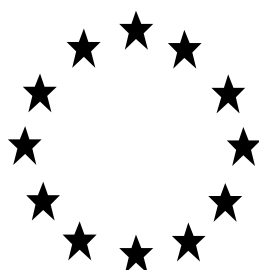


Regulation (EU) No 528/2012 concerning the
making available on the market and use of biocidal
products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT FOR NATIONAL
AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



Loppex

Product type 18

Permethrin

Case Number in R4BP: BC-PA023978-37

Evaluating Competent Authority: Denmark

Date: 21. September 2018

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1 CONCLUSION

Loppex is an insecticide used for the control of adult squirrel flea (*Ceratophyllus sciurorum*) containing 1% permethrin in the form of a dustable powder (DP) formulation which is ready to use. The product contains diatomaceous earth as a dispersant.

Sufficient data has been provided to verify the outcome and conclusions and permit a preliminary authorisation of the biocidal product according to the following conditions:

- 1: Target organism: adult squirrel flea (*Ceratophyllus sciurorum*).
- 2: User:professionals.
3. The concentration of the active substance permethrin in the biocidal product is 1% (w/w). The approved supplier of permethrin is Tagros Chemicals India LTD.
- 4: The product is used indoor in mink stables.
- 5: The application rate is 2.5 g Loppex per nest box maximum four times per year.
- 6: Shelf life of 24 months is applied for (date of the manufacture must be shown on the label or packaging). Please see "requirements for further information".
- 7: The product is used according to the instructions of use.
- 8: The risk mitigation measures and conditions of storage must be followed.

Physical-chemical hazard

The solid product is not flammable, oxidising, self-heating or explosive and should not be classified for physical-chemical hazards.

Human health hazard

The content of 1% permethrin results in labelling of the product with H317 skin sensitizing and the prescription of using gloves during loading and application of the product. Dermal absorption values for Loppex was determined based on a re-evaluation of the dermal absorption study presented in the permethrin assessment report (see annex 3.3.) The risk assessment for Loppex demonstrates unacceptable risk for the user during application without PPE (gloves and coated coveralls). A safe use was demonstrated when applying PPE to the risk assessment for application of Loppex.

Environmental risk assessment

The current harmonised classification of the active substance permethrin (H410, M1000, chronic) is based on Regulation (EC) No. 1272/2008¹. Considering the M-factor, Loppex's content of 1% permethrin results in H410 with the pictogram GHS09. The risk assessment for the environment is based in the active substance. There are no unacceptable risks identified as a result of the indoor application in mink stables for any of the environmental compartments if the product is used according to the directions for use.

¹ <https://echa.europa.eu/da/information-on-chemicals/cl-inventory-database/-/discli/details/59336>

Efficacy

An acceptable efficacy was documented against adult squirrel flea (*Ceratophyllus sciurorum*).

The use of the product may cause resistance development since the product is used on confined populations and the immigration rate of susceptible squirrel fleas is low. To reduce the risk of developing resistance against permethrin it is recommended to switch between products with different actives.

Because of the selection pressure on confined local populations it is recommended to have a strategy for resistance management.

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

Previous use

Loppex has been authorised in Denmark since 2009.

On basis of the Assessment report of the active substance and the Product Assessment Report it is the opinion of ref-MS Denmark to authorise the product Loppex to be used as an insecticide in mink stables against adult squirrel flea (*Ceratophyllus sciurorum*). The conditions are outlined in the Summary Product Characteristics (SPC).

Necessary issues accounted for in the product label

The use of the product may cause resistance development. To reduce the risk of developing resistance against permethrin it is recommended to switch between products with different modes of action.

May not be disposed of in sewers, including rainwater canals.

Wear protective chemical resistant gloves (material must be specified by the authorisation holder with the product), and overalls when handling the product.

Mink must not be present during treatment of nests.

Do not apply Loppex to nest before cubs are 8 weeks.

Requirement for further information

A preliminary authorization is granted on the condition that the final report on the long term stability study is submitted as soon as it becomes available and no later than 1. November 2018 showing an acceptable degradation after 24 months.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
Loppex	Denmark Norway (cMS) Iceland (cMS)

Dossier UUID: de69df5c-a32d-4f53-a6d4-b61d512390ef (22/6-18)

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	Trinol A/S
	Address	Søagervej 9, 9500 Hobro, Denmark
Authorisation number	DK: 730-30	
Date of the authorisation	21-09-2018	
Expiry date of the authorisation	21-09-2028	

2.1.1.3 Manufacturer of the product

Name of manufacturer	Battle, Hayward & Bower Ltd.
Address of manufacturer	Crofton Drive, Allenby Road Industrial Estate LN3 4NP Lincoln UK
Location of manufacturing sites	Crofton Drive, Allenby Road Industrial Estate LN3 4NP Lincoln UK

2.1.1.4 Manufacturer of the active substance

Active substance	Permethrin
Name of manufacturer	Tagros Chemicals India LTD
Address of manufacturer	Jhaver Centre, Rajah Annamalai Building IV floor 72, Marshalls Road, Egmore 600.008 Chennai India
Location of manufacturing sites	Jhaver Centre, Rajah Annamalai Building IV floor 72, Marshalls Road, Egmore 600.008 Chennai

India

2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential 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

2.1.2.1 Identity of the active substance

Main constituent	
ISO name	Permethrin (ISO) m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cis:trans ratio: 25:75)
IUPAC or EC name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Permethrin)
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	≥ 93.0
Structural formula	Permethrin has four stereoisomers: 1Rcis, 1Scis, 1Rtrans, and 1Strans. Two pairs of diastereomers (each consisting of a nonracemic pair of enantiomers) are present in a ratio of ca. 25:75. For more information reference is made to section 2.1.1 in the Assessment Report for permethrin ² .

2.1.2.2 Candidate(s) for substitution

At the moment, permethrin is not a candidate for substitution in accordance with Article 10 of BPR. Depending on the outcome of the ECHA PBT working group there may be a requirement for the substance to be considered as a candidate for substitution as identified in the provisions of Article 10 of Regulation (EU) No 528/2012 according to the Assessment Report for permethrin. Permethrin has not been considered as a candidate for substitution in the evaluation of Loppex.

² Assessment Report, Permethrin, Product-type 18, RMS: Ireland; April 2014.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cis:trans ratio: 25:75)	Active substance	52645-53-1	258-067-9	1.0
Diatomaceous earth, natural Kieselguhr	No IUPAC name Amorphous silicon dioxide Silica Diatomite	Anti-caking/dispersant Substance of concern in the formulation	61790-53-2	Not allocated	3.0

2.1.2.4 Information on technical equivalence

The source of active substance used in the biocidal product is the same as the source considered for active substance approval and the technical specifications for the active substance have been evaluated at that stage. The minimum purity of active substance specified at active substance approval is 92.4% w/w, and the DK CA believes that there are no issues regarding the technical equivalence of the active substance.

2.1.2.5 Information on the substance(s) of concern

Loppex contains 3% diatomaceous earth. The latter is added as an anticaking agent in the product and is not claimed to have any insecticidal effect in the product due to the low content. Diatomaceous earth (Kieselguhr) is under evaluation as an active substance under the regulation (EU) No 528/2012, and is therefore considered as a substance of concern in the formulation. A Final competent assessment report (CAR) has been published in November 2015 by rMS France.

2.1.2.6 Type of formulation

Ready to use powder (DP)

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

The following classification for the product is based on the harmonised classification of permethrin (H302, H317, H332, H400 and H410).

Classification	
Hazard category	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H317 May cause an allergic skin reaction H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning (GHS07 and GHS09 pictogram)
Hazard statements	H317: May cause an allergic skin reaction H410: Very toxic to aquatic life with long lasting effects
Precautionary statements	P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach for children P261: Avoid breathing powder P280: Wear protective gloves P302 +P352: IF ON SKIN: Wash with plenty of soap and water P333+313: If skin irritation or rash occurs: Get medical advice/attention P362 +P364: Take off contaminated clothing and wash before reuse P273: Avoid release to the environment P391: Collect spillage P501: Dispose of contents/container in accordance with local regulations
Note	Keep away from food, drink and animal feedingstuffs. The use of the product may cause resistance development. To reduce the risk of developing resistance against permethrin it is recommended to switch between products with different modes of action. May not be disposed of in sewers, including rainwater canals.

Permethrin is classified as H400 and H410 (Acute M-faktor: 100, Chronic M-faktor: 10000) based in $0.001 < L(E)C50 \leq 0.01$ and $0.000001 < NOEC \leq 0.00001$, NRD.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 2.1. To be used at mink farms in nests for the control of the squirrel flea (*Ceratophyllus sciurorum*).

Product Type	18
Where relevant, an	To be used in nests at mink farms for the control of the

exact description of the authorised use	squirrel flea (<i>Ceratophyllus sciurorum</i>). Application can be made with a LOPPEX sprinkle canister. The straw in the nest boxes is to be dusted with 2.5 g LOPPEX per nest box (equivalent to shaking the canister three times). The canister holds about 500 g - sufficient to treat about 200 nest boxes.
Target organism (including development stage)	Squirrel flea (<i>Ceratophyllus sciurorum</i>), Adults
Field of use	Indoor
Application method(s)	Dusting/sprinkling
Application rate(s) and frequency	Application rate: 2.5 g LOPPEX per nest box (equivalent to shaking the canister three times). Frequency: There should be a re-treatment with LOPPEX each time the straw is replaced - also at winter and fall. If sporadic flea infestations occur, treatment may be repeated at 4 week intervals until fleas are no longer observed. Loppex is applied in mink farms maximum four times per year.
Category(ies) of users	Professional
Pack sizes and packaging material	8.6 L powder container (Polypropylene plastic).

2.1.4.2 Use-specific instructions for use

The straw in the nest boxes is to be dusted with 2.5 g LOPPEX per nest box (equivalent to shaking the canister three times). There should be a re-treatment with LOPPEX each time the straw is replaced - also at winter and fall. If sporadic flea infestations occur, treatment may be repeated at 4 week intervals until fleas are no longer observed. The use of the product may cause resistance development. To reduce the risk of developing resistance against permethrin it is recommended to switch between products with different modes of action.

2.1.4.3 Use-specific risk mitigation measures

Use PPE:

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder with the product information).

Wear coveralls

Avoid breathing powder.

Keep out of reach of children.

Keep away from food, drink and animal feedingstuffs.

Mink must not be present during treatment of nests.

Do not apply Loppex to nest before cubs are 8 weeks.

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

First aid measures:

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

In case of skin contact: Wash off with soap and plenty of water.

Environmental precautions:

Do not flush into surface water or sanitary systems, including rainwater canals.

Keep in suitable, closed containers for disposal.

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

May not be disposed of in sewers, including rainwater canals.

Dispose of waste as hazardous waste.

Contaminated packaging: Dispose of as unused product.

Empty containers should be disposed of in accordance with local regulations.

Collect spills and waste in closed, leak-proof containers for disposal at the local hazardous waste site.

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

The product should be stored safely.

Keep container tightly closed in a dry and well-ventilated place.

Store at ambient temperature.

Store in opaque packaging.

Shelf-life: 24 months

2.1.5 General directions for use

2.1.5.1 Instructions for use

See authorised uses

2.1.5.2 Risk mitigation measures

See authorised uses

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

See authorised uses

2.1.5.4 Instructions for safe disposal of the product and its packaging

See authorised uses

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

See authorised uses

2.1.6 Other information

Not relevant

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bucket	8.6 L	Polypropylene plastic	Polypropylene plastic	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Find a complete reference list of studies submitted for the product during product authorisation in Annex 1, section 3.1

2.1.8.2 Access to documentation

Letter of Access to data concerning Permethrin Technical (Tagros) concerning Denmark, Norway and Iceland is attached in IUCLID, section 13.

2.2 Assessment of the biocidal product

2.2.1 Intended use as applied for by the applicant

Table 1.2. Intended use

Product Type	18
Where relevant, an exact description of the authorised use	To be used in nests at mink farms for the control of adult squirrel flea (<i>Ceratophyllus sciurorum</i>). Application can be made with a LOPPEX sprinkle canister. The straw in the nest boxes is to be dusted with 2.5 g LOPPEX per nest box (equivalent to shaking the canister three times). The canister holds about 500 g - sufficient to treat about 200 nest boxes.
Target organism (including development stage)	The squirrel flea (<i>Ceratophyllus sciurorum</i>). Adults
Field of use	Indoor
Application method(s)	Dusting/sprinkling
Application rate(s) and frequency	Application rate 2.5 g LOPPEX per nest box (equivalent to shaking the canister three times). The canister holds about 500 g - sufficient to treat about 200 nest boxes. Frequency: There should be a re-treatment with LOPPEX each time the straw is replaced - also at winter and fall. If sporadic flea infestations occur, treatment may be repeated at 4 week intervals until fleas are no longer observed.
Category(ies) of user(s)	Professional
Pack sizes and packaging material	8.6 L powder container (Polypropylene plastic)

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	Not applicable	Powder.	
Colour at 20 °C and 101.3 kPa	Visual inspection	Not applicable	White / off-white	
Odour at 20 °C and 101.3 kPa	Visual inspection	Not applicable	Odourless	Not applicable
Acidity / alkalinity	CIPAC MT 75.3 1 % dilution	Not applicable	pH Prior to storage: 7.3 Following 2 weeks storage	Morsing and Klamer, 2016 (IUCLID 3.4.1)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			at 54 °C: 7.4 Not relevant to test acidity/alkalinity as pH is not <4 or >10	
Relative density / bulk density	Tap Density according to OECD 109	Not applicable	The tap density of the test item "Loppex" at 20°C proved to be 0.86 g/ml. Since the procedure involves the measure of the pour density, this determination was also carried out. The pour density of the test item "Loppex" at 20°C proved to be 0.65 g/ml.	Bjerring, T., 2018 (IUCLID 3.3)
Storage stability test – accelerated storage	CIPAC MT 46.3	Not applicable	Content of permethrin (active substance) prior to storage: 1.01% w/w (1% more than declared content of 1%) Following 2 weeks storage at 54°C: 1.02% w/w Variation: 0.99%	Morsing and Klamer, 2016 (IUCLID 3.4.1)
Storage stability test – long term storage at ambient temperature	The product is stored at 21-23 °C in 2 years. The permethrin	-	A study is expected to be finished in October 2018	A study is expected to be finished in October 2018

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	content and pH is determined before and after storage.-			
Storage stability test – low temperature stability test for liquids	-	-	Not required for solids	-
Effects on content of the active substance and technical characteristics of the biocidal product – light	-	-	Not applicable. Sealed packaging prevents effects on content of active substance due to light, temperature and humidity. The substance of concern diatomaceous earth has not been included in the study, as it is a natural occurring mineral and in- or decrease in the content is therefore expected.	-
Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity	-	-	Not applicable. Sealed packaging prevents effects on content of active substance due to light, temperature and humidity	-
Effects on content of the active substance and technical characteristics of the biocidal product – reactivity towards	-	-	-	Study is expected to be finished in October 2018

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
container material				
Wettability	-	-	Justification for data waiving: Loppex is a powder and is applied as such	-
Suspensibility, spontaneity and dispersion stability	-	-	Justification for data waiving: Loppex is a powder and is applied as such	-
Wet sieve analysis and dry sieve test	Equivalent or similar to: CIPAC 59.1 Mechanical sieving was performed on a Struers JEL sieving tower using a 15 minutes standard sieving program. Seven sieves in the interval 63 µm to 4 mm were used (0.063, 0.125, 0.25, 0.5, 1, 2, and 4 mm sieve openings). A subsample weight of 175 g was used for the test.	Not applicable	Loppex: The material showed a very adhesive behavior and it was not possible to make a reliable sieving tower test, despite the fact that the sieving tower used a standard sieving program with horizontal circular movement for better particle throughput – please see particle size distribution by laser diffraction and photo in the enclosure. Photos enclosed in the testreport showed that no sample at all was found on the 63 µm mesh sieve. Celite 209 &	Pedersen, P.B. and Madsen, M.G., 2016 (IUCLID 3.5) Raw Material Specification for Celite 209 (IUCLID 13)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Data regarding sieving tests listed in the raw material specifications for Celite 209 shows 99.0% and 95 % passage respectively through a 53 µm sieve.	
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Justification for data waiving: Loppex is a powder and is applied as such	-
Disintegration time	-	-	Justification for data waiving: Loppex is a powder, not applied in tablet form	-
Particle size distribution, content of dust/fines, attrition, friability	Equivalent or similar to: CIPAC MT 187 CIPAC MT 171	Not applicable	Particle size distribution: d0.1 = 5.0 µm d0.5 = 21 µm d0.9 = 51 µm Loppex consist of fine powder with 90 % of the particles having a diameter below 51 µm.	Pedersen, P.B. and Madsen, M.G., 2016 (IUCLID 3.5)
Persistent foaming	Not relevant	-	-	-
Flowability/Pourability/Dustability	25 g was placed in a 44 cm high vertical sample pipe. Dust was measured by laser diffraction using a	-	Content of dust: Compared with the maximum permissible value for total inorganic dust on 10 mg/m ³ defined by the Danish Working	Pedersen, P.B. and Madsen, M.G., 2016, IUCLID 3.5

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	DustTrack (PM total) that was started 60 s before dumping the sample into the sample chamber (30x30x30 cm ³). Measurements ended after 1 h with a time resolution of 10 s. T= 0 was used as background. The sample drops 74 cm.		Environmental Authority it takes 7,5 minutes before the measured dust level is below this limit. Furthermore, it took 10 minutes 10 seconds before the measured level was below the required limit for total inorganic respirable dust. This value is 5 mg/m ³ . It took 50 minutes before the measured value was on level with the initial background level, i.e. all the dust had subsided.	
Physical compatibility	Not relevant	-	Jusification for data waiving: Loppex is not to be used in combination with other products.	-
Chemical compatibility	Not relevant	-	Jusification for data waiving: Loppex is not to be used in combination with other products.	-
Degree of dissolution and dilution stability	Not relevant	-	Jusification for data waiving: Not applicable for solid formulations	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			(Loppex is a powder).	
Surface tension	Not relevant	-	Jusification for data waiving: Not applicable for solid formulations (Loppex is a powder).	-
Viscosity	Not relevant	-	Jusification for data waiving: Not applicable for solid formulations (Loppex is a powder).	-

Conclusion on the physical, chemical and technical properties of the product

Loppex is a White/off-white odourless powder smooth to the touch with a tap density of approximately 2.84. It's a fine powder – analysis of the particle size distribution resulting in a d0.9 of 51 µm.

The physical-chemical properties of Loppex is considered acceptable on basis of the current data. A shelf life of 24 months is accepted on basis of the data from the accelerated storage test. It will however need to be confirmed by the final 24 months long-term stability data, which must be submitted in October 2018 at latest.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Explosives	-	-	Jusification for data waiving: Neither diatomaceous earth or permethrin has explosive properties.	-
Flammable gases	Not relevant	-	Loppex is a solid powder	-
Flammable aerosols	Not relevant	-	Loppex is a solid powder	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Oxidising gases	Not relevant	-	Loppex is a solid powder	-
Gases under pressure	Not relevant	-	Loppex is a solid	-
Flammable liquids	Not relevant	-	Loppex is a solid powder	-
Flammable solids	-	-	<p>Justification for data waiving:</p> <p>Neither diatomaceous earth or permethrin has flammable properties. Therefore it is assessed that there is no concern regarding the flammable properties of the product.</p>	-
Self-reactive substances and mixtures	-	-	Loppex is not classified as a self-reacting formulation and contain primarily inert and thermally stable ingredients.	-
Pyrophoric liquids	Not relevant	-	Loppex is a solid powder	-
Pyrophoric solids	-	-	<p>Justification for data waiving:</p> <p>Neither diatomaceous earth or permethrin have pyrophoric properties.</p>	-
Self-heating substances and mixtures	-	-	<p>Justification for data waiving:</p> <p>Neither diatomaceous earth or</p>	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			permethrin are substances with self-heating properties.	
Substances and mixtures which in contact with water emit flammable gases	-	-	Jusification for data waiving: Neither diatomaceous earth or permethrin emits flammable gases when mixed with water.	-
Oxidising liquids	-	-	Loppex is a solid powder	-
Oxidising solids	-	-	Jusification for data waiving: Neither diatomaceous earth or permethrin has oxidising properties.	-
Organic peroxides	-	-	Neither diatomaceous earth or permethrin contains organic peroxides.	-
Corrosive to metals	-	-	Jusification for data waiving: Neither diatomaceous earth or permethrin are corrosive to metals.	-
Auto-ignition temperatures of products (liquids and gases)	Not relevant	-	Loppex is a solid powder	-
Relative self-ignition temperature for solids	-	-	Jusification for data waiving:	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Neither diatomaceous earth or permethrin are substances with self-ignition properties. Therefore it is assessed that there is no concern regarding the self-ignition properties of the product.	
Dust explosion hazard	-	-	Justification for data waiving: Neither diatomaceous earth or permethrin has explosive properties.	-

Conclusion on the physical hazards and respective characteristics of the product

The solid product is not flammable, oxidising, self-heating or explosive and should not be classified for physical hazards.

2.2.4 Methods for detection and identification

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	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
<i>Permethrin (active substance)</i>	LC-MS/MS	Five concentrations in the range of 4-12 µg/L (cis-trans 1:1)	>0.998	Acceptable chromatograms of a blank sample (loppex without permethrin), a standard and a test	99.4-104.4 (3 samples)	101.3	2.7	Not relevant	Jensen, K. and Birkler, R. (2017) IUCLID 5

				sample were provided. All include the internal standard cypermethr in-d6 No interferences with other substances were detected.					
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Study of Jensen and Birkler (2017):

Recovery (accuracy) – An assessment of the method accuracy was made by determining the recovery of three replicates (double determination). The mean recovery was 101.3%.

Precision (repeatability) – An assessment of the precision of the analytical method was made by determining the active substance content in seven (n = 7) replicates (double determination). The associated %RSD value was 4.3

Linearity – The linearity of the detector response was determined at five (n = 5) concentrations ranging from 4 – 12 µg/mL. Samples were diluted accordingly to be within this range. A linear relationship was demonstrated with a correlation coefficient (r): >0.998.

Specificity – No interferences from the matrix were detected. Acceptable chromatograms (test sample, active substance analytical standard, formulation blank) were provided and confirm the specificity of the method.

The DK CA considers that the method is satisfactorily validated in accordance with the EU guidance document SANCO/3030/99 rev. 4. No further consideration is required.

An acceptable validated method for residues of permethrin in soil was provided in the assessment report for permethrin as well as acceptable validated methods for residues of permethrin in water and in air.

Conclusion on the methods for detection and identification of the product

The analytical method provided in support of this application for permethrin (active substance) is considered validated according to requirements in the ECHA guidance on information requirements.

Acceptable methods for permethrin are available for all relevant matrices (soil, air and water) in the active substance dossier and does not need to be submitted for the product.

Furthermore, analytical methods for determination of permethrin in food and feeding stuffs and in tissue are not required considering the intended use of the biocidal product and the toxicity.

Besides permethrin, Loppex contains diatomaceous earth, which is considered a substances of concern in the product. According to the "Guidance on information requirements (Version 1.1 November 2014)", further studies for relevant components of the biocidal product or the biocidal product itself, need not to be performed if the data on the active substance gives sufficient information and if there are no indications of risk due to specific properties of the biocidal product. Diatomaceous earth is not expected to have any insecticidal effect in the product due to the low content. There is no risk concerning

human health risk assessment due to the low concentration of diatomaceous earth in Loppex.

Furthermore diatomaceous earth is not expected to influence the environmental risk assessment as it is a natural occurring mineral and based on the low content in the product and the low ecotoxicity of the substance.

The available data on the active substance are sufficient for the performance of the environmental and human health risk assessment and further methods for determination of diatomaceous earth is not required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

PT18 – Insecticide. To be used at mink farms for the control of the squirrel flea (*Ceratophyllus sciurorum*).

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

The squirrel flea (*Ceratophyllus sciurorum*). Adults.

2.2.5.2 Effects on target organisms, including unacceptable suffering

Permethrin is an acute toxin with fast knock-down effect.

2.2.5.3 Mode of action, including time delay

Permethrin is a synthetic pyrethroids belonging to IRAC Mode of action Group 3. It is a sodium channel modulator keep sodium channels open, causing hyperexcitation and, in some cases, nerve block. Sodium channels are involved in the propagation of action potentials along nerve axons.

Permethrin is a fast acting contact insecticide, which causes convulsions, paralysis and ultimately death in target organisms.

2.2.5.4 Efficacy data

Conclusion on the efficacy of the product

Laboratory and field evaluation of Pulvex (former name of Loppex) for control of the squirrel flea (*Monopsyllus sciurorum*) confirmed that product used in a dosage of 2.5 g per nest box is effective against the squirrel flea (*Ceratophyllus sciurorum* Wagner, 1898 Synonym: *Monopsyllus sciurorum* (Schrank, 1803)).

2.2.5.5 Occurrence of resistance and resistance management

The use of the product may cause resistance development since the product is used on confined populations and the immigration rate of susceptible squirrel fleas is low. To

reduce the risk of developing resistance against permethrin it is recommended to switch between products with different actives.

Because of the selection pressure on confined local populations it is recommended to have a strategy for resistance management. A rotation of products with different modes of action is anticipated to be sufficient.

2.2.5.6 Known limitations

None.

2.2.5.7 Evaluation of the label claims

The label should claim "The use of the product may cause resistance development. To reduce the risk of developing resistance against permethrin it is recommended to switch between products with different modes of action."

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

None.

2.2.6 Risk assessment for human health

Loppex was not assessed, as a representative product, during the evaluation of the active substance permethrine.

The toxicology of the active substance permethrin was evaluated according to requirements in the review programme for inclusion of permethrin in Annex I of regulation No. 528/2012. The toxicological properties of the active substance are summarised in the CA report (RMS IE, 2014).

Toxicological test for acute toxicity, skin and eye irritation and skin and respiratory sensitisation have not been performed on product Loppex. The classification of the product was done following the criteria for classification of mixtures according to the CLP regulation 1272/2008, resulting in a classification of Loppex as a skin sensitiser (H317).

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Loppex is not irritating or corrosive to skin
Justification for the value/conclusion	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected
Classification of the product according to CLP and DSD	According to CLP, Loppex is not to be classified concerning skin irritation/skin corrosion

Data waiving	
Information requirement	Study scientifically unjustified
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Reference is made to the EU - Assessment Report for permethrin as well as the SDS for the active substances permethrin og co-formulants Loppex is not to be classified concerning skin irritation/skin corrosion.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Loppex is not irritating to eye.
Justification for the value/conclusion	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
Classification of the product according to CLP and DSD	According to CLP, Loppex is not to be classified concerning Eye irritation

Data waiving	
Information requirement	Study scientifically unjustified
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Reference is made to the EU - Assessment Report for permethrin as well as the SDS for permethrin and co-fomulants. Loppex is not to be classified concerning eye irritation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract
Justification for the conclusion	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Reference is made to the EU - Assessment Report for permethrin as well as the SDS for permethrin and co formulants Loppex is not to be classified concerning respiratory tract irritation.
Classification of the product according to CLP and DSD	According to CLP, Loppex is not to be classified concerning Respiratory tract irritation

Data waiving	
Information requirement	Study scientifically unjustified
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Loppex is a skin sensitiser.
Justification for the value/conclusion	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). The available information results in the product being classified for skin sensitisation. This is based on the content of 1 % w/w permethrin. Reference is made to the EU - Assessment Report for permethrin as well as the SDS for permethrin and the co-formulants.
Classification of the product according to CLP and DSD	Skin Sens 1; H317

Data waiving	
Information requirement	Study scientifically unjustified
Justification	There are valid data available on each of the components in the

	mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). The available information results in the product being classified for skin sensitisation. This is based on the content of 1 % w/w permethrin.
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Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Reference is made to the EU - Assessment Report for permethrin as well as the SDS for permethrin and co formulants. Loppex is not to be classified concerning respiratory sensitisation
Classification of the product according to CLP and DSD	According to CLP, Loppex is not to be classified concerning respiratory sensitisation

Data waiving	
Information requirement	Study scientifically unjustified
Justification	Not applicable – not a requirement/CDS

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Loppex is not acute oral toxic (by oral route).
Justification for the selected value	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
Classification of the product according to CLP and DSD	According to CLP, Loppex is not to be classified concerning acute oral toxicity.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and

	synergistic effects between any of the components are not expected. Reference is made to the EU - Assessment Report for permethrin as well as the SDS for permethrin and co-formulants.
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Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Loppex is not Acute toxic (by inhalation)
Justification for the selected value	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
Classification of the product according to CLP and DSD	According to CLP, Loppex is not to be classified concerning acute inhalation toxicity.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Reference is made to the EU - Assessment Report for permethrin as well as the SDS for permethrin and co-formulants.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Loppex is not acute dermal toxicity.
Justification for the selected value	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
Classification of the product according to CLP and DSD	According to CLP, Loppex is not to be classified concerning acute dermal toxicity.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

	Reference is made to the EU - Assessment Report for permethrin as well as the SDS for permethrin and co-fomulants.
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Information on dermal absorption

Value used in the Risk Assessment – Dermal absorption	
Substance	Permethrin
Value(s)*	23%
Justification for the selected value(s)	Refer to annex 3.3

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

The product also contains diatomaceous earth (DE), which is under evaluation as an active substance in PT18 under the regulation (EU) No 528/2012.

Since no systemic effects were observed in the studies evaluated in the assesment report for DE, no AELs have been derived.

Local effects were observed in animal studies due to accumulation of DE in the lungs of the animals. Acute, medium and long-term AECs were derived for inhalation and were based on a 28-day inhalation study in rats. NOEAC was set at 1 mg/m³ based on changes in the bronchoalveolar fluids and increased relative lung weight associated with minimal increase in alveolar macrophages.

When deriving a long term AEC, an overall AF of 75 was applied (2.5 for inter-species variation, 10 for intra-species variation and 6 for duration extrapolation from sub-acute to chronic), resulting in a AEC_{long-term} = 0.007 mg/m³/day.

Assuming an inhalation rate of 1,25 m³/h, a working day of 8 hours, a body weight of 60 kg and an inhalation absorption of 70% as given in the draft CAR for DE, the maximum exposure to the DE for was calculated for a 8 hours working day:

$$\frac{\left(0,007 \frac{\text{mg}}{\text{m}^3} * \left(1,25 \frac{\text{m}^3}{\text{h}} * 8 \text{ h}\right)\right) * 70 \%}{60 \text{ kg}} = 0,082 \text{ mg/kg bw/day}$$

This value is referred to as the systemic exposure reference value.

A risk assesment was preformed concerning inhalation of DE during the use of Loppex, which has been included in a separate confidential annex. Results of the risk assesment is presented under local effects.

2.2.6.2 Exposure assessment

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

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	n.a.	n.a.	Yes	n.a.	n.a.
Dermal	n.a.	yes	n.a.	n.a.	Yes	n.a.	n.a.
Oral	n.a.	no	n.a.	n.a.	no	n.a.	n.a.

List of scenarios

Exposure of professional users to the active substance permethrin during application of Loppex is calculated for the intended use to control mink fleas in farmed mink.

Loppex is not intended to be used by industrial or non-professional users.

An exposure and risk assessment for the mink during exposure in the treated nests is performed.

Risk for dietary exposure is not assessed as the product will not come into contact with food or feedingstuff or animals used in food production.

Summary table: scenarios			
Scenario number	Scenario (e.g. mixing/loading)	Primary or secondary exposure Description of scenario	Exposed group (e.g. professionals, non-professionals, bystanders)
1.	Mixing/Loading	Primary: Loading the product into a LOPPEX sprinkle canister.	professional
2.	Application of product	Primary: Dusting of nests with hand-held flexible canister	professional
3.	Cleaning sprinkle canister	Primary: Cleaning sprinkle canister after end application	Professional
4.	Cleaning	Secondary: The cleaning of nest boxes.	professional
5.	Handling of animals and fur	Secondary: The daily handling of the animals in the stable, handling of dead animals and mink fur	professional

Professional exposure

Combined scenarios

Summary table: combined systemic exposure from professional uses				
Scenarios combined	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenarios [1](tier1)+ [2](Tier 2)	0.0082	0.0057	n.a.	0,00883

Post application/Secondary exposure of professionalsScenario [3] Primary exposure from cleaning

Cleaning the sprinkle canister is considered covered by the application scenario. It would be expected that the worker might wipe of powder remainings from the outer surface of the sprinkle canister in connection with loading the canister or after application. However, it is reasonable to consider that application of powder is a more prone activity as compared to cleaning the canister sprinkle. Therefore, it is concluded that exposure due to cleaning is covered by the exposure assessment for application of Loppex.

Scenarios [4] and [5] Secondary exposure of professionals

Secondary exposure is considered to be negligible. During application, other workers may enter the areas being treated, but they would be expected to wear appropriate PPE as the workers during the actual application.

Workers may be exposed toward permethrin when cleaning of the housing/nest, but would be expected to wear appropriate PPE, and this task is not expected to be done by the same worker on the same day as application of Loppex is performed.

Furthermore, workers may be exposed when handling animals from Loppex treated nest and when handling the mink fur. The workers wear gloves for safety when handling animals to avoid bites and for general hygienic reason when handling dead animals or mink fur.

Overall, secondary exposure can be expected to be considerably lower than primary exposure. Thus, the workers' risk due to secondary exposure is covered by the primary exposure calculations.

Exposure of the general public

Exposure of the general public is not expected to occur. The general public (adults or children) are not present during the application, and is not expected to either enter treated areas, or to get in contact with treated straw or with the animals.

Exposure to permethrin when wearing mink fur is expected to be negligible because any residues of Loppex are removed during the several cleaning step in the procedure for finishing mink skin. Assessment of the exposure of the general public is therefore not considered relevant.

Animal exposure

Summary table: scenarios			
Scenario number	Scenario (e.g. mixing/loading)	Primary or secondary exposure Description of scenario	Exposed group (e.g. professionals, non-professionals, bystanders)
1.	Post application (animals)	Secondary: Animal exposure in nests	Animal

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake
1+2	professionals	Tier 2 w/PPE	0,00883 mg/kg/d
2	Mink	Not relevant	0.023 mg/kg/d

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF*	Correction for oral absorption	Value
AELshort-term	2-year oral study in rats	59,4 mg/kg bw/day	100	-	0.5 mg/kg bw/day
AELmedium-term	12 month study in dog	5 mg/kg bw/day	100	-	0.05 mg/kg bw/day
AELlong-term	12 month study in dog	5 mg/kg bw/day	100	-	0.05 mg/kg bw/day

* Compensating for inter/intra species variation

Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
[1] Mixing and loading	1	5	0.05	0.00008	0.2%	Yes

[2] Application	1	5	0.05	0.076	157.1%	No
[2] Application	2	5	0.05	0.006	17.5%	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
[1]+[2]	Scenario 1- tier 1 Scenario 2- Tier 2	5	0.05	0.0065	17.7%	yes

Local effects

Loppex contains 1 % (w/w) permethrin which is classified as a skin sensitizer. As a result Loppex is classified Skin sens 1; H317 according to CLP. According to BRP guidance³ a qualitative risk characterisation has to be performed for the product.

Taking into account that Loppex is only for professional use, the mandatory use of protective gloves, limited application of the product and permethrin not being regarded as a strong skin sensitizer the risk characterisation of the use of Loppex is estimated to be categorised as "medium" or "low" (e.i. the use is regarded as safe).

A risk assessment for inhalation of diatomaceous earth (DE) was performed on the local effect of accumulation in the lungs. Risk assessment shows no risk for DE during the use of Loppex.

Conclusion

The loading of canister and application of Loppex by professional is considered acceptable when using the appropriate PPE (gloves and coated coveralls) for application.

Secondary exposure of professionals is not considered significant. The potential exposure due to secondary task with mink are considered to be covered by the risk assessment of the primary exposure of professionals.

Risk for the general public

No risk for the general public. The product is intended for professional use only and the general public is not expected to be exposed.

Exposure of the general public to permethrin from contact to Loppex is not expected to occur. The general public are not present during the application of the product, nor expected to enter treated areas or get in contact with treated straw and animals. Mink fur is either first washed in soapwater or tumbled with sawdust, and then after skinning and

³ Guidance on the BPR: Volume III, Part B, Risk Assessment, Version 2.0 October 2015, ECHA

scraping tumbled with sawdust. Therefore it is unlikely that the mink fur contains residues of Loppex when reaching the consumers.

2.2.7 Risk assessment for animal health

Minks are not present during application but can be exposed mainly via dermal route when placed back into the threatened nests. The first application of Loppex is done at pre-mating. Each breeding female mink is kept individually in one cage within the nest boxes that have already been treated with Loppex. After the cubs are born, mother and cubs stay together in one cage for approximately 8 weeks. The second application of Loppex is done when the cubs are separated from the mother at 8 weeks.

There is no data available on the NOAEL for permethrin regarding the mink. For the risk assessment for mink, it is considered the most relevant value to use is the NOAEL from the 12-month dog study, which has the lowest identified NOAEL. There are no information of the toxicokinetic properties for mink, nor the toxicokinetic difference between the mink and the dog, and the dog is a larger animal than the mink. Therefore, an assessment factor of 10 is used to take potential differences in toxicokinetics into account, and to cover the interspecies differences when extrapolating between dog and mink.

When comparing the combined dermal and oral exposure of 0.023 mg/kg w/d with the lowest NOAEL of 5 mg /kg bw/d including an AF of 10 (0.5 mg /kg bw/d), the exposure of the adult mink is 4.7 %.

Therefore, the application of Loppex to nest is demonstrated to be safe and no unacceptable health risk has been identified for adult mink. If sporadic flea infestation occurs, treatment may be possible in 4 weeks intervals until flea are no longer observed. The applicant describes a worst case scenario, with one preventive treatments of the nest and additional three applications after mother and cubs are separated. The total exposure of 4 application would be 18.4% and also considered to be safe.

When considering mink pups, they weigh less and are thus potentially more susceptible to the effects of Loppex than adult mink. The exposure of the adult mink is only 4.7% with one application. It is assumed that Loppex applied pre-mating in the winter is not assessable, because the powder is laying in the bottom of the nest underneath the bedding material. Taking this into consideration it is assumed that the exposure of mink cubs are safe.

In addition, the applicant has submitted a safety evaluation of 1 % permethrin (Pulvex) dusting powder to new borne mink cubs which was conducted in 2002 at The Danish Fur Breeders Research Centre. The powder was administered to the nest as a dermal application to the coat of the cubs (5 g to each nest (2 x recommended dose)). The number of dead mink cubs in treated group did not differentiate from the control group. No signs of clinical toxicity were seen in any of the treated animals. It was concluded that application of 1 % permethrin dusting powder should be safe for use on new borne mink pups (less than one day old). Taking this information into account in addition to the risk assessment of mink cubs the exposure is considered acceptable.

2.2.8 Risk assessment for the environment

Loppex is a ready-to-use powder containing 1% permethrin for use indoor in nest boxes in mink farms. It was not the representative formulation considered for the permethrin approval. The intended use are not similar to those presented in the CAR for the reference product.

No new data on environment and exposure for the product or the active substance was submitted.

The product also contains diatomaceous earth (DE), which is under evaluation as an active substance in PT18 (insecticides, acaricides and products to control other arthropods) under the regulation (EU) No 528/2012. Diatomaceous earth is an abrasive, fine white powder and a natural component of all aquatic ecosystems. It is chemically inert and non soluble, neither in water, nor in lipids. Due to its insolubility and density, diatomaceous earth will undergo sedimentation if it enters natural water bodies. Considering its origin and composition, DE is impossible to differentiate from the naturally occurring silicates in the sediment. In water and under high relative humidity DE becomes water saturated and loses its insecticidal effect. Considering the low content and application rate in the product releases to the environmental compartment (i.e. soil) should be considered negligible compared to the background level in soil of 706 g/kg_{dw}. Because of the very low effect and the negligible release expected based on the described use of the product, diatomaceous earth is not considered further in the environmental risk assessment of Loppex.

With exception of active substance there are no substance of environmental concern in the biocidal product.

The release of the total amount of permethrin applied in the mink farm is considered in the environmental risk assessment.

2.2.8.1 Effects assessment on the environment

The assessment is based on the data presented for the active substance permethrin in the CAR, including relevant metabolites, as there has not been submitted any effect studies regarding the product, and as there is no substance of environmental concern in the product.

Summary of PNEC values for the active substance and metabolites			
<i>Compartment</i>	<i>Permethrin</i>	DCVA	PBA
Surface water	0.00047 µg/L	0.015 mg/L	0.010 mg/L
Sediment	0.000217 mg/kg wwt	0.055 mg/kg dwt (0.012 mg/kg wwt)	0.042 mg/kg dwt (0.009 mg/kg wwt)
Soil	0.198 mg/kg wwt*	4.6 mg/kg wwt	1.44 mg/kg wwt
Oral bird	16.7 mg/kg food		
Small mammal	120 mg/kg food		

*As decided on the 22nd Coordination Group meeting

Harmonised environmental classification of the active substances

The environmental classification of the active substance is the following:

Harmonised env. classification for the active substances			
Substance	Env. classification	M-factor	Concentration of a.s. in the product (%)
Permethrin	H400, H410	M(acute)=1000 ¹	1.0

¹ The M-factors proposed in the assessment report for permethrin in PT8 and 18 is M(acute)=100 and M(chronic)=10.000. This will not change the classification of the product.

Environmental classification of the substance(s) of concern

Considering the low content and application rate in the product releases to the environmental compartment (i.e. soil) should be considered negligible compared to the background level in soil of 706 g/kg_{dw}. Because of the very low effect and the negligible release expected based on the described use of the product, diatomaceous earth is not considered further in the environmental risk assessment of Loppex. Diatomaceous earth has no environmental classification according to the CLP regulation.

With exception of active substance there are no substance of environmental concern in the biocidal product.

The biocidal product does not contain any other substances, which may influence the environmental classification.

Environmental classification of the biocidal product

Regarding the ecotoxicological properties, the formulation is very toxic to aquatic organisms. According to Regulation (EC) No 1272/2008 the product is classified as Aquatic Acute 1 (H400: Very toxic to aquatic life)/Aquatic Chronic 1 (H410: Very toxic to aquatic life with long lasting effects) with the signal word "Warning".

Further Ecotoxicological studies

No new ecotoxicological studies has been submitted.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Loppex is only to be used indoor at mink farms in nest boxes in the stables. Accordingly the use may result in indirect exposure of the soil compartment and ground water via application of manure and straw. In general, across Europe, it is prohibited to discharge waste from stables to the public sewer. Furthermore, the biocidal product is applied to the mink nest boxes alone. The nest boxes and the floor beneath are not wet cleaned during the mink breeding season. Between the seasons the nest boxes may be wet cleaned. It is assumed that the amount of biocide product left in the nest boxes after removal of straw and solid waste between the seasons will be negligible. Straw containing the biocidal product from the nest boxes and beneath the nest boxes is collected and placed in heaps and applied to land. Therefore emissions of the biocidal product to sewage treatment plants are not to be expected from mink farms and not considered in the evaluation of Loppex. Surface waters and sediment may indirectly be exposed via run-off from soil. Due to the low vapour pressure of permethrin volatilization of permethrin is considered to be negligible and therefore the air compartment is not considered further.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Indoor dusting of straw in nest boxes at mink farms. The product is a ready-to-use product that is manually loaded from a container into a Loppex sprinkle canister (applicator) with a capacity of 500 g. The task will be performed indoor (in the stable) by a professional worker and the mixing and loading step will be covered by the application step.
ESD(s) used	ESD for insecticides in mink farms agreed at WGII-2018 and Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, (OECD series No. 14, 2006)
Approach	Scenario 1: Average consumption
Distribution in the environment	Calculation based on Guidance on the Biocidal Product Regulation, Volume IV Environment – Assessment and Evaluation (Part B + C), October 2017 (Vol VI, 2017)
Groundwater simulation	Performed
Confidential Annexes	No
Life cycle steps assessed	Scenario 1: Production: No Formulation: No Use: No Service life: Yes
Remarks	

Emission estimation

Emission Scenario Document for Product Type 18: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, January 2006 does not contain a suitable scenario for the applied use of the product. The emission is therefore estimated based on conditions in the Nordic countries including Denmark. Denmark has the highest production of mink in Europe (Kopenhagen Fur, 2016).

According to a Swedish statistics it is assumed that the average number of female breeding animals in one farm is 3,000 (Swedish Board of Agriculture, 2013). The mean number of female breeding animals in one farm in Denmark is below 2,400 animals in 2015 according to the Danish Fur Breeders' Association, Kopenhagen Fur (Clausen, 2016). It is assumed that the mean size of the mink farms in Denmark and Sweden covers the conditions in the other European countries. The size of the farm is however not used for calculation of the release as the release depends on the amount of breeding females (mothers and cubs) per ha (or the release of straw/manure from them).

Default values have been determined based on information from industry and regulatory bodies in the Nordic countries in order to prepare an emission scenario where regulation and general practice in mink production regarding flea control, breeding cycle of mink and handling of manure and straw are included.

Soil might be exposed indirectly to the active substance by spreading the treated straw from mink farms on arable land or grassland. However, only arable land has to be considered, because solid waste shall be ploughed down immediately after application to

soil in Europe according to the working group II 2018 decision. The emission of the active substance from mink farms may be calculated based on application (amount applied to nest boxes).

It is assumed that each breeding animal is kept individually in one cage to be treated at the beginning of the breeding season. Mother and cubs stay together in one cage after the cubs are born. After the lactation period they are separated into pairs and all cages will be (re)treated. It is further assumed that each breeding female will bear 5.46 cubs per year including males according to Danish regulation (Bekendtgørelse nr. 374 af 19. april 2017) and guidance (Miljø- og Fødevareministeriet. 2017) so that the number of animals referred to as "breeding females" (BF) is 1 mother + 5.46 cubs, where the males are included in the amount. The number of nest boxes per BF may be calculated as follows: 1 animal per nest box before separation (first application) and 6.46 animals per BF/2 animals per nestbox (= 3) nest boxes per BF after separation (during the later applications). The timing of the application is essential in order to calculate how many nest boxes are treated according to before/after separation of the mother and cubs. Loppex is usually only applied once a year as a preventive treatment during the preparation of the nest boxes. In support of the label instructions ("There should be a re-treatment with Loppex each time the straw in the boxes is replaced"; "If sporadic flea infestation occurs, treatment may be possible in 4 weeks intervals until fleas are no longer observed") and as a worst case scenario, one preventive treatment of the nest boxes is assumed and a further three additional applications after mother and cubs have been separated.

The worst case of emission of product to the field is based on the regulation of straw/manure application to land in the Nordic countries considering the amount of straw/manure per BF.

It is further assumed that the product is only applied to straw in the nest box of a cage. If the product is applied directly onto the mink it may be considered a veterinary medicinal product and therefore not a biocide. Faeces and urine are collected separately in slurry drains and not mixed with the biocide-treated straw on most farms - 90% of the Danish farms has this system. Over the course of a season, straw waste containing the biocide product is removed from the nest boxes and placed in a single heap on concrete floor in open air with partial coverage under plastic sheeting to avoid spreading by wind and to avoid flies to feed and breed. The straw waste is applied to land later on. Straw and manure are in general mixed before application to land to obtain a high manorial value via an optimal ratio between nitrogen and phosphate for the land. Norm values that regulate the amount of straw applied to the field may in some countries depend on if the straw is mixed with the manure before application. Straw/manure from the heap is applied to land in Denmark until 15th of November or in the following spring where it is applied to fields and ploughed in to avoid removal of the straw by wind. Usually the straw/manure is applied to land once a year. In Denmark straw may only be applied to bare land, i.e. in the period after harvest and before sowing.

Degradation in the manure is not considered in the estimation.

Amount of straw applied to land

The yearly amount of straw including manure has been calculated for Denmark, Finland and Sweden. Iceland and Norway has comparable regulations to the Danish regulation. Generally speaking for the Nordic countries, the emission of manure/straw may be from maximum 40 BF per hectare per year, which is the legal maximum standard for application of straw/manure in Denmark.

Scenario 1

Summary table on calculated PEC values on arable land for permethrin						
	PEC _{water}	PEC _{sed}	PIEC _{soil}	PEC _{soil, TWA, 180 days}	PIEC _{soil, 10 years}	PEC _{GW}
	[µg/l]	[mg/kg _{wwt}]	[mg/kg _{wwt}]	[mg/kg _{wwt}]	[mg/kg _{wwt}]	[µg/l]
permethrin	$< 5 \cdot 10^{-5}$	$< 2.93 \cdot 10^{-5}$	0.00294	0.0019	0.00324	<0.000
DCVA	0.0034	$5.4 \cdot 10^{-6}$	$1.8 \cdot 10^{-4}$	$1.5 \cdot 10^{-4}$	$2.3 \cdot 10^{-4}$	<0.025
PBA	$7.0 \cdot 10^{-3}$	$3.42 \cdot 10^{-5}$	$2.4 \cdot 10^{-4}$	$4.8 \cdot 10^{-6}$	$2.4 \cdot 10^{-4}$	0.070

Summary table on calculated PEC _{gw} values on arable land (µg/L)		
Tier	1	2 using FOCUS PELMO (ver. 5.5.3)
Permethrin	$6.80 \cdot 10^{-3}$	<0.000
DCVA	0.3	0.34
PBA	0.07	-

Secondary poisoning

As the calculated PEC_{Coral, predatorS} << PNEC for both "oral Bird" and "Small mammal" (16.7 and 120 mg/kg food respectively) there is no risk of secondary poisoning via the terrestrial food chain either.

2.2.8.3 Risk characterisation

Risk characterisation ratios (PEC/PNEC) are provided for the aquatic and the terrestrial compartment in the following for permethrin and the two relevant metabolites DCVA and PBA. As stated in section 2.2.8.2 above, air and the STP are not regarded as compartments of concern for this product with the proposed used pattern.

Summary table for the PEC/PNECs for permethrin				
Compartment	Unit	PEC	PNEC	PEC/PNEC
Surface water, tier 1	µg/L	6.8E-04	0.00047	1.4
Surface water, tier 2	µg/L	5.0E-05	0.00047	0.1
Sediment	mg/kg _{wwt}	2.9E-05	0.000217	0.1
Soil, initial	mg/kg _{wwt}	2.9E-04	0.198	0.001
Soil, TWA, 10 years	mg/kg _{wwt}	1.9E-03	0.198	0.01
Soil, 10 years	mg/kg _{wwt}	3.2E-03	0.198	0.02

Summary table for the PEC/PNECs for DCVA				
Compartment	Unit	PEC	PNEC	PEC/PNEC
Surface water, tier 1	µg/L	3.0E-02	0.015	2.0

Surface water, tier 2	µg/L	3.4E-03	0.015	0.2
Sediment	mg/kg _{wwt}	4.0E-06	0.012	0.000
Soil, initial	mg/kg _{wwt}	1.8E-04	4.6	0.000
Soil, TWA, 10 years	mg/kg _{wwt}	1.4E-04	4.6	0.000
Soil, 10 years	mg/kg _{wwt}	2.3E-04	4.6	0.000

Summary table for the PEC/PNECs for PBA				
Compartment	Unit	PEC	PNEC	PEC/PNEC
Surface water, tier 1	µg/L	7.0E-03	0.01	0.7
Sediment	mg/kg _{wwt}	3.4E-05	0.009	0.004
Soil, initial	mg/kg _{wwt}	2.4E-04	1.44	0.000
Soil, TWA, 10 years	mg/kg _{wwt}	4.8E-06	1.44	0.000
Soil, 10 years	mg/kg _{wwt}	2.4E-04	1.44	0.000

The maximum calculated PEC_{gw} for permethrin and the metabolites DCVA and PBA are well below the acceptable limit of 0.1 µg/L. Accordingly the application of Loppex-contaminated straw/manure to soil (arable land) does not pose a risk to the ground water.

Secondary poisoning

Secondary poisoning

Summary table on secondary poisoning						
Compartment	Unit	PEC oral predator	PNEC birds	PEC/PNEC birds	PNEC Mammals	PEC/PNEC mammals
Aquatic	mg/kg _{wwt} fish	5.7E-05	16.7	0.00	120	0.00
Terrestrial, Vol IV	mg/kg	0.00416	16.7	0.00	120	0.00
Terrestrial, CAR	mg/kg	0.103	16.7	0.01	120	0.00

Conclusion: As the calculated PEC_{oral, predator's} << PNEC for both "oral Bird" and "Small mammal" (16.7 and 120 mg/kg food respectively) there is no risk of secondary poisoning via neither the terrestrial food chain nor the aquatic food chain.

Mixture toxicity

The product contains only one active substance (permethrin) and only one substance of concern (diatomaceous earth) that is not of environmental concern. Therefore an assessment of mixture toxicity is not relevant.

Aggregated exposure (combined for relevant emission sources)

Aggregated exposure is not relevant for the product.

Overall conclusion on the risk assessment for the environment of the product

The PEC/PNEC values for permethrin and the two metabolites DCVA and PBA considering the initial as well as the TWA approach based on the worst case assessment are below 1 for all compartments except for surface water for permethrin and the metabolite DCVA. The result from the refined exposure assessment for surface water using FOCUS resulted in PEC/PNEC values below 1 for both permethrin and DCVA.

Therefore it is concluded that there is no unacceptable risk for the environment considering the proposed dosage and the use of Loppex as insecticide in mink nests.

2.2.9 Measures to protect man, animals and the environment

Reference is made to section 2.1.4 and the SPC.

2.2.10 Assessment of a combination of biocidal products

The product is not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Since all substances included in this formulation are not considered to be substances for substitution, no comparative assessment has to be performed.

3 ANNEXES

3.1 References

Kopenhagen Fur. 2016. Verdensproduktionen af mink falder.

<http://www.kopenhagenfur.com/da/nyheder/2016/juni/verdensproduktionen-af-mink-falder>.
Accessed 22. November 2017.

Swedish Board of Agriculture. 2013. Yearbook of agricultural statistics 2013 at

<http://www.jordbruksverket.se>

Clausen J. 2016. Avlsdyrtælling 2015. Dansk Pelsdyravl. Juni 2016 no. 5. pp36-37.

<http://ipaper.ipapercms.dk/KopenhagenFur/DanskPelsdyravlJuni2015/>

3.2 List of studies for the biocidal product

Legal entity owner for all references listed below is Trinol A/S							
Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Endpoint names	Endpoint UUIDs
Morsing, E. and Klamer, M.	2016	Storage Stability of Trinol "Loppex"	Storage Stability of Trinol "Loppex", 1 December 2016, Prepared by Elisabeth Morsing and Morten Klamer, Order no. 712963_rev1, Danish Technological Institute	Danish Technological Institute	712963	3.2; 3.4.1	IUC5-b50d6faa-153e-4c7a-9128-76e7803e607a; b637df14-ec68-403e-aaf2-f88c040edc9a
Bjerring, T.	2018	ANALYTICAL TEST REPORT Tap Density acc. to OECD 109		Eurofins Product Testing A/S	392-2018-00120401_EN	3.3	Submitted to DEPA at Clockstop 6
Baker, I.P.	1984	Storage Data Sheet No. C007/84, Coopers Animal Health, nov. 1984		Formulation Laboratory, Coopers Animal Health	Experimental reference 533/3/186	3.4.1	4a963336-2e8a-4681-863e-8b9bc16a3c55
Pedersen, P.B. and Madsen, M.G.	2016	Analysis report 685549 Test on Loppex		Danish Technological Institute	685549	3.5	IUC5-0303bb2c-ca0d-4502-9b7f-641550c34151; IUC5-fb33e3a6-bdf7-4957-aa88-7f314cc9eb6b; IUC5-26c91b9a-3710-44fb-

							879d-54b345f1d0b8
Heike, M.S.	2016	Report on testing the substance "Loppex" according the UN-Test N.1; Bundesanstalt für Materialforschung und -prüfung (BAM), 7/10 2016.		BAM	16042323	4.2	52850a24-a741-4be1-a85d-303bc68803ed
Jensen, K. and Birkler, R.	2017	Loppex - validation report_20170130 (project no. 1379321)_Danish Meat Research Institute, 30th of January 2017.		Danish Meat Research Institute	Project no. 1379321	5	b46c0ccc-6d22-4428-b4c6-25db292cf3ad
Larsen, K.	1991	Laboratory and field evaluation of Pulvex for control of the squirrel flea (Monopsyllus sciurorum)		Landbrugsministeriet, Statens Skadedyrlaboratorium	55-1991	6.7	abf3c93f-1f79-3664-b148-5ee80648bcf3
	1981	An investigation into the absorption of permethrin from impregnated clothing		Wellcome Researc and Development, Beckenham		8.6	IUC5-29ed279b-aa0d-4b2f-b0a3-9af7872ea1c1

Clausen, T.N.	2002	Safety evaluation of 1 % permethrin (Pulvex) dusting powder to new borne mink kits		Danish Fur Breeders Research Centre		8.7.1	IUC5-69ff90f8-7960-497b- a2c7-d9a7f470e8db
Storm, M.	2016	Dosage Test of Loppex with canister		Trinol A/S		13	IUC5-ec272f5f-32cf-4192- bda5-8430f229e598

3.3 Information on dermal absorption – Loppex

No dermal absorption study on the b.p. has been performed. According to EFSA Scientific Opinion on the Science behind the Revision of the Guidance Document on Dermal Absorption (2011), 5.8 and OECD 156, 7.2.3: *“it may be assumed that skin penetration of water-based plant protection or biocide formulations or of solid materials (such as granules) will be equal to or less than for organic solvent-based formulations of the same active compound at the same concentration level, although there may be exceptions. Provided there are no further co-formulants contained that might alter dermal uptake, experimental data obtained with an organic solvent-based test preparation may be considered as a worst case”*

For solids or dried formulations, read-across to the tested permethrin formulation in the Competent Authority Report for permethrin, is considered as a worst-case approach. According to DocIIA page 32, a dermal absorption study *in vitro* on human skin will be required for each formulation type at product authorisation. Dermal absorption has been set at 2% in the CAR for permethrin derived in the *Bartelt & Hubbell 1987* study. In the pilot study, the first two volunteers was excluded from the derivation as they have a very low recovery (48-61%) and they seemed to be outliers compared to the other 4 volunteers (recovery 75-80%). In addition, the values have been normalised to 100% to compensate for the low recovery allowing derivation of a dermal absorption value of 2%. Since only four individuals are included in the study, one could expect a significant variation between replicates. Further, isopropanol is volatile and therefore it is expected that a isopropanol formulation will result in a lower recovery due to evaporation. As a result, a recovery of 75-80% for the isopropanol-containing formulation is not considered unacceptable and of concern. According to OECD 427, the duration of exposure is the time interval between application and removal of test preparation by skin washing. A relevant exposure period (typically 6 or 24 hours) should be used, based on the expected human exposure duration. In the *Bartelt & Hubbell 1987* study, skin wash is performed after 120 hours. It is therefore assumed that any potential available residues for dermal uptake in the skin, is included in the absorption value. Since no relevant amounts of residues was identified in tape strips and dressings after 120 hours, the measured urine concentration at 120 hours, DocIIIA page 56, is expected to cover dermal uptake and potential skin residues after 120 hours. According to the study report, 20 tape strippings per dressing change are performed “at specific schedule”. However, no elaboration of this schedule, number of tape strips and dressing changes is reported. Overall the information in DocIIIA is inconclusive and contains very few kinetic references. Only results from urine samples, dressings, faeces and skin wash after final wash (120 hours) have been reported, DocIIIA, 6.2(2), Bartelt N. 1987. Therefore, it is not possible to quantify the amount of residues, which was removed during dressing change and tape stripping and potentially could have been available for dermal uptake.

According to EFSA guidance on dermal absorption, 2017 the missing material shall be added to the observed amount if the calculated dermal absorption value is <5% and recovery <95%. As a result the RMS DK is of the opinion that missing material should be included in the absorption value for permethrin resulting in a dermal absorption value of 23%. Please refer to table 2.

Table 3.1: Results from *Bartelt & Hubbell 1987*

Volunteer	Urine	Faeces	Non-occlusive dressing	Final skin washing	SUM
1	0,4	0,02	59,6	0,012	61,0
2	0,29	0,01	46,1	0,0004	48,4
3	1,28	0,02	75,6	0,01	79,91
4	2	0,08	74,4	0,005	80,5
5	1,82	0,06	68,6	0,01	75,5
6	1,39	0,05	70,2	0,04	77,7
Mean main study	1,62	-	-	-	78,4
Mean pilot study	0,35	-	-	-	63,1
Dermal absorption, mean main study plus "missing test material"	23,23				

3.4 Output tables from exposure assessment tools

3.5 FOCUS PELMO v. 5.5.3 – output tables

Annual average concentrations of Permethrin, DCVA and PBA in the leachate at 1 meters depth:

3.5.1 Permethrin - Maize

*** FOCUSPELMO 5. 5. 3 *** (PELMO 4.01)

Ver 3 Hamburg, maize

(H) Trinol-Loppex

Ver 3 Hamburg scenario (53.63 N, 10.00 E) Year:01

Results for ACTIVE SUBSTANCE (Permethrin) in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00E+00	158.000	0.000
2	0.00E+00	112.700	0.000
3	1.81E-19	253.900	0.000
4	9.79E-18	274.600	0.000
5	6.47E-16	476.000	0.000
6	1.13E-14	489.000	0.000

7	8.86E-15	119.600	0.000
8	1.03E-14	113.000	0.000
9	3.17E-14	265.700	0.000
10	6.32E-14	305.000	0.000
11	7.49E-14	228.800	0.000
12	3.00E-13	515.400	0.000
13	5.36E-13	447.900	0.000
14	2.76E-13	179.100	0.000
15	6.55E-13	367.700	0.000
16	6.44E-13	312.500	0.000
17	4.00E-13	196.800	0.000
18	5.13E-13	257.100	0.000
19	4.90E-13	257.000	0.000
20	6.94E-13	316.900	0.000
21	2.96E-13	162.700	0.000
22	1.60E-13	112.700	0.000
23	2.74E-13	253.900	0.000
24	2.51E-13	274.600	0.000
25	3.60E-13	476.000	0.000
26	4.45E-13	489.000	0.000

Total	6.48E-12	5651.40	0.000
Perc.(18/19)	1.00E-12	514.100	0.000

Results for ACTIVE SUBSTANCE (Permethrin) in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00E+00	158.000	0.000
2	0.00E+00	112.700	0.000
3	4.99E-22	253.900	0.000
4	1.64E-18	274.600	0.000
5	2.11E-16	476.000	0.000
6	5.39E-15	489.000	0.000

7	4.46E-15	119.600	0.000
8	6.99E-15	113.000	0.000
9	2.47E-14	265.700	0.000
10	4.78E-14	305.000	0.000
11	5.73E-14	228.800	0.000
12	2.35E-13	515.400	0.000
13	4.45E-13	447.900	0.000
14	2.38E-13	179.100	0.000
15	5.84E-13	367.700	0.000
16	6.34E-13	312.500	0.000
17	4.04E-13	196.800	0.000
18	5.21E-13	257.100	0.000
19	5.07E-13	257.000	0.000
20	6.31E-13	316.900	0.000
21	3.59E-13	162.700	0.000
22	2.12E-13	112.700	0.000
23	3.52E-13	253.900	0.000
24	2.78E-13	274.600	0.000
25	3.81E-13	476.000	0.000
26	4.24E-13	489.000	0.000

Total	6.34E-12	5651.40	0.000
80 Perc.(18/20)	1.15E-12	574.000	0.000

*** FOCUSPELMO 5. 5. 3 *** (PELMO 4.01)

Ver 3 Hamburg, maize

(H) Trinol-Loppex

Ver 3 Hamburg scenario (53.63 N, 10.00 E) Year:01

Results for ACTIVE SUBSTANCE (Permethrin) in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)

1	8.86E-15	119.600	0.000
2	1.03E-14	113.000	0.000
3	3.17E-14	265.700	0.000
4	6.32E-14	305.000	0.000
5	7.49E-14	228.800	0.000
6	3.00E-13	515.400	0.000
7	5.36E-13	447.900	0.000
8	2.76E-13	179.100	0.000
9	6.55E-13	367.700	0.000
10	6.44E-13	312.500	0.000
11	4.00E-13	196.800	0.000

12	5.13E-13	257.100	0.000
13	4.90E-13	257.000	0.000
14	6.94E-13	316.900	0.000
15	2.96E-13	162.700	0.000
16	1.60E-13	112.700	0.000
17	2.74E-13	253.900	0.000
18	2.51E-13	274.600	0.000
19	3.60E-13	476.000	0.000
20	4.45E-13	489.000	0.000

Total	6.48E-12	5651.40	0.000
80 Perc.(12/13)	1.00E-12	514.100	0.000

Results for ACTIVE SUBSTANCE (Permethrin) in the percolate at the bottom of the simulated soil core

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)

1	4.46E-15	119.600	0.000
2	6.99E-15	113.000	0.000
3	2.47E-14	265.700	0.000
4	4.78E-14	305.000	0.000
5	5.73E-14	228.800	0.000
6	2.35E-13	515.400	0.000
7	4.45E-13	447.900	0.000
8	2.38E-13	179.100	0.000
9	5.84E-13	367.700	0.000
10	6.34E-13	312.500	0.000
11	4.04E-13	196.800	0.000
12	5.21E-13	257.100	0.000
13	5.07E-13	257.000	0.000
14	6.31E-13	316.900	0.000
15	3.59E-13	162.700	0.000
16	2.12E-13	112.700	0.000
17	3.52E-13	253.900	0.000
18	2.78E-13	274.600	0.000
19	3.81E-13	476.000	0.000
20	4.24E-13	489.000	0.000

Total	6.35E-12	5651.40	0.000
80 Perc.(12/14)	1.15E-12	574.000	0.000

3.5.2 DCVA - Maize

*** FOCUSPELMO 5. 5. 3 *** (PELMO 4.01)

Ver 3 Hamburg, maize

(H) Insert Title

Ver 3 Hamburg scenario (53.63 N, 10.00 E) Year:01

Results for ACTIVE SUBSTANCE (DCVA) in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	3.47E-06	158.000	0.000
2	2.65E-04	112.700	0.000
3	0.0111300	253.900	0.004
4	0.0422900	274.600	0.015
5	0.1051000	476.000	0.022
6	0.1361000	489.000	0.028

7	0.0232300	119.600	0.019
8	0.0224800	113.000	0.020
9	0.0491800	265.700	0.019
10	0.0627100	305.000	0.021
11	0.0563000	228.800	0.025
12	0.1414000	515.400	0.027
13	0.1470000	447.900	0.033
14	0.0364600	179.100	0.020
15	0.0743900	367.700	0.020
16	0.0667700	312.500	0.021
17	0.0422400	196.800	0.021
18	0.0578100	257.100	0.022
19	0.0570900	257.000	0.022
20	0.0801300	316.900	0.025
21	0.0349600	162.700	0.021
22	0.0191100	112.700	0.017
23	0.0410400	253.900	0.016
24	0.0557900	274.600	0.020
25	0.1092000	476.000	0.023
26	0.1365000	489.000	0.028

Total	1.3137900	5651.40	0.023
Perc.(20/11)	0.1364300	545.700	0.025

Results for ACTIVE SUBSTANCE (DCVA) in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	2.55E-09	158.000	0.000
2	3.06E-06	112.700	0.000
3	0.0023440	253.900	0.001
4	0.0228300	274.600	0.008
5	0.0953900	476.000	0.020
6	0.1356000	489.000	0.028

7	0.0292700	119.600	0.024
8	0.0229800	113.000	0.020
9	0.0512700	265.700	0.019
10	0.0581700	305.000	0.019
11	0.0499700	228.800	0.022
12	0.1322000	515.400	0.026
13	0.1526000	447.900	0.034
14	0.0471500	179.100	0.026

15	0.0714700	367.700	0.019
16	0.0691400	312.500	0.022
17	0.0412300	196.800	0.021
18	0.0556800	257.100	0.022
19	0.0585000	257.000	0.023
20	0.0725800	316.900	0.023
21	0.0424600	162.700	0.026
22	0.0253300	112.700	0.022
23	0.0436700	253.900	0.017
24	0.0475700	274.600	0.017
25	0.1055000	476.000	0.022
26	0.1365000	489.000	0.028

 Total 1.3132400 5651.40 0.023
 80 Perc.(21/12) 0.1746600 678.100 0.026

*** FOCUSPELMO 5. 5. 3 *** (PELMO 4.01)

Ver 3 Hamburg, maize

(H) Insert Title

Ver 3 Hamburg scenario (53.63 N, 10.00 E) Year:01

Results for ACTIVE SUBSTANCE (DCVA) in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0232300	119.600	0.019
2	0.0224800	113.000	0.020
3	0.0491800	265.700	0.019
4	0.0627100	305.000	0.021
5	0.0563000	228.800	0.025
6	0.1414000	515.400	0.027
7	0.1470000	447.900	0.033
8	0.0364600	179.100	0.020
9	0.0743900	367.700	0.020
10	0.0667700	312.500	0.021
11	0.0422400	196.800	0.021
12	0.0578100	257.100	0.022
13	0.0570900	257.000	0.022
14	0.0801300	316.900	0.025
15	0.0349600	162.700	0.021
16	0.0191100	112.700	0.017
17	0.0410400	253.900	0.016
18	0.0557900	274.600	0.020
19	0.1092000	476.000	0.023
20	0.1365000	489.000	0.028

Total	1.3137900	5651.40	0.023
80 Perc.(14/5)	0.1364300	545.700	0.025

Results for ACTIVE SUBSTANCE (DCVA) in the percolate at the bottom of the simulated soil core

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.0292700	119.600	0.024
2	0.0229800	113.000	0.020
3	0.0512700	265.700	0.019
4	0.0581700	305.000	0.019
5	0.0499700	228.800	0.022
6	0.1322000	515.400	0.026
7	0.1526000	447.900	0.034
8	0.0471500	179.100	0.026
9	0.0714700	367.700	0.019
10	0.0691400	312.500	0.022
11	0.0412300	196.800	0.021
12	0.0556800	257.100	0.022
13	0.0585000	257.000	0.023
14	0.0725800	316.900	0.023
15	0.0424600	162.700	0.026
16	0.0253300	112.700	0.022
17	0.0436700	253.900	0.017
18	0.0475700	274.600	0.017
19	0.1055000	476.000	0.022
20	0.1365000	489.000	0.028
Total	1.3132400	5651.40	0.023
80 Perc.(15/6)	0.1746600	678.100	0.026

3.5.3 PBA - Maize

*** FOCUSPELMO 5. 5. 3 *** (PELMO 4.01)

Ver 3 Hamburg, maize

(H) Insert Title

Ver 3 Hamburg scenario (53.63 N, 10.00 E) Year:01

Results for ACTIVE SUBSTANCE (PBA) in the percolate at 1 m soil depth

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	7.82E-20	158.000	0.000
2	0.00E+00	112.700	0.000
3	0.00E+00	253.900	0.000
4	2.70E-19	274.600	0.000
5	1.56E-20	476.000	0.000
6	0.00E+00	489.000	0.000
7	0.00E+00	119.600	0.000
8	0.00E+00	113.000	0.000
9	0.00E+00	265.700	0.000
10	0.00E+00	305.000	0.000
11	0.00E+00	228.800	0.000
12	2.93E-18	515.400	0.000
13	0.00E+00	447.900	0.000
14	0.00E+00	179.100	0.000
15	1.07E-21	367.700	0.000

16	0.00E+00	312.500	0.000
17	0.00E+00	196.800	0.000
18	0.00E+00	257.100	0.000
19	0.00E+00	257.000	0.000
20	0.00E+00	316.900	0.000
21	2.34E-19	162.700	0.000
22	-2.92E-22	112.700	0.000
23	0.00E+00	253.900	0.000
24	2.70E-19	274.600	0.000
25	1.56E-20	476.000	0.000
26	0.00E+00	489.000	0.000

Total	3.45E-18	5651.40	0.000
Perc.(25/15)	1.66E-20	843.700	0.000

Results for ACTIVE SUBSTANCE (PBA) in the percolate at the bottom of the simulated soil core

Year	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	2.69E-22	158.000	0.000
2	9.95E-21	112.700	0.000
3	0.00E+00	253.900	0.000
4	5.21E-20	274.600	0.000
5	1.14E-19	476.000	0.000
6	0.00E+00	489.000	0.000

7	0.00E+00	119.600	0.000
8	0.00E+00	113.000	0.000
9	0.00E+00	265.700	0.000
10	0.00E+00	305.000	0.000
11	0.00E+00	228.800	0.000
12	2.52E-18	515.400	0.000
13	9.91E-20	447.900	0.000
14	0.00E+00	179.100	0.000
15	0.00E+00	367.700	0.000
16	0.00E+00	312.500	0.000
17	0.00E+00	196.800	0.000
18	0.00E+00	257.100	0.000
19	0.00E+00	257.000	0.000
20	0.00E+00	316.900	0.000
21	7.17E-21	162.700	0.000
22	7.98E-20	112.700	0.000
23	1.77E-20	253.900	0.000
24	5.21E-20	274.600	0.000
25	1.14E-19	476.000	0.000
26	0.00E+00	489.000	0.000

Total	2.89E-18	5651.40	0.000
80 Perc.(13/24)	1.51E-19	722.500	0.000

*** FOCUSPELMO 5. 5. 3 *** (PELMO 4.01)

Ver 3 Hamburg, maize

(H) Insert Title

Ver 3 Hamburg scenario (53.63 N, 10.00 E) Year:01

Results for ACTIVE SUBSTANCE (PBA) in the percolate at 1 m soil depth

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00E+00	119.600	0.000
2	0.00E+00	113.000	0.000
3	0.00E+00	265.700	0.000
4	0.00E+00	305.000	0.000
5	0.00E+00	228.800	0.000
6	2.93E-18	515.400	0.000
7	0.00E+00	447.900	0.000
8	0.00E+00	179.100	0.000
9	1.07E-21	367.700	0.000
10	0.00E+00	312.500	0.000
11	0.00E+00	196.800	0.000
12	0.00E+00	257.100	0.000
13	0.00E+00	257.000	0.000
14	0.00E+00	316.900	0.000
15	2.34E-19	162.700	0.000
16	-2.92E-22	112.700	0.000
17	0.00E+00	253.900	0.000
18	2.70E-19	274.600	0.000
19	1.56E-20	476.000	0.000
20	0.00E+00	489.000	0.000
Total	3.45E-18	5651.40	0.000
80 Perc.(19/9)	1.67E-20	843.700	0.000

Results for ACTIVE SUBSTANCE (PBA) in the percolate at the bottom of the simulated soil core

Period	Pesticide Flux (g/ha)	Percolate (L/m ²)	Pesticide Conc. (µg/L)
1	0.00E+00	119.600	0.000
2	0.00E+00	113.000	0.000
3	0.00E+00	265.700	0.000
4	0.00E+00	305.000	0.000
5	0.00E+00	228.800	0.000
6	2.52E-18	515.400	0.000
7	9.91E-20	447.900	0.000
8	0.00E+00	179.100	0.000
9	0.00E+00	367.700	0.000
10	0.00E+00	312.500	0.000
11	0.00E+00	196.800	0.000
12	0.00E+00	257.100	0.000
13	0.00E+00	257.000	0.000
14	0.00E+00	316.900	0.000
15	7.17E-21	162.700	0.000

DK	Loppex		PT18
16	7.98E-20	112.700	0.000
17	1.77E-20	253.900	0.000
18	5.21E-20	274.600	0.000
19	1.14E-19	476.000	0.000
20	0.00E+00	489.000	0.000

Total	2.89E-18	5651.40	0.000
80 Perc.(7/18)	1.51E-19	722.500	0.000

3.6 Summaries of the efficacy studies

Reference is made to efficacy study attached in IUCLID, section 6.7

3.7 Confidential annex

Please see separate confidential annex.

3.8 Other