp/m², (corresponding to 10.4 mg imidacloprid and 2 mg cis-tricos-9-ene per m² floor surface) – Use #4 bait application: 1 bait station per 10 m², in 1 bait station 20 g bp (2 g bp/m², corresponding to 10.4 mg imidacloprid and 2 mg cis-tricos-9-ene per m²)
	Concentration of active substance in biocidal product ($C_{a.s.}$)	– Imidacloprid: 0.52 % (w/w) = 0.0052 g a.s./g bp – Cis-tricos-9-ene: 0.1 % (w/w) = 0.001 g a.s./g bp
	Maximal application rate active substance ($R_{appl.\ a.s.}$)	– Imidacloprid: 0.0104 g a.s./m² =10.4 mg a.s./m² – Cis-tricos-9-ene: 0.002 g a.s./m² =2 mg a.s./m²
	Treated surface area per stable (floor area) ($A_{treated\ stable\ surface}$)	– beef cattle: 370 m^2 – dairy cattle: 1170 m^2 – calves: 160 m^2 – fattening pigs: 600 m^2 – breeding pigs (group housing)*: 710 m^2 – broiler chicken (parent broiler, free range, grating floor)*: 390 m^2 – laying hen (free range, litter floor)*: 1430 m^2 – rabbit: 0.24 m² – Sheep, lamb, goat, turkey, horse: No harmonized default values available so far. * worst-case housing condition regarding exposure calculations
	No. of animals per stable ($N_{animals}$)	– beef cattle: 125 – dairy cattle: 100 – calves: 80 – fattening pigs: 400 – breeding pigs (group housing)*: 132 – broiler chicken (parent broiler, free range, grating floor)*: 7000 – laying hen (free range, litter floor)*: 10000 – rabbit: 5 – Sheep, lamb, goat, turkey, horse: No harmonized default values available so far. * worst-case housing condition regarding exposure calculations

	Animal body weight (bw $_{animal}$)	– beef cattle: 500 kg – dairy cattle: 650 kg – calves: 200 kg – fattening pigs: 100 kg – breeding pigs: 260 kg – sheep: 75 kg – lamb:40 kg – slaughter goat: 13 kg – lactating goat: 70 kg – broiler chicken: 1.7 kg – laying hen: 1.9 kg – turkey:7 kg – horse: 400 kg – rabbit: 2.5 kg
RWCE Oral exposure - Ingestion of dead insects (poultry only)	**Consumption of b.p./a.s. by flies per day (Consumpt$_{. a.s\ by\ flies}$)**	3.5 mg b.p./day – Imidacloprid: 0.0182 mg a.s./fly/day – Cis-tricos-9-ene: 0.0035 mg a.s./fly/day
	No. of flies consumed per animal per day (N_{flies})	10 flies/day
RWCE Inhalative exposure - Saturated Vapour Concentration Model (SVC)	**Vapour pressure (VP)**(1)	– Imidacloprid: 4 x 10^{-10} Pa (20°C = 293 K) – Cis-tricos-9-ene: 0.064 Pa (20°C = 293 K)
	Molecular weight (MW)(1)	– Imidacloprid: 255.7 g/mol – Cis-tricos-9-ene: 322.6 g/mol
	Gas constant (R)	8.31451 J/K mol
	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 – sheep: 12 m^3/d – lamb: 7 m^3/d – slaughter goat: 3 m^3/d – lactating goat: 11 m^3/d – broiler chicken: 0.2 m^3/d – laying hen: 0.2 m^3/d – turkey: 0.6 m^3/d – horse: 43 m^3/d – rabbit: 0.9 m^3/d
TIER II (Refined RWCE)		
Refined oral exposure	**Log $P_{O/W}$(1)**	– Imidacloprid: 0.57 – Cis-tricos-9-ene: >8.2
Refined inhalative exposure – RIVM ConsExpo Web, version 1.1.1	**Weight fraction substance** (ConsExpo calculation)	Fraction of active substance in biocidal product – Cis-tricos-9-ene: 0.1 %
	Use frequency (ConsExpo calculation)	Application frequency of biocidal product: – up to 6 applications per year
	Model (ConsExpo calculation)	exposure to vapour

	Mode of release (ConsExpo calculation)	constant rate
	Exposure duration (ConsExpo calculation)	Default: 24 h
	Product amount (ConsExpo calculation)	Application rate biocidal product: 2 g/m² (corresponding to 2 mg cis-tricos-9-ene per m² floor surface) Values for individual animal species (considering default stable floor size): – beef cattle: 370 m^2 x 2 g/ m^2 = 740 g – dairy cattle: 1170 m^2 x 2 g/ m^2 = 2340 g – calves: 160 m^2 x 2 g/ m^2 = 320 g – fattening pigs: 600 m^2 x 2 g/ m^2 = 1200 g – breeding pigs (group housing)*: 710 m^2 x 2 g/ m^2 = 1420 g – broiler chicken (parent broiler, free range, grating floor)*: 390 m^2 x 2 g/ m^2 = 780 g – laying hen (free range, litter floor)*: 1430 m^2 x 2 g/ m^2 = 2860 g – rabbit: 0.24 m² x 2 g/m² = 0.48 g – Sheep, lamb, goat, turkey, horse: No harmonized default values available so far. * worst-case housing condition regarding exposure calculations
	Room volume per stable	– beef cattle: 3063 m^3 – dairy cattle: 9630 m^3 – calves: 590 m^3 – fattening pigs: 2110 m^3 – breeding pigs (group housing)*: 2480 m^3 – broiler chicken (parent broiler, free range, grating floor)*: 1458 m^3 – laying hen (free range, litter floor)*: 5360 m^3 – rabbit: 0.072 m^3 – Sheep, lamb, goat, turkey, horse: No harmonized default values available so far. * worst-case housing condition regarding exposure calculations
	Room ventilation rate	Winter season as worst case – beef cattle: 2 per h – dairy cattle: 0.9 per h – calves: 4.1 per h – fattening pigs: 1.9 per h – breeding pigs (group housing)*: 2.8 per h – broiler chicken : 4.3 per h – laying hen (free range, litter floor)*: 1.3 per h – Sheep, lamb, goat, turkey, horse, rabbit: No harmonized default values available so far. * worst-case housing condition regarding exposure calculations
	Emission duration (ConsExpo calculation)	Worst case estimate for time period during which the product is emitted in the stable: 4 weeks
	Absorption fraction (ConsExpo calculation)	Default: 100 %

	Alveolar ventilation rate (unit as applied in ConsExpo calculation)	– beef cattle: 2110 L/h – dairy cattle: 2589 L/h – calves: 1032 L/h – fattening pigs: 601 L/h – breeding pigs: 1267 L/h – sheep: 480 L/h – lamb: 294 L/h – slaughter goat: 122 L/h – lactating goat: 455 L/h – broiler chicken: 8.2 L/h – laying hen: 8.9 L/h – turkey: 23 L/h – horse: 1773 L/h – rabbit: 34 L/h

(1) Imidacloprid CAR, PT18, 2011, RMS: DE; cis-tricos-9-ene CAR, PT19, 2012, RMS: AT

Results of calculations for estimating livestock and consumer exposure for DRA-[1]

Calculations as described in the "Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017".

Screening:

Surface treatment of animal housing (floor area)

$$Exp_{ext.\ livestock} = (R_{appl.\ a.s.} \times A_{treated\ stable\ surface}) \div (N_{animals} \times bw_{animal})$$

Realistic worst-case:

Oral exposure - Ingestion of dead insects

$$Exp_{ext.\ livestock} = Consumpt._{a.s\ by\ flies.} \times N_{flies} \div bw_{animal}$$

Inhalative exposure - SVC model

$$Exp_{ext.\ livestock} = (VP \times MW) \div (R \times T) \times AVR \div bw_{animal}$$

Imidacloprid

TIER I: External exposure assessment for livestock

Table 3.46 Internal dose received by the animal TIER I - imidacloprid

	Screening		Realistic Worst-Case Estimate (RWCE)			
	External livestock exposure [mg a.s./kg bw/d]	**Trigger value of 0.004 mg/kg bw/d exceeded?**	**Oral exposure - Ingestion of flies** [mg a.s./kg bw/d]	**Inhalative exposure – SVC model** [mg a.s./kg bw/d]	**RWCE total exposure** [mg a.s./kg bw/d]	**Trigger value of 0.004 mg/kg bw/d exceeded?**
Beef cattle	0.0616	Yes	n.a.	4.280E-09	4.280E-09	No
Dairy cattle	0.1872	Yes	n.a.	4.003E-09	4.003E-09	No
Calf	0.1040	Yes	n.a.	5.245E-09	5.245E-09	No
Fattening pig	0.1560	Yes	n.a.	5.875E-09	5.875E-09	No
Breeding pig (group housing)	0.2152	Yes	n.a.	4.842E-09	4.842E-09	No
Sheep	n.a.	n.a.	n.a.	6.714E-09	6.714E-09	No
Lamb	n.a.	n.a.	n.a.	7.343E-09	7.343E-09	No
Slaughter goat	n.a.	n.a.	n.a.	9.684E-09	9.684E-09	No
Lactating goat	n.a.	n.a.	n.a.	6.594E-09	6.594E-09	No
Broilers (parent broilers, free range, grating floor)	0.3408	Yes	0.1071	4.937E-09	0.1071	Yes
Laying hen (free range, litter floor)	0.7827	Yes	0.0958	4.417E-09	0.0958	Yes
Turkey	n.a.	n.a.	0.0260	3.597E-09	0.0260	Yes
Horse	n.a.	n.a.	n.a.	4.511E-09	4.511E-09	No
Rabbit	0.1997	Yes	n.a.	1.511E-08	1.511E-08	No

Conclusions on TIER I calculations of external livestock exposure for imidacloprid

The external exposure estimate for livestock animals using the screening scenario "Surface treatment of animal housing (floor only)" shows 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 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.

TIER II: Refined exposure estimate for livestock

According to the Guidance on Estimating Livestock Exposure to Biocidal Active Substances a TIER II refinement is performed for the critical exposure scenario "ingestion of dead insects" (for broiler chicken, laying hen and turkey) identified in TIER I. For meat fat and eggs the refinement is based on metabolism studies in laying hen, while for liver and kidney the refinement is based on empirical transfer factors considering the log $P_{O/W.}$

A) Metabolism studies

Metabolism studies with imidacloprid in laying hens described in the CAR (2011) reported residues of 0.575 mg/kg (muscle), 0.49 mg/kg (fat), and 0.023 mg/kg (eggs) imidacloprid, respectively, following a daily exposure of 10 mg imidacloprid on 3 consecutive days.
The oral exposure scenario "ingestion of dead insects" considers a daily uptake of 3.5 mg biocidal product per fly, 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. Compared to the estimated daily imidacloprid uptake, the metabolism study applied an about 50-fold higher daily dosage. Therefore, the expected residues were extrapolated for meat, fat and eggs with an extrapolation factor of 50 (meat 0.0115 mg/kg, fat 0.0098 mg/kg, eggs 0.0005 mg/kg).

B) Empirical transfer factors based on log $P_{O/W}$

In TIER I it was assumed that the estimated external livestock exposure reflects the internal livestock exposure. For refinement the calculated external oral exposure estimate for chicken (broilers 0.1071 mg/kg bw/d, laying hen 0.0958 mg/kg bw/d, turkey 0.0260 mg/kg bw/d) was multiplied with empirical transfer factors based on log $P_{O/W}$ according to 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). Imidacloprid has a Log Po/w of 0.57. Therefore, a transfer factor of 0.3 was applied to estimate residues in chicken liver and kidney.

Table 47

TIER II -imidacloprid					
	Meat[A]	**Fat**[A]	**Liver**[B]	**Kidney**[B]	**Eggs**[A]
Broilers	0.0115	0.0098	0.0321	0.0321	n.a.
Laying hen	0.0115	0.0098	0.0287	0.0287	0.0005
Turkey	0.0115	0.0098	0.0078	0.0078	n.a.

A – Refinement based on metabolism studies (extrapolation factor 50)
B – Refinement with empirical transfer factors based on log $P_{O/W}$

Conclusions on TIER II refinements of livestock exposure assessment for imidacloprid

The refinement of the oral exposure estimate for imidacloprid in poultry results in exposure values above the trigger value of 0.004 mg/kg bw/d. Therefore, an estimate of the worst case consumer exposure (WCCE) is required (according to the EMA Guideline on risk characterization and assessment of maximum residue limits (MRL) for biocides (EMA/CVMP/SWP/90250/2010)).

TIER III: Worst case consumer exposure

Worst-case consumer exposure (WCCE) calculation is performed with consumption values from the EMA food basket for adults (daily intake of 300 g muscle, 100 g liver, 50 g fat (poultry 90 g), 50 g kidney (poultry 10g), 1500 g milk and 100 g eggs). The food basket is mainly reflecting the dietary pattern of adults (bw_{human} 60 kg), which differs from the children's pattern. This difference is not fully covered by the food basket, but the EMA considered that the system in place for the establishment of MRLs for milk is adequate also for children (EMEA/CVMP/391/02-FINAL-corrigendum November 2002).

Animals with the highest amount of residues were included in WCCE calculations:

- Meat: Broilers (0.0115 mg/kg bw/d)
- Fat: Broilers (0.0098 mg/kg bw/d)
- Liver: Broilers (0.0321 mg/kg bw/d)
- Kidney: Broilers (0.0321 mg/kg bw/d)
- Eggs: Laying hen (0.0005 mg/kg bw/d)
- Milk: Sheep (6.714E-09 mg/kg bw/d)

Calculation of WCCE:

WCCE = residues x food intake per day ÷ human body weight = R x I/day ÷ bw_{human}

$WCCE_{total} = WCCE_{meat} + WCCE_{fat} + WCCE_{liver}\ WCCE_{kidney} + WCCE_{milk} + WCCE_{eggs}$

Reference value for imidacloprid:

ADI = 0.06 mg/kg bw/day

A separate acute risk assessment including comparison of intake with the value of the acute reference dose ARfD (0.08 mg/kg bw) is not conducted, as the calculated dietary risk based on consumption data from EMA Food basket is considered to also cover the assessment of acute effects.

Table 48

TIER III - imidacloprid			
Edible tissue	**Internal exposure of livestock animals** [mg/kg bw/d]	**Food intake** [kg/d]	**$WCCE_{tissue}$** [mg/kg bw/d]
Meat	0.0115	0.3	5.75E-05
Fat	0.0098	0.09	1.47E-05
Liver	0.0321	0.1	5.35E-05
Kidney	0.0321	0.01	5.35E-06
Eggs	0.0005	0.1	8.33E-07
Milk	6.714E-09	1.5	1.68E-10
		$WCCE_{total}$	**1.32E-04**

TIER III - imidacloprid			
Edible tissue	**Internal exposure of livestock animals** [mg/kg bw/d]	**Food intake** [kg/d]	**$WCCE_{tissue}$** [mg/kg bw/d]
		[mg/kg bw/d]	
		% ADI	**0.2 %**

Conclusions on WCCE

A risk for consumers via dietary uptake of imidacloprid residues from the intended biocidal use is not expected.

Cis-tricos-9-ene

TIER I: External exposure assessment for livestock
Table 49

TIER I - cis-tricos-9-ene						
	Screening		**Realistic Worst-Case Estimate (RWCE)**			
	External livestock exposure [mg a.s./kg bw/d]	**Trigger value of 0.004 mg/kg bw/d exceeded?**	**Oral exposure - Ingestion of flies** [mg a.s./kg bw/d]	**Inhalative exposure – SVC model** [mg a.s./kg bw/d]	**RWCE total exposure** [mg a.s./kg bw/d]	**Trigger value of 0.004 mg/kg bw/d exceeded?**
Beef cattle	0.0118	Yes	n.a.	0.864	0.864	Yes
Dairy cattle	0.0360	Yes	n.a.	0.808	0.808	Yes
Calf	0.0200	Yes	n.a.	1.059	1.059	Yes
Fattening pig	0.0300	Yes	n.a.	1.186	1.186	Yes
Breeding pig (group housing)	0.0414	Yes	n.a.	0.977	0.977	Yes
Sheep	n.a.	n.a.	n.a.	1.355	1.355	Yes
Lamb	n.a.	n.a.	n.a.	1.482	1.482	Yes
Slaughter goat	n.a.	n.a.	n.a.	1.955	1.955	Yes
Lactating goat	n.a.	n.a.	n.a.	1.331	1.331	Yes
Broilers (parent broilers, free range, grating floor)	0.0655	Yes	0.0206	0.997	1.0171	Yes
Laying hen (free range, litter floor)	0.1505	Yes	0.0184	0.892	0.9101	Yes
Turkey	n.a.	n.a.	0.0050	0.726	0.7311	Yes
Horse	n.a.	n.a.	n.a.	0.911	0.911	Yes
Rabbit	0.0384	Yes	n.a.	3.049	3.049	Yes

Conclusions on TIER I calculations of external livestock exposure for cis-tricos-9-ene

The external exposure estimate for livestock animals using the screening scenario "Surface treatment of animal housing (floor only)" shows 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"
- inhalative exposure scenario "SVC model"

TIER II: Refined exposure estimate for livestock

According to the Guidance on Estimating Livestock Exposure to Biocidal Active Substances a TIER II refinement is performed for the critical exposure scenarios "ingestion of dead insects" (for broiler chicken, laying hen and turkey) and "inhalative exposure" identified in TIER I.

A) Refinement of oral exposure: Empirical transfer factors based on log $P_{O/W}$

In TIER I it was assumed that the estimated external livestock exposure reflects the internal livestock exposure. For refinement in TIER II, the calculated external oral exposure estimate for chicken (broilers 0.0206 mg/kg bw/d, laying hen 0.0184 mg/kg bw/d, turkey 0.0050 mg/kg bw/d) was multiplied with empirical transfer factors based on log $P_{O/W}$ according to 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). Cis-tricos-9-ene has a Log Po/w above 8.2. Therefore, the following transfer factors are applied to estimate residues in chicken edible tissue and eggs. The factors are applicable for oral uptake only.

Table 50

Transfer factors based on log $P_{O/W}$ for cis-tricos-9-ene						
LogP_{OW} range	**Eggs**	**Milk**	**Muscle**	**Fat**	**Liver**	**Kidney**
>8	0.21	0.32	0.04	0.74	0.08	0.08

Table 51

TIER II – Refined oral exposure - cis-tricos-9-ene Values that exceed the trigger value of 0.004 mg/kg bw/d are highlighted in red					
	Meat	**Fat**	**Liver**	**Kidney**	**Eggs**
Broilers (parent broilers, free range, grating floor)	0.0008	0.0152	0.0016	0.0016	n.a.
Laying hen (free range, litter floor)	0.0008	0.0152	0.0016	0.0016	0.0043
Turkey	0.0002	0.0037	0.0004	0.0004	n.a.

Conclusions

The refinement of the oral exposure estimate for cis-tricos-9-ene in poultry results in exposure values below the trigger value of 0.004 mg/kg bw/d, except for fat of broilers and laying hens as well as chicken eggs.

B) Refinement of inhalation exposure: ConsExpo

In TIER I 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 vapour concentration (SVC). In TIER II the estimation of inhalation exposure is refined using the RIVM ConsExpo Web model (version 1.1.1, 17-01-2023) "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. Default values are applied as reported in Table 81 "Input parameters for DRA-[1]"

Results of the ConsExpo calculations (external event dose) are summarized in the table below.

Table 52

	External event dose* [mg a.s./kg bw/d]	**Trigger value of 0.004 mg/kg bw/d exceeded?**
Beef cattle	1.8E-05	No
Dairy cattle	3.7E-05	No
Calf	2.4E-05	No
Fattening pig	3.1E-05	No
Breeding pig (group housing)	4.6E-05	No
Sheep	n.a.	n.a.
Lamb	n.a.	n.a.
Slaughter goat	n.a.	n.a.
Lactating goat	n.a.	n.a.
Broilers (parent broilers, free range (grating floor))	2.2E-05	No
Laying hen (free range (litter floor))	6.6E-05	No
Turkey	n.a.	n.a.
Horse	n.a.	n.a.
Rabbit	n.a.	No

* the amount potentially absorbed by inhalation per kg body weight during one event

Conclusions

The refinement of the inhalative exposure estimate for cis-tricos-9-ene in poultry results in exposure values below the trigger value of 0.004 mg/kg bw/d.

No ConsExpo calculations could be performed for sheep, goat, turkey, horse and rabbit as no default values are available. Nevertheless, it is assumed that the inhalative exposure of these animal species is in a similar range as for the calculated livestock species and consequently, that the trigger value is not exceeded.

Total refined exposure

Table 53

TIER II – Total refined exposure (oral + inhalative) - Cis-tricos-9-ene Values that exceed the trigger value of 0.004 mg/kg bw/d are highlighted in red						
	Meat	**Fat**	**Liver**	**Kidney**	**Eggs**	**Milk**
Beef cattle	1.8E-05	1.8E-05	1.8E-05	1.8E-05	n.a.	n.a.
Dairy cattle	3.7E-05	3.7E-05	3.7E-05	3.7E-05	n.a.	3.7E-05
Calf	2.4E-05	2.4E-05	2.4E-05	2.4E-05	n.a.	n.a.
Fattening pig	3.1E-05	3.1E-05	3.1E-05	3.1E-05	n.a.	n.a.
Breeding pig (group housing)	4.6E-05	4.6E-05	4.6E-05	4.6E-05	n.a.	n.a.
Broilers (parent broilers, free range, grating floor))	8.22E-04	1.52E-02	1.62E-03	1.62E-03	n.a.	n.a.
Laying hen (free range, litter floor)	8.66E-04	1.53E-02	1.67E-03	1.67E-03	4.37E-03	n.a.
Turkey	2.00E-04	3.70E-03	4.00E-04	4.00E-04	n.a.	n.a.

Conclusions on TIER II refinements of livestock exposure assessment for cis-tricos-9-ene

The refinement of the oral and inhalative exposure estimate for cis-tricos-9-ene results in livestock exposure values below the trigger value of 0.004 mg/kg bw/d, except for poultry fat (0.0152 mg/kg bw/d) and chicken eggs (0.00437 mg/kg bw/d). Therefore, an estimate of the worst case consumer exposure (WCCE) is required (according to the EMA Guideline on risk characterization and assessment of maximum residue limits (MRL) for biocides (EMA/CVMP/SWP/90250/2010)).

TIER III: Worst case consumer exposure

Worst-case consumer exposure (WCCE) calculation is performed with consumption values from the EMA food basket for adults (daily intake of 300 g muscle, 100 g liver, 50 g fat (poultry 90 g), 50 g kidney (poultry 10g), 1500 g milk and 100 g eggs). The food basket is mainly reflecting the dietary pattern of adults (bw_{human} 60 kg), which differs from the children's pattern. This difference is not fully covered by the food basket, but the EMA considered that the system in place for the establishment of MRLs for milk is adequate also for children (EMEA/CVMP/391/02-FINAL-corrigendum November 2002).

Animals with the highest amount of residues were included in WCCE calculations:

- Meat: Broilers (8.22E-04 mg/kg bw/d)
- Fat: Broilers (1.52E-02 mg/kg bw/d)
- Liver: Broilers (1.62E-03 mg/kg bw/d)
- Kidney: Broilers (1.62E-03 mg/kg bw/d)
- Eggs: Laying hen (4.37E-03 mg/kg bw/d)
- Milk: Dairy cattle (3.7E-05 mg/kg bw/d)

Calculation of WCCE:

WCCE = residues x food intake per day ÷ human body weight = R x I/day ÷ bw_{human}

$WCCE_{total} = WCCE_{meat} + WCCE_{fat} + WCCE_{liver}\ WCCE_{kidney} + WCCE_{milk} + WCCE_{eggs}$

Reference value for cis-tricos-9-ene:

$AEL_{long\text{-}term}$ = 0.024 mg/kg bw/d (cis-tricos-9-ene CAR, PT19, 2012, RMS: AT)

Table 54

TIER III - cis-tricos-9-ene			
Edible tissue	**Internal exposure of livestock animals** [mg/kg bw/d]	**Food intake** [kg/d]	**$WCCE_{tissue}$** [mg/kg bw/d]
Meat	0.0008	0.3	4.11E-06
Fat	0.0152	0.09	2.28E-05
Liver	0.0016	0.1	2.70E-06
Kidney	0.0016	0.01	2.70E-07
Eggs	0.0044	0.1	7.28E-06
Milk	0.00004	1.5	9.25E-07
		$WCCE_{total}$ [mg/kg bw/d]	**3.81E-05**
		% $AEL_{long-term}$	**0.16 %**

Conclusions on WCCE
A risk for consumers via dietary uptake of cis-tricos-9-ene residues from the intended biocidal use is not expected.

3.6.8.4 Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s) and consumer exposure

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

3.6.8.5 Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure

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

3.6.8.6 Maximum residue limits or equivalent

Table 3.55 Maximum residue limits or equivalent

MRLs or other relevant reference values	**Reference**	**Relevant commodities**	**Value**	**Estimated food concentration (mg/kg)**	**MRL exceedance (Yes/No)**
MRL (imidacloprid)	Reg. (EU) 2021/1881	Food of plant and animal origin	- Products of plant origin: 0.01* - 15 mg/kg - Products of animal origin:	Between 4.0E-09 mg/kg and 0.0321 mg/kg	Yes

			0.01* mg/kg (except for honey 0.05* mg/kg)		
Default MRL (cis-tricos-9-ene)	Art 18(1)(b) Reg 396 / 2005	Food of plant and animal origin	0.01 mg/kg	Between 1.8E-05 mg/kg and 0.015 mg/kg	Yes

*MRL set at limit of quantification (LOQ)

Imidacloprid

The estimated imidacloprid residues in chicken meat, liver and kidney for broiler, laying hen and turkey exceed the current MRLs of 0.01 mg imidacloprid/kg (see TIER II results for imidacloprid). Nevertheless, exceedance of imidacloprid MRLs in chicken edible tissues from the intended biocidal use is not expected as the exposure estimate for the scenario "Oral intake of dead flies" is based on conservative assumptions.

The study Kustiati et al. (J. Entomol., 13 (1-2): 40-47, 2016) analysed the toxicity of imidacloprid in 33 house fly strains resulting in LD50 values in the range of 0.009 to 0.14 mg imidacloprid/g sucrose. As this is well below the SOFAST application rate of 5.2 mg imidacloprid per g biocidal product (concentration of imidacloprid in biocidal product 0.52 % (w/w), biocidal product primarily consists of sucrose) it seems reasonable to assume that the actual amount of imidacloprid in a dead fly is significantly lower than initially assumed in the calculations and consequently the uptake of imidacloprid by chicken via flies is significantly lower than calculated. According to Guidance on BPR (Vol III, Part B+C, 2017, Example 1.2 on page 345 ff) LD50 measurements flies are a suitable refinement option to determine the active substance concentration in flies.

Considering the highest LD50 value (0.14 mg imidacloprid/g sucrose) and assuming that one fly consumes 3.5 mg dried sucrose per day, it can be calculated that one fly takes up 0.00049 mg imidacloprid /day. Assuming an uptake of 10 flies per chicken per day, the livestock exposure is reduced to 0.0029 mg/kg bw/d for broilers, 0.0026 mg/kg bw/d for laying hens and 0.0007 mg/kg bw/d for turkey. This is well below the MRL of 0.01 mg/kg for imidacloprid in poultry tissue.

Cis-tricos-9-ene

The estimated cis-tricos-9-ene residues in chicken fat for broiler and laying hen slightly exceed the current default MRL of 0.01 mg cis-tricos-9-ene /kg (see TIER II results for cis-tricos-9-ene). Nevertheless, exceedance of the MRL in chicken fat tissues from the intended biocidal use is not expected for the following reasons:

- In the scenario "Oral intake of dead flies" a worst-case uptake of 3.5 µg cis-tricos-9-ene per fly is assumed (uptake of 3.5 mg biocidal product containing 0.1 % cis-tricos-9-ene). However due to its high volatility cis-tricos-9-ene dissipates rapidly in the environment, so that the amount of the substance at the place of biocidal product application is constantly decreasing and thus the actual amount taken up per fly is expected to be lower than the assumed 3.5 µg/fly.
- Regarding the metabolism of cis-tricos-9-ene it is stated in the CAR (Doc IIA, 2012, eCA: AT) that "in case the substance reaches systemic availability it may be expected that it is oxidised by cytochrome P450 enzymes to various alcohols." These alcohols

may then be further metabolised into long chain fatty acids which undergo further ß-oxidation finally leading to complete oxidation in the mitochondria. "Alternatively the alcohols may be conjugated with glucuronide and excreted via the kidneys." It is expected that similar degradation occurs in livestock animals and that residues of cis-tricos-9-ene may not be distinguishable from endogenous fatty acid metabolites..

- Cis-tricos-9-ene is a naturally occurring pheromone of the housefly with natural levels up to 1.5 µg per fly (Dillwith et al., J. Insect Pysiol., Vol. 29, No. 5, pp. 377-386, 1983) which is in the same order of magnitude as the assumed uptake from the biocidal product.

3.6.9 Aggregated exposure and risk characterisation

Not relevant.

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

Tier 1 and tier 2

Table 3.56 Scenario BfR 1-1, adults, re-entry, tier 1 and tier 2

Scenario BfR 1-1	Imidacloprid	*cis*-tricos-9-ene	Conclusions
Medium-term			
Tier 1	5.5 % AEL	15.4 % AEL	Acceptable
Tier 2	0.055	0.154	Acceptable
	HI = 0.209		

Table 3.57 Scenario BfR 1-2, children, re-entry, tier 1 and tier 2

Scenario BfR 1-2	Imidacloprid	*cis*-tricos-9-ene	Conclusions
Medium-term			
Tier 1	18.0% AEL	45.8% AEL	Acceptable
Tier 2	0.180	0.458	Acceptable
	HI = 0.638		

Table 3.58 Scenario BfR 1-3, toddlers, re-entry, tier 1 and tier 2

Scenario BfR 1-1	Imidacloprid	*cis*-tricos-9-ene	Conclusions
Medium-term			
Tier 1	28.2 % AEL	65.8 % AEL	Acceptable
Tier 2	0.282	0.658	Acceptable
	HI = 0.940		

Approach is neither applicable nor required for Scenario BfR 2 (reverse reference scenario).

Professional user:

Tier 1 and tier 2

Table 3.59 Tier 1 and Tier 2

Scenario FB4_1a Primary exposure	**Active substance Imidacloprid**	**Active substance cis-tricos-9-ene**	**Conclusions**
Without PPE			
Tier 1[a]	*147% AEL*	*71% AEL*	*Not Acceptable*
Tier 2[b]	*1.47*	*0.71*	
		HI = 2.18	*Not acceptable*
With PPE			
Tier 1[a]	*15% AEL*	*7% AEL*	*Acceptable*
Tier 2[b]	*0.15*	*0.07*	
		HI = 0.22	*Acceptable*
Scenario FB4_1b Primary exposure	**Active substance Imidacloprid**	**Active substance cis-tricos-9-ene**	**Conclusions**
Without PPE			
Tier 1[a]	*68% AEL*	*33% AEL*	*Acceptable*
Tier 2[b]	*0.68*	*0.33*	
		HI = 1.01	*Not Acceptable*
With PPE			
Tier 1[a]	*7% AEL*	*7% AEL*	*Acceptable*
Tier 2[b]	*0.07*	*0.07*	
		HI = 0.1	*Acceptable*
Scenario FB4_2 Primary exposure	**Active substance Imidacloprid**	**Active substance cis-tricos-9-ene**	**Conclusions**
Without PPE			
Tier 1[a]	*44% AEL*	*21% AEL*	*Acceptable*
Tier 2[b]	*0.44*	*0.21*	*Acceptable*
		HI = 0.65	
Tier 1[a]	*23% AEL*	*11% AEL*	*Acceptable*
Tier 2[b]	*0.23*	*0.11*	
		HI = 0.34	*Acceptable*
Scenario 4_1c (combined FB4_1a + FB4_1b) Combined primary exposure	**Active substance Imidacloprid**	**Active substance cis-tricos-9-ene**	**Conclusions**
Without PPE			
Tier 1[a]	*215% AEL*	*103% AEL*	*Not acceptable*
Tier 2[b]	*2.15*	*1.03*	
		HI = 3.18	*Not acceptable*
With PPE			
Tier 1[a]	*22% AEL*	*10% AEL*	*Acceptable*
Tier 2[b]	*0.22*	*0.10*	*Acceptable*

a: Tier 1 here is an intermediary step to verify risk acceptability for each individual substance (active substance or SoC) with systemic effects used in the product and is followed by
b: Tier 2 to assess the combined exposure/toxixity of the biocidal product/~ family.

Tier 3a
Not applicable for professional user

Tier 3b
Not applicable for professional user

3.6.11 Overall conclusion on risk assessment for human health

Table 3.60 Overall conclusion on the risk assessment for human health from systemic and local exposure

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
[1] + [3] (Scenario FB4_1a)	Professional use: Brushing on cardboards	*acceptable with the following risk mitigation measures:* Respiratory tract: no protection Body: coverall type 6 Hands: protective gloves Feet: n.a.	Wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by brushing. Wear a protective coverall (at least type 6, EN 13034).
[1] + [3] (Scenario FB4_1b)	Placing of cardboards	*acceptable with the following risk mitigation measure:* Respiratory tract: no protection Body: no protection Hands: protective gloves Feet: n.a.	Wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by brushing.
[2] + [4] (Scenario FB4_2)	Professional use: bait application in disposable shallow dishes	*Acceptable without PPE* Respiratory tract: no protection Body: no protection Hands: no protection Feet: n.a.	-
[1]	Professional use: painting on cardboards in industrial/commercial	The use is considered acceptable for the general public (secondary exposure) if the treated cardboards are placed out of reach of children. Children are not present during	Attach treated cardboards inaccessible for children.

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
	premises; households/ private areas; public areas	application.	Children should not be present during mixing / loading and the application to cardboards
[2]	Professional use: bait application in disposable shallow dishes in industrial/commercial premises; households/ private areas; public areas	The use is only considered acceptable for the general public (secondary exposure) if shallow dishes are place inaccessible for children.	Place product out of the reach of children.
[3]	Professional use in livestock facilities: painting on cardboards	The use is considered acceptable for the general public (secondary exposure) if the treated cardboards are placed out of reach of children. Children are not present during application.	Attach treated cardboards inaccessible for children. Children should not be present during mixing / loading and the application to cardboards
[4]	Professional use in livestock facilities: bait application in bait stations	The use is only considered acceptable for the general public (secondary exposure) if bait stations are placed inaccessible for children	Place product out of the reach of children.

3.7 Risk assessment for animal health

3.7.1 Risk for companion animals

In the absence of specific guidance, it is assumed that the human exposure and risk assessment for the general public, particularly for children covers also companion animals. Hence, similar risk mitigation measures also apply to companion animals to prevent exposure. The measures listed in section 3.6.11 will be extended for pets.

Attach treated cardboards inaccessible for children and pets, (livestock animals and other non-target animals). (use 1+3)
Children and pets should not be present during mixing / loading and the application to cardboards. (use 1+3)
Place product out of the reach of children, (birds,) pets, (farm animals and other non-target animals). (use 2+4)

3.7.2 Risk for livestock animals

Based on the dietary exposure assessment the following systemic exposure values have been estimated in Tier 2 for full-grown animals (for details refer to the section Dietary Exposure).

Table 3.61 Risk for livestock animals, imidacloprid

	Dairy cattle, beef cattle, caf, fattening pig, breeding pig, sheep, lamb, slaughter goat, lactating goat, horse, rabbit [mg a.s./ kg bw/d]	**Laying hen [mg a.s./ kg bw/d]**	**Broiler [mg a.s./kg bw/d]**	**Turkey [mg a.s./ kg bw/d]**
Total exposure refined (TIER II)	4.00×10^{-9} - 1.51×10^{-8}	0.0958	0.1071	0.0260
Human NOAEL	6	6	6	6
Margin of Exposure (MoE)	1.50×10^{-9} – 3.97×10^{-8}	63	56	231

Table 3.62 Risk for livestock animals, *cis*-tricos-9-ene

	Dairy cattle, beef cattle, caf, fattening pig, breeding pig, sheep, lamb, slaughter goat, lactating goat, horse, rabbit [mg a.s./ kg bw/d]	Laying hen [mg a.s./ kg bw/d]	Broiler [mg a.s./kg bw/d]	Turkey [mg a.s./ kg bw/d]
Total exposure refined (TIER II)	1.80×10^{-5} – 6.60×10^{-5}	0.018466	0.020622	0.005066
Human AEC	0.024	0.024	0.024	0.024
% AEC	0.075 – 0.275	77	86	21

Risk assessment for imidacloprid

Based on the assessment above, the MoE is above 100 for all relevant livestock animals except for laying hens and broilers with a MoE of 63 and 56, respectively. Based on the discussion on WG-II-2021 a MoE of 10 or even 5 is considered sufficient for livestock animals taking into account the conservative elements of such assessments (see WGII2021_TOX_7-6_Cyromazine_PT18_Minutes_FINAL.docx). Hence, the MoEs here are sufficiently high for all full-grown animals regarding the exposure to imidacloprid. The livestock animal exposure assessment for dietary exposure refers only to full-grown animals (except for calves). However, for the assessment of animal health also younger animals (like piglets or chicks) have to be taken into consideration. For these animals, a higher exposure has to be assumed due to their different body parameter (e.g. body weight, surface area, inhalation rate, feed intake). As already mentioned above, the minimum MoE considered as safe according to the discussion on WG-II-2021 is 10 or even 5 under specific circumstances. The minimum MoE of full-grown animals is about 56. This margin between the reference MoE and the minimum MoE of full-grown animals is considered sufficient to protect even young animals. This is also supported by the equation provided in Table 56 of the Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017 on the estimation of birds alveolar ventilation rates based on the body weight. Assuming that the inhalation exposure in mainly influenced by the AVR and the body weight, it is clear from this equation that the relation between body weight and AVR in a chick of 60 g is approximately 4-fold higher than the ratio in a broiler of 1900 g. Thus, the MoE of a chick would be still above 10.

Risk assessment for *cis*-tricos-9-ene

For *cis*-tricos-9-ene exposure assessment, the Tier 1 approach for inhalation exposure is performed using the saturated vapour concentration. This results in unrealistic high values. Therefore, the inhalation exposure assessment is refined using the ConsExpo evaporation model. However, this assessment could not be performed for all animals as several input parameters were not available for them. Therefore, this assessment was only conducted for dairy cattle, beef cattle, calf, fattening pig, breeding pig, broiler and laying hen. For sheep, lamb, slaughter goat, lactating goat, horse, rabbit, and turkey these data are missing. However, as stated in the section on dietary assessment it is assumed that the assessment for the animals stated above with the available input parameters also covers the exposure of the other animals. In this context, please note that in the table above the inhalation exposure of broilers was also used to estimate an exposure value for turkeys.

For *cis*-tricos-9-ene no NOAEL is available as the derived human AELs are not based on corresponding toxicological studies. Therefore, the animal exposure was compared to the human $AEL_{long\text{-}term}$. For all animals, the exposure values are below the human $AEC_{long\text{-}term}$.
It should be noted that for livestock animals a safety factor of 5 to 10 is considered acceptable instead of a MoE of 100 as used for human assessment. By implication, the human AEL is considered as very conservative for livestock animals.
Thus, exposure of all full-grown animals is considered safe.

These facts on safety factors and MoE should also be taken into consideration when assessing the health risks for younger animals. Based on the fact that a human AEL include normally a safety factor of hundred, exposure to younger animals is also considered safe for *cis*-tricos-9-ene.

In conclusion, exposure to livestock animals is considered safe if the biocidal product is used as intended. According to the dietary exposure assessment, the intended use include the following measures relevant for livestock exposure assessment.

- Attach treated cardboards inaccessible for (children, pets,) livestock animals (and other non-target animals). (Uses 1 and 3)
- Place product out of the reach of (children, birds, pets,) farm animals and (other non-target animals). (Uses 2 and 4)

3.8 Risk assessment for the environment

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance(s), metabolite(s) and transformation product(s)

No new studies have been submitted since the approval of the active substance Imidacloprid. The risk assessment is entirely based on the list of endpoints as published in the Assessment Report (PT18, July 2015) for which DE was the rapporteur member state. The Assessment Report is available on the ECHA website.

For the 2nd active substance in the b.p., *cis*-Tricos-9-ene (Muscalure), no PNECs were derived in the CAR due to the 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.

The endpoints applied in the environmental risk assessment are summarised in the tables below. The values are taken from the Assessment Report of Imidacloprid (ECHA, 2011, rev. 2015) and the 3rd party dossier[10]. The values for *cis*-Tricos-9-ene are taken from the Assessment Report (ECHA, 2012, PT19) and amended by values taken from the original PAR for Sofast (2017).

Table 62 Endpoints and PNEC values for the active substances applied in the environmental risk assessment

Endpoints and PNEC values for the active substances applied in the environmental risk assessment				
	Value		**Unit**	**Remarks**
	Active substance 1: Imidacloprid	**Active substance 2: cis-Tricos-9-ene (Muscalure)**		
Fate and behaviour in the environment				
Molecular weight	255.7	322.6	g/mol	
Melting point	144	-2	°C	
Vapour pressure (at 20°C)	4×10^{-10}	6.4×10^{-2}	Pa	
Water solubility (at 20°C)	613	$<7 \times 10^{-3}$	mg/L	

[10] For details please refer to the document 170929_PAR_DE.pdf (Assett No: DE-0008815-0000)

Log Octanol/water partition coefficient (K_{ow})	0.57	>8.2	Log 10	
Organic carbon/water partition coefficient (K_{oc})	186.6	5 x 10^6	L/kg	mean value (substance approval and 3rdparty dossier for the a.s.imidacloprid)
Henry's Law Constant (at 20°C)	1.675 × 10^{-10}	2.95 x 10^3	Pa/m^3/mol	
Characterisation of biodegradability	Not readily biodegradable	Readily biodegradable	-	
Rate constant for STP	0	0.3	h^{-1}	
DT_{50} for hydrolysis	2.75	-	years (at 12ºC)	
DT_{50} for degradation in soil	135.1	1000000	d (at 12ºC)	geometric mean over Europe at 12°C for Imidacloprid
DT_{50} for degradation in air	2.54	-	hr	
Predicted no effect concentrations (PNEC)				
Sewage treatment plant	61.3	-	mg/L	Infobox Nr. 7 inGuidance on the BPR, Vol. IV, Part B+C (2017)
Surface water	4.8 x 10^{-6}	-	mg/L	based on three long-term studies and an assessment factor of 5. *Caenis horariais* most sensitive for Imidacloprid
Sediment	28 x 10^{-6}	-	mg/kg wwt	No data available. PNEC was calculated from the PNEC for surface water for Imidacloprid
Soil	15.75 x 10^{-3}	-	mg/kg wwt	based on NOEC of > 0.178 mg/kg ww from earthworm reproduction study and an assessment factor of 10 for Imidacloprid
Bird	4.2	-	mg/kg food	based on NOEC of 260 mg/kg food from reproduction study with bobwhite quail and assessment factor 30 for Imidacloprid

Mammals	8.33	-	mg/kg food	based on NOEC of 250 mg/kg food from a 2-generation study with rats and an assessment factor of 30 for Imidacloprid

3.8.1.2 Endpoints for the product

There are no new additional data available for the product. The exposure assessment and classification and labelling are based on the agreed endpoints for the active substances.

3.8.1.3 Substance(s) of concern

No substances of concern regarding the environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)). Consequently, only the active substances were addressed in the environmental risk assessment.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

In the CAR for Imidacloprid (eCA DE, 2011), there is no information available with regard to ED properties. According to the CAR for *cis*-Tricos-9-ene (eCA AT, 2012), there are no indications for endocrine disrupting properties of this active substance on environmental non-target organisms. For both active substances, a comprehensive ED-assessment according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage.

The full composition of the product as well as the results of the ED-assessment of the co-formulants are summarised in respective section of the Confidential Annex to the PAR.

3.8.1.5 PBT-Assessment

The assessment of the PBT criteria for the active substances Imidacloprid and cis-Tricos-9-ene are adapted from the respective ARs (Imidacloprid: DE, rev. 2015; cis-Tricos-9-ene: AT, 2012), which considered the specifications according to Annex XIII of the REACH regulation EC/1907/2006.

- **P/vP**

  Apart from the submission of a test on ready biodegradability in which **Imidacloprid** is confirmed to be not readily biodegradable, no new information compared to the CAR has been provided. 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.

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

- **B/vB**

  The calculated bioconcentration factor for **Imidacloprid** 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.

  In the AR for **cis-Tricos-9-ene** the log BCF_{fish} is ≥ 2.9 with the conclusion, that the B-criterion is probably met though it is unlikely that Muscalure will bioaccumulate in aquatic species.

- **T**

  For **Imidacloprid**, the 28d-EC_{10} (equivalent to NOEC) for chironomids (*Chironomus riparius*), is 0.87 µg/L after 28 days. For the most sensitive species, *Caenis horaria*, the 28d-EC_{10} is 0.024 µg/L. Therefore, the T criterion is complied.

  Based on acute toxicity data on fish and daphnids for **cis-Tricos-9-ene**, no indication exists that the chronic NOEC of Muscalure is <0.01 mg/L.

- **Conclusion on the PBT assessment for the active substances**

  Even though the vP- and the T-criteria are fulfilled for **Imidacloprid**, the active substance is neither a PBT - nor vP/vB - candidate as the B-criterion is not fulfilled.

  cis-Tricos-9-ene does not meet the PBT nor the vP/vB criteria.

3.8.2 Emission estimation

3.8.2.1 General information

The biocidal product (b.p.) Sofast is an insecticidal granular formulation containing 0.52% w/w Imidacloprid and 0.1% w/w *cis*-Tricos-9-ene. Sofast is applied indoors in households, commercial and public areas, and livestock facilities for professional use. The product is either applied as water based solution by brushing or as ready to use granular bait by professionals:

Brushing on cardboards: A rate of 200 g of the b. p. is diluted in 150 mL of water to be applied by brushing 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.

Distribution in the STP has been calculated based on the physical-chemical properties as listed in Table 62 and using SimpleTreat version 4.0.

Table 63: Distribution in the STP

	Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**		**Remarks**
	Imidacloprid	*cis*-Tricos-9-ene	
Air	0	1.33	Calculated with SimpleTreat 4.0
Water	97.11	7.03	
Sludge	2.89	91.92	
Degraded in STP	0	0.36	

Release of active substances during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substances are added are disposed as solid waste and usually incinerated.

The risk assessment approach is summarised below.

Table 64 Environmental risk assessment

Environmental risk assessment					
Use number	**Scenario assessed**	**ESD applied**	**Maximum in-use concentration of the active substance(s)**	**Maximum in-use concentration of substance(s) of concern**	**Receiving compartments**
[1]	Professional use: brushing on cardboards; Indoor use in industrial/commercial premises; households/private areas; public areas	Not assessed as environmental emissions are considered not relevant	Imidacloprid: 0.52% cis-Tricos-9-ene: 0.1%	-	-
[2]	Professional use: bait application in disposable shallow dishes; Indoor use in industrial/commercial premises; households/private areas; public areas			-	-
[3]	Professional use in livestock facilities: brushing on cardboards	Not assessed as environmental emissions are considered not relevant		-	-
[4]	Professional use in livestock facilities: bait application in bait stations	Not assessed as environmental emissions are considered not relevant		-	-

3.8.2.2 Emission estimation for the scenario(s)

During the first approval process several uses were applied for and assessed and unacceptable risks were identified. As proposed by the applicant and agreed in the following mutual recognition process, extensive risk mitigation measures had to be implemented such that a release into the environment in a relevant quantity can be prevented. To make sure that the RMMs can be followed when using the product, the use was furthermore restricted to professional users only. Consequently, as it was agreed during the mutual recognition that these risk mitigation measures are sufficient to achieve the goal of not relevant exposure, it was concluded by the RefMS for the renewal that these measures should already be implemented as use instructions. In this case, no quantitative exposure assessment would have to be conducted. In the following, the use instructions to be complied with are presented for each application and reasons are given as to why only not relevant emissions to the environment are to be expected.

Scenario 1 - Professional use: brushing on cardboards

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 and shall be fixed to walls or ceilings where flies prefer to rest. Due to the proposed use pattern of the b.p., the application mode can be described as target spot application. The maximum number of applications is 6 applications per year.

In principal, environmental exposure may arise either due to washing of contaminated clothes from the applicator, due to wet cleaning of the floor surrounding the mixing and loading place (both pathways are a consequence of mixing and loading) or the treated surface and its surrounding floor surface. All pathways would subsequently lead to release of contaminated waste water to the STP system.

Release during mixing and loading

Sofast is formulated as granules and has to be diluted in water before application. During the mixing and loading step, the following use instructions have to be followed to ensure only not relevant emissions to the environment:

1) The area, where mixing/loading takes place, must be covered with a disposable plastic sheet in order to avoid contamination of adjacent surfaces and floor.
2) For the mixing/loading step the applicator must wear a disposable protective coverall (at least type 6, EN 13034) to avoid emissions to the sewer system due to washing of contaminated clothes.
3) Brushes are to be disposed of after application to avoid emissions to the sewer system due to cleaning of the brushes.

The RefMS is of the opinion that on the basis of these use instructions not relevant emissions to the environment can be assumed. All aspects of the mixing/loading step are covered and relevant emissions are assumed to be not relevant.

Release during application

During the application step, the following use instructions have to be followed to ensure only not relevant emissions to the environment:

1) Apply only on cardboards which are then to be fixed to walls or ceilings where flies prefer to rest.
2) For application of the dispersion on cardboards the applicator must use a disposable brush.
3) The area, where the application to cardboards takes place, must be covered with a disposable plastic sheet in order to avoid contamination of adjacent surfaces and floor.
4) For the application step the applicator must wear disposable protective coverall (at least type 6, EN 13034) to avoid emissions to the sewer system due to washing of contaminated clothes.
5) Do not let the product or its residues or brushing sludge enter soil, water courses or the sewer systems.
6) Do not clean the cardboards.

All aspects and physical steps of application process are covered and possible emissions to the environment are assumed to be not relevant.

Release estimation to sewage treatment plant

As 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 is required, only not relevant emissions are foreseen. Hence, no quantitative assessment is necessary.

Scenario 2 - Professional use: bait application in disposable shallow dishes

Sofast should be applied as bait application in disposable shallow dishes. 20g of the granules should be used for 10m^2 floor area to be treated. One bait point (disposable shallow dish) per 10m^2 floor area should be established. The maximum number of applications is 6 applications per year.

Release during mixing and loading

According to ESD PT18 No. 18 (2008), emissions to the environment during loading step are not expected in case of application as granular bait.

Release during application

During the application step, the following use instructions have to be followed to ensure only not relevant emissions to the environment:

1) Use the included dosing spoon/beaker when measuring the granules.
2) Create bait points with 20g granules every 10m², only up high (shelves, ledges, walls).
3) The people responsible for cleaning the treated areas are to be instructed by the professional user on the use instructionsto ensure that the product does not reach the sewer system.
4) Use only disposable shallow dishes and the dosing spoon to place the granular bait.
5) Product spills, residues and dead flies must be collected immediately by dry cleaning methods only (i.e. vacuum cleaner or disposable cloth) with subsequent disposal via solid waste.
6) Do not wet wash the surfaces contaminated with the product or its residues. In case that the surfaces are cleaned, use disposable wet wipes with subsequent disposal via solid waste.

7) Ensure that spills from the application devices are avoided by un-intentional movement of the product through e.g. wind, humans or larger animals.
8) Do not wet clean the dosing spoon and the disposable shallow dishes.
9) Collect product residues, product spills and all other waste for disposal in accordance with local requirement after treatment.
10) Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.

All aspects of the application step are covered and relevant emissions are prevented. Therefore, possible emissions to the environment are assumed to be not relevant.

Release estimation to sewage treatment plant

As only not relevant exposure is foreseen, no quanitative assessment is necessary.

Scenario 3- Scenario 3 - Professional use in livestock facilities: brushing on cardboards

Only a qualitative risk assessment has been carried out for this scenario. The biocidal product Sofast is intended to be used by professionals in livestock facilities to control flies (indoor). In order to treat the livestock facilities, 200 g of the product is dispersed in 150 mL water and applied to cardboard sheets with a total surface of 1 m^2 which is adequate for 100 m^2 stable floor area. The maximum number of applcations is 6 applications per year.

During the application step, the use instructions mentioned in scenario 1 and the additional ones have to be followed to ensure only not relevant emissions to the environment:

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

All aspects of the application step are covered and relevant emissions are prevented. Therefore, possible emissions to the environment are assumed to be not relevant.

Exposure to the atmosphere is also considered not relevant as the b.p. is not applied via fogging or as an aerosol in livestock facilities (ref. to OECD ESD PT18 No. 14 (2006)). Potentially emitted volatilised components of the biocidal product might be expected (cis-Tricos-9-ene), however, relevant concentrations are not realistic.

Regarding the mentioned instructions for use emissions to the environment can be considered as not relevant. Hence, neither environmental emission estimation has been performed nor PECs have been calculated.

Scenario 4 - Professional use in livestock facilities: bait application in bait stations

A qualitative risk assessment has also been carried out for the use in livestock facilities as granular solid bait in bait stations. In order to treat the livestock facilities, 20 g of the product is applied in a bait station to control a 10 m^2 stable floor area. The bait stations are then

placed in different places where flies preferentially rest.
The maximum number of application is 6 applications per year.

During the application step, the following use instructions have to be followed to ensure only not relevant emissions to the environment:

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) Do not apply the biocidal product directly on manure/slurry.
4) Remove all bait stations before cleaning and/or disinfectant events in livestock facilities.

All aspects of the application step are covered and relevant emissions are prevented. Therefore, possible emissions to the environment are assumed to be not relevant.

Exposure to the atmosphere is also considered not relevant as the b.p. is not applied via fogging or as an aerosol in the animal housing (ref. to OECD ESD PT18 No. 14 (2006)). Potentially emitted volatilised components of the biocidal product might be expected (cis-Tricos-9-ene), however, relevant concentrations are not realistic.

Regarding the mentioned instructions for use emissions to the environment can be considered as not relevant. Hence, neither environmental emission estimation has been performed nor PECs have been calculated.

3.8.3 Exposure calculation and risk characterisation

No environmental exposure concentration were calculated as emission to the relevant environmental compartments are considered to be not relevant.

Conclusion: No environmental exposure concentration were calculated as emission to the environmental compartments are considered to be not relevant. Therefore, no unacceptable risks are identified.

Risk for bees

The product is used only indoor, therefore a risk assessment for bees is not considered necessary. Furthermore, at the time the PAR was prepared, the ECHA Guidance Document for risk assessment of pollinators was not finalised.

In the Assessment Report for active substance **Imidacloprid** the toxicity for *Apis mellifera* (honey bee) was given as LD_{50} acute oral (48 h) = 0.0037 µg/bee and LD_{50} acute contact (48 h) = 0.081 µg/bee. According to CA-Dec20-Doc.4.1final_rev1 (96th CA-Meeting, June 2022) a warning sentence should be included in the authorisations of products containing hazardous substances to bees granted or renewed from 1 January 2021. An active substance would be found to be below the harmonised toxicity threshold if a standard contact or oral acute LD_{50} datapoint on adult honeybees, bumble bees or solitary bees exists for that substance and is below 11 µg/bee (WGIII2021_ENV_8-2_WarningSentence_Rev1). As both the acute oral and the acute contact LD_{50} for Imidacloprid are below the threshold value, the following warning sentence has to be added to the SPC:

This product contains Imidacloprid which is dangerous for bees.

3.8.4 Primary and secondary poisoning

3.8.4.1 Primary poisoning

Not relevant, as only indoor uses of the product are authorised.

3.8.4.2 Secondary poisoning

Not relevant, as only indoor uses of the product are authorised.
Furthermore, due to the low bioaccumulation potential no assessment for secondary poisoning for fish or worm eating birds and mammals is necessary.

Conclusion: Risk of primary and secondary poisoning is not considered relevant and an quantitative risk assessment was not conducted.

3.8.5 Mixture toxicity

No environmental exposure concentration were calculated as emission to the environmental compartments are considered to be not relevant. Furthermore, no substances of concern were identified.
As a consequence, mixture toxicity assessment is not considered relevant.

3.8.6 Aggregated exposure (combined for relevant emission sources)

No environmental exposure concentration were calculated as emission to the environmental compartments are considered to be not relevant.
As a consequence, aggregated exposure assessment is not considered relevant.

3.8.7 Overall conclusion on the risk assessment for the environment

Table 65 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
[1]	Professional use:brushing on cardboards; Indoor use in industrial /commercial premises; households/private areas; public areas	Not assessed as environmental emissions are considered not relevant.	-

Overall conclusion on the risk assessment for the environment			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
[2]	Professional use: bait application in disposable shallow dishes; Indoor use in industrial /commercial premises; households/private areas; public areas		-
[3]	Professional use in livestock facilities: brushing on cardboards	Not assessed as environmental emissions are considered not relevant.	-
[4]	Professional use in livestock facilities: bait application in bait stations		-

As no quantitative risk assessment was done, no risk mitigation measures are necessary.

The following list of **use-specific instructions for use** are imposed to ensure not relevant exposure during the use of the product and in consequence ensuring a safe use.

use 1: professional use, brushing on cardboards, indoor

1) Apply only on cardboards which are then to be fixed to walls or ceilings where flies prefer to rest.
2) For application of the dispersion on cardboards the applicator must use a disposable brush.
3) The area, where mixing/loading and the application to cardboards takes place, must be covered with a disposable plastic sheet in order to avoid contamination of adjacent surfaces and floor.
4) For the mixing/loading and the application step the applicator must wear a disposable protective coverall (at least type 6, EN 13034) to avoid emissions to the sewer system due to washing of contaminated clothes.
5) Do not let the product or its residues or brushing sludge enter soil, water courses or the sewer systems
6) Do not clean the cardboards.
7) Dead flies must be collected immediately by dry cleaning methods only (i.e. vacuum cleaner or disposable cloth) with subsequent disposal via solid waste."

use 2: professional use, bait application in disposable shallow dishes, indoor

1) Use the included dosing spoon/beaker when measuring the granules.
2) Create bait points with 20g granules every 10m², only up high (shelves, ledges, walls).
3) The people responsible for cleaning the treated areas are to be instructed by the professional user on the use instructions to ensure that the product does not reach the sewer system.
4) Use only disposable shallow dishes and the dosing spoon to place the granular bait.
5) Product spills, residues and dead flies must be collected immediately by dry cleaning methods only (i.e. vacuum cleaner or disposable cloth) with subsequent disposal via solid waste.

6) Do not wet wash the surfaces contaminated with the product or its residues. In case that the surfaces are cleaned, use disposable wet wipes with subsequent disposal via solid waste.
7) Ensure that spills from the application devices are avoided by un-intentional movement of the product through e.g. wind, humans or larger animals.
8) Do not wet clean the disposable shallow dishes.
9) Collect product residues, product spills and all other waste for disposal in accordance with local requirement after treatment.
10) Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.

use 3: professional use, brushing on cardboards, livestock facilities

In addition to the use-instructions for use 1, the following use-instructions specific for use in livestock facilities are implemented:

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

use 4: professional use, bait application in bait stations, livestock facilities

The following use-instructions specific for use in livestock facilities are implemented:

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) Do not apply the biocidal product directly on manure/slurry.
4) Remove all bait stations before cleaning and/or disinfectant events in livestock facilities.

3.9 Assessment of a combination of biocidal products

Not relevant (a use with other biocidal products is not intended).

3.10 Comparative assessment

The biocidal product contains Imidacloprid which meets the conditions laid down in Article 10 (1) of Regulation (EU) No 528/2012 and is considered as a candidate for substitution based on the following criteria: it meets two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006.

However, a comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 should be carried out only when the active substance is identified as meeting the substitution criteria in the renewal of approval Regulation in accordance with Article 10 (5) of the BPR (CA-June22-Doc.4.2[11]).

Therefore, a comparative assessment of the biocidal product is not required.

[11] The document is available in CIRCABC at https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/aa098b99-9f78-4606-b9e0-9275764168d2/details.

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Professional user:
For the scenarios (No. 1a, 1b, 2), please refer to chapter 3.6.6.3.
For the exposure calculations, please refer to the seperate document "Calculation_Professional.xlsx"

Non-professional user:
For the exposure calculations, please refer to the seperate document "SceBfr1 Consexpo + SceBfR2.xlsx"

4.1.2 Dietary assessment

Not relevant.

4.1.3 Environment

Not relevant.

4.2 New information on the active substance(s) and substance(s) of concern

Not relevant (no new information on the active substance(s) is available).

Not relevant (no substance(s) of concern identified).

4.3 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Year	Title Reference type Report and/or Study No. Source or Testing facility, if different from Sponsor	Study sponsor	IUCLID section (endpoint)	GLP	Data protection claimed
2013	**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 Laborato** Study report Report No.: DNA2047 David Norris Analytical Laboratories Ltd, Units 13-14, Swan Business Park, Sandpit Road, Dartford, Kent DAl1 5ED	Sharda WorIdwide Exports Pvt. Ltd., Domnic Holm, 29th Road, Bandra (West), Mumbai 400050 – (India)	3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour)	yes (incl. QA statement)	yes
			3.2 Acidity, alkalinity (pH)	yes (incl. QA statement)	yes
			3.3 Relative density (liquids) and bulk, tap density (solids) (tap density)	yes (incl. QA statement)	yes
			3.4.1 Storage stability tests (storage stability and reactivity towards container material)	yes (incl. QA statement)	yes
			3.5 Technical characteristics of the biocidal product (particle size distribution, content of dust/fines, attrition, friability)	yes (incl. QA statement)	yes
				yes (incl. QA statement)	yes
			3.5 Technical characteristics of the biocidal product (flowability / pourability / dustability)	yes (incl. QA statement)	yes
			4.2 Flammability (flammable solids)	yes (incl. QA statement)	yes
				yes (incl. QA	yes

				statement)	
			4.4 Oxidising properties (oxidising solids)	yes (incl. QA statement)	yes
			5 Methods of detection and identification (analytical methods)	yes (incl. QA statement)	yes
				yes (incl. QA statement)	yes
2015	**Imidacloprid 0.5% + tricosene 0.1% GR. Determination of the technical properties after accelerated storage** Study report Report No.: BF-41/14 Institute of Industrial Organic Chemistry, Pesticides Application and Formulation Department, 6 Annopol Street, 03-236 Warsaw, Poland	Sharda Cropchem Ltd., Sharda International DMCC Dominic Holm, 29th Road, Bandra (West) Mumbai - 400050, India	3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour)	yes	yes
			3.2 Acidity, alkalinity (pH)	yes	yes
			3.5 Technical characteristics of the biocidal product (wettability)	yes	yes
			3.5 Technical characteristics of the biocidal product (suspensibility, spontaneity and dispersion stability)	yes	yes
			3.5 Technical characteristics of the biocidal product (particle size distribution, content of dust/fines, attrition, friability)	yes	yes
				yes	yes
				yes	yes
			3.5 Technical characteristics of the biocidal product (flowability / pourability / dustability)	yes	yes
2022	**Storage Stability Study of Imidacloprid 0.5% + Cistricos-9-ene 0.1% GR (2 years)** Study report	SHARDA CROPCHEM LIMITED, Mumbai, India	3.1 Appearance (at 20°C and 101.3 kPa) (appearance / physical state / colour)	yes (incl. QA statement)	yes

	Study No.: 5015/2019 BIOSCIENCE RESEARCH FOUNDATION, Tamilnadu, India		3.2 Acidity, alkalinity (pH)	yes (incl. QA statement)	yes
			3.4.1 Storage stability tests (storage stability and reactivity towards container material)	yes (incl. QA statement)	yes
			3.5 Technical characteristics of the biocidal product (wettability)	yes (incl. QA statement)	yes
			3.5 Technical characteristics of the biocidal product (suspensibility, spontaneity and dispersion stability)	yes (incl. QA statement)	yes
			3.5 Technical characteristics of the biocidal product (wet sieve analysis and dry sieve test)	yes (incl. QA statement)	yes
			3.5 Technical characteristics of the biocidal product (particle size distribution, content of dust/fines, attrition, friability)	yes (incl. QA statement)	yes
				yes (incl. QA statement)	yes
			3.5 Technical characteristics of the biocidal product (persistent of foaming)	yes (incl. QA statement)	yes
2015	**Imidacloprid 0.5% + Tricosene 0.1% GR Determination of physicochemical properties of the initial preparation** Study report Report No.: BF-41/14 Institute of Industrial Organic Chemistry, Pesticides	Sharda Cropchem Ltd., Sharda International DMCC Dominic Holm, 29th Road, Bandra (West)	3.3 Relative density (liquids) and bulk, tap density (solids) (tap density)	yes	yes

	Application and Formulation Department, 6 Annopol Street, 03-236 Warsaw, Poland	Mumbai - 400050, India			
2015	**Imidacloprid 0.5% + Tricosene 0.1% GR Stage I a: Active ingredients content evaluation of the initial preparation and after accelerated storage** Study report Report No.: BF-22/15 Institute of Industrial Organic Chemistry, Pesticides Application and Formulation Department, 6 Annopol Street, 03-236 Warsaw, Poland	Sharda Cropchem Ltd., Sharda International DMCC Dominic Holm, 29th Road, Bandra (West) Mumbai - 400050, India	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	yes	yes
2023	**Test de estabilidad** Study report Study No.: S-23-0354/1 IDUQC Laboratorios Parque científico de Murcia Calle Campus Universitario 30100, Espinardo (Murcia) España	Sharda Cropchem Limited, 2nd floor Prime Business Park, Dashratal Joshi Road, Vile Parle, Mumbai 400056, India	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	no	yes
2014	**Imidacloprid 0.5% + Tricosene 0.1% GR - Determination of explosive properties** Study report Report No.: BW-19/14 Institute of industrial organic chemistry, High-energy Materials Department, 6 Annopol Street, 03-236 Warsaw, Poland	Sharda Cropchem Limited, Sharda International, DMCC Dominic Holm, 29th Road, Bandra (West) Mumbai - 400050, India	4.1 Explosiveness (explosiveness, other)	yes (incl. QA statement)	yes
2023	**SOFAST (Imidacloprid 0.5% GR) Dust cloud flammability testing** Study report Study No.: S3016013705R1/2023	Sharda Biocides, Edificio Atalayas Business Center, Murcia,	4.1 Explosiveness (explosiveness, other)	yes (incl. QA statement)	yes

	DEKRA Organisational and Process Safety, Phi House, Southampton Science Park, Southampton, Hampshire, UK	Spain.			
2023	**SOFAST (Imidacloprid 0.5% GR) Ignition Sensitivity and Explosion Severity testing** Study report Study No.: S3016014097R1/2023 DEKRA Organisational and Process Safety, Phi House, Southampton Science Park, Southampton, Hampshire, S016 7NS, UK	Sharda Biocides, Edificio Atalayas Business Center, Carril Condonima 3, planta 12, puerta A, 30006 Murcia.	4.1 Explosiveness (explosive properties of explosives)	yes (incl. QA statement)	yes
2015	**Imidacloprid 0.5% + Tricosene 0.1% GR Determination of flammability, ability of solids to self-heating up to self-ignition and oxidizing properties for solids** Study report Report No.: BC-48/14 Institute of industrial organic chemistry, Chemical Safety and Static Electricity Department, 6 Annopol Str., 03-236 Warsaw	Sharda Cropchem Ltd. Domnic Holm, 29th Road, Bandra (W), Mumbai 400050, India	4.2 Flammability (flammable solids)	yes (incl. QA statement)	yes
				yes (incl. QA statement)	yes
			4.4 Oxidising properties (oxidising solids)	yes (incl. QA statement)	yes
			4.17 Additional physical indicators for hazards	yes	yes
2023	**Determination of self-reactive mixtures properties (DSC method)** Study report Study No.: P-23-0101/S-23-0121 IUDQC Laboratorios Almabe Parque científico de Murcia Edificio R, Planta 2º 30100 Espinardo Murcia, España	Sharda Cropchem Limited 2nd floor, Prime Business Park	4.8 Self-reactive substances and mixtures (self-reactive substances)	GLP information not provided	yes
2023	**Heat accumulation storage testing on a sample of SOFAST (Imidacloprid 0.5% GR)**	Sharda Biocides;	4.8 Self-reactive substances and mixtures	yes (incl. QA statement)	yes

	Study report Study No.: GLP3016013982R1/2023 DEKRA UK Ltd Phi House Southampton Science Park Southampton SO16 7NS United Kingdom	Edificio Atalayas Business Center; Carril Condomina 3; planta 12, puerta A; 30006 Murcia, Spain	(self-reactive substances)		
2023	**SOFAST (Imidacloprid 0.5% GR) Dust cloud flammability testing** Study report Study No.: S3016013705R1/2023 Dekra organisational and process safety, Phi House Southampton Science Park, Southampton, Hampshire, UK	Sharda Biocides, Edificio Atalayas Business Center, Murcia	4.17 Additional physical indicators for hazards (other: Dust explosion)	yes (incl. QA statement)	yes
2015	**Imidacloprid 0.5 % + Tricosene 0.1 % GR Method development and validation for determination of the content of active substances in the formulation** Study report Study No.: BA-46/14 Institute of industrial organic chemistry - Analytical department, Warsaw, Poland	Sharda Cropchem. Ltd.	5 Methods of detection and identification (methods for the analysis of the (formulated) product)	yes (incl. QA statement)	yes
2013	**Efficacy of a fly bait granule product against house flies and Stable flies** Study report Report No.: BIO39a-13 ; Study No.: MO4649 BioGenius GmbH, 51429 Bergisch Gladbach, Germany	Sharda Worldwide Exports Pvt, Ltd, Mumbai, India	6.7 Efficacy data to support these claims (efficacy data)	yes (incl. QA statement)	yes
2015	**Field trials to determine the effciacy of Imdacloprid 0.5% + tricosene 0.1 % GR (SOFAST) against**	Sharda CropChem Ltd,	6.7 Efficacy data to support these claims	yes (incl. QA statement)	yes

	houseflies and stable flies Study report Study No.: 15/177 i2LResearch Ltd, Cardiff CF3 2PX, UK	Mumbai, India	(efficacy data)		
2015	**Field trials to determine the efficacy of Imidacloprid 0.5% + Tricosene 0.1% GR (SOFAST) against houseflies and stable flies** Study report Study No.: 15/178 i2LResearch Ltd, Cardiff CF3 2PX, UK	Sharda CropChem Ltd, Mumbai, India	6.7 Efficacy data to support these claims (efficacy data)	yes (incl. QA statement)	yes
2019	**Efficacy assessment of Imidacloprid 0.5% + Tricosene 0.1% GR under field conditions against flies (House fly & Stomoxys calcitrans)** Study report Study No.: 4518/2018 BIOSCIENCE RESEARCH FOUNDATION	SHARDA CROPCHEM LTD.	6.7 Efficacy data to support these claims (efficacy data)	yes - Included in the report	yes
2020	**Bioefficacy & Persistency of Sofast (Bait Box with Imidacloprid 0.5% + cis-Tricos-9-ene 0.1% GR) against House fly** Study report Study No.: 368EAMG3968/R0 Ross Lifescience Private Limited	Sharda Cropchem Ltd	6.7 Efficacy data to support these claims (efficacy data)	yes	yes
2020	**Bio-efficacy & Persistency of Sofast (Bait Box with Imidacloprid 0.5% + cis-Tricos-9-ene 0.1% GR) against Stable Fly**	Sharda Cropchem Ltd	6.7 Efficacy data to support these claims (efficacy data)	yes	yes

	Study report Study No.: 368EAMG3969/R0 Ross Lifescience Private Limited				
2019	**To evaluate palatability of a bait product (Imidacloprid 0.5% + Tricosene 0.1% GR - SOFAST) fresh and aged under accelerated conditions, against housefly (Musca domestica) and stable fly (Stomoxys calcitrans).** Study report Study No.: 368DALG2814/R0 Ross Lifescience Private Limited	Sharda Cropchem Limited	6.7 Efficacy data to support these claims (efficacy data)	yes	yes
2014	**Acute dermal irritation study of imidacloprid 0.5% GR in rabbits** Study report Study No.: 406-1-01-8869 [redacted]	Sharda Cropchem Limited	8.1.1 Skin irritation / corrosion (skin irritation: in vivo)	yes (incl. QA statement)	yes
2014	**Acute eye irritation study of imidacloprid 0.5% GR in rabbits** Study report Study No.: 407-1-01-8870 [redacted]	Sharda Cropchem Limited	8.1.2 Serious eye damage or eye irritation (eye irritation: in vivo)	yes (incl. QA statement)	yes
2014	**Skin sensitisation study of imidacloprid 0.5% GR in guinea pigs (Guinea pig maximization test)**	Sharda Cropchem Limited	8.3.1 Skin sensitisation (skin sensitisation: in vivo (non-LLNA))	yes	yes

	Study report Study No.: 408-1-01-8871 [redacted]				
2014	**Acute oral toxicity study of imidacloprid 0.5% GR in rats** Study report Study No.: 401-1-01-8866 [redacted]	Sharda Cropchem Limited	8.5.1 Acute toxicity: oral (acute toxicity: oral)	yes (incl. QA statement)	yes
2014	**Acute inhalation toxicity study of Imidacloprid 0.5% GR in rats** Study report Study No.: 405-1-01-8868 [redacted]	Sharda Cropchem Limited	8.5.2 Acute toxicity: inhalation (acute toxicity: inhalation)	yes (incl. QA statement)	yes
2014	**Acute dermal toxicity of Imidacloprid 0.5% GR in rats** Study report Study No.: 403-1-01-8867 [redacted]	Sharda Corpchem Limited	8.5.3 Acute toxicity: dermal (acute toxicity: dermal)	yes (incl. QA statement)	yes

4.4 References

4.4.1 References other than list of studies for the BPF

4.4.2 Guidance documents

Packaging
- Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008
- Guidance on the Biocidal Products Regulation: Volume I: Identity of the active substance/physico-chemical properties/analytical methodology - Parts A+B+C: Information Requirements, Evaluation and Assessment, 2022
- International Transportation of Dangerous Goods by Road (ADR), Volume 1,2 / 2021

Physical, chemical, and technical properties
- Guidance on the BPR: Volume I Parts A+B+C - v 2.0, 2018
- Technical Agreements for Biocides (TAB) – APCP v.2.0, 2020

Physical hazards and respective characteristics
- Guidance on the BPR: Volume I Parts A+B+C - v 2.0, 2018
- Technical Agreements for Biocides (TAB) – APCP v.2.0, 2020
- Guidance on the Application of the CLP Criteria – v 5.0, 2017
- UN Manual of Tests and Criteria – 7th revised edition, 2019

Methods for detection and identification
- Guidance on the Biocidal Products Regulation, Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.1, March 2022 https://echa.europa.eu/documents/10162/2324906/bpr_guidance_vols_i_part_abc_en.pdf
- Guidance for waiving of data requirements for pheromones for inclusion in Annex I/IA of directive 98/8/EG https://echa.europa.eu/documents/10162/983772/bpd_guid_addendum-tnsg-data_requirements_pt19_pheromones_en.pdf/e18e5e11-551b-4037-b5d1-43d566bac046
- Technical Agreements for Biocides (TAB) – APCP v.2.0, 2020

Efficacy
Guidance on the Biocidal Products Regulation (BPR) (Volume II Efficacy - Assessment and Evaluation (Parts B+C); Version 3.0; April 2018; chapter 5.6.4.13)
Technical Agreements for Biocides (TAB) Efficacy (EFF) Version 2.2; July 2020; chapter 4 and 18
Product Performance Test Guidelines OCSPP 810.3500: Premises Treatments; August 2019

Human health
- EFSA guidance on dermal absorption, 2017 https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2017.4873

- Guidance on the Biocidal Products Regulation Volume III Human Health – Assessment & Evaluation (Parts B+C), Version 4.0, December 2017 (https://echa.europa.eu/documents/10162/23036412/biocides_guidance_human_health_ra_iii_part_bc_en.pdf/30d53d7d-9723-7db4-357a-ca68739f5094)
- Biocides Human Health Exposure Methodology, 2020 (https://echa.europa.eu/de/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure)
- EMA Guideline on risk characterization and assessment of maximum residue limits (MRL) for biocides (EMA/CVMP/SWP/90250/2010) https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-risk-characterisation-assessment-maximum-residue-limits-mrl-biocides_en.pdf

- Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0, 2017, https://echa.europa.eu/documents/10162/2324906/biocides_guidance_human_health_ra_iii_part_bc_en.pdf ;
- Biocides Human Health Exposure Methodology, version 1, Oct. 2015, https://echa.europa.eu/documents/10162/992289/bpr_exposuremethodbiochh_en.rtf/17e40d4c-5f48-4e12-952b-5372bfe2403c?t=1444729148304

Animal health
No guidance agreed yet.
- Doc. no. CG-30-2018-09-vf: Agenda item 7.3: Risk assessment for animal health

Environment
- Guidance on the BPR: Volume IV Environment (Parts B+C), version 2.0., 2017 https://echa.europa.eu/documents/10162/2324906/bpr_guidance_ra_vol_iv_part_b-c_en.pdf/e2622aea-0b93-493f-85a3-f9cb42be16ae
- Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses (ESD PT 18, OECD No. 18) Microsoft Word - ENV-JM-MONO_2008_14.doc (europa.eu)
- Emission scenario document for insecticides for stables and manure storage systems ESD PT 18, OECD No. 14) Microsoft Word - ESD Stables and Manure Final for Publication.doc (europa.eu)

4.4.3 Legal texts

- 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 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0528)
- 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 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1272)

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.