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)

Luxan Houtinsecticide-P

Product type PT8

Permethrin as included in the Union list of approved active substances

Asset Number: NL-0016852-0000

Evaluating Competent Authority: NL

Date: July 2020

Table of Contents

1 CONCLUSION

The product Luxan Houtinsecticide-P containing 0.20% permethrin (pure) is used for preventive treatment of wood in use class 1 and for curative treatment of wood against the larvae of wood boring beetles by professionals and non-professionals by spraying and brushing.
Preventive treatment of wood in use class 2 was also applied for, but this was not assessed as in line with efficacy guidance part B/C and EN599-1 fungicidal activity would also be required.

Luxan Houtinsecticide-P is a clear, homogeneous, colourless liquid with a hydrocarbon solvent odour. It is a ready to use formulation. The relative density of the product is 0.792 and its viscosity is 2.0 mPa.s at 20°C (2.53 mm^2/s). The surface tension is estimated to be 26mN/m. Based on accelerated storage stability data shelf life is two years at ambient storage conditions in coex PE/PA, HDPE or steel packaging.
For all three packaging materials the long term storage stability report has to be provided when available.

The product is classified as Aspiration Hazard (H304 is assigned) as it contains >10% H304 classified components and the kinematic viscosity is < 20.5 mm^2/s.

The product is not classified for any physical hazards according to Regulation (EC) No. 1272/2008. It is neither explosive nor oxidizing, and its flash point is 70°C. It is not flammable and not pyrophoric. The auto-ignition temperature is estimated to be 236°C.

The available analytical method for determination of permethrin in Luxan Houtinsecticide-P is validated and acceptable.
Analytical methods for residues in soil, air and water are accepted at active substance level. The analytical methods for residues in body fluids and tissues, food/feed of plant origin, and food/feed of animal origin are not available. Based on the toxicity of the active substance and the use of the product, these methods are not required.

In the coordinaton group meeting (number 22) of 22 March 2017 it was noted that the analytical method for residues in water as submitted in the Permethrin dossier, is not sensitive enough to enable monitoring at the PNEC. Therefore, new analytical methods for residues in surface water with an adequate limit of quantification should be submitted at the renewal of the active substance dossier.

The product is sufficiently efficacious against larvae of wood boring beetles in both preventative (125 g/m^2) and curative (250 g/m^2) applications.

It was concluded that the Tier 1 assessment for professional users applying Luxan Houtinsecticide-P by brushing or by spraying is acceptable. The estimated uptake during spraying, including loading of the ready to use product, covers 88.6% of the AEL (0.05 mg/kg bw/day) and during brushing, including loading, and cleaning of the brush the estimated uptake covers 8.4 % of the AEL. However, based on the local effects assessment, gloves are considered necessary during handling of Luxan Houtinsecticide-P.

It was concluded that the Tier 1 assessment for non-professional users (general public/consumers) applying Luxan Houtinsecticide-P by paint brushing or by spraying is

acceptable. The estimated uptake during spraying, including loading of the ready to use product, covers 0.50 % of the AEL (0.5 mg/kg bw/day) and during brushing, including loading, the estimated uptake covers 0.61% of the AEL.
In line with the risk assessment for the environment, utensils need to be disposed of after use. The following sentence is included in the use-specific risk mitigation measures of non-professional uses:
After use, dispose trigger sprayer or brush to hazardous or special waste collection point.

It can be concluded that the Tier 1 assessment for secondary exposure following chronic inhalation is acceptable. The secondary exposure is negligible (0.2% for adults and 0.4% for small children).

It is expected that the possible exposure to animals will also be negligible. However, as it cannot be fully excluded a risk mitigation measure is included: keep pets/animals out of reach during treatment and during drying of the wood.

Since no environmental emission is foreseen, no environmental risks have been identified. A potential risk exists for bats roosting on treated wood. A precautionary measure needs to be added to the SPC indicating that the product must not be used in areas where protected species such as bats, hornets or birds reside.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
Luxan Houtinsecticide-P	Netherlands (RMS)

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	[redacted]
	Address	[redacted]
Authorisation number	NL-0016852-0000	
Date of the authorisation	3 July 2020	
Expiry date of the authorisation	3 July 2030	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	[redacted]
Address of manufacturer	[redacted]
Location of manufacturing sites	[redacted]

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

Active substance	Permethrin
Name of manufacturer	[redacted]
Address of manufacturer	[redacted]
Location of manufacturing sites	[redacted]

2.1.2 Product (family) composition and formulation

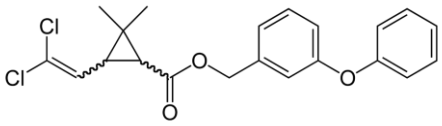
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

1 Please fill in here the identifying product name from R4BP.

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(s)	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
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	

2.1.2.2 Candidate(s) for substitution

Permethrin (various isomer mixtures) is not a PBT candidate nor are its individual constituent isomers.

Permethrin is considered to fulfill the T criteria, but does not fulfill the B criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the *cis* isomer) and therefore fulfills the P criteria. Guidance on PBT assessment (ECHA Guidance: Chapter R.11: PBT Assessment, v.1.1, November 2012) indicates that since the *cis* isomer constituent is present within permethrin at amounts ≥0.1 % w/w then the multi-constituent substance, permethrin, should also be treated as potentially persistent. In this situation permethrin may potentially fulfill the persistence criteria and, hence, fulfill two out of the three PBT criteria. Due to this borderline status and to the difficulties pertaining to the determination of the P classification, permethrin is currently assessed by the ECHA PBT working group. 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.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[2]

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**

2 Please delete as appropriate.

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.20 (technical : 0.22)
Shellsol D70	Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics aromatics <2% cyclics	Substance of concern	64742-47-8	none assigned	> 50

For full composition, refer to the confidential annex 3.6.1.

2.1.2.4 Information on technical equivalence

The active substance sources are included in the evaluation of permethrin and considered as reference sources of the active substance dossier.

2.1.2.5 Information on the substance(s) of concern

Shellsol D70 is a substance of concern. Please see the confidential annex for further details on the substance of concern.

2.1.2.6 endocrine disrupting properties

None of the co-formulants triggered an alert for ED property. See chapter 2.2.6.1 for more information for human health or chapter 2.2.8 for more information on environment.

2.1.2.7 Type of formulation

AL

2.1.3 Hazard and precautionary statements[3]

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

Professional use

Classification	
Hazard category	Aspiration Toxicity 1 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H304: May be fatal if swallowed and enters airways H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Hazard statements	H304: May be fatal if swallowed and enters airways H410: Very toxic to aquatic life with long lasting effects
Precautionary statements	P273: Avoid release to the environment P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor P331: Do NOT induce vomiting P501: Dispose of contents/container to a container park in accordance with local regulations
Additional labelling	EUH208: Contains permethrin. May produce an allergic reaction. EUH066: Repeated exposure may cause skin dryness or cracking.
Note	The identity of substances in the mixture that contribute to the classification of the mixture : Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, < 2% aromatics.

[3] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Non-Professional use

Classification	
Hazard category	Aspiration Toxicity 1 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H304: May be fatal if swallowed and enters airways H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Hazard statements	H304: May be fatal if swallowed and enters airways 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 of children P273: Avoid release to the environment P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor P331: Do NOT induce vomiting P405 : Store locked up P501: Dispose of contents/container to a container park in accordance with local regulations
Additional labelling	EUH208: Contains permethrin. May produce an allergic reaction. EUH066: Repeated exposure may cause skin dryness or cracking.
Note	The identity of substances in the mixture that contribute to the classification of the mixture : Hydrocarbons, C10-C14, n-alkanes, isoalkanes, cyclics, < 2% aromatics. Packaging supplied to the non-professional users has to be fitted with a child-resistant-fastening and a tactile warning.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Professional – Preventive application

Product Type	PT 8 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Wood boring beetles – larvae
Field of use	Indoor Preventive treatment of wood in Use Class 1
Application method(s)	Spraying with a spraying device at low pressure with large droplets or brushing (standard brush).
Application rate(s) and frequency	125 gram product per m² wood corresponding to about 158 mL product per m² wood Frequency of application: 1-2 times during the service life of the wood
Category(ies) of users	professional
Pack sizes and packaging material	5 – 1000 L HDPE, COEX PE/PA and steel

2.1.4.2 Use-specific instructions for use

Professional preventive spraying or brushing: Apply 125 gram product per m² wood corresponding to about 158 mL product per m² wood with a brush or with a spraying device for large droplets/low pressure.

2.1.4.3 Use-specific risk mitigation measures

Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information) during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

Table 2. Use # 2 – Professional – Curative application

Product Type	PT08 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Wood boring beetles – larvae
Field of use	Indoor In-situ treatment of wood in service.
Application method(s)	Spraying with a spraying device at low pressure with large droplets or brushing (standard brush).
Application rate(s) and frequency	250 gram product per m² wood corresponding to about 316 mL product per m² wood Frequency of application: 1-2 times during the service life of the wood
Category(ies) of users	professional
Pack sizes and packaging material	5 – 1000 L HDPE, COEX PE/PA and steel

2.1.4.7 Use-specific instructions for use

Professional curative spraying or brushing: Apply 250 gram product per m² wood corresponding to about 316 mL product per m² wood with a brush or with a spraying device for large droplets/low pressure.

Apply the required amount of product in two applications, in such a manner that runoff is prevented.

It is advised to perform periodical checks and at least a check one year after treatment. When wood dust/frass is found a second (local) treatment is required.

2.1.4.8 Use-specific risk mitigation measures

Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information) during handling of the product.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

Table 3. Use # 3 – Non-professional – Preventive application

Product Type	PT08 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Wood boring beetles - larvae
Field of use	Indoor Preventive treatment of wood in Use Class 1
Application method(s)	Trigger spraying or brushing
Application rate(s) and frequency	125 gram product per m² wood corresponding to about 158 mL product per m² wood Frequency of application: 1-2 times during the service life of the wood
Category(ies) of users	non-professional
Pack sizes and packaging material	0.5 - 5 L HDPE, COEX PE/PA and steel

2.1.4.12 Use-specific instructions for use

Non-professional preventive spraying or brushing: Apply 125 gram product per m² wood corresponding to about 158 mL product per m² wood with a brush or with a hand-held trigger spray.

2.1.4.13 Use-specific risk mitigation measures

Do not apply the product overhead using trigger sprayer After use, dispose trigger sprayer or brush to hazardous or special waste collection point.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

Table 4. Use # 4 – Non-professional - Curative application

Product Type	PT08 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Wood boring beetles - larvae
Field of use	Indoor In-situ treatment of wood in service.
Application method(s)	Trigger spraying or brushing
Application rate(s) and frequency	250 gram product per m² wood corresponding to about 316 mL product per m² wood Frequency of application: 1-2 times during the service life of the wood
Category(ies) of users	non-professional
Pack sizes and packaging material	0.5 - 5 L HDPE, COEX PE/PA and steel

2.1.4.17 Use-specific instructions for use

Non-professional curative spraying or brushing: Apply 250 gram product per m² wood corresponding to about 316 mL product per m² wood with a brush or hand-held trigger spray.

Apply the required amount of product in a two applications, in such a manner that runoff is prevented.

It is advised to perform periodical checks and at least a check one year after treatment. When wood dust/frass is found, then a second (local) treatment is required.

2.1.4.18 Use-specific risk mitigation measures

Do not apply the product overhead using trigger sprayer

After use, dispose trigger sprayer or brush to hazardous or special waste collection point.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Before treatment: First clean the wood from dust, dirt, frass. This has to be done 'dry'. Both frass and disposed wood need to be removed and preferably burnt. Remove paint, stain or wax layers. All required work on the wood (sanding, sawing etc.) has to be finished before treatment with the product is started.

2.1.5.2 Risk mitigation measures

Only allowed on covered wood (use class 1) Do not use the product in places accessible to children aged 0-4 years To protect aquatic organisms, run-off to soil or surface water needs to be prevented. Therefore treatment with this product needs to take place indoors. Discharge of leftover product and residues containing the product (e.g. solvents or water used for the cleaning of brushes or trigger spray bottles) to the sewer, soil or surface water is not permitted. Leftovers and residues containing the product (e.g. solvents or water used for cleaning of trigger spray bottles) need to be treated and discarded as chemical waste. Can be harmful to protected species such as bats, hornets or birds. The presence of protected species in the area to be treated must be assessed prior to use of the product. Appropriate protective measures must be taken if necessary. Do not put food/feed on treated (wet or dry) floors/wood/surfaces. Keep pets/animals out of reach during treatment and during drying of the wood. Avoid prolonged contact of pets, particularly cats, to treated surfaces Do not get in eyes, on skin, or on clothing

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

Particulars of likely direct or indirect effects: Possible effects (poisoning is unlikely, given permethrin concentration in product; common effect of pyrethroid intoxication: tingling sensation in extremities might be possible):

May be fatal if swallowed and enters airways (aspiration hazard).
Repeated exposure may cause skin dryness or cracking

First aid:
Symptoms/injuries after ingestion : May be fatal if swallowed.
Treat symptomatically. No specific antidote known.
First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If feeling unwell, seek medical advice.
First-aid measures after skin contact : Remove contaminated clothing and wash skin thoroughly with soap and water. Repeated exposure may cause skin dryness or cracking. Seek medical attention if irritation develops.
First-aid measures after eye contact : Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Seek medical advice and show container or label.
First-aid measures after ingestion : Seek medical advice immediately and show container or label. Do NOT induce vomiting.

Emergency measures to protect the environment:
Avoid release to the environment.
For containment : Clean up any spills as soon as possible by means of an absorbent material.
Methods for cleaning up : Small quantities of liquid spill: take up in non-combustible absorbent material and transfer to container for disposal. This material and its container must be disposed of in a safe way, compliant with local legislation.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Waste disposal recommendations : Dispose of this material and its container to hazardous or special waste collection point.

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

Storage conditions :
Store in original container. Keep out of reach of children. Do not store below 0°C.
Shelf life 2 years

2.1.6 Other information

Additional info on 2.1

Shellsol D70 content **> 50 %**

Remark on 3 precautionary statements: for non-professional only:

P102 Keep out of reach of childern

P101 If medical advice is needed, have product container or label at hand

P405 Store locked up

Additional info on 3:

The identity of substances in the mixture that contribute to the classification of the mixture : Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, < 2% aromatics

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)
Can, jerry can, drum, IBC	5-1000 L	HDPE, COEX PE/PA, steel	Polypropylene/HDPE/steel screw cap with tamper evident	Professional	Yes
Can, jerry can	0.5 – 5 L	HDPE, COEX PE/PA, steel	Accordingly child safety closures: Polypropylene screw cap with tamper evident tear off ratchet. Wad stuck	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

See Annex 3.1 with the reference of the product data. There are no new data on the active substance.

2.1.8.2 Access to documentation

A letter of access to the EU assessment dossier is available.

2.2 Assessment of the biocidal product (family)

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

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

See 2.1.4 for the authorised uses, after assessment of the dossier.

Table 5. Use # 1 – Professional – spraying

Product Type	PT08
Where relevant, an exact description of the authorised use	Professional spraying for curative or preventive treatment of wood under cover (roof). Apply the required amount of product in a single application, in such a manner that runoff is prevented.
Target organism (including development stage)	Wood boring beetles (larvae – curative use); Wood boring beetles (eggs/newly hatched larvae – preventative use).
Field of use	In-situ treatment of wood in service, in Use Classes 1 and 2
Application method(s)	spraying (low pressure, large droplets)
Application rate(s) and frequency	250 gram product per m2 wood corresponding to about 316 mL product per m2 wood (curative) 125 gram product per m2 wood corresponding to about 158 mL product per m2 wood (preventive) Frequency for the wood: once to twice in a service life of the wood Frequency for applying by professional users will be several times per year
Category(ies) of users	professional
Pack sizes and packaging material	5 – 1000 L HDPE, COEX PE/PA and metal

Table 6. Use # 2 – Professional – brushing

Product Type	PT 8
Where relevant, an exact description of the authorised use	professional brushing for curative or preventive treatment of wood wood under cover (roof). Apply the required amount of product in a single application, in such a manner that runoff is prevented.
Target organism (including development stage)	Wood boring beetles (larvae – curative use); Wood boring beetles (eggs/newly hatched larvae – preventative use).
Field of use	In-situ treatment of wood in service, in Use Classes 1 and 2
Application method(s)	brushing
Application rate(s) and frequency	250 gram product per m2 wood corresponding to about 316 mL product per m2 wood (curative) 125 gram product per m2 wood corresponding to about 158

	mL product per m2 wood (preventive) Frequency for the wood: once to twice in a service life of the wood Frequency for applying by professional users will be several of times per year
Category(ies) of users	professional
Pack sizes and packaging material	5 – 1000 L HDPE, COEX HDPE/PA and metal

Table 7. Use # 3 – Non-professional – spraying

Product Type	PT 8
Where relevant, an exact description of the authorised use	non-professional (general public) spraying for curative or preventive treatment of wood under cover (roof). Apply the required amount of product in a single application, in such a manner that runoff is prevented.
Target organism (including development stage)	Wood boring beetles (larvae – curative use); Wood boring beetles (eggs/newly hatched larvae – preventative use).
Field of use	In-situ treatment of wood in service, in Use Classes 1 and 2
Application method(s)	spraying (low pressure, large droplets) trigger spray bottle (plantenspuit)
Application rate(s) and frequency	250 gram product per m2 wood corresponding to about 316 mL product per m2 wood (curative) 125 gram product per m2 wood corresponding to about 158 mL product per m2 wood (preventive) Frequency for the wood: once to twice in a service life of the wood Frequency for applying for the non-professional user is also limited to 1 to 2 times per year
Category(ies) of users	non-professional
Pack sizes and packaging material	0,5 - 5 L HDPE, COEX HDPE/PA and metal

Table 8. Use # 4 – Non-professional - brushing

Product Type	PT 8
Where relevant, an exact description of the authorised use	non-professional (general public) brushing for curative or preventive treatment of wood under cover (roof). Apply the required amount of product in a single application, in such a manner that runoff is prevented.
Target organism (including development stage)	Wood boring beetles (larvae – curative use); Wood boring beetles (eggs/newly hatched larvae – preventative use).
Field of use	In-situ treatment of wood in service, in Use Classes 1 and 2
Application method(s)	brushing
Application rate(s) and frequency	250 gram product per m2 wood corresponding to about 316 mL product per m2 wood (curative) 125 gram product per m2 wood corresponding to about 158 mL product per m2 wood (preventive) Frequency for the wood: once to twice in a service life of the wood Frequency for applying for the non-professional user is also limited to 1 to 2 times per year
Category(ies) of users	non-professional
Pack sizes and packaging material	0,5 - 5 L HDPE, COEX HDPE/PA and metal

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	Observation	0.20% permethrin, neat product	Clear, homogeneous liquid	[redacted] (2016)
Colour at 20 °C and 101.3 kPa	Observation	0.20% permethrin, neat product	Colourless	[redacted] (2016)
Odour at 20 °C and 101.3 kPa	Observation	0.20% permethrin, neat product	Solvent	[redacted] (2016)
Acidity / alkalinity	n.a.	n.a.	Not required:The product is not an aqueous biocidal product nor is it to be applied as aqueous dilution eCA remark: Acceptable for both pH and acidity / alkalinity.	n.a.
Relative density / bulk density	EU Test Method A.3; oscillating densitimeter	0.20% permethrin, neat product	D_4^{20} = 0.792 eCA remark: Acceptable	[redacted] (2016)
Storage stability test – **accelerated storage**	CIPAC guideline MT 46.3; 2 weeks at 54°C	0.20% permethrin, neat product	Tested in PE/PA (100 mL), HDPE (100 mL) and steel (250 mL) packaging. Tested parameters: appearance, relative density, viscosity, a.s. content, stability of the packaging, and weight loss. A.s. content in Coex PE/PA packaging: 0.208% w/w (t=0) 0.207% w/w (t=2 weeks) A.s. content in HDPE packaging: 0.209% w/w (t=0)	[redacted] (2016)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			0.216% w/w (t=2 weeks) A.s. content in steel packaging: 0.209% w/w (t=0) 0.207% w/w (t=2 weeks) Appearance before and after storage in all three packaging: Clear, colourless liquid Stability of the packaging before and after storage for all three packaging: Sound condition, sealed and without leakages, no change after storage Weight loss Coex PE/PA packaging: 0.01-0.11% w/w Weight loss HDPE packaging: 2.63-3.06% w/w Weight loss steel packaging: 0.25-0.33% w/w Relative density in Coex PE/PA packaging: 0.7922 (t=0) 0.7922 (t=2 weeks) Relative density in HDPE packaging: 0.7922 (t=0) 0.7924 (t=2 weeks) Relative density in steel packaging: 0.7908 (t=0)	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			0.7922 (t=2 weeks) Viscosity before and after storage for all three packaging: 2.0 mPa.s (t=0) 2.0 mPa.s (t=2 weeks)All parameters remained within acceptable limits. eCA remark: Acceptable.	
Storage stability test – **long term storage at ambient temperature**	No guideline followed; 20±5°C in the dark, 7 month interim report	0.20% permethrin, neat product	Tested in HDPE and coex PE/PA packaging (both 100 mL bottles). Tested parameters: a.s. content, density, appearance of the packaging and appearance of the product. A.s. content in HDPE packaging: 0.200% w/w (t=0) 0.201% w/w (t=7 months) A.s. content in coex PE/PA packaging: 0.200% w/w (t=0) 0.201% w/w (t=7 months) Density in both packaging: 0.793 (t=0) 0.792 (t=7 months) Appearance in both packaging: Clear colourless liquid, no change after storage Appearance of both	[redacted] B. (2016)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			packaging: No change in appearance after storage eCA remark: Acceptable. The report contains interim data of a 36 months study. The final report should be provided when available. This will be included as a post authorisation requirement.	
Storage stability test – **low temperature stability test for liquids**	Waiver	n.a.	Not required: it is clearly stated on the label that the product must not be stored under conditions of ≤0°C eCA remark: Acceptable.	n.a.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver	n.a.	Not relevant: permethrin is not susceptible to breakdown by light (maximum UV/VIS absorption below 290 nm) and the product is packed in non-transparent packages. eCA remark: Acceptable	n.a.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Waiver	n.a.	Not relevant: product is to be stored in original packaging; accelerated storage stability tests showed product to be stable during 2 weeks at 54°C eCA remark:	n.a.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Acceptable	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC guideline MT 46.3 (2 weeks at 54°C), EU Test Method A.3, CIPAC guideline MT 192, observation and weighing	0.20% permethrin, neat product	The integrity, sealing, leakage, and dimensions of the packages were monitored during the storage stability test (2 weeks at 54°C). Test items remained in sound conditions. eCA remark: Acceptable.	[redacted] (2016)
Wettability	n.a.	n.a.	Not applicable; product is a liquid eCA remark: Acceptable	n.a.
Suspensibility, spontaneity and dispersion stability	n.a.	n.a.	Not required for AL formulation type eCA remark: Acceptable	n.a.
Wet sieve analysis and dry sieve test	n.a.	n.a.	Not required for AL formulation type eCA remark: Acceptable	n.a.
Emulsifiability, re-emulsifiability and emulsion stability	n.a.	n.a.	Not required for AL formulation type eCA remark: Acceptable	n.a.
Disintegration time	n.a.	n.a.	Not applicable; product is a liquid eCA remark: Acceptable	n.a.
Particle size distribution, content of dust/fines, attrition, friability	n.a.	n.a.	Not applicable; product is a liquid eCA remark: Acceptable	n.a.
Persistent foaming	n.a.	n.a.	Not required for a ready-to-use product	n.a.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			eCA remark: Acceptable	
Flowability/Pourability/Dustability	n.a.	n.a.	Not required for AL formulation type eCA remark: Acceptable	n.a.
Burning rate — smoke generators	n.a.	n.a.	Not applicable; product is not used for generating smoke eCA remark: Acceptable	n.a.
Burning completeness — smoke generators	n.a.	n.a.	Not applicable; product is not used for generating smoke eCA remark: Acceptable	n.a.
Composition of smoke — smoke generators	n.a.	n.a.	Not applicable; product is not used for generating smoke eCA remark: Acceptable	n.a.
Spraying pattern — aerosols	n.a.	n.a.	Not required; product is not intended for use as aerosol eCA remark: Acceptable	n.a.
Physical compatibility	n.a.	n.a.	Not required; Product is not to be used together with other products eCA remark: Acceptable	n.a.
Chemical compatibility	n.a.	n.a.	Not required; Product is not to be used together with other products eCA remark: Acceptable	n.a.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Degree of dissolution and dilution stability	n.a.	n.a.	Not applicable for a ready-to-use product eCA remark: Acceptable	n.a.
Surface tension	Theoretical assessment		26 mN/m at 20°C (comparable to that of the main solvent) eCA remark: Acceptable The applicant proposes to use read-across from the surface tension of the solvent to the product. The eCA considers this acceptable. Refer to confidential annex for justification.	n.a.
Viscosity	CIPAC guideline MT 192; rotational viscometer	Neat product	2.0 mPa · s at 20°C eCA remark: Acceptable. The viscosity at 40°C was not measured. It is not expected that the information obtained from this measurement changes the conclusions. The viscosity at 40°C will also be below the limit for H304 classification. Furthermore for the viscosity of the product read-across can be used from the viscosity of the solvent. Refer to confidential annex for justification.	[redacted] (2016)

Conclusion on the physical, chemical and technical properties of the product
Luxan Houtinsecticide-P is a clear, homogeneous, colourless liquid with a hydrocarbon solvent odour, an any-other-liquid, ready to use formulation. It has a relative density of 0.792 and its viscosity is 2.0 mPa.s at 20°C. Its surface tension is estimated to be 26mN/m). Based on acceleratred storage stability data it has a shelf life of two years at ambient storage conditions in coex PE/PA, HDPE or steel packaging. The report contains interim data of a 36 months study. The final report should be provided when available. This will be included as a post authorisation requirement. H304 is assigned because the product contains >10% H304 classified components and has a kinematic viscosity of < 20.5 mm^2/s.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waiver based on properties components	n.a.	Not explosive eCA remark: Acceptable	[redacted] (2015)
Flammable gases	n.a.	n.a.	Not applicable; product is a liquid eCA remark: Acceptable	n.a.
Flammable aerosols	n.a.	n.a.	Not applicable; product is not used as aerosol eCA remark: Acceptable	n.a.
Oxidising gases	n.a.	n.a.	Not applicable; product is a liquid eCA remark: Acceptable	n.a.
Gases under pressure	n.a.	n.a.	Not applicable; product is a liquid eCA remark: Acceptable	n.a.
Flammable liquids	ASTM D93 (Pensky-Martens closed cup)	0.20% permethrin, neat product	Flashpoint 70.0°C: non flammable eCA remark: Acceptable	[redacted] (2018)
Flammable solids	n.a.	n.a.	Not applicable; product is a liquid eCA remark: Acceptable	n.a.
Self-reactive substances and mixtures	Waiver	n.a.	Not applicable; product contains no components that are thermally unstable	n.a.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			eCA remark: Acceptable	
Pyrophoric liquids	Waiver	n.a.	Not applicable; product contains no pyrophoric components eCA remark: Acceptable	n.a.
Pyrophoric solids	Waiver	n.a.	Not applicable; product is a liquid eCA remark: Acceptable	n.a.
Self-heating substances and mixtures	Waiver	n.a.	Not applicable; product contains no self-heating components eCA remark: Acceptable	n.a.
Substances and mixtures which in contact with water emit flammable gases	Waiver	n.a.	Not applicable; product contains no components which in contact with water emit flammable gases eCA remark: Acceptable	n.a.
Oxidising liquids	Waiver based on structure components	n.a.	Not oxidising eCA remark: Acceptable	[redacted] (2015)
Oxidising solids	n.a.	n.a.	Not applicable; product is a liquid eCA remark: Acceptable	n.a.
Organic peroxides	Waiver	n.a.	Not applicable; product contains no organic	n.a.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			peroxides eCA remark: Acceptable	
Corrosive to metals	Waiver	n.a.	Not applicable; product contains no components that are corrosive to metals eCA remark: Acceptable	n.a.
Auto-ignition temperatures of products (liquids and gases)	Estimation	n.a.	~236°C eCA remark: Acceptable The auto-ignition temperature of each of the components is >200°C. Therefore, an estimation of the auto-ignition is acceptable.	n.a.
Relative self-ignition temperature for solids	n.a.	n.a.	Not applicable; product is a liquid	n.a.
Dust explosion hazard	n.a.	n.a.	Not applicable; product is a liquid	n.a.

Conclusion on the physical hazards and respective characteristics of the product
Luxan Houtinsecticide-P is a clear, homogeneous, colourless liquid with a solvent odour, an any-other-liquid ready to use formulation. The product does not have to be classified for any physical hazards according to Regulation (EC) No. 1272/2008. It is neither explosive nor oxidizing, and its flash point is 70°C. It is not flammable and not pyrophoric. Its auto-ignition temperature is estimated to be 236°C.

2.2.4 Methods for detection and identification

The product Luxan Houtinsecticide-P contains permethrin as active substance, which has been included in the current Union List of authorized active substances; an EU Assessment Report is available. Applicant has a Letter of Access to the Union List inclusion dossier for permethrin. For analytical methods, reference is made to the permethrin Assessment Report.

The GC-FID method used to determine the permethrin concentration in the product in the accelerated storage stability study was validated in a separate study. The validation study (see summary in IUCLID section 5) showed precision, accuracy, linearity and specificity of the analytical method to be acceptable (see table below).
For determination of linearity of detector response for permethrin six concentration levels were assessed ranging from 0.2519 to 0.6717 mg/mL (all solutions were injected three times).
For determination of accuracy (recovery) aliquots of placebo sample were spiked with permethrin at three levels (70, 100 and 130%, each level in triplo) and injected in duplicate.
For verification of system precision, six samples were measured (each sample injected twice). The determined method precision is 0.48%. This result meets the acceptance criterion RSD < 3.41 (maximum relative standard deviation calculated according to the modified Horwitz equation).

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		
Permethrin	GC-FID	70, 100, 130% / 3	r = 1.00 Linearity range: 0.2519 – 0.6717 mg/mL; 6 concen-tration levels	No interference from matrix (degree of interference less than 3%)	99.0-100.5	99.8	0.5	Not applicable; method will only be used for testing of specification limit.	[redacted] (2015)

Conclusion on the methods for detection and identification of the product
The available analytical method for determination of permethrin in Luxan Houtinsecticide-P is acceptable. Analytical methods for residues in soil, air and water are accepted at active substance level. The analytical methods for residues in body fluids and tissues, food/feed of plant origin, and food/feed of animal origin are not available. Based on the toxicity of the active

substance and the use of the product, these methods are also not required.

eCA remark:
Acceptable.

In the coordinaton group meeting (number 22) of 22 March 2017 it was noted that the analytical method for residues in water as submitted in the Permethrin dossier, is not sensitive enough to enable monitoring at the PNEC. Therefore, new analytical methods for residues in surface water with an adequate limit of quantification should be submitted at the renewal of the active substance dossier.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Luxan Houtinsecticide-P is an insecticide used as a preventative and curative preservative for wood against wood-boring beetles; the active substance is permethrin (1.6 g/L). It is intended for *in-situ* use by both professionals and the general public (non-professional users), on wood in service in Use Class 1. A claims matrix as defined in the Transitional Guidance on Efficacy Assessment for PT 8 is included below.

Categories	**Matrix wording**	**Code for product**
User category	Professional	A.30
	General public	A.10
Wood category	Softwood	B.10
	Hardwood	B.20
Wood product	Solid wood	C.10
	Panels	C.20
Application aim and field of use	Preventive / protection of wood from damage by woodboring beetles – use class 1	D.40; E.10
Method of application and rate	Superficial application – brushing; 125 g/m^2	F.10
	Superficial application – spraying; 125 g/m^2	F.11
Application aim and field of use	Curative / wood in service – use class 1	D.50; E.10
Method of application and rate	Superficial application – brushing; 250 g/m^2	F.10
	Superficial application – spraying; 250 g/m^2	F.11
Target organisms	Wood boring beetles	G.30

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

Luxan Houtinsecticide-P is intended to kill wood-boring beetles, more specifically their larvae, both preventative (preventing beetle eggs deposited in treated wood to hatch, or killing newly hatched larvae upon emergence from the egg), and curative (killing growing larvae in the wood after an infestation has been identified); the product is intended to protect covered and indoor wood in service.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Killing of (primarily) larvae of wood-boring beetles through disruption of neurological control, leading to paralysis and death. As the target animals are invertebrates, animal welfare is not assessed.

2.2.5.4 Mode of action, including time delay

Permethrin is a synthetic pyrethroid. The principal effect of this group of active substances is to delay sodium channel closure on nerve axons, which in turn delays membrane repolarisation following an action potential. This leads to spontaneous repetitive nerve firing and convulsions.

The visible symptoms of pyrethroid poisoning are typically a lack of co-ordination of movement and normal behaviour (often termed the "knockdown or kd effect"), the appearance of convulsive activity, regurgitation of alimentary canal contents, and ultimately paralysis and death. Symptoms which inhibit feeding and movement occur within minutes of dosing, but, depending on dose death due to dehydration and other secondary effects may take up to 24 hours.

2.2.5.5 Efficacy data

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**
Insecticidal wood preservative (PT 8)	Preventive wood preservation (Use Class 1)	Houtinsecticide-P (ready to use)*	*Hylotrupes bajulus*	EN 46-1 in combination with EN 73	Scots Pine sapwood treated with product (applied by brushing), aged and exposed to newly hatched larvae / 125.6 g product/m^2 (0.254 g permethrin/m^2) / up to 4 weeks	100 % mortality (control 3.5 %)	[redacted] (2015). Prüfbericht. BAM Report No 15026022 Hb, Berlin, Germany
Insecticidal wood preservative (PT 8)	Curative wood preservation	Houtinsecticide-P (ready to use)*	*Anobium punctatum*	EN 48	Scots Pine and Beech sapwood, aged, exposed to pests	98.6 % mortality in pine (control 11.1 %), 100 %	[redacted] Prüfbericht. BAM

					(ovipositing beetles), and treated with product (brushing) / 250 g product/m^2 (0.505 g permethrin/m^2) / up to 3 months	mortality in beech (control 8.3 %)	Report No 15026022 An1, Berlin, Germany
Insecticidal wood preservative (PT 8)	Curative wood preservation	Houtinsecticide-P (ready to use)*	*Anobium punctatum*	EN 370	Scots Pine sapwood, treated with product (brushing), aged and exposed to newly hatched larvae / 250 g product/m^2 (0.505 g permethrin/m^2) / up to 7.5 months	100 % prevention of emergence (control 67 % emergence)	[redacted] (2016). Prüfbericht. BAM Report No 15026022 An, Berlin, Germany

*) All efficacy tests were performed with „Houtinsecticide-P (ready to use)" which is identical in composition to the product to be authorized.

Conclusion on the efficacy of the product
The product is sufficiently efficacious against wood boring beetles in both preventative (125 g/m^2) and curative (250 g/m^2) applications.

2.2.5.6 Occurrence of resistance and resistance management

There are no reported cases of development of resistance involving the use of permethrin in wood preservation. Resistance has been documented when using permethrin as a general insecticide (documented in the PT18 assessment report). In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. Recent work shows that resistance against synthetic pyrethroids in bed bugs may result primarily from increased cuticle thickness and therefore reduced penetration. Since no resistance is known to occur when using permethrin as a wood preservative, no management is currently recommended other than vigilance for reduced efficacy.

2.2.5.7 Known limitations

No known limitations.

2.2.5.8 Evaluation of the label claims

Luxan Houtinsecticide-P is intended as preventative and curative treatment for wood in Use Class 1 against wood-destroying insects, more specifically 'wood boring beetles'. According to the Transitional Guidance on Efficacy Assessment for PT 8, dated March 2015, for wood in Use Class 1, preventative efficacy should be demonstrated against insects preferably according to EN 599-1, on wood test blocks aged according to EN 73. Acceptable beetle indicator species are *Hylotrupes bajulus*, *Anobium punctatum*, and *Lyctus brunneus*. For general claims against "wood boring beetles" it is noted that demonstration of preventive efficacy against *H. bajulus* will be considered adequate to cover this claim.

The preventative efficacy of Luxan Houtinsecticide-P was demonstrated in a test according to EN46-1 for superficial application in combination with EN73 against larvae of *Hylotrupes bajulus* at an application rate of 125 g/m^2. A 100% mortality was achieved, which is above the pass criterion of 80% mortality.

A literature survey was performed to demonstrate that *H. bajulus* is the worst case test organism for preventive use. [redacted] (1983) reported a toxic value for permethrin of 0.5-5.0 g/m^3 for eggs / egg larvae of *A. punctatum* and a toxic value of 5.5-11.9 g/m^3 for freshly hatched larvae of *H. bajulus*. These data support the fact that for this developmental stage (relevant for preventive use) *H.* bajulus is the least sensitive species.

According to the Transitional Guidance on Efficacy Assessment for PT 8, dated March 2015, curative efficacy against insect should be demonstrated against insects preferably according to EN14128. Minimum beetle indicator species for general claims are *Hylotrupes bajulus* and *Anobium punctatum*. Two studies were provided to demonstrate curative efficacy of the product.

The curative efficacy of Luxan Houtinsecticide-P was demonstrated in test according to EN 48 against *Anobium punctatum*, at a rate of 250 g/m^2. In this test a mortality of 100% and an emergence rate of 0% were achieved, which is above the respective pass criteria of 80% mortality and 3 out of 72 larvae emerging. Demonstrating curative efficacy with an EN48 test corresponds with a slow acting product. A second study according to EN370 was disregarded for evaluation as it was not performed in combination with EN73 as required by EN14128.

A literature survey has been provided to demonstrate that *A. punctatum* is the worst case test organism for curative use. [redacted]. (1983) reported a toxic value for permethrin of 42.4–96.3 g/m^3 for mature larvae of *A. punctatum* and a toxic value of 13.4-27.0g/m^3 for mature larvae of *H. bajulus*. These data support the fact that for this developmental stage (relevant for curtive use) *A. punctatum* is the least sensitive species. This fully supports the curative efficacy of Luxan Houtinsecticide-P as a wood preservative against wood boring beetles at an application rate of 250 g /m^2.

Tests done to establish the curative efficacy of Luxan Houtinsecticide-P were done according to specific test guidelines EN 48 and EN 370, subject to general guideline EN 14128. Guideline EN 14128 stipulates (section 5.2.6) that "[t]he maximum application limit shall not exceed 300 ml per square meter". However, it also states in NOTE 1 to 5.2.6 that "[i]f the curative wood preservative is specified by the manufacturer to be used at a higher application in practice, the manufacturer should define how this amount is to be achieved under practical conditions". EN 14128 does not provide an explicit rationale for the maximum application limit of 300 mL/m^2, but it appears that the maximum was

established to prevent runoff during application, which would negatively impact the actual dose received by the treated wood. The recommended curative dosage for Luxan Houtinsecticide-P is 316 mL (250 g product) per square meter, which is only slightly higher than the maximum rate recommended in EN 14128. Any risks of product runoff during curative use, by either brushing or spraying, can easily be prevented by recommending, in the instructions for use, that the prescribed dose is applied in such a manner that runoff is prevented, preferably by applying the recommended amount in two passes, with a short waiting time in between to allow the solvent to either be absorbed by the wood or evaporate.

References: [redacted] *(1983). Aspects of wood Protection research 1981-1982 at the BRE Princes Risborough Laboratory. BWPA Annual Convention 1983, pp 3-15.*

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

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

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

2.2.6.2 An expert statement is included in IUCLID. This statement addresses the acute toxicity of the biocidal product (Verhaar 2015).

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Luxan Houtinsecticide-P does not have to be classified as skin irritant.
Justification for the value/conclusion	According to the CLP Criteria a mixture does not have to be classified for skin irritation hazard if the total content of category 2 skin irritants <10% and the total content of skin corrosive components is < 1%. Based on the compostion as explained in detail in the confidential part (Annex 3.5), the product Luxan Houtinsecticide-P does not have to be classified as skin irritant.
Classification of the product according to CLP and DSD	Not required.

Data waiving	
Information requirement	IUCLID section 8.1
Justification	With the product Luxan Houtinsecticide-P no tests for skin irritation have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Luxan Houtinsecticide-P does not have to be classified as eye irritant.
Justification for the value/conclusion	According to the CLP Criteria a mixture does not have to be classified for eye irritation hazard if the total content of category 1 eye irritants is >3%. Based on the compostion as explained in detail in the confidential part (Annex 3.5), the product Luxan Houtinsecticide-P does not have to be classified as eye irritant.
Classification of the product according to CLP and DSD	Not required

Data waiving

Information requirement	IUCLID section 8.2
Justification	With the product Luxan Houtinsecticide-P no tests for eye irritation have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not applicable.
Justification for the conclusion	There are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation. It is noted that one of the formulants is classified for respiratory tract irritation, however the concentration of this formulants is lower than 1%. For further details see under 'other toxicity'.
Classification of the product according to CLP and DSD	Not required

Data waiving	
Information requirement	not in IUCLID
Justification	With the product Luxan Houtinsecticide-P no tests for respiratory tract irritation have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Luxan Houtinsecticide-P does not have to be classified as skin sensitizer
Justification for the value/conclusion	Among the formulants Permethrin (0.2% = 1.6 g/L) is classified for sensitizing properties (cat 1B), however it does not exceed the 1% and the product does not have to be classified. In the EU, the special hazard phrase EUH208, intended to protect persons previously sensitized to certain substances, is required for a mixture containing at least one substance classified as sensitising and present in a concentration equal to or greater than 0.1% or in a concentration equal to or greater than that specified under a specific note for the substance in part 3 of Annex VI. Therefore, Luxan Houtinsecticide-P label (SDS) shall bear the

	statement: „Contains permethrin . May produce an allergic reaction.”
Classification of the product according to CLP and DSD	EUH208: „Contains permethrin . May produce an allergic reaction.”

Data waiving	
Information requirement	IUCLID section 8.3
Justification	With the product Luxan Houtinsecticide-P no tests for skin sensitization have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Luxan Houtinsecticide-P does not have to be classified as respiratory sensitizer
Justification for the value/conclusion	Luxan Houtinsecticide-P does not contain formulants classified as respiratory sensitizer.
Classification of the product according to CLP and DSD	No classification is required

Data waiving	
Information requirement	IUCLID section 8.4
Justification	Not applicable

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	The product does not have to be classified for acute oral toxicity.
Justification for the selected value	With the product Luxan Houtinsecticide-P no tests for acute oral toxicity have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC. Based on the calculation rules and the compostion as explained in detail in the confidential part (Annex 3.5), the product Luxan Houtinsecticide-P does not have to be classified for acute oral toxicity.
Classification of the product according to CLP and DSD	Not required

Data waiving	
Information requirement	IUCLID section 8.5.1
Justification	With the product Luxan Houtinsecticide-P no tests for acute oral toxicity have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	The product does not have to be classified for acute inhalation toxicity.
Justification for the selected value	With the product Luxan Houtinsecticide-P no tests for acute inhalation toxicity have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC. Based on calculation rules and the compostion as explained in detail in the confidential part (Annex 3.5), the product Luxan Houtinsecticide-P does not have to be classified for acute inhalation toxicity.
Classification of the product according to CLP and DSD	Not required.

Data waiving	
Information requirement	IUCLID section 8.5.2
Justification	With the product Luxan Houtinsecticide-P no tests for acute inhalation toxicity have been performed. The classification and labelling of the product has been prepared based on the ingredients and the

	calculation method described in Annex I of Regulation 1272/2008/EC.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	The product does not have to be classified for acute dermal toxicity.
Justification for the selected value	Based on calculation rules and the compostion as explained in detail in the confidential part (Annex 3.5), the product Luxan Houtinsecticide-P does not have to be classified for acute dermal toxicity.
Classification of the product according to CLP and DSD	Not required

Data waiving	
Information requirement	IUCLID section 8.5.3
Justification	With the product Luxan Houtinsecticide-P no tests for acute dermal toxicity have been performed. The classification and labelling of the product has been prepared based on the ingredients and the calculation method described in Annex I of Regulation 1272/2008/EC.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	permethrin		
Value(s)*	3%		
Justification for the selected value(s)	set in EU assessment report		

Data waiving	
Information requirement	IUCLID section 8.6
Justification	With the product Luxan Houtinsecticide-P no tests for dermal absorption of permethrin have been performed. Details on the dermal absorption information can be found in the EU assessment of the active substance permethrin. In the EU LOEP a dermal absorption of 3% is set for permethrin. This 3% dermal absorption value is derived from a human volunteer study. As concluded in the AR: "Dermal absorption has been set at 3% derived in a human dermal penetration study. The first two volunteers have been excluded from the derivation as they have a very low recovery and were regarded as outliers compared to the other 4 volunteers. In addition,

	the values have been normalised to 100% to compensate for the low recovery allowing derivation of a dermal absorption value of 3% as a rounded figure." Details of this study can be found in the EU dossier, part III and a copy is included in Appendix 3.7 – confidential annex. In this human volunteer study a solvent-based formulation was used, containing 637.5 ug permethrin/mL solvent, corresponding to 0.6375 g/L, or 0.06%; the solvent was isopropanol. Luxan Houtinsecticide-P is also solvent-based product, containing 0.2% permethrin w/w (2 g/L) in Shellsol D70. When comparing these two formulations it should be noted that -the formulation matrix in Luxan Houtinsecticide-P (Shellsol D70, being a mixture of aliphatic hydrocarbons, predominantly C11-C14 paraffins (alkanes) and naphthenes (cycloalkanes)) is significantly more hydrophobic (log Kow dodecane 6.10 – from EPI Suite experimental database) than the formulation matrix in the product used in the human volunteer study (isopropanol, log Kow 0.05 – from EPI Suite experimental database); -the formulation Luxan Houtinsecticide-P contains a higher concentration of permethrin (0.2% w/w) than the formulation used in the human volunteer study (0.06%). Consequently, it can be argued that dermal uptake of permethrin, being primarily a partitioning process between two phases, the formulation matrix in contact with the skin, and the skin and underlying compartment, of permethrin, a hydrophobic substance (log Kow) from a hydrophobic matrix to skin will be lower and slower than from a matrix of intermediate hydrophobicity; stated differently, more permethrin will remain in a Shellsol matrix than in a comparable isopropanol matrix. It can also be argued that initial dermal uptake, being a kinetically controlled process, will deplete a matrix with a lower concentration faster than a matrix with a higher concentration, under comparable conditions. As such, both aspects of Luxan Houtinsecticide-P (nature of matrix and concentration of solute) indicate that dermal uptake, expressed as percentage of the amount present in the matrix applied to skin, will be lower for Luxan Houtinsecticide-P than for the formulation used in the human volunteer study. Therefore it is warranted to consider the results from the human volunteer study as conservative when compared to results expected for Luxan Houtinsecticide-P; the dermal uptake percentage observed in the human volunteer study can be used as a conservative estimate of the expected dermal uptake of permethrin from Luxan Houtinsecticide-P. Additionally, in line with the EFSA guidance on dermal absorption ((EFSA Journal 2012;10(4):2665) the following read-across points are considered as well: synergist and safener content, skin irritancy, sensitising potential. Luxan Houtinsecticide-P does not contain safeners and synergists (see also Appendix 3.6 confidential annex) and also based on the information above, the related criteria does not apply.

	The biocidal product should have the same or no sensitising potential based on classification. Luxan Houtinsecticide-P is not classified for sensitizing properties. However, for the active substance itself, permethrin, the following phrase is assigned EUH208: „Contains permethrin. May produce an allergic reaction.". Permethrin is present in the product (0.20%) as well as in the reference formulation (0.6%) and as such this criterion is considered to be fulfilled. *The biocidal product is of the same or lower skin irritancy based on scores in studies. These must include initial findings (as dermal absorption is often significant within the first 24 hours), not just the classification. If no skin irritation study is available, a comparison based on the irritancy of the components can be performed, but the outcome should be interpreted with care as classification does not take initial irritation scores into account*. There are no skin irritation scores (tests) available with the product or the reference formulation, they are both not classified for skin irritation. One formulant of the biocidal product is classified for skin irritancy – cat 2 skin irritant (SDS). Permethrin is not a skin irritant (EU LOEP). According to the CLP Criteria a mixture does not have to be classified for skin irritation hazard if the total content of category 2 skin irritants <10% and the total content of skin corrosive components is < 1%. Based on the composition as explained in detail in the confidential part (Annex 3.5), the product Luxan Houtinsecticide-P does not have to be classified as skin irritant. The formulant in the reference formulation, isopropanol, is not classified for skin irritation, but was found in literature to be a mild skin irritant (UK public health England: Isopropanol 2016, and WHO INCHEM visited 14.06.2018). As such it can be concluded that both the reference formulation and the product Luxan Houtinsecticide-P are not classified for skin irritancy, although both contain a component that is considered a (mild) skin irritant. The reference product consists for over 99% of this component and the biocidal product does only contain a small amount of this component. As such the criterion that the biocidal product should be of the same or lower irritancy is fulfilled. There is no influence on the dermal absorption values expected and based on the above information, the value of 3% can be used for Luxan Houtinsecticide-P. NL CA note – dermal absorption was discussed during mutual recognition process in which the classification of the co-formulant as included in the product and from the tested formulation of the human volunteer study as included in the PAR was discussed. Additional information is provided below. In the human volunteer study radioactive labelled permethrin was diluted in isopropanol. For isopropanol a harmonised classification is available which includes classification for irritating effects: H319. Furthermore, in the LoEP for isopropoanol the following classification proposal is included for human health: H319 and EUH066. Comparing the classification of Shellsol D70 and isopropanol, we think isopropanol can be considered worst case for Shellsol 70 for potential effect on dermal absorption, as it contains the same (i.e.

	EUH066) or more irritating properties (H319) which could potentially affect the dermal absorption. Furthermore, it is noted that Luxan Houtinsecticide-P is classified for EUH066 (not for H319). Considering this, including the arguments already included in the PAR and noting that the derived 3% is a rounded up value from study results, we are still of the opinion that for dermal absorption the value of 3% is applicable.

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

Luxan Houtinsecticide-P contains ShellSol D70 (Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, < 2% aromatics) at a concentration > 90% (see confidential part for exact concentration), as Shellsol D70 is classified with H304, the product will also be classified with H304. Considering the CA guidance for substances of concern (SoCs) (CA-Nov14-Doc.5.11), criteria 1, Shellsol D70 is considered a substance of concern. According to the CA guidance, H304 is in band A and no further risk assessment is required, when the relevant P-phrases related to the H phrase are applied. Based on H304 classification, P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor and P331: Do NOT induce vomiting are assigned to professional and non-profiessional use are highly recommended according to the Labelling Guidance. Furthermore for non-professional use, P405 : Store locked up is also added as this phrase is indicated as highly recommended for the general public in accordance to the Labelling Guidance.

See also Appendix 3.6 (confidential part) for further information on the substances of concern.

Available toxicological data relating to a mixture

This is not applicable as there is no mixture that a substances of concern is a component of.

Other

The following toxicity endpoints are collected under 'other': Aspiration hazard, skin dryness, local effects and Genotoxicity, carcinogenicity and reprotoxicity:

Aspiration hazard

Value used in the Risk Assessment – Aspiration hazard	
Value	Aspiration hazard.
Justification for the selected value	One of the formulants is classified in catergory 1 for aspiration hazards which results in H304. Luxan Houtinsecticide-P contains >50% of this formulant (for detailed information on the compositions please refer to the confidential Annex 3.5) and as such shall also be labelled with H304.
Classification of the product according to CLP and DSD	Category 1, Aspiration Hazard H304 'May be fatal if swallowed and enters airways'

Skin dryness

Value used in the Risk Assessment – Skin dryness	
Value	skin dryness
Justification for the selected value	One of the formulants is labelled with EUH066. Luxan Houtinsecticide-P contains >50% of this formulant (for detailed information on the compositions please refer to the confidential Annex 3.5) and should be labelled EUH066 as well.
Classification of the product according to CLP and DSD	EUH066: 'Repeated exposure may cause skin dryness or cracking'

Local effects

Value used in the Risk Assessment – Local effects	
Value	Minor local skin effects
Justification for the selected value	Permethrin is a pyrethroid. Pyrethroids produces very slight and reversible paresthesia (itching or tingling sensation), which is probably the result of local irritation of the peripheral nerves. The following phrase: "Do not get in eyes, on skin, or on clothing" is assigned as a risk mitigation measure.
Classification of the product according to CLP	"Do not get in eyes, on skin, or on clothing" will be included as a risk mitigation measure

Genotoxicity, carcinogenicity and reprotoxicity

Value used in the Risk Assessment – Genotoxicity, carcinogenicity and reprotoxicity	
Value	no effects
Justification for the selected value	None of the formulants in Luxan Houtinsecticide-P possess genotoxicy/carcinogenic/reproductive toxic properties.
Classification of the product according to CLP and DSD	not required

Assessment for endocrine disrupting properties

According to the ED (endocrine disruptor) criteria with respect to humans established in the Comission Delgated Regulation (EU) 2017/2100, a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

To examine if any of the co-formulants contained in the product may possess ED properties, a screening was performed by examining whether the co-formulants are

- Classified as CMR or PBT;
- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
- Identified as ED in the EU list of potential endocrine disruptors; or
- Listed in CoRAP linked to ED concerns.

None of the co-formulants triggered an alert for ED property.

Subsequently, it was examined if there are any concerns for adverse effects to meet the critaria a) as described above using ECHA REACH database. This examination did not result in alerts, and therefore it was concluded that no further ED assessment was required for Luxan houtinsecticide-P.

2.2.6.3 Exposure assessment

Luxan Houtinsecticide-P (containing 0.2% equal to 1.6 g/L permethrin) is applied by brushing (painting) or by spraying the ready-to-use product at low volume with large droplets (for example a trigger spray).
Both spraying and brushing are done with 250 gram product per m^2 wood corresponding to about 316 mL product per m^2 wood for curative treatment or with 125 gram product per m^2 wood corresponding to about 158 mL product per m^2 wood for preventive treatment.

The frequency for the wood treatment is once in the service life of wood to be treated, possibly repeated after 6 – 12 months, depending on the infestation status of the wood and whether preventive or curative treatment (dosage) has been applied.

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	yes	n.a.	yes	yes	n.a.
Dermal	n.a.	yes	yes	n.a.	n.a.	yes	n.a.
Oral	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Luxan Houtinsecticide-P is intended for in-situ treatment of wood in service in Use Class 1, is not intended to be used outside and there will be no contact between food/feed and the treated wood. RMM will be added to the lable not to put food/feed on treated (wet or dry) floors/wood.

List of scenarios

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 exposure loading spraying equipment with ready to use product	professional
	application	Primary exposure spraying with low volume/large droplets	professional
	Cleaning	No cleaning of spraying equipment as it is re-used with same product without cleaning in between.	professional
2	mixing/ loading	Primary exposure loading/pouring for brushing with ready to use product is relevant, pouring from large packaging into smaller	professional
	application	Primary exposure brushing	professional
	Cleaning	Cleaning brush	professional
3.	mixing/ loading	Primary exposure loading spraying equipment (trigger spray) with ready to use product	non-professional
	application	Primary exposure spraying with hand-held trigger spraying	non-professional
	Cleaning	Not applicable; incidental consumer use and trigger spray is disposed off	non-professional
4.	mixing/ loading	Primary exposure loading/pouring for brushing with ready to use product is relevant	non-professional
	application	Primary exposure brushing	non-professional
	Cleaning	Not applicable; incidental consumer use and brush is disposed off	non-professional
5.	chronic inhalation	secondary exposure Inhalation of volatilised residues	general public
6.	Playing on playground structure outdoors	Secondary exposure Child playing on treated structure (chronic exposure)	general public

Industrial exposure

No industrial 'end-uses' are intended, the intended use is brushing or spraying of wood by both professionals and non-professionals.

Professional exposure

Luxan Houtinsecticide-P is applied by brushing (painting) or by spraying at low volume(pressure) / large droplets. For curative use it is important to apply the required amount of product in a single session, in such a manner that runoff is prevented, e.g. by applying in two passes with a short waiting time in between allowing the product to be absorbed by the wood or the solvent to evaporate during application.

Scenario 1 Professional spraying

Luxan Houtinsecticide-P is applied with a spraying device (low pressure, large droplets/trigger spray) at a maximum of 250 gram (316 mL) product per m^2 (curative treatment) or 125 gram (158 mL) per m^2 (preventive treatment). Package is 5 – 1000 L.
For spraying of wood preservatives by professionals, Spraying model 2 TNsG part 2, p 146 is proposed in the EU TNsG User Guidance: 'HUMAN EXPOSURE TO BIOCIDAL PRODUCTS (TNsG June 2002) USER GUIDANCE version 1' (further referred to as TNsG User Guidance).
This model covers *Professional mixing, loading and applicating liquids in reservoir for powered spray application indoors and outdoors, in overhead and downward direction. This model relates to application of remedial biocides to structural timbers and masonry in industrial, recreational and residential settings. The model will also apply to other operations involving application using a pump-pressurised sprayer. Hand exposure is actual exposure inside gloves.*
The duration of spraying is set at 80 minutes per day (see HEAdhoc recommendation 6).

No cleaning of spraying equipment is considered as the spraying equipment is re-used with same product without cleaning in between.

Description of Scenario 1. Professional Spraying		
Luxan Houtinsecticide-P is applied indoor by a professional with a spraying device (low pressure, large droplets/trigger spray) at a maximum of 250 gram (316 mL) product per m^2 (curative) or 125 gram (158 mL) per m^2 (preventive). Package is 5 – 1000 L. Frequency for the wood: once to twice in a service life of the wood Frequency for applying by professional users will be several of times per year Spraying model 2 TNsG part 2, p 146 is proposed in the EU TNsG User Guidance: 'HUMAN EXPOSURE TO BIOCIDAL PRODUCTS (TNsG June 2002) USER GUIDANCE version 1' (further referred to as TNsG User Guidance). For details on the exposure calculation, please refer to Annex 3.2		
	Parameters	Value
Tier 1	mixing and loading	included in spraying model 2
	Duration mixing and loading	included in spraying model 2
	number of events for m&l	included in spraying model 2
	application	Spraying model 2 TNsG

	duration spraying[1]	80 minutes(HEAdhoc recomm.no 6)
	no PPE / clothing penetration	100%
	inhalation rate[3]	0.021 m^3/min (default)
	Hands[2]	273 mg/min
	Body[2]	222 mg/min
	Inhalation[2]	76 mg/m3
	Body weight[3]	60 kg
	Dermal absorption	3 %
Tier 2	Hands (inside gloves data in model)[2]	7.8 mg/min

[1] HEAdhoc recommendation 6
[2] Spraying model 2 TNsG part 2, p 146
[3] HEEG opinion 14, default human factor values for use in exposure assessment for biocidal products

Calculations for Scenario 1 Professional spraying

The details of the calculations are present in Annex 3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake* (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
Spraying, including mixing and loading	Tier 1 / no PPE	0.0043	0.040	0	0.044
	Tier 2 / with gloves	0.0043	0.029	0	0.033

Scenario 2 Professional brushing

Luxan Houtinsecticide-P is applied with a brush at a maximum of 250 gram (316 mL) product per m^2 (curative) or 125 gram (158 mL) per m^2 (preventive). Package is 5 – 1000 L.
The Consumer painting model 3 in HEAd hoc rec 6 is proposed, assuming a duration of 240 minutes.

Mixing and loading for a ready for use wood preservative is defined as 'fill undiluted product' and the duration is set at 10 minutes (TNsG User Guidance).
The TNsG presents several modals for mixing and loading, none of these exactly covering this activity (filling undiluted RFU wood preservative).
The default number of events is 3 times for mixing and loading (TNsG User Guidance).
The following model is suggested: Mixing and loading model 4 (TNsG) for medium size (5-10-20L) packaging and Mixing and loading model 7 for pumping from large (1000L) packaging.

Cleaning of brush is calculated with HEEG Opinion 11, the related spreadsheet is presented below as well.

Description of Scenario 2. Professional brushing		
Luxan Houtinsecticide-P is applied indoors by a professional with a brush at a maximum of 250 gram (316 mL) product per m2 (curative) or 125 gram (158 mL) per m2 (preventive). Package is 5 – 1000 L. Frequency for the wood: once to twice in a service life of the wood Frequency for applying by professional users will be several times per year Mixing and loading is calculated with Mixing and Loading model 4 (or 7) and the brushing is calculated with Consumer painting model 3 in Heeg AdHoc rec 6. Cleaning of brush is calculated with HEEG Opinion 11, the related spreadsheet with details is presented below. It is noted that this model was defined for solvent based paints, not cleaned with water under the sink. In case for water-based paint cleaned with water, no exposure is assumed by HEEG Opinion 11 as all residue is assumed to be washed off with the water. Dermal exposure is calculated following the proposed cleaning steps, inhalation exposure is not considered in HEEG Opinion 11. For details on the exposure calculation, please refer to Annex 3.2		
	Parameters[1]	Value
Tier 1	mixing and loading	Mixing and Loading model 4 TNsG
	Duration mixing and loading	10 minutes (default); worst-case
	number of events	3 times (default)
	Hand exposure[2]	0.5 mL product per action for a 10 to 20 L product 1000 L with pumping scenario from model 7
	Inhalation exposure	Not relevant for liquid products
	application	Consumer Product Painting model 3 HEAdhoc Recommendation 6
	duration brushing[1]	240 minutes (default)
	no PPE clothing penetration	100%
	inhalation rate	0.021 m^3/min (default)
	Hands[1]	0.5417 mg/m2
	Body[1]	0.2382 mg/m2
	Inhalation[1]	0.0016 mg/m2 (non volatile)
	Body weight[3]	60
	Application area[1]	31.6 m2
	Dermal absorption	3%

	Cleaning brush[4]	HEEG Opinion 11 Using 0.79 g/mL density and 0.2% concentration AS in paint
Tier 2	not applicable	
Tier 3	not applicable	

[1] HEAdhoc recommendation 6
[2] Mixing and loading model 4
[3] HEEG opinion 14, default human factor values for use in exposureassessment for biocidal products
[4] HEEG Opinion 11, Exposure model
Primary exposure scenario – washing out of a brush which has been used to apply a paint

Calculations for Scenario 2 Professional brushing

The details of the calculations are present in Annex 3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/ day)**	**Estimated dermal uptake* (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
loading product	Tier 1 / no PPE	0.000156	0.0014	0	0.0012 – 0.0015 (pumping worst-case)
brushing	Tier 1 / no PPE	0.00017	0.0.0024	0	0.0026
Cleaning brush	Tier 1 / no PPE	0	0.0001	0	0.0001
Brushing total	Tier 1 / no PPE	0.000326	0.0039	0	0.0042

Non-professional exposure

Luxan Houtinsecticide-P is applied by brushing (painting) or by hand-held trigger spraying.

Scenario 3 Non-professional spraying

Luxan Houtinsecticide-P is applied with a trigger spray (large droplets/low pressure) at a maximum of 250 gram (316 mL) product per m2 (curative) or 125 gram (158 mL) per m2 (preventive). Package is 0.5 – 5 Litre.
For spraying of wood preservatives by non-professionals, Mixing and loading is calculated with Mixing and Loading model 4 and the non-professional spraying is calculated with

Trigger spray consumer spraying and dusting model 2 – hand held trigger spray (HEAd hoc rec 6 page 7-8) with a duration of 30 minutes
The default number of events is 3 times for mixing and loading (TNsG User Guidance).

For the non-professional users it is advised that no cleaning will take place. The product is only used incidentally and trigger spray-can will be disposed off after use. This will also prevent possible residual contamination following re-use for other purposes.

Note NL CA: In line with the risk assessment for the environment, utensils should not be washed but need to be disposed after use, to prevent discharge of permethrin to the environment. The following sentence is included in the use-specific risk mitigation measures of non-professional uses:

After use, dispose trigger sprayer or brush to hazardous or special waste collection point.

Description of Scenario 3. Non-Professional Spraying		
Luxan Houtinsecticide-P is applied indoor by a non-professional with a trigger spray (large droplets/low pressure) at a maximum of 250 gram (316 mL) product per m2 (curative) or 125 gram (158 mL) per m2 (preventive). Package is 0.5 – 5 Litre. Frequency for the wood: once to twice in a service life of the wood Frequency for applying for the non-professional user is also limited to 1 to 2 times per year. Mixing and loading is calculated with Mixing and Loading model 4 and the non-professional spraying is calculated with Trigger spray consumer spraying and dusting model 2 – hand held trigger spray (HEAd hoc rec 6 page 7-8) For details on the exposure calculation, please refer to Annex 3.2		
	Parameters[1]	Value
Tier 1	mixing and loading	Mixing and Loading model 4
	Duration mixing and loading	10 minutes (default); very worst case and not applicable for this model
	number of events	3 times (default)
	Hand exposure	0.2 mL product per action for a 5L package
	Inhalation exposure	Not relevant for liquid products
	application	Trigger spray consumer spraying and dusting model 2 – hand held trigger spray
	duration spraying	40 minutes (BHHEM)
	no PPE clothing penetration	100%
	inhalation rate	0.021 m^3/min (default)
	Hand/forearm[1]	36.1 mg/min
	Body[1]	Not in model
	Inhalation[1]	10.5 mg/m3

	Body weight[2]	60 kg
	Dermal absorption	3 %
Tier 2	not applicable	
Tier 3	not applicable	

[1] HEAdhoc recommendation 6
[2] Mixing and loading model 4

Calculations for Scenario 3 Non-professional spraying

The details of the calculations are present in Annex 3.2

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake* (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/y)**	**Estimated total uptake (mg/kg bw/day)**
loading product	Tier 1 / no PPE	0	0.00048	0	0.00048
Spraying	Tier 1 / no PPE	0.0003	0.0018	0	0.0021
Spraying including loading	Tier 1 / no PPE	0.0003	0.0022	0	0.0025

Scenario 4 Non-professional brushing

Luxan Houtinsecticide-P is applied with a brush at a maximum of 250 gram (316 mL) product per m2 (curative) or 125 gram (158 mL) per m2 (preventive). Package is 0.5 – 5 Litre.
The Consumer painting model 3 in Heeg AdHoc rec 6 is proposed, assuming a duration of 240 minutes.
There is no mixing and loading for the smaller packaging, the consumer product is packaged and marketed in a packaging form/volume ready for brushing directly from the commercial packaging. The exposure for the 5L product is calculated with mixing and loading model 4 as a worst-case.

No cleaning of spraying equipment is considered incidental consumer use and brush is disposed off.

Note NL CA: In line with the risk assessment for the environment, utensils should not be washed but need to be disposed after use, to prevent discharge of permethrin to the environment. The following sentence is included in the use-specific risk mitigation measures of non-professional uses:

After use, dispose trigger sprayer or brush to hazardous or special waste collection point.

Description of Scenario 4. Non-professional brushing		
Luxan Houtinsecticide-P is applied indoor by a non-professional with a brush at a maximum of 250 gram (316 mL) product per m2 (curative) or 125 gram (158 mL) per m2 (preventive). Package is 0.5 – 5 Litre. Frequency for the wood: once to twice in a service life of the wood Frequency for applying for the non-professional user is also limited to 1 to 2 times per year Mixing and loading is calculated with Mixing and Loading model 4 and the brushing is calculated with Consumer painting model 3 in Heeg AdHoc rec 10 for non-professional users. For details on the exposure calculation, please refer to Annex 3.2		
	Parameters[1]	Value
Tier 1	mixing and loading	Not applicable, brushing directly from packaging for small packages up to 1 L. For 5 L packages mixng and loading Model 4 is used
	duration	n.a.
	number of events	n.a.
	Hand exposure	0.2 mL product per action for a 5L package
	Inhalation exposure	Not relevant for liquid products
	application	Consumer product painting model 3 in Heeg AdHoc rec 10
	duration brushing	240 minutes (default); seems worst-case for non-professional user
	no PPE clothing penetration	100%
	inhalation rate	0.021 m^3/min(default)
	Hands[1]	0.5417 mg/m2
	Body[1]	0.2382 mg/m2
	Inhalation[1]	0.0016 mg/m2 (non volatile)
	Body weight[2]	60
	Application area	31.6 m2
	Dermal absorption	3%
Tier 2	not applicable	
Tier 3	not applicable	

[1] HEAdhoc recommendation 6
[2] Mixing and loading model 4
[3] HEEG opinion 17, default human factor values for use in exposure assessment for biocidal products

Calculations for Scenario 4 Non-professional brushing

The details of the calculations are present in Annex 3.2

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake* (mg/kg bw/day)**	**Estimated oral uptake (mg/kg bw/day)**	**Estimated total uptake (mg/kg bw/day)**
loading product	Tier 1 / no PPE	0	0.00048	0	0.00048
brushing	Tier 1 / no PPE	0.00017	0.0024	0	0.0026
Brushing total	Tier 1 / no PPE	0.00017	0.0029	0	0.0031

Exposure of the general public

For secondary exposure (exposure via the environment or indirectly after application of the biocidal product) the following scenarios are defined for wood preservatives (TNsG 2007 and 2002):
-for adults sanding treated wood posts by the inhalation route (acute and chronic),
-for infants chewing wood offcut,
-for children playing on playground structure outdoors
-for infants playing on weathered (playground) structure and mouthing (dermal and ingestion).

As a number of restrictions are already in place concerning the use of Luxan Houtinsecticide-P, secondary exposure scenarios is unlikely.

As it is not allowed (with the current restrictions) to use to product in places accessible for children aged 0-4 years, all the secondary exposure scenarios related to children and infants playing on or touching treated wood are not relevant. Additonally, the product is not intended for use on playground structures outdoors either.

As it is prescribed (current restrictions) that the treated wood is not further worked on (sanding, sawing, etc.), the scenario for sanding is not applicable either.

Moreover, according to TNsG User Guidance , the above scenarios are only relevant for the industrial pre-treatment uses and not for in-situ applications of wood preservatives.

However, it cannot be completely excluded that a child is exposed to the product if they crawl into spaces such as under roof or floor while they are playing. This secondary exposure scenario is therefore evaluated (scenario 6).

According to the guidance document, for the intended uses of Luxan Houtinsecticide-P, the chronic secondary inhalation exposure might be relevant. This scenario addresses adults, infants and children taking into account chronic exposure to wood preservatives which may arise from indoor remedial treatment (inhalation of volatilised residues indoors) (scenario 5).

Scenario 5 Inhalation of volatilised residues

The permethrin EU assessment report states: Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155 x 10^{-6} Pa at 20°C, 25:75 *cis:trans*) and Henry constant (4.6 x 10^{-3} - > 4.5 x 10^{-2}
Pa m^3 mol^{-1}) and molecular weight of 391.29. Considering the low vapour pressure of permethrin the output of the calculation for chronic inhalation exposure will be negligible. No secondary chronic inhalation exposure will be expected.

A calculation is made based on the worked examples in the TNsG and using HEEG opinion no. 13 taking 24 hours exposure to air saturated with vapourized permethrin as the worst case (no ventilation). For a child breathing rates and other human default factors are included in HEAdhoc recommendation no.14.

The concentration in mg/m3 is given by: (vapour pressure x volume of air x molecular weight)/(gas constant x temperature) = (2.155 x 10^{-6} x1 x 391.29)/(8.314 x(278+20) = 0,00034 mg/m^3

Infant (bw = 8kg)

Daily Inhalation Rate	5.4	m^3/day
SVC for Permethrin at 20ºC	3.4×10^{-4}	mg m^{-3}
Daily inhalation of Permethrin = SVC for Permethrin daily inhalation rate x Daily Inhalation Rate	1.84×10^{-3}	
Daily dose of Permethrin for 8 kg infant	0.0002	mg/kg bw/day
Adult (bw = 60kg)		
Daily Inhalation Rate	16	m^3/day
SVC for Permethrin at 20ºC	3.4×10^{-4}	mg m^{-3}
Daily inhalation of Permethrin = SVC for Permethrin daily inhalation rate x Daily Inhalation Rate	5.44×10^{-3}	
Daily dose of Permethrin for 60 kg adult	0.0001	mg/kg bw/day

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake (mg/kg bw/day)**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Chronic inhalation adult	1	0.0001	0	0	0
Chronic inhalation infant	1	0.0002	0	0	0

Scenario 6 Child playing on treated structure

Description of Scenario 6. Child playing on treated structure		
Children may have dermal contact with treated surfaces which are dried, e.g. during playing in a space under roof or floor. Oral exposure via hand-to-mouth transfer is negligible considering this scenario is relevant only for children older than c.a. 4 years old, and not for infant or toddler. This scenario is considered a chronic exposure scenario. The dermal exposure assessment of this secondary exposure scenario is performed according to the scenario "Child playing playground structure" as descriedin the CAR for permethrin, with an adjustment for the assumed age group.		
	Parameters[1]	Value
Tier 1	Application rate of the product	250 g/m^2 (=25 mg/cm^2)
	Concentration of permethrin	0.2%
	Dermal penetration	3%
	Transfer coefficient of dried paint from rough-sawn wood (acc. to Biocides Human Health Exposure Methodology, vers. 1, October 2015 p. 171)	2%

	Percentage of hand area in contact with preservative (acc. to HEAdhoc recommendation 5, 2015)	20% of palms contaminated
	Palm area (HEAd hoc recommendation no.14)	Child (2 to <6 years old) 115.5 cm^2
	Body weight	Child (2 to <6 years old) 15.6 kg

The dermal exposure is calculated as following:
25 mg/cm^2 x 0.2% x 165.5 cm^2 x 20% x 2% transfer x 3% dermal absorption ÷ 15.6 kg = 6.4E-5 mg/kg bw

Combined scenarios

Based on the above information, it can be concluded that the secondary exposure is low, rather negligible, and not comparable to any reference value yet. As such there will be no combination of primary and/or secondary exposure scenarios for the professional or non-professional user.
Furthermore, the product contains one active substance therefore combined scenarios are not applicable.
The worst-case situation is the professional sprayer who is also exposed secondary, but the additional secondary estimated exposure is negligible on top of the primary exposure and does not effect the total uptake when rounded of.

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Chronic inhalation adult	1	0.0001	0	0	0.0001
Chronic inhalation infant	1	0.0002	0	0	0.0002
Prof spraying total	Tier 1 / no PPE	0.0043	0.040	0	0.044
Prof Brushing total	Tier 1 / no PPE	0.00033	0.0038	0	0.0041
Non prof Spraying total	Tier 1 / no PPE	0.0003	0.0022	0	0.0025
Non prof Brushing total	Tier 1 / no PPE	0.00017	0.0029	0	0.0031

Monitoring data

Not available and not applicable.

Dietary exposure

The intended use of Luxan Houtinsecticide-P as wood preservative does not result in exposure to food, drinking water or livestock.
There will be no contact between food/feed and the treated wood. RMM will be added to the lable; Do not to put food/feed on treated (wet or dry) floors/wood.

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

The active substance is not produced by the applicant and covered in the EU assessment. The applicant formulates the product according to standard workplace safety rules and no exposure will take place.

Disposal
It is obliged to dispose of this material and its container to hazardous or special waste collection point. As such no further exposure is expected.
Cleaning of equipment is not applicable, the equipment is not re-used and should be disposed of to a special waste collection point, like the disposal of empty packaging.

Aggregated exposure

Not applicable, methodology is under development.

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 (mg/kg bw/day)**
1.	Professional spraying (including loading)	Tier 1 / no PPE	0.044
2.	Professional brushing (including loading)	Tier 1 / no PPE	0.0041
3.	non-professional spraying (including loading)	Tier 1 / no PPE	0.0025
4.	non-professional brushing (including loading)	Tier 1 / no PPE	0.0031
5.	secondary exposure (chronic inhalation)	Adult (60 kg)	0.0001
		Child (8 kg)	0.0002
6.	Secondary exposure (child playing on treated structure)	Tier 1 / no PPE	6.4E-5

2.2.6.4 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study (mg/kg bw/day)	NOAEL (LOAEL) (mg/kg bw/day)	AF[1]	Correction for oral absorption	
AELshort-term	0.5	0.2201 mg/L (inhalation)or 59 mg/kg bw/day oral	100	no	
AELmedium-term	0.05	5 mg/kg bw/day (12 months dog)	100	no	
AELong-term	0.05	5 mg/kg bw/day (12 months dog)	100	no	
ARfD (AEL acute)	-				
ADI	-				

[1] Please explain background and reason for assessment factor: assessment factor is set in EU assessment

Specific reference value for groundwater

There is no emission to the groundwater and this is not relevant.

Risk for industrial users

The product is not intended for use by industrial users.

Risk for professional users

The ris for professional users is summarized in the table below.

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw*/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
spraying, including mixing and loading cleaning not relevant**	1	0.05	0.044	88.6 %	yes
brushing,	1	0.05	0.0042	8.4 %	yes

including mixing and loading and cleaning					

**taking 60 kg as a default adult body weight*

*** cleaning is considered not relevant as the spraying equipment is re-used with same product without cleaning in between.*

Combined scenarios

Not applicable

Local effects

Luxan Houtinsecticide-P is labeled with EUH208: "Contains permethrin. May produce an allergic reaction". The following phrase: "Do not get in eyes, on skin, or on clothing" is assigned as a risk mitigation measure. As such local effects will be limited.

The product is also labelled with EUH066: Repeated exposure may cause skin dryness or cracking. In this case the product is only used one to two times in the service life of the wood. For non-professionals this means once to twice per year and for professional users several times per year.

Table 27 of the BPR guidance (vol. III B+C, version 4.0, table 26, p259) which includes guidance for acceptability of the risk for the professional user, indicates that EUH066 is categorised in "low" hazard. The frequency and duration of exposure is more than few minutes but equal to or less than few hours per day. Furthermore, for a professional user, measures to control exposure (i.e. minimisation of manual phase, minimisation of splashes and spills etc can be taken into account. As repeated exposure cannot be excluded, gloves need to be included as a RMM for the professional user to prevent human health effects.

Conclusion

It can be concluded that the Tier 1 assessment for professional users applying Luxan Houtinsecticide-P by brushing or by spraying is acceptable. The estimated uptake during spraying, including loading of the ready to use product, covers 88.6% of the AEL (0.05 mg/kg bw/day) and during brushing, including loading, the estimated uptake covers 8.4 % of the AEL. However, based on the local effects assessment, gloves are considered necessary during handling of Luxan Houtinsecticide-P.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw*/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
spraying, including mixing and loading cleaning not relevant*	1	0.5	0.0025	0.50 %	yes
brushing, including mixing and loading cleaning not relevant*	1	0.5	0.0031	0.61 %	yes

* not relevant as application utensils need to be disposed after use

Combined scenarios
Not applicable

Local effects
Luxan Houtinsecticide-P is labeled with EUH208: Contains permethrin. May produce an allergic reaction'. The following phrase: "Do not get in eyes, on skin, or on clothing" is assigned as a risk mitigation measure. As such local effects will be limited.
The product is also labelled with EUH066: Repeated exposure may cause skin dryness or cracking. In this case the product is only used one to two times in the service life of the wood. For non-professionals this means once to twice per year and for professional users several times per year.
Table 26 of the BPR guidance (vol. III B+C, version 4.0, table 26, p253) which includes guidance for acceptability of the risk for the general public, indicates that EUH066 is categorized in "low" hazard. The frequency and duration of exposure is equal to or less than one hour per day. The product is applied once, maybe twice a year, not on a frequent daily basis. Furthermore, the following RMMs will be prescribed to minimize exposure: "Do not apply the product overhead using trigger sprayer" and "Do not get in eyes, on skin, or on clothing".
As repeated exposure is excluded, gloves are not needed for the non-professional user.

Conclusion
It can be concluded that the Tier 1 assessment for non-professional users (general public/consumers) applying Luxan Houtinsecticide-P by paint brushing or by spraying is acceptable. The estimated uptake during spraying, including loading of the ready to use product, covers 0.50 % of the AEL (0.5 mg/kg bw/day) and during brushing, including loading, the estimated uptake covers 0.61% of the AEL.

In line with the risk assessment for the environment, utensils should not be washed but need to be disposed after use, to prevent discharge of permethrin to the environment. The

following sentence is included in the use-specific risk mitigation measures of non-professional uses:

After use, dispose trigger sprayer or brush to hazardous or special waste collection point.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
secondary chronic inhalation adult	1	0.05	0.0001	0.2 %	Yes
Secondary chronic inhalation infant	1	0.05	0.0002	0.4 %	Yes
Chronic Child playing on treated structure	1	0.05	6.4E-5	0.1%	Yes

Combined scenarios

Not applicable, the additional secondary exposure is that low that it does not increase the primary exposure.

Local effects

Not applicable. The possible local effects are related directly to contact (and skin effects) with the product. The secondary exposure is not related to direct contact with the paint, only possible inhalation contact is considered and local effects are not relevant for this.

Conclusion

It can be concluded that the Tier 1 assessment for secondary exposure following chronic exposure is acceptable.

Risk for consumers via residues in food

Not applicable for the intended PT 8 wood preservative uses.
A RMM will be added to the label not to put food/feed on treated (wet or dry) floors/wood/surfaces.

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

Not applicable because the product contains only one active substance so there is no combined exposure to several active substances. There is also one substance of concern, but a quantitative risk assessment is not required and exposure is excluded by P phrases. A risk assessment for combined exposure is not considered relevant.

2.2.7 Risk assessment for animal health

Animals, theoretically, can be exposed when they re-enter a room (stable) where the wood under the rooftops has been treated with Luxan Houtinsecticide-P. As the secondary chronic inhalation exposure for humans is negligible, due to the low vapour pressure of permethrin, it is expected that the possible exposure to animals will also be negligible. However, it is well known that cats are more sensitive against pyrethroids than other animals or humans. As it can not be fully excluded the following risk mitigation measures are included:

- keep pets/animals out of reach during treatment and during drying of the wood.
- Avoid prolonged contact of pets, particularly cats, to treated surfaces

2.2.8 Risk assessment for the environment

No new information on environmental fate and ecotoxicology of the active substance or product was generated or is submitted; all ecotoxicological information is taken from the active substance dossier that was submitted by the main notifier, to which PELSIS IP have a letter of access, viz. from the 2014 permethrin Assessment Report. No environmental fate information is required for the product, since its use pattern results in negligible emission to the environment, as per the Revised Emission Scenario Document for Wood Preservatives, ENV/JM/MONO(2013)21.

2.2.8.1 Effects assessment on the environment

The following PNECs for permethrin have been taken from the PT 8 Assessment Report.

PNEC values for the a.s. permethrin and the major metabolites PBA and DCVA (according to assessment report, 2014[4])			
Substance	**Compartment**	**Value**	**Unit**
Permethrin	Fresh water	4.7×10^{-4}	µg/L
	Sediment	2.17×10^{-4}	mg/kg_{wwt}
	STP	4.95	µg/L

[4] Assessment Report Permethrin, April 2014. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Permethrin, Product-Type 18.

	Soil	0.175	mg/kg_{wwt*}
	Birds	16.7	mg/kg_{food}
	Mammals	120	mg/kg_{food}
3-Phenoxybenzoic acid (PBA)	Fresh water	0.01	mg/L
	Sediment	0.009	mg/kg_{wwt}
	Soil	1.44	mg/kg_{wwt}
DCVA	Fresh water	0.015	mg/L
	Sediment	0.012	mg/kg_{wwt}
	Soil	4.6	mg/kg_{wwt}

*The IE (RMS for permethrin) evaluation of the permethrin confirmatory data was discussed at the BPC Meeting in early March 2017. IE informed the CG members that an Env WG e-consultation was requested by BPC Members during the BPC meeting in March 2017, regarding the PNECsoil.The e-consultation concluded on the 13th March 2017.
It was agreed that the conclusions of this e-consultation could be announced at CG-22 in the event of a clear majority opinion. The opinions received from MSs in the e-consultation provided a clear majority opinion in relation to the proposed PNECsoil.
The MSs were in favour of using an AF of 50 and deriving the PNECsoil for permethrin on the soil micro-organism study. The new PNECsoil is 0.198 mg/kg dwt, corresponding to 0.175 mg/kg wwt.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

The following lowest acute and chronic end points for taxonomic groups relevant for classification and labelling were taken from the Assessment Report (permethrin) and the SDS (Shellsol D70). Product end points were calculated based on the weight fraction of the individual toxic components and their individual end points, assuming strict independent action mixture toxicity; this is warranted since the MoAs of Shellsol D70 (hydrocarbon mixture; non-specific baseline toxicity or nonpolar narcosis) and permethrin (highly specific interaction with sodium channels; neurotoxic) are completely different. Any possible contribution of permethrin to the overall baseline toxicity of the product is negligible in comparison to its specific action toxicity.

<u>Acute toxicity fish</u>
Permethrin LC_{50} 0.0051 mg/L
Shellsol D70 LC_{50} > 100 mg/L
Product (independent action): LC_{50} 2.43 mg/L

<u>Acute toxicity aquatic invertebrates</u>
Permethrin EC_{50} 0.00127 mg/L
Shellsol D70 EC_{50} > 100 mg/L
Product (independent action): EC_{50} 0.605 mg/L

<u>Toxicity algae</u>
Permethrin E_rC_{50} > 1.13 mg/L

Shellsol D70 E_rC_{50} > 100 mg/L
Product (independent action): E_rC_{50} > 100 mg/L

Long term toxicity fish
Permethrin NOEC 0.00041 mg/L
Product NOEC 0.195 mg/L

Long term toxicity aquatic invertebrates
Permethrin NOEC 0.0000047 mg/L
Product NOEC 0.00224 mg/L

Further Ecotoxicological studies

No further data/studies with either active substance or biocidal product are available. Please refer to the active substance dossier for further information.

Conclusion used in Risk Assessment – Effects on specific, non-target organisms	
Value/conclusion	Not applicable
Justification for the value/conclusion	-
Data waiving	
Information requirement	BPR Annex III 9.3. - Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk
Justification	This is not a Core Data Set requirement for biocidal products. Bats are believed to be potentially at risk. Testing on the biocidal product does not need to be conducted: there are valid data on toxicity to bats available for relevant components of the biocidal product.

Supervised trials to assess risks to non-target organisms under field conditions

No further data/studies with either active substance or biocidal product are available. Please refer to the active substance dossier for further information.

Conclusion used in Risk Assessment – supervised trial to non-target organisms in field conditions	
Value/conclusion	Not applicable
Justification for the value/conclusion	-
Data waiving	
Information requirement	BPR Annex III 9.4.1 - Supervised trials to assess risk to non-target organisms under field conditions
Justification	The product is not in the form of bait or granules, therefore this information requirement does not exist for this product.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No further data/studies with either active substance or biocidal product are available. Please refer to the active substance dossier for further information.

Conclusion used in Risk Assessment – Aceptance by ingestion by non-target organisms	
Value/conclusion	Not applicable
Justification for the value/conclusion	-
Data waiving	
Information requirement	BPR Annex III 9.4.2 - Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
Justification	The product is not in the form of bait or granules, therefore this information requirement does not exist for this product.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Luxan Houtinsecticide-P is intended for in-situ treatment of wood in service in Use Class 1. No emission to the environment is foreseen; this Additional Data Set requirement is not relevant for this product.

Assessment for endocrine disrupting properties

As discussed in Section 2.2.6.1, the Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).

No further ecotoxicological studies are available for Luxan Houtinsecticide-P and this were not tested for potential endocrine disruption properties. Luxan Houtinsecticide-P contains the active substance permethrin and various co-formulants (see confidential annex).

For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. As discussed in the Assessment Report for permethrin (April 2014), acute and chronic exposure to permethrin was highly toxic to the three groups of aquatic organisms, affecting reproduction and survival in fish and D*aphnia* (Daphnia was the most sensitive species in the acute and chronic tests). Permethrin does not have an endocrine effect on fish.

For the co-formulants a screening was performed by consulting:

- ECHA data for identification of ED and PBT, under REACH or BPR or CLP
- The United States EPA
- The United Nations Environment Program (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

None of the co-formulants triggered an alert for potential endocrine disruption properties. Hence, no further ED assessments are required for Luxan Houtinsecticide-P.

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

No environmental emission is foreseen from in-situ treatment of wood in service in Use Class 1, cf. the OECD environmental emission scenario document for wood preservatives. Non-professional brushing is done directly from the commercial container. Professional brushing is done directly from the commercial container (small scale applications) or from a paint bucket filled from a larger commercial container. Empty containers, paint buckets and brushes should not be rinsed but treated as chemical waste or be stored as is and reused later (unlikely). Professional and non-professional low-pressure spraying is done with trigger spray bottles filled directly from commercial containers. Used trigger spray bottles should not be rinsed but treated as chemical waste or reused.
Note that ShellSol D70 does not mix with water, and therefore cannot effectively be rinsed with water anyway. Rinsing is possible with light organic solvents (e.g. thinner, benzine, or white spirit) but such washings should be collected and discarded as chemical waste – regardless of whether the rinsate contains biocides or not.
As such exposure of surface water to permethrin via STP following application of Luxan Houtinsecticide-P is considered not relevant.

Further studies on fate and behaviour in the environment (ADS)

No further data/studies with either active substance or biocidal product are available. Please refer to the active substance dossier for further information.

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment	
Value/conclusion	Not relevant
Justification for the value/conclusion	-

Data waiving	
Information requirement	BPR Annex III 10.2. - Further studies on fate and behaviour in the environment
Justification	This is not a Core Data Set requirement for biocidal products. The product is intended for in-situ treatment of wood in service in Use Class 1. The product is not to be used outside; therefore no further studies on fate and behaviour in the environment are required.

Leaching behaviour (ADS)

Leaching studies are not relevant, and not required, for products intended for in-situ treatment of wood in service in Use Class 1.

Testing for distribution and dissipation in soil (ADS)

No further data/studies with either active substance or biocidal product are available. Please refer to the active substance dossier for further information.

Conclusion used in Risk Assessment –Distribution and dissipation in soil	
Value/conclusion	Not relevant
Justification for the value/conclusion	-

Data waiving	
Information requirement	BPR Annex III 10.4.1. - Testing for distribution and dissipation in soil
Justification	This is not a Core Data Set requirement for biocidal products. The product is intended for in-situ treatment of wood in service in Use Class 1. The product is not to be used outside; emission to soil is not relevant.

Testing for distribution and dissipation in water and sediment (ADS)

No further data/studies with either active substance or biocidal product are available. Please refer to the active substance dossier for further information.

Conclusion used in Risk Assessment –Distribution and dissipation in water and sediment	
Value/conclusion	Not relevant
Justification for the value/conclusion	-

Data waiving	
Information requirement	BPR Annex III 10.4.2. - Testing for distribution and dissipation in water and sediment
Justification	This is not a Core Data Set requirement for biocidal products. The product is intended for in-situ treatment of wood in service in Use Class 1. The product is not to be used outside; emission to water and sediment is not relevant.

Testing for distribution and dissipation in air (ADS)

No further data/studies with either active substance or biocidal product are available. Please refer to the active substance dossier for further information.

Conclusion used in Risk Assessment –Distribution and dissipation in air	
Value/conclusion	Not relevant
Justification for the value/conclusion	-

Data waiving	
Information requirement	BPR Annex III 10.4.3. - Testing for distribution and dissipation in air
Justification	This is not a Core Data Set requirement for biocidal products. The product is intended for in-situ treatment of wood in service in Use

	Class 1. The product is not to be used outside; emission to air is not relevant.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Luxan Houtinsecticide-P is intended for in-situ treatment of wood in service in Use Class 1. The product is not to be sprayed near to surface waters. This Additional Data Set requirement is not relevant for this product.

Conclusion used in Risk Assessment – Acute aquatic toxicity	
Value/conclusion	Not relevant
Justification for the value/conclusion	-

Data waiving	
Information requirement	BPR Annex III 10.5. – Overspray study
Justification	This is not a Core Data Set requirement for biocidal products. The product is intended for in-situ treatment of wood in service in Use Class 1. The product is not to be sprayed near to surface waters; therefore no overspray study is required.

Conclusion used in Risk Assessment- Chronic Aquatic toxicity	
Value/conclusion	Not relevant
Justification for the value/conclusion	-

Data waiving	
Information requirement	BPR Annex III 10.5. – Overspray study
Justification	This is not a Core Data Set requirement for biocidal products. The product is intended for in-situ treatment of wood in service in Use Class 1. The product is not to be sprayed near to surface waters; therefore no overspray study is required.

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	Not relevant
Justification for the value/conclusion	-

Data waiving

Information requirement	BPR Annex III 10.5. – Overspray study
Justification	This is not a Core Data Set requirement for biocidal products. The product is intended for in-situ treatment of wood in service in Use Class 1. The product is not to be sprayed near to surface waters; therefore no overspray study is required.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Luxan Houtinsecticide-P is intended for in-situ treatment of wood in service in Use Class 1. The product is not to be sprayed outside and there is no potential for large scale formation of dust. This Additional Data Set requirement is not relevant for this product.

2.2.8.2 Exposure assessment

Emission estimation

According to the Revised Emission Scenario Document for Wood Preservatives, ENV/JM/MONO(2013)21, no emission of active substance or other material to the environment is foreseen from in-situ treatment of wood in service with PT8 wood preservatives in Use Class 1.

Luxan Houtinsecticide-P is intended for in-situ treatment of wood in service in Use Class 1. As the product is intended for use inside a construction, no emissions to the environment during application (spraying or brushing) will occur.

To minimise the risks for the environment in the waste phase, the following RMM is included in the PAR and SPC:
'Discharge of leftover product and residues containing the product (e.g. solvents or water used for the cleaning of brushes or trigger spray bottles) to the sewer, soil or surface water is not permitted. Leftovers and residues containing the product (e.g. solvents or water used for cleaning of trigger spray bottles) need to be treated and discarded as chemical waste.'

Primary and secondary poisoning

The proposed use will not result in (in)direct exposure of birds and mammals to the product or contaminated aquatic or terrestrial organisms in case treatment of wood takes place indoors and when used in accordance with the proposed label (SPC).However, indoor treatments are relevant for the exposure assessment of bats in countries where bats are protected animals (e.g. in most European countries). Bats may be orally exposed due to cleaning of their furs that are in direct contact to treated wood.

2.2.8.3 Risk characterisation

Atmosphere

The vapour pressure (2.16 x 10-6 Pa at 20°C) of permethrin is < 3E-6 Pa. AOPwin calculates for permethrin a half life of 0.701 day in air (24hr day, 0.5E+06 OH/cm3), which is below the trigger value of < 2 days. Permethrin is not listed as "controlled substance'' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament and therefore not expected to be harmful for the ozone layer. No significant exposure of the compartment 'air' is foreseen.

Aquatic compartment (incl. sediment and sewage treatment plant (STP)

The proposed applications of the product will not result in exposure of the aquatic compartment and the STP in case treatment of wood takes place indoors and when used in accordance with the proposed label (SPC).The risk for aquatic and sediment dwelling organisms and micro organisms in the STP is considered acceptable.

Terrestrial compartment (incl. groundwater)

The proposed applications of the product and indoor in service use of the treated wood will not result in exposure of the soil compartment in case treatment of wood takes place indoors and when used in accordance with the proposed label (SPC). The risk for soil

organisms and non target arthropods (including bees) is considered acceptable when used in accordance with the proposed label (SPC).

Primary and secondary poisoning

For the proposed use of the active substance as wood preservative indoors indirect exposure of birds and mammals (other than bats) to the active substance or contaminated aquatic and terrestrial organisms is considered negligible. Thus the risk for secondary poisoning of birds and mammals is considered acceptable.

Bats are directly exposed to treated wood via skin contact (i.e. beams). An active substance can be subsequently orally ingested when furs and feet are cleaned.
In an acute toxicity study with bats (see AR of permethrin) a permethrin product was applied to the plywood lining of a steel cage 6 weeks to 14 months before bats (*Pipistrellus pipistrellus*) were introduced. The plywood was grooved to allow bats to climb and hang. Negative (solvent) controls were included in the experimental design. Wild caught bats (10 per cage) were introduced and fed ad libitum. No obvious harm was caused to the bats roosting for 16 to 22 weeks in cages lined with permethrin treated plywood.
As the active substance is considered not bioaccumulative, the risk for the primary poisoning of birds and mammals (including bats) is considered acceptable. The proposed application meets the standards for birds and mammals (including bats).

Note that a risk assessment for bats roosting on treated wood may be relevant for products applied on wood with use class 1. Wood treated with Luxan Houtinsecticide-P may be harmful to juvenile bats as these can be more sensitive than adult bats. A precautionary measure needs to be added to the SPC indicating that the product must not be used in areas where protected species such as bats, hornets or birds reside.

Mixture toxicity

Luxan Houtinsecticide-P consists of one specifically-acting active substance and a 'baseline toxicity' solvent (mixture of aliphatic and alicyclic hydrocarbons). Solvent makes up more than 50% of the product. The MoA of the solvent and the active substance are completely different. Mixture toxicity should be considered based on the mechanism of independent action. Within that context the toxicity of the product is completely determined by the toxicity of permethrin, even at the low a.s. concentration. As such the product toxicity can simply be derived from a.s. toxicity divided by a.s. weight fraction.

Aggregated exposure (combined for relevant emmission sources)

No environmental emission of Luxan Houtinsecticide-P is foreseen. Without emission source aggregated exposure is not relevant.

Nonetheless, a qualitative analysis is presented based on the decision scheme developed by UBA:

The annual tonnage of the active substance permethrin and the percentage used as biocide is unknown. Part 1: The current submission includes 1 PT8 product. There are different user categories (professionals and non-professionals) and uses (preventive and curative), but there is no overlap in time and space in treatment for these uses and user categories (curative and preventive treatment of an object are not done at the same point in time and treatment of an object is not done by both professional and non-professional user at the same time and place). Part 2 and 3: Luxan Houtinsecticide-P is not used in other PTs and permethrin is the only active substance (no other a.s. affected). From the

decision scheme it is concluded that aggregated exposure estimation is not required for Luxan Houtinsecticide-P.

Overall conclusion on the risk assessment for the environment of the product
Since no environmental emission is foreseen, no environmental risks have been identified. A potential risk exists for bats roosting on treated wood. A precautionary measure needs to be added to the SPC indicating that the product must not be used in areas where protected species such as bats, hornets or birds reside.

2.2.9 Measures to protect man, animals and the environment

For the measures to protect animals and the environment we refer to sections 2.2.6, 2.2.7 and 2.2.8 and the SPC.

2.2.10 Assessment of a combination of biocidal products

Not applicable. Luxan Houtinsecticide-P is not intended to be authorised for use in combination with other biocidal products.
Anti-fungal treatment is not allowed together or shortly after treatment with Luxan Houtinsecticide-P.

2.2.11 Comparative assessment

Not relevant.

3 ANNEXES[5]

3.1 List of studies for the biocidal product (family)

[redacted] (2016). Luxan Houtinsecticide-P Safety Data Sheet

[redacted] (2015). Validation of Method: MV129 - EDX: GC-Determination of Permethrin in Permethrin OL RTU. BioGenius GmbH Report # Mo5371, Bergisch Gladbach, Germany

[redacted] (2015). Prüfbericht. BAM Report # 15026022 Hb, Berlin, Germany

[redacted] (2016a). Prüfbericht. BAM Report # 15026022 An1, Berlin, Germany

[redacted] (2016b). Prüfbericht. BAM Report # 15026022 An, Berlin, Germany

[redacted] Determination of Physico-Chemical Properties and Accelerated Storage Stability Test for Permethrin OL RTU (DRE900). BioGenius GmbH Report # Mo5372, Bergisch Gladbach, Germany

[redacted] (1986). The residual effects of remedial timber treatments on bats. Biological conservation 35(3).

[redacted](1991). Toxicity and tissue distribution of pentachlorophenol and permethrin in pipistrelle bats experimentally exposed to treated timber. Environmental Pollution 73(2).

[redacted]. (2015). DRE900; Physicochemical properties of a mixture. TheOxide BV Report # TO-HV-DI-20150020a, Eindhoven, the Netherlands

[redacted]. (2015). DRE900; Acute toxicity of a mixture. TheOxide BV Report # TO-HV-DI-20150020b, Eindhoven, the Netherlands

[redacted] (2017). Efficacy of Luxan Houtinsectide. The susceptibility of Anobium and Hylotrupes for permethrin. BV-HV-DI-20170001, Almere, the Netherlands

[redacted] (2016). Storage stability of Luxan Houtinsecticide-P. Denka International B.V. Report, Barneveld, the Netherlands

5 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

3.2 Output tables from exposure assessment tools

Output tables for human exposure assessment

Professional spraying

Spraying model 2 (M&L included) and the assumptions in HeAdhoc recommendation no. 6.

DERMAL		
hands exposure value	273	mg b.p/min
hands exposure value (with gloves)	7,8	mg b.p/min
body exposure value	222	mg b.p/min
body exposure value (with coverall)	22,2	mg b.p/min
duration	80	min
dermal exposure value to product	39600	mg b.p
dermal exposure value to product with PPE	2400	mg b.p
concentration active	0,202	%
dermal absorption	3,000	%
systemic dermal systemic dose	2,39976	mg a.s.
systemic dermal systemic dose with PPE	1,7278272	mg a.s.
body weight	60	kg
systemic dermal dose per kg bw	0,04000	mg a.s./kg bw
systemic dermal dose per kg bw with PPE	0,029	mg a.s./kg bw
INHALATION		
inhalation exposure value	76	mg b.p/m3
duration	80	min
inhalation rate	0,021	m3/min
inhalation exposure to product	126,667	mg b.p
concentration active	0,202	%
inhalation absorption	100	%
systemic inhalation dose	0,255866667	mg a.s.
systemic inhalation dose per kg bw	0,00426	mg a.s./kg bw
systemic inhalation dose per kg bw with RPE	0,000	mg a.s./kg bw

TOTAL

Systemic dose (no PPE)	0,04426	mg a.s./kg bw
Systemic dose (with PPE)	0,033	mg a.s./kg bw

Systemic dose (with PPE and RPE)	0,029	mg a.s./kg bw

RISK

	total exposure	AEL
Systemic dose (no PPE)	0,044	0,05
Systemic dose (with PPE)	0,033	0,05
Systemic dose (with PPE and RPE)	0,029	0,05

Professional painting

Painting model ***Heeg Adhoc recommendation 6***						
Product		**units**	**tier 1**			
active substance		%	0,202			
		permethrin				
potential body exposure						
clothing type			none		mg/m2	m2
indicative value		mg/day	7,52712		0,2382	31,6
duration		day	1	value calculated in mg/day		
potential dermal deposit		mg	7,52712			
clothing penetration		%	100			
actual dermal deposit (product)		mg	7,52712			
hand exposure						
gloves worn			no		mg/m2	m2
indicative value		mg/day	16,26452		0,5147	31,6
duration		day	1			
actual hand deposit (product)		mg	16,26452			
total dermal exposure						
product		mg	23,79164			
active substance		mg	4,805911			
dermal absorption		%	3			
absorbed active substance		mg	0,144177			
exposure by inhalation					mg/m2	m2
indicative value		mg/day	0,05056		0,0016	31,6
duration		day	1			
inhalation rate		m3/min	n.a.			
inhaled volume		m3	n.a.			
mitigation by RPE		value	none			
inhaled (product)		mg	0,05056			
inhaled active substance		mg	0,010213			
total systemic exposure		mg	0,15439			

Professional mixinig and loading

mixing and loadingn model 7 volgens Heeg Opinion 1				
Product	**units**			
active substance	%	0,202	0,202	
	permethrin			
potential body exposure		**pumping**	**loading**	
clothing type		none	none	
indicative value	mg/min	0	0	
duration	min	10	10	
potential dermal deposit	mg	0	0	
clothing penetration	%	100	100	
actual dermal deposit (product)	mg	0	0	
hand exposure				
gloves worn		no	no	
indicative value	mg/min	138	101	
duration	min	10	10	
actual hand deposit (product)	mg	1380	1010	
total dermal exposure				
product	mg	1380	1010	
active substance	mg	2,7876	2,0402	
dermal absorption	%	3	3	
absorbed active substance	mg	0,083628	0,061206	
exposure by inhalation				
indicative value	mg/m3	22	0,94	
duration	min	10	10	
inhalation rate	m3/min	0,021	0,021	
inhaled volume	m3	0,21	0,21	
mitigation by RPE	value	none	none	
inhaled (product)	mg	4,62	0,1974	
inhaled active substance	mg	0,009332	0,000399	
total systemic exposure	mg	0,09296	0,061605	

Professional cleaning of brush

Spreadsheet calculation Heeg Opinion 11

General Exposure Calculator For Washing Out Of Brushes The systemic dermal exposure is calculated as follows:			
Activity and Parameters	**Tier 1 No gloves**	**Tier 2 Gloves**	**Units**
Volume of brush	**200**	**200**	**ml**
Volume of paint remaining on brush after painting ($^1/_8$ of 200 ml = 25 ml)	25	25	ml
Density of paint	**0,79**	**0,79**	**g/ml**
Weight of paint on brush after painting = volume of paint remaining on brush after painting (ml) x density of paint (g/ml)	19,80	19,75	g
Concentration of a.s. in paint	**0,20**	**0,20**	**% w/w**
A. Weight of a.s. on brush after painting	39,6000	39,5000	mg
B. Residues of a.s. on brush after 1st washing (10% of A)	3,9600	3,9500	mg
Amount of a.s. removed from the brush into the cleaning fluid (A-B)	35,6400	35,5500	mg
C. Weight of a.s. squeezed out from brush onto cloth (50% of B)	1,9800	1,9750	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of C)	0,1980	0,1975	mg
Penetration of a.s. through gloves	**100**	**10**	**%**
Weight of a.s. on hand	0,19800	0,01975	mg
Dermal absorption of a.s.	**3,00**	**3,00**	**%**
Weight of a.s. entering the body	0,00594	0,00059	mg
D. Weight of a.s. left on the brush after 1st wash and squeezing (B – C)	1,9800	1,9750	mg
E. Residues of a.s. on brush after 2nd washing (10% of D)	0,1980	0,1975	mg
Amount of a.s. removed from the brush into the cleaning fluid (D-E)	1,7820	1,7775	mg
F. Weight of a.s. squeezed out from brush onto cloth (50% of E)	0,0990	0,0988	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of F)	0,0099	0,0099	mg
Penetration of a.s. through gloves	100	10	%
Weight of a.s. on hand	0,00990	0,00099	mg
Dermal absorption of a.s.	3,00	3,00	%
Weight of a.s. entering the body	0,00030	0,00003	mg
G. Weight of a.s. left on the brush after 2nd wash and squeezing (**E** – **F**)	0,0990	0,0988	mg
H. Residues of a.s. on brush after 3rd washing (10% of G)	0,0099	0,0099	mg
Amount of a.s. removed from the brush into the cleaning fluid (G – H)	0,0891	0,0889	mg
I. Weight of a.s. squeezed out from a brush onto a cloth (50% of H)	0,0050	0,0049	mg
Cloth absorbs 90% of a.s. squeezed out of brush therefore, weight of a.s. available to contaminate the hand (10% of I)	0,0005	0,0005	mg
Penetration of **a.s.** through gloves	100	10	%
Weight of a.s. on hand	0,00050	0,00005	mg
Dermal absorption of a.s.	3,00	3,00	%
Weight of a.s. entering the body	0,00001	0,00000	mg
Total weight of a.s. entering the body *(to 4 decimal places)*	**0,0063**	**0,0006**	**mg**
Body weight	**60**	**60**	**kg**
TOTAL SYSTEMIC DERMAL DOSE OF ACTIVE SUBSTANCE *(to 4 decimal places)*	**0,0001**	**0,0000**	**mg a.s./kg bw**

Non-professional spraying

Consumer spraying and dusting model 2 Hand-held trigger spray	**Tier 1**
Product	

active substance	% w/w	0,202
body weight	kg	60
dermal absorption	%	3
Dermal exposure		
Potential hand/forearm exposure		
indicative value	mg/min	36,1
duration	min	40,0
potential hand deposit	mg	1444,00
penetration through gloves	%	100
actual hand deposit	mg	1444,00
Potential legs, feet and face exposure		
indicative value	mg/min	9,7
duration	min	30,0
potential legs, feet and face deposit	mg	291
penetration through clothing	%	100
actual legs, feet and face deposit	mg	291,00
Total dermal dermal exposure		
total dermal deposit (a.s.)	mg	3,50
penetration through skin (a.s.)	mg	0,11
systemic exposure via dermal route	**mg/kg bw/d**	**1,75E-03**
Inhalation exposure		
indicative value	mg/m3	10,5
duration	min	40,0
inhalation rate	m3/min	0,02
inhaled volume	m3	0,83
inhaled product	mg	8,75
inhaled a.s.	mg	0,02
inhaled a.s.	m/m3	0,02
systemic exposure via inhalation route	**mg/kg bw/d**	**2,95E-04**
Total systemic exposure	**mg/kg bw/d**	**2,05E-03**

Non-professional painting

Painting model ***Heeg Adhoc recommendation 6***						
Product		**units**	**tier 1**	**tier 2**		
active substance		%	0,202			
		permethrin				
potential body exposure						
clothing type			none		mg/m2	m2
indicative value		mg/min	7,52712		0,2382	31,6
duration		min	1	value calculated in mg/day		
potential dermal deposit		mg	7,52712			
clothing penetration		%	100			
actual dermal deposit (product)		mg	7,52712			
hand exposure						
gloves worn			no		mg/m2	m2
indicative value		mg/min	16,26452		0,5147	31,6
duration		min	1			
actual hand deposit (product)		mg	16,26452			
total dermal exposure						
product		mg	23,79164			
active substance		mg	4,805911			
dermal absorption		%	3			
absorbed active substance		mg	0,144177			
exposure by inhalation					mg/m2	m2
indicative value		mg/m3	0,05056		0,0016	31,6
duration		min	1			
inhalation rate		m3/min	n.a.			
inhaled volume		m3	n.a.			
mitigation by RPE		value	none			
inhaled (product)		mg	0,05056			
inhaled active substance		mg	0,010213			
total systemic exposure		mg	0,15439			

Non professional mixing/loading

Mixing and loading model 4 TNsG part 2, p. 134							
Product		**units**	**non-prof**	**prof**			
active substance		product contains 1.6 mg permethrin / ml					
dermal exposure		ml	mg	**1 ml =**	1,6	mg	
bij 5 L		0,2	0,32				
bij 10 en 20 L		0,5	0,8				
bij 5L maar met dop 45 of 63 mm		0,01	0,016				
bij 10L met dop 45 mm		0,01	0,016				
bij 10 L met dop 63 mm		0,05	0,08				
hand exposure			5L package	10-20 L package			
gloves worn			no	no			
indicative value		mg/event	0,32	0,8			
duration		event	3	3			
actual hand deposit (product)		mg	0,96	2,4			
total dermal exposure							
active substance		mg	0,96	2,4			
active substance		mg	0,96	2,4			
dermal absorption		%	3	3			
absorbed active substance		mg	0,0288	0,072			
exposure by inhalation							
indicative value		mg/m3	0	0			
duration		min					
inhalation rate		m3/min					
inhaled volume		m3/min					
mitigation by RPE		value					
inhaled (product)		mg					
inhaled active substance		mg	0	0			
total systemic exposure		mg	0,0288	0,072			
	mg/kg bw/day		0,00048	0,0012			
			non prof	prof			

3.3 New information on the active substance

Not applicable.

3.4 Residue behaviour

Not applicable.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Please see 2.2.5.5 and the IUCLID dataset/dossier for summaries of the efficacy studies.