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

Product identifier in R4BP	Stallfliegenmittel Alba
Product type(s):	18 (Insecticides)
Active ingredient(s):	Clothianidin Cis-tricos-9-ene (Muscalure)
Case No. in R4BP	BC-WY027200-15
Asset No. in R4BP	DE-0016891-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/18.00020 710-05-18-00020-00-00-00-0000
Date	07.12.2022

Table of content

1 Conclusion

“Stallfliegenmittel Alba” is a water-dilutable suspension concentrate containing clothianidin and cis-tricos-9-ene as active substances. The product is used as an insecticide (product-type 18) by professional users for the control of flies in stables and barns except poultry.

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[1] (BPR) and therefore can be authorised for the use “spraying on cardboards”, as specified in the Summary of Product Characteristics (SPC).

For the intended use “painting on cardboards” efficacy was not shown and the conditions for granting an authorisation according to Article 19 (1) b) iii) BPR are therefore not fulfilled.

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 3.1 the PAR.

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

The biocidal product contains the following non-active substance (so called “co-formulant”) which is considered as a substance of concern:

- 1,2-Benzisothiazol-3(2H)-one (BIT) (CAS No. 2634-33-5) (for human health and environment)

More detailed information on the substance of concern is provided in chapter 2.2.3.

Based on the available information, the biocidal product should be considered not to have endocrine-disrupting properties. More information is available in sections 3.6.2.11 and 3.8.4.2 of the PAR and in the confidential PAR.

As the active substance clothianidin is classified as toxic (T) and very persistent (vP) it is a candidate for substitution according to Article 10 (1) BPR. Therefore, a comparative assessment has been performed in accordance with Article 23(1) of BPR and following the Technical Guidance Note on comparative

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[2]. The assessment is presented under section 3.9 of the PAR. The corresponding Comparative Assessment Report was forwarded to ECHA on 16.11.2022. The German CA concludes that without the clothianidin and cis-tricos-9-ene based biocidal product “Stallfliegenmittel Alba” there is not an adequate chemical diversity. Therefore the biocidal product is authorised for five years in accordance with Article 23 (6) BPR.

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

Composition and formulation

The water-dilutable viscous liquid “Stallfliegenmittel Alba” is a suspension concentrate and contains the active substances clothianidin and cis-tricos-9-ene.

The substance 1,2-Benzisothiazol-3(2H)-one (BIT) (CAS No. 2634-33-5) has been identified as substance of concern. Please refer to chapter 2.2.3 for further information.

Please refer to chapter 2.2 (Composition and formulation) and the confidential PAR for detailed information.

Physical, chemical and technical properties

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

Physical hazards and respective characteristics

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

Methods for detection and identification

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

Efficacy against target organisms

The product has been shown to be efficacious for the use appropriate for authorisation listed in chapter 2.4. For the intended use “painting on cardboards” efficacy was not shown and the conditions for granting

[2] The document is available in CIRCABC at https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3.

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

an authorisation according to Article 19 (1) b) iii) BPR are therefore not fulfilled. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

The human health risk assessment for this product is based on the active substances and substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) (CAS No. 2634-33-5) and has been carried out for professional use of the product (see chapter 3.6) for all intended uses (see chapter 3.1). A human health risk assessment for non-professional users is not required since the biocidal product is for professional use only.

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

A human health risk assessment has been performed for persons of the general public entering treated animal housings. No human health risk was identified from exposure to the active substances and the identified substance of concern. Hence, the biocidal product is considered safe for the general public if used as intended and if all safety advices are followed during application.

The exposure assessment was based on the assumption that the treated cardboards are placed on the walls in the stables in which insect pests are likely to occur, where they will not get in contact with the general public. Thus, no dermal and oral exposure is expected for the general public. An appropriate labelling is required.

Risk assessment for the environment

The biocidal product contains two active substances clothianidin and cis-tricos-9-ene (Muscalure). Moreover, the substance 1,2-Benzisothiazol-3(2H)-one has been identified as substance of concern, because it is an active substance of other product types. However, the biocidal product has to be applied on cardboards in combination with a set of use instructions in order to avoid an exposure of the environment. Provided that the user applies these instructions carefully, a negligible exposure can be assumed and no unacceptable risk is to be expected for any environmental compartment. Therefore, a qualitative risk assessment for the environment has been carried out for the professional use of the product (see chapter 3.8) and the substance of concern has not been considered further for the environmental assessment.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Stallfliegenmittel Alba

2.1.2 Manufacturer(s) of the product

Name of manufacturer	Certis Europe B.V.
Address of manufacturer	Stadsplateau 3521 AZ Utrecht Netherlands
Location of manufacturing sites	Ploss Chemicals GmbH, Flosshafenstrasse 11 97199 Ochsenfurt Deutschland Schirm GmbH, Mecklenburger Str. 229 23568 Lübeck Deutschland PHYTEUROP, Z.I. de Champagne Rue Pierre My, 49260 MONTREUIL-BELLAY, FRANCE

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

Active substance	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (Clothianidin)
Name of manufacturer	Sumitomo Chemical Agro Europe SAS (France) (Acting for Sumitomo Chemical (UK) PLC)
Address of manufacturer	7-1, Nihonbashi 2-chome, Chuo-ku 103-6020 Tokyo Japan

Location of manufacturing sites	Oita Plant, 2200, Tsurusaki, Oita City 870-0106 Oita Japan Hikari Plant, Sumitomo Chemical Takeda Agro Company, Ltd., 4720 Takeda, Mitsui, Hikari, Yamaguchi 743-8502, Japan

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

Active substance	Cis-tricos-9-ene (Muscalure)
Name of manufacturer	Denka International B.V.
Address of manufacturer	Gildeweg 37 3771 NIB Barneveld Netherlands
Location of manufacturing sites	Hanzeweg 1 3771 NG Barneveld Netherlands

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Clothianidin	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-Nitroguanidine	Active substance	210880-92-5	433-460-1	Technical: 2.4 Pure: 2.3
Muscalure	*cis*-tricos-9-ene	Active substance	27519-02-4	248-505-7	Technical: 0.05 Pure: 0.04

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Benzisothiazolone (BIT)	1,2-Benzothiazol-3(2H)-one	Non-active substance: SoC	2634-33-5	220-120-9	0.2

- Information on the full composition is provided in the confidential[4] annex.

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

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

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☒
  No ☒ (The technical equivalence of the active substance from the new source was established by ECHA, see asset number EU-0016728-0000)

2.2.3 Information on the substance(s) of concern

The following substance of concern was identified:

- 1,2-Benzisothiazol-3(2H)-one (BIT) (CAS No. 2634-33-5)

1,2-Benzisothiazol-3(2H)-one is identified to be substance of concern for human health due to its skin sensitising properties. In the biocidal product Stallfliegenmittel Alba, 1,2-Benzisothiazol-3(2H)-one is present at a concentration that requires classification and labelling of the biocidal product.

1,2-Benzisothiazol-3(2H)-one is identified as a substance of concern for the environment[5], because it is an active substance of other product types and contained in the biocidal product at a concentration

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

[5] For information: The application for authorisation of the biocidal product has been submitted to the German CA in 2016. New guidance on the assessment of substances of concern has been implemented into the Guidance on

≥ 0.1%. However, due to the intended use (only indoors in animal housings and on non-absorbent cardboards) negligible emissions of the biocidal product to the environment is expected (please see also chapter 3.8.3). Therefore, the SoC 1,2-Benzisothiazol-3(2H)-one has not been considered further in the environmental risk assessment.

- (Further) information on the substance(s) of concern is provided in chapter 3.6.2.8. and the confidential PAR.

2.2.4 Candidate(s) for substitution

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

- Clothianidin

The following criteria for substitution are met:

- Very persistent/Persistent
- Toxic

Clothianidin does meet the conditions laid down in Article 10 of Regulation (EU) No. 528/2012, and is therefore considered as a candidate for substitution by being vP and T.
Clothianidin does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.
The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[6]. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b and d).

2.2.5 Type of formulation

SC (suspension concentrate, dilutable with water for spraying)

the Biocidal Products Regulation, Volume IV - Version 2.0, published in October 2017. New guidance is mandatory to be considered two years after its publication.

[6] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[7]

Beside the active substance clothianidin and the co-formulant 1,2-benzisothiazol-3(2*H*)-one (BIT, CAS-No: 2634-33-5) other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance clothianidin is based on Commission Regulation (EU) No. 790/2009 (1st ATP[8]):
Acute Tox. 4, H302 – Harmful if swallowed
Aquatic Acute 1, H400 – Very toxic to aquatic life
Aquatic Chronic 1, H410 – Very toxic to aquatic life with long lasting effects
M = 10

Please note that for the active substance clothianidin a RAC opinion has been adopted in September 2021[9]. In such a case, compliance with the existing harmonised C&L is legally required until the latter is formally changed by the Commission via an ATP-Regulation (please also refer to CA-Document "CA-May13-Doc.5.4.rev 1"[10]).

The current harmonised classification of the co-formulant 1,2-benzisothiazol-3(2*H*)-one (BIT) is based on Regulation (EC) 1272/2008.
Acute Tox. 4, H302 – Harmful if swallowed
Skin Irrit. 2, H315 – Causes skin irritation
Eye Dam. 1, H318 – Causes severe eye damage
Skin Sens 1, H317 – May cause an allergic skin reaction (SCL Skin Sens. 1, H317: C ≥ 0.05 %)
Aquatic Acute 1, H400 – Very toxic to aquatic life[11]

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7 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.
8 See: http://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/22870
9 https://echa.europa.eu/documents/10162/54f075c5-9342-3217-f4fd-a00a708fb10f
10 CA-May13-Doc.5.4.rev 1 (amended as per CA-March16-Doc.4.1) and CA/35/2013: Note for Guidance: Classification and labelling of biocidal products
https://circabc.europa.eu/sd/a/e4e143d0-cae8-41cb-b4b6-c762e6f44622/CA-May13-Doc.5.4%20Classification%20and%20labelling%20of%20biocidal%20products.doc
11 As no M factor is given in Annex VI of Regulation (EC) 1272/2008 an M = 1 shall be applied based on the new RAC opinion (November 2021).

The classification of the biocidal product for human health is triggered by the substance of concern 1,2-benzisothiazol-3(2H)-one (BIT). For details on the classification with respect to human health of the active substances, the substance of concern and the biocidal product refer to section 3.6.1 and 3.6.2.

For the environmental classification, in addition to the information on the components of the biocidal product, also toxicity data for one contained co-formulant was provided in the submitted SDS. This toxicity data on the mixture as a whole triggers the additional classification of the biocidal product as Aquatic Acute 1, H400. In combination with the long-term classification as Aquatic Chronic 2, H411 the labelling as H410 is relevant. For details refer to the confidential annex.

Please note that for the co-formulant 1,2-benzisothiazol-3(2*H*)-one (BIT) a RAC opinion[12] has been adopted in November 2021 (as for clothianidin please refer to CA-Document “CA-May13-Doc.5.4.rev 1”).

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.5.2 and if applicable to chapter 2.5.

[12] https://echa.europa.eu/documents/10162/0323edae-ef6f-48ec-d8bb-d6002766ccd1

Table 2

Classification Hazard classes, Hazard categories	**Hazard statements**	
Aquatic Acute 1	H400: Very toxic to aquatic life	
Aquatic chronic 2	H411: Toxic to aquatic life with long lasting effects.	
Skin Sens. 1	H317: May cause an allergic skin reaction.	
Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS07	
	GHS09	
Signal word		Warning
Hazard statements	H410	Very toxic to aquatic life with long lasting effects.
	H317	May cause an allergic skin reaction
Supplemental hazard information	-	-
Supplemental label elements	-	-
Precautionary statements	P261	Avoid breathing spray.
	P272	Contaminated work clothing should not be allowed out of the workplace.
	P273:	Avoid release to the environment
	P280	Wear protective gloves/protective clothing.
	P302 + P352	IF ON SKIN: Wash with plenty of water.
	P321	Specific treatment (see … on this label).
	P333 + P313	If skin irritation or rash occurs: Get medical advice.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P391:	Collect spillage
	P501:	Dispose of contents/container in accordance with local regulation.
Note	-	

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.5.2 and 2.5.

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

For Human Health:

Based on the additional classification of the active substance clothianidin as Repr. 2, H361f, and STOT SE 1, H370 (nervous system), according to the RAC opinion CLH-O-0000007020-91-01/F (16th September 2021), the biocidal product would require additional classification as STOT SE2, H371 (nervous system). The revised classification of the substance of concern 1,2-benzisothiazol-3(2H)-one (BIT) according to the RAC opinion CLH-O-0000007051-86-01/F (26th November 2021) will not lead to a change in the classification of the biocidal product.

For Environment:

Based on the RAC opinion CLH-O-0000007020-91-01/F (16th September 2021) the updated harmonised classification of the active substance clothianidin is H400 – Very toxic to aquatic life (M = 10) and H410 – Very toxic to aquatic life with long lasting effects (M = 100).

Furthermore, based on the RAC opinion CLH-O-0000007051-86-01/F (26th November 2021) the revised harmonised classification of the component 1,2-benzisothiazol-3(2H)-one (BIT) is H400 – Very toxic to aquatic life (M = 1) and H410 – Very toxic to aquatic life with long lasting effects (M = 1).

Pursuant to the above mentioned RAC opinions, the revised long-term classification of the biocidal product is

H410 – Very toxic to aquatic life with long lasting effects.

The relevant acute classification as H400 – Very toxic to aquatic life remains unchanged.

2.4 Use(s) appropriate for authorisation[13]

2.4.1 Use 1 appropriate for authorisation – Spraying on cardboards attached to surfaces

Product Type(s)	18
Where relevant, an exact description of the use	Insecticides, against flies
Target organism(s) (including development stage)	Flies (Adult) (*Musca domestica* House fly; *Stomoxys calcitrans* Stable flies)
Field(s) of use	Indoor: Application in animal housings like cattle stable, calves stable, piggery, piglet stable, horse stable, sheep pens. Product is not to be used in poultry houses.
Application method(s)	Spraying: A handhold or backpack/knapsack sprayer with manually operated low pressure (3 bar or below) device has to be used.
Application rate(s) and frequency	Mixing and loading of spray dilution: 1 vol product plus 2 vol water. For a stable/barn of 200 m² ground floor area: 500ml product plus 1L water is distributed to 30-60 cardboards to an overall size of max. 10% of the stable size. Frequency: Apply in the fly season. (spring and beginning of summer). Apply maximum 3 times per year (If required. The interval between two applications must be at least 30 days, as it takes up to 30 days after treatment for the biocidal product to efficiently control fly populations).
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle, HDPE, 670 mL brimful capacity, content: 500 mL product. Further, 100 mL, 250 mL, and 1000 mL in HDPE bottles. 63 mm cap with tamper evident ring (HDPE).

2.4.1.1 Use-specific instructions for use

See chapter 2.5.1

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

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5.2

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

See chapter 2.5.3

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

See chapter 2.5.4

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

See chapter 2.5.1

2.5 General directions for use

2.5.1 Instructions for use

1) A handhold or backpack/knapsack sprayer with manually operated low pressure (3 bar or below) device has to be used. 2) Prepare not more solution than needed. 3) No storage of diluted product. Aqueous solution has to be used on the day of mixing. 4) Do not apply the biocidal product directly onto surfaces (e.g. walls) in the building. 5) Do not apply the biocidal product directly on manure/slurry. 6) Do not apply the product in areas subject to washing/sluicing.

Safe application of the product onto the cardboards (to be considered for each new application event):

7) For the mixing/loading and the application step the applicator must wear disposable clothes (e.g. protective gloves and coverall) to avoid emissions to the sewer system due to washing of contaminated clothes.
8) The area where mixing/loading and the application to cardboards takes place, must be covered with a disposable plastic sheet/foil in order to avoid contamination of adjacent surfaces and floor.
9) At application the cardboard is laying horizontally on an area covered with a disposable foil in order to avoid contamination of adjacent surface/floor.
10) All contaminated equipment may be re-used without cleaning (if possible) and always be disposed of safely according to local regulations (with no discharge to waste water).
11) Do not let the product or its residues enter soil, sinks, water courses or the sewer systems.
12) Disposal of contaminated plastic sheets and disposable clothes after use to residual waste as specified by the regional disposer (incineration).

Safe handling of contaminated cardboards:

13) Apply only on non-absorbent cardboards which are then to be fixed to walls or ceilings where flies prefer to rest (e.g. warm sunny places on boards, piles, poles, window frames or cants of walls), but out of range of farm animals.
14) A drying period of 5 - 15min might be necessary prior to attachment of cardboard dependent on environmental and operating conditions.
15) Do not clean the cardboards.
16) Remove all cardboard sheets, which are treated with the product before cleaning and/or disinfectant events in animal housings/shelters.
17) Disposal of contaminated cardboards after use to residual waste as specified by the regional disposer (incineration).
18) Attach treated cardboards inaccessible for the general public, pets, livestock animals and other non-target animals.

Resistance management measures

19) A change to another product with an active substance with a different mode of action is then recommended.
20) In order to avoid the occurrence of resistance to any active ingredient, products with different modes of action should be used in alternation and the frequent repeated use of the same active substance should be avoided.

21) The use of this product alone may be insufficient to control high infestations. It is recommendable to treat livestock facilities with a larvicide product at the beginning of the fly season.
22) The use of biocidal products 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, where this is commercially viable) within an integrated fly control program.
23) Fly infestation in the 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.
24) Products should always be used in accordance with label recommendations.

2.5.2 Risk mitigation measures

1) Do not apply directly on or near feed or drinks, or on surfaces or utensils likely to be in direct contact with feed, drinks and livestock.
2) Attach treated cardboards inaccessible for the general public, pets, livestock animals and other non-target animals.
3) For use only in areas that are inaccessible to the general public, pets and non-target animals.
4) Spraying is only allowed in the downward direction.
5) When applying the product on cardboards leave an untreated area around the edge.
6) When fixing the treated cardboards to walls or ceilings or collecting them for disposal touch only the untreated area around the edge.
7) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn. The use of waterproof footwear is recommended when applying the product. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.'

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

1) Avoid waste of product.
2) IF ON SKIN: Wash skin with plenty of water.
3) If skin irritation or rash occur: Get medical advice.
4) Take off all contaminated clothing and wash it before reuse.
5) Specific treatment (see … on this label).
6) IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

7) IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

2.5.4 Instructions for safe disposal of the product and its packaging

1) Residues of the biocidal product must be disposed of in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations. Leave biocidal products in original containers. Do not mix with other wastes. Containers containing residues of the product have to be handled accordingly. Waste entry on pesticides: 20 01 19 Waste entry on packaging containing residues of or contaminated by dangerous substances: 15 01 10 (General) 2) After use, dispose treated cardboard in containers inaccessible for the general public, pets and non-target animals.

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

1) Do not store near food, drink and feed. 2) Keep container tightly closed and dry in a cool, dark, well-ventilated place. Shelf-life: 24 months

2.5.6 Other information

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2.6 Packaging

Table 3

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
bottle	670 mL container size, content: 500	Plastic: HDPE	HDPE, 63 mm cap with tamper evident ring	professional	Yes

	mL, 100 mL, 250 mL and 1000 mL in HDPE bottles				

3 Assessment of the product

3.1 Intended use(s) as applied for by the applicant[14]

3.1.1 Intended use 1 – Painting on cardboards attached to surfaces

Product Type(s)	PT18 (Insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the use	Painting application: Application of undiluted b.p. by brushing on non-absorbent paper cardboards which were fixed safe first in different places in stables/barns (except for poultry) where flies prefer to rest, but out of the reach of farm animals.
Target organism(s) (including development stage)	*Musca domestica:* House fly (Adults) *Musca autumnalis:* Stable flies (Adults) *Stomoxys calcitrans* Stable flies (Adults)
Field(s) of use	Indoor
Application method(s)	Painting
Application rate(s) and frequency	For a stable/barn of 200 m² ground floor area, 500 ml Alba is distributed to 30–60 cardboards that were fixed first in different places in the stable/barn (spots of approx. 10x30 cm, with sums up to an overall size of approx. 1.8 m² treated area on cardboards, handle only small areas). Frequency: in the fly season, max. 3 times per year (every 12 weeks if required). Disposal of cardboards after use/fly season to residual waste as specified by the regional disposer.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle, HDPE, 63 mm cap with tamper evident ring, 670 mL brimful capacity, content: 500 mL Alba. Further, 100 mL, 250 mL, and 1000 mL b.p. in HDPE bottles adopted in size are intended to be put on the market. Cap with tamper evident ring.

3.1.2 Intended use 2 – Spraying on cardboards attached to surfaces

Product Type(s)	PT18 (Insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the use	Spraying application: Application of diluted b.p. (1 vol b.p. plus 2 vol water) by coarse low pressure (1-3 bar) on non-absorbent paper cardboard attached to surfaces close to the animals where flies prefer

[14] Please note that the applicant has withdrawn the uses “painting on surfaces” and “spraying on surfaces” in his message of 22.01.2019. Accordingly, these uses have not been assessed.

	to rest (but out of the range of farm animals). This time-saving application is employed preferably in large scale barns.
Target organism(s) (including development stage)	*Musca domestica:* House fly (Adults) *Musca autumnalis:* Stable flies (Adults) *Stomoxys calcitrans* Stable flies (Adults)
Field(s) of use	Indoor
Application method(s)	Spraying
Application rate(s) and frequency	For a stable/barn of 200 m² ground floor area, 500 ml Alba plus 1000 mL water is distributed to 30–60 small areas (max 25 mL each) on 30-60 cardboards, that were fixed first in different places in the barns/stables) to an overall size of max. 10 % of the stable size (handle small areas best possible and feasible) with the help of a hand held or backpack sprayer (coarse low pressure, 1-3 bar). Frequency: in the fly season, max 3 times per year (every 12 weeks if required). Disposal of cardboards after use/fly season to residual waste as specified by the regional disposer.
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle, HDPE, 63 mm cap with tamper evident ring, 670 mL brimful capacity, content: 500 mL Alba. Further, 100 mL, 250 mL, and 1000 mL b.p. in HDPE bottles adopted in size are intended to be put on the market. Cap with tamper evident ring.

3.2 Physical, chemical and technical properties

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

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	visual inspection	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.3% (w/w) Clothianidin	slight viscous liquid	[redacted] (2007) 20071164/01-PCAS
	visual inspection	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	paste	[redacted] (2014) T07STI03
	visual inspection	Alba (Product code: SPU-02740-I), Batch No: OX0701001	slight viscous liquid	[redacted] (2007) 20071164/01-PCCS
	visual inspection	Alba (Product code: SPU-02740-I), Batch No: 201406005: 2.2% (w/w) Clothianidin 0.05% (w/w) Muscalure	viscous liquid	[redacted] (2016) S15-00745
Colour at 20 °C and 101.3 kPa	visual inspection	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.3% (w/w) Clothianidin	uniform white, opaque	[redacted] (2007) 20071164/01-PCAS
	visual inspection	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	uniform white, opaque	[redacted] (2014) T07STI03
	visual inspection	Alba (Product code: SPU-02740-I),	uniform white, opaque	[redacted] (2007) 20071164/01-PCCS

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Batch No: OX0701001		
	visual inspection	Alba (Product code: SPU-02740-I), Batch No: 201406005: 2.2% (w/w) Clothianidin 0.05% (w/w) Muscalure	white, opaque	[redacted] (2016) S15-00745
Odour at 20 °C and 101.3 kPa	olfactory inspection	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.3% (w/w) Clothianidin	weak unspecific odour	[redacted] (2007) 20071164/01-PCAS
	olfactory inspection	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	hardly perceptible	[redacted] (2014) T07STI03
	olfactory inspection	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.2% (w/w) Clothianidin	weak unspecific odour	[redacted] (2007) 20071164/01-PCCS
	olfactory inspection	Alba (Product code: SPU-02740-I), Batch No: 201406005: 2.2% (w/w) Clothianidin 0.05% (w/w) Muscalure	slightly solvent- and almond like odour	[redacted] (2016) S15-00745
Acidity / alkalinity	CIPAC MT 75.3	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.3% (w/w) Clothianidin	pH of 1 % aqueous suspension: 7.94	[redacted] (2007) 20071164/01-PCAS
	CIPAC MT 75.3	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	pH of 1 % aqueous suspension: 7.4	[redacted] (2014) T07STI03

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	CIPAC MT 75.3	Alba (Product code: SPU-02740-I), Batch No: 201406005: 2.2% (w/w) Clothianidin 0.05% (w/w) Muscalure	pH of 1 % (w/w) dilution in water: 7.38	[redacted] (2016) S15-00745
Relative density / bulk density	EU Method A.3 (Relative Density), pycnometer method	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.2% (w/w) Clothianidin	density: 1.1273 g/mL (20.1 °C)	[redacted] (2007) 20071164/01-PCRD
	CIPAC method MT 3.3, EU method A.3	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	density: 1.13 g/mL rel. density: 1.13	[redacted] (2014) T07STI03
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.3% (w/w) Clothianidin	Storage for 2 weeks at 54 °C: **After storage for 2 weeks at 54 °C:** No changes in appearance and odour. No significant changes in suspensibility (clothianidin), wet sieve test, pourability or viscosity. **Stability of the original test item container (visual):** before: The containers (screw capped PE-PA bottles) shut tightly and no damage was observed. after: The containers (screw capped PE-PA bottles) shut tightly and no damage or deterioration of containers was observed after storage. **Weight change of the test item container:**	[redacted] (2007) 20071164/01-PCAS

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			after: loss in total weight <0.04 % **Physical state, colour and odour (visual, olfactory):** before: uniform, white, opaque, slight viscous liquid with a weak unspecific odour after: uniform, white, opaque, slight viscous liquid with a weak unspecific odour (no change) **pH value (CIPAC MT 75.3):** before: 7.94 after: 7.92 **Clothianidin content (HPLC):** before: 2.28% (w/w) after: 2.24% (w/w) **Suspensibility (a.s.) (CIPAC MT 184):** before: after 30 min of standing; spray concentration: 500 mL/1 L water (v/v) = 100% after: after 30 min of standing; spray concentration: 500 mL/1 L water (v/v) = 99.8% **Wet sieving (CIPAC MT 185):** before: residue on 75 µm sieve ≤ 0.004 % after: residue on 75 µm sieve ≤ 0.007 % **Pourability (CIPAC MT 148):** before: residue R: 3.9%; rinsed residue R': 0.3% after: residue R: 3.8%; rinsed residue R': 0.2%	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Viscosity (OECD 114): before: 842 mPa s (5 s-1) at 20 °C 77 mPa s (120 s-1) at 20 °C 798 mPa s (5 s-1) at 40°C 72 mPa s (120 s-1) at 40°C (non-Newtonian liquid) after: 895 mPa s (5 s-1) at 20 °C 89 mPa s (120 s-1) at 20 °C 781 mPa s (5 s-1) at 40°C 70 mPa s (120 s-1) at 40°C (non-Newtonian liquid)	
	CIPAC MT 46.3	Alba (Product code: SPU-02740-I), Batch No: 2011-000230 2.3% (w/w) Clothianidin 0.05% (w/w) Muscalure	Storage for 2 weeks at 54 °C: **Clothianidin content (HPLC/UV):** before: 2.25% (w/w) after: 2.24% (w/w) **Muscalure content (GC/FID):** before: 0.0452% (w/w) after: 0.0458% (w/w)	[redacted] (2011) S11-00931
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No. 17, Crop Life International, June 2009	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	5 year storage stability test: **After storage for 61 months at ambient temperature:** No changes in appearance and odour. No significant changes in relative density, persistent foaming, suspensibility (clothianidin), wet sieve test, pourability or viscosity. **pH value (CIPAC MT 75.3):** before storage: 7.4	[redacted] (2014) T07STI03

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			after 13 months: 7.7 after 26 months: 6.8 after 41 months: 7.6 after 48 months: 7.6 after 61 months: 7.5 **Clothianidin content (HPLC):** before storage: 25.4 g/L (2.25% w/w) after 13 months: 25.2 g/L (2.23% w/w) after 26 months: 25.9 g/L (2.29% w/w) after 41 months: 25.8 g/L (2.28% w/w) after 48 months: 25.5 g/L (2.26% w/w) after 61 months: 25.6 g/L (2.27% w/w)	
		Alba (Product code: SPU-02740-I), Batch No: 201406005: 2.2% (w/w) Clothianidin 0.05% (w/w) Muscalure	3 year storage stability test: **After storage for 36 months at ambient temperature:** No changes in appearance and odour. No significant changes in spontaneity (both a.s.), suspensibility (both a.s.), wet sieve test or pourability. **pH value (CIPAC MT 75.3):** before storage: 7.38 after 6 months: 7.36 after 12 months: 7.56 after 24 months: 7.66 after 36 months: 7.52 **Clothianidin content (HPLC/UV):** before storage: 2.16% w/w after 6 months: 2.19% w/w (+1.37%) after 12 months: 2.19% w/w (+1.37%)	[redacted] (2016) S15-00745

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			after 24 months: 2.26% w/w (+4.63%) after 36 months: 2.24% (w/w) +3.70%) **Muscalure content (GC/FID):** before storage: 0.052% w/w after 6 months: 0.053% w/w (+1.92%) after 12 months: 0.054% w/w (+3.85%) after 24 months: 0.046% w/w (-11.54%) after 36 months: 0.045% w/w (-13.46%) Based on the given results from the long term stability test and the corresponding decrease in the content of the a.s. Muscalure a shelf-life of 12 months would be assumed.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.2% (w/w) Clothianidin	The appearance of the product remains un-changed after storage at 0°C for 7 days; no phase separation was observed.	[redacted] (2007) 20071164/01-PCCS
eCA remark on shelf-life	Based on efficacy data on the aged product a shelf-life of 24 months can be assigned.			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The applicant states as label claim "Keep container tightly closed and dry in a cool, dark, well-ventilated place."	Waiving[15]
Effects on content of the active substance and technical characteristics of the biocidal product –	-	-	The effects of temperature and humidity on the content of the active substance and technical characteristics of the (water-based) biocidal product were tested within the long term	-

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

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
temperature and humidity			storage at ambient temperature and the accelerated storage test. (The product was found to be thermal stable after storage at 54 °C for 2 weeks.)	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			After storage for 61 months at ambient temperature: The packaging showed no evidence of peeling, cracking, discoloration or swelling.	[redacted] (2014) T07STI03
Wettability	-	-	Data waiving was acceptable (only required for solid preparations).	-
Suspensibility, spontaneity and dispersion stability	CIPAC MT 184	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.3% (w/w) Clothianidin	100 % suspensibility of SPU-02740-I (500 mL/1 L water (v/v)) determined by a.s. Clothianidin.	[redacted] (2007) 20071164/01-PCAS
	CIPAC MT 184	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	100 % suspensibility of SPU-02740-I without pre-treatment determined by a.s. Clothianidin.	[redacted] (2014) T07STI03
	CIPAC MT 184	Alba (Product code: SPU-02740-I), Batch No: 201406005: 2.2% (w/w) Clothianidin 0.05% (w/w) Muscalure	Suspensibility (33.3 % v/v spray concentration), determined by Clothianidin: 99.7% (before storage) 100.7% (after 24 months)	[redacted] (2016) S15-00745
	CIPAC MT 160	Alba (Product code: SPU-02740-I), Batch No: 201406005: 2.2% (w/w) Clothianidin 0.05% (w/w) Muscalure	Spontaneity, determined by Clothianidin: 82.7% (before storage) 83.2% (after 24 months)	[redacted] (2016) S15-00745
Wet sieve analysis and dry sieve test	CIPAC MT 185	Alba (Product code: SPU-02740-I),	≤ 0.004 % of the test item remain on a 75 µm mesh size test sieve.	[redacted] (2007) 20071164/01-PCAS

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		Batch No: OX0701001 2.3% (w/w) Clothianidin		
	CIPAC MT 185	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	wet sieve residue of the test item SPU-02740-I: < 0.001 %	[redacted] (2014) T07STI03
	CIPAC MT 185	Alba (Product code: SPU-02740-I), Batch No: 201406005: 2.2% (w/w) Clothianidin 0.05% (w/w) Muscalure	The wet sieve analysis of the test item showed a residue of ≤ 0.03 % on a 75 µm sieve. (before storage) of ≤ 0.01 % on a 75 µm sieve (after 24 months)	[redacted] (2016) S15-00745
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Data waiving was acceptable based on the formulation type of the product	-
Disintegration time	-	-	Data waiving was acceptable based on the formulation type of the product	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Data waiving was acceptable based on the formulation type of the product	-
Persistent foaming	CIPAC MT 47.2	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.3% (w/w) Clothianidin	No foam (0 mL) was found from an aqueous solution of 66.67 mL (59.1 g) of the test item and 133.3 mL CIPAC standard water D (1/2 (v/v) dilution of SPU-02740-I in water).	[redacted] (2007) 20071164/01-PCPF
	CIPAC MT 47.2	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	The foam volume of SPU-02740-I was 0 mL. (at 0 and 26 months)	[redacted] (2014) T07STI03
Flowability/Pourability/Dustability	CIPAC MT 148	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.3% (w/w) Clothianidin	Pourability of SPU-02740-I: R (residue) [%]: 3.9 R´ (rinsed residue) [%]: 0.3	[redacted] (2007) 20071164/01-PCAS

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	CIPAC MT 148.1	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	The pourability of SPU-02740-I: residue of 3.5 %.	[redacted] (2014) T07STI03
	CIPAC MT 148	Alba (Product code: SPU-02740-I), Batch No: 201406005: 2.2% (w/w) Clothianidin 0.05% (w/w) Muscalure	Pourability: Before storage: R (residue) [%]: 2.61 R´ (rinsed residue) [%]: 0.23 After 24 months: R (residue) [%]: 4.62 R´ (rinsed residue) [%]: 0.32	[redacted] (2016) S15-00745
Burning rate — smoke generators	-	-	Data waiving was acceptable (Alba is not proposed to be applied as a smoke).	-
Burning completeness — smoke generators	-	-	Data waiving was acceptable (Alba is not proposed to be applied as a smoke).	-
Composition of smoke — smoke generators	-	-	Data waiving was acceptable (Alba is not proposed to be applied as a smoke).	-
Spraying pattern — aerosols	-	-	Data waiving was acceptable (Alba is not applied as an aerosol).	-
Physical compatibility	-	-	Data waiving was acceptable (concomitant use with other products is not intended).	-
Chemical compatibility	-	-	Data waiving was acceptable (concomitant use with other products is not intended).	-
Degree of dissolution and dilution stability	-	-	Data waiving was acceptable. (For the spraying application of Alba, dilution of the water-based product Alba (SC) with water is foreseen, but no keeping or storage of the aqueous dilution is recommended (Testing of MT 41 after 18 h). Direct and complete application of the preparation is advised: Label claim “No storage of diluted product, aqueous solution has to be	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			used on the day of mixing for spraying application." Comprehensive information on the suspensibility of Alba (MT 184) and its spontaneity of dispersion (MT 160) are available providing the corresponding information concerning the product characteristics.))	
Surface tension	EC A.5 and OECD 115	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.3% (w/w) Clothianidin	Since the surface tension was above 60 mN/m, the test item has to be regarded to be not surface active. (72.1 mN/m (20°C), 1 g/L)	[redacted] (2007) 20071164/01-PCST
Viscosity	OECD 114 and CIPAC MT 192	Alba (Product code: SPU-02740-I), Batch No: OX0701001 2.3% (w/w) Clothianidin	The test item could be considered as a non-Newtonian liquid, because the viscosity was not constant with the shear rates. 842 mPa s (5 s-1) at 20 °C 77 mPa s (120 s-1) at 20 °C 798 mPa s (5 s-1) at 40°C 72 mPa s (120 s-1) at 40°C	[redacted] (2007) 20071164/01-PCAS
	CIPAC MT 192 rotational viscometer (dynamic)	Alba (Product code: SPU-02740-I), Batch No: 0701001 2.3% (w/w) Clothianidin	dynamic viscosity (in mPa s): 85.0 – 88.0 [shear rate: 106 s-1, 20°C] 35.0 – 37.0 [shear rate: 424 s-1, 20°C]	[redacted] (2014) T07STI03

Table 5

Conclusion on the physical, chemical and technical properties	
The data provided by the applicant was acceptable. The biocidal product Stallfliegenmittel Alba is a white, opaque viscous liquid with a slightly solvent- and almond like odour. The pH value of a 1 % (w/w) dilution of the product in water is 7.38. The density of the product is about 1.13 g/mL at 20°C. The product Stallfliegenmittel Alba is stable for 2 weeks at 54 °C, did not separate after 7 days at 0°C and based on the results of the long term storage test, a shelf-life of 12 months would be assumed. Nevertheless, based on efficacy data on the aged product a shelf-life of 24 months can be assigned. The suspensibility and spontaneity of dispersion of the product Stallfliegenmittel Alba were sufficient. Based on the results of the wet sieve test the product Stallfliegenmittel Alba showed a residue of ≤ 0.03 % on a 75 µm sieve. No foam generation was observed in the test on persistent foaming (0 mL). With regard to the pourability, the residue observed with MT 148 was 2.61% residue and the rinsed residue was 0.23%. Since the surface tension of the product Stallfliegenmittel Alba is 72.1 mN/m (at 20°C, 1 g/L), the product is not regarded as surface active. The dynamic viscosity of the product Stallfliegenmittel Alba at 20°C is 85.0 – 88.0 mPa s at a shear rate of 106 s-1 and 35.0 – 37.0 at a shear rate of 424 s-1.	
Data waiving was acceptable for the following information requirements	
Information requirement	1. Effects on content of the active substance and technical characteristics of the biocidal product - light 2. Wettability 3. Emulsifiability, re-emulsifiability and emulsion stability 4. Disintegration time 5. Particle size distribution, content of dust/fines, attrition, friability 6. Burning rate — smoke generators 7. Burning completeness — smoke generators 8. Composition of smoke — smoke generators 9. Spraying pattern — aero-sols 10. Physical compatibility 11. Chemical compatibility 12. Degree of dissolution and dilution stability

3.3 Physical hazards and respective characteristics

Table 6: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	study scientifically not necessary			Waiver: The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties. The only substances comprising chemical groups (listed in table A6.1 of the UN-MTC), which are associated with explosive properties are Clothianidin, Muscalure and Benzisothiazolone. However, all three substances were shown to be not explosive (according to EU method A.14, cf. ECHA dissemination page). Therefore, the biocidal mixture is not regarded as explosive.	IUCLID[16]
Flammable gases	study scientifically unjustified			Not applicable. The product is liquid.	IUCLID[16]
Flammable aerosols	study scientifically unjustified			Not applicable. The product is liquid and not applied as an aerosol.	IUCLID[16]
Oxidising gases	study scientifically unjustified			Not applicable. The product is liquid.	IUCLID[16]

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

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Gases under pressure	study scientifically unjustified			Not applicable. The product is liquid.	IUCLID[16]
Flammable liquids	DIN EN ISO 2719	SPU-02740-I, Batch No: OX0701001 25.1 g/l Clothianidin	Flash point: No flash point under atmospheric condition was observed, the test item boiled at approximately 100 °C.	Not classified based on GHS/CLP criteria as the flash point is > 60 °C.	[redacted] (2007), SPU-02740-I, Report no. 20070271.01.
Flammable solids	study scientifically unjustified			Not applicable. The product is liquid.	IUCLID[16]
Self-reactive substances and mixtures	study scientifically not necessary			Waiver (accepted by BAM experts): The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied. For further information please refer to section 1.1.2.1 the conf. annex of the PAR.	
Pyrophoric liquids	study scientifically not necessary			Waiver: The study does not need to be conducted because the mixture is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure does not need to be applied (based on experience).	IUCLID[16]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Pyrophoric solids	study scientifically unjustified			Not applicable. The product is liquid.	IUCLID[16]
Self-heating substances and mixtures	study scientifically unjustified			Not applicable. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore, liquids are not classified as self-heating.	IUCLID[16]
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Waiver: The study does not need to be conducted because the experience in production or handling shows that the substance does not react with water, e.g. the substance is manufactured with water or washed with water.	IUCLID[16]
Oxidising liquids	EEC method A.21, theoretical assessment of the chemical structure	SPU-02740-I	The study does not need to be conducted because there are no chemical groups present in the active substance or in any of the co-formulants, which are associated with oxidising properties.	In all substances present in the biocidal mixture oxygen and/or halogens are solely bound to hydrogen or carbon. The only exception is the active substance (clothianidin) which is not oxidising according to EU method A.17 (cf. ECHA dissemination page). Not classified based on GHS/CLP criteria.	[redacted] (2007), Oxidising properties of SPU-02740-I, Document no. Wa-181207-02740
Oxidising solids	study scientifically unjustified			Not applicable. The product is liquid.	IUCLID[16]
Organic peroxides	study scientifically not necessary			Waiver: The study does not need to be conducted because the substance does not fall under the	IUCLID[16]

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
				definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	
Corrosive to metals	study scientifically not necessary			Waiver: Based on the composition of the product and following the indications in the TAB entry 4.2.1.4 a test on corrosivity to metals is not necessary. For further information: Please refer to section 1.1.2.2 of the confidential Annex of the PAR.	IUCLID[16]
Auto-ignition temperature (liquids and gases)	DIN 51794	SPU-02740-I, Batch No: OX0701001 25.1 g/l Clothianidin	Auto-ignition temperature: 430 °C		[redacted] (2007), SPU-02740-I, Report no. 20070271.01
Relative self-ignition temperature for solids	study scientifically unjustified			Not applicable. The product is liquid.	IUCLID[16]
Dust explosion hazard	study scientifically unjustified			Not applicable. The product is liquid.	IUCLID[16]

Table 7

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. Experimental data on flash point and auto-ignition temperature (430 °C) were provided for the product. No flash point was observed, measurement carried out until boiling temperature at approximately 100 °C. Based on experience in production and handling it can be concluded that the product is not pyrophoric, does not evolve flammable gases in contact with water and is not considered as being corrosive to metals. The product is not expected to have any explosive or oxidising properties because it mainly consists of food-grade materials. Conclusions on classification and labelling: In regard of the physical and chemical properties, the biocidal product does not fulfil the criteria for classification according to Regulation (EC) No 1272/2008 and therefore, no labelling is required for physical-chemical hazards.

3.4 Methods for detection and identification

Table 8

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Clothianidin in Alba / SPU02740-I [26 g/L/2.3 % w/w clothianidin]	HPLC-UV, external standard calibration with Clothianidin	No interference (< 3 % of total peak area for target analyte) was obtained from the analysis.	10.0296 – 100.296 mg/L R^2=1.000 5 concentrations measured in duplicate	2.3 % w/w (26.0 g/L) 5 measurements	99.6 – 100.0	99.8	±0.158	n.a.	[redacted] (2007) WA-07-09-02740
Clothianidin in Alba / SPU02740-I [26 g/L/2.3 % w/w clothianidin]	HPLC-UV	Highly specific and selective. No relevant interference found.	1.01 – 101.0 mg/L R^2=1.000 8 concentration levels	Low Recovery: 3.28 mg/L 5 measurements	102 – 107	104	1.7	LOQ: 3.28 mg/L	[redacted] (2016) S15-00743
				Medium Recovery: 24.5 mg/L 5 measurements	97.1 - 103	101	2.1		
				High Recovery: 49.0 mg/L 5 measurements	102 - 103	102	0.4		
Clothianidin in Alba / SPU02740-I	HPLC-UV	Highly specific. No interference detectable.	5.1 – 101.0 mg/L R^2=1.000	Low Recovery: 1.14 % (w/w) 5 measurements	98.3 – 99.9	99.0	0.72	LOQ: 1.14 % (w/w) LOD: 0.03 % (w/w)	[redacted] (2016)

[26 g/L/2.3 % w/w clothianidin]			7 concentration levels	High Recovery: 3.35 % (w/w) 5 measurements	99.1 – 99.7	99.4	0.25		S15-00744
Muscalure in Alba / SPU02740-I [0.5 g/L/0.04 % w/w Muscalure]	GC-FID	(Z)-9-Tricosene was identified by retention time compared with certified reference item. No interferences detectable.	5.42 – 75.81 mg/L R^2=1.000 5 concentrations measured in duplicate	Low Recovery: 15.15 mg/L 5 measurements	97.2 - 100.3	99.1	1.0	n.a.	[redacted] (2011) S11-00930
				High Recovery: 46.62 mg/L 5 measurements	94.9 – 97.4	95.7	1.0		
Muscalure in Alba / SPU02740-I [0.5 g/L/0.04 % w/w Muscalure]	GC-FID	GC/FID analysis of blanks showed no interference with (Z)-9-Tricosene (interferences not detectable). The analytical method can therefore regarded as highly specific and selective for (Z)-9-Tricosene.	0.505 – 10.1 mg/L R^2=1.000 6 concentration levels; 5.3 – 105.5 mg/L R^2=0.9995 6 concentration levels	Low 5.20 mg/L 5 measurements	90.1 – 94.5	91.9	1.7	LOQ: 0.99 mg/L	[redacted] (2016) S15-00742
				Medium 118.0 mg/L 5 measurements	104 – 114	109	3.7		
				High 235.7 mg/L 5 measurements	104 – 109	107	2.1		

Table 9

Relevant residue definitions for monitoring and levels for which compliance is required for Clothianidin			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	Clothianidin	0.05 mg/kg	Common limit
Drinking water	Clothianidin	0.1 µg/L	Minimal requirement of the Drinking Water Act (Trinkwasser-VO)
Surface water	Clothianidin	0.08 µg/L	PNEC water: 0.08 µg/L based on EC10 *Chironomus riparius*: 0.4 µg/L, AF 5, AR for PT18, chapter 2.2.2.2, 10/2014
Air	Not relevant		Not required for general public because of professional use
Animal and human body fluids and tissues	Not relevant		Not classified as toxic or very toxic, AR for PT18, list of endpoints, 10/2014
Food of plant origin	Clothianidin	0.01 mg/kg	Reg. (EU) 2017/671, annex II
Food of animal origin	Clothianidin	0.01 mg/kg	Reg. (EU) 2017/671, annex II, however, in CAR, list of endpoints is stated, that methods are not required

Table 10

Relevant residue definitions for monitoring and levels for which compliance is required for (Z)-9-tricosene			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	Not relevant		Relevant Residues not expected, CAR for PT19, doc I, chapter 2.1.1
Drinking water	Not relevant		Relevant Residues not expected, CAR for PT19, doc I, chapter 2.1.1
Surface water	Not relevant		Relevant Residues not expected, CAR for PT19, doc I, chapter 2.1.1
Air	Not relevant		Not required for general public because of professional use
Animal and human body fluids and tissues	Not relevant		Not classified as toxic or very toxic
Food of plant origin	(Z)-9-Tricosene	0.01 mg/kg	Default MRL according to art. 18(1) (b), Reg. (EC) No. 396/2005, Not relevant for the intended use
Food of animal origin	(Z)-9-Tricosene	0.01 mg/kg	Default MRL according to art. 18(1) (b), Reg. (EC) No. 396/2005

Table 11

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Clothianidin	SPE on C18, HPLC-UV, 270 nm, (1) LiChrospher 100 C18 (2) LiChrospher 100 CN	Blank values < 30 % of LOQ, confirmation included by using of HPLC column of different selectivity, validated for surface water but also accepted for drinking water	linear (10 – 500 ng/mL corresponding to 0.01 – 0.5 µg/L in samples R^2=1.0000)	0.05 µg/L/ 5 0.5 µg/L / 5 0.05 µg/L/ 1 0.5 µg/L/ 1	86-97 73-86 - -	92 80 88 88	4.3 6.4 - -	LOQ: 0.05 µg/L	[redacted] 2000b, CAR for PT 18, A4.2/05, report no. BAY-009V / Az. G00-0065

Table 12

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Clothianidin	Extraction by ASE, LC-MS/MS; Inertsil ODS-3, ESI+, m/z 250→169	Blank values < 30 % of LOQ	Linear (1-500 ng/mL corresponding to 0.0025 – 1.25 mg/kg in soil samples, R=0.9999)	0.005 mg/kg / 5 0.05 mg/kg / 5 (soil BBA 4.2) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Höfchen)	103-112 95-104 97-111 96-107	108.1 100.2 103.4 101.2	3.5 3.1 5.3 4.6	LOQ: 0.005 mg/kg	[redacted] 2000a; CAR for PT18, doc IIA, A 4.2/01, report no. MR-654/98

TZNG (metabolite of clothianidin)	Extraction by ASE, LC-MS/MS, Inertsil ODS-3, ESI+, m/z 236→132	Blank values < 30 % of LOQ	Linear (1-500 ng/mL corresponding to 0.0025 – 1.25 mg/kg in soil samples, R=0.9997)	0.005 mg/kg / 5 0.05 mg/kg / 5 (soil BBA 4.2) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Höfchen)	85-112 95-109 85-106 94-109	98.9 103.5 96.4 100.7	10.6 5.2 10.1 5.3	LOQ: 0.005 mg/kg	[redacted] 2000a; CAR for PT18, doc IIA, A 4.2/01, report no. MR-654/98
MNG (metabolite of clothianidin	Extraction by ASE, LC-MS/MS, Inertsil ODS-3, ESI+,	Blank values < 30 % of LOQ	Linear (1-500 ng/mL corresponding to 0.0025 – 1.25 mg/kg in soil samples, R=0.9995)	0.005 mg/kg / 5 0.05 mg/kg / 5 (soil BBA 4.2) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Höfchen)	100-112 92-96 91-110 87-99	106.7 93.8 100.8 94.2	4.4 7.2 2.2 5.2	LOQ: 0.005 mg/kg	[redacted] 2000a; CAR for PT18, doc IIA, A 4.2/01, report no. MR-654/98
Clothianidin	Extraction by ASE, LC-MS/MS; Luna Phenyl-hexyl, ESI+, m/z 250→169	Blank values < 30 % of LOQ	Linear (1-500 ng/mL corresponding to 0.0025- 1.25 mg/kg in soil samples, R= 0.993)	0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Watsonville) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Howe) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Höfchen)	87-99 95-106 93-110 93-107 91-106 96-101	92.3 99.0 101.8 101.2 96.5 99.5	6.1 4.6 6.9 5.0 6.5 2.3	LOQ: 0.005 mg/kg	[redacted] 1999; CAR for PT18, docIIA, A 4.2/03 report no. MR-343/98
TZNG (metabolite of clothianidin)	Extraction by ASE, LC-MS/MS; Luna Phenyl-hexyl, ESI+, m/z 236→132	Blank values < 30 % of LOQ	Linear (1-500 ng/mL corresponding to 0.0025- 1.25 mg/kg in soil samples, R=0.9988)	0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Watsonville) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Howe) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Höfchen)	87-97 91-105 88-100 90-108 87-97 86-99	92.2 96.2 93.6 95.9 91.5 92.3	5.3 5.7 4.5 7.7 5.0 5.0	LOQ: 0.005 mg/kg	[redacted] 1999; CAR for PT18, docIIA, A 4.2/03 report no. MR-343/98

MNG (metabolite of clothianidin)	Extraction by ASE, LC-MS/MS; Luna Phenyl-hexyl, ESI+, m/z 119→173	Blank values < 30 % of LOQ	Linear (1-500 ng/mL corresponding to 0.0025- 1.25 mg/kg in soil samples, R=0.9999)	0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Watsonville) 0.005 mg/kg / 5 0.05 mg/kg / 5(soil Howe) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Höfchen)	67-81 79-111 75-96 91-104 69-89 90-109	73.4 96.0 81.4 98.1 80.1 96.2	7.7 12.0 10.4 5.3 10.0 7.9	LOQ: 0.005 mg/kg	[redacted] 1999; CAR for PT18, docIIA, A 4.2/03 report no. MR-343/98
TZMU (metabolite of clothianidin)	Extraction by ASE, LC-MS/MS; Luna Phenyl-hexyl, ESI+, m/z 206→175	Blank values < 30 % of LOQ	Linear (1-500 ng/mL corresponding to 0.0025- 1.25 mg/kg in soil samples, R= 0.9985)	0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Watsonville) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Howe) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Höfchen)	86-107 79-93 79-105 88-101 91-103 84-101	97.2 87.0 91.5 94.9 96.6 93.4	9.3 6.8 10.4 5.5 5.4 6.8	LOQ: 0.005 mg/kg	[redacted] 1999; CAR for PT18, docIIA, A 4.2/03 report no. MR-343/98
TMG (metabolite of clothianidin)	Extraction by ASE, LC-MS/MS; Luna Phenyl-hexyl, ESI+, m/z 205→132	Blank values < 30 % of LOQ	Linear (1-500 ng/mL corresponding to 0.0025- 1.25 mg/kg in soil samples, R=0.9997)	0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Watsonville) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Howe) 0.005 mg/kg / 5 0.05 mg/kg / 5 (soil Höfchen)	88-112 88-110 92-134 101-114 88-99 92-126	97.0 96.5 106.6 106.6 93.4 100.4	10.0 8.7 14.8 4.8 4.7 14.3	LOQ: 0.005 mg/kg	[redacted] 1999; CAR for PT18, docIIA, A 4.2/03 report no. MR-343/98
Clothianidin	Solvent extraction, HPLC-UV, 270	Blank values < 30 % of LOQ	Linear (20-1000 ng/mL corresponding	0.01 mg/kg / 5 0.1 mg/kg 8 1	92-105 96-104	97 100	5.5 3.3	LOQ: 0.01 mg/kg	[redacted] 2000a; CAR for PT18, doc IIA, A4.2/02

	nm (1) LiChrospher 100 RP18, (2) LiChrospher CN		to 0.002 – 0.1 mg/kg in soil samples, R=0.9997)	(soil LUFA Speyer 2.2)	- -	97 96	- -		report no. BAY0010V/ Az. G00-0066

Table 13:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
1,2-benzisothiazol-3/2H)-one, BIT	UPLC-MS/MS	Low Recovery: 12.63 µg/m³ /5 replicates	$r^2 \geq 0.992$	Yes	85-87	86.1	≤2.8	12.63 µg/m³	[redacted] (2018) 171006EW /CRA18032
		High Recovery: 126.3 µg/m³ /5 replicates			77-86	81.4	≤8.0		

Table 14

Analytical methods for surface water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Clothianidin	SPE on C18, HPLC-UV, (1)	Blank values < 30 % of LOQ, confirmation included by using of HPLC column of	Linear (10 – 500 ng/mL corresponding	0.05 µg/L / 5 0.5 µg/L / 5	86-97 73-86	92 80	4.3 6.4	LOQ: 0.05 µg/L	[redacted] 2000b, CAR for PT 18, A4.2/05, report

	LiChrospher 100 C18, 270 nm (2) LiChrospher 100 CN	different selectivity, validated for surface water but also accepted for drinking water	to 0.01 – 0.5 µg/L in samples R^2=1.0000)	0.05 µg/L / 1 0.5 µg/L / 1	- -	88 88	- -		no. BAY-009V / Az. G00-0065

Table 15

Analytical methods for monitoring of active substances and residues in food and feeding stuff of plant origin									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Clothianidin	Extraction with acetone/water (3/1, v/v), cleanup by partition on ChemElut, column chromato-graphy on Florisil, HPLC-UV, 270 nm, (1) LiChrospher 100 RP 18 (2) LiChrospher 100 RP-CN	Blank value < 30 % LOQ	Linear (10-1000 ng/mL or responding to 0.004-0.2 mg/kg, R=1.0000)	0.01 mg/kg / 5 (apple fruit) 0.01 mg/kg / 5 (wheat grain) 0.01 mg/kg / 5 (sugar beet) 0.01 mg/kg / 5 (oilseed rape) 0.01 mg/kg / 1 (apple fruit) 0.01 mg/kg / 1 (wheat grain) 0.01 mg/kg / 1	72-86 71-90 70-77 78-88 - - -	79 79 73 82 83 105 103	6.7 9.2 4.0 4.8 - - -	LOQ: 0.01 mg/kg	[redacted] 2001; CAR for PT18, A4.3/02, report no. BAY113-V/Az. G01-0098

				(sugar beet) 0.01 mg/kg / 1 (oilseed rape)	- -	75	-		

Table 16

Analytical methods for monitoring of active substances and residues in food and feeding stuff of animal origin									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
(Z)-9-tricosene	Extraction with ethanol/diethyl ether (3/1, v/v), partition with diethyl ether, GC-MS/MS, TG 5 Sil MS column, EI, m/z 322→111 m/z 322→97	Blank values < 30 % of LOQ	Linear (0.15 – 6 ng/mL corresponding to 0.003 – 0.12 mg/kg in meat, milk, eggs, liver ; 0.09 – 1.8 ng/mL corresponding to 0.006 – 0.12 mg/kg in fat; R^2 > 0.9945)	0.01 mg/kg / 5 0.1 mg/kg / 5 (milk) 0.01 mg/kg / 4 0.1 mg/kg / 5 (eggs) 0.01 mg/kg / 5 0.1 mg/kg / 5 meat) 0.01 mg/kg / 5 0.1 mg/kg / 4 (liver) 0.01 mg/kg / 5 0.1 mg/kg / 5 (fat) 0.01 mg/kg / 5 0.1 mg/kg / 5 (milk) 0.01 mg/kg / 4 0.1 mg/kg / 5 (eggs) 0.01 mg/kg / 5 0.1 mg/kg / 5 meat) 0.01 mg/kg / 5 0.1 mg/kg / 4 (liver) 0.01 mg/kg / 5 0.1 mg/kg / 5 (fat)	57-95 75-95 95-106 105-120 85-109 92-106 80-96 91-99 65-122 85-116 84-109 76-94 85-116 104-120	82 88 100 113 97 99 90 96 84 104 94 86 105 114 95 101	19 8.8 4.7 5.4 10 6.1 6.6 3.6 24 12 11 8.7 11 5.7 15 8.4	LOQ: 0.01 mg/kg (milk, eggs, meat, liver) LOQ: 0.1 mg/kg (fat)	[redacted] 2019, study no. 170921EW/ CRA18471

					80-116 93-112 83-95 91-99 93-108 82-111	 88 96 103 100	 6.8 4.1 5.6 11		

Table 17

Data waiving was acceptable for the following information requirements	
Information requirement	1. 5.1. Analytical method including validation parameters for determining the concentration of the substances of concern BIT in the biocidal product were waived based on the fact that it is not formed during storage. 2. 5.2.1. Soil for (Z)-9-Tricosene 3. 5.2.2. Air: An analytic method for determination of the a.s. clothianidin was provided in the CAR. An analytic method for determination of the a.s. cis-tricos-9-en was not provided in the CAR for this substance, however, inhalation exposure towards this substance is expected at the workplace to be far below the reference values and waiving of an analytical method is therefore considered acceptable. 4. 5.2.3. Water (including drinking water) and sediment for (Z)-9-Tricosene 5. 5.2.4. Animal and human body fluids and tissues for clothianidin and (Z)-9-tricosene 5.3. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant origin for (Z)-9-Tricosenene and of animal origin or feeding stuffs and other products where relevant[17] for clothianidin
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 18

Conclusion on the methods for detection and identification
The methods provided regarding the active substances were acceptable. Residue analytical methods were acceptable for clothianidin in plant commodities, soil, drinking water and surface water. Residue analytical methods were acceptable for (Z)-9-Tricosene for animal commodities. The method regarding residues of the substance of concern BIT in air is acceptable.

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

3.5 Efficacy against target organisms

3.5.1 Function and field of use

The product “Stallfliegenmittel Alba” is an insecticide (PT18) containing 2,4% Clothianidin as well as 0.05% Muscalure (Tricosene) as attractant for indoor use in stables and barns to control adult flies (e.g. house flies, *Musca domestica,* and stable flies, *Stomoxys calcitrans*).

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

The product is an insecticide designed to control adult flies (e.g. house flies, *Musca domestica,* and stable flies, *Stomoxys calcitrans*). It is designed for indoor use in stables and barns. The applications applied for are:

i) painting onto cardboard sheets, that were fixed in different places in the stable/barn with a total surface of 1.8 m^2 treated area on cardboards in a stable/barn of 200 m^2 ground floor,
ii) spraying of the diluted b.p. (1:2 with water) onto cardboard sheets, that were fixed in different places in the stable/barn with an overall treated size of max. 10% of the stable size in a stable/barn of 200 m^2 ground floor.

The submitted efficacy studies do only support a claim against “adult flies (*Musca domestica*, *Stomoxys calcitrans*) for indoor use in stables and barns applied by spraying of the diluted product “Stallfliegenmittel Alba” on cardboard sheets”.

3.5.3 Effects on target organisms, including unacceptable suffering

Clothianidin has a systemic insecticidal (killing) effect by contact and ingestion on the target organisms. Muscalure (cis-Tricos-9-ene; $C_{23}H_{46}$) is the major component of the housefly aggregation pheromone. Although some questions as to the exact role and biochemistry of the pheromone still remain to be answered, the wealth of studies performed until now, unambiguously demonstrate the strong attractive activity of the pheromone on flies of both sexes and the strong increase of the efficacy of housefly traps when the pheromone is used as an attractant. The subject has been reviewed several times. For a recent review, the reader is referred to the thesis of [redacted] (2001; Doc. IV-A5.1.1) and to the review [redacted] (2008) documented in Doc. IV-A5.1.28. The applicant provided reference to literature indicating that to date parasitoid bycatches have not been thoroughly investigated. The application of traps baited with (Z)-9-tricosene may lead to a decreased use of insecticides which may in turn promotes parasitoids and predators of *M. domestica* (see A5.1.9. – TNO R8415_translation.DOC).

3.5.4 Mode of action, including time delay

Clothianidin belongs to the chemical class of insecticides known as neonicotinoids or chloronicotinyls, which interfere with the nicotinic acetylcholine receptors at the postsynaptic membrane. The compound acts agonistically on insect nicotinic acetylcholine receptors located in the central nervous system. Clothianidin has an insecticidal effect by contact and ingestion (systemic insecticide).

Muscalure is produced by female housefly as component of the wax layer on the cuticle, together with a series of related compounds. In the laboratory, this mixture brings the sexes together (aggregation) and stimulates the male housefly into mating. The influence of Muscalure on male-housefly behaviour is such that, notwithstanding its low volatility and vapour pressure, it can be put to good use in housefly control ([redacted] 2001; Doc. IV-A5.1.1; [redacted] 2008; Doc. IV-A5.1.28).

3.5.5 Efficacy data

In all submitted efficacy studies a product called “Stallfliegenmittel Alba” containing 26.0 g/L Clothianidin and 0.5 g/L (Z)-9-Tricosene), which corresponds to 2.3% Clothianidin and 0.05% Muscalure, was used. The slightly lower Clothianidin content in the test product (2.3% instead of 2.4%) is acceptable, as it does not influence the efficacy evaluation. If the efficacy is proven with the test product in the lower concentration, a slightly higher concentrated product is even more effective.

Table 19

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

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
PT18	Indoor use in stables and barns	Stallfliegenmittel Alba (26.0 g/L Clothianidin, 0.5 g/L (Z)-9-Tricosene)	*Musca domestica* adults, *Stomoxys calcitrans* adults	Simulated-use test with different application methods and dosages: 1. Painted on cardboard sheets 2. Diluted product (1:2) sprayed on	20 m^3 test chamber, 100 flies per replicate Food: 2 plastic beakers containing a sponge soaked with 10% sugar solution Dosage: Paint application: equivalent to 1.8 m^2 treated surface per 200 m^2 ground floor area as claimed on the label, 100% dosage and 50% dosage were tested	Application method: Results for all observed time points Knock-down after 8 h / Mortality after 24 h 100% dosage painting: *M. domestica* 86 - 99% / *M. domestica* 94 - 100%; *S. calcitrans* 96 – 100% / *S. calcitrans* 99 – 100% 50% dosage painting: *M. domestica* 82 - 96% / *M. domestica* 93 - 100%; *S. calcitrans* 88 – 100% / *S. calcitrans* 96 – 100% 100% dosage spraying: *M. domestica* 81 - 96% / *M. domestica* 96 - 100%; *S. calcitrans* 92 – 100% / *S. calcitrans* 92 – 100% 50% dosage spraying: *M. domestica* 80 - 97% / *M. domestica* 93 - 100%	[redacted] 2016 A comparison of efficacy of Stallfliegen-mittel Alba (SPU-02740-I-O-PA) (26.0 g/L Clothianidin, 0.5 g/L (Z)-9-Tricosene)

				cardboard sheets	Spray application: 0.75 m^2 treated surface/7.5 m^2, equivalent to 10% of the treated area as claimed on the label, 100% and 50% dosage of the 1:2 diluted b.p. were tested Exposure time: 24 h at different time points: 1 day, 2, 4, 6, 8, 12, 24 weeks after application 4 replicates for each species, each application method, each time point and 4 control replicates for each species, each application method, each time point	<table><tr><td></td><td>*S. calcitrans* 86 – 100%</td><td>*S. calcitrans* 99 – 100%</td></tr></table> Consistently above 80% knockdown and 90% mortality 24 h after insect exposure. Valid study for proving mortality and knock-down activity according to the TNsG 2012.	vs. Interfly-Tox against House flies, *Musca domestica*, and Stable flies, *Stomoxys calcitrans*; Study No. Mo5338, Report No. BIO022c-16
PT18	Indoor use in stables and barns	Stallfliegenmittel Alba (26.0 g/L Clothianidin, 0.5 g/L (Z)-9-Tricosene); fresh and 2 year-old	*Musca domestica adults*, *Stomoxys calcitrans* adults	Simulated-use test with different application methods and dosages: 1) Painted on cardboard sheets 2) Diluted product (1:2) sprayed on cardboard sheets	20 m^3 test chamber, 100 flies of each species per replicate Food: 2 plastic beakers containing a sponge soaked with 10% sugar solution Dosage: Paint application: equivalent to 1.8 m^2 treated surface per 200 m^2 ground floor area as claimed on the	<table><tr><td>Application method</td><td>Knock-down after 8 h</td><td>Mortality after 24 h</td></tr><tr><td>Painting Fresh product</td><td>*M. domestica* 94 - 100% *S. calcitrans* 96 – 100%</td><td>*M. domestica* 97 - 100% *S. calcitrans* 94 – 100%</td></tr><tr><td>Painting 2 years old product</td><td>*M. domestica* 93 - 98% *S. calcitrans* 78 – 100%</td><td>*M. domestica* 98 - 100% *S. calcitrans* 92 – 100%</td></tr><tr><td>Spraying Fresh product</td><td>*M. domestica* 91 - 98% *S. calcitrans* 71 – 99%</td><td>*M. domestica* 99 - 100% *S. calcitrans* 95 – 100%</td></tr><tr><td>Spraying</td><td>*M. domestica* 91 - 98%</td><td>*M. domestica* 90 - 100%</td></tr></table>	[redacted] 2018 Efficacy of Stallfliegen-mittel Alba (26.0 g/L Clothianidin, 0.5 g/L (Z)-9-Tricosene) against House flies, *Musca domestica*,

<table>
<tr>
<td></td><td></td><td></td><td></td><td></td>
<td>label, 100% dosage tested
Spray application: 0.75 m² treated surface/7.5 m², equivalent to 10% of the treated area as claimed on the label, 100% dosage of the 1:2 diluted b.p. tested

Exposure time: 24 h
1 day, after application fresh product and 2 years old product

4 replicates for each species, each application method, each time point and 4 control replicates for each species, each application method, each time point</td>
<td>
<table>
<tr><td>2 years old product</td><td>S. calcitrans 89 – 99%</td><td>S. calcitrans 96 – 100%</td></tr>
</table>
Consistently on average above 80% knockdown and consistently above 90% mortality 24 h after insect exposure.
No differences between fresh and 2 year-old products.

Valid study for proving mortality and knock-down activity according to the TNsG 2012.
</td>
<td>and Stable flies, Stomoxys calcitrans tested in 20 m³ chambers; Study No. Mo6118</td>
</tr>
<tr>
<td>PT18</td><td>Indoor use in stables and barns</td><td>Stallfliegenmittel Alba (26.0 g/L Clothianidin, 0.5 g/L (Z)-9-Tricosene)</td><td>Musca domestica, Musca autumnalis</td><td>Field trial in a cowshed, Schleswig Holstein, Germany, 2.8.2006 – 9.10.2006
Painting application</td>
<td>Dose: 500 ml/200 m²
Product painted on the cap inside of wasp traps, equivalent to 1.8 m² treated surface per 200 m² ground floor area as claimed on the label
4 traps hanged randomized in the same cowshed with naturally infestation of flies</td>
<td>Collection of dead flies in wasp traps
<table>
<tr><th rowspan="2">Days after application</th><th colspan="2">Mean no. dead flies</th></tr>
<tr><th>Stallfliegenmittel Alba</th><th>Control</th></tr>
<tr><td>4d</td><td>306</td><td>0</td></tr>
<tr><td>7d</td><td>182</td><td>0</td></tr>
<tr><td>13d</td><td>432</td><td>0</td></tr>
<tr><td>18d</td><td>196</td><td>0</td></tr>
<tr><td>24d</td><td>192</td><td>0</td></tr>
<tr><td>31d</td><td>134</td><td>0</td></tr>
<tr><td>38d</td><td>42</td><td>0</td></tr>
</table>
</td>
<td>[redacted] 2009a, Evaluation of the long term effect of Stallfliegen-mittel Alba new against stable fly (Musca autumnalis) (Stallfliege)</td>
</tr>
</table>

<table>
<tr>
<td></td><td></td><td></td><td></td><td></td><td>Exposure time:
4, 7, 13, 18, 24, 31, 38, 48, 66 days after application</td>
<td>
<table>
<tr><td>48d</td><td>80</td><td>0</td></tr>
<tr><td>66d</td><td>132</td><td>0</td></tr>
</table>
Invalid study for proving efficacy according to the TNsG 2012:
Population size before application has not been observed. Therefore, no statement regarding the population reduction can be made.
Fly species were not identified. Therefore, no statement regarding the efficacy against specific fly species can be made.
</td>
<td>(MUSCAU) and house fly (Musca domestica) (MUSCDO) "Painting application", Study No. I06PUX037-2</td>
</tr>
<tr>
<td>PT18</td><td>Indoor use in stables and barns</td><td>Stallfliegenmittel Alba (26.0 g/L Clothianidin, 0.5 g/L (Z)-9-Tricosene)</td><td>Musca domestica, Musca autumnalis</td><td>Field trial in a cowshed, Schleswig Holstein, Germany, 10.7.2006 – 9.10.2006 Painting application</td><td>Dose: 500 ml/200 m^2
Product painted on the cap inside of wasp traps, equivalent to 1.8 m^2 treated surface per 200 m² ground floor area as claimed on the label
3 traps hanged randomized in the same cowshed with naturally infestation of flies

Observation interval:
7, 13,15,22, 27,30,36,41,47, 54, 61, 71, 89 days after application</td>
<td>Collection of dead flies in wasp traps within a cowshed
<table>
<tr><td rowspan="2">Days after application</td><td colspan="2">Mean no. dead flies</td></tr>
<tr><td>Stallfliegenmittel Alba</td><td>Control</td></tr>
<tr><td>7d</td><td>117</td><td>0</td></tr>
<tr><td>13d</td><td>361</td><td>0</td></tr>
<tr><td>15d</td><td>166</td><td>0</td></tr>
<tr><td>22d</td><td>400</td><td>0</td></tr>
<tr><td>27d</td><td>452</td><td>0</td></tr>
<tr><td>30d</td><td>212</td><td>0</td></tr>
<tr><td>36d</td><td>584</td><td>0</td></tr>
<tr><td>41d</td><td>340</td><td>0</td></tr>
<tr><td>47d</td><td>315</td><td>0</td></tr>
<tr><td>54d</td><td>208</td><td>0</td></tr>
<tr><td>61d</td><td>34</td><td>0</td></tr>
<tr><td>71d</td><td>43</td><td>0</td></tr>
<tr><td>89d</td><td>116</td><td>0</td></tr>
</table>
Invalid study for proving efficacy according to the TNsG 2012:
Population size before application has not been observed. Therefore, no statement regarding the population reduction can be made.
</td>
<td>[redacted] 2009b, Evaluation of the long term effect of Stallfliegen-mittel Alba new against stable fly (Musca autumnalis) (Stallfliege) (MUSCAU) and house fly (Musca domestica) (MUSCDO) "Painting application", Study No. I06PUX019</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Fly species were not identified. Therefore, no statement regarding the efficacy against specific fly species can be made.</td><td></td></tr>
<tr><td>PT18</td><td>Indoor use in stables and barns</td><td>Stallfliegenmittel Alba (26.0 g/L Clothianidin, 0.5 g/L (Z)-9-Tricosene)</td><td>Musca domestica, Musca autumnalis</td><td>Field trial in a cowshed, Schleswig Holstein, Germany, 7.8.2007 – 25.9.2007
Painting application</td><td>Dose: 500 ml/200 m^2
Product painted on the cap inside of wasp traps, equivalent to 1.8 m^2 treated surface per 200 m² ground floor area as claimed on the label
4 traps hanged randomized in the same cowshed with naturally infestation of flies

Exposure time: 5,8,19,36,47 days after application</td><td>Collection of dead flies in wasp traps within a cowshed
<table><tr><td rowspan="2">Days after application</td><td colspan="2">Mean no. dead flies</td></tr><tr><td>Stallfliegenmittel Alba</td><td>Control</td></tr><tr><td>5</td><td>264</td><td>0</td></tr><tr><td>8</td><td>35</td><td>0</td></tr><tr><td>19</td><td>535</td><td>0</td></tr><tr><td>36</td><td>520</td><td>0</td></tr><tr><td>47</td><td>189</td><td>0</td></tr></table>
Invalid study for proving efficacy according to the TNsG 2012:
Population size before application has not been observed. Therefore, no statement regarding the population reduction can be made.
Fly species were not identified. Therefore, no statement regarding the efficacy against specific fly species can be made.</td><td>[redacted] 2009c, Evaluation of the long term effect of Stallfliegen-mittel Alba new against stable fly (Musca autumnalis) (Stallfliege) (MUSCAU) and house fly (Musca domestica) (MUSCDO) "Painting application", Study No. I07PUX50</td></tr>
<tr><td>PT18</td><td>Indoor use in stables and barns</td><td>Stallfliegenmittel Alba (26.0 g/L Clothianidin, 0.5 g/L (Z)-9-Tricosene)</td><td>Musca domestica, Musca autumnalis, Stomoxys calcitrans</td><td>Field trial in a calf stable, Schleswig Holstein Germany, Two application methods: Painting on cardboards Spraying on cardboards</td><td>4 replicates
Dose:
Painting application
500 ml/200 m^2 or 250 ml/200 m^2 product painted on cardboards, equivalent to 1.8 m^2 treated surface per 200 m² ground floor area as claimed on the label
Spraying application</td><td>100% dose - Number of reduced flies/m^3 compared to the untreated control in the same stable
<table><tr><td>Weeks after application</td><td>Painting</td><td>Spraying</td></tr><tr><td>1</td><td>107</td><td>92</td></tr><tr><td>2</td><td>215</td><td>129</td></tr><tr><td>3</td><td>385</td><td>180</td></tr><tr><td>4</td><td>538</td><td>215</td></tr><tr><td>5</td><td>566</td><td>219</td></tr><tr><td>6</td><td>582</td><td>222</td></tr><tr><td>7</td><td>628</td><td>229</td></tr></table></td><td>[redacted] 2016, Evaluation of the efficacy of Stallfliegen-mittel Alba with different application rates against</td></tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>18.06.2015 – 02.10.2015</td>
<td>product 1:2 dissolved in water at a rate of 500 mL/200 m² or 250 ml/200 m² stable ground floor, equivalent to 10% treated surface per 200 m² ground floor area as claimed on the label
Trial with treated cardboards on sticky traps and untreated traps as control in the same stable. Traps are for collecting dead flies for counting.</td>
<td>
<table>
<tr><td>8</td><td>635</td><td>229</td></tr>
<tr><td>9</td><td>641</td><td>229</td></tr>
<tr><td>10</td><td>696</td><td>142</td></tr>
<tr><td>11</td><td>746</td><td>146</td></tr>
<tr><td>12</td><td>787</td><td>256</td></tr>
<tr><td>13</td><td>822</td><td>256</td></tr>
<tr><td>14</td><td>841</td><td>264</td></tr>
<tr><td>15</td><td>868</td><td>270</td></tr>
<tr><td>16</td><td>107</td><td>107</td></tr>
</table>

50% dose, Number of reduced flies/m³ compared to the untreated control in the same stable

<table>
<tr><td>Weeks after application</td><td>Painting</td><td>Spraying</td></tr>
<tr><td>1</td><td>101</td><td>61</td></tr>
<tr><td>2</td><td>201</td><td>89</td></tr>
<tr><td>3</td><td>318</td><td>113</td></tr>
<tr><td>4</td><td>420</td><td>130</td></tr>
<tr><td>5</td><td>431</td><td>132</td></tr>
<tr><td>6</td><td>437</td><td>133</td></tr>
<tr><td>7</td><td>455</td><td>137</td></tr>
<tr><td>8</td><td>457</td><td>136</td></tr>
<tr><td>9</td><td>460</td><td>137</td></tr>
<tr><td>10</td><td>484</td><td>213</td></tr>
<tr><td>11</td><td>510</td><td>217</td></tr>
<tr><td>12</td><td>533</td><td>152</td></tr>
<tr><td>13</td><td>547</td><td>150</td></tr>
<tr><td>14</td><td>554</td><td>157</td></tr>
<tr><td>15</td><td>562</td><td>152</td></tr>
<tr><td>16</td><td>101</td><td>101</td></tr>
</table>

Invalid study for proving efficacy according to the TNsG 2012:
Population size before application has not been observed. Therefore, no statement regarding the population reduction can be made.
</td>
<td>autumn fly (Musca autumnalis), house fly (Musca domestica) and biting house fly (Stomoxys calcitrans) “Painting and spraying application"; Study No. I15PUX01</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td>Fly species were not identified. Therefore, no statement regarding the efficacy against specific fly species can be made.
Based on the study, only a comparison of the efficacy of the two application methods and the two doses can be made at each time point.</td><td></td></tr>
<tr><td>PT18</td><td>Indoor use in stables and barns</td><td>Stallfliegenmittel Alba (26.0 g/L Clothianidin, 0.5 g/L (Z)-9-Tricosene)</td><td>Musca domestica</td><td>Field trial,
Nine test sizes within six farms in South Wales, UK
25.8.2010 – 20.10.2010
Painting application onto cardboards</td><td>Dose:
Painting undissolved product equivalent to 1.8 m^2 treated surface per 200 m² ground floor area as claimed on the label
3 replicates for each treatment and control</td><td>Present number of visible houseflies at 20 “landmarks” (1 m^2)/replicate was assessed for 1 minute
<table>
<tr><th rowspan="2">weeks after application</th><th colspan="2">Population reduction %</th></tr>
<tr><th>Stallfliegenmittel Alba</th><th>Control</th></tr>
<tr><td>1</td><td>53 ± 13</td><td>24 ± 20</td></tr>
<tr><td>2</td><td>70 ± 8</td><td>26 ± 16</td></tr>
<tr><td>3</td><td>69 ± 10</td><td>27 ± 34</td></tr>
<tr><td>4</td><td>78 ± 9</td><td>14 ± 29</td></tr>
<tr><td>5</td><td>69 ± 7</td><td>43 ± 28</td></tr>
<tr><td>6</td><td>79 ± 12</td><td>48 ± 17</td></tr>
<tr><td>7</td><td>90 ± 4</td><td>49 ± 30</td></tr>
</table>
Until 6 weeks after application the required population reduction of 80% has not been observed. The field trials were started at the end of summer and ran until autumn. A natural population decline was observed with 43%, 48%, and 49% population decrease in the control stables in the last 3 weeks of the trial. Thus, 5 – 7 weeks after application the population decrease in the treated stables could be caused by natural population decline.

The efficacy against flies in stables is not sufficiently proven for painting application.</td><td>[redacted] 2010, Field trial to determine the efficacy of products against houseflies, Musca domestica, Study code: 10/77</td></tr>
</table>

<table>
<tr>
<td>PT18</td>
<td>Indoor use in stables and barns</td>
<td>Stallfliegenmittel Alba (26.0 g/L Clothianidin, 0.5 g/L (Z)-9-Tricosene)</td>
<td>Musca domestica, Stomoxys calcitrans</td>
<td>Field trial in livestock and equine holdings, Spain, 12.7.2018 – 9.10.2018
Two application methods:
Painting onto cardboards
Spraying onto cardboards</td>
<td>Dose:
Painting undissolved product equivalent to 1.8 m² treated surface per 200 m² ground floor area as claimed on the label
Spraying product 1:2 dissolved in water at a rate of 500 mL/200 m² stable ground floor

Observation interval:
2, 4, 7, 14, 21, 30, 45, 60, 75 and 84 days post initial treatment application.

3 replicates for each application method and control

Population size determined by 10 monitoring traps in each test site</td>
<td>Stomoxys calcitrans % population reduction from pre-treatment values, bold: reduction values > 80%
<table>
<tr><th>Days after application</th><th>Painting</th><th>Spraying</th><th>Control</th></tr>
<tr><td>2 d</td><td>Site 1:: 18.8%
Site 2: 36.1%
Site 3: 35.1%</td><td>Site 4: 20.5%
Site 5: -49.7%
Site 6: 70.3%</td><td>-40±18.6%</td></tr>
<tr><td>4 d</td><td>Site 1: 41.7%
Site 2: 50.0%
Site 3: 49.5%</td><td>Site 4: 11.1%
Site 5: -106.8%
Site 6: 10.8%</td><td>-30.8±12.6%</td></tr>
<tr><td>7 d</td><td>Site 1: 65.3%
Site 2: 40.0%
Site 3: 13.5%</td><td>Site 4: -5.3%
Site 5: -112.2%
Site 6: 64.0%</td><td>-97.5±91.4%</td></tr>
<tr><td>14 d</td><td>Site 1: 80.7%
Site 2: 66.1%
Site 3: 73.0%</td><td>Site 4: 55.4%
Site 5: 49.9%
Site 6: 88.8%</td><td>13.2±8.7%</td></tr>
<tr><td>21 d</td><td>Site 1: 79.2%
Site 2: 63.0%
Site 3: 70.0%</td><td>Site 4: 59.9%
Site 5: 75.5%
Site 6: 85.3%</td><td>19.4±13.1%</td></tr>
<tr><td>30 d</td><td>Site 1: 92.1%
Site 2: 79.0%
Site 3: 45.9%</td><td>Site 4: 92.2%
Site 5: 87.3%
Site 6: 85.0%</td><td>23.1±9.1%</td></tr>
<tr><td>45 d</td><td>Site 1: 80.6%</td><td>Site 4: 80.1%</td><td>15.7±9.9%</td></tr>
</table>
</td>
<td>[redacted] 2018, Field trial to determine the efficacy of products against houseflies, Musca domestica and stable flies, Stomoxys calcitrans, Study code 18/128</td>
</tr>
</table>

							Site 2: 86.7% Site 3: 75.4%	**Site 5: 80.2%** **Site 6: 89.8%**	
						60 d	**Site 1: 85.0%** Site 2: 45.6% Site 3: 39.1%	Site 4: 78.4% Site 5: 56.5% **Site 6: 80.9%**	16.2±6.2%
						75 d	**Site 1: 81.3%** **Site 2: 81.0%** Site 3: 7.3%	Site 4: 67.3% Site 5: 62.3% **Site 6: 85.3%**	49.6±14.2%
						84 d	**Site 1: 88.5%** Site 2: 52.6% Site 3: 33.8%	Site 4: 75.4% **Site 5: 90.9%** **Site 6: 84.5%**	**88±1.9%**

Musca domestica % population reduction from pre-treatment values, bold: reduction values > 80%

Days after application	Painting	Spraying	Control
2 d	Site 1: 40.9% Site 2: 4.1% Site 3: 25.1%	Site 4: 21.8% Site 5: 27.5% Site 6: 56.3%	-2.3±25.9%
4 d	Site 1: 47.0% Site 2: 21.1% Site 3: 76.0%	Site 4: 63.7% Site 5: 70.2% Site 6: 8.6%	-3.4±10.4%
7 d	Site 1: 72% Site 2: 8.0%	Site 4: 17.8%	6.3±34.4%

							Site 3: 33.3%	Site 5: 55.5% Site 6: -24.4%		
						14 d	Site 1: 72.6% Site 2: 41.8% Site 3: 61.0%	**Site 4: 88.7%** Site 5: 73.3% Site 6: -42.7%	37.3±5.9%	
						21 d	Site 1: 76.8% Site 2: 9.8% **Site 3: 80.2%**	**Site 4: 87.8%** Site 5: 75.0% Site 6: -182.8%	3.7±9.5%	
						30 d	**Site 1: 82.2%** Site 2: 41.6% Site 3: 26.8%	**Site 4: 87.1%** **Site 5: 90.2%** Site 6: -51.2%	30±22.1%	
						45 d	**Site 1: 84.1%** Site 2: 29.0% Site 3: 63.9%	Site 4: 75.1% **Site 5: 85.5%** Site 6: -106.4%	13.5 ±13.8%	
						60 d	Site 1: 78.8% Site 2: 2.9% Site 3: 42.4%	**Site 4: 84.0%** **Site 5: 81.3%** Site 6: -59.2%	13.2±8.9%	
						75 d	**Site 1: 90.2%** Site 2: 33.2% Site 3: 52.2%	Site 4: 69.9% **Site 5: 87.4%** Site 6: -44.7%	22.9 ±16.6%	
						84 d	**Site 1: 83.8%**	**Site 4: 87.8%**	71.1 ±12%	

	Site 2: 20.9% Site 3: 65.0%	**Site 5: 94.5%** Site 6: - 74.6%	

Painting application:
For both fly species the required population reduction of > 80% has not been shown in all 3 replicates during the entire observation period. Therefore, the efficacy against flies in stables is not sufficiently proven.

Spraying application:
For *S. calcitrans,* 30 days and 45 days after application a population reduction > 80% was observed.
For *M. domestica,* 30 days after application a population reduction > 80% was observed in two of three observed stables. In one stable (site 6), a population increase was observed from the first week after product application until the end of the trial. This population increase (24% - 183%) was greater than the population variation of *M. domestica* in the untreated control stables within 6 weeks after initial product application. In the control stables, there was a maximum population increase of 52.9% and a maximum population reduction of 55.3%. In the same stable (site 6), the population reduction for *S. calcitrans* was ≥80% from the second week after treatment on. Despite good hygiene measures in this stable, there must have been a reinvasion of house flies from outside the treated barn. We consider this study to be valid to prove the efficacy of the product, because the required population reduction was observed in two stables (two replicates). Based on the decision on another biocidal product, a reinvasion of target organisms in a field trial is possible and

						cannot be considered as a failure of the biocidal product application. Therefore, the efficacy against flies in stables is sufficiently proven.	

The requirements for “products intended for use as general surface treatment, space treatment or vaporisers in stables and waste dumps” (TNsG, 2012) are i) a laboratory test showing mortality and/or knockdown and/or residual efficacy, depending on the claim, and ii) a field trial according to the directions for use.

The simulated-use studies by [redacted] (2016, 2018) are sufficient to show a > 80% level of knockdown efficacy and > 90% mortality after 24 hours (in accordance with the TNsG, 2012; chapter: 13.3.1) for the fresh as well as a 2 years old product applied by painting and spraying.

The field trials by [redacted] 2009 a, b, c, 2016 and [redacted] 2010 were not sufficient to prove the efficacy of the product application in stables. The submitted field trials could not prove the efficacy due to the following reasons:

i. In the field trials by [redacted] (2009 a, b, c, 2016) the population size before application has not been observed. Therefore, no statement regarding the population reduction can be made.
ii. In the field trials by [redacted] (2009 a, b, c, 2016) the species of dead observed flies were not determined. Thus, it is not possible to specify which fly species were fought with the product.
iii. For adulticide products against flies in stables a minimum population reduction of 80% was agreed for field trials in the e-consultation from 04.01.2016 (participating states: UK, NL, DK, FR, BE and DE) as criterion for proof of efficacy. The required population reduction of at least 80% was not achieved in the submitted field trials.
iv. The field trial by [redacted] (2010) were started at the end of summer (25.08.2010) and ran until autumn (20.20.2010). It is stated in the TNsG (2012) “*Tests are done preferably during spring and beginning of summer. At the end of summer and autumn population decline might be due to natural causes instead of the insecticide treatment*”. A natural population decline was observed with 43%, 48%, and 49% population decrease in the control stables in the last 3 weeks of the trial. Thus, the population decrease in the treated stables could be caused by natural population decline.

The field trial by [redacted] (2018) is sufficient to show a > 80% population reduction until 30 days after initial product application by spraying for both observed fly species (*M. domestica, S. calcitrans*). For painting application, the required population reduction was not proven. The trial was started at the end of summer (12.7.2018) and ran until autumn (09.10.2018). It is stated in the TNsG (2012) “*Tests are done preferably during spring and beginning of summer. At the end of summer and autumn population decline might be due to natural causes instead of the insecticide treatment*”. In the field trial by [redacted] (2018), the population declined in the control stables by 71% and 88% at the end of the trial. Thus, the population decrease in the treated stables could have been caused by natural population decline and only data until 45 days after initial application can be used to prove the product efficacy.

The efficacy of the product “Stallfliegenmittel Alba” applied by painting on cardboards is not proven, because of insufficient efficacy against stable and houseflies in a field trial ([redacted] 2018).

The efficacy of the product “Stallfliegenmittel Alba” for use against adult flies in stables 30 days after initial application by spraying on cardboards is proven by simulated-use tests ([redacted] 2016 & 2018)

and a field trial ([redacted] 2018). In accordance with the TNsG (2012, chapter 13.2.1) for a general claim against flies in livestock facilities and animal housings both the housefly (*Musca domestica*) and the stable fly (*Stomoxys calcitrans*) should be tested. As the efficacy was proven against *Musca domestica* and *Stomoxys calcitrans* a general claim against "flies" can be authorised.
Furthermore, the efficacy of the 2 years old product is proven by simulated-use test ([redacted] 2018).

3.5.6 Occurrence of resistance and resistance management

Resistance and cross-resistance against neonicotinoids (including clothianidin), a group of insecticides acting agonistically on insect nicotinic acetylcholine receptors (nAChRs), can occur in relevant susceptible pests in Europe. 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.
"Stallfliegenmittel Alba" 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 Muscalure is highly unlikely considering that Muscalure 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 and the bait has been taken up, the development of resistance should be suspected.
The following general resistance management measures are proposed:

- A change to another product with an active substance with a different mode of action is then recommended.
- In order to avoid the occurrence of resistance to any active ingredient, products with different modes of action should be used in alternation and the frequent repeated use of the same active substance should be avoided.
- It is recommendable to complement the treatment in livestock facilities with a larvicide product.
- The use of biocidal products 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, where this is commercially viable) within an integrated fly control program.
- Fly infestation in the 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 Evaluation of the label claims

“Stallfliegenmittel Alba” is a bait insecticide against adult flies (*Musca domestica*, *Stomoxys calcitrans*). It is intended to be used for the treatment of fly populations in stables and barns.

Spraying application on cardboards:
The efficacy of the product “Stallfliegenmittel Alba” is sufficiently proven against adult house flies and stable flies until 30 days after initial application by spraying on cardboards. Furthermore the efficacy of the 2 years old product is proven.

Painting application on cardboards:
The efficacy of the product “Stallfliegenmittel Alba” applied by painting on cardboards was not demonstrated, because of insufficient efficacy against stable and housefly populations in the field.

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

Not known.

3.5.10 Data waiving and conclusion

Table 20

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

Table 21

Conclusion on the efficacy
The efficacy of the product “Stallfliegenmittel Alba” (containing 2.4% Clothianidin and 0.05% Muscalure) against house flies (*Musca domestica*) and stable flies (*Stomoxys calcitrans*) was demonstrated for the spraying application on cardboards until 30 days after initial application. The efficacy of the 2 years old product was demonstrated.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 22

Clothianidin	Value	Study	Safety factor
AEL long-term	0.1 mg/kg bw/d	2-yr rat, supported by 2-gen. rat	100
AEL medium-term	0.2 mg/kg bw/d	90-d dog, supported by 90-d rat and embryotoxicity	100 / > 90 % [2]
AEL acute	0.25 mg/kg bw	Pharmacology study, mouse	100

[1] AEL: Systemic (= Internal) Acceptable Exposure Level
[2] Oral absorption

Table 23

Clothianidin	Value	Reference
Oral absorption	Rapid oral absorption > 90 %	Assessment Report Report (RMS DE (2014))

Table 24

Cis-Tricos-9-ene (Muscalure)	Value	Study
AEL long-term	> 0.024 mg/kg bw/d	Assessment Report Report (RMS AT (2012))
AEL medium-term	> 0.024 mg/kg bw/d	Assessment Report Report (RMS AT (2012))
AEL acute	> 0.57 mg/kg bw/d	Assessment Report Report (RMS AT (2012))

Table 25

Cis-Tricos-9-ene (Muscalure)	Value	Reference
Inhalative absorption	100 %	Default value / Assessment Report Report (RMS AT (2012))
Oral absorption	100 %	Default value / Assessment Report Report (RMS AT (2012))

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

An animal study on dermal irritation (OECD 404) with the product is provided.

Table 26

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle(s), Dose levels, Duration(s) of exposure**	**Results** *Average score (from findings at 24, 48 & 72h), observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 404, GLP: yes, Reliability: 1	Rabbit (Himalayan), 3 males	Alba (SPU-02740-I): 0.5 mL/patch and animal, 4 h	Average score per animal (24/48/72 h) Erythema: 0/0/0 Oedema: 0/0/0 Non-irritant	For the initial test in one animal, the test site was not examined immediately after the patch removal, however, this does not affect the outcome of the study	[redacted]

Table 27

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Average score (24, 48, 72 h): Erythema: 0/0/0, Oedema: 0/0/0. Stallfliegenmittel Alba (SPU-02740-I) is not irritating to the rabbits' skin.
Justification for the value/conclusion	Based on the results of the GLP-study on rabbits (OECD 404), Stallfliegenmittel Alba (SPU-02740-I) is non-irritating to the skin.
Classification of the product according to CLP	None

3.6.2.2 Eye irritation

An animal study on eye irritation (OECD 405) with the product is provided.

Table 28

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 405, GLP: yes, Reliability: 2	Rabbit (Himalayan), 3 males	Alba (SPU-02740-I): 0.1 mL/eye Exposure: 24 h	Average score per animal 24/48/72 h Cornea: 0/0/0 Iris: 0/0/0 Conjunctiva redness: 0.3/0.67/0.67 Conjunctiva chemosis: 0/0/0 Reversible, Non-irritant	24 hours after administra-tion the eyes were rinsed with 20 mL aqueous NaCl solution. Although no justification is provided in the study report this is not assumed to affect the outcome of the study.	[redacted]

Table 29

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Average score per animal 24/48/72 h: Cornea: 0/0/0, Iris: 0/0/0, Conjunctiva redness: 0.3/0.67/0.67, Conjunctiva chemosis: 0/0/0 Stallfliegenmittel Alba (SPU-02740-I) is not irritating to the rabbits' eye.
Justification for the value/conclusion	Based on the results of the GLP-study on rabbits (OECD 405), Stallfliegenmittel Alba (SPU-02740-I) is non-irritating to the eye.
Classification of the product according to CLP	None

3.6.2.3 Respiratory tract irritation

Table 30

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, “other endpoints”
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008. The biocidal product does not contain components classified for respiratory irritation in relevant concentrations.

Table 31

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract
Justification for the value/conclusion	Neither the active substances nor the other components are classified for respiratory irritation. Based on the information on the components and/or its classification the biocidal product is considered not irritating to the respiratory tract.
Classification of the product according to CLP	None

3.6.2.4 Skin sensitisation

No study on skin sensitisation with the product is submitted. Thus, classification and labelling is based on information on active substances and other ingredients.

Table 32

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.3 “Skin sensitisation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, 2018), “testing on the biocidal product does not need to be conducted if there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available through safety data sheets and other information for each of the individual components in the product. Information on synergistic effects is not available.

Table 33

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Skin sensitising
Justification for the value/conclusion	The active substance cis-tricos-9-ene of the biocidal product is classified for skin sensitisation according to Regulation (EC) No 1272/2008. However, its concentration is below the limit for classification: Cis-tricos-9-ene (CAS No 27519-02-4, C = 0.05 % (w/w)): Skin Sens. 1B [1)] (GCL H317: C ≥ 1 %; EUH208: C > 0.1 %) [2)] The biocidal product contains one co-formulant classified for skin sensitisation according to Regulation (EC) No 1272/2008. Its concentration triggers classification: 1,2-Benzisothiazol-3(2H)-one (CAS No 2634-33-5, C = 0.2 % (w/w)): Skin Sens. 1 [1)] (SCL H317: C ≥ 0.05 %; EUH208: C > 0.005 %) [1)]
Classification of the product according to CLP	Skin Sens 1, H317

[1)] According to Annex VI of Regulation (EC) No 1272/2008, note that for 1,2-Benzisothiazol-3(2H)-one a RAC opinion from November 2021 is available with (among others) a classification as Skin Sens. 1A, H317 and with a slightly lower SCL of 0.036 %
[2)] According to Regulation (EC) No 1272/2008

3.6.2.5 Respiratory sensitisation (ADS)

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	Data on respiratory sensitisation for the biocidal product or its component are not available.

Table 35

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Respiratory sensitisation is not expected from available data.
Justification for the value/conclusion	Data on respiratory sensitisation for the biocidal product or its components are not available.
Classification of the product according to CLP	None

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

An animal study on acute oral toxicity (OECD 423, ATC-method) with the product is provided.

Table 36

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels, Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 423, GLP yes, Reliability 1	Rat, Crl: CD(SD), females, 6 per group	Test substance SPU-02740-I, 2000 mg/kg bw, single administration (limit test, oral: gavage)	Rats did not reveal any signs of toxicity, all animals gained the expected body weight, no mortality, no pathological findings were noted at necropsy.	> 2000 mg/kg bw	None	[redacted]

Table 37

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} (female rats) > 2000 mg/kg bw
Justification for the selected value	Under the present test conditions, a single oral administration of 2000 mg SPU-02740-I /kg bw to rats did not reveal any signs of toxicity. No mortality occurred. Based on the results of the GLP-study on rats (OECD 423), Stallfliegenmittel Alba (SPU-02740-I) is not classified for acute oral toxicity.
Classification of the product according to CLP	None

3.6.2.6.2 Acute toxicity by inhalation

No study on acute toxicity by inhalation with the product is submitted. Thus, classification and labelling is based on information on active substances and other ingredients.

Table 38

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	Studies on acute inhalation toxicity of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.5 “Acute toxicity” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.2, Nov. 2018), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008, and synergistic effects between any of the components are not expected.” For the biocidal product the composition is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the products. There is no information on synergistic effects between any of the components. Consequently, classification of the biocidal product can be made according to the calculation rules laid down in Regulation (EC) No 1272/2008 and testing of the biocidal product is not required.

Table 39

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on the inhalation LC_{50} available for the single components the inhalation LC_{50} of the biocidal product is estimated as > 5 mg/L. Note that based on the RAC opinion from November 2021, 1,2-benzisothiazol-3(2H)-one is classified with Acute Tox. 2, H330 with an ATE of 0.21 mg/L (dust or mist). However, this has no impact on the classification of the biocidal product.
Classification of the product according to CLP	None

3.6.2.6.3 Acute toxicity by dermal route

An animal study on acute dermal toxicity (OECD 402) with the product is provided.

Table 40

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 402, GLP yes, Reliability 1	Rat, Crl:CD(SD), males and females, 5 per sex per group	Test substance SPU-02740-I, occlusive, no vehicle, 2000 mg/kg bw on 5x6 cm, approx. 1/10 of body surface, duration 24h)	Rats did not reveal any signs of toxicity, all animals gained the expected body weight, no mortality, no macroscopic findings were noted at necropsy.	LD_{50} > 2000 mg/kg bw	None	[redacted]

Table 41

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} > 2000 mg/kg bw
Justification for the selected value	Under the present test conditions, a single dermal administration of 2000 mg SPU-02740-I /kg bw to rats did not reveal any signs of toxicity. No mortality occurred. Based on the results of the GLP-study on rats (OECD 402), Alba (SPU-02740-I) is not classified for acute dermal toxicity.
Classification of the product according to CLP	None

3.6.2.7 Information on dermal absorption

For the active substance clothianidin and the substance of concern 1,2-benzisothiazol-3(2H)-one, a study on dermal absorption (*in vitro* human skin, [redacted] (2018)) was submitted. The study was performed with the biocidal product itself (concentrated) and with the respective spray dilution (1:3). The evaluation is performed according to EFSA Guidance on dermal Absorption (2017) because this was done by the applicant, too. The derived dermal absorption values can be used for risk assessment of the product and its dilution. For the active substance cis-tricos-9-ene, no study on dermal absorption with the product or a comparable formulation is submitted by the applicant. Thus, default values have to be used for risk assessment. Referring to the BPC-meeting on 06.03.2018, the EFSA Guidance on Dermal Absorption (2017) may be applied for biocidal products, too. Thus, as this was proposed by the applicant, too, the default values according to EFSA (2017) were derived. It should be noted that the additional cut-off criteria of 5 % was used for categorisation of concentrate or dilution as agreed by the SCoPAFF meeting (25.05.2018, SANTE/2018/10591).

Table 42

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Species, Age/Sex, Localisation, Number of skin samples and donors tested per dose, exposure and post-exposure time, other relevant information about the study**	**Test substance, Formulation details incl. identify and concentration, Doses (total volume/mass applied per area, amount of a.s. applied per area)**	**Absorption data for each compartment (mean and SD as percentage of dose), Absorption (percentage of dose) calculated in accordance with EFSA Guidance on Dermal Absorption (2017) and final absorption value**	**Remarks (e.g. major deviations statements on variability and time-course, justification of non-inclusion of certain compartments, other relevant information, e.g. receptor fluid)**	**Reference**
Percutaneous absorption, in vitro, OECD 428,	Species: Human Age/Sex: 36-42, female	Test substance: clothianidin and 1,2-	Clothianidin high dose (26 g/L):	Both test substances: Tape strips (3 to x) were excluded to the	[redacted] (2018)

GLP: yes, Reliability 1	Localisation: breast and abdomen Number of skin samples and donors tested per dose: 4 donors, 2 per donor and dose, 8 samples Exposure time: 8 h Post exposure time: 16 h	benzisothiazol-3(2H)-one Water based formulation Alba (SPU-02740-I) + radio labelled test compound (clothianidin or 1,2-benzisothiazol-3(2H)-one); Tested concentrations and corresponding doses: clothianidin: high dose 26 g/L (= 260 µg/cm²) + low dose 8.67 g/L (= 86.7 µg/cm²) benzisothiazol-3(2H)-one: high dose 2.26 g/L (= 226 µg/cm²) + low dose 0.75 g/L (= 75 µg/cm²)	Receptor fluid: 0.09 % ± 0.02 % Receptor compartment wash: 0.001 % ± 0 % Stripped skin: 0.03 % ± 0.01 % Tape strips (excl. 1 and 2): 0.03 % ± 0.01 % Skin wash: 99.09 %± 4.4 %, Donor chamber wash: 0.11 % ± 0.12 % Absorbed dose: 0.12 % ± 0.02 % **Rounded final dermal absorption value:** **0.14 %** Clothianidin low dose (8.67 g/L): Receptor fluid: 0.13 % ± 0.02 % Receptor compartment wash: 0.0023 % ± 0.0005 % Stripped skin: 0.11 % ± 0.05 % Tape strips (excl. 1 and 2): 0.07 % ± 0.04 % Skin wash: 98.76 %± 1.17 %, Donor	absorbable dose since the absorption during the first 12 h was above 75 %. Recovery was within the recommended range of 95 % to 105 %; thus, no consideration of missing amounts is required.	

			chamber wash: 0.04 % ± 0.03 % Absorbed dose: 0.24 % ± 0.06 % **Rounded final dermal absorption value:** **0.29 %** Benzisothiazol-3(2H)-one high dose (2.26 g/L): Receptor fluid: 3.65 % ± 1.68 % Receptor compartment wash: 0.03 % ± 0.01 % Stripped skin: 3.52 % ± 1.27 % Tape strips (excl. 1 and 2): 0.25 % ± 0.17 % Skin wash: 91.10 %± 4.45 %, Donor chamber wash: 0.10 % ± 0.08 % Absorbed dose: 7.45 % ± 2.35 % **Rounded final dermal absorption value:** **9.4 %**		

			Benzisothiazol-3(2H)-one low dose (0.75 g/L): Receptor fluid: 9.08 % ± 4.52 % Receptor compartment wash: 0.01 % ± 0.03 % Stripped skin: 9.46 % ± 3.78 % Tape strips (excl. 1 and 2): 1.1 % ± 0.43 % Skin wash: 78.6 %± 7.62 %, Donor chamber wash: 0.31 % ± 0.21 % Absorbed dose: 19.74 % ± 6.57 % **Rounded final dermal absorption value:** **25 %**		

Table 43

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	For cis-tricos-9-ene, the applicant proposed to use dermal absorption default values according to EFSA Guidance on Dermal Absorption (2017). Hence, the default value of 50 % for dilutions of water-based formulations according to EFSA Guidance on Dermal Absorption (2017) has to be applied for the active substance cis-tricos-9-ene (C = 0.05 % in the undiluted product, ≤5 %), For categorisation of concentrate or dilution, the additional cut-off criteria of 5 % was used as agreed by the SCoPAFF meeting (25.05.2018, SANTE/2018/10591).

Table 44

Value(s) used in the Risk Assessment – Dermal absorption			
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	Use/application of concentrated products	Use/application of 1:3 diluted products	Dried products on surface (secondary exposure)
Value(s)	cis-Tricos-9-ene: 50 % Clothianidin: 0.14 % 1,2-Benzisothiazol-3(2H)-one: 9.4 %	cis-Tricos-9-ene: 50 % Clothianidin: 0.29 % 1,2-Benzisothiazol-3(2H)-one: 25 %	cis-Tricos-9-ene: 50 % Clothianidin: 0.29 % 1,2-Benzisothiazol-3(2H)-one: 25 %
Justification for the selected value(s)	cis-Tricos-9-ene: default acc. to EFSA Guidance on Dermal Absorption (2017) Clothianidin: *in vitro* study (human skin) ([redacted] 2018) 1,2-Benzisothiazol-3(2H)-one: *in vitro* study (human skin) ([redacted] 2018)	cis-Tricos-9-ene: default acc. to EFSA Guidance on Dermal Absorption (2017) Clothianidin: *in vitro* study (human skin) ([redacted] 2018) 1,2-Benzisothiazol-3(2H)-one: *in vitro* study (human skin) ([redacted] 2018)	cis-Tricos-9-ene: default acc. to EFSA Guidance on Dermal Absorption (2017) Clothianidin: *in vitro* study (human skin) ([redacted] 2018) 1,2-Benzisothiazol-3(2H)-one: *in vitro* study (human skin) ([redacted] 2018)

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

3.6.2.8.1 1,2-Benzisothiazol-3(2H)-one (CAS No. 2634-33-5)

Summary		
	Value	Source
AEL long-term	0.025 mg/kg bw/day, ,	90 days oral study in dog (BPC-WG, Nov. 2015)
AEL medium-term	0.05 mg/kg bw/day,	90 days oral study in dog, (Revised First Draft CAR 2015, ES)
AEL acute	0.06 mg/kg bw/day,	Rabbit developmental study (Revised First Draft CAR 2015, ES)
Inhalative absorption	-	Default value
Oral absorption	100 % fast	(Revised First Draft CAR 2015, ES)

Classification	
Proposed, with regard to toxicological data according to RAC opinion from 2021-11-26	Acute Toxicity 4, H302 (ATE = 450 mg/kg bw) Acute Toxicity 2, H330 (ATE = 0.21 mg/L, dusts or mists) Skin Irrit. 2, H315 Eye Damage 1, H318 Skin Sens. 1A, H317 (SCL, Skin Sens. 1A c ≥ 0.036%)

3.6.2.9 Available toxicological data relating to a mixture

Not available.

3.6.2.10 Other

Please note that for the active substance clothianidin a RAC opinion has been adopted in September 2021. The biocidal product might be classified with STOT SE 2, H371 when the existing harmonised C&L is changed by the Commission via an ATP-Regulation.

3.6.2.11 Endocrine disrupting properties

According to the current CARs, the active substances clothianidin and cis-tricos-9-ene (Muscalure) are not considered as endocrine disruptors.

To date (July 2021), no co-formulant of the biocidal product was identified as an ED in accordance with Article 57(f) and Article 59 (1) REACH or in any EU decision. Therefore, the co-formulants of the biocidal product are not considered to have endocrine disrupting properties.

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

3.6.2.12 Summary of effects assessment

Table 45

Endpoint	Brief description
Skin corrosion and irritation	Based on a submitted animal study (OECD 404), classification for skin corrosion or skin irritation is not required.
Eye irritation	Based on a submitted animal study (OECD 405), classification for eye damage or eye irritation is not required.
Respiratory tract irritation	Based on the available information on the intrinsic properties of the single components classification for respiratory tract irritation is not required.
Skin sensitisation	Based on the available information on the intrinsic properties of the single components the following classification and labelling is required: Skin Sens 1, H317
Respiratory sensitization (ADS)	Based on the available information on the intrinsic properties of the single components classification for respiratory tract sensitisation is not required.
Acute toxicity by oral route	Based on a submitted animal study (OECD 423), classification for acute oral toxicity is not required.
Acute toxicity by inhalation	Based on the available information on the intrinsic properties of the single components classification for acute toxicity by inhalation is not required.
Acute toxicity by dermal route	Based on a submitted animal study (OECD 402), classification for acute dermal toxicity is not required.
Information on dermal absorption	Based on an *in vitro* human skin study, dermal absorption values were derived for clothianidin and 1,2-Benzisothiazol-3(2H)-one ([redacted] (2018). For cis-tricos-9-ene, default values acc. To EFSA (2017) were derived. **Concentrated product:** cis-Tricos-9-ene: 50 % Clothianidin: 0.14 % 1,2-Benzisothiazol-3(2H)-one: 9.4 % **In use dilution (1:3):** cis-Tricos-9-ene: 50 % Clothianidin: 0.29 % 1,2-Benzisothiazol-3(2H)-one: 25 %

	dried products on surface (secondary exposure): cis-Tricos-9-ene: 50 % Clothianidin: 0.29 % 1,2-Benzisothiazol-3(2H)-one: 25 %
Available toxicological data relating to non-active substance(s)	Refer to sections above.
Available toxicological data relating to a mixture	Not available.
Other relevant information	Please note that for the active substance clothianidin a RAC opinion has been adopted in September 2021. The biocidal product might be classified with STOT SE 2, H371 when the existing harmonised C&L is changed by the Commission via an ATP-Regulation.

According to Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C), version 2.1 (2017) the following hazard category is allocated for local risk assessment:

Hazard category “medium”

Justification: Classification of the product as Skin Sens. 1, H317.

3.6.3 Exposure assessment

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

Table 46

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	yes	No	n.a.	no	Yes	n.a.
Dermal	n.a.	yes	No	n.a.	no	No*	n.a.
Oral	n.a.	n.a.	No	n.a.	n.a.	No*	No

* For the general public, dermal and oral contacts are excluded if the biocidal product is used as intended according to applicant's instructions. It has to be clearly indicated in these instructions that cardboards, which have been treated with biocidal product, have to be kept out of the reach of children during use and after disposal. In addition, only surfaces not accessible for the general public shall be treated with the biocidal product.

List of scenarios

Table 47

Summary table: scenarios				
Use number	**Scenario number**	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group**
1	1	Brush treatment	Primary exposure of workers resulting from application of the b.p. onto cardboards using hand held equipment such as a brush or a roller and cleaning of equipment. Secondary exposure of a professional bystander is not expected.	Professional user
2	2	Manual spray treatment (downwards)	Primary exposure of workers resulting from dilution and application of the b.p. onto cardboards using a hand-held manual spraying device (0.1 L/min) in downward direction in or around buildings and cleaning of the equipment. Secondary exposure of a professional bystander is not expected.	Professional user

1, 2	3	Handling of treated cardboards	Primary exposure of workers resulting from handling of treated cardboards. Secondary exposure of a professional bystander is not expected.	Professional user
1, 2	4	Re-entry	Re-entry of the general public- stay in a stable	General public

3.6.3.1.1 Professional exposure

Stallfliegenmittel Alba is a viscous liquid insecticide to control flies. It is applied by brushing (painting) or spraying an application liquid onto cardboards. The treated cardboards are then hung in stables/barns.

For brushing, Stallfliegenmittel Alba is used as a viscous liquid (ready-to-use) insecticide while for spraying, the viscous liquid has to be diluted before application. It contains the a.s. clothianidin ((E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine, CAS-No.: 210880-92-5, 2.40 % (w/w)) and the a.s. *cis*-tricos-9-ene (*cis*-tricos-9-ene, CAS-No.: 27519-02-4, 0.05 % (w/w)). The biocidal product also contains the SoC 1,2-Benzisothiazol-3(2H)-one (BIT, CAS-No.: 2634-33-5, 0.2 % (w/w)).

The biocidal product is marketed in different package sizes: Bottle, HDPE, 63 mm cap with tamper evident ring, 670 mL brimful capacity, content: 500 mL Alba. Further, 100 mL, 250 mL, and 1000 mL b.p. in HDPE bottles adopted in size are intended to be put on the market, each having a cap with tamper evident ring.

The exposures to the a.s./SoC. are assessed separately for the different application techniques and will thus be described in individual subsections of the current section. It is usually based on the harmonised document “Biocides Human Health Exposure Methodology” (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007. In addition, an expert judgment is applied if necessary.
For the volatile a.s. *cis*-tricos-9-ene, the inhalation exposure to vapours during the application phase for the scenario 1 “Brush treatment” and scenario 2 “Manual spray treatment (downwards)” was assessed, using the consumer exposure model ConsExpo which is applicable to assess the volatile substance.

For the SoC 1,2-Benzisothiazol-3(2H)-one (BIT, CAS-No.: 2634-33-5), in addition to the quantitative risk assessment, a qualitative risk assessment for professional users is performed based on the P-statements. The quantitative and qualitative risk assessment of a.s./ SoC is described in chapter 3.6.4.5. In Annex 4.5.1, the details of the exposure calculations to the a.s./SoC. for the professional user are laid out.

- **Scenario 1 – Brush treatment**

Description

A harmonised approach for exposure assessment of brush treatment is described in the *Biocides Human Health Exposure Methodology document* (October 2015, version 1). The assessment laid out in this PAR follows this approach.

Stallfliegenmittel Alba is a viscous liquid (ready-to-use for painting) insecticide which is applied to cardboards using hand-held equipment such as brush or roller. The cardboards are subsequently hung up in stables; the exposure resulting from this task is calculated as a separate scenario and considered, together with exposure from brushing, in a combined scenario, *Dermal exposure.*
Exposure to skin is considered to occur during all phases of handling.

Due to the process of loading, for the manual mixing and loading phase (e.g. use of 1000 ml bottle) exposure to hands is expected. The calculation is based on the “Mixing and loading model 4” (*Biocides Human Health Exposure Methodology Document Version 1 (October 2015), recommendation of Human Exposure Expert Group HEEG*).
For the application process, exposure to skin is expected to occur through direct contact to the b.p.. For the application phase no appropriate exposure model for professional brushing is available. Therefore, the dermal exposure is assessed using ”Consumer product painting Model 3” (Biocides Human Health Exposure Methodology Document Version 1 (October 2015)). The model describes brush painting of sheds and fences by non-professionals. Taking into account a similar kind of treated surfaces as cardboards and assuming that professional users have more experience in brush treatment than non-professionals, the assessment may represent a worst-case calculation. The model provides data of potential body and potential/actual hand exposure (measurements of hand exposure outside/inside gloves).

Additionally, exposure of hands during cleaning of the brush is considered. As a worst case assumption this post-application phase is calculated on the basis of the “Human Exposure Expert Group (HEEG) opinion 11 on Exposure model Primary exposure scenario - washing out of a brush which has been used to apply a paint”.

Exposure by inhalation
Exposures to aerosols and vapours during the phases mixing/loading and post-application are not expected. In case of the volatile substance cis-Tricos-9-ene, exposure to vapours by inhalation is considered to be negligible during the mixing and loading phase.

Inhalation exposure during the application of the product is expected and is assessed using ”Consumer product painting Model 3” (Biocides Human Health Exposure Methodology Document Version 1 (October 2015)). In addition, inhalation exposure to vapour has to be calculated for the volatile substance cis-Tricos-9-ene using ConsExpo 4.1. The identified value has been taken into account for the exposure and risk assessment.

Exposure to the eyes

During the application of the b.p. by brush treatment splashes may occur, hence eye contact in consequence of splashes cannot be excluded.

Table 48

Details of Scenario 1	
Parameters	**Value**
Concentration of a.s. Clothianidin in b.p.	2.40 % (w/w)
Concentration of a.s. cis-Tricos-9-ene in b.p.	0.05 % (w/w)
Concentration of SoC 1,2-Benzisothiazol-3(2H)-one in b.p.	0.2 % (w/w)
Concentration of b.p. in application liquid	100 %
Density of the b.p.	1.13 g/cm³
Number of loadings	5
Total amount of b.p. used	4,96 kg
Treated area	16 m²
Application duration	120 min

Calculations for Scenario 1

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 51. It is expected that treated cardboards may be hung up the same day as they were treated, thus a combined scenario was calculated, comprising treatment and placing of the cardboards. The results of the combined scenarios are shown in Table 52. For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.5.1 of this PAR.

For risk characterisation, see chapter 3.6.4.

Further information and considerations on scenario 1

The classification of the b.p. and the application liquid require additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users).

Due to the identified risk in Tier 1 a refined exposure assessment (Tier 2) is performed.
The following safety measures are included for Tier 2: protective gloves.

- **Scenario 2 – Manual spray treatment (downwards)**

Description

A harmonised approach for exposure assessment of spray treatment in downward direction is described in the Biocides Human Health Exposure Methodology document (October 2015, version 1). The assessment laid out in this PAR follows this approach.

Stallfliegenmittel Alba is a viscous liquid for control of insects which has to be diluted prior to application by spraying. Subsequently, the application liquid is sprayed with application rates up to 0.1 L/min using hand-held manual spray equipment (knapsack sprayer, portable pump pressure sprayer) in downward direction onto cardboards. The cardboards are subsequently hung up in stables; the exposure resulting from this task is calculated as a separate scenario and considered, together with exposure from downward spraying, in a combined scenario,

Dermal exposure

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

Due to the process of dilution, for the manual mixing and loading phase (e.g. use of 1000 ml bottle) exposure to hands is expected. The calculation is based on the “Mixing and loading model 4” (*Biocides Human Health Exposure Methodology Document Version 1 (October 2015), recommendation of Human Exposure Expert Group HEEG*).

During the application process exposure via skin seems likely, especially due to the deposition of the generated droplets on the lower part of the work clothing (legs) and the hands of the operator and through contact with contaminated surfaces (e.g. treated surfaces, equipment). For the application method of spraying in downward direction the dermal exposure is assessed using the model RISKOFDERM (recommendation no. 3 of the BPC Ad hoc Working Group on Human Exposure on “Spraying models for assessing exposure to insecticides for low pressure downward uses”). The model is based on data from a variety of different studies encompassing mainly spraying applications for insecticide applications or close to insecticide applications and provides data of potential body and potential hand exposure. For the exposure assessment a model scenario for spraying indoors in downward direction with the source being less than 1 meter situated apart from the worker is selected. The assessment is based on application rates of up to 0.1 L/min, according to the intended application.

In addition, exposure of hands during cleaning of the equipment has to be considered. This post-application phase is assessed using the model presented in the “Recommendation no. 4 of the BPC Ad hoc Working Group on Human Exposure: Cleaning of spray equipment in antifouling use (PT 21)”. However, the assessor assumes that a thorough cleaning for 20 minutes as considered in the above mentioned document for PT 21 is not needed in case of low concentrated water-based application solutions; instead, a figure of 5 min seems to be appropriate here.

Exposure by inhalation

Exposure to aerosols and vapours is not expected during the phases mixing/loading and post-application. In case of the volatile substance cis-Tricos-9-ene, exposure to vapours by inhalation is considered to be negligible during the mixing and loading phase.

For the application phase (spraying), the model ART (recommendation no. 3 of the BPC Ad hoc Working Group on Human Exposure on “Spraying models for assessing exposure to insecticides for low pressure downward uses”) was taken into account. The model is based on data from a variety of different studies encompassing mainly spraying applications for insecticide applications or close to insecticide applications. For the exposure assessment a model scenario for spraying indoors in downward direction with the source being less than 1 meter situated apart from the worker is selected. The assessment is based on application rates of up to 3 l/min. In addition, inhalation exposure to vapours has to be calculated for the volatile substance cis-Tricos-9-ene using ConsExpo 4.1. The identified value has been taken into account for the exposure and risk assessment.

Exposure to the eyes

During the application of the b.p. by spray treatment, aerosols are likely to occur. However spraying is limited to downward spraying. Thus, it is rather unlikely that aerosols reaching the face Eye contact with aerosols is therefore excluded.

Table 49

Details of Scenario 2	
Parameters	**Value**
Concentration of a.s. Clothianidin in b.p.	2.40 % (w/w)
Concentration of a.s. cis-Tricos-9-ene in b.p.	0.05 % (w/w)
Concentration of SoC 1,2-Benzisothiazol-3(2H)-one in b.p.	0.2 % (w/w)
Concentration of b.p. in application liquid	36.1 %

Density of the application liquid	1.04 g/cm³
Number of loadings	5
Total amount of application liquid	13.7 kg
Treated area	16 m²
Application duration	120 min
Flowrate of application liquid	0.1 L/min

Calculations for Scenario 2

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 51. It is expected that treated cardboards may be hung up the same day as they were treated, thus a combined scenario was calculated, comprising treatment and placing of the cardboards. The results of the combined scenarios are shown in Table 52. Due to the identified risk in Tier 1 a refined exposure assessment (Tier 2) is performed. The following safety measures are included for Tier 2: protective gloves. Additionally, when pouring the application liquid with a watering can exposure to the feet is expected. Thus, waterproof footwear (e.g. rubber boots) is useful and recommended.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.5.1 of this PAR.
For risk characterisation, see chapter 3.6.4.

Further information and considerations on scenario 2

The classification of the b.p. and the application liquid require additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users).

- **Scenario 3 – Handling of treated cardboards**

Description

Exposure of workers due to contact with treated cardboard surfaces cannot be excluded. Exposure is especially likely when the treated cardboards are hung up in the stables.

Dermal exposure

It is expected that dermal exposure of a professional user is possible when the treated cardboard is fixed to walls as well as when it is collected for disposal. The contact is estimated to be incidental and can be minimized by additional risk mitigation measures:
Application by spray and brush treatment on cardboard should be carried out leaving an untreated area around the edge (approx. 15 cm).
When the treated cardboard is fixed to walls or is collected for disposal only the untreated area around the edge should be touched.

Inhalation exposure

Inhalation exposure of a professional user due to handling of treated cardboard is not expected because the cardboard is only handled after drying. In case of the volatile substance cis-Tricos-9-ene, exposure to vapours by inhalation is also not expected to occur.

Table 50

Details of Scenario 3	
Parameters	**Value**
Concentration of a.s. Clothianidin in b.p.	2.40 % (w/w)
Concentration of a.s. cis-Tricos-9-ene in b.p.	0.05 % (w/w)
Concentration of SoC 1,2-Benzisothiazol-3(2H)-one in b.p.	0.2 % (w/w)
Use rate (weight per area treated)	314 g b.p./m^2
Hand area: palms of both hands	410 cm^2
Exposed hand area[1)]	135 cm^2
Transfer coefficient[2)]	50 %

1) 1/3 of the palms of both hands

2) Expert judgement

Calculations for Scenario 3

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 51. It is expected that treated cardboards may be hung up the same day as they were treated, thus a combined scenario was calculated, comprising treatment and placing of the cardboards. The results of the combined scenarios are shown in Table 51.

For details of the calculation of dermal and inhalation exposure, please refer to Annex Safety for professional users of this PAR.

For risk characterisation, see chapter 3.6.4.

Combined scenario:

Brush treatment + Handling of treated cardboards

It is assumed that the professional user is primary exposed during brushing and subsequently exposed during the handling of the treated cardboards. The results of the calculation for combined exposure are summarised in Table 51.

Manual spray treatment downwards + Handling of treated cardboards

It is assumed that the professional user is primary exposed during spray treatment and subsequently exposed during the handling of the treated cardboards. The results of the calculation for combined exposure are summarised in Table 54.

Further information and considerations on scenario 3

The classification of the b.p. and the application liquid require additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users).

- **Summary of professional exposure**

The scenarios described here include all phases of application (mixing and loading, application and post-application). Therefore, the values in the following table are combined exposure values of all phases (however, hanging up of the cardboards is not included; this task is additionally considered in the combined scenarios below).

Table 51

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated. For combined exposure, please see Table 52							
Exposure scenario	**Tier/PPE**	**a.s.: Clothianidin**		**a.s.: cis-Tricos-9-ene**		**SoC: BIT**	
		Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**	**Estimated external inhalation exposure [mg/m³]**	**Estimated external dermal exposure [mg/day]**	**Estimated external inhalation exposure [mg/m³]**	**Estimated external dermal exposure [mg/day]**
Scenario 1: Brush treatment	Tier 1: no PPE	9.78E-03	79.16	2.74E-04	1.65	8.15E-04	6.60
	Tier 2: Protective gloves (EN 374)	9.78E-03	57.42	2.74E-04	1.20	8.15E-04	4.78
Scenario 2[1)]: Manual spray treatment (downwards)	Tier 1: no PPE	2.60E-02	67.38	5.68E-04	1.40	2.17E-03	5.62
	Tier 2: Protective gloves (EN 374)	2.60E-02	49.11	5.68E-04	1.02	2.17E-03	4.09
Scenario 3[2)]: Handling of treated Cardboards	Tier 1: no PPE	not expected	50.96	negligible	1.06	not expected	4.25
	Tier 2: Protective gloves (EN 374)	not expected	5.10	negligible	0.11	not expected	0.42

1) Generally the use of waterproof footwear (e.g. rubber boots) is recommended. Combined scenarios may require further additional protective equipment (for details see chapter 3.6.4).

2) According to the calculation performed in Tier 1, additional protective equipment is not necessary; a risk for professional users is unlikely. Combined scenarios may require further additional protective equipment (for details see chapter 3.6.4).

The described summary is valid for professional users. The frequency of application is assumed to be up to daily.

- **Combined scenarios**

For a worst case scenario it is assumed that the professional user is primary exposed during brushing (scenario 1) or spraying (scenario 2) and subsequently exposed during handling of the treated cardboards (scenario 3). The scenarios described here include all phases of application (mixing and loading, application and post-application), and additionally the exposure resulting from handling of the treated cardboards (especially hanging them up in the stable) is considered.

Table 52

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated. For combined exposure, please see Table 51.							
Exposure scenario	**Tier/PPE**	**a.s.: Clothianidin**		**a.s.: cis-Tricos-9-ene**		**SoC: BIT**	
		Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**	**Estimated external inhalation exposure [mg/m³]**	**Estimated external dermal exposure [mg/day]**	**Estimated external inhalation exposure [mg/m³]**	**Estimated external dermal exposure [mg/day]**
Scenario 1+3 (Brush treatment + Handling of treated Cardboards)	Tier 1: no PPE	9.78E-03	130.12	2.74E-04	2.71	8.15E-04	10.84
	Tier 2: Protective gloves (EN 374)	9.78E-03	62.51	2.74E-04	1.30	8.15E-04	5.21
Scenario 2+3[1)] (Manual spray treatment + Handling of treated Cardboards)	Tier 1: no PPE	2.60E-02	118.34	5.68E-04	2.47	2.17E-03	9.86
	Tier 2: Protective gloves (EN 374)	2.60E-02	54.21	5.68E-04	1.13	2.17E-03	4.52

1) Generally the use of waterproof footwear (e.g. rubber boots) is recommended.

The described summary is valid for professional users. The frequency of application is assumed to be up to daily.

3.6.3.1.2 Non-professional exposure

Non-professional use is not intended. Thus, no exposure assessment is performed**.**

3.6.3.1.3 Secondary exposure of the general public

The biocidal product is used as an insecticide against flies inside animal housings. It is applied on cardboards. According to the applicant, the treated cardboards are placed on the walls in the stables in which insect pests are likely to occur, where they will not be contacted by the general public. The frequency of single treatment is max. 3 times/year (fly season, long last effect, efficacy every 30 days). However, the general public may enter treated stables daily, thus possible exposure scenarios are assessed and exposure is considered long-term.

- **Scenario [4]: Re-entry of the general public- stay in a stable, dermal and oral contact with treated cardboards and inhalation of volatilised residues**

Secondary exposure via the dermal and oral route to children and adults is not expected if the biocidal product is used as intended according to the applicant's instructions. The instructions for use have to indicate clearly that cardboards, which have been treated with the biocidal product, have to be kept out of the reach of children/adults during use and after disposal. It is expected that improper application of the biocidal product may lead to considerable exposure levels, particularly for children.

Table 53

Description of Scenario [4]		
Secondary exposure via the dermal and oral route to children and adults is not expected if the biocidal product is used as intended according to the applicant's instructions (see above). Secondary inhalation exposure to the biocidal product Stallfliegenmittel Alba is considered possible for people entering a treated stable. People present in the stable after application are potentially exposed to residues in air. Therefore inhalation exposure is assessed in a first screening approach using the criteria of HEEG Opinion 13 "Assessment of Inhalation Exposure of Volatilised Biocide Active Substance" for the active substances clothianidin and cis-tricos-9-ene, and the identified substance of concern 1,2-Benzothiazol-3(2H)-one. The estimation of air concentrations by saturated vapour pressure is a conservative but very simple approach. According to the HEEG Opinion 13, 24 hours is assumed as exposure duration (worst-case). The possible inhalation exposure to toddlers is calculated as worst-case representative for children. A human health risk is identified for cis-tricos-9-ene, and the identified substance of concern 1,2-Benzothiazol-3(2H)-one. Hence, exposure assessment was refined for this active substance and the SoC using the evaporation model of Consexpo 4.1. The product amount was calculated from the application rate (2.5 mL/m^2) taking into account a stable size of 200 m^2. According to the applicant, a room volume of 600 m^3 is used (200 m^2 x 3 m height). The application duration reflect the time interval the active substance evaporates (24 h). The default for the mass transfer rate was estimated according to Langmuir method, which (according to Consexpo) generally overestimates the evaporation rate. For the molecular weight of the matrix in the Consexpo model the average molecular weight of the main co-formulant (saccharose) after drying was chosen. Other minor components are considered to be not relevant. A ventilation rate of 5.6 times per hour is chosen for stables (summer season, ECHA Guidance on BPR: Volume III Parts B+C, Version 4, December 2017 (ECHA, 2017), 6. Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products, Table 53, p. 367). This exposure assessment for toddlers represents also a worst case for other members of the general public.		
	Parameters	Value
Tier 1	Molecular weight clothianidin (CAR/AR, 2014)	249.7 g/mol
	Vapour pressure clothianidin (25 °C, worst case due to conditions in stables, CAR/AR 2014,)	1.3 x 10^{-11} Pa

	Molecular weight cis-tricos-9-ene (CAR/AR, 2012)	322.6 g/mol
	Vapour pressure cis-tricos-9-ene (25 °C, worst case due to conditions in stables, CAR/AR, 2012)	0.119 Pa
	Molecular weight 1,2-Benzothiazol-3(2H)-one (draft CAR, 2015)	151.19 g/mol
	Vapour pressure 1,2-Benzothiazol-3(2H)-one (25 °C, worst case due to conditions in stables, draft CAR, 2015)	8.91 x 10^{-3} Pa
	Gas constant (Atkins Physical Chemistry, 5th Edition)	8.31451 J/mol/K
	Temperature (assumed temperature in stables = 25 °C HEEG opinion No. 13, 2011)	298 K
	Saturated vapour pressure clothianidin (calculated acc. to HEEG opinion No. 13, 2011)	1.31 x 10^{-9}mg/m^3
	Saturated vapour pressure cis-tricos-9-ene (calculated acc. to HEEG opinion No. 13, 2011)	15.49 mg/m^3
	Saturated vapour pressure 1,2-Benzothiazol-3(2H)-one (calculated acc. to HEEG opinion No. 13, 2011)	5.44 x 10^{-1}mg/m^3
	Exposure duration (expert assumption, one afternoon for the general public)	24 h
	Inhalation rate, toddler (HEAdhoc Recommendation No 14, long-term exposure)	8 m^3/ 24 h
	Inhalation absorption (CAR/AR of all a.s., default)	100 %
	Body weight, toddler (HEEG opinion No. 17, 2013)	10 kg
Tier 2 (for cis-tricos-9-ene and 1,2-Benzothiazol-3(2H)-one only)	Product amount for treatment of 200 m^2 stable (refer to intended use)	500 mL
	Density of the product (refer to the applicant's dossier)	1.13 g/cm^3
	Product amount for treatment of 200 m^2 stable (refer to intended use)	565 g
	Concentration cis-tricos-9-ene	0.05 % (w/w)
	Concentration 1,2-Benzothiazol-3(2H)-one	0.2 % (w/w)

	Room volume (refer to the applicant, 200 m² surface x height 3 m)	600 m^3
	Ventilation rate (summer season, ECHA Guidance on BPR: Volume III Parts B+C, Version 4, December 2017, Table 53, p. 367)	5.6 h^{-1}
	Release area (refer to intended use)	1.8 m^2
	Exposure duration (one afternoon stay)	4 h
	Application duration (time interval the a.s. evaporates)	24 h
	Mass transfer rate cis-tricos-9-ene (Langmuir, Consexpo)	2.08 x 10^3 m/min
	Mass transfer rate 1,2-Benzothiazol-3(2H)-one (Langmuir, Consexpo)	3.04 x 10^3 m/min
	Molecular weight matrix (estimated from the main co-formulant after drying (saccharosse)	342 g/mol
	Inhalation rate, toddler (HEAdhoc Recommendation No 14, short-term exposure used to assume activity)	1.26 m^3/ h
	For other parameters refer to Tier 1	

Calculations for Scenario [4]

Tier 1:

Systemic inhalation exposure

$Exposure_{inhalation}$ = saturated vapour concentration a.s. x inhalation rate x inhalation duration x inhalation absorption / body weight toddler

Clothianidin

$Exposure_{inhalation}$ = 1.31 x 10^{-9} mg/m^3 x 8 m^3/d x 1 d x 100 % / 10 kg
= 1.048 x 10^{-9} mg a.s./kg bw/d

cis-Tricos-9-ene

$Exposure_{inhalation}$ = 15.49 mg/m^3 x 8 m^3/d x 1 d x 100 % / 10 kg
= 12.392 mg a.s./kg bw/d

1,2-Benzothiazol-3(2H)-one

$Exposure_{inhalation}$ = 5.44 x 10^{-1} mg/m^3 x 8 m^3/d x 1 d x 100 % / 10 kg
= 4.352 x 10^{-1} mg a.s./kg bw/d

Tier 2:

cis-Tricos-9-ene

ConsExpo 4.1 report

Compound

Compound name :	cis-tricos-9-ene	
CAS number :	27519-02-4	
molecular weight	323	g/mol
vapour pressure	0,119	Pascal
KOW		linear

General Exposure Data

exposure frequency	1	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	0,05	%
exposure duration	4	hour
room volume	600	m3
ventilation rate	5,6	1/hr
applied amount	565	gram
release area	1,8	m2
application duration	24	hour
mol weight matrix	342	g/mol
mass transfer rate	2,08E3	m/min

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	1,26	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,00672	mg/m3
inhalation mean concentration on day of exposure:	0,00112	mg/m3
inhalation air concentration year average :	0,00112	mg/m3/day
inhalation acute (internal) dose :	0,00338	mg/kg
inhalation chronic (internal) dose :	0,00338	mg/kg/day

Integrated (point estimates)

total external dose:	0,00338	mg/kg
total acute dose (internal):	0,00338	mg/kg
total chronic dose (internal):	0,00338	mg/kg/day

1,2-Benzothiazol-3(2H)-one

ConsExpo 4.1 report

Compound

Compound name :	1,2-Benzothiazol-3(2H)-one	
CAS number :	2634-33-5	
molecular weight	151	g/mol
vapour pressure	0,00891	Pascal
KOW		linear

General Exposure Data

exposure frequency	1	1/day
body weight	10	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	0,2	%
exposure duration	4	hour
room volume	600	m3
ventilation rate	5,6	1/hr
applied amount	565	gram
release area	1,8	m2
application duration	24	hour
mol weight matrix	342	g/mol
mass transfer rate	3,04E3	m/min

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	1,26	m3/hour

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,00243	mg/m3
inhalation mean concentration on day of exposure:	0,000405	mg/m3
inhalation air concentration year average :	0,000405	mg/m3/day
inhalation acute (internal) dose :	0,00123	mg/kg
inhalation chronic (internal) dose :	0,00123	mg/kg/day

Integrated (point estimates)

total external dose:	0,00123	mg/kg
total acute dose (internal):	0,00123	mg/kg
total chronic dose (internal):	0,00123	mg/kg/day

Table 54

Summary table: systemic exposure of the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [4] Re-entry of the general public- stay in a stable, dermal and oral contact with treated cardboards and inhalation of volatilised residues	Tier 1 Labelling: Apply and keep out of the reach of children/adults during use and after disposal. Application only in areas inaccessible for children/adults.	Clothianidin: 1.048×10^{-9} mg a.s./kg bw/d Cis-Tricos-9-ene: 12.392 mg a.s./kg bw/d SoC: 1,2-Benzothiazol-3(2H)-one: 4.352×10^{-1} mg a.s./kg bw/d	Not assessed due to labelling instructions	Not assessed due to labelling instructions	Not assessed due to labelling instructions
	Tier 2 Labelling: Apply and keep out of the reach of children/adults during use and after disposal. Application only in areas inaccessible for children/adults.	Clothianidin: not required, see Tier 1 Cis-Tricos-9-ene: 0.00338 mg/kg/d SoC: 1,2-Benzothiazol-3(2H)-one: 0.00123 mg/kg/d	Not assessed due to labelling instructions	Not assessed due to labelling instructions	Not assessed due to labelling instructions

- **Combined scenarios**

Not relevant for secondary exposure of the general public.

3.6.3.2 Dietary exposure

3.6.3.2.1 Representative dietary exposure scenarios

Table 55

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	clothianidin cis-tricos-9-ene (Muscalure)
Type of formulation	Viscous liquid (ready-to-use) for painting, SC (suspension concentrate, dilutable with water for spraying) for spraying
Substance(s) of concern	1,2-benzisothiazol-3(2H)-one (BIT)
Field(s) of use	indoor use in animal housings for cattle, calves, pigs, horses, sheep, **application in poultry houses is excluded**
Target organism(s)	House fly (*Musca domestica*), Stable flies (*Musca autumnalis*: *Stomoxys calcitrans*) development stage: adults
Application rate(s) and frequency	Application of biocidal product during fly season (i.e. typically from April to October), depending on fly population pressure max. 3 applications/year with intervals of 30 days <u>Density of the biocidal product (according to safety data sheet)</u> 1.13 g/mL (20°C) <u>Paint application</u> Painting of undiluted biocidal product (containing 24 g clothianidin/kg, 0.5 g cis-tricos-9-ene /kg, 2g 1,2-benzisothiazol-3(2H)-one/kg) on cardboard stripes, which are then attached on many small areas on walls, poles, window frames etc., but out of reach of animals. During application the cardboard is laying horizontally on an area covered with disposable foil in order to avoid contamination of adjacent surface/floor. For a stable/barn of 200 m² ground floor area, 500 mL biocidal product is distributed to 30–60 stripes of approx. 15 cm x 20 cm, located in different places in the stable/barn. The size of the overall treated surface area is approximately 1.8 m². *Maximal application rate per m² painted cardboard surface area* *7.5 g clothianidin, 0.16 g cis-tricos-9-ene, 0.63 g 1,2-benzisothiazol-3(2H)-one* *Maximal application rate per m² ground floor area in stable* *0.068 g clothianidin, 0.0014 g cis-tricos-9-ene, 0.0056 g 1,2-benzisothiazol-3(2H)-one* <u>Spray application</u> Spraying of diluted biocidal product (500 mL biocidal product + 1 L water) on cardboard stripes, which are then attached on many small areas on walls, poles, window frames etc., but out

	of reach of animals. During application the cardboard is laying horizontally on an area covered with disposable foil in order to avoid contamination of adjacent surface/floor. For a stable/barn of 200 m² ground floor area 30-60 stripes are treated with about 25 mL diluted product each. Maximally an overall area corresponding to 10 % of the stable size is treated. *Maximal application rate per m² sprayed cardboard surface area* *0.68 g clothianidin, 0.014 g cis-tricos-9-ene, 0.056 g 1,2-benzisothiazol-3(2H)-one* *Maximal application rate per m² ground floor area in stable* *0.068 g clothianidin, 0.0014 g cis-tricos-9-ene, 0.0056 g 1,2-benzisothiazol-3(2H)-one*
Category(ies) of users	professional
Waiting periods after treatment	not applicable
Further information	Relevant risk mitigation measures according to the applicant´s dossier - Attachment of treated cardboards out of the reach of animals/farm animals. - Apply in distance to animal's feed. - Do not spray on animals. - Do not store near food, drink and feed. - Do not contaminate water with the product or its containers.

Critical scenarios with respect to consumer dietary intake for the biocidal product "Stallfliegenmittel Alba" are presented in the following table. They have been selected based on the information on the intended uses given in Table 55.

Table 56

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
Livestock exposure			
1.	animal husbandry	indoor paint (ready-to-use viscous liquid) or spray (aqueous dilution of concentrate) application of biocidal product on cardboard stripes which are then attached in livestock facilities (out of reach of animals)	livestock animals, except poultry

Relevant scenarios for dietary risk assessment

- inhalation exposure (cattle, pig)

The following scenarios are excluded by risk mitigation measures proposed by the applicant:

- oral exposure by licking of treated surfaces (cattle, pig)
- oral exposure via uptake of feed contaminated in trough (cattle, pig)
- dermal exposure by rubbing against surfaces (cattle, pig)
- Note: Exposure of poultry is not relevant as the biocidal product is not intended to be used in poultry stables.

External livestock exposure has been estimated for the active substances clothianidin and cis-tricos-9-ene as well as the substance of concern BIT. Values and assumptions applied in these calculations are summarised in the table below:

Table 57

Values and assumptions applied in livestock exposure calculations		
Parameter	**Value**	**Reference**
Tier 1 (Screening model and realistic worst case exposure estimate according to Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017)		
maximal application rate ($R_{appl.\ a.s.}$)	For a stable of 200 m² ground floor area, 500 mL biocidal product is applied to 30–60 stripes/spots of approx. 15 cm x 20 cm, located in different places in the stable. The size of the overall treated surface area is approximately 1.8 m². Maximal application rate per m^2 treated cardboard surface area *0.68 g clothianidin, 0.014 g cis-tricos-9-ene, 0.056 g 1,2-benzisothiazol-3(2H)-one* Maximal application rate per m^2 ground floor area in stable 68 mg clothianidin, 1.4 mg cis-tricos-9-ene, 5.6 mg 1,2-benzisothiazol-3(2H)-one	Product specific information
concentration of active substance in the biocidal product ($c_{a.s.\ in\ b.p.}$)	24 g clothianidin/kg 0.5 g cis-tricos-9-ene /kg 2 g 1,2-benzisothiazol-3(2H)-one/kg	Product specific information
vapour pressure (vp)	clothianidin: 1.3 x 10^{-10} Pa (25°C) cis-tricos-9-ene: 0.064 Pa (20°C) BIT: 8.91 x 10^{-3} Pa (25°C)	clothianidin: AR, PT18, 2014, RMS:DE cis-tricos-9-ene: CAR, PT19, 2012, RMS: AT BIT Draft CAR, LOEP, May 2015, (most critical value in LOEP)
representative animal species	As application of biocidal product is foreseen for various animal species calculations were performed for beef and dairy cattle, as well as pigs. As application of the biocidal product in poultry houses is excluded, no assessment is performed for broiler chicken and laying hen.	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017

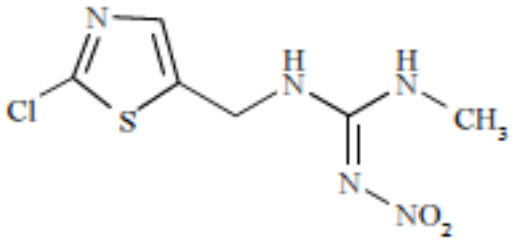
animal body weight (bw)	beef cattle: 500 kg calves: 200 kg dairy cattle: 650 kg breeding pigs: 260 kg fattening pigs: 100 kg	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
No. of animals per stable ($N_{animals}$)	beef cattle: 125 calves: 80 dairy cattle: 100 breeding pigs (individual&group housing): 132 fattening pigs: 400	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
floor area per stable (A_{stable})	beef cattle: 370 m^2 calves: 160 m^2 dairy cattle: 1170 m^2 breeding pigs (individual housing): 560 m^2 breeding pigs (group housing): 710 m^2 fattening pigs: 600 m^2	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
alveolar ventilation rate (AVR) (= inhalation rate in ConsExpo 4.1)	beef cattle: 51 m^3/d (2110 L/h) calves: 25 m^3/d (1032 L/h) dairy cattle: 62 m^3/d (2589 L/h) breeding pigs: 30 m^3/d (1267 L/h) fattening pigs: 14 m^3/d (601 L/h)	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
gas constant (R)	8.31451 J/K mol	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
Molecular weight (MW)	clothianidin 249.7 $g \cdot mol^{-1}$ cis-tricos-9-ene 322.6 $g \cdot mol^{-1}$ BIT 151.19 $g \cdot mol^{-1}$	clothianidin: AR, PT18, 2014, RMS:DE cis-tricos-9-ene: CAR, PT19, 2012, RMS: AT BIT Draft CAR, May 2015
Tier 2 (Refined realistic worst-case scenario: inhalation exposure according to ConsExpo 4.1)		
weight fraction substance	0.0005 (fraction of active substance in biocidal product)	Product specific information
use frequency	3/year	Product specific information
Model	exposure to vapour	ConsExpo Fact Sheet
Mode of release	constant rate	ConsExpo Fact Sheet
exposure duration	default: 24 h	ConsExpo Fact Sheet
product amount	500 mL (= 565 g) of biocidal product used in a stable with 200 m^2 floor surface area, i.e. 2.825 g biocidal product per m^2 floor area of stable <u>values for individual animal species (considering default stable size)</u> beef cattle: 370 m^2 * 2.825 g/ m^2 = 1045.25 g calves: 160 m^2 * 2.825 g/ m^2 = 452 g dairy cattle: 1170 m^2 * 2.825 g/ m^2 = 3303.25 g breeding pigs (individual housing): 560 m^2 * 2.825 g/ m^2 = 1582 g breeding pigs (group housing): 710 m^2* 2.825 g/ m^2 = 2005.75 fattening pigs: 600 m^2 * 2.825 g/ m^2 = 1695 g	Product specific information

room volume	beef cattle: 3063 m^3 calves: 590 m^3 dairy cattle: 9630 m^3 breeding pigs (individual housing): 1960 m^3 breeding pigs (group housing): 2480 m^3 fattening pigs: 2110 m^3	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
room ventilation rate	beef cattle: 2 per h calves: 4.1 per h dairy cattle: 0.9 per h breeding pigs (individual housing): 3.5 per h breeding pigs (group housing): 2.8 per h fattening pigs: 1.9 per h (winter season as worst case)	Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017
emission duration	4 weeks (worst case estimate for time period during which the product is emitted in the stable. According to the applicant´s dossier efficacy of the biocidal product has been shown for 12 weeks.)	ConsExpo Fact Sheet
absorption fraction	default: 100 %	ConsExpo Fact Sheet

3.6.3.2.2 Clothianidin (active substance)

3.6.3.2.2.1 General information on active substance(s)

Table 58

Active substance (Common Name)	Clothianidin
CAS number	210880-92-5
Chemical structure	
Molecular formular	$C_6H_8ClN_5O_2S$
Molar mass	249.7 g/mol
Log Po/w	pH 7: 0.905 in buffer at 25 °C (shakeflask method); 0.7 at 25°C (HPLC method) (AR, clothianidin, PT18, 2014, eCA:DE)
Active substance approval	PT: 18; RMS: DE
Restrictions	BPC Opinion, 2014, section 2.3

	For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/20092 or Regulation (EC) No 396/20053 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. BPC Opinion, 2014, section 2.4 No. 4 Residues in food and feed are not expected. However this assumption may not be true for biocidal products other than the representative product. Therefore, at product authorisation level a dietary risk assessment has to be conducted according to agreed guidance. In case the use leads to residues, analytical methods for food and feed must be provided.
Current regulations on MRLs	Reg. (EU) 2017/671

3.6.3.2.2.2 Information of non-biocidal use of the active substance

Table 59

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products	Insecticide used in various plant protection products	MRLs for clothianidin according to Reg. (EU) 2017/671: (more information on residue definitions see below) for food of animal origin: Swine, bovine, sheep, goat, horses, other farm animals Muscle 0.02* mg/kg Fat 0.02* mg/kg Liver 0.2 mg/kg Kidney 0.02* mg/kg Edible offal 0.2 mg/kg Poultry Muscle, fat, kidney 0.01* mg/kg Liver, edible offal 0.1 mg/kg Milk 0.02 mg/kg Birds eggs 0.01* mg/kg Various values for food of plant origin

* MRLs set at LOQ

3.6.3.2.2.3 Nature of residues

Significant residues of clothianidin from the intended uses are not expected in food of animal origin (see livestock exposure estimate below). Therefore, an evaluation of the nature of residues is not required (according to Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017).

3.6.3.2.2.4 Estimating Livestock Exposure to Active Substances used in Biocidal Products

Description of scenarios

See section 3.6.3.2.1 “Representative dietary exposure scenarios” above.

Calculations for estimating external livestock exposure

The estimation of external livestock exposure (Tier 1) has been performed according to the Guidance on BPR: Volume III Parts B+C, section 6, Version 4.0, December 2017.

- **Tier 1** (External exposure assessment for livestock animals)

Table 60

Screening scenario: External livestock exposure (mg clothianidin/kg bw/d)					
- For the screening scenario it is assumed that the whole amount of biocidal product applied in a stable is taken up by animals in that stable. - Calculation and default values according to the screening scenario “surface treatment of animal housing (floor only)” as described in the Guidance on BPR: Volume III Parts B+C, section 6, Version 4.0, December 2017. For relevant default values see also PAR section 3.6.3.2.1 “Representative dietary exposure scenarios”, table “Values and assumptions applied in livestock exposure calculations”. - For the assessment a calculated maximal application rate of 68 mg clothianidin per m^2 stable floor area has been considered. (Note the actual surface area of treated cardboards in the stable is only about 1 % of the stable floor area.) - External livestock exposure calculated as $Exp_{livestock} = (R_{appl} \times A_{stable} \div N_{animals\ per\ stable}) \div bw$ with $Exp_{livestock}$: external livestock exposure (mg/kg bw/d); R_{appl}: application rate per stable floor area (mg/m^2); A_{stable}: floor area per stable (m^2); $N_{animals\ per\ stable}$: No. of animal per stable; bw: bodyweight (kg)					
	Beef cattle	**Calves**	**Dairy cattle**	**Fattening pig**	**Breeding pig**
Screening: External livestock exposure (mg/kg bw/d)	0.4026	0.6800	1.2240	1.0200	individual housing 1.1096 group housing 1.4068
Trigger value exceeded?	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**

Conclusion
As the trigger value of 0.004 mg/kg bw/d is exceeded, the assessment will proceed with the estimation of external livestock exposure considering relevant realistic worst case scenarios.

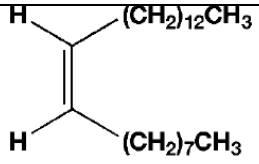
Table 61

Realistic worst-case scenarios: External livestock exposure (mg clothianidin/kg bw/d)					
Relevant scenario: inhalation exposure (cattle, pig) - The inhalative SVC model considers that the animal is exposed to air containing the active substance at its saturated vapour pressure. - External livestock exposure calculated as $Exp_{livestock}$ = SVC x AVR ÷ bw with $Exp_{livestock}$: external livestock exposure (mg/kg bw/d); SVC: saturated vapour concentration (mg a.s./m^3); AVR: alveolar ventilation rate (m^3/d); bw: bodyweight (kg) - SVC = (VP x MW) ÷ (R x T) with VP: vapour pressure (Pa); MW: molecular weight (g/mol); R: gas constant (8.31451 J/K mol); T: temperature (K)					
	Beef cattle	**Calves**	**Dairy cattle**	**Fattening pig**	**Breeding pig**
Inhalative (SVC model)	$1.31x10^{-9}$	$1.64x10^{-9}$	$1.25x10^{-9}$	$1.83x10^{-9}$	$1.51x10^{-9}$
Trigger value exceeded?	**No**	**No**	**No**	**No**	**No**
Conclusion The inhalation exposure estimate for clothianidin in livestock animals results in exposure values well below the trigger value of 0.004 mg/kg bw/d. Significant residues of clothianidin in livestock animals from the intended use are not expected.					

3.6.3.2.3 Cis-tricos-9-ene (active substance)

3.6.3.2.3.1 General information on active substance(s)

Table 62

Active substance (Common Name)	*cis*-Tricos-9-ene
CAS number	27519-02-4
Chemical structure	
Molecular formular	$C_{23}H_{46}$
Molar mass	322.6 g/mol
Log Po/w	pH 7: >8.2 (20 °C)
Active substance approval	PT: 19; RMS: Austria
Restrictions	CAR (2012) Doc I 3.3 c

	No dietary risk assessment was submitted by the applicant. Oral exposure estimates of farm animals result above the actually proposed dietary risk assessment trigger value of 0.004 mg/kg bw Inhalative exposure of farm animals kept in stables / animal houses, where Denka Flylure is used as intended, was estimated only as tier 1 without refinements and acceptable risk was only shown for cattle and pigs, not for poultry. No acceptable data on analytic methods and exposure of food/feeding stuff were provided. Therefore for products containing cis-tricos-9-ene that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded. In addition a refined risk assessment for farm animals and data on analytic methods of food/feeding stuff, as appropriate – may therefore be required at product authorization stage.
Current regulations on MRLs	Active substance not approved for plant protection products: Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396 / 2005 applies.

3.6.3.2.3.2 Information on non-biocidal use of the active substance

Cis-tricos-9-ene is a naturally occurring pheromone (attractant) produced by flies and bees. No further information is available on non-biocidal uses.

3.6.3.2.3.3 Nature of residues

Significant residues of cis-tricos-9-ene from the intended uses are not expected in food of animal origin (see livestock exposure estimate below). Therefore an evaluation of the nature of residues is not required (according to Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017).

3.6.3.2.3.4 Estimating Livestock Exposure to Active Substances used in Biocidal Products

Description of scenarios

See section 3.6.3.2.1 “Representative dietary exposure scenarios” above

Calculations for estimating external livestock exposure

The estimation of external livestock exposure (Tier 1 and Tier 2) has been performed according to the Guidance on BPR: Volume III Parts B+C, section 6, Version 4.0, December 2017.

- **Tier 1** (External exposure assessment for livestock animals)

Table 63

Screening scenario: External livestock exposure (mg cis-tricos-9-ene/kg bw/d)					
- For the screening scenario it is assumed that the whole amount of biocidal product applied in a stable is taken up by animals in that stable. - Calculation and default values according to the screening scenario "surface treatment of animal housing (floor only)" as described in the Guidance on BPR: Volume III Parts B+C, section 6, Version 4.0, December 2017. For relevant default values see also PAR section 3.6.3.2.1 "representative dietary exposure scenarios". - For the assessment a calculated maximal application rate of 1.4 mg cis-tricos-9-ene per m^2 stable floor area has been considered. (Note the actual surface area of treated cardboards in the stable is only about 1 % of the stable floor area.) - External livestock exposure calculated as $Exp_{livestock} = (R_{appl} \times A_{stable} \div N_{animals\ per\ stable}) \div bw$ with $Exp_{livestock}$: external livestock exposure (mg/kg bw/d); R_{appl}: application rate per stable floor area (mg/m^2); A_{stable}: floor area per stable (m^2); $N_{animals\ per\ stable}$: No. of animal per stable; bw: bodyweight (kg)					
	Beef cattle	**Calves**	**Dairy cattle**	**Fattening pig**	**Breeding pig**
Screening: External livestock exposure (mg/kg bw/d)	0.0083	0.0140	0.0252	0.210	individual housing 0.0228 group housing 0.0290
Trigger value exceeded?	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Conclusion As the trigger value of 0.004 mg/kg bw/d is exceeded, the assessment will proceed with the estimation of external livestock exposure considering realistic worst case scenarios.					

Table 64

Realistic worst-case scenario: External livestock exposure (mg cis-tricos-9-ene/kg bw/d)
Relevant scenario: inhalation exposure (cattle, pig) - The inhalative SVC model considers that the animal is exposed to air containing the active substance at its saturated vapour pressure. - calculated as $Exp_{livestock} = SVC \times AVR \div bw$ with $Exp_{livestock}$: external livestock exposure (mg/kg bw/d); SVC: saturated vapour concentration (mg a.s./m^3); AVR: alveolar ventilation rate (m^3/d); bw: bodyweight (kg)

- SVC = (VP x MW) ÷ (R x T) with VP: vapour pressure (Pa); MW: molecular weight (g/mol); R: gas constant (8.31451 J/K mol); T: temperature (K)

	Beef cattle	Calves	Dairy cattle	Fattening pig	Breeding pig
Inhalative (SVC model)	0.8333	1.042	0.7948	1.167	0.9615
Trigger value exceeded?	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**

Conclusion

The trigger value of 0.004 mg/kg bw/d is exceeded for external livestock exposure estimated for the relevant realistic worst case scenario. Therefore (according to the Guidance on BPR: Volume III Parts B+C, section 6, Version 4.0, December 2017) a Tier 2 refinement is performed for the critical exposure scenario identified in Tier 1.

- **Tier 2** (Refined external exposure estimate for livestock animals)

In tier 1 inhalation exposure of livestock animals has been estimated using the SVC model, which assumes as worst case that livestock animals are exposed to air containing cis-tricos-9-ene at its saturated vapor concentration (SVC).
As tier 2 the estimation of inhalation exposure was refined using the ConsExpo 4.1 model “Inhalation: Exposure to vapour – constant rate” that considers more realistic conditions such as the applied amount of biocidal product, room volume and room ventilation rates.
Results of the calculations estimating inhalation exposure from treated surfaces are summarised in the table below. ConsExpo reports for the individual animal species are reproduced in annex 4.5 “Output tables from exposure assessment tools”.

Table 65

Refined realistic worst-case scenario: External livestock exposure (mg cis-tricos-9-ene /kg bw/d)

- Calculation of livestock animal exposure to cis-tricos-9-ene using the ConsExpo 4.1 inhalation model “Exposure to vapour – Constant rate”.

- Default values as reported in section “Representative dietary exposure scenarios”, table “Values and assumptions applied in livestock exposure calculations” above.

- ConsExpo reports for the individual animal species are reproduced in annex 4.5 “Output tables from exposure assessment tools”.

	Beef cattle	Calves	Dairy cattle	Fattening pig	Breeding pig
Inhalative (Cons Expo Web)	1.3×10^{-5}	1.7×10^{-5}	2.6×10^{-5}	4.3×10^{-5}	individual housing 2.0×10^{-5} group housing 2.4×10^{-5}
Trigger value exceeded?	**No**	**No**	**No**	**No**	**No**

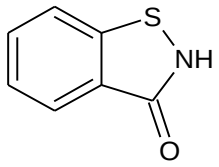
Conclusion

The refinement of the inhalation exposure estimate for cis-tricos-9-ene in livestock animals results in exposure values well below the trigger value of 0.004 mg/kg bw/d. Significant residues in livestock animals from inhalation exposure are not expected.

3.6.3.2.4 BIT (substance of concern)

3.6.3.2.4.1 General information on substance of concern

Table 66

Substance of concern (Common Name)	1,2-Benzothiazol-3(2H)-one (BIT)
CAS number	2634-33-5
Chemical structure	
Molecular formular	C_7H_5NOS
Molar mass	151.19 g/mol
Log Po/w	< 3 (at pH 5, 7, 9 and various temperatures) (Draft CAR, BIT PT2, 6, 9 to 12, under evaluation)
Substance of concern is evaluated as biocidal active substance	currently under evaluation for PTs 2, 6, 9 to 12

3.6.3.2.4.2 Nature of residues

Significant residues of BIT from the intended uses are not expected in food of animal origin (see livestock exposure estimate below). Therefore an evaluation of the nature of residues is not required (according to Guidance on BPR: Volume III Parts B+C, Version 4.0, December 2017).

3.6.3.2.4.3 Estimating Livestock Exposure to Active Substances used in Biocidal Products

Description of scenarios

See section 3.6.3.2.1 “Representative dietary exposure scenarios” above.

Calculations for estimating external livestock exposure

The estimation of external livestock exposure (Tier 1) has been performed according to the Guidance on BPR: Volume III Parts B+C, section 6, Version 4.0, December 2017.

- **Tier 1** (External exposure assessment for livestock animals)

Table 67

Screening scenario: External livestock exposure (mg BIT/kg bw/d)					
- For the screening scenario it is assumed that the whole amount of biocidal product applied in a stable is taken up by animals in that stable. - Calculation and default values according to the screening scenario "surface treatment of animal housing (floor only)" as described in the Guidance on BPR: Volume III Parts B+C, section 6, Version 4.0, December 2017. For relevant default values see also PAR section 3.6.3.2.1 "representative dietary exposure scenarios". - For the assessment a calculated maximal application rate of 5.6 mg BIT per m^2 stable floor area has been considered. (Note the actual surface area of treated cardboards in the stable is only about 1 % of the stable floor area.) - External livestock exposure calculated as $Exp_{livestock} = (R_{appl} \times A_{stable} \div N_{animals\ per\ stable}) \div bw$ with $Exp_{livestock}$: external livestock exposure (mg/kg bw/d); R_{appl}: application rate per stable floor area (mg/m^2); A_{stable}: floor area per stable (m^2); $N_{animals\ per\ stable}$: No. of animal per stable; bw: bodyweight (kg)					
	Beef cattle	**Calves**	**Dairy cattle**	**Fattening pig**	**Breeding pig**
Screening: External livestock exposure (mg/kg bw/d)	0.0332	0.0560	0.1008	0.0840	individual housing 0.0914 group housing 0.1159
Trigger value exceeded?	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**
Conclusion As the trigger value of 0.004 mg/kg bw/d is exceeded, the assessment will proceed with the estimation of external livestock exposure considering realistic worst case scenarios.					

Table 68

Realistic worst-case scenarios: External livestock exposure (mg BIT/kg bw/d)					
Relevant scenario: inhalation exposure (cattle, pig) - The inhalative SVC model considers that the animal is exposed to air containing the substance of concern at its saturated vapour pressure. - calculated as $Exp_{livestock} = SVC \times AVR \div bw$ with $Exp_{livestock}$: external livestock exposure (mg/kg bw/d); SVC: saturated vapour concentration (mg a.s./m^3); AVR: alveolar ventilation rate (m^3/d); bw: bodyweight (kg) - SVC = (VP x MW) ÷ (R x T) with VP: vapour pressure (Pa); MW: molecular weight (g/mol); R: gas constant (8.31451 J/K mol); T: temperature (K)					
	Beef cattle	**Calves**	**Dairy cattle**	**Fattening pig**	**Breeding pig**
Inhalative (SVC model)	6.11×10^{-5}	6.80×10^{-5}	5.19×10^{-5}	7.61×10^{-5}	6.27×10^{-5}
Trigger value exceeded?	**No**	**No**	**No**	**No**	**No**

Conclusion

The inhalation exposure estimate for BIT in livestock animals results in exposure values well below the trigger value of 0.004 mg/kg bw/d. Significant residues in livestock animals from inhalation exposure are not expected.

3.6.3.2.5 Overall conclusion for dietary exposure

External exposure of livestock animals from the intended use of the biocidal product “Stallfliegenmittel Alba” has been estimated for the active substances clothianidin and cis-tricos-9-ene, as well as for the substance of concern Benzisothiazolone (BIT) resulting in values below the trigger value of 0.004 mg/kg bw/d. Therefore significant residues of clothianidin, cis-tricos-9-ene and BIT from the intended uses are not expected in food of animal origin.

Note: As the intended use does not include the application of the biocidal product in poultry stables, no exposure assessment for poultry has been performed. Consequently no conclusion can be drawn on potential residues in poultry edible tissues and eggs.

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

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

3.6.3.4 Summary of exposure assessment

Table 69

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
Scenario 1: Brush treatment	Professionals	Tier 1 [2)]/no PPE	Acceptable
Scenario 2: Manual spray treatment (downwards)	Professionals	Tier 1[2)]/no PPE	Acceptable
Scenario 3: Handling of treated Cardboards	Professionals	Tier 1[2)]/no PPE	Acceptable
Combined scenario: brush treatment + handling of treated cardboards	Professionals	Tier 2[2)] /protective gloves	Acceptable
Combined scenario: manual spray treatment (downwards) + handling of treated cardboards	Professionals	Tier 2[2)] /protective gloves	Acceptable
Scenario 4:]: Re-entry of the general public- stay in a stable, dermal and oral contact with treated cardboards and inhalation of volatilised residues	General public	Tier 1 Application only in areas inaccessible for the general public.	Clothianidin: 1.048 x 10^{-9} mg a.s./kg bw/d Cis-Tricos-9-ene: 12.392 mg a.s./kg bw/d SoC: 1,2-Benzothiazol-3(2H)-one: 4.352 x 10^{-1} mg a.s./kg bw/d

	General public	Tier 2 Application only in areas inaccessible for the general public.	Clothianidin: Not necessary, see Tier 1 Cis-Tricos-9-ene: 0.00338 mg a.s./kg bw/d SoC: 1,2-Benzothiazol-3(2H)-one: 0.00123 mg a.s./kg bw/d

1) External exposure values for professional user are available in Table 52.

2) The Tier with the acceptable risk for the professional user is listed in the table.

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in chapter 3.6.1 Assessment of effects of the active substance on human health.
For the Substance of concern see Section 3.6.2.8 Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern).

3.6.4.2 Maximum residue limits or equivalent

Residue definitions

Table 70

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL (clothianidin)	Reg. (EU) 2017/671	food of plant and animal origin	variable
MRL (cis-tricos-9-ene)	Reg 396 / 2005 Art 18(1)(b)	food of plant and animal origin	default: 0.01 mg/kg

3.6.4.3 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.6.4.4 Risk for industrial users

No industrial applications are intended.

3.6.4.5 Risk for professional users

The occupational risk assessment for the biocidal product Stallfliegenmittel Alba takes into account systemic effects of the active substances clothianidin and cis-tricos-9-ene (Muscalure) as well as systemic and local effects of the substance of concern 1,2-benzisothiazol-3(2H)-one (BIT).

Exposure of professional users to biocidal products generally takes place via the inhalation and/or dermal route and is usually assessed by means of external inhalation and/or dermal exposure values. For many substances (both active substances and substances of concern) external reference values such as occupational exposure limits (OELs) are available. By contrast, internal reference values (AELs) normally exist for active substances only. Therefore, external reference values will preferably be the basis for the risk characterisation of biocidal products as chemical mixtures. In case only internal reference values are available, they will be converted to external reference values in order to allow for a comparison with external exposure values.

Systemic effects – Clothianidin

The primary toxic effect of the active substance clothianidin in a 104-wk rat study is interstitial cell hyperplasia of the ovaries. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to clothianidin resulting from use of the biocidal product. As reference value the $AEL_{long\text{-}term}$ of 0.1 mg/kg bw/day is used.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from exposure of professional users to clothianidin from the biocidal product Stallfliegenmittel Alba, inhalation and dermal exposure to clothianidin is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ (0.1 mg/kg bw/d) of clothianidin is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of clothianidin, the corresponding $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) and an external dermal reference value (RV_{derm}) according to the following equations:

RV_{inhal} (in mg/m³) = $AEL_{long\text{-}term}$ of clothianidin (in mg/kg bw/d) x 60 kg / 10 m³ x100 % / 100 %-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{long\text{-}term}$ of clothianidin (in mg/kg bw/d) / 0.29 %-dermal absorption x 100 %.

By this means RV_{inhal} equivalent to 0.60 mg/m³ and RV_{derm} equivalent to 34.48 mg/kg bw/d are calculated for clothianidin.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the active substance clothianidin.

Dermal absorption rate

As dermal absorption of the active substance the value of 0.29 % derived from *in vitro* study (human skin), [redacted] 2018 is used.

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for the inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the active substance clothianidin resulting from use of the biocidal product Stallfliegenmittel Alba is determined according to the following equations:

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

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

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

The summation of RQ_{inhal} and RQ_{derm} for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 71 gives a detailed overview of the risk assessment results referring to the active substance clothianidin for the biocidal product. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 71. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance clothianidin resulting from the use of the biocidal product Stallfliegenmittel Alba is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 71, the considered scenarios ‘brush treatment’, ‘manual spray treatment (downwards)’ and ‘handling of treated cardboards’ yield RIs of less than 1 already in TIER 1.

Table 71: Overview of detailed risk assessment results referring to the active substance clothianidin for the biocidal product Stallfliegenmittel Alba

Scenario		inhalation external			dermal external				RI	Acceptable
		potential/actual exposure mg/m³	RV_{inhal} mg/m³	RQ_{inhal}	potential/actual exposure mg/person	mg/kg bw/d	RV_{derm} mg/kg bw/d	RQ_{derm}		(yes/no)
brush treatment	Tier 1	0.01	0.60	0.02	79.16	1.32	34.48	0.04	0.05	**yes**
	Tier 2	0.01	0.60	0.02	57.42	0.96	34.48	0.03	0.04	yes
manual spray treatment (downwards)	Tier 1	0.03	0.60	0.04	67.38	1.12	34.48	0.03	0.08	**yes**
	Tier 2	0.03	0.60	0.04	49.11	0.82	34.48	0.02	0.07	yes
handling of treated cardboards	Tier 1	not expected			50.96	0.85	34.48	0.02	0.02	**yes**
	Tier 2				5.10	0.08	34.48	2.46×10^{-3}	2.46×10^{-3}	yes

RV_{inhal}: reference value for the inhalation route

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI: substance specific risk index

Conclusion

Based on the risk assessment of the active substance clothianidin via the inhalation and dermal route, a risk for professional users resulting from the uses ‘brush treatment’, ‘manual spray treatment (downwards)’ and ‘handling of treated cardboards’ with the biocidal product Stallfliegenmittel Alba is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 after TIER 1 consideration. Regarding occupational safety, there are no objections against the uses.

Combined scenarios

A risk characterisation for combined scenarios is carried out. The details of the risk characterisation for combined scenarios are described below.

A risk for professional users referring to the active substance clothianidin resulting from the combined uses of the biocidal product Stallfliegenmittel Alba is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. Table 72 gives a detailed overview of the risk assessment results referring to the active substance clothianidin for the biocidal product Stallfliegenmittel Alba. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 72. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 72, all combined scenarios considered (‘brush treatment + handling of treated cardboards’ and ‘manual spray treatment (downwards) + handling of treated cardboards’) yield RIs of less than 1 already in TIER 1. This means that after TIER 1 consideration no risk for professional users is identified.

Table 72: Overview of detailed systemic risk assessment results referring to the active substance clothianidin regarding combined scenarios for the biocidal product Stallfliegenmittel Alba

combined scenario		inhalation external			dermal external				RI	Acceptable
		potential/actual exposure mg/m³	RV_{inhal} mg/m³	RQ_{inhal}	potential/actual exposure mg/person	mg/kg bw/d	RV_{derm} mg/kg bw/d	RQ_{derm}		(yes/no)
brush treatment + handling of treated cardboards	Tier 1	0.01	0.60	0.02	130.12	2.17	34.48	0.06	0.08	**yes**
	Tier 2	0.01	0.60	0.02	62.51	1.04	34.48	0.03	0.05	yes
manual spray treatment (downwards) + handling of treated cardboards	Tier 1	0.03	0.60	0.04	118.34	1.97	34.48	0.06	0.10	**yes**
	Tier 2	0.03	0.60	0.04	54.21	0.90	34.48	0.03	0.07	yes

RV_{inhal}: reference value for the inhalation route

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI: substance specific risk index

Conclusion

Based on the systemic risk assessment of the active substance clothianidin via the inhalation and dermal route, a risk for professional users resulting from the combined scenarios ‘brush treatment + handling of treated cardboards’ and ‘manual spray treatment (downwards) + handling of treated cardboards’ is unlikely since the respective risk characterisation consistently yields RI of less than 1 after TIER 1 consideration.

Systemic effects – Cis-Tricos-9-ene (Muscalure)

The active substance has no structural alerts for specific toxic effects. Nevertheless, cis-tricos-9-ene (Muscalure) has a moderate skin sensitisation property. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to cis-tricos-9-ene (Muscalure) resulting from use of the biocidal product. As reference value the $AEL_{long\text{-}term}$ of 0.024 mg/kg bw/day is used.

Details of risk characterisation

Reference values

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

RV_{inhal} (in mg/m³) = $AEL_{long\text{-}term}$ of cis-tricos-9-ene (Muscalure) (in mg/kg bw/d) x 60 kg / 10 m³ x 100 % / 100 %-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{long\text{-}term}$ of cis-tricos-9-ene (Muscalure) (in mg/kg bw/d) / 50 %-dermal absorption x 100 %.

By this means RV_{inhal} equivalent to 0.14 mg/m³ and RV_{derm} equivalent to 0.05 mg/kg bw/d are calculated for cis-tricos-9-ene (Muscalure).

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the active substance cis-tricos-9-ene (Muscalure).

Dermal absorption rate

Valid data are not available for the biocidal product Stallfliegenmittel Alba. Therefore, the default value of 50 % according to the EFSA Guidance on Dermal Absorption, 2017 has to be taken into consideration for risk assessment.

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for the inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the active substance cis-tricos-9-ene (Muscalure) resulting from use of the biocidal product Stallfliegenmittel Alba is determined according to the following equations:

RQ_{inhal} = inhalation exposure to cis-tricos-9-ene (Muscalure) (in mg/m³) / RV_{inhal} of cis-tricos-9-ene (Muscalure) (in mg/m³).

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

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

The summation of RQ_{inhal} and RQ_{derm} for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 73 gives a detailed overview of the risk assessment results referring to the active substance cis-tricos-9-ene (Muscalure) for the biocidal product. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 73. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance cis-tricos-9-ene (Muscalure) resulting from the use of the biocidal product Stallfliegenmittel Alba is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 73, the considered scenarios ‘brush treatment’, ‘manual spray treatment (downwards)’ and ‘handling of treated cardboards’ yield RIs of less than 1 already in TIER 1.

Table 73: Overview of detailed risk assessment results referring to the active substance cis-tricos-9-ene (Muscalure) for the biocidal product Stallfliegenmittel Alba

Scenario		inhalation external			dermal external				RI	Acceptable
		potential/actual exposure	RV_{inhal}	RQ_{inhal}	potential/actual exposure		RV_{derm}	RQ_{derm}		
		mg/m^3	mg/m^3		mg/person	mg/kg bw/d	mg/kg bw/d			(yes/no)
brush treatment	Tier 1	$2.74x10^{-4}$	0.14	$1.90x10^{-3}$	1.65	0.03	0.05	0.57	0.57	**yes**
	Tier 2	$2.74x10^{-4}$	0.14	$1.90x10^{-3}$	1.20	0.02	0.05	0.42	0.42	yes
manual spray treatment (downwards)	Tier 1	$5.68x10^{-4}$	0.14	$3.94x10^{-3}$	1.40	0.02	0.05	0.49	0.49	**yes**
	Tier 2	$5.68x10^{-4}$	0.14	$3.94x10^{-3}$	1.02	0.02	0.05	0.36	0.36	yes
handling of treated cardboards	Tier 1	negligible			1.06	0.02	0.05	0.37	0.37	**yes**
	Tier 2				0.11	$1.77x10^{-3}$	0.05	0.04	0.04	yes

RV_{inhal}: reference value for the inhalation route

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI: substance specific risk index

Conclusion

Based on the risk assessment of the active substance cis-tricos-9-ene (Muscalure) via the inhalation and dermal route, a risk for professional users resulting from the uses (‘brush treatment’, ‘manual spray treatment (downwards)’, and ‘handling of treated cardboards’) with the biocidal product Stallfliegenmittel Alba is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 after TIER 1 consideration. Regarding occupational safety, there are no objections against the uses.

Combined scenarios

A risk characterisation for combined scenarios is carried out. The details of the risk characterisation for combined scenarios are described below.

A risk for professional users referring to the active substance cis-tricos-9-ene (Muscalure) resulting from the combined uses of the biocidal product Stallfliegenmittel Alba is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. Table 74 gives a detailed overview of the risk assessment results referring to the active substance cis-tricos-9-ene (Muscalure) for the biocidal product Stallfliegenmittel Alba. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 74. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 74, all combined scenarios considered (‘brush treatment + handling of treated cardboards’ and ‘manual spray treatment (downwards) + handling of treated cardboards’) yield RIs of less than 1 already in TIER 1. This means that after TIER 1 consideration no risk for professional users is identified.

Table 74: Overview of detailed systemic risk assessment results referring to the active substance cis-tricos-9-ene (Muscalure) regarding combined scenarios for the biocidal product Stallfliegenmittel Alba

combined scenario		inhalation external			dermal external				RI	Acceptable
		potential/actual exposure mg/m³	RV_{inhal} mg/m³	RQ_{inhal}	potential/actual exposure mg/person	mg/kg bw/d	RV_{derm} mg/kg bw/d	RQ_{derm}		(yes/no)
brush treatment + handling of treated cardboards	Tier 1	$2.74x10^{-4}$	0.14	$1.90x10^{-3}$	2.71	0.05	0.05	0.94	0.94	**yes**
	Tier 2	$2.74x10^{-4}$	0.14	$1.90x10^{-3}$	1.30	0.02	0.05	0.45	0.45	yes
manual spray treatment (downwards) + handling of treated cardboards	Tier 1	$5.68x10^{-4}$	0.14	$3.94x10^{-3}$	2.47	0.04	0.05	0.86	0.86	**yes**
	Tier 2	$5.68x10^{-4}$	0.14	$3.94x10^{-3}$	1.13	0.02	0.05	0.39	0.40	yes

RV_{inhal}: reference value for the inhalation route

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI: substance specific risk index

Conclusion

Based on the systemic risk assessment of the active substance cis-tricos-9-ene (Muscalure) via the inhalation and dermal route, a risk for professional users resulting from the combined scenarios 'brush treatment + handling of treated cardboards' and 'manual spray treatment (downwards) + handling of treated cardboards' is unlikely since the respective risk characterisation consistently yields RI of less than 1 after TIER 1 consideration.

Systemic effects – 1,2-Benzisothiazol-3(2H)-one (BIT)

The primary toxic effects of the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) are gastrointestinal and hepatic changes. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to 1,2-Benzisothiazol-3(2H)-one (BIT) resulting from use of the biocidal product. As reference value the $AEL_{long\text{-}term}$ of 0.025 mg/kg bw/day from the revised first draft CAR, 2015 ES is used.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from exposure of professional users to 1,2-Benzisothiazol-3(2H)-one (BIT) from the biocidal product Stallfliegenmittel Alba, inhalation and dermal exposure to 1,2-Benzisothiazol-3(2H)-one (BIT) is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ (0.025 mg/kg bw/d) of 1,2-Benzisothiazol-3(2H)-one (BIT) is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of 1,2-Benzisothiazol-3(2H)-one (BIT), the corresponding $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) and an external dermal reference value (RV_{derm}) according to the following equations:

RV_{inhal} (in mg/m³) = $AEL_{long\text{-}term}$ of 1,2-Benzisothiazol-3(2H)-one (BIT) (in mg/kg bw/d) x 60 kg / 10 m³ x100 % / 100 %-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{long\text{-}term}$ of 1,2-Benzisothiazol-3(2H)-one (BIT) (in mg/kg bw/d) / 25 %-dermal absorption x 100 %.

By this means RV_{inhal} equivalent to 0.15 mg/m³ and RV_{derm} equivalent to 0.10 mg/kg bw/d are calculated for 1,2-Benzisothiazol-3(2H)-one (BIT).

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT).

Dermal absorption rate

As dermal absorption of the substance of concern the value of 25 % derived from in vitro study (human skin), [redacted] 2018 is used.

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for the inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) resulting from use of the biocidal product Stallfliegenmittel Alba is determined according to the following equations:

RQ_{inhal} = inhalation exposure to 1,2-Benzisothiazol-3(2H)-one (BIT) (in mg/m³) / RV_{inhal} of 1,2-Benzisothiazol-3(2H)-one (BIT) (in mg/m³).

RQ_{derm} = dermal exposure to 1,2-Benzisothiazol-3(2H)-one (BIT) (in mg/kg bw/d) / RV_{derm} of 1,2-Benzisothiazol-3(2H)-one (BIT) (in mg/kg bw/d).

Dermal exposure to 1,2-Benzisothiazol-3(2H)-one (BIT) given in mg/kg bw/d is calculated from dermal exposure to 1,2-Benzisothiazol-3(2H)-one (BIT) given in mg/person through division by 60 kg/person.

The summation of RQ_{inhal} and RQ_{derm} for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 75 gives a detailed overview of the risk assessment results referring to the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) for the biocidal product. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 75. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) resulting from the use of the biocidal product Stallfliegenmittel Alba is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 75, the scenarios ‘manual spray treatment (downwards)’ and ‘handling of treated cardboards’ yield RIs of less than 1 already in TIER 1. By contrast, the RI of the scenario ‘brush treatment’ exceeds the value of 1 after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenario. However when risk mitigation measures are implemented the risk characterisation results consistently yield RI of less than 1 in TIER 2.

Table 75: Overview of detailed risk assessment results referring to the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) for the biocidal product Stallfliegenmittel Alba

Scenario		inhalation external			dermal external				RI	Acceptable
		potential/actual exposure	RV_{inhal}	RQ_{inhal}	potential/actual exposure		RV_{derm}	RQ_{derm}		
		mg/m³	mg/m³		mg/person	mg/kg bw/d	mg/kg bw/d			(yes/no)
brush treatment	Tier 1	$8.15x10^{-4}$	0.15	$5.43x10^{-3}$	6.60	0.11	0.10	1.10	1.10	no
	Tier 2	$8.15x10^{-4}$	0.15	$5.43x10^{-3}$	4.78	0.08	0.10	0.80	0.80	**yes**
manual spray treatment (downwards)	Tier 1	$2.17x10^{-3}$	0.15	0.01	5.62	0.09	0.10	0.94	0.95	**yes**
	Tier 2	2.17x10-3	0.15	0.01	4.09	0.07	0.10	0.68	0.70	yes
handling of treated cardboards	Tier 1	not expected			4.25	0.07	0.10	0.71	0.71	**yes**
	Tier 2				0.42	$7.09x10^{-3}$	0.10	0.07	0.07	yes

RV_{inhal}: reference value for the inhalation route

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI: substance specific risk index

Conclusion

Based on the risk assessment of the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) via the inhalation and dermal route, a risk for professional users resulting from the uses (‘brush treatment’, ‘manual spray treatment (downwards)’ and ‘handling of cardboards’) with the biocidal product Stallfliegenmittel Alba is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 at least after TIER 2 consideration. Regarding occupational safety, there are no objections against the uses taking into account the provisions described in chapter 2.5 of this PAR.

Combined scenarios

A risk characterisation for combined scenarios is carried out. The details of the risk characterisation for combined scenarios are described below.

A risk for professional users referring to the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) resulting from the combined uses of the biocidal product Stallfliegenmittel Alba is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. Table 76 gives a detailed overview of the risk assessment results referring to the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) for the biocidal product Stallfliegenmittel Alba. It is noted that for clarity reasons exposure values are rounded to two decimal places in Table 76. However, the underlying calculations are based on unrounded exposure values.

As shown in Table 76, all combined scenarios considered (‘brush treatment + handling of treated cardboards’ and ‘manual spray treatment (downwards) + handling of treated cardboards’) exceed the value of 1 after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenarios. However when risk mitigation measures are implemented the risk characterisation results consistently yield RI of less than 1 in TIER 2.

Table 76: Overview of detailed systemic risk assessment results referring to the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) regarding combined scenarios for the biocidal product Stallfliegenmittel Alba

combined scenario		inhalation external			dermal external				RI	Acceptable
		potential/actual exposure	RV_{inhal}	RQ_{inhal}	potential/actual exposure		RV_{derm}	RQ_{derm}		
		mg/m³	mg/m³		mg/person	mg/kg bw/d	mg/kg bw/d			(yes/no)
brush treatment + handling of treated cardboards	Tier 1	$8.15x10^{-4}$	0.15	$5.43x10^{-3}$	10.84	0.18	0.10	1.81	1.81	no
	Tier 2	$8.15x10^{-4}$	0.15	$5.43x10^{-3}$	5.21	0.09	0.10	0.87	0.87	**yes**
manual spray treatment (downwards) + handling of treated cardboards	Tier 1	$2.17x10^{-3}$	0.15	0.01	9.86	0.16	0.10	1.64	1.66	no
	Tier 2	$2.17x10^{-3}$	0.15	0.01	4.52	0.08	0.10	0.75	0.77	**yes**

RV_{inhal}: reference value for the inhalation route

RQ_{inhal}: risk quotient for the inhalation route

RV_{derm}: reference value for the dermal route

RQ_{derm}: risk quotient for the dermal route

RI: substance specific risk index

Conclusion

Based on the systemic risk assessment of the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) via the inhalation and dermal route, a risk for professional users resulting from the combined scenarios 'brush treatment + handling of cardboards' and 'manual spray treatment (downwards) + handling of treated cardboards' is unlikely since the respective risk characterisation consistently yields RI of less than 1 at least after TIER 2 consideration.

- **Local effects**

The local toxicity profile of the substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) is considered. This substance triggers the classification of the biocidal product Stallfliegenmittel Alba with H317("May cause an allergic skin reaction").

Qualitative local risk characterisation

The substance of concern 1,2-Benzisothiazol-3(2H)-one (BIT) triggers the classification of the biocidal product Stallfliegenmittel Alba with H317 ("May cause an allergic skin reaction") and is therefore assigned in hazard classification band B according to the Guidance on substances of concern (Annex A to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)). This guidance states that for these substances of concern a qualitative exposure and risk assessment should be performed to determine whether precautionary statements associated with hazard statements are sufficient or whether other risk mitigation measures should be applied.
It is assumed that the application of the precautionary statements associated with the concerned hazard statement H317 and the provisions described in chapter 2.5 are sufficient to minimise the risk for professional users.

Table 77: Relevant classification and resulting hazard categories

b.p. concentration in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)
100	Skin Sens. 1, H317	medium

For the concentrated biocidal product local risk assessment is triggered by the skin sensitisation (Skin Sens. 1, H317) as this classification is allocated to the hazard category "medium" (Table 77).
For a concentration of biocidal product in application solution of 36 % no classification for local effects is required. Thus local risk assessment is not performed.
Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part

B Risk Assessment (December 2017) the following tables are prepared to carry out the qualitative risk assessment for local effects regarding contact with the skin of the biocidal product Stallfliegenmittel Alba for the intended uses ‘brush treatment’ (Table 78), ‘manual spray treatment (downwards)’ (Table 79), and ‘handling of treated cardboards’ (Table 80). With the proposed risk mitigation measures the reduction of dermal contact minimises the anticipated health risk to an acceptable level for the intended uses.

Table 78: Summary of qualitative conclusions for local risk assessment for scenario 'brush treatment'

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing and loading Dilution of b.p. (Manual pouring)	100 %	H317	medium	5 pouring, few minutes per day	Skin: Incidental contact to hands Eyes: Contact unlikely	**Technical Measure: -** **Organisation[1]:** - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Chemical protective gloves (EN 374)	**Acceptable** + Used for short duration + Professionals using appropriate PPE

Application of insecticide using a brush	100 %	H317	medium	120 min per day	Skin: Contact of hands and body expected. Eyes: incidental contact possible	**Technical Measure:** - **Organisation[1]:** - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Chemical protective gloves (EN 374) - protective coverall (at least type 6, EN 13034)	**Acceptable** + Professionals using appropriate PPE

Washing out a brush	100 %	H317	medium	Few minutes per day	<u>Skin:</u> Contact of hands expected <u>Eyes:</u> Contact unlikely	**Technical Measure: -** **Organisation[1]:** - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Chemical protective gloves (EN 374)	**Acceptable** + Used for short duration + Professionals using appropriate PPE

[1)] Organisational measures include implementation of occupational hygiene standards. In Germany, the provisions of the Hazardous Substances Ordinance are obeyed.

Table 79: Summary of qualitative conclusions for local risk assessment for scenario 'manual spray treatment (downwards)'

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Mixing and loading Dilution of b.p. (Manual pouring)	100 %	H317	medium	few minutes per day	Skin: Incidental contact to hands Eyes: contact unlikely	**Technical Measure:** - **Organisation[1]:** - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Chemical protective gloves (EN 374)	**Acceptable** + Used for short duration + Professionals using appropriate PPE

Application of insecticide by spraying	36 %	H317	medium	120 min per day	Skin: Contact of hands and body expected. Eyes: contact unlikely	**Technical Measure:** - **Organisation[1]:** - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Chemical protective gloves (EN 374) - protective coverall (at least type 6, EN 13034)	**Acceptable** + Professionals using appropriate PPE
Cleaning of spray equipment	36 %	H317	medium	5 minutes per day	Skin: Contact of hands and body expected Eyes: Contact unlikely	**Technical Measure:** - **Organisation[1]:** - Regular cleaning of equipment - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Chemical protective gloves (EN 374) - protective coverall (at least type 6, EN 13034)	**Acceptable** + Used for short duration + Professionals using appropriate PPE

[1)] Organisational measures include implementation of occupational hygiene standards. In Germany, the provisions of the Hazardous Substances Ordinance are obeyed.

Table 80: Summary of qualitative conclusions for local risk assessment for scenario 'handling of treated cardboards'

Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Acceptability
Handling of treated cardboards	100 %	H317	medium	several minutes per day	Skin: Incidental contact to hands Eyes: contact unlikely	**Technical Measure:** - **Organisation[1]:** - Avoidance of contact with contaminated tools and objects - Management/supervision in place to check that the RMMs in place are being used correctly - Training for staff on good practice - Good standard of personal hygiene **PPE:** - Chemical protective gloves (EN 374)	**Acceptable** + Professionals using appropriate PPE

[1)] Organisational measures include implementation of occupational hygiene standards. In Germany, the provisions of the Hazardous Substances Ordinance are obeyed.

Conclusion

Concerning the sensitising properties of biocidal product Stallfliegenmittel Alba, exposure should be minimised with risk mitigation measures. If the proposed risk mitigation measures are implemented, the intended uses ('brush treatment', 'manual spray treatment (downwards)', and 'handling of treated cardboards') do not lead to concern for professional users.

Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product Stallfliegenmittel Alba is unlikely for the intended uses 'brush treatment', 'manual spray treatment (downwards)', and 'handling of treated cardboards'. Risk mitigation measures described in chapter 2.5 have to be taken into account in order to ensure safe use of the biocidal product Stallfliegenmittel Alba.

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

3.6.4.6 Risk for non-professional users

Not relevant.

3.6.4.7 Risk for the general public

Table 81: Systemic effects

Clothianidin:

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Re-entry of the general public-stay in a stable, dermal and oral contact with treated cardboards and inhalation of volatilised residues	1	10	0.1	1.048×10^{-9}	1.05×10^{-6}	yes

Cis-Tricos-9-ene:

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Re-entry of the general public-stay in a stable, dermal and oral contact with treated cardboards and inhalation of volatilised residues	1	AEL is based on intake rates of the structurally related higher-mono-alkenes (C17:1-C30:1) as natural food component of various sources	0.024	12.392	51633 %	no
	2		0.024	0.00338	14.1 %	yes

1,2-Benzisothiazol-3(2H)-one:

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/d)	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Re-entry of the general public-stay in a stable, dermal and oral contact with treated cardboards and inhalation of volatilised residues	1	5	0.025	0.4352	1741	no
	2	5	0.025	0.00123	4.9	yes

Combined scenarios are not required for the general public because only inhalation exposure during re-entry is considered relevant.

- **Local effects**

The biocidal product is classified as Skin Sens. 1, H317. Due to label instructions as proposed by the applicant, dermal and oral contact is excluded for the general public. Thus, no local effects due to dermal exposure are expected to occur. No additional risk mitigation measures are required.

Cumulative exposure estimate

Table 82: Systemic effects

Task/ Scenario	Tier	Estimated exposure (mg/kg bw/d)		AEL (mg/kg bw/d)		Hazard index	Acceptable (yes/no)
Re-entry of the general public - stay in a stable	1	Clothianidin:	1.048×10^{-9}	Clothianidin:	0.1	0.19	yes
	2	cis-Tricos-9-ene:	0.00338	cis-Tricos-9-ene:	0.024		
	2	BIT:	0.00123	BIT:	0.025		

Conclusion

No human health risk was identified from exposure to the active substances and the identified substance of concern.

Hence, the biocidal product is considered safe for the general public if used as intended and if all safety advices are followed during application.

The exposure assessment was based on the assumption that the treated cardboards are placed on the walls in the stables in which insect pests are likely to occur, where they will not be contacted by the general public. Thus, no dermal and oral exposure is expected for the general public. An appropriate labelling is required.

3.6.4.8 Risk for consumers via residues in food

External exposure of livestock animals (except poultry) from the intended use of the biocidal product “Stallfliegenmittel Alba” has been estimated for the active substances clothianidin and cis-tricos-9-ene, as well as for the substance of concern Benzisothiazolone (BIT) resulting in values below the trigger value of 0.004 mg/kg bw/d. Therefore, significant residues of clothianidin, cis-tricos-9-ene and BIT from the intended uses are not expected in food of animal origin.

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

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

A combined exposure and risk assessment for medium and long-term exposure is necessary for the active substance clothianidin and the co-formulant BIT. The derivation of the reference values for each substance is based on the most sensitive endpoint and species (for an overview see table).

After repeatedly administration of clothianidin, animal experiments showed primarily effects on organs of the haematopoietic system and reproductive organs. Furthermore, neurotoxic effects and effects on body weight and local effects on the stomach are reported.

After BIT exposure, adverse effects on clinical chemical parameters and body weight were shown in various studies. Furthermore, local effects on the stomach were seen. At the BPC-WG (Now. 2015) it was agreed to base the $AEL_{medium-term}$ and $AEL_{long-term}$ on the same study and use an additional safety factor of 2 for the extrapolation from medium-term to long-term.

The primary target organs are not completely identical, but both substances show effects on body weight (medium- and long-term) and hepatotoxic effects as well as local effects on the stomach (long-term). For these endpoints, the reference values were adjusted as part of an "aHI" for a Tier IIIb in accordance with the "Guidance on the BPR (2017)" (Chapter 4.4.1). If the applicant provides suitable data to elucidate the mode of action that is responsible for the effects on body weight, a further, albeit very complex, refinement might be theoretically conceivable.

For the active substance cis-tricos-9-ene no organ specific endpoints are known. In the CAR no animal studies with repeated administration are reported. The toxicological assessment is based as a conservative approach on a read-across from the food intake of mono alkenes with higher chain length. Therefore, it is not necessary to include the active substance cis-tricos-9-ene into a combined exposure and risk assessment.

Table 83: Overview of end points used in reference values derivation

		Clothianidin[18]	*Cis*-Tricos-9-ene[19]	BIT[20] (1,2-Benzisothia-zol-3(2H)-one)
Short –term	$AEL_{short-term}$	0.25 mg/kg bw	0.57 mg/kg bw/d	0.06 mg/kg bw/d
	Critical target organ	Central nervous system	none; read a cross to food intake of higher chain length mono alkanes	Maternal body weight in a developmental toxicity study
	Further target organs	Body weight, organs of the haematopoietic system		none
Medium-term	$AEL_{medium-term}$	0.2 mg/kg bw/d	0.024 mg/kg bw/d	0.05 mg/kg bw/d
	Critical target organ	Organs of the haematopoietic system; developmental toxic effects	None; read a cross to food intake of mono	Change of clinical-chemical parameters, local effects on the stomach

[18] CAR Clothianidin 2014, PT 18

[19] CAR *cis*-Tricos-9-ene 2012, PT 19

[20] CAR 1,2-BENZISOTHIAZOL-3-(2H)-ONE (BIT) 2015, PT 2, 6, 9, 10, 11, 12, 13

	Further target organs	Body weight, kidney	alkanes of higher chain length	Body weight, liver
Long-term	$AEL_{long-term}$	0.1 mg/kg bw/d	0.024 mg/kg bw/d	0.025 mg/kg bw/d[21]
	Critical target organ	Organs of the reproductive system (Ovary, sperms) local effects on the stomach	None; read a cross to food intake of mono alkanes of higher chain length	Change of clinical-chemical parameters, local effects on the stomach
	Further target organs	Body weight, nervous system, kidney, liver		Body weight, liver

For acute exposure scenarios no combined assessment is necessary, as only for clothianidin the central nervous system is the primary target organ. Effects on the body weight of clothianidin and BIT are not seen as relevant acute effects but are taken into account in scenarios with repeated exposure (medium- and long-term).

The following table gives adjusted reference values for organ specific adjusted HI target-organ (aHIto) for medium- and long-term scenarios which can be used for a tier IIIB refinement according to “Guidance on the BPC (2017)” (Table 84).

Table 84: Adjusted reference values for organ specific adjusted HI target-organ (aHIto)

Reference value			Studie	SF
medium-term				
adjusted $AEL_{medium-term}$ body weight	Clothianidin	0.27 mg/kg bw/d[22]	90-d rat; [redacted] (1997) 104-w rat; [redacted] (2000)	100 100
	BIT	0.25 mg/kg bw/d	90-d rat; [redacted] (2007)	100
long-term				
adjusted $AEL_{long-term}$ body weight	Clothianidin	0.27 mg/kg bw/d	104-w rat; [redacted] (2000)	100
	BIT	0.13 mg/kg bw/d	90-d rat; [redacted] (2007)	200
adjusted $AEL_{long-term}$ **stomach**	Clothianidin	0.82 mg/kg bw/d	104-w rat; [redacted] (2000)	100
	BIT	0.05 mg/kg bw/d	90-d rat; [redacted] (2007)	200
adjusted $AEL_{long-term}$ **liver**	Clothianidin	0.47 mg/kg bw/d	78-w mice; [redacted] (2000)	100
	BIT	0.025 mg/kg bw/d[5]	90-d rat; [redacted] (2007)	200

The aHIto needs to be derived for all target organs in long-term scenarios and the most critical values are used for further risk characterisation.

[21] BPC-WG, Nov. 2015

[22] No further refinement was possible

3.6.4.9.1 Summary of risk characterisation for cumulative indirect exposure

The cumulative risk characterization for indirect exposure was based on not adjusted reference values as no risk was identified without refinement.

Table 85 Systemic effects

Task/ Scenario	Tier	Estimated exposure (mg/kg bw/d)	AEL (mg/kg bw/d)	Hazard index	Acceptable (yes/no)
Re-entry of the general public - stay in a stable	1/2	Clothianidin: 1.048 x 10^{-9} cis-Tricos-9-ene: 0.00338 BIT: 0.00123	Clothianidin: 0.1 cis-Tricos-9-ene:0.024 BIT: 0.025	0.19	yes

Tier 2 - Cumulative risk characterisation for the professional user

Based on the above presented analysis a combined/cumulative risk assessment involving the active substance clothianidin and the substance of concern BIT is required for all the assessed scenarios for the professional user.

Table 86: Tier 2 cumulative risk assessment for the professional user for the active substances clothianidin and cis-tricos-9-ene as well as the substance of concern BIT

Scenario		HQ			HI[1]	acceptable
		Clothianidin	Cis-tricos-9-ene	BIT		(yes/no)
Brush treatment - indoors-formulation type: liquid	Tier 1	0.055	0.575	1.105	1.73	no
	Tier 2	0.044	0.417	0.803	1.26	no
Manual spray treatment downwards	Tier 1	0.076	0.491	0.950	1.52	no
	Tier 2	0.076	0.359	0.697	1.12	no
Handling of treated cardboards	Tier 1	0.025	0.369	0.708	1.10	no
	Tier 2	2.46x10^{-3}	0.037	0.071	0.11	yes
Combined scenario						
Brush treatment - indoors-formulation type: liquid + Handling of treated cardboards	Tier 1	0.079	0.943	1.813	2.84	no
	Tier 2	0.047	0.454	0.874	1.37	no
Manual spray treatment downwards + Handling of treated cardboards	Tier 1	0.101	0.860	1.658	2.62	no
	Tier 2	0.070	0.396	0.767	1.23	no

[1]: HI: Hazard Index; sum of the Hazard Quotients (HQs) for each substance. HQ: estimation of internal exposure/AEL. Acceptable, if HI ≤ 1

On a Tier II (cumulative risk assessment) basis a risk was identified for the professional users for all scenarios except “Handling of treated cardboards” where a risk for the professional user was unlikely after tier II consideration. Thus for the two single as well as the combined scenarios a Tier IIIa assessment was performed.

Tier IIa – Cumulative risk assessment for the professional user

Based on the above presented analysis a combined/cumulative risk assessment involving the active substance clothianidin and the substance of concern BIT is required on the Tier IIIa (cumulative assessment) basis, as for the active substance cis-tricos-9-ene no organ specific endpoints are known. Therefore, it is not necessary to include the active substance cis-tricos-9-ene into a Tier IIIa combined exposure and risk assessment.

Table 87**: Tier IIIa cumulative risk assessment for the professional user for the active substance clothianidin and the substance of concern BIT**

Scenario		HQ		HI[1]	acceptable
		Clothianidin	BIT		(yes/no)
Brush treatment - indoors-formulation type: liquid	Tier 1	0.055	1.105	1.16	no
	Tier 2	0.044	0.803	0.85	yes
Manual spray treatment downwards	Tier 1	0.076	0.950	1.03	no
	Tier 2	0.076	0.697	0.76	yes
Handling of treated cardboards	Tier 1	0.025	0.708	0.73	yes
	Tier 2	2.46×10^{-3}	0.071	0.07	yes
Combined scenario					
Brush treatment - indoors-formulation type: liquid + Handling of treated cardboards	Tier 1	0.079	1.813	1.89	no
	Tier 2	0.047	0.874	0.92	yes
Manual spray treatment downwards + Handling of treated cardboards	Tier 1	0.101	1.658	1.76	no
	Tier 2	0.070	0.767	0.84	yes

[1]: HI: Hazard Index; sum of the Hazard Quotients (HQs) for each substance. HQ: estimation of internal exposure/AEL. Acceptable, if HI ≤ 1

Conclusion

Calculation of the Hazard Index (HI) in a Tier IIIa cumulative risk assessment indicated no risk for any of the exposure scenarios at the latest in tier II after consideration of risk mitigation measures. Hence, no further refinement of the assessment (Tier IIIb/c cumulative risk assessment) is required.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

No industrial applications are intended.

3.6.4.10.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product Stallfliegenmittel Alba is unlikely for the intended uses ‘brush treatment’, ‘manual spray treatment (downwards)’ and ‘handling of treated cardboards’. Risk mitigation measures described in chapter 2.5 have to be taken into account in order to ensure safe use of the biocidal product Stallfliegenmittel Alba.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.10.3 Summary of risk characterisation for indirect exposure

Table 88

Scenario, Tier	**Relevant reference value**	**Estimated uptake** mg/kg bw/d	**Estimated uptake/ reference value** (%)	**Acceptable** (yes/no)
Re-entry of the general public- stay in a stable, dermal and oral contact with treated cardboards and inhalation of volatilised residues – Tier 1	Clothianidin: 0.1 mg/kg bw/d	1.048×10^{-9} mg a.s./kg bw/d	1.05×10^{-6} %	yes
	Cis-Tricos-9-ene: 0.024 mg/kg bw/d	12.392 mg a.s./kg bw/d	51633 %	no
	1,2-Benzisothiazol-3(2H)-one: 0.025 mg/kg bw/d	4.352×10^{-1} mg a.s./kg bw/d	1741 %	no
Re-entry of the general public- stay in a stable, dermal and oral contact with treated cardboards and inhalation of volatilised residues – Tier 2	Cis-Tricos-9-ene: 0.024 mg/kg bw/d	0.00338 mg a.s./kg bw/d	14.1 %	yes
	1,2-Benzisothiazol-3(2H)-one: 0.025 mg/kg bw/d	0.00123 mg a.s./kg bw/d	4.9 %	yes

3.7 Risk assessment for animal health[23]

Exposure of the general public to the biocidal product Stallfliegenmittel Alba containing 2.4 % (w/w) clothianidin and 0.05 % (w/w) cis-tricos-9-ene as active substances and 0.2 % 1,2-Benzothiazol-3(2H)-one as identified substance of concern is considered acceptable in Tier 2, if the biocidal product is used as intended and all safety advices are followed.
This also applies to pets because exposure of pets is expected to be covered by exposure to toddlers.

As the biocidal product is applied in animal housings also livestock animals can be exposed. To assess such an exposure the realistic worst case scenarios of the dietary exposure assessment are adopted. For details on the assessment, refer to section 3.6.3.2. According to this section the following scenarios were excluded by risk mitigation measures proposed by the applicant:

- oral exposure by licking of treated surfaces (cattle, pig)
- oral exposure via uptake of feed contaminated in trough (cattle, pig)
- dermal exposure by rubbing against surfaces (cattle, pig)

The following risk mitigation measures are required:

1. Do not apply directly on or near feed or drinks, or on surfaces or utensils likely to be in direct contact with feed, drinks and livestock.
2. Attach treated cardboards inaccessible for the general public, pets, livestock animals and other non-target animals.
3. For use only in areas that are inaccessible to the general public, pets and non-target animals.

In the absence of animal-specific reference values, exposure estimates are compared to the human $AEL_{longterm}$, assumed to be a worst case.

23 Pets and domestic animals. Regarding wild animals, please refer to chapter 3.6.3.2.

Realistic worst-case scenarios: External livestock exposure (mg clothianidin/kg bw/d)					
Relevant scenario: inhalation exposure (cattle, pig) The inhalative SVC model considers that the animal is exposed to air containing the substance of concern at its saturated vapour pressure.					
	Beef cattle	**Calves**	**Dairy cattle**	**Fattening pig**	**Breeding pig**
Inhalative (SVC model)	1.31×10^{-9}	1.64×10^{-9}	1.25×10^{-9}	1.83×10^{-9}	1.51×10^{-9}
Human $_{AEL long-term}$	0.1	0.1	0.1	0.1	0.1
% AEL	0.000001	0.000002	0.000001	0.000002	0.000002
Acceptable	Yes	Yes	Yes	Yes	Yes

Refined realistic worst-case scenario: External livestock exposure (mg cis-tricos-9-ene /kg bw/d)					
- Calculation of livestock animal exposure to cis-tricos-9-ene using the ConsExpo 4.1 inhalation model "Exposure to vapour – Constant rate".					
	Beef cattle	**Calves**	**Dairy cattle**	**Fattening pig**	**Breeding pig**
Inhalative (Cons Expo)	1.3×10^{-5}	1.7×10^{-5}	2.6×10^{-5}	4.3×10^{-5}	2.4×10^{-5} *
Human $_{AEL long-term}$	0.024	0.024	0.024	0.024	0.024
% AEL	0.054167	0.070833	0.108333	0.179167	0.100000
Acceptable	Yes	Yes	Yes	Yes	Yes

* group housing

Realistic worst-case scenarios: External livestock exposure (mg BIT/kg bw/d)					
Relevant scenario: inhalation exposure (cattle, pig) - The inhalative SVC model considers that the animal is exposed to air containing the substance of concern at its saturated vapour pressure.					
	Beef cattle	**Calves**	**Dairy cattle**	**Fattening pig**	**Breeding pig**
Inhalative (SVC model)	6.11×10^{-5}	6.80×10^{-5}	5.19×10^{-5}	7.61×10^{-5}	6.27×10^{-5}
Human $_{AEL long-term}$	0.025	0.025	0.025	0.025	0.025
% AEL	0.244400	0.272000	0.207600	0.304400	0.250800
Acceptable	Yes	Yes	Yes	Yes	Yes

Cumulative assessment for livestock animals

For cumulative assessment the risk ratios of the singles components are summed up (Harzard index).

	Beef cattle	Calves	Dairy cattle	Fattening pig	Breeding pig
Hazard index	0.002986	0.003428	0.003159	0.004836	0.003508
Acceptable	Yes	Yes	Yes	Yes	Yes

If all risk mitigation measures described above are followed, no health risk is identified for the corresponding animal species if exposure values are compared to the human $AEL_{long\text{-}term}$. Even for cumulative assessment the risk ratio is far below 1. It must be noted that exposure estimates for dietary exposure do not take into consideration that the animals are very much smaller when they enter the stable. Based on the anthropometric parameters this may result in higher exposure estimates. However, as the risk ratios for cumulative exposure are in maximum 200-fold below the threshold of 1, no animal health risk is expected even for these smaller animals.

3.8 Risk assessment for the environment

3.8.1 General information

The biocidal product (b.p.) 'Stallfliegenmittel Alba' is used as insecticide (PT18) for the control of stable flies and house flies in animal housings (cattle stable, piggery, horse stable, and sheep pens) by professional users (farmers). The b.p. has to be applied on 30-60 prepunched non-absorbent cardboards/stripes (max. 1.8 m² per 200 m² stable floor area), which will be fixed in different places where flies preferentially rest. The product has been assessed as applied by the applicant for the use on cardboards, namely by applying the undiluted product via painting and the diluted product by low pressure coarse spraying.

The b.p. 'Stallfliegenmittel Alba' contains the two active substances clothianidin (2.4% w/w equal to 26.04 g a.s./L by considering product density of 1.13 g/mL and a.s. purity of 96%) and *cis*-tricos-9-ene (Muscalure, 0.05%) as potentially relevant for risk assessment. However, the environmental assessment for the biocidal product 'Stallfliegenmittel Alba' is solely based on the neonicotinoid clothianidin for the following reasons:
According to the assessment report of Austria (2012) cis-tricos-9-ene is a sex pheromone released by flies to attract male and female adults of the species *Musca domestica* and only limited information is available for this a.s. Nonetheless, the available data also indicate that *cis*-tricos-9-ene has a highly target-specific mode of action and only a low (eco)toxicity in non-target organisms. The available aquatic ecotoxicity studies with fish and daphnids show no toxic effects up to and above the water solubility limit of *cis*-tricos-9-ene. Furthermore, cis-tricos-9-ene is ready biodegradable and has a high vapour pressure and acts by slowly vaporising, resulting in a low steady state indoor air concentration.
Due to the above reasons and the fact that the product 'Stallfliegenmittel Alba' is intended to be used exclusively indoors it is reasonable to assume that any hazard or risk for environmental non-target organisms will be driven by the application of the neonicotinoid clothianidin. Therefore, the active substance cis-tricos-9-ene is not further considered for the environmental assessment of the product 'Stallfliegenmittel Alba'.

The applicant has a full letter of access to the data from the active substance dossier.
No new further information concerning fate and behaviour or environmental effects of clothianidin compared to the CAR has been provided for product authorisation of 'Stallfliegenmittel Alba', so that the environmental assessment is based upon data given in the agreed CAR and AR (DE 2014) for clothianidin.

3.8.1.1 Mixture toxicity

No ecotoxicological data is available for the biocidal product 'Stallfliegenmittel Alba'. For mixture toxicity assessment, active substances and substances of concern (SoC) should be taken into account.
As discussed above, only the active substance clothianidin is considered as relevant for the effects assessment of the product. Furthermore, the product 'Stallfliegenmittel Alba' is intended to be used indoors in animal housings and on non-absorbent cardboards only and negligible emissions to the environment are expected during the use of the biocidal product. Therefore, an assessment of mixture toxicity is not necessary.

3.8.1.2 Aquatic compartment (including sediment and STP)

For clothianidin, a **$PNEC_{water}$ of 0.08 µg/L** was derived in the CAR by applying an assessment factor of 5 to the lowest long-term effect value of 0.4 µg/L for *Chironomus riparius*

For the sediment compartment, a **$PNEC_{sed}$ of 0.34 µg/kg ww** was derived from the $PNEC_{water}$ using the equilibrium partitioning method, as no tests with spiked sediment were available.

In an activated sludge respiration inhibition test with sludge from domestic sewage treatment plant a NOEC of 1000 mg/L was found. A **$PNEC_{STP}$ of 100 mg/L** was derived from the available study.

Table 89

Conclusion used in Risk Assessment –Aquatic toxicity	
Value/conclusion	$PNEC_{water}$ = 0.08 µg/L $PNEC_{sed}$ = 0.34 µg/kg ww $PNEC_{STP}$ = 100 mg/L
Justification for the value/conclusion	The $PNEC_{water}$ was derived by applying an assessment factor of 5 to the lowest effect value for *Chironomus riparius*. The $PNEC_{sed}$ was derived from the $PNEC_{water}$ using equilibrium partitioning method, as no tests with spiked sediment are available. The $PNEC_{STP}$ was derived by applying an assessment factor of 10 to the no effect concentration.

3.8.1.3 Terrestrial compartment (including groundwater)

For clothianidin, a **$PNEC_{soil}$ of 1.8 µg/kg ww** was derived in the CAR based on the lowest effect value of 0.02 mg/kg dw for *Poecilus cupreus* and using an assessment factor of 10.

For the metabolite TMG that is formed by degradation of clothianidin in manure, it was concluded in the CAR that it has the same toxicity to soil organism as the parent substance clothianidin. Therefore, the $PNEC_{soil}$ derived for clothianidin is also applicable for the assessment of the metabolite TMG in soil.

Bees:

Clothianidin has shown to be highly toxic to bees both by oral and contact exposure (48h-$LD_{50,}$oral = 0.0038 µg/bee). No agreed assessment concept is currently available to assess the risk for bees (honeybees as well as wild bees). In the CAR, a $PNEC_{bee}$ of 14.6 µg a.s./kg nectar/pollen was derived using an assessment factor of 10 in a first approach. However, it can be assumed that an assessment factor of 10 might be too small to consider both long-term sublethal effect as well as extrapolation from honey bees to solitary bees and bumblebees. Thus, the $PNEC_{bee}$ is not used for the further risk assessment.

To alert the user that the product 'Stallfliegenmittel Alba' potentially endangers bees and that the product should be used carefully according to the instructions on the label, at the 90. CA Meeting 2020 the following warning sentence was agreed: "This biocidal product contains clothianidin which is dangerous to bees." However, it was agreed to assign this warning sentence only for products used outdoor. As the product "Stallfliegenmittel Alba" is only used indoor, the warning sentence should not be added to the product label.

Table 90

Conclusion used in Risk Assessment –Terrestrial toxicity	
Value/conclusion	Clothianidin: $PNEC_{soil}$ = 1.8 µg/kg ww TMG: $PNEC_{soil}$ = 1.8µg/kg ww
Justification for the value/conclusion	The $PNEC_{soil}$ for clothianidin was derived by applying an assessment factor of 10 on the lowest effect value for *Poecilus cupreus.* It is concluded that the metabolite TMG has the same toxicity to soil organisms as the parent substance clothianidin.

3.8.1.4 Atmosphere

Accumulation of clothianidin in the air is not to be expected, because the vapour pressure of clothianidin ranges from 3.8 x 10^{-11} to 1.3 x 10^{-10} Pa and consequently direct evaporation is not expected. The Henry's Constant is 2.9 x 10^{-11} at 20°C, therefore, clothianidin has a low potential of volatilising from water. The half-life of clothianidin in the troposphere was estimated to be 2.8 hours (chemical lifetime: 4.1 hours) considering a global 24-hours mean OH-radical concentration.

3.8.1.5 Non-compartment specific effects

Due to the low bioaccumulation potential of the active substance clothianidin and the indoor use of the product 'Stallfliegenmittel Alba', an assessment of primary or secondary exposure is not required.

3.8.1.6 Summary of effects assessment

The PNEC values for clothianidin from the CAR are summarized in the following table:

Table 91

Summary table on calculated PNEC values	
Compartment	**PNEC**
STP	100 mg/L
Surface water	0.08 µg/L
sediment	0.34 µg/kg ww
soil	1.8 µg/kg ww

3.8.2 Fate and behaviour

Clothianidin

For the environmental exposure estimation, the following information and endpoints have to be considered:

The vapour pressure of clothianidin ranges from 3.8 x 10^{-11} to 1.3 x 10^{-10} Pa. Direct evaporation is not expected, consequently. The Henry's Constant is 2.9 x 10^{-11} at 20°C, therefore, clothianidin has a low potential of volatilising from water. The half-life of clothianidin in the troposphere was estimated to be 2.8 hours (chemical lifetime: 4.1 hours) considering a global 24-hours mean OH-radical concentration. Based on these results, accumulation of clothianidin in the air is not to be expected.

The water solubility is 0.327 g/L at 20 °C. Hydrolysis only occurs at high pH (e.g. 9) and high temperature. Solar radiation will lead to a rapid photolytic degradation of clothianidin in aquatic systems under experimental conditions. Aqueous photolysis studies with clothianidin show that the compound degraded rapidly with an experimental half-life (DT_{50}) of 3.3 hours (first order rate constant = 0.2088 h^{-1}). However, the transferability of the degradation rates to environmental conditions is rather limited.

According to the AR (Ref MS DE, 2014), clothianidin is not readily biodegradable. In two German water-sediment systems partial degradation was observed. However, primary degradation of clothianidin in the water phase and in the entire systems is slow.

Taking into account the three assessment-relevant parameters primary and ultimate degradation together with the extent of bound residues in the sediment, clothianidin must be considered to be persistent in aquatic systems. In both water-sediment systems, the metabolite TMG was observed in the sediments

phase as major metabolite. As TMG could also be detected in the anaerobic manure samples (see the text below), it seems to be the main metabolite of the anaerobic degradation pathway of clothianidin.
Degradation rate and route of clothianidin was also investigated in veal calf, pig and chicken manure, respectively. The veal calf and pig manures were incubated under anaerobic laboratory conditions, the chicken manure samples under aerobic conditions. In the manure extracts under anaerobic conditions, only the metabolite TMG was identified. The DT_{50} value for the metabolite derived from the degradation study in manure indicates a high persistency under anaerobic conditions.
From soil laboratory studies it can be concluded that clothianidin is persistent under aerobic conditions, as the mineralisation of clothianidin was found to be low to negligible. Nevertheless, four metabolites were detected in the soil extracts: MNG (N-methyl-N'-nitroguanidine) and TZNG (N-(2-chloro-5-thiazolylmethyl)-N'-nitroguanidine) besides TZMU (N-(2-chlorothiazol-5-ylmethyl)-N'-methylurea) and NTG (Nitroguanidine) as minor metabolites. Only in one soil, the metabolite MNG is barely over 10% AR. Besides MNG, the metabolite TZNG was further investigated in laboratory soil studies under aerobic conditions.

The adsorption and desorption laboratory studies resulted in an arithmetic mean Koc of 160 mL/g for clothianidin. Clothianidin was found to be stable during both processes, i.e. adsorption and desorption. The major soil metabolite MNG is characterised by a K_{aOC} of 21 mL/g whereas TZNG provided a K_{aOC} of 276 mL/g. The metabolites remained unchanged in the soil. These results indicate that the parent compound and the major transformation products (MNG, TZNG) have medium to very high potential for leaching. However, this was not confirmed in lysimeter and biodegradation field studies. The distribution of clothianidin in the sewage treatment plant is calculated using the SimpleTreat 4.0-model with the following release fractions: to air 0 %, to water 97.8 %, to sludge 2.1 % and the degraded fraction is 0 %.

3.8.2.1 Bioconcentration

No study on bioaccumulation is available for clothianidin. The low Kow of 0.7 indicates that clothianidin has low potential to bioaccumulate in organisms. Both estimated bioconcentration factors for the aquatic (BCF_{fish} = 0.78) and the terrestrial compartment ($BCF_{earthworm}$ = 0.9) are considered to be low.

3.8.3 Exposure assessment

3.8.3.1 General information

The biocidal product (b.p.) 'Stallfliegenmittel Alba' is used as insecticide (PT18) for the control of stable flies and house flies in animal housings (cattle stable, piggery, horse stable, and sheep pens) by professional users (farmers).

Table 92

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Insecticide application in animal housings – painting (smearing) Scenario 2: Insecticide application in animal housings – spraying
ESD(s) used	OECD Emission Scenario Document for Insecticides for stables and Manure Storage Systems No. 14 PT18 (2006)
Approach	Scenario 1: Average consumption Scenario 2: Average consumption
Distribution in the environment	Calculated based on Guidance BPR ENV Vol. IV ENV Part B+C (2017)
Groundwater simulation	Simulation for leaching to groundwater using a higher tier model was not needed
Confidential Annexes	No
Life cycle steps assessed	Scenario 1 and 2: Production: No Formulation No Use: Yes Service life: No
Remarks	

For the biocidal product "Stallfliegenmittel Alba" environmental assessment of the following life cycles are relevant:

- Production of the active substance
- Formulation of the biocidal product
- Application by painting/spraying the b.p. to non-absorbent cardboards by professional farmers
- Waste treatment

Production and formulation

For the life cycle stages 'production' and 'formulation' no exposure assessment has been performed. The production of the active substance takes place outside of the EU and thus has not been assessed in this

report. The stage of formulation, which takes places inside the EU is subject to REACH regulations and thus is also not covered by this report.

Application

The biocidal product ‘Stallfliegenmittel Alba’ is intended to be used by professionals in animal housings (with the exception of poultry stables) to control flies in summertime with an effective in-use period of at least 12 weeks (84 days) before reapplication of biocide might be required. The maximum application frequency is indicated with 3 applications over a period of 6 months per year. The product should be applied on about 30-60 non-absorbent cardboards/stripes (sum ca. 1.8 to 2 m²) either by painting as supplied indoors (in the stable) with a disposable brush (scenario 1) or diluted with water and applied by low pressure coarse spraying by hand held or backpack/knapsack sprayer (scenario 2). During product application the cardboards/stripes are laying horizontally on an area covered with a disposable foil in order to prevent contamination of adjacent stable floor. In case of painting 500 mL of the b.p. should be applied with a disposable brush to pre-punched cardboards. After a drying period, the cardboards will be fixed then in different places where flies preferentially rest (near sunny places on boards, piles, window frames, cants of walls etc.). The cardboards are placed well out of reach of livestock animals. An effective application surface of 1.8 to 2 m² cardboards/stripes is foreseen to treat 200 m² stable floor area. As the b.p. contains 26.04 g a.s./L, the application rate will be 0.065 g a.s. per m² stable floor area. For the spraying application on cardboards/strips 500 mL b.p. will be diluted with 1 L water, the application rate of a.s. will result in the same value of 0.065 g clothianidin per m² stable floor area (and 0.00125 g cis-tricos-9-ene per m² stable floor area).

The applicant provided the following statement which is supported by RefMS DE: Due to the specific application of the b.p. ‘Stallfliegenmittel Alba’ onto cardboards (maximum 3 times per year in the fly season), an exposure to the environment either via direct emission or via manure/slurry is negligible. The product is either used directly as ready-to-use product by painting/brushing onto cardboards or diluted before use and applied by spraying onto cardboards. According to the application description both applications are situated indoors (in the stables) with the cardboards on the ground which is covered with a foil. Thus, no relevant exposure to the environment is foreseen during the application or during the in use period for the active substances or the substance of concern. Exposure to the atmosphere is also considered negligible. Potentially emitted volatilised components of the biocidal product might be expected (cis-tricos-9-ene), however, relevant concentrations are not realistic, as in an open stable air exchange is thinning down the amount volatilised and cis-tricos-9-ene is rapidly eliminated by photo-oxidative reactions. Data on this are available from the AR. Cis-tricos-9-ene, volatilised from the product, decomposes by photooxidation with half-lives of 4.7 hours by OH-radicals and of 2.1 hours by ozone radicals. Because of degradation and physico-chemical properties no effects on the atmospheric environment are likely.

In conclusion due to the proposed use, emissions to the environment can be considered as negligible.

Waste disposal

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

3.8.3.2 Fate and distribution in exposed environmental compartments

Table 93

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Soil	Ground-water	Air	Other
Scenario 1	No	No	No	No	No	No	No	No	No
Scenario 2	No	No	No	No	No	No	No	No	No

Table 94

Summary table on relevant metabolites		
Metabolite/transformation- or reaction product	**Compartment**	**% Active Substance**
MNG (N-methyl-N'-nitroguanidine)	soil	max. 10.7 % AR
TZNG (N-(2-chloro-5-thiazolylmethyl)-N'-nitroguanidine)	soil	max. 9.1 % AR
TMG	manure	max. 58.4 % AR
TMG	sediment	max. 22.9 % AR

Table 95

	Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**		**Unit**	**Remarks**
	clothianidin	**cis-tricos-9-ene**		
Molecular weight	249.7	322.6	g/Mol	
Melting point	176.8	-2	°C	
Boiling point		380	°C	
Vapour pressure (at 12°C)	2.136×10^{-11}	3.597×10^{-2}	Pa	
Water solubility (at 12°C)	291.4	6.238×10^{-3}	mg/L	
Log Octanol/water partition coefficient	0.905	> 8.2	Log 10	
Organic carbon/water partition coefficient (Koc)	160	5.01×10^{7}	L/kg	
Henry's Law Constant	1.83×10^{-11}	1.86×10^{3}	Pa m^3/mol	

Biodegradability	Not ready biodegradable	Ready biodegradable		
Rate constant for biodegradation in STP (k_{STP})	0	0.3	h^{-1}	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.4, table 4
DT_{50} for biodegradation in surface water	145.3	-	d (at 12ºC)	Worst case value, total system
DT_{50} for hydrolysis	96 – 301 (pH 9)	no hydrolysable functional groups.	d (at 12ºC /pH)	
DT_{50} for photolysis in water	3.3	no chromophore properties at wavelengths above 290 nm	h (at 25°C)	
DT_{50} for degradation in soil	Clothianidin: 429.8 MNG: 173.7 TZNG: 161.8	1000000	d (at 12ºC)	
DT_{50} for degradation in manure	Clothianidin: 59.9 TMG: 375.5	-	d (at 12ºC)	
DT_{50} for degradation in air	4.1	4.7	h	

- **Emission estimation**

As described above, no emission estimation for the production and formulation steps are required.
As only negligible emissions to relevant environmental compartments are to be expected during the use of the b.p. due to the application on cardboards/strips, an exposure assessment for this lifecycle step is not necessary.
Hence, neither environmental emission estimation has been performed nor PECs have been calculated.

3.8.3.3 Non-compartment specific effects

Due to negligible emissions no PECs have been calculated, neither primary nor secondary poisoning nor aggregated exposure have been assessed.

3.8.4 Risk characterisation

The product ‘Stallfliegenmittel Alba’ is used indoor and has to be applied on non-absorbent cardboards either by painting or by low pressure coarse spraying. In order to ensure an environmentally safe use considering negligible environmental exposure a set of use instructions has been agreed with the applicant. Provided that the professional user applies these instructions carefully, a negligible exposure can be assumed and consequently no PECs have been calculated. Hence, no unacceptable risk is to be expected for any environmental compartment and a quantitative risk characterisation was not performed.

The necessary use instructions to be followed in order to assume a negligible environmental exposure are as follows:

Safe handling of contaminated cardboards:

1) Apply only on non-absorbent cardboards which are then to be fixed to walls or ceilings where flies prefer to rest (e.g. warm sunny places on boards, piles, poles, window frames or cants of walls), but out of range of farm animals.
2) Do not clean the cardboards.
3) Remove all cardboard sheets, which are treated with the b.p. before cleaning and/or disinfectant events in animal housings/shelters.
4) Disposal of contaminated cardboards after use to residual waste as specified by the regional disposer (incineration).
5) Do not apply the biocidal product directly onto surfaces (e.g. walls) in the building.
6) Do not apply the biocidal product directly on manure/slurry.
7) Do not apply the product in areas subject to washing/sluicing.

Safe application of the product onto the cardboards (to be considered for each new application event):

8) For the mixing/loading and the application step the applicator must wear disposable clothes (e.g. protective gloves and coverall) to avoid emissions to the sewer system due to washing of contaminated clothes.
9) The area where mixing/loading and the application to cardboards takes place, must be covered with a disposable plastic sheet/foil in order to avoid contamination of adjacent surfaces and floor.
10) Equipment used in connection with the paint-on application (e.g. disposable brushes, roller) shall not be cleaned with (running) water after use. All contaminated equipment may be re-used without cleaning (if possible) and always be disposed of safely according to local regulations (with no discharge to waste water).
11) Do not let the product or its residues or painting sludge enter soil, sinks, water courses or the sewer systems.

12) Disposal of contaminated plastic sheets and disposable clothes after use to residual waste as specified by the regional disposer.
13) For the spray application a handhold or backpack/knapsack sprayer with manually operated low pressure (3 bar or below) device has to be used.

3.8.4.1 PBT assessment

P criterion

Studies of the dissipation of clothianidin in the water sediment system suggest for the whole system a DT_{50} of 109 and 145 days and a $DissT_{50}$ of 58 and 94 days for the water phase under aerobic conditions at an EU average outdoor temperature of 12°C. Although the $DissT_{50}$ cannot be used to conclude on the P criterion as it does not allow to differentiate between degradation and any other dissipation process, it supports the conclusion drawn from total system $DegT_{50}$ that the P and vP trigger values in freshwater (P criterion half-life > 40 d freshwater and vP criterion > 60 d freshwater) are fulfilled under worst case consideration. Regarding the total system $DegT_{50}$ values, both P trigger values for freshwater and freshwater sediment (P criterion: half-life >120 d and vP criterion: half-life or >180 d) are fulfilled.
In laboratory studies on aerobic degradation in soil DT_{50}-values between 143 days and more than one year were measured at a temperature of 20°C (geometric mean = 518 days, n=9), corresponding to values from 271 days to >> 1 year at 12°C (geometric mean= 983 days, n=9). Taking into account the soil trigger values for the P (> 120 d in soil) and vP (> 180 d in soil) criteria of the REACH legislation, both trigger values are fulfilled for clothianidin.

The metabolite TMG was observed in sediments of the aerobic water-sediment up to maximum levels of 23 % of applied radioactivity and in anaerobic manures (manure study) up to maximum levels of 58 % of applied radioactivity. TMG seems to be the main metabolite of the anaerobic degradation pathway of clothianidin. At least in anaerobic manure TMG is very persistent (DT_{50} 259.2 – 375.5 days at 12°C). No information is currently available about degradation half-lives in sediments.

B criterion

For clothianidin the calculated bioconcentration factor in fish is 0.78 and for earthworm is 0.9. Therefore, neither the B- (BCF > 2000) nor the vB-criterion (BCF > 5000) is fulfilled.

T criterion

The EC_{10} (equivalent to NOEC) for chironomids, the most sensitive species, is 0.0004 mg/L after 28 days. The value is much lower than the specified T trigger value of NOEC = 0.01 mg/L and therefore clothianidin has to be considered to fulfil the T criterion.

Conclusion

Clothianidin fulfils the T-criterion as well as the P- and vP-criterion, but the B and vB-criteria are not fulfilled. Furthermore the biocidal product ‘Stallfliegenmittel Alba’” does not contain co-formulants which fulfil the PBT criteria.

3.8.4.2 Endocrine disrupting properties

According to the AR for cis-9-tricos-ene (eCA: AT, 2012), the substance is a sex pheromone released by flies to attract male and female adults of the species *Musca domestica*. The data provided indicate that the pheromone has a highly specific mode of action and does not cause any adverse effects in other environmental organisms than the target organisms. There are no indications for endocrine disrupting properties of the substance on vertebrates.

According to the AR for clothianidin (eCA: DE, 2014) there are no indications for endocrine disrupting properties of this active substance on environmental non-target organisms. However, a comprehensive ED-assessment according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed for both active substances cis-9-tricos-ene and clothianidin at the renewal stage. This statement is also valid for the other biocidal active substance which is contained as co-formulant in the product.

The full composition of the product is listed in the Document „Confidential PAR“. There are no indications that a non-active substance of the product may have endocrine disrupting properties on environmental non-target organisms based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation, the community rolling action plan (CoRAP) or the activities coordination tool (ACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards or ECHA’s endocrine disruptor assessment list. For none of the co-formulants indications on potential ED effects on environmental non-target organisms were found in scientific literature. The details of the ED assessment of the co-formulants of the biocidal product “Stallfliegenmittel Alba” are included in section 1.2 of the confidential PAR.

3.8.4.3 Summary of risk characterisation

The product ‘Stallfliegenmittel Alba’ is used indoor against stable flies and house flies in animal housings (cattle stable, piggery, horse stable, and sheep pens) by professional users (farmers). ‘Stallfliegenmittel Alba’ contains the two active substances clothianidin and the pheromone *cis*-tricos-9-ene (Muscalure). It is assumed that any hazard or risk for environmental organisms will be driven by the application of the neonicotinoid clothianidin and any contribution of cis-tricos-9-ene to the product’s toxicity will be

negligible, due to its specific mode of action and low ecotoxicity in other environmental non-target organisms.

The product has to be applied on cardboards either by painting (ready to use product) or after dilution of the biocidal product with water by low pressure coarse spraying. In order to ensure an environmentally safe use without an environmental exposure a set of use instructions has been agreed with the applicant. Provided that the professional user applies these instructions carefully, a negligible exposure can be assumed and no unacceptable risk is to be expected for any environmental compartment.

3.9 Comparative assessment

3.9.1 Background

The biocidal product (BP) “Stallfliegenmittel Alba” contains – in addition to cis-tricos-9-ene - the active substance clothianidin, which meets the criteria for substitution under Article 10 of Biocidal Product Regulation (BPR) (EU) No. 528/2012. Clothianidin is considered “very persistent” (vP) and “toxic” (T) and therefore meets two of the criteria for being PBT. Therefore, in accordance with Article 23 of the BPR No. 528/2012 the German competent authority conducted a comparative assessment for the product “Stallfliegenmittel Alba” following the “Technical Guidance Note on comparative assessment of biocidal products” (document: CA-May-15-Doc-4.3a-Final-TNG on comparative assessment.doc).

3.9.2 Application administrative details

Procedure: National Authorisation (NA)
Purpose: Authorisation
Case Number in R4BP: BC-WY027200-15
Evaluating Competent Authority: Germany (BAuA)
Applicant: Certis Europe BV
(Prospective) Authorisation holder: Sumitomo Chemical Agro Europe SAS

3.9.3 Administrative information of the BP

Product name: Stallfliegenmittel Alba
Trade names: Desintec AnoEX, K-Alba, LD 100 K, Zidapp K, Stallfliegenmittel Alba
Product type: PT18 (Insecticides, acaricides and products to control other arthropods)
Active substances: Clothiandin (CAS-Nr.: 210880-92-5), cis-tricos-9-ene (CAS-Nr.:27519-02-4)

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

The biocidal product Stallfliegenmittel Alba is an insecticide (PT18) effective against stable and house flies, which contains the active substances clothianidin and cis-tricos-9-ene. The product is used by professionals in stables and barns except poultry stables and protects animals from flies.

Table 96 lists the intended uses of the biocidal product, which determines the focus of the comparative assessment.

Table 96: Intended use(s) of the biocidal product

Product type(s)	Insecticides, acaricides and products to control other arthropods (PT 18)
Where relevant, an exact description of the authorised use	This product can only be used for the control of flies
Target organism (including, where relevant) development stage)	Flies (Adult) *(Musca domestica* House fly; *Stomoxys calcitrans* Stable fly)
Field(s) of use	Indoor
Application method(s)	Spraying
Category(ies) of users	Professional

The product “Stallfliegenmittel Alba” is a water-dilutable viscous liquid product. It is effective against house and stable flies (House fly (*Musca domestica*), Stable fly (*Stomoxys calcitrans*)).

The active substance clothianidin belongs to the neonicotinoids. This group of insecticides act as acetylcholine agonists and specifically bind to nicotinic acetylcholine receptors (nAChRs). In insects, these receptors are limited to the central nervous system and binding of the agonist clothianidin causes an activation of post-synaptic acetylcholine receptors. This leads to high levels of nervous overstimulation and a blockage of the receptor, which results in paralysis and death of the target organism. Under normal conditions, the enzyme acetylcholinesterase would break down acetylcholine and therewith terminate the nervous signal, but the binding of clothianidin is irreversible and therefore cannot be broken.

3.9.5 Mapping of existing alternatives to the relevant BP in Germany

Identified eligible alternative BPs[24]

As of 16.12.2021, there are only three products (two of which belong to one biocidal product family) authorised in Germany that have a similar use to the relevant biocidal product, i.e. application of the products by spraying and the target organism flies (Muscidae; *Musca domestica* and *Stomoxys calcitrans*).

The single product contains the active substance spinosad, which is considered as a candidate for substitution and is therefore excluded from the ongoing comparative assessment.

[24] In accordance with the Technical Guidance Note on comparative assessment of biocidal products (CA-May-15-Doc-4.3a-final) the biocidal product Imidasect Ants was only compared to the alternative biocidal products authorised in Germany as the R4BP3 is not yet populated with searchable SPCs and no search tool has been provided by ECHA yet.

The two products of the product family contain the active substance deltamethrin, which itself is not a candidate for substitution.

Accordingly, the only remaining alternative products for the control of flies in Germany are deltamethrin containing products.

Table 97 lists the mode of action of the remaining active substance and the risk of resistance development.

Table 97: Mode of action and risk of resistance development for PT18 (Insecticides, acaricides and products to control other arthropods)

Active Substance	Mode of action	Resistance reported
Deltamethrin	The active substance belongs to the pyrethroids and is a sodium channel modulator. Pyrethroids impair ion transport through the membrane of nerve axons, causing muscular paralysis in the insect; death seems to follow a nervous system impairment that occurs a few minutes to several hours after pesticide absorption. The primary site of activity of deltamethrin is the voltage sensitive sodium channel in nerve membrane. Deltamethrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyperexcitability. Deltamethrin acts primarily by contact but also by ingestion.	Yes

Identified eligible non-chemical alternatives

In Germany, there are a few preventive non-chemical alternatives against flies in stables. Information on these alternatives were provided by the applicant.

One option are sticky traps without attractants, but they are only partially approached by flies and are therefore not efficient enough.

Another option are electric traps, which attract flies by UV-light (violet and green) and kill them by electric shocks. However, these traps only have a small contact area to kill flies and therefore the needed efficacy against flies cannot be achieved.

Additionally these traps are risky for stables and the farm animals: These electrically operated traps use a mechanism to kill flies by electric shocks. However, this mechanism is not limited to insects that contact the trap – it is also triggered by anything else contacting the trap - therefore a fire risk is posed by the trap. Further on, the traps cause persistent noise and development of odour, which disturb the animals.

3.9.6 Screening phase

According to Article 23 (3b) BPR No. 528/2012 the chemical diversity of active substances has to be adequate to minimise the occurrence of resistances in the target organisms. As defined by the “Technical Guidance Note on comparative assessment of biocidal products” an adequate chemical diversity is given, when a suitable number of available active substances having different modes of action on the harmful organism are present to minimise resistance development or selection. For the present biocidal product only two alternative BPs of one BPF with the active substance deltamethrin were identified. From this it can be concluded, that chemical diversity is not adequate to minimise resistances in the target organisms.

Conclusion of the screening phase
Stop comparative assessment. The German CA concludes that without clothianidin based products there is not an adequate chemical diversity, taking into account the potential for resistance development in flies.

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

4 Annexes

4.1 List of studies for the biocidal product

Table 98

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.1 Appearance (at 20°C and 101.3 kPa)	Physico-chemical properties of the formulation SPU-02740-I before and after accelerated storage at 54 °C for 2 weeks	[redacted]	2007	Certis Europe BV
2	3.1 Appearance (at 20°C and 101.3 kPa)	Interim report to the shelf life test of the test item SPU-02740-I at ambient temperature according to Technical-Monograph No. 17	[redacted]	2014	Certis Europe BV
3	3.1 Appearance (at 20°C and 101.3 kPa)	Storage stability of the liquid formulation SPU-02740-I at 0 °C for 7 days.	[redacted]	2007	Certis Europe BV
4	3.1 Appearance (at 20°C and 101.3 kPa)	Physico-chemical Properties of SPU-02740-I over a 2 Year Storage Period at 20 °C (Results before and after 12 months of storage)	[redacted]	2016	Certis Europe BV
5	3.2 Acidity, alkalinity	Physico-chemical properties of the formulation SPU-02740-I before and after accelerated storage at 54 °C for 2 weeks	[redacted]	2007	Certis Europe BV
6	3.2 Acidity, alkalinity	Interim report to the shelf life test of the test item SPU-02740-I at ambient temperature according to Technical-Monograph No. 17	[redacted]	2014	Certis Europe BV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
7	3.2 Acidity, alkalinity	Physico-chemical Properties of SPU-02740-I over a 2 Year Storage Period at 20 °C (Results before and after 12 months of storage	[redacted]	2016	Certis Europe BV
8	3.3 Relative density (liquids) and bulk, tap density (solids)	Relative density of SPU-02740-I	[redacted]	2007	Certis Europe BV
9	3.3 Relative density (liquids) and bulk, tap density (solids)	Interim report to the shelf life test of the test item SPU-02740-I at ambient temperature according to Technical-Monograph No. 17	[redacted]	2014	Certis Europe BV
10	3.4.1 Storage stability tests	Physico-chemical properties of the formulation SPU-02740-I before and after accelerated storage at 54 °C for 2 weeks	[redacted]	2007	Certis Europe BV
11	3.4.1 Storage stability tests	Physico-chemical Properties of the Formulation SPU-02740-I before and after accelerated storage at 54°C for 2 week	[redacted]	2011	Certis Europe BV
12	3.4.1 Storage stability tests	Storage stability of the liquid formulation SPU-02740-I at 0 °C for 7 days.	[redacted]	2007	Certis Europe BV
13	3.4.1 Storage stability tests	Interim report to the shelf life test of the test item SPU-02740-I at ambient temperature according to Technical-Monograph No. 17	[redacted]	2014	Certis Europe BV
14	3.4.1 Storage stability tests	Physico-chemical Properties of SPU-02740-I over a 2 Year Storage Period at 20 °C (Results before and after 12 months of storage)	[redacted]	2016	Certis Europe BV
15	3.4.1 Storage stability tests	Physico-chemical Properties of SPU-02740-I over a 2 Year Storage Period at 20 °C	[redacted]	2017	Certis Europe BV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
16	3.4.1 Storage stability tests	Report Amendment No. 1 - Physico-chemical Properties of SPU-02740-I over a 2 Year Storage Period at 20 °C	[redacted]	2018	Certis Europe B.V.
17	3.4.1 Storage stability tests	Physico-chemical Properties of SPU-02740-I over a 3 Year Storage Period at 20 °C	[redacted]	2018	Certis Europe B.V.
18	3.4.2.1 Light	Physico-chemical properties of the formulation SPU-02740-I before and after accelerated storage at 54 °C for 2 weeks	[redacted]	2007	Certis Europe BV
19	3.4.2.1 Light	Interim report to the shelf life test of the test item SPU-02740-I at ambient temperature according to Technical-Monograph No. 17	[redacted]	2014	Certis Europe BV
20	3.4.2.1 Light	Physico-chemical Properties of SPU-02740-I over a 2 Year Storage Period at 20 °C (Results before and after 12 months of storage)	[redacted]	2016	Certis Europe BV
21	3.5 Technical characteristics of the biocidal product	Persistent foaming of SPU-02740-I	[redacted]	2007	Certis Europe BV
22	3.5 Technical characteristics of the biocidal product	Interim report to the shelf life test of the test item SPU-02740-I at ambient temperature according to Technical-Monograph No. 17	[redacted]	2014	Certis Europe BV
23	3.5 Technical characteristics of the biocidal product	Physico-chemical properties of the formulation SPU-02740-I before and after accelerated storage at 54 °C for 2 weeks	[redacted]	2007	Certis Europe BV
24	3.5 Technical characteristics of	Physico-chemical Properties of SPU-02740-I over a 2 Year Storage Period at 20 °C (Results before and after 12 months of storage)	[redacted]	2016	Certis Europe BV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
	the biocidal product				
25	3.8 Surface tension	Surface tension of SPU-02740-I	[redacted]	2007	Certis Europe BV
26	3.9 Viscosity	Physico-chemical properties of the formulation SPU-02740-I before and after accelerated storage at 54 °C for 2 weeks	[redacted]	2007	Certis Europe BV
27	3.9 Viscosity	Interim report to the shelf life test of the test item SPU-02740-I at ambient temperature according to Technical-Monograph No. 17	[redacted]	2014	Certis Europe BV
28	4.1 Explosives	Explosive properties of SPU-02740-I, EEC method A.21	[redacted]	2007	Certis Europe BV
29	4.4 Oxidising properties	[redacted]	[redacted]	2007	Certis Europe BV
30	4.6. Flammable liquids	SPU-02740-I: Flash point A.9, Auto-flammability (Determination of the temperature of self-ignition of volatile liquids and of gases) A.15	[redacted]	2007	Certis Europe BV
31	4.13. Oxidising liquids	Oxidising properties of SPU-02740-I	[redacted]	2007	Certis Europe BV
32	4.17.1. Auto-ignition temperatures of products (liquids and gases)	SPU-02740-I: Flash point A.9, Auto-flammability (Determination of the temperature of self-ignition of volatile liquids and of gases) A.15	[redacted]	2007	Certis Europe BV
33	5. Methods of detection and identification	Validated method of analysis for the determination of Clothianidin in SPU-02740-I	[redacted]	2007	Certis Europe BV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
34	5. Methods of detection and identification	Development and Validation of an Analytical Method for the determination of (Z)-9-Tricosene in SPU-02740-I	[redacted]	2011	Certis Europe BV
35	5. Methods of detection and identification	Development and validation of an Analytical Method for the Determination of Clothianidin in aqueous Dilutions of SPU-02740-I	[redacted]	2016	Certis Europe BV
36	5. Methods of detection and identification	Development and Validation of an Analytical Method for the Determination of the Content of Clothianidin in SPU-02740-I	[redacted]	2016	Certis Europe BV
37	5. Methods of detection and identification	Pretest for Development and Validation of an Analytical Method for the Determination of the Content of 1,2-Benzisothiazolin-3-one in the Formulation SPU-02740-I	[redacted]	2015	Certis Europe BV
38	5. Methods of detection and identification	Development and Validation of an analytical method for the Determination of (Z)-9-Tricosene in aqueous Dilutions of SPU-02740-I	[redacted]	2016	Certis Europe BV
39	5. Methods of detection and identification	1,2-Benzisothiazol-3(2H)-one - Residue analytical method for the determination in air	[redacted]	2018	Certis Europe B.V.
40	5. Methods of detection and identification	cis-Tricos-9-en Residue Analytical Method for the Determination in Foodstuff of Animal Origin	[redacted]	2019	Certis Europe B.V.
41	5. Methods of detection and identification	1,2-Benzisothiazol-3(2H)-one - Residue Analytical Method for the Determination on PTFE Filter	[redacted]	2019	Certis Europe B.V.
42	5. Methods of detection and identification	Expert Statement on Sampling of the Inhalable Fraction of 1,2-Benzisothiazol-3(2H)-one in Air Samples	[redacted]	2019	Certis Europe B.V.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
43	6.7 Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Evaluation of the long term effect of Stallfliegenmittel Alba new against stable fly (musca autumnalis) (Stallfliege) (MUSCAU) and house fly (musca domestica) (MUSCDO) “Painting application”	[redacted]	2009	Certis Europe BV
44	6.7 Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Addendum to the final report Evaluation of the long term effect of Stallfliegenmittel Alba new against stable fly (musca autumnalis) (Stallfliege) (MUSCAU) and house fly (musca domestica) (MUSCDO) “Painting application”	[redacted]	2019	Certis Europe BV
45	6.7 Efficacy data to support these claims, including	Field trial to determine the efficacy of products against houseflies, Musca domestica	[redacted]	2010	Certis Europe BV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
	any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant				
46	6.7 Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Evaluation of the efficacy of Stallfliegenmittel Alba with different application rates against autumn fly (Musca autumnalis), house fly (Musca domestica) and biting house fly (Stomoxys calcitrans) “Painting and spraying application”	[redacted]	2016	Certis Europe BV
47	6.7 Efficacy data to support these claims, including any available standard protocols,	Addendum to the final report Evaluation of the efficacy of Stallfliegenmittel Alba	[redacted]	2019	Certis Europe BV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
	laboratory tests or field trials used including performance standards where appropriate and relevant				
48	6.7 Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Biological test report - A comparison of efficacy of Stallfliegenmittel Alba (SPU-02740-I-O-PA) (26.0 g/L) Clothianidin 0.5g/L (Z)-9-Tricosene) vs. Interfly-Tox against House flies, Musca domestica, and Stable flies, Stomoxys calcitrans	[redacted]	2016	Certis Europe BV
49	6.7 Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including	Biological Test Report - Efficacy of a fly product in a simulated use test against flies	[redacted]	2018	Certis Europe B.V.

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
	performance standards where appropriate and relevant				
50	6.7 Efficacy data to support these claims, including any available standard protocols, laboratory tests or field trials used including performance standards where appropriate and relevant	Field trial to determine the efficacy of products against houseflies, Musca domestica and stable flies, Stomoxys calcitrans	[redacted]	2019	Certis Europe B.V.
51	8.1 Skin corrosion or skin irritation	Acute dermal irritation/ corrosion test (patch test) of SPU-02740-I in rabbits	[redacted]	2007	Certis Europe BV
52	8.2 Eye irritation	Acute eye irritation/ corrosion test of SPU-02740-I in rabbits	[redacted]	2007	Certis Europe BV
53	8.5.1 Acute toxicity: oral	Acute oral toxicity study of SPU-02740-I in rats	[redacted]	2007	Certis Europe BV
54	8.5.3 Acute toxicity: dermal	Acute dermal toxicity study of SPU-02740-I in CD rats	[redacted]	2007	Certis Europe BV
55	8.6 Dermal absorption	In vitro percutaneous absorption of Clothianidin and 1,2-Benzisothiazol-3(2H)-one, formlated as Alba (SPU-02740-I), through human skin	[redacted]	2018	Certis Europe BV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
56	8.6 Dermal absorption	In vitro percutaneous absorption of Clothianidin and 1,2-Benzisothiazol-3(2H)-one, formlated as Alba (SPU-02740-I), through human skin	[redacted]	2018	Certis Europe BV

4.2 List of studies for the active substance(s)

4.3 Clothianidin

4.3.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[25]) of the active substance clothianidin for use in Insecticides, acaricides and products to control other arthropods (product-type 18). Please, refer to the corresponding Assessment Report for a reference list.

4.3.1.2 New information on the active substance

Not relevant.

4.3.1.3 List of studies 3rd party dossier

Not relevant.

4.4 Cis-tricos-9-ene

4.4.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[26]) of the active substance cis-tricos-9-ene for use in Repellents and Attractants (product-type 19). Please, refer to the corresponding Assessment Report for a reference list.

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

4.4.1.2 New information on the active substance

Not relevant.

4.4.1.3 List of studies 3rd party dossier

Not relevant.

4.5 Output tables from exposure assessment tools

4.5.1 Safety for professional users

Exposure assessment

4.5.2 Livestock exposure (ConsExpo 4.1 reports)

4.5.2.1 Beef cattle

ConsExpo 4.1 report

file name: beef cattle.Ce4
Report date: 27.11.2018

Product

Stallfliegenmittel Alba

Compound

Compound name :	cis-tricos-9-ene	
CAS number :	27519-02-4	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	3	1/year
body weight	500	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,05	%
exposure duration	24	hour
room volume	3,06E3	m3
ventilation rate	2	1/hr
applied amount	1,05E3	gram
release duration	4	week

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	51	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,000124	mg/m3
inhalation mean concentration on day of exposure:	0,000124	mg/m3
inhalation air concentration year average :	1,02E-6	mg/m3/day
inhalation acute (internal) dose :	1,27E-5	mg/kg
inhalation chronic (internal) dose :	1,04E-7	mg/kg/day

Integrated (point estimates)

total external dose:	1,27E-5	mg/kg
total acute dose (internal):	1,27E-5	mg/kg
total chronic dose (internal):	1,04E-7	mg/kg/day

4.5.2.2 Calves

ConsExpo 4.1 report

file name: calves.Ce4
Report date: 27.11.2018

Product

Stallfliegenmittel Alba

Compound

Compound name :	cis-tricos-9-ene	
CAS number :	27519-02-4	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	3	1/year
body weight	200	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,05	%
exposure duration	24	hour
room volume	590	m3
ventilation rate	4,1	1/hr
applied amount	452	gram
release duration	4	week

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	25	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,000137	mg/m3
inhalation mean concentration on day of exposure:	0,000137	mg/m3
inhalation air concentration year average :	1,13E-6	mg/m3/day
inhalation acute (internal) dose :	1,72E-5	mg/kg
inhalation chronic (internal) dose :	1,41E-7	mg/kg/day

Integrated (point estimates)

total external dose:	1,72E-5	mg/kg
total acute dose (internal):	1,72E-5	mg/kg
total chronic dose (internal):	1,41E-7	mg/kg/day

4.5.2.3 Dairy cattle

ConsExpo 4.1 report

file name: dairy cattle.Ce4
Report date: 27.11.2018

Product

Stallfliegenmittel Alba

Compound

Compound name :	cis-tricos-9-ene	
CAS number :	27519-02-4	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	3	1/year
body weight	650	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,05	%
exposure duration	24	hour
room volume	9,63E3	m3
ventilation rate	0,9	1/hr
applied amount	3,3E3	gram
release duration	4	week

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	62	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,00027	mg/m3
inhalation mean concentration on day of exposure:	0,00027	mg/m3
inhalation air concentration year average :	2,22E-6	mg/m3/day
inhalation acute (internal) dose :	2,58E-5	mg/kg
inhalation chronic (internal) dose :	2,12E-7	mg/kg/day

Integrated (point estimates)

total external dose:	2,58E-5	mg/kg
total acute dose (internal):	2,58E-5	mg/kg
total chronic dose (internal):	2,12E-7	mg/kg/day

4.5.2.4 Fattening pigs

ConsExpo 4.1 report

file name:fattening pigs.Ce4
Report date: 27.11.2018

Product

Stallfliegenmittel Alba

Compound

Compound name :	cis-tricos-9-ene	
CAS number :	27519-02-4	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	3	1/year
body weight	100	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,05	%
exposure duration	24	hour
room volume	2,11E3	m3
ventilation rate	1,9	1/hr
applied amount	1,7E3	gram
release duration	4	week

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	14	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,000307	mg/m3
inhalation mean concentration on day of exposure:	0,000307	mg/m3
inhalation air concentration year average :	2,52E-6	mg/m3/day
inhalation acute (internal) dose :	4,3E-5	mg/kg
inhalation chronic (internal) dose :	3,53E-7	mg/kg/day

Integrated (point estimates)

total external dose:	4,3E-5	mg/kg
total acute dose (internal):	4,3E-5	mg/kg
total chronic dose (internal):	3,53E-7	mg/kg/day

4.5.2.5 Breeding pigs (individual housing)

ConsExpo 4.1 report

file name:breeding pigs - indiv housing.Ce4
Report date: 27.11.2018

Product

Stallfliegenmittel Alba

Compound

Compound name :	cis-tricos-9-ene	
CAS number :	27519-02-4	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	3	1/year
body weight	260	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,05	%
exposure duration	24	hour
room volume	1,96E3	m3
ventilation rate	3,5	1/hr
applied amount	1,58E3	gram
release duration	4	week

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	30	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,000169	mg/m3
inhalation mean concentration on day of exposure:	0,000169	mg/m3
inhalation air concentration year average :	1,39E-6	mg/m3/day
inhalation acute (internal) dose :	1,95E-5	mg/kg
inhalation chronic (internal) dose :	1,61E-7	mg/kg/day

Integrated (point estimates)

total external dose:	1,95E-5	mg/kg
total acute dose (internal):	1,95E-5	mg/kg
total chronic dose (internal):	1,61E-7	mg/kg/day

4.5.2.6 Breeding pigs (group housing)

ConsExpo 4.1 report

file name:breeding pigs - group housing.Ce4
Report date: 27.11.2018

Product

Stallfliegenmittel Alba

Compound

Compound name :	cis-tricos-9-ene	
CAS number :	27519-02-4	
molecular weight	323	g/mol
vapour pressure	0,064	Pascal
KOW		linear

General Exposure Data

exposure frequency	3	1/year
body weight	260	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0,05	%
exposure duration	24	hour
room volume	2,48E3	m3
ventilation rate	2,8	1/hr
applied amount	2,01E3	gram
release duration	4	week

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	30	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0,000212	mg/m3
inhalation mean concentration on day of exposure:	0,000212	mg/m3
inhalation air concentration year average :	1,74E-6	mg/m3/day
inhalation acute (internal) dose :	2,44E-5	mg/kg
inhalation chronic (internal) dose :	2E-7	mg/kg/day

Integrated (point estimates)

total external dose:	2,44E-5	mg/kg
total acute dose (internal):	2,44E-5	mg/kg
total chronic dose (internal):	2E-7	mg/kg/day