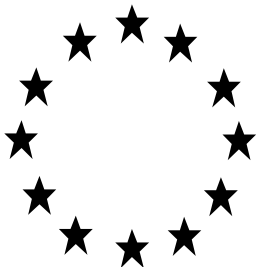
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



Wood preservative aerosol Permethrin

Product type [08]

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-XU023589-94

Evaluating Competent Authority: ES CA

Date: July 2021

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1 CONCLUSION

Physical-chemical properties

The biocidal product WOOD PRESERVATIVE AEROSOL PERMETHRIN contains 0.25 %w/w permethrin and given the nature of the formulation the product is classified H304 Cat 1 Mention Danger and H222/H229 according to CLP criteria.

Wood Preservative Aerosol Permethrin is a ready for use product in a pressurized can like an aerosol container. It is composed by a homogeneous solution of solvents, propellant and permethrin. The active substance is solved in the liquid system.

The product is stable after storage 4 weeks at 50°C and 12 months at 25°C. The shelf life can be deemed as 2 years taking into account the results obtained from the accelerated storage study. The authorization is conditioned to the submission of the complete long term storage study. The label sentences 'protect from frost' and 'store away from light' must be included in the label.

A validated analytical method is available for determining the concentration of permethrin in the biocidal product. Validated analytical methods are also available for the determination of permethrin in soil, water and air matrices. Other analytical methods are not required.

Efficacy:

The product is intended to be use:

- Preventive treatment use class 1, against wood boring beeatles by spraying.
  Dose rate: 200 g/m^2 (300ml/m^2)
- Preventive treatment, in situation of use class 1, against termites by spraying.
  Dose rate: 153 g/m^3 (227ml/m^2)
- Curative treatment against wood boring beeatles by spraying and by injection to complementary treatment.
  Dose rate: 200 g/m^2(300 mL/m^2)

Human health:

For the classification and labelling of the biocidal product the concentration of active substance and co-formulants in the product without propellant is taken into account. In addition to the active substance, other substances of concern for human health have been identified.

According to the CAR and BPC Opinion for permethrin, is not considered to have endocrine disrupting properties.

After reviewing the potential ED properties of co-formulants, several substances have been identified as having potential endocrine disrupting properties. If these substances are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

After evaluating the exposure and characterizing the risk to human health of the biocidal product according to the pattern of use requested by the applicant, a maximum dose injection application of 1640 mL/m^2 is recommended.

Risk is acceptable for non-professional users (without PPE) for spray application alone and for spraying combined with injection.

There is no risk identified for general publics.

Risk for consumers via residues:
The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses. Wood treated with WOOD PRESERVATIVE AEROSOL PERMETHIRN must contain label restrictions against use in contact with livestock, food and feed.

Environmental risk assessment
Following indirect releases to the environment via the STP, all calculated PEC/PNEC ratios were < 1 for STP, surface water, soil and groundwater. Thus the risk for these environmental compartments is acceptable. Nevertheless, regarding the exposure of the sediment, RCR values was > 1 indicating unacceptable risk to this environmental compartment.

A risk mitigation measure is proposed to prevent the exposure of the sediment compartment: During the application step, a disposable, non-permeable cover should be used under the material to be treated. In this way, the emission to the floor can be prevented. The application of this risk mitigation measure preventing emissons to the environment would achieve acceptable risks..

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	**Country (if relevant)**
WOOD PRESERVATIVE AEROSOL PERMETHRIN	Spain (rMS)
CARCOMIN PLUS	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Henkel Global Supply Chain B.V.
	Address	Gustav Mahlerlaan 2970 ,1081 LA, Amsterdam, Netherlands
Authorisation number	ES/APP(NA)-2021-08-00767	
Date of the authorisation	30/07/2021	
Expiry date of the authorisation	30/04/2026	

2.1.1.3 Manufacturer of the products of the family

Name of manufacturer	Henkel Global Supply Chain B.V.
Address of manufacturer	Gustav Mahlerlaan 2970 , 1081 LA, Amsterdam, Netherlands
Location of manufacturing sites	-Laboratorio Chimico Farmaceutico Sanmarinese, Strada del Marano 95, 47896 Faetano, SAN MARINO -Eugenio Santos Envasados y Servicios S.L., Polígono Industrial "Llanos de la Estación", Calle de Tomás Edison, s/n, 50800 Zuera, Zaragoza, SPAIN

2.1.1.4 Manufacturer of the active substance

Active substance	Permethrin
Name of manufacturer	Tagros Chemicals India Limited Article 95 list: Caldic Denmark A/S (Denmark) (Acting for Tagros Chemicals India Limited (India))
Address of manufacturer	Jhaver Centre, Rajah Annamalai Building, IV Floor, 72 Marshalls Road, Egmore - 600008, Chennai, Tamil Nadu, India
Location of manufacturing sites	A4/1&2, SIPCOT Industrial Complex, Pachayankuppam, 607 005, Cuddalore, Tamil Nadu, India

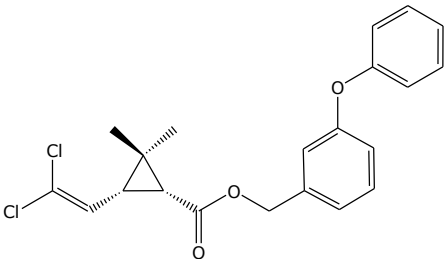
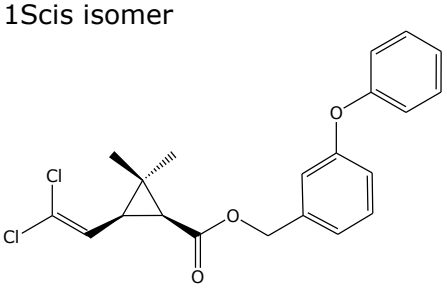
2.1.2 Product composition and formulation

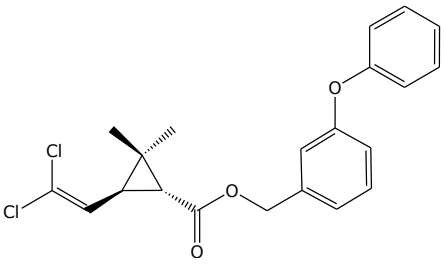
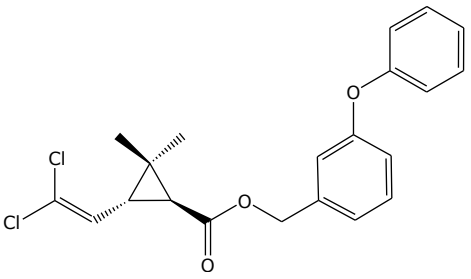
NB: the full composition of the product has been provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl (1RS, 3RS; 1RS, 3RS)-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	930g/kg (93%) Permethrin has four stereoisomers: 1Rcis, 1Scis, 1Rtrans, 1Strans. Two pairs of diastereomers (each consisting of a non-racemic pair of enantiomers) are present is a ratio of ca. 25:75. Specification ≥ 93.0% w/w sum of all permethrin isomers. Permethrin is a reaction mass of four stereoisomers 1Rcis permethrin content = 5.0 - 10.0 %w/w 1Scis permethrin content = 15.0 - 20.0 %w/w 1Rtrans permethrin content = 45.0 - 55.0 %w/w 1Strans permethrin content = 17.0 - 27.0 %w/w
Structural formula	1Rcis isomer  1Scis isomer 

	1Rtrans isomer  1Strans isomer 

2.1.2.2 Candidate for substitution

There are no indications that permethrin would fulfil the exclusion criteria specified in article 5(1), nor the substitution criteria specified in Article 10 (1) of Regulation (EU) No 528/2012.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin	3-phenoxybenzyl (1RS, 3RS; 1RS, 3RS)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.25 (technical) 0.23 (pure)
Ethanol		Non-active substance			23.93
Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics		Non-active substance	Related CAS No 64742-47-8	926-141-6	21.05
Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics		Non-active substance	Related CAS No 64742-49-0	920-750-0	13.5

Note: The concentrations of active substance and co-formulants in the product with propellant are considered.

The composition of the product without propellant has been provided in the confidential annex.

2.1.2.4 Information on technical equivalence

Technical equivalence does not need to be demonstrated as the supplier of the active ingredient is also registration holder for this substance (included in the Article 95 Union list of approved active substances under Regulation No. 528/2012 list).

2.1.2.5 Information on the substances of concern

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), WOOD PRESERVATIVE AEROSOL PERMETHRIN contains several substances of concern. Please see the confidential annex for further details.

2.1.2.6 Type of formulation

AE- Aerosol dispenser

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Flammable Aerosol 1H222 H229 Asp. Toxic 1 H304 Eye irrit 2; H319 STOT SE 3; H336 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
Hazard statement	H222: Extremely flammable aerosol H229: Pressurized container: may burst if heated H304: May be fatal if swallowed and enters airways H336: May cause drowsiness or dizziness H319: Causes serious eye irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Pictograms.	GHS02, GHS07, GHS09
Signal words	Danger
Hazard statements	H222: Extremely flammable aerosol H229: Pressurized container: may burst if heated H319: Causes serious eye irritation H336: May cause drowsiness or dizziness H410: Very toxic to aquatic life with long lasting effects EUH066: Repeated exposure may cause skin dryness or cracking.

	EUH208: Contains "permethrin". May produce an allergic reaction.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P210: Keep away from heat / sparks / open flames / hot surfaces. No smoking. P211: Do not spray on an open flame or other ignition source. P251: Pressurized container: do not pierce or burn, even after use. P261: Avoid breathing dust/fume/gas/mist/vapours/ spray. P271: Use only outdoors or in a well-ventilated area. P264: Wash … thoroughly after handling. P273: Avoid release to the environment. P391: Collect spillage. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention. P410+P412: Protect from sunlight. Do no expose to temperatures exceeding 50°C / 122°F. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of content and / or its container as hazardous waste according to the regulations in force.

Note: As the propellant will quickly evaporate (it is liquefied and has a vapour pressure (20°C) ≥ 10 kPa), for the classification and labelling of the biocidal product the concentration of active substance and co-formulants in the product without propellant is taken into account, as classification of solely the other constituents of the aerosol is more "relevant" within the meaning of Article 6(1) of the CLP Regulation (Doc. CA/58/2020 Final of CARACAL).

2.1.4 Authorised uses

2.1.4.1 Use description 1

Table 1. Use # 1 – Preventive treatment. Surface application by spraying- General public (non professional).

Product Type	TP8. Wood preservatives.
Where relevant, an exact description of the authorised use	Indoor anti-woodworm aerosol for non-professionals against wood boring beetles (spraying application). Use class 1: situation in which the wood or wood based product is inside a construction, not exposed to the weather and wetting.
Target organism (including development stage)	Wood boring beetles). Larvae.
Field of use	Indoors Protection for transformed wood used in joinery, furniture and woodwork.
Application methods	Spray directly on the non-varnished parts of the wood or

	furniture.
Application rate and frequency	Dose rate: 200 g/m^2 or 300 mL/m^2 (after degassing) Frequency: Repeat the treatment max. 1 to 2 times per year.
Category of users	General public (non professional)
Pack sizes and packaging material	250 mL, 375 mL, 400 mL, 500 mL, 600 mL, 750 mL aerosol tin-plate containers.

2.1.4.1.1 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.1.2 Use-specific risk mitigation measures

See section 2.1.5.2.

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

See section 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5.

2.1.4.2 Use description 2

Table 2. Use # 2 – Preventive treatment. Surface application by spraying- General public (non professional).

Product Type	TP8. Wood preservatives.
Where relevant, an exact description of the authorised use	Indoor anti-woodworm aerosol for non-professionals against termites (spraying application). In situation in which the wood or wood based product is inside a construction, not exposed to the weather and wetting.
Target organism (including development stage)	Termites (*Reticulitermes spp*). Workers, nymphs, and soldiers.
Field of use	Indoors Protection for transformed wood used in joinery, furniture and woodwork.

Application methods	Spray directly on the non-varnished parts of the wood or furniture.
Application rate and frequency	Dose rate: 153 g/m^2 or 227 mL/m^2 (after degassing) Frequency: Repeat the treatment max. 1 to 2 times per year.
Category of users	General public (non professional)
Pack sizes and packaging material	250 mL, 375 mL, 400 mL, 500 mL, 600 mL, 750 mL aerosol tin-plate containers.

2.1.4.2.1 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.2.2 Use-specific risk mitigation measures

See section 2.1.5.2.

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

See section 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5.

2.1.4.3 Use description 3

Table 3. Use # 3 – Curative treatment Surface application by spraying- General public (non professional).

Product Type	TP8. Wood preservatives.
Where relevant, an exact description of the authorised use	Indoor anti-woodworm aerosol for non-professionals against wood boring beetles (spraying and inject application with a canule).
Target organism (including development stage)	Wood boring beetles. Larvae.
Field of use	Indoors. Protection for transformed wood used in joinery, furniture and woodwork.
Application methods	Surface treatment:

	- Spray. - Injection (combined with spray)
Application rate and frequency	Dose rate: 200 g/m^2 or 300 mL/m^2 (after degassing). For intensive treatment combine surface spraying with the application of the product using the applicator tube into some holes every 10-15 cm distance. Frequency: Repeat the treatment max. 1 to 2 times per year.
Category of users	General public (non professional)
Pack sizes and packaging material	250 mL, 375 mL, 400 mL, 500 mL, 600 mL, 750 mL aerosol tin-plate containers.

2.1.4.3.1 Use-specific instructions for use

Furniture that has been attacked by woodworms will have visible holes; spray with the applicator tube inside each hole, making sure that the holes are filled with liquid. Quick-acting curative product.

Curative treatments performed by injection must always be combined with curative treatments applied by superficial application.

Applicator tube spraying:

1) Remove the applicator tube.
2) Place the tube in the nozzle.(canule)

2.1.4.3.2 Use-specific risk mitigation measures

See section 5.2.

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

See section 5.3.

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

See section 5.4.

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

See section 5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Read the label carefully before using the product.

Surface spraying: Hold the nozzle about 30 cm away from the surface, press the button

and spray on the area requiring treatment ensuring that all the surface to treat is wet.

Product intended to be used only for softwood.

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.

2.1.5.2 Risk mitigation measures

Keep children and pets away from treated surfaces until dried.

Do not use/applay directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.

Avoid contact with skin. In case of contact with skin wash immediately with plenty of soap and water without rubbing.

Avoid bunching of electrostatic charges.

Do not spray on a naked flame or any incandescent body.

Adequately ventilate the room where the product is applied; as vapours may catch fire (and an explosion may occur), the accumulation of vapours should be avoided.

Not to be mixed with any other chemical product.

During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

Contain permethrin (pyrethroids), may be lethal to cats. Cats must be avoid contact with treated object area.

Remove or cover terrariums, aquariums, and animal cages before application. Turn off aquarium air-filter while spraying.

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

Response precautionary statements related to first aid instructions in point 2.1.3 of this PAR shall apply in this section. In addition:

- IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.
- IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.
- IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.
- IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor..

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

<u>Accidental exposure of men and environment:</u>
Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site. Send away individuals who are not suitably equipped. Wear protective gloves / protective clothing / eye protection / face protection.

Do not discharge the biocidal product nor the diluted solution of the biocidal product into the sewage system or the environment.

Prevent all product entry into drains or waterways.

Place containers or drums for disposal of waste recovered in accordance with applicable regulations.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Eliminate any remains of the product and its containers with all necessary precautions.
Do not puncture or burn, even after use.
Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.
Do not release to soil, ground, surface water or any kind of sewer.

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

Shelf-life: 2 years.
Protect from frost
Store in a place where adequate ventilation is ensured, away from direct sunlight at a temperature below 50°C, away from any combustion sources.
Do not smoke.
Do not store near food, drink and animal feedingstuff.
Keep out of reach of children and non-target animals/pets.

2.1.6 Other information

Definitions:

- **General public (non-professional user):** Users who are not professionals and who apply the product in the context of their private life.

This product contains a bittering agent that makes it repulsive to people or pets.

The authorization is conditioned to the submission of the complete long term storage study.

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)
Aerosol container, 3 piece necked-in cans in accordance with EN	Aerosols volume range: From 250 mL to 750 mL	Tin plate can (1)	1" valve with vapor phase Actuator: polyethylene Stem: acetalic resin or Nylon or	Non Professional	Yes

15007			Natural PA Int gasket: neoprene or Buna Ext gasket: Buna NBR or sleeve gasket Mounting cup: tin plate Spring: stainless steel Housing: acetalic resin or nylon or natural PA Dip tube: polyethylene LD or HD		

(1): Details on inside and outside coating is provided in the Packaging specification report (ArdaghGroup, 2015)

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the biocidal product described within this application.
The reference list (including updates) for the studies submitted in support of the BPD dossier has been included in Annex 3.1 whilst the reference list for the studies considered confidential has been included in the confidential PAR.

2.1.8.2 Access to documentation

The registration holder of the dossier for the Wood Preservative Aerosol Permethrin (Carcomin Plus) has received a Letter of Access for the active ingredient "permethrin" of this biocidal product. A letter of access from Tagros Chemical India Ltd to the dossier assessed for the approval of the active substance permethrin (PT 8) has been granted to Henkel Global Supply Chain B.V.

Regarding efficacy the tests have been carried out with the product carcomin plus, one of the names that the wood preservatives aerosol product will have. The sponsors have been Helnkel Iberica, a subsidiary of Henkel Global Supply and Sara Lee, S.L. who has provided the necessary documentation for Henkel to use these tests.

2.2 Assessment of the biocidal product

2.2.1 Intended use as applied for by the applicant

Table 1. Use # 1 – Indoor anti-woodworm aerosol·

Product Type	8 – Wood preservatives
Where relevant, an exact description of the authorised use	Indoor anti-woodworm aerosol for non-professionals against wood boring beetles and termites (spraying or direct application with a canule)

Target organism (including development stage)	Against wood boring beetles and termites
Field of use	Indoor Curative and preventive protection of indoor wood material (e.g. furniture) (PT8). Spraying the product in the holes with the application tube, or directly on a surface without the tube, from a distance of 30 cm.
Application methods	**CURATIVE TREATMENT:** Surface spraying: Hold the nozzle about 30 cm away from the surface, press the button and spray on the area requiring treatment ensuring that all the surface to treat is wet. One can (250 mL) is enough to treat a surface of about 1 m^2. Applicator tube spraying: ` 1) Remove the applicator tube 2) Place the tube in the nozzle Furniture that has been attacked by woodworms will have visible holes; spray with the applicator tube inside each hole, making sure that the holes are filled with liquid. For intensive treatment combine surface spraying with the application of the product using the applicator tube into some holes every 10-15 cm distance.Repeat the treatment max. 1 to 2 times per year. **PREVENTIVE TREATMENT:** Spray directly on the non-varnished parts of the wood or furniture using the surface spraying method described as above. Repeat the treatment max. 1 to 2 times per year.
Application rates and frequency	Application rate: Curative: 200 g/m^2 Preventive: 180 g/m^2 Once or twice per year.
Category of user	Non-professional users
Pack sizes and packaging material	250 mL, 375 mL, 400 mL, 500 mL, 600 mL, 750 mL aerosol tin-plate containers (details in Packaging specification reports (ArdaghGroup, 2015; Coster 2012)

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	Anti-Woodworm Aerosol, IIRD-01116.2 Batch: Not available.	Initially and after storage studies: Emulsion	See Confidential PAR
		Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9073LC02.	Initially and after storage studies: Emulsion	See Confidential PAR
Colour at 20 °C and		Anti-Woodworm	Initially and after	See

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
101.3 kPa		Aerosol, IIRD-01116.2 Batch: Not available.	storage studies: Colourless	Confidential PAR
		Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9073LC02.	Initially and after storage studies: Colourless	See Confidential PAR
Odour at 20 °C and 101.3 kPa	Organoleptic	Anti-Woodworm Aerosol, IIRD-01116.2 BATCH: Not available.	Initially and after storage studies: Characteristic	See Confidential PAR
		Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9073LC02.	Initially and after storage studies: Characteristic	See Confidential PAR
Acidity / alkalinity			Not applicable.	
Relative density / bulk density	Theoretical determination	Concentrated of wood preservative aerosol Permethrin (0.42% permethrin) Batch: 9073LC02-Concentrate	0.672 kg/L	See Confidential PAR
Storage stability test – **accelerated storage**	CIPAC method MT46.3.	Anti-Woodworm Aerosol, IIRD-01116.2 Batch: Not available.	The product is stable 2 weeks at 54ºC.	See Confidential PAR
Active substance content	GC-FID		Initially: 0.44 % w/w After 2 weeks at 54ºC: 0.46 % w/w Difference: 4.54 % w/w	
Homogeneity of application			No changes observed.	
Appearance and stability of the package			No changes observed.	
Storage stability test – **accelerated storage**	CIPAC method MT46.3.	Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9073LC02	The product is stable 4 weeks at 50ºC.	See Confidential PAR
Active substance content	GC-FID		Initially: 0.237 % w/w After 4 weeks at 50ºC: 0.237 % w/w Difference: 0.00 % w/w	
Homogeneity of application			No changes observed.	
Appearance and stability of the package			No changes observed.	
Storage stability test – **long term**	CIPAC method	Anti-Woodworm Aerosol, IIRD-01116.2	The study is stable 68 months	See Confidential

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
storage at ambient temperature	MT46.3.	Batch: Not available.	at 20-22ºC.	PAR
Active substance content	GC-FID		Initially: 0.23 % w/w After 68 months at 20-22ºC: 0.226 % w/w Difference: -1.74 % w/w	
Homogeneity of application			No changes observed.	
Appearance and stability of the package			No changes observed.	
Storage stability test – **long term storage at ambient temperature**	CIPAC method MT46.3.	Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9134LC03	The study is ongoing.	See Confidential PAR
Active substance content	GC-FID		Initially: 0.225 % w/w After 6 months at 25ºC: 0.232% w/w Difference: 3.11 % w/w After 12 months at 25ºC: 0.225% w/w Difference: 0.00 % w/w After 24 months at 25ºC: ongoing	
Homogeneity of application			No changes were observed at initial time nor after 6 and 12 months. ongoing	
Appearance and stability of the package			No changes were observed at initial time nor after 6 and 12 months. ongoing	
Storage stability test – **low temperature**			Not available.	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
stability test for liquids				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**		Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9134LC03	No changes observed.	See Confidential PAR
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9134LC03	No changes observed.	See Confidential PAR
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9134LC03	No changes observed.	See Confidential PAR
Wettability			Not applicable.	
Suspensibility, spontaneity and dispersion stability			Not applicable.	
Wet sieve analysis and dry sieve test			Not applicable.	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable.	
Disintegration time			Not applicable.	
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187	Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 5110LC03	<u>Initially with cannula:</u> Dv 10: 12.20 µm Dv 50: 37.47 µm Dv 90: 78.94 µm Average Particle Size: 42.27 µm <u>Initially without cannula:</u> Dv 10: 20 µm Dv 50: 45.95 µm Dv 90: 90.84 µm Average Particle Size: 51.27 µm	See Confidential PAR

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Persistent foaming			Not applicable.	
Flowability/Pourability/Dustability			Not applicable.	
Burning rate — smoke generators			Not applicable.	
Burning completeness — smoke generators			Not applicable.	
Composition of smoke — smoke generators			Not applicable.	
Spraying pattern — aerosols	FEA 644 FEA 643	Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 5110LC03	Iniatilly with cannula: Discharge rate: 0.73 g/s Iniatilly without cannula: Discharge rate: 0.84 g/s	See Confidential PAR
		Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9134LC03	Initially: Spray pattern: 15 cm: d= 5.5 cm 25 cm: d= 9 cm Internal pressure: 3.5 Bar Discharge rate: 0.83 g/s After 4 weeks at 50ºC: Spray pattern: 15 cm: d= 5 cm 25 cm: d= 8 cm Internal pressure: 4 Bar Discharge rate: 0.9 g/s After 6 months at 25ºC: Spray pattern: 15 cm: d= 6 cm 25 cm: d= 9 cm Internal pressure: 3.5 Bar Discharge rate: 0.89 g/s After 12 months at 25ºC: Spray pattern: 15 cm: d= 5.5 cm 25 cm: d= 8 cm Internal pressure:	See Confidential PAR

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			3.7 Bar Discharge rate: 1.00 g/s After 24 months at 25ºC: Ongoing	
Physical compatibility			Not applicable.	
Chemical compatibility			Not applicable.	
Degree of dissolution and dilution stability			Not applicable.	
Surface tension			Not available.	
Viscosity	ISO 3219:1993	Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9073LC02-Concetrate	4.08 mP*s at 20ºC.	See Confidential PAR

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

NOTE:
The applicant has noted that the studied batches have the same composition as the marketed formulation.

Appearance
The product is a colourless gas/oil mixture. The odour is characteristic of aromatic compounds.

Acidity / alkalinity
The product is an aerosol, and the concentrated liquid phase is not water-based. Therefore, the determination of the pH is not relevant.

Relative density
Concentrate has a density of 0.780 g/mL, and represents 60% of the aerosol.
Propellant has a density of 0.556 g/mL, and represents 40% of the aerosol.
The theoretical determined density is 0.672 g/mL.

Accelerated storage
After 2 weeks at temperature of 54ºC or 4 weeks at 50ºC (simulating room temperature long term ageing of the product of at least 2 years) the content of active ingredient is within specification and tolerances accepted (criterion: nominal value +/- 10%).

Long term storage at ambient temperature
After a 68 months storage at ambient temperature of 20-22ºC the content of active ingredient is within specification and tolerances accepted (criterion: nominal value +/- 10%). The storage had no adverse impact on the packaging or on the dispensing mechanism.
The new long term storage study after 2 years at room temperature is ongoing. The product is stable after 1 year at 25ºC for now.

Low temperature stability test for liquids
If the low temperature storage does not perform, a phrase like 'protect from frost' must be included in the label.

Effects of light
The product is kept in a container and is not exposed to light. The stability of the product in the container is demonstrated in the storage stability study.

Effects of temperature and humidity
The impact of temperature has been investigated during the accelerated stability test. Product is stored in a closed container and therefore humidity is not a relevant parameter.

Reactivity towards container material
The reactivity towards container material has been investigated during the long term stability test.

Technical characteristics of the biocidal
Particle size distribution: Particle size using cannula is 30% lower than aerosol without cannula. The average particle size of the aerosol without cannula is 51.27 µm, and with cannula, 42.27 µm.
For the application of the product, the following characteristics are not relevant: wettability, suspensibility, emulsifiability, persistent foaming and other technical characteristics. Not relevant conclusions for this endpoint.

Spraying pattern — aerosols
A homogenous spray pattern was obtained, and the different samples resulted in similar spray patterns; pictures of the patterns were taken within 10 seconds after the execution of each test.

Physical and chemical compatibility with other products
Data are required when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products. This is not the case for Wood Preservative Aerosol Permethrin.

Surface Tension
The surface tension at the highest in use concentration recommended for use should be determined for liquid biocidal products. Wood preservative aerosol permethrin, however, is an aerosol.

Viscosity
For concentrate viscosity equals 4.08 mmPa*S at 20ºC. Given the classification of product as flammable and asp. tox. 1, the viscosity at 40ºC is not measured for safety reasons.

Conclusions
Wood Preservative Aerosol Permethrin is a ready for use product in a pressurized can like an aerosol container. It is composed by a homogeneous solution of solvents, propellant and permethrin. The active substance is solved in the liquid system.

The product is a colourless gas/oil mixture. The theoretical relative density of the test item was 0.672 g/cc.

Reference samples have been stored under long term conditions (2 years at room temperature) and active substance content, appearance and stability of the packaging have been determined prior to and after 6 and 12 months of storage. The study is ongoing but all results look as expected and within trend, so we do not identify any issues with the products or formulations under long term conditions. The shelf life can be deemed as 2 years taking into account the results obtained from the accelerated storage study.
According to the study conclusions, a label statement was added for specifying corrosion resistance of the dispender after storage life.
The phrase 'protect from frost' must be included in the label.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Explosives	Theoretical assessment		Not explosive	Henkel
Flammable gases			Not applicable	
Flammable aerosols	Test according to 75/324/EC amended by 2008/47/EC which are harmonised with UN-MTC Section 31.	Anti-Woodworm Aerosol, IIRD-01116.2 Batch: Not available	Flammable aerosol 1 - H222, H299	Henkel
Oxidising gases			Not applicable	
Gases under pressure			Not applicable	
Flammable liquids	Theoretical assessment		Flammable.	Henkel
Flammable solids			Not applicable	
Self-reactive substances and mixtures			Not applicable	
Pyrophoric liquids			Not applicable	
Pyrophoric solids			Not applicable	
Self-heating substances and mixtures			Not applicable	
Substances and mixtures which in contact with water emit flammable gases			Not applicable	
Oxidising liquids	Theoretical assessment		Not oxidasing properties.	Henkel.
Oxidising solids			Not applicable	
Organic peroxides			Not	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			applicable	
Corrosive to metals	Visual method	Anti-Woodworm Aerosol, IIRD-01116.2 Batch: 9073LC02	Not corrosive.	See Confidential PAR
Auto-ignition temperatures of products (liquids and gases)			Not applicable	
Relative self-ignition temperature for solids			Not applicable	
Dust explosion hazard			Not applicable	

Conclusion on the physical hazards and respective characteristics of the product

Note:
The applicant has noted that the studied batches have the same composition as the marketed formulation.

Explosives
None of the constituents of the mixture are considered as explosives; chemical groups that may indicate explosive properties are not present in the mixture. According to Annex 1 of the CLP Regulation (section 2.1.4.3), there is no need to conducts tests when the molecules do not contain chemical groups associated with explosive properties.

Flammability
The liquid concentrate that serves as a basis for the aerosol contains several components that are classified as Flam. Liq. Cat 2: Ethanol, acetone and C7-C9 hydrocarbons. Furthermore, the biocidal product contains 40% of C3-C4 hydrocarbons (Petroleum gas) that has the function of propellant for the concentrate (liquid, dispersed as aerosol). This propellant has a H222 classification (Flam. Cat.1). Therefore, the product is classified as Flammable Aerosol Cat. 1 (H222, H229).

Self-reactive substances and mixtures
The classification procedures for self-reactive substances and mixtures need not to be applied if there are no chemical groups present in the molecules that can be associated with explosive or self-reactive properties (CLP Annex I). None of the components of Carcomin Plus have explosive or self-reactive properties.

Pyrophoric liquids
Pyrophoric liquid refers to a liquid substance or mixture which, even in small quantities, is liable to ignite within five minutes after coming into contact with air. Pyrophoricity (= the ability to spontaneously ignite in air) is the result of a reaction with the oxygen in the air. The reaction is exothermic and has the particularity that it starts spontaneously, i.e. without the aid of a supplied spark, flame, heat or other energy source; the auto-ignition temperature for a pyrophoric substance or mixture is lower than room (ambient)

temperature. None of the liquid components of the product Carcomin Plus have pyrophoric properties.

Self-heating substances and mixtures
A self-heating substance or mixture is a liquid or solid substance or mixture, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this substance or mixture differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days). None of the liquid components in the product Carcomin Plus have self-heating properties.

Substances and mixtures which in contact with water emit flammable gases
None of the components that are present in the product Wood preservative aerosol permethrin produces flammable gasses when in contact with water.

Oxidising properties
Oxidising liquid refers to a liquid substance or mixture which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material. The liquid phase of Carcomin Plus is not considered as an oxidising liquid as it is not expected to react exothermically with combustible materials on the basis of their chemical structure. Moreover, for organic substances or mixtures the classification procedure for this class shall not apply if the product does not contain oxygen, fluorine or chlorine.

Self-reactive substances and mixtures
The classification procedures for self-reactive substances and mixtures need not to be applied if there are no chemical groups present in the molecules that can be associated with explosive or self-reactive properties (CLP Annex I). None of the components of Wood preservative aerosol permethrin have explosive or self-reactive properties.

Corrosive to metals
None of the components of the product Wood preservative aerosol permethrin are corrosive to metals. Furthermore, after the storage stability at 50ºC for 4 weeks, can is emptied and opened in order to check internal corrosion. No visible corrosion observed.

Auto-ignition temperature (liquids and gases)
This test is not applicable; test procedure is applicable to gases, liquids and vapours which, in the presence of air, can be ignited by a hot surface.

Conclusions
The propellant determines in major way the flammability of Wood Preservative Aerosol Permethrin. The Lower and Upper explosion limits for "Hydrocarbons rich in C3-C4" are 1.9 and 8.5 %".

The product Wood Preservative Aerosol Permethrin is classified as flammable aerosol cat. 1, H222 and H229, GHS02 Danger according to CLP regulation (EC) No.1272/2008.

The product Wood Preservative Aerosol Permethrin is not expected to present a significant hazard for explosive and oxidising properties, corrosion and auto-flammability.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Permethrin	HRGC-FID	14.5 mg n = 5	0.06 – 0.9 mg/mL y = 0.00896 + 1.1130x R2: 0.9997 n = 5	Yes	99.2-101.1	100.3%	0.70	1.4 µg /mL	See Confidential PAR
All four permethrin stereoisomers in an EW formulation	Chiral HPLC-DAD	CIPAC Validated	CIPAC Validated	CIPAC/4946**	CIPAC Validated	CIPAC Validated	CIPAC Validated	CIPAC Validated	A.R. (addendum 2016)
All four permethrin stereoisomers in an EC formulation	Chiral HPLC-DAD	1S-cis Permethrin (S,S) 0.69 %w - 4.63%w 1R-cis Permethrin (R,R) 0.69 %w -4.59 %w 1S-trans Permethrin (S,R) 1.93 %w - 12.9 %w	R^2 = 1.000 for all 1S-cis Permethrin (S,S): 0.013-0.34 mg/mL (n = 6 points) 1R-cis Permethrin (R,R): 0.013-0.33 mg/mL (n = 6 points) 1S-trans Permethrin (S,R):	No significant interference	n = 2 at each level – 3 levels 1S-cis Permethrin (S,S) 97.3 – 98.7% 1R-cis Permethrin (R,R) 98.2 – 99.5%	n = 2 at each level – 3 levels 1S-cis Permethrin (S,S) Recovery level (0.69 %w):97.3% Recovery level (2.31%w): 98.7 % Recovery level (4.63%w): 98.3 %	Six samples (single injection) from 1 batch – 1S-cis Permethrin (S,S): 0.46 %. 1R-cis Permethrin (R,R): 0.41 % 1S-trans Permethrin (S,R):	Not applicable	A.R. (addendum 2016)

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		
		1R-trans Permethrin (R,S) 1.91 %w - 12.8 %w	0.035-0.93 mg/mL (n = 6 points) 1R-trans Permethrin (R,S): 0.035-0.93 mg/mL (n = 6 points)		1S-trans Permethrin (S,R) 97.5 – 99.5% 1R-trans Permethrin (R,S) 96.6 – 99.1%	1R-cis Permethrin (R,R) (n = 2) Recovery level (0.69 %w):98.6% Recovery level (2.30 %w):99.5% Recovery level (4.59 %w):98.2% 1S-trans Permethrin (S,R) (n = 2) Recovery level (1.93 %w):97.5% Recovery level (6.43 %w):99.5% Recovery level (12.9 %w):98.1% 1R-trans Permethrin	0.34 % 1R-trans Permethrin (R,S): 0.62 %		

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		
						(R,S) (n = 2) Recovery level (1.91 %w):96.6% Recovery level (6.38 %w):99.1% Recovery level (12.8 %w):98.0%			
All four permethrin stereoisomers in an WP formulation	Chiral HPLC-DAD	1S-cis Permethrin (S,S) 0.99 %w – 6.57%w 1R-cis Permethrin (R,R) 0.98 %w -6.52 %w 1S-trans Permethrin (S,R) 2.74 %w - 18.3 %w	As for EC formulation above	No significant interference	n = 2 at each level – 3 levels 1S-cis Permethrin (S,S) 98.8 – 101.2% 1R-cis Permethrin (R,R) 98.0 – 101.4% 1S-trans Permethrin (S,R)	n = 2 at each level – 3 levels 1S-cis Permethrin (S,S) Recovery level (0.99% w/w):98.8 % Recovery level (3.29%): 100.7 % Recovery level (6.57%): 101.2 %	Six samples (single injection) from 1 batch – 1S-cis Permethrin (S,S): 1.08%. 1R-cis Permethrin (R,R): 1.11 % 1S-trans Permethrin (S,R): 0.96 %	Not applicable	A.R.(addendum 2016)

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		
		1R-trans Permethrin (R,S) 2.72 %w - 18.3 %w			99.3 – 100.9% 1R-trans Permethrin (R,S) 99.4 – 101.0%	1R-cis Permethrin (R,R) Recovery level (0.98% w/w): 98.0 % Recovery level (3.26%): 100.8 % Recovery level (6.52%): 101.4 % 1S-trans Permethrin (S,R) Recovery level (2.74%): 99.3 % Recovery level (9.13%): 100.9 % Recovery level (18.3%	1R-trans Permethrin (R,S): 0.93 %		

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		
						w/w): 100.8 % <u>1R-trans Permethrin (R,S)</u> Recovery level (2.72% w/w): 99.4 % Recovery level (9.05% w/w): 101.0 % Recovery level (18.1 % w/w): 100.9 %			
All four permethrin stereoisomers in wood preservatives with common co-formulants	Chiral HPLC-DAD	No data provided	No data provided	No significant interference for TC or basic product formulation, however significant interference when formulations became more complex (higher	No data provided	No data provided	No data provided	Not applicable	A.R.(addendum 2016)

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		
				number of actives and or higher number of common co-formulants found in wood preservatives.					
Impurities in Permethrin	GC-FID, HPLC-UV, and GC-MS								A. R. (2014)
* Limit of quantification determined for the analytical method according to report nº 057623-1. ** The method has been peer-validated by CIPAC for EW formulations and is available under the pre-publication scheme (CIPAC/4946).									

Analytical methods for soil									
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 in silt and sandy loam	HPLC/MS/MS	5 µg/kg (= LOQ level), and 50 µg/kg	1 µg/L to 100 µg/L (2 to 200 µg/kg) r > 0.9992	No signals / peaks interfering with the detection of the analyte were observed in extracts of untreated blank control	70-110		<20	5.0 µg/kg	A. R. (2014)

				specimens.					

Analytical methods for air									
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	HPLC/MS/MS	LOQ and 10-fold LOQ n = 5	5.0 ng/mL to 500 ng/mL r = 0.997	The chromatograms of the control specimens showed no signals (<1 µg/m^3) at the retention time of permethrin.	87-92	89.63	≤6 %	5 µg/m^3	A. R. (2014)
	GC-MS/MS	0.0001 and 0.001 mg/m^3	0.05-10 mg/L. y = 152187.4x + 1081.4 r = 1.0	The method is specific for the determination of Permethrin in air since no interferences were observed in the chromatograms of solvent, control samples and fortification levels.	72-74	73	1.85-3.35	0.0001 mg/m^3	

Analytical methods for water									
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 in drinking and surface water	HPLC/MS/MS	0.05 µg/L and 0.5 µg/L n = 10	0.04 µg/L -10 µg/L r > 0.9995	The control chromatograms generally have no peaks above the chromatographic background and the spiked sample chromatograms contain only the analyte peak of interest.	70-110		1.7-2.2	0.05 µg/L	A. R. (2014)

Conclusion on the methods for detection and identification of the product
Analytical methods for the analysis of the product as such including the active substance, impurities and residues A suitable combination method (achiral and chiral) was peer-validated by CIPAC. The validation study reports (EC, EW and WP) indicated that the chiral CIPAC method of analysis was considered acceptable for EC, EW and WP formulations. However, the study indicated that considerable interference can occur with some complex wood preservative formulations, and that the CIPAC chiral method may not be suitable under these more complex conditions. The method submitted by the applicant for analysing the active substance in the biocidal product could be considered acceptable. **Analytical methods for soil** An acceptable validated method for residues of Permethrin in soil was presented. **Analytical methods for air** Acceptable validated methods were provided for residues of Permethrin in air. **Analytical methods for water** Acceptable validated methods were provided for residues of permethrin in water. **Analytical methods for animal and human body fluids and tissues** Not relevant as the active substances are neither toxic nor highly toxic. **Analytical methods for monitoring of active substances and residues in food and feeding stuff** Food and feeding stuff will not be exposed to permethrin based on the proposed usage. **Conclusion** The methods are indicated in the Assessment Report for the inclusion in annex I (PT08). The applicant has also submitted the letter of access granted by Tagros Chemicals India Pvt. Ltd. for information on analytical methods for the Permethrin active substance. Finally, the analytical method submitted for the analyses of the active substance in the formulation is deemed sufficiently specific and precise.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Wood preservative aerosol permethrin (Carcomin plus) is a solvent based wood preservative, for preventive and curative protection for transformed wood used in joiner, furniture and woodwork, (constructional timber, joints, doors, windows, fences, burgles, etc.), used by non-professional user, to prevent the action wood-boring beetles and termites.

Carcomin plus is a product for use class 1 according to the European standard EN 335 and EN 599:situation in which the wood or wood based products is inside a construction, not expose to the weather and wetting.

The product is applied by spray on surfaces for preventive and curative purposes and in combination with the injection method for more intense curative treatments.

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

The efficacy of the product Carcomin Plus has been demonstrated for the two following species:

- *Hylotrupes bajulus* (European wood borer): preventive and curative action.
- *Reticulitermes grassei* (subterraneam termites): preventive and curative action.

Therefore, Carcomin plus is intended to be use against wood-boring beetles and termites on softwood used in wood material (E.g furniture).

2.2.5.3 Effects on target organisms, including unacceptable suffering

Wood boring beetle larvae and termites are killed after contact with treated wood.
Unacceptable suffering for insect larvae cannot be assessed.

2.2.5.4 Mode of action, including time delay

As an insecticide and according to IRAC, permethrin when formulated as a wood preservative, is an axonic poison, binding to protein in nerves (voltage-gated sodium channel). Normally, this protein opens causing stimulation of the nerve and closes to terminate the nerve signal. Pyrethroids bind to this gate and prevent it from closing normally which results in continuous nerve stimulation.

2.2.5.5 Efficacy data

All efficacy data has been performed on the formulation itself. no changes were made to the formulation being registered compared to the tested formulation. The active substance content in the concentrate is 0.42%. The measured active content in test batches remains within the allowed tolerance limits (0.36-0.48% w/w) both according to bpr vol. i a+b+c and annex b of en599.1. In conclusion, there is no unacceptable variation described according to annex a & b of en-599.1.

Experimental data on the efficacy of the biocidal product against target organism							
Test substance	**Field of use envisaged**	**Organisms to be protected**	**Test organism**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
CARCOMIN IIRD-01116.1	Wood preservative Preventive treatment	*Pinus sylvestris*	*Hylotrupes bajulus*	EN46:2006 +EN73.	•Dipping application method (60 minutes) •.100 % (w/w) • Toxic value: 180±23.26 g/m^2 • Drying: 4 weeks • Ageing: 12 weeks • Exposure: 4 weeks. (The trial ended at 4 weeks because all larvae were dead on the surface of the treated specimens and the control specimens were heavily attacked. (> 70% of the larvae had made borings).	>90% larvae were recovered dead without having made tunnels in the wood. Two larvae were not recovered. At least 80% of the larvae inserted in all untreated control specimens survive.	Nº report: 16072.3-a (2008)
CARCOMIN PLUS IIRD-01116.2	Wood preservative Preventive treatment.	*Pinus sylvestris*	*Reticulitermes grassei.*	EN118:2013 + EN73.	• Superficial treatment (brushing) •100% (w/w) • 150.68 ± 2.03 g/m^2 or 223.93 ± 3.01 ml/m² • Exposure: 8 weeks	The study is validated. All control specimens are ranked as 4. 5 of the treated blocks are ranked as 1 an one of then is ranked as 2 at the end of the study. 100% of mortality.	Nº report: 052084.1-a (2015)
CARCOMIN IIRD-01116.1	Wood preservative Curative treatment	*Pinus sylvestris*	*Hylotrupes bajulus*	EN1390:2007	• Brushing •100% (w/w) • toxic value: 297.76±3.04 ml/m^2 •Exposure 12 weeks. Quick action. • 10 specimens treated. • 6 larvae per specimen. • 3 untreated control.(17 larvae)	Mortality rate: 80.36% after 12 weeks of exposure. 14 larvae of the untreated control specimen were alive, 2 larvae were dead and a	Nº report: 16072.2-a (2008)

						larva reached an adult stage. Test meets the requirement of curative norm.(EN 14128)	

Conclusion on the efficacy of the product

The applicant has submitted three studies to support the claims.

Preventive treatment:

According to the applicant, WOOD PRESERVATIVE AEROSOL PERMETHRIN is intended to be use as preventive treatment against wood boring beetles and termites by spraying as a surface treatment.

To claim use class 1, in accordance with the minimum requirements according to the Efficacy Guideline and the EN599-1 standard, it is necessary to provide at least one test against *Hylotrupes bajulus, Anobium puctatum or Lyctus bruneus*. The applicant has provided a study against *Hylotrupes bajulus* and another against subterranean termites.

The study against *Hylotrupes bajulus* (EN 46-1, test report 16072.3-a) has demonstrated an efficacy of more than 90% with no dilution by dipping application for 60 minutes at a dose of 180.00 ± 23.26 g/m^2). Althought, the intended application method is spray, the Applicant has submitted a justification to accept this method for the laboratory test:

Immersion treatment does not differ from brushing in terms of biological efficacy as long as the heads or faces of the test tubes that will not be exposed to insects are filled.

In both methods, the product absorption calculations are made in g / m2, so both methods must achieve the same retention values of the formula before exposing the specimens to woodworms. Before carrying out the tests, it must be ensured that the absorbed grams of the product do not exceed the grams established according to the EN 599-1 standard. Since the absorbed grams of product is the parameter that we take into account before carrying out the tests, we can say that both methods, brushing or dipping, may be appropriate to evaluate the efficacy of a spray.

We accept this justification and consider the essay adequate.

According to the Transitional Guidance on Efficacy Assessment (2015), data against only *Hylotrupes bajulus* is considered adequate to cover a general claim "wood boring beetles".

The study against *Reticulitermes grassei* (EN118, test report 052084.1-a) has demonstrated an efficacy of 100% mortality with no dilution by brushing method at a dose of 150.68 ± 2.03 g/m^2. The treatment of the specimens in the standard is by brushing or pipetting. Therefore we accept brushing as a surface treatment to cover the spray method. According to the Guidances, the study against this kind of termites covers the general claim termites.

At the request of the applicant, the use of preventive treatment has been separated into a specific use only against wood booring beetles and another specific use only against termites.

The use against termites cannot be classified as use class 1, since the minimum mandatory organisms for this class are not claimed, but it is classified as indoors in situation of use class 1.

Therefore, the product can be authorized for preventive treatment by spray method against wood-boring beetles at a dose of 200g/m^2 and termites at a dose of 153 g/m^2 for softwood.

Curative treatment

According to the applicant, CARCOMIN PLUS is intended to be use as curative treatment only against wood boring beetles by spraying as a surface treatment. In addition, for intensive treatment the spray method can be combinated with the injection method.

The study against *Hylotrupes bajulus* (EN 1390, test report 16072.2-a) has shown an efficacy of 80.36% mortality at a dose of 297.76 ml/m^2 ± 3.04 ml/m^2 (equals approx. 201 g/m^2 at a product density of 0.67 g/ml)by brushing and with quick acting effect.
We consider that the deviation from the use of three samples without treatment instead of two samples does not have a final impact on the validation of the study, since if we withdraw the T2 sample, which is the most favorable, the number of live larvae is 10 of the 12 larvae from untreated control samples.
The standard on which this test is based only describes application by brushing or pipetting. Therefore we accept brushing as a surface treatment to cover the spray method.
Finally, the basic curative norm (EN14128) indicates that insecticidal activity tests should be carried out against *Hylotrupes bajulus* and *Anobium punctatum* or only against the most resistant insect. (section 5.2.3 a and b).
The laboratory has justified that *Hylotrupes bajulus* is more ressistant than *Anobium puctatum*. It is based on the smaller size of *Anobium puctatum*, the laying of eggs in the most superficial layers of the wood and the faster biological cycle with respect to *Hylotrupes bajulus*. This causes the Annobium larvae to die earlier, since they need less wood and less exposure time. They also report that they have verified over the years that *Hylotrupes bajulus* is more resistant than *Anobium*.
In conclusion, a general wood boring beetle claim for curative treatment is covered at 200g /m^2 (corresponding to 300 ml/m^2; at product density 0.67 g/ml)."

According to the TNsG, the treatments against termites are designed to kill termites that their are already found in the wood and to prevent the degradation of wood. So preventive efficacy test can be extrapolated for a curative treatment.
On the other side, according to the applicant, *the inyection method is indicated to be combined with superficial treatments. The dose rate of injection is not specified, as it is sufficient to completely fill each hole with product (the number of holes depends on the severity of infestation). The filling is considered completed when liquid starts to come out of the hole.*
Adding one specific dose rate in case of injection is considered irrelevant and as such use instructions will not apply for each individual infestation and will therefore not provide usefull info to the non-professional user.
We consider that the product has already proven to be sufficiently effective only with the spray application method and therefore, an additional dose is a better case.
From the point of view of efficacy evaluation, we accept the justification for not providing the additional dose for injection method.

The applicant has requested that the use of curative treatment be splitted into a specific use only against wood-boring beetles and another specific use only against termites. In this case, the efficacy guide refers us directly to the basic standard EN 14128 where the minimum requirements necessary for the product to be claimed as curative are established. Therefore, we consider that a curative claim only against termites is not acceptable, always having to include wood-booring bleetles.
In this case, the applicant has rejected the claim against termites in curative use.

The product can be authorized for curative treatment by spray method against wood-boring beetles at a dose of 300 ml/m^2 for softwood. For intensive

treatments, the application rate of 300ml/m^2 + fill boring holes with liquid' is appropriate for application method: superficial treatment+injection.

2.2.5.6 Occurrence of resistance and resistance management

Resistance to pyrethroid insecticides such as permethrin has been reported for a number of pests both in agriculture and public health. However, no data has been found in the literature regarding resistance occurrence to permethrin among wood-boring beetle and termites.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the following recommendations have to be implemented:

- Always read the label or leaflet before use and follow all the instructions provided.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder.

2.2.5.7 Known limitations

No limitations are known.

2.2.5.8 Evaluationof the label claims

Matrix claim:

Use 1:

User category	General public	A.30
Wood category	Solid wood	C.10
Wood product	Softwood	B.10
Application aim	Preventive	D.40.
Field of use	Use class 1 (preventive)	E.10
Method of application	- Surface application/brush	F10
Target organisms.	Wood boring beetles: House longhorn beetle (*Hylotrupes bajulus*)	G30 G.31 and/or C-H

Use 2:

User category	General public	A.30
Wood category	Solid wood	C.10
Wood product	Softwood	B.10
Application aim	Preventive treatment	D.40.
Field of use	Indoors. In situation to use class 1.	-
Method of application	Surface application/brush.	F10
Target organisms.	Subterranean termites (*Reticulitermes spp*)	G.51

Use 3:

User category	General public	A.30
Wood category	Solid wood	C.10
Wood product	Softwood	B.10
Application aim	Curative treatment (Quick action)	D.50
Field of use	Indoors	-
Method of application	Surface application /brush +Injection.	F10+F.20
Target organisms.	Wood boring beetles: House longhorn beetle (*Hylotrupes bajulus*)	G.31 and/or C-H

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

Not applicable.

2.2.6 Risk assessment for human health

WOOD PRESERVATIVE AEROSOL PERMETHRIN contains one active substance, i.e. PERMETHRIN (0.25% w/w with a purity of minimum 93%) and other co-formulants.
No studies on the effects of WOOD PRESERVATIVE AEROSOL PERMETHRIN on human health have been submitted in the dossier of this biocidal product. However there are valid data available on each of the components in the mixture sufficient to allow the classification according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP Regulation). Active substance effects and critical concentrations are described in the permethrin assessment report (April 2014). Information on co-formulants are found on the ECHA dissemination website and the SDSs submitted. Therefore new studies with the biocidal product are scientifically not justified.
According to of document *CA/58/2020 Final* of CARACAL as the propellant will quickly evaporate (it is liquefied and has a vapour pressure (20°C) ≥ 10 kPa), for the classification and labelling of the biocidal product, the concentration of active substance and co-formulants in the product without propellant is taken into account, as classification of solely the other constituents of the aerosol is more "relevant" within the meaning of Article 6(1) of the CLP Regulation.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	WOOD PRESERVATIVE AEROSOL PERMETHRIN is neither irritant nor corrosive to the skin.
Justification for the value/conclusion	Based on the classification of the active substance and the coformulants and their respective content in the final formulation. The concentration of components classified for skin irritation or corrosivity is below the limits for classification. Therefore, the product does not meet the criteria for classification for skin corrosion or irritation according to Regulation (EC) Nº 1272/2008. However, taking into account that some of the co-formulants are

	labelled as EUH066, an appropriate labelling for skin dryness and cracking is indicated.
Classification of the product according to CLP	No classification is required. Labelling with supplemental hazard statement EUH066: "Repeated exposure may cause skin dryness or cracking" is required.

Data waiving	
Information requirement	Skin corrosion/irritation study
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Irritant to eyes.
Justification for the value/conclusion	Based on the classification of the active substance and the coformulants and their respective content in the final formulation. There are components classified as irritant to eyes above 10% with no specific classification limits, so the biocidal product must be classified as irritant to eyes.
Classification of the product according to CLP	WOOD PRESERVATIVE AEROSOL PERMETHRIN is classified as eye irritant (eye irrit 2; H319).

Data waiving	
Information requirement	Eye irritation study
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Based on the classification of permethrin and the different co-formulants and, their respective content in the final formulation. The biocidal product does not meet the criteria for classification for respiratory tract irritation according to Regulation (EC) No 1272/2008.

Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Respiratory tract irritation data.
Justification	No experimental data on respiratory tract irritation of the biocidal product is available. However, the composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	WOOD PRESERVATIVE AEROSOL PERMETHRIN is not a skin sensitizer
Justification for the value/conclusion	Based on the classification of permethrin and the different co-formulants and, their respective content in the final formulation. Permethrin is classified for skin sensitisation according to annex VI of Regulation (EC) No 1272/2008. Since its concentration is below 1% but higher than 0.1% (threshold limit for elicitation), EUH 208 should be required on the label.
Classification of the product according to CLP	Classification for skin sensitisation is not required. Labelling with EUH208: Contains permethrin. May produce an allergic reaction.

Data waiving	
Information requirement	Skin sensitization study.
Justification	For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available from safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	WOOD PRESERVATIVE AEROSOL PERMETHRIN is not a respiratory sensitizer
Justification for the value/conclusion	Based on the classification of permethrin and the different co-formulants and, their respective content in the final formulation. None of the components of the product is classified for respiratory sensitization. Therefore, the product does not meet the criteria for classification for respiratory sensitisation according to Regulation (EC) No 1272/2008.

Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Respiratory sensitization data
Justification	For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available from safety data sheets and other information for each of the individual components in the product. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008. None of the ingredients are classified as respiratory sensitizers, so the product is not classified.

Acute toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	DL_{50}: >2000mg/kg bw.
Justification for the selected value	The classification of the biocidal product was conducted using endpoints included in Assessment Report (PT18) of permethrin and the SDSs of the other components. According to Assessment Report, the worst case acute oral LD_{50} for Permethrin is 480mg/kg bw. Some components of the product are classified for acute toxicity by oral route but are below their generic cut-off values (table 1.1. of CLP Regulation) hence, they are not included in the calculation of the acute oral ATE (Acute Toxicity Estimate) of the biocidal product. The calculated oral ATE for WOOD PRESERVATIVE AEROSOL PERMETHRIN is higher than 2000mg/kg bw. Therefore the product does not meet the criteria for classification for acute oral toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Acute oral toxicity study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity

Value	CL50: >5mg/l
Justification for the selected value	The classification of the biocidal product was conducted using endpoints included in Assessment Report of permethrin and the SDSs of the other components. According to Assessment Report, the worst case acute inhalation LC_{50} for Permethrin is 4.6mg/l. Some components of the product are classified for acute toxicity by inhalation route but are below their generic cut-off values (table 1.1. of CLP Regulation) hence they are not included in the calculation of the acute oral ATE (Acute Toxicity Estimate) of the biocidal product. The calculated inhalation ATE for WOOD PRESERVATIVE AEROSOL PERMETHRIN is higher than 5mg/l. Therefore the product does not meet the criteria for classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Acute inhalation toxicity study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	WOOD PRESERVATIVE AEROSOL PERMETHRIN is not classified for acute dermal toxicity
Justification for the selected value	Based on the classification of permethrin and the different co-formulants and, their respective content in the final formulation. None of the components of the product is classified for acute dermal toxicity. Therefore, the product does not meet the criteria for classification according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Acute dermal toxicity study
Justification	No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the

	mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Permethrin
Value(s)*	70%
Justification for the selected value(s)	Default value from EFSA guidance on dermal absorption for organic solvent-based dilution.(EFSA Journal 2017; 15(6):4873)

Data waiving	
Information requirement	Dermal absorption study
Justification	There is no experimental data available on the dermal absorption of WOOD PRESERVATIVE AEROSOL PERMETHRIN since no study has been conducted thus far. As a result, risk assessment calculations for human exposure have been made according to the EFSA guidance on dermal absorption (EFSA Journal, 2017;15(6):4873) using a default value of 70% dermal absorption for this product.

Endocrine disrupting properties

Since 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, endocrine disrupting properties assessment of active substance and co-formulants is mandatory according to the article 19 of BPR.
According to the CAR and BPC Opinion (April 2014), permethrin is not considered to have endocrine disrupting properties. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the "Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption" will need to be performed at the renewal stage.
After examining the possible ED properties of co-formulants, several substances have been identified as having potential endocrine disrupting properties. If these substances are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.
Please, refer to the confidential annex for more information.

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

Several substance of concerns have been identified for human health:
Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics is classified as Asp tox 1; H304 (May be fatal if swallowed and enters airways). EUH066 (Repeated exposure may cause skin dryness or cracking) is proposed, based on local skin effects and reactions that have been described for hydrocarbon solvents.
Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics is classified as Asp tox 1; H304 (May be fatal if swallowed and enters airways) and STOT SE; H336 (May cause drowsiness or dizziness). EUH066 (Repeated exposure may cause skin dryness or cracking) is

proposed, based on local skin effects and reactions that have been described for hydrocarbon solvents.
ETHANOL is classified as eye irrt 2; H319 (Causes serious eye irritation).In addition, ethanol is currently under assessment as active substance for PT 1, 2, 4 and 6. According to the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), active substances as co-formulants present in a biocidal product should be considered as SoCs if a draft final Competent Authority Report (CAR) (with agreed reference values) is available. In this case, the initial application for approval of ethanol is in progress (for PT 1, 2, 4 and 6) and a draft final CAR is not available. Therefore, ethanol does not meet the criterion 2 but meets criterion 1.
These co-formulants trigger the classification of WOOD PRESERVATIVE AEROSOL PERMETHRIN for moderate acute toxicity by themselves. According to the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), SoCs contained in the product are included in Band A. Associated evaluation and risk management requirements according to the SoC banding approach for Band A are limited to the application of P-statements normally associated with concerned H statements.
For more information see confidential annex.

Available toxicological data relating to a mixture

Information on the toxicology of the other components of the product was provided based on the corresponding Material Safety Data Sheets. No additionally toxicological concerns are raised by the co-formulants according to the Material Safety Data Sheets for which additionally toxicity testing would be required.
See confidential annex

Other

WOOD PRESERVATIVE AEROSOL PERMETHRIN contains two hydrocabon solvents which classified as Asp tox 1; H304 triggering the classifaction of biocidal product as Asp tox 1; H304. However, according to annex I section 1.3.3 of CLP Regulation, mixtures classified in accordance with aspiration hazard criteria need not be labelled for this hazard when placed on the market in aerosol containers.

Value used in the Risk Assessment – Specific target organ toxicity — Single exposure, Hazard Category 3, Narcosis	
Value/conclusion	STOT SE; H336
Justification	For *Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics* a concern for specific target organ toxicity was identified. The biocidal product is a mixture placed on the market in aerosol dispenser for which taking into account its conditions of use, the classification of solely the other constituents of the aerosol (i.e without propellant) is more "relevant" within the meaning of Article 6(1) of the CLP Regulation. Therefore, as the content of this coformulant without propellant is 22.5%, above of its generic concentration limit (point 3.8.3.4.5. of CLP Regulation ≥ 20%), it triggers the classification of the biocidal product
Classification of the product according to CLP	WOOD PRESERVATIVE AEROSOL PERMETHRIN is classified as STOT SE 3; H336

2.2.6.2 Exposure assessment

WOOD PRESERVATIVE AEROSOL PERMETHRIN is a ready-to-use solvent-based wood preservative containing 0.23% w/w permethrin (pure) (0.38% w/w permethrin (pure) in the liquid formulation without propellant) as active substance. As the propellant will quickly evaporate, the concentration of active substance (technical) in the product without propellant (0.42%w/w) is considered for the exposure assessment.

The application rates validated are the following:

- Preventive treatments: superficial application at max. 200 g of biocidal product / m² of wood.
- Curative treatment: superficial application at max. 200 g of b.p. / m^2 of wood (300 mL of biocidal product/m² of wood).

The product is applied by spray on surfaces for preventive and curative purposes and in combination with the injection method for more intense curative treatments.
The applicant has not validated the superficial application + injection rate. Therefore, the application 200 g of biocidal product / m² of wood will be deemed in the human risk assessment as a worst case. Afterwards, a reverse scenario for toddlers playing and mouthing on a weathered (playground) structure will be proposed to predict the safe injection dose using in the intense curative treatments.

The biocidal product is intended for **non-professional** use only. Adult users can get exposed during application of the product, through inhalation and dermal contact. Primary oral exposure is considered not to be relevant. Secondary exposure is possible for the general public, when entering a room after treatment. Here dermal and inhalation exposure is relevant. For children, also oral exposure needs to be considered.

The SoCs detected in the biocidal product are not included in the exposure assessment according to the conclusions detailed in the Assessment of effects on Human Health (section 2.2.6.1).

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.	n.a.	Yes	n.a.	n.a.	Yes	n.a.
Dermal	n.a.	n.a.	Yes	n.a.	n.a.	Yes	n.a.
Oral	n.a.	n.a.	No	n.a.	n.a.	Yes (toddler)	n.a.

n.a. = not applicable

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.	Spray application	**Primary inhalation and dermal exposure** During spraying of the biocidal product from 30 cm distance, non-professional users are exposed via dermal and inhalation routes.	Non-professionals Adults
2.	Spray application + injection	**Primary inhalation and dermal exposure** If a treatment by injection is done, it has to be combined with a spray treatment. Both treatments can be done on a same day. So this scenario presents the assessment of exposure during injection and combines it with the exposure assessment for spray application.	Non-professionals, adults
3	Handling treated timber	An adult who takes in contact with treated wood to move, it. The wood is dryed and only dermal exposure is foreseeable as secondary exposure. Curative treatment considers the highest dose application (200 g or 300 mL/m^2) and it was assessed in the present dossier as worse case.	Non-professionals
4	Adult amateur sanding/processing of treated wood composites	**Acute secondary dermal and inhalation exposures** After treatment of the wood, adult can be exposed by inhalation and dermal contact to the product when sanding or processing of treated wood composites.	Adult amateur (general public)
5	Toddler chewing wood composite chips treated	**Acute secondary oral exposure** Oral exposure to the product can occur for infant putting into his mouth treated wood chips. In this scenario, it has been calculated the oral exposure considering the size of the wood composite chips, the amount of active substance contained in treated wood and that 10% of this content is released during chewing into the infant's mouth. As a worst-case, it has been considered that the wood was treated with a total application dose of 200 g or 300 mL/m^2, corresponding to the highest dose application.	Toddler (general public)
6	Inhalation of volatilised residues indoors	**Chronic secondary exposure by inhalation** Inhalation exposure to the biocidal product volatilised residues can occur.	Adult, Toddler & Child (general public)
7	Toddler playing on playground structure and mouthing	**Chronic secondary oral and dermal exposures** In the playground (outdoors), children can play on wood structures that can be treated with biocidal product and put it in contact with mouth. Therefore, oral and dermal exposures occur.	Toddler (general public)

Industrial exposure

No industrial exposure is foreseen.

Professional exposure
No industrial exposure is foreseen.

Non-professional exposure

Scenario [1] – Spray Application

Description of Scenario [1]		
To assess exposure during the use of the product for spray application, "Consumer Spraying model 2 with aerosol can" was used according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure. Considering the packaging sizes (maximum 750 mL), it is assumed that non-professionals will use this product for small surface applications because for larger applications other types of products or application methods would be preferred. In that sense, we have supposed 2 aerosol cans of 750 mL (the big one) are applying by non-professionals. From physical, chemical and technical properties assessment, the value of volume delivered per spraying is 1.00 g/s. The application duration of emptying 2 aerosol cans will be: 2 x 750 mL x 0.778 g/mL / (1 g/s) = 1167 s ~ 20 min In the Biocide Human Health Exposure Methodology guidance, it is indicated that exposure values from Consumer Spraying model 2 with aerosol can are normalised for a product with a density of 1. The relative density of Carcomin Plus is about 0.78, so exposure values were corrected according to this value. The product can be used 1 or 2 times per year.		
	Parameters	Value
Tier 1	% of active substance in the biocidal product without VVOCs	0.42%
	Body weight[1]	60 kg
	use frequency	2/year (product data)
	spray duration	20 min
	relative density	0.78 g/cc
	Dermal exposure	
	Dermal absorption permethrin[2]	70%
	Indicative value hand and forerarm exposure[3]	64.7 mg/min (75th % value)
	Indicative value legs, feet and face exposure[3]	45.2 mg/min (highest value)
	No PPE, clothing penetration	100%
	Inhalation exposure	
	Inhalation absorption	100%
	Indicative value inhalation[3]	35.9 mg/m^3 (75th % value)

	Inhalation rate[1]	1.25 m^3/h

[1] *Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure, Default human factor values for use in exposure assessments for biocidal products.*
[2] *Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873.*
[3] *Biocidal Human Health Exposure methodology (p221).*

Calculations for Scenario [1]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	1/no PPE	8.17E-04	8.40E-02	--	8.48E-02

See Annex 3.2 for more information.

Further information and considerations on scenario [1]
Not applicable

Scenario [2] – Spray Application + injection

Description of Scenario [2]		
As injection is always combined with a surface spray application, exposure estimations presented below are the combination of spray application estimations and exposure estimation for injection application. There is no specific model for the injection application. The subsoil treatment model 2 can't be applied as it is based on professional exposure data and only hand exposure under gloves is available. For this scenario, values of the exposure model for spray application have been used as no scenario is available for injection by non-professional users. Multiplying exposure obtained for spray application by two, will be used as worst case estimation for application by spraying followed by injection. In the Biocidal Human Health Exposure Methodology guidance, it is indicated that exposure values from Consumer Spraying model 2 with aerosol can are normalised for a product with a density of 1. The relative density of Carcomin Plus is about 0.78, exposure values were corrected to this value.		
	Parameters	Value
Tier 1	% active substance in the biocidal product without VVOCs	0.42%
	Body weight[1]	60 kg
	use frequency	2/year (product data)
	spray duration	20 min
	relative density	0.78 g/cc
	Dermal absorption	

	Dermal absorption permethrin[2]	70%
	Indicative value hand and forerarm exposure[3]	64.7 x 2 = 129.4 mg/min (75th % value)
	Indicative value legs, feet and face exposure[3]	45.2 x 2 = 90.4 mg/min (highest value)
	No PPE, clothing penetration	100%
	Inhalation exposure	
	Inhalation absorption	100%
	Indicative value inhalation[3]	35.9 x 2 = 71.8 mg/m^3 (75th % value)
	Inhalation rate[1]	1.25 m^3/h

[1] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure, Default human factor values for use in exposure assessments for biocidal products.
[2] Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873.
[3] Biocidal Human Health Exposure methodology (p221).

Calculations for Scenario [2]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	1/no PPE	1.63E-03	1.68E-01	--	1.70E-01

See Annex 3.2 for more information.

Further information and considerations on scenario [2]
Not applicable

Scenario [3] Handling treated timber

Description of Scenario [3]
An adult who takes in contact with treated wood to move it. The wood is dried and only dermal exposure is foreseeable as secondary exposure. Curative treatment considers the validated dose application (200 g or 300 mL/m^2) and it was assessed in the present dossier as worse case. According to HEEG Opinion 7, 2012 US EPA Standard Operating Procedure (SOPs) – Residential exposure assessment: 10.2.1 Section Post-Application Dermal Exposure Assessment, has been used for exposure assessment.

	Parameters[1]	Value	Unit	Reference
	Dermal exposure			
Tier 1	Exposure duration	1	h	HEEG opinion 9
	Product density	0.78	mg/µL	Applicant data
	Percentage dislodgeable (%)	10	%	HEEG opinion 9
	Transfer coefficient	7,80E-01	m^2/h	Recommendation no. 12
	$F_{body}(S_{palms}/S_{body})$	2,4699E-02		Recommendation no. 14
	Active substance dermal absorption	70	%	EFSA
	No PPE, clothing penetration	100	%	HEEG opinion 9

Calculations for Scenario [3]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	1/no PPE	--	2.21E-02	--	2.21E-02

See Annex 3.2 for more information.

Further information and considerations on scenario [3]
Not applicable

Combined scenarios
Combined exposures by same active substance by different tasks may occur. For this assessment, spraying + injection (2) and handling treated timber (3) for non-professionals are combined for active substance.

Combined estimated exposure from non-professional uses			
Combined -scenarios (Scenario) Tier/PPE	**Systemic exposure Scenario (2) mg/kg/d**	**Systemic exposure Scenario (3) mg/kg/d**	**Total Systemic exposure mg/kg/d**
(Spraying + Injection) (2) + Handling (3)	1.70E-01	2.21E-02	1.92E-01

Exposure of the general public
Preserved wood is not placed on the market until the product is dry. The product is suitable for indoor or outdoor use. The reference scenarios modelled are as follows:

- Acute phase reference scenarios
  - Adult cutting and sanding treated wood - inhalation and dermal route.
  - Infant acute chewing wood off-cut - ingestion route.

- Chronic phase reference scenarios
  - Adult inhalation of volatilised residues indoors - inhalation route.
  - Infant playing on weathered structure and mouthing - dermal and ingestion.

Indirect exposure via the environment is considered to be of minor importance as the release to the environment is limited.

Scenario [4] - Adult amateur sanding processing wood (acute exposure)

Description of Scenario [4]		
For the assessment of dermal and inhalation exposures during sanding/processing of treated wood composites by an adult, it has been considered an application rate product of 200 g or 300 mL/m² (worst-case). The area of wood to be sanded was calculated considering a piece of wood with a length of 250 cm and a height of 4 cm. It has been considered that the exposure comes from the outer layer of the piece of wood (thickness of 1 cm).		
	Parameters	Value
Tier 1	Application rate	200 g/m^2 or 300 mL/m^2
	% of active substance in the biocidal product without VVOCs	0.42%
	Wood density[1]	0.4 g/cc
	Dust concentration in air[2]	5 mg/m^3
	Exposure duration	1 h
	Inhalation rate[3]	1.25 m^3/h
	Protection factor (No PPE)	1
	Retention active susbtance	100%
	Percentage dislogeable[4]	2%
	Hand surface[3]	410 cm^2
	Dermal absorption[5]	70%

[1] *MOTA, 2013 from TM III 2008*.
[2] *TNsG on Human Exposure (2002) Part 3, Page 50*.
[3] *HEAd Hoc recommendation 14*
[4] *TNsG 2002.*
[5] *Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873.*

Calculations for Scenario [4]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [4]	1/no PPE	2.58E-05	1.95E-03	--	1.95E-03

See Annex 3.2 for more information.

Further information and considerations on scenario [4]

Not applicable.

Scenario [5] - Toddler chewing wood composite chips treated (acute exposure)

Description of Scenario [5]		
In this scenario, oral exposure has been calculated considering the size of the wood composite chips, the amount of active substance contained in treated wood and that 10% of this content is released during chewing into the toddler's mouth according to TNsG on Human Exposure to Biocidal Products Part 3, p50-51 as revised by User Guidance version 1 p54-57 (EC, 2002a). As a worst-case, it has been considered that the wood was treated with a total application dose of 200 g or 300 mL/m^2, corresponding to a curative treatment.		
	Parameters	Value
Tier 1	Application rate	200 g/m^2 or 300 mL/m^2
	% of active substance in the biocidal product without VVOCs	0.42%
	Release of bound active substance by chewing[1]	10%
	Size of wood composite chips[1]	16 cm^3
	Surface of wood composite chip treated[1]	16 cm^2
	Toddler body weight[2]	10 kg
	Oral absorption	100%

[1] *TNsG on Human Exposure to Biocidal Products Part 3, p42 as revised by User Guidance version 1 p50-54 (EC, 2002a)*
[2] *HEAd Hoc recommendation 14*

Calculations for Scenario [5]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [5]	1/no PPE	--	--	1.57E-02	1.57E-02

See Annex 3.2 for more information.

Further information and considerations on scenario [5]
Not applicable

Scenario [6] - Adult, Inhalation of volatilised residues indoors (chronic exposure)

Professional and general public may be exposed to volatilised residues from treated wood installed indoors. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, it might not be necessary to calculate the exposure to volatilised residues:

- For permethrin:

$0.328*(Mw*Vp)/AEL_{long\text{-}term}$ = (0.328*391.29*2.16E-06)/0.05 = 5.53E-03 ≤ 1

Remark: the mw (molecular weight), vp (vapour pressure) and $AEL_{long\text{-}term}$ come from the Assessment Report on Permethrin.

- Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics:

  $0.410*(Mw*Vp)/AEL_{long\text{-}term}$ = (0.410*177*20)/1200 = 1.21 > 1

  Remark: the mw (molecular weight), vp (vapour pressure) and $DNEL_{Long\text{-}term}$ come from the MSDS.
- Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics:

  $0.410*(Mw*Vp)/AEL_{long\text{-}term}$ = (0.410*107*2000)/608 = 144 > 1

  Remark: the mw (molecular weight), vp (vapour pressure) and $DNEL_{Long\text{-}term}$ come from the MSDS.
- For ETHANOL:

  $0.410*(Mw*Vp)/AEL_{long\text{-}term}$ = (0.410*46.07*57.26E+02)/114 = 949 > 1

  Remark: the mw (molecular weight), vp (vapour pressure) and $DNEL_{Long\text{-}term\ (general\ public)}$ come from the MSDS and ECHA database.

The result of this equation is lower than 1 for Permethrin. The **exposure to volatilised residues indoor** can be considered **negligible** for general public for these active substances.

The result of this equation is higher than 1 for the rest of substances of concern. The **exposure to volatilised residues** indoor cannot be considered negligible for general public but this exposure is not calculated according to the assessment of effects on human health conclusions.

Description of Scenario [6]		
Chronic inhalation exposure to volatilised residues indoors has been assessed for adult considering the scenario ”assessment of Inhalation Exposure of Volatilised Biocide Active Substance” from the Opinion n°13 of HEEG with calculation of the Saturated Vapour Concentration (SVC) for 24 hours (worst-case) following this formula: SVC = Mw x vp : R x T (mg/m^3) The exposure is calculated with the following formula : Exposure = SVC x inhalation rate / body weight (mg/kg bw/d)		
	Parameters	Value
Tier 1	Vapour pressure (Vp):[1] Permethrin Ethanol Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics	 2.16×10^{-6} Pa 5726 Pa 20 Pa 2000 Pa
	Molecular weight (Mw):[1] Permethrin Ethanol Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics	 391.29 g/mol 46.07 g/mol 177 g/mol 107 g/mol

	Gas constant (R)	8.31451 $J.mol^{-1}.K^{-1}$
	Temperature (T)	293 K
	Body weight:[2] Adult Child Toddler Infant	 60 kg 23.9 kg 10 kg 8 kg
	Inhalation rate:[2] Adult Child Toddler Infant	 16 m^3/24h 12 m^3/24h 8 m^3/24h 5.4 m^3/24h

[1] *AR of permethrin and MSDSs for co-formulants.*
[2] *HEAD Hoc Recommendation n° 14*

Calculations for Scenario [6]
No calculations are needed.

Further information and considerations on scenario [6]
According to the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), SoCs contained in the product are included in Band A. Associated evaluation and risk management requirements according to the SoC banding approach for Band A are limited to the application of P-statements normally associated with concerned H statements.

Scenario [7] - Toddler playing and mouthing on playground weathered wood structure outdoors (chronic exposure)

Description of Scenario [7]		
For the assessment of this exposure, during playing on timber wheathered structure, dermal as well as oral (through hand-to-mouth transfer) exposure is considered. For the assessment of this scenario, it has been considered an application rate product of 200 g or 300 mL/m² (worst-case)		
	Parameters	Value
Tier 1	Application rate product	200 g/m^2 or 300 mL/m²
	% active substance in the biocidal product without VVOCs	0.42%
	Toddler body weight[1]	10 kg
	Dermal exposure	
	Hand surface area contact[1]	231 cm²
	Contaminated area[2]	20 %
	Dislogeable fraction[3]	2 %
	Dermal absorption	70 %
	Oral exposure	

	Transferable coefficient of dried paint from hand to mouth[4]	50%
	Oral absorption	100%

[1] *HEAD Hoc Recommendation n° 14*.
[2] *TNsG, 2002, v1, part 3, p 51*
[3] *TNsG, 2002, v1, part 2, p 204 (rough sawn wood-dried fluid)*
[4] *Recommendation no 5 (Consexpo. Pest Control Fact Sheet, 2006; section 2.2.7 "Parameters for hand-mouth contact")*

Calculations for Scenario [7]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/kg bw/d)	**Estimated dermal uptake** (mg/kg bw/d)	**Estimated oral uptake** (mg/kg bw/d)	**Estimated total uptake** (mg/kg bw/d)
Scenario [7]	Tier 1 / No PPE	--	3.18E-03	4.55E-03	7.73E-03

Further information and considerations on scenario [7]

Tier 1 estimations presented here is a worst case assumption where the dislodgeability is 2% and the application is only by spraying.
The product is applied by spray on surfaces for preventive and curative purposes and in combination with the injection method for more intense curative treatments.
The applicant has not validated the superficial application (300 mL of biocidal product / m² of wood) + injection rate. Therefore, we decide to calculate the maximum product dose of application by injection to reach the permethrin AEL using an reverse scenario. A reverse scenario for toddlers playing and mouthing on a playground structure (group more sensitive) is proposed to predict the safe injection dose.

Table above shows results using for handing the curative dose of 300 mL/m^2 without taking into account the injection dose.

Assuming that Scenario(7) is the necessary to reach the permethrin AEL (0.05mg/Kg/d), the estimated total exposure results in 5.00 E-02 mg/Kg/d.
Using this value as maximum exposure and developing a reverse scenario, we obtain the value of 1.94 L/m^2 for maximum application product dose to reach the Permethrin AEL.
As the spraying dose for curative treatment is 3.00E-01 L/m^2, the maximum dose to reach the permethrin AEL for this scenario is 1.64 L/m^2.
See Annex 3.2.
From this point, to calculate the exposure for the rest of scenarios, the maximum injection dose will be used as a worst case when necessary.
For clarity and well-understanding, an injection dose of 1640 mL/m^2 could be recommended to users on the label.
Tables below show exposure results using 1940 mL/m^2 for spraying + injection intensive curative dose:

Summary table: systemic exposure from non-professional uses

Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/kg bw/d)	**Estimated dermal uptake** (mg/kg bw/d)	**Estimated oral uptake** (mg/kg bw/d)	**Estimated total uptake** (mg/kg bw/d)
Scenario [7]	Tier 1 / No PPE	--	2.06E-02	2.94E-02	5.00E-02

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [5]	1/no PPE	--	--	1.02E-01	1.02E-01

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [4]	1/no PPE	1.67E-04	1.25E-02	--	1.26E-02

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	1/no PPE	--	1.43E-01	--	1.43E-01

Combined estimated exposure from non-professional uses			
Combined -scenarios (Scenario) Tier/PPE	**Systemic exposure Scenario (2)[1] mg/kg/d**	**Systemic exposure Scenario (3) mg/kg/d**	**Total Systemic exposure mg/kg/d**
(Spraying + Injection) (2) + Handling (3)	1.70E-01	1.43E-01	3.12E-01
[1] It is important to note that the exposure by handling depends on the dose of product applied, but it is not the case for spraying and injection.			

Combined scenarios
Not applicable.

Monitoring data
No monitoring studies have been performed with the formulated product as they are not considered necessary.

Dietary exposure
Indirect exposure via food, drinking water or livestock is not foreseen from the proposed uses of WOOD PRESERVATIVE AEROSOL PERMETHRIN.

According to Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017, 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses, the following risk mitigation measures are added to PAR required:

- Do not use on wood which may come into direct contact with food, feeding stuffs and livestock animals.
- Treated wood should not be intended for uses involving contact with food, feed or livestock.

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

Exposure during the production and formulation of the biocidal product should be addressed under other EU legislation (e.g. REACH).
According to the EU waste legislation waste from wood preservative products and application solutions are considered hazardous waste. Therefore, application solutions must be collected and reused or disposed of as hazardous waste and they must not be released to soil, surface water or any kind of sewer.
Disposal should be done as described according to label instructions.

Aggregated exposure

Not applicable as this product is not intended to be used under a different biocidal product type such as PT8.

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 using curative dose as worst case**	**Estimated total uptake using preventive (spraying + injection) dose as worst case**
Primary exposures				
1. Spray application	Non-professional users	Tier 1	8.48E-02	8.48E-02
2. Spray application + injection	Non-professional users	Tier 1	1.70E-01	1.70E-01
3. Handling treated timber	Non-professional users	Tier 1	2.21E-02	1.43E-01
2 + 3. Combined scenarios	Non-professional users	Tier 1	1.92E-01	3.12E-01
Secondary exposures				
4. Adult amateur sanding/processing of treated wood composites	Adult amateur (general public)	Tier 1	1.95E-03	1.26E-02

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier / PPE**	**Estimated total uptake using curative dose as worst case**	**Estimated total uptake using preventive (spraying + injection) dose as worst case**
5. Toddler chewing wood composite chips treated	Toddler (general public)	Tier 1	1.57E-02	1.02E-01
6. Inhalation of volatilised residues indoors (chronic)	Adult, Toddler & Child (general public)	Tier 1	--	--
7. Toddler playing on playground structure and mouthing (chronic)	Toddler (general public)	Tier 1	7.73E-03	5.00E-02

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
AELshort-term	2-year rat toxicity study	NOAEL = 50 mg/kg bw/d	100	No	0.5
AELmedium-term/long-term	1-year dog chronic toxicity study	NOAEL = 5 mg/kg bw/d	100	No	0.05
ARfD	2-year rat toxicity study	NOAEL = 50 mg/kg bw/d	100	No	0.5
ADI	1-year dog study	NOAEL = 5 mg/kg bw/d	100	No	0.05

[1] Please explain background and reason for assessment factor.

Maximum residue limits or equivalent

MRLs or other relevant reference values	**Reference**	**Relevant commodities**	**Value**
MRL	EU Reg. 396/2005 (PPP)	All commodities	Cf: Reg. (EU) 2017/623
	EU Reg. 470/2009 (VMP)	Food of animal origin (bovine)	Cf: Reg (EU) 37/2010

PPP: plant protection product
VMP: veterinary medicinal product

As the product is to be used for preventive and curative treatment of interior woods that do not come in direct contact with food and feedstuff, the existing MRLs are not expected to be exceeded.

Risk for industrial users

Not applicable.

Risk for professional users

Not applicable.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1. Spray application	Tier 1	50	0.5	8.48E-02	17.0	Yes
2. Spray application + injection	Tier 1	50	0.5	1.70E-01	33.9	Yes
3. Handling treated wood	Tier 1	50	0.5	2.21E-02	4.4	Yes
2 + 3. Combined scenarios	Tier 1	50	0.5	1.92E-01	38.3	Yes

Systemic effects using maximun dose of product (Dmax) to reach AEL

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1. Spray application	Tier 1	50	0.5	8.48E-02	17.0	Yes
2. Spray application + injection	Tier 1	50	0.5	1.70E-01	33.9	Yes
3. Handling treated wood	Tier 1	50	0.5	1.43E-01	28.6	Yes
2 + 3. Combined scenarios	Tier 1	50	0.5	3.12E-01	62.5	Yes

Local effects

According to the BPR Guidance Volume III Human health – Part B and C Risk Assessment, the BAND A evaluation scheme is applied for the labeling EUH 066.

Conclusion

In conclusion for non-professional users, the risk is acceptable for all scenarios without PPE.

In order to take into account the risk of skin dryness or cracking during the handling of product (repeated exposure), the following RMMs are added:

- Avoid contact with skin;
- Wash hands thoroughly after handling.

Note: The dose of 1640 mL/m^2 at the injection stage must not be exceeded in the intensive curative treatment (spraying + injection).

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
4. Adult amateur sanding/processing of treated wood composites (acute)	Tier 1	50	0.5	1.95E-03	0.4	Yes
5. Toddler chewing wood composite chips treated (acute)	Tier 1	50	0.5	1.57E-02	3.14	Yes
6. Inhalation of volatilised residues indoors (chronic)	Tier 1	5	0.05	--	--	Yes
7. Toddler playing on playground structure and mouthing (chronic)	Tier 1	5	0.05	7.73E-03	15.5	Yes

Systemic effects using maximun dose of product (Dmax) to reach AEL

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
4. Adult amateur sanding/processing of treated wood composites (acute)	Tier 1	50	0.5	1.26E-02	2.5	Yes
5. Toddler chewing wood composite chips treated (acute)	Tier 1	50	0.5	1.02E-01	20.3	Yes
6. Inhalation of volatilised residues indoors (chronic)	Tier 1	5	0.05	--	--	Yes
7. Toddler playing on playground structure and mouthing (chronic)	Tier 1	5	0.05	5.00E-02	100.0	Yes

Conclusion

There is no risk for human health by using this product according to use instructions.

It should be noted that the exposure and risk assessment of the general public in the PAR applies only to dried residues. Potential contact to wet surfaces was not assessed. For adults it can be assumed that they generally avoid contact to wet treated surfaces. However, for younger children and for pets this cannot be assumed. To avoid contact to wet surfaces by children and pets, the following RMM was therefore assigned:

- *Keep children and pets away from treated surfaces until dried.*

Note: The dose of 1640 mL/m^2 at the injection stage must not be exceeded in the intensive curative treatment (spraying + injection).

Risk for consumers via residues in food

The product is not intended to be used in places where food is kept or entrance in contact with food during its application. Therefore, no risk is derived for consumers via residues in food. In addition, in order to avoid any potential risk by its use, the following RMM is set on product's label:

- *Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.*

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

Not relevant.

2.2.7 Risk assessment for animal health

The product CORPOL ANTIXILÓFAGOS AEROSOL is intended to be used indoors on wood surfaces (beams, posts, window frames,…) without animal presence, hence, no animal exposure is foreseeable.

In adition, to prevent any exposure of animals the following RMMs are included:

- *Keep away from food, drink or animal feedstuffs.*
- *Do not use on wood which may come in direct contact with food, feeding stuff, and livestock animals*
- *Keep children and pets away from treated surfaces until they have dried.*
- *Avoid prolonged contact of pets, particularly cats, to treated surfaces.*
- *Remove or cover terrariums, aquariums, and animal cages before application. Turn off aquarium air-filter while spraying.*

2.2.8 Risk assessment for the environment

Please notice that the risk assessment for the environment (section 2.2.8) is reported as provided by the applicant. The ES CA position is presented in **grey boxes.**

2.2.8.1 Effects assessment on the environment

ES CA position:

PNEC values were proposed in the Assessment Report of Permethrin PT18

PNEC derivation- Active substance

Summary table on PNEC for Permethrin	
Environmental compartment	**PNEC value**
STP	4.95E-03 $mg.L^{-1}$
Surface water	4.7E-04 $\mu g.L^{-1}$
Freshwater sediment	2.17E-04 $mg.kg_{wwt}^{-1}$
Soil	0.175 $mg.kg_{wwt}^{-1*}$
PNEC oral bird	≥16.7 $mg.kg_{food}$
PNEC oral small mammal	120 $mg.kg_{food}$

- The new agreed PNEC

PNEC derivation- Metabolites of active substance

Summary table on PNEC for DCVA	
Environmental compartment	**PNEC value**
Surface water	1.5E-02 $mg.L^{-1}$
Freshwater sediment	1.2E-02 $mg.kg_{wwt}^{-1}$
Soil	4.6 $mg.kg_{wwt}^{-1}$

Summary table on PNEC for PBA	
Environmental compartment	**PNEC value**
Surface water	>1E-02 $mg.L^{-1}$
Freshwater sediment	9E-03 $mg.kg_{wwt}^{-1}$
Soil	1.44 $mg.kg_{wwt}^{-1}$

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

Three ingredients of Carcomin have an environmental classification (complete product – incl the propellant – is considered for the environmental classification:

Identification.	**Conc. %**	**Classification 67/548/EEC.**	**Classification 1272/2008 (CLP)**
Permethrin TG *CAS. 52645-53-1* 0 *EC. 258-067-9* *INDEX. -*	0.25	Xn R20/22, Xi R43, N R50/53	Acute Tox. 4 H302, Acute Tox. 4 H332, Skin Sens. 1 H317, Aquatic Acute 1 H400, M=100 ; Aquatic Chronic 1 H410 M=10000 (1)
Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics *CAS. -* *EC. 920-750-0* *INDEX. -* *Reg. no. 01-2119473851-33*	13.5	R66, R67, F R11, Xn R65, N R51/53	Flam. Liq. 2 H225, Asp. Tox. 1 H304, STOT SE 3 H336, Aquatic Chronic 2 H411, EUH066
Fragrance	0.2		Skin irritation, Category 2 H315 Eye irritation, Category 2 H319 Skin sensitization, Category 1 H317. Chronic aquatic toxicity, Category 2 H411

(1): M-factors are taken from the active substance dossier for permethrin

As Permethrin has an acute M-factor of 100 and its concentration is 0.25%, CarcominPlus is classified as Aquatic Acute Cat. 1 (100*0.25 % ≥ 25%).

Based on the chronic M factor of 10000 of permethrin, CarcominPlus is also classified as Aquatic Chronic Cat. 1 (10000*0.25 ≥ 25%).
The PNEC-values are taken as determined in the CAR of Permethrin (PT08).

For Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics and the fragrance are both classified as Chronic Aq. Tox. Cat 2. Although both substances are classified, they do not contribute to the classification of the product. The highest concern will be exposure of the environment to the active substance.

ES CA position:
We consider that the substance Hydrocarbons, C7-C9, n-alkanes, isoalkanes, cyclics (EC.920-750-0) is a substance meets the criteria for classification as hazardous according to Regulaton (EC) NO 1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation. However this substance has not been taken account in the risk evaluation due to the risk mitigation measure proposed.

Further Ecotoxicological studies
No data available.

ES CA position:
No new data is available.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
No data available.

ES CA position:
No new data is available.

Supervised trials to assess risks to non-target organisms under field conditions
No data available.

ES CA position:
No new data is available.

*Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk*No data available.

ES CA position:
No new data is available.

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

Not relevant

ES CA position:
No new data is available.

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

The wood preservative product will only be used by non-professionals for indoor treatments. The emission to the indoor air during application of the product is considered to be completely released to outdoor air by venting the room. Other emissions during the use of the product will only be released to an environmental compartment during the cleaning phase. Emissions through wet cleaning will be directed towards the Sewage Treatment Plant (STP). Indirectly, releases to surface water and water sediments are also considered, due to the effluent of the STP being further diluted into surface water. Subsequent adsorption to suspended matter in the surface water is possible, suspended matter can eventually settle as sediment and also leads to exposure to the sediment compartment (and its organisms). Via usage of sewage sludge, the soil compartment can also by exposed indirectly.

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

No data available.

ES CA position:
No new data is available.

Leaching behaviour (ADS)

No data available.

ES CA position:
No new data is available.

Testing for distribution and dissipation in soil (ADS)

No data available.

ES CA position:
No new data is available.

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

No data available.

ES CA position:
No new data is available.

Testing for distribution and dissipation in air (ADS)

No data available.

ES CA position:
No new data is available.

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)

Not relevant.

ES CA position:
No new data is available.

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)
Not relevant.

ES CA position:
No new data is available.

2.2.8.2 Exposure assessment

General information

Assessed PT	*PT 8*
Assessed scenarios	*Scenario 1: Indoor spraying application for surface treatment, (to prevent/cure infestation of woodworms on wooden furniture.)*
ESD(s) used	*For indoor treatments by spraying, brushing and injection, no scenarios are proposed in the ESD for PT8 because related emissions to the environment are considered to be negligible. Reference is made to indoor surface treatments described in the OECD ESD for PT18*
Approach	*Approach is consumption based, following ESD PT18*
Distribution in the environment	*Calculated based on TGD 2003 (alternative: based on measured data)*
Groundwater simulation	*no groundwater simulation performed*
Confidential Annexes	*NO / YES: In the confidential Annex 1 to Part B the tonnage based scenarios 2 and 3 are provided*
Life cycle steps assessed	*Scenario 1:* *Production: No* *Formulation No* *Use: Yes* *Service life: No*
Remarks	

ES CA position:
WOOD PRESERVATIVE AEROSOL PERMETHRIN is wood preservative for non professionals to be used indoor for curative and preventive protection of wood material (e.g. furniture) (PT8). Spraying the product in the holes with the application tube, or directly on a surface without the tube, from a distance of 30 cm. The product is used against wood boring beetles and termites. Termite treatment is covered by both OECD ESDs, PT8 and PT18. The OECD ESD for PT18 sumarizes emission scenarios for termite treatment covered by the respective ESDs:

Sub-scenario	2003 ESD for wood preservatives	ESD for insecticides, acaricides and products to control other arthropods for household and professional uses
Indoor injection (curative & preventive treatment)	Section 6.4.2.4: Not covered because environmental emissions considered negligible	Sub-scenarios covered are: - injection in indoor floor (section 3.4.4) - injection in indoor walls (section 3.4.4)
Outdoor injection (preventive & curative treatment)	Sections 6.4.2.4 / 6.4.2.2: Covered for transmission poles	2.4.4 Not covered
Spraying treatment	Indoor: not covered Outdoor: pre-treatment of foundation and post-treatment of trenches is covered	Indoor spraying treatments (section 3.3.1.2) Outdoor spraying treatment (section 4.3)
Outdoor traps	Not covered	Traps: the emissions are considered as negligible

According to this table, the application method through a specific tube is not covered for any to ghe ESDs because environmental emissions are considered negligible (ESD PT8), however for the other method, surface treatment, emissions are expected and this assessmente is coverd by the ESD for PT18 (indoor spraying treatment).

According to the ESD PT8 for the risk assessment, emissions to the environmental compartments should be calculate: 1) during the preservative application process and storage of the treated wood prior shipment and 2) from the treated wood in service. For the used of this product, emissions are only expected during the preservative application step, then the treated wood materials are going to be indoor.

Emission estimation

Scenario 1, 1st TIER

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: indoor spray application for surface treatment			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	200	g/m²	highest dosing rate (for curative treatment, covers the preventive treatment with rate of 180g/m2)
Concentration of active substance in the product	0.42	%	
Area of treated wood with the product	2	m^2	Default, indoor targeted spot application
Fraction emitted to air during application	0.02	(-)	
Fraction emitted to applicator during application	0.004	(-)	Self-pressurised aerosol dispenser (surface treatment)
Fraction emitted to floor during application	0.126	(-)	Self-pressurised aerosol dispenser (surface treatment)

Fraction emitted to treated surface	0.85	(-)	
Fraction emitted to waste water from applicator	1	(-)	No coveralls to be used by consumers, washing clothes will lead to emission to STP
Fraction emitted to waste water from cleaning floor	1	(-)	Worst case
Fraction emitted to waste water from cleaning treated material	0	(-)	Wooden furniture is not cleaned wet
Cleaning efficiency	20	%	cleaning efficiency for RTU aerosol
Simultaneity factor**	0.2	%	% houses treated at the same time for use of biocidal products 1 to 2 times per year

* VVOCs /propellants will have evaporated during application, 200 g product/m2 is used according to efficacy. This product amount corresponds to the absorbed part of formulation only (=no VVOCs). The permethrin content in the formulation without VVOCs is 0.42 % w/w.
** Simultaneity factor = (0.54*37.82)/100

ES CA position:

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: indoor spray application for surface treatment			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	200	g/m²	Application rete indicated by the applicant
Concentration of active substance in the product	0.25	%	
Area of treated wood with the product	2	m^2	Default, indoor targeted spot application
Fraction emitted to air during application	0.02	(-)	
Fraction emitted to applicator during application	0.02	(-)	
Fraction emitted to floor during application	0.11	(-)	
Fraction emitted to treated surface	0.85	(-)	
Fraction emitted to waste water from applicator	1	(-)	No coveralls to be used by consumers, washing clothes will lead to emission to STP
Fraction emitted to waste water from cleaning floor	1	(-)	Worst case

Cleaning efficiency	20	%	cleaning efficiency for RTU aerosol
Simultaneity factor	0.204	%	% houses treated at the same time for use of biocidal products 1 to 2 times per year

The biocidal product is only intended for indoor use, by non-professional users.
If wet cleaning is assumed, the only environmental compartment being directly exposed, is the **Sewage Treatment Plant (STP).** Indirectly, releases to surface water and water sediments are also considered, due to the effluent of the STP being further diluted into surface water. Subsequent adsorption to suspended matter in the surface water is possible, suspended matter can eventually settle as **sediment** and also leads to exposure to the sediment compartment. The sludge from STP can be applied on agricultural and grassland soil. As sludge is applied more frequently on agricultural **soil**. This will be set as worst case for the **soil** compartment.

No mixing and loading step will be required, since the product is a ready-to-use spray.
The application step itself will not lead to a direct release to an environmental compartment. The emission to indoor air is considered to be completely released by venting the room to the outdoor air compartment. The other exposed compartments will only be 'intermediate' receiving compartment, i.e. the floor, the treated surface and the floor around the treated surface. Only the subsequent cleaning step will lead to emission to the STP compartment.

Next to wet cleaning, dry cleaning is also possible. However, the indirect environmental exposure via waste disposal to landfill, as a result of dry cleaning, has not been considered in this exposure assessment. This is because this route of exposure is much less likely to be of concern when compared to the direct exposure via the STP compartment. In addition, the effect of its dilution with other wastes and the significant containment measures at landfill sites according to European Union (EU) waste regulations (EU Directive 99/31/EC) reduce any concerns further.

Calculations for Scenario 1
Calculations were performed using EUSES 2.1.2 software. The results are given below-

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	4.02E-04	Emission from cleaning after application, from 4000 houses connected to STP
Air	3.44E-05	indoor air emissions is completely released to outdoor air compartment

ES CA: The local emission of the a.s. has been calculated by EUSES 2.2. value is indicated in the table below:

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission a.s. ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.72E-03	Emission from cleaning after application, from 4000 houses connected to STP

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	(yes)	(yes)	Not relevant	Not relevant	yes	yes	(yes)	(yes)	Not relevant

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	391.29	g/mol	
Melting point	35	°C	
Boiling point	305	°C	
Vapour pressure (at XC)	2.155E-06	Pa	
Water solubility (at X°C)	0.00495	mg/l	
Log Octanol/water partition coefficient	4.67	Log 10	25°C
Organic carbon/water partition coefficient (Koc)	26930	l/kg	(Arithmetic mean, n= 10)
Henry's Law Constant (at X C)*[if measured data available]*	4.5E-02	Pa/m3/mol	
Biodegradability	No		(Study performed following investigation using test guidelines OECD 301F and OECD 301B with < 100% 25:75 *cis:trans*)
DT_{50} for degradation in soil	106	d (at 12ºC)	(geometric mean, n=5)
DT_{50} for degradation in water	40.4	d (at 12ºC)	Total system
DT_{50} for biodegradation in STP	2.38	d (at 23.5 °C)	Updated list of endpoints for permethrin PT08 and PT18 (based on new OECD 314B test study)

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	remarks
	Scenario 1	Calculations according to Technical Agreement for Biocides (ENV;2018) entry ENV9
Air	1.20E-03	Simple Treat 4.0
Water	26.6	
Sludge	71.7	
Degraded in STP	1.71	

ES CA position:
Active substance: Permethrin

Input parameters used in the environmental exposure assessments according to the CAR (April, 2014)		
Input	Value	Unit
Permethrin		
CAS number	52645-53-1	-
Molecular weight	391.29	$g.mol^{-1}$
Vapour pressure (at 20°C)	2.16E-06	Pa
Water solubility (at 20°C)	4.95E-03	$mg.L^{-1}$
Partition coefficient (log P_{OW}) (pH 7)	4.67	Log 10
Biodegradability	Not Ready biodegradable	
Degradation in soil (DT_{50}) (at 12°C)	106	days
Adsorption / desorption Koc	26930	$L.kg^{-1}$
BCF fish	570	$L.kg^{-1}$
BMF fish	1	-
BCF earthworms	15108	$L.kg^{-1}$
Metabolites		
DCVA		
Molecular weight	209.07	$g.mol^{-1}$
Degradation in soil (DT_{50}) (at 12°C)	175	days
Max. % occurrence water	62.6	%
Max. % occurrence soil	11.3	%
Koc	188.53	$L.kg^{-1}$
PBA		
Molecular weight	214.22	$g.mol^{-1}$
Degradation in soil (DT_{50}) (at 12°C)	2.5	days
Max. % occurrence water	28.8	%
Max. % occurrence soil	15	%
Koc	37.55	$L.kg^{-1}$

Calculated fate and distribution of Permethrin in the STP (EUSES model 2.2)	
Compartment	Percentage [%]
Air	0
Water	27.6
Sludge	72.4
Degraded in STP	0

Calculation method of metabolites emissions
According to Permethrin Assessment Report, Inclusion of active substances in the positive list to Regulation (EU) No 528/2012, Ireland, April 2014, the degradation of Permethrin in soil and in the aquatic systems leads to formation of DCVA (2,2-dimethyl-3-(2,2-dichlorovinyl) cyclopropane carboxylic acid) and PBA (3-phenoxybenzoic acid) as the principal metabolites. To

estimate PEC in the environmental compartments for the metabolites DCVA and PBA, their own Koc values and DT50 in soil at 12°C have been considered. Following the application of WOOD PRESERVATIVE AEROSOL PERMETHRIN, concentrations were estimated considering the ratio of the molecular weight of the metabolite compared to the molecular weight of permethrin (0.534 for DCVA and 0.547 for PBA), and considering the metabolite formation fraction (max. % occurrence) for the compartment in question (soil and water) as presented above.

Given the percentage released to the air in the STP, the emission from the STP to air is considered to be negligible. Release is mainly directed towards the sewage sludge (>70%) and to the STP effluent (>25%).
The sewage sludge is not considered to be applied to agricultural soil as soil fertiliser in most European countries. However, the calculations for indirect exposure to agricultural soil were included. The STP effluent is considered to be released and diluted to the surface water. The distribution in the environmental compartments by the emission to the STP leads to the PEC-values stated below.

Calculated PEC values

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**$PEC_{sediment}$**	**PEC_{air}**	**$PEC_{agr\ soil}$**
	[mg/l	[mg/l]	[mg/kg wwt]	[mg/m^3]	[mg/kg wwt]
Scenario 1 (tier 1)	2.09E-05	2.01E-06	1.93E-03	3.68E-15	4.45E-04
Scenario 1 (tier 2)	7.59E-06	2.75E-07	1.61E-04	-	-

ES position: PEC values have been obtained using EUSES 2.2. The concentrations in the different environmental compartments following releases to the STP for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following table:

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**$PEC_{sediment}$**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l	[mg/l]	[mg/kg wwt]	[mg/kg wwt]	[mg/l]
Permethrin	2.25E-04	2.16E-05	1.3E-02	2.29E-03	3.12E-06
DCVA	-	7.22E-06	3.52E-05	5.23E-06	1.12E-06
PBA	-	3.41E-06	1.66E-05	1.48E-07	7.48E-09

Primary and secondary poisoning

Primary poisoning
No data available. Product is only used as indoor wood preservative, no direct or indirect exposure is considered to birds or other mammals

Secondary poisoning
No data available. Product is only used as indoor wood preservative, no direct or indirect exposure is considered to birds or other mammals.

ES CA position:
The active substance permethrin has a log Kow > 3 (log Kow = 4.67) and a BCF > 100

(mean BCF in fish = 570 $L.kg^{-1}$, BMF = 1 and BCF in earthworm = 15108 $L.kg^{-1}$). According to the scenario secondary poisoning may occur via the aquatic food chain and/or via the terrestrial food chain. The concentration of permethrin in food (i.e. in fish and in earthworm) of fish-eating and worm-eating predators (birds or mammals) has been calculated (EUSES 2.2).

The results for each scenario are summarised in the following tables.

Summary table on estimated theoretical exposition for the permethrin		
	PEC in fish	**PEC in earthworm**
	[$mg.kg_{wet\ fish}^{-1}$]	[$mg.kg_{wet\ earthworm}^{-1}$]
Scenario 1	6.17E-03	2.1E-02

2.2.8.3 Risk characterisation

Atmosphere

The concentration of the active substance released to outdoor air is negligible.

Conclusion: The low vapour pressure of active substance permethrin leads to very low calculated concentrations in the air. There is no unacceptable risk for emission of the product to the air compartment.

ES CA position:
Due to the used proposed, exposure of the environment via air is not expected. According to the CAR, volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155×10^{-6} Pa at 20°C) and Henry constant (4.5×10^{-2} $Pa.m^3.mole^{-1}$). Permethrin would not be transported over large distances in the atmosphere in gaseous phase.

Conclusion: Emissions and PECs in air are considered as negligible. It can be concluded that the use of the product WOOD PRESERVATIVE AEROSOL PERMETHRIN will not pose a significant risk to the atmospheric compartment.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	4.22E-03

Conclusion: The direct release to the sewage treatment plant from the use of the product does not lead to an unacceptable risk.

ES CA position:

Summary table on calculated PEC/PNEC values for permethrin		**Conclusion**
	$PEC/PNEC_{STP}$	
Scenario 1	4.55E-02	Acceptable

Conclusion:
The risk for the STP is acceptable for the use proposed for the product WOOD

PRESERVATIVE AEROSOL PERMETHRIN.
No ecotoxicological data are available to set a PNEC value for the metabolites for the STP compartment.

Aquatic compartment

Tier 1:
The indirect release to surface water from the discharge of the STP effluent to surface water poses a risk for the surface water and sediment compartment.
Conclusion: To reduce the risk levels, a higher tier in the risk assessment calculations is proposed. The justification is given in the section below.
Tier 2:
In the ESD for PT18 biocidal products, emissions to wastewater are based upon a PT2 scenario (private area and public health area disinfectants) assuming 100% emission to wastewater, a cleaning efficiency of 100% and daily wet cleaning. This is applicable for disinfectants for professional use. The product under consideration in this risk assessment is a wood preservative intended for non-professional use only.
In order to prevent release to STP as much as possible, a disposable, non-permeable cover should be used under the material to be treated. In this way, the emission to the floor can be prevented. If emission to STP is only originating from the applicator, the PEC/PNEC value
for water and sediment compartment are acceptable.

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1 (tier 1)	**4.28**	**8.89**
Scenario 1 (tier 2)	0.59	0.74

Conclusion: After refinement at a second tier, the risk for water and sediment compartments can be considered acceptable. The risk mitigation measure to use a non-permeable cover under the wooden furniture during application, should be included in the use instructions to reduce the chance of indirect release to water and sediments. More in general, release to STP should be prevented where possible.

ES CA position:

Summary table on calculated PEC/PNEC values				**Conclusion**
		PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	
Scenario 1	Permethrin	4,60E-02	5,99E+01	Unacceptable
	DCVA	4,81E-04	2,93E-03	Acceptable
	PBA	3,41E-04	1,84E-03	Acceptable

Conclusion:
Unaceptable risk to the sediment environment has been found for the used of the product WOOD PRESERVATIVE AEROSOL PERMETHRIN.

The risk for the environment has been performed according to de OCDE ESD PT18, considering that the treated wood material is a wet cleaning zone however, although this is the worst case, it is not realistic because, a wood material, such us furniture,

cannot be considered as a wet cleaning area. For this kind of treated materials (furniture…), residues are removed through dry cleaning whith disposable clothes thus, the residues from the treated surface are not emitted to the wastewater compartment but to the municipal landfill.
The new assessment is summarized below:

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: indoor spray application for surface treatment			
Application rate of biocidal product *[alternative: annual tonnage in the EU]*	200	g/m²	Application rete indicated by the applicant
Concentration of active substance in the product	0.25	%	
Area of treated wood with the product	2	m^2	Default, indoor targeted spot application
Fraction emitted to air during application	0.02	(-)	
Fraction emitted to applicator during application	0.02	(-)	
Fraction emitted to floor during application	0.11	(-)	
Fraction emitted to treated surface	0.85	(-)	
Fraction emitted to waste water from applicator	1	(-)	No coveralls to be used by consumers, washing clothes will lead to emission to STP
Fraction emitted to waste water from cleaning floor	1	(-)	Worst case
Fraction emitted to waste water from cleaning treated material	0	(-)	Wooden furniture is not cleaned wet
Cleaning efficiency	20	%	cleaning efficiency for RTU aerosol
Simultaneity factor	0.204	%	% houses treated at the same time for use of biocidal products 1 to 2 times per year

Local emission to the waste water:

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission a.s. ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	3.43E-04	Emission from cleaning after application, from 4000 houses connected to STP

PEC/PNEC value for sediment compartment		
	PEC	PEC/PNEC
SEDIMENT	2.48 E-04 mg/kg	1.55

Since there is still risk to the sediment compartment, a risk mitigation measure is proposed to prevent the exposure of the sediment compartment: During the application step, a disposable, non-permeable cover should be used under the material to be treated. In this way, the emission to the floor can be prevented. The application of this risk mitigation measure preventing emissions to the environment would achieve acceptable risks.

Terrestrial compartment

Exposure to the soil compartment is only considered by indirect exposure through application of sewage sludge on soil.

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	0.160

Conclusion: The indirect release to agricultural and grassland soil will not lead to an unacceptable risk

ES CA position:

Summary table on calculated PEC/PNEC soil values			**Conclusion**
		$PEC/PNEC_{soil}$	
Scenario 1	Permethrin	1,31E-02	Acceptable
	DCVA	1,14E-06	Acceptable
	PBA	1,03E-07	Acceptable

Conclusion:
The risks for the terrestrial compartment related to the use of WOOD PRESERVATIVE AEROSOL PERMETHRIN is acceptable for the soil compartment.

Groundwater

Groundwater will only be reached due to leaching from the soil compartment. The concentration in groundwater is calculated for indirect exposure of humans through drinking water. As an indication for potential groundwater levels, the concentration in porewater of agricultural soil is taken. This is a worst-case assumption, neglecting transformation and dilution in deeper soil layers. The concentration in groundwater should be <0.1 µg/L.

Summary table on calculated PEC vs. trigger value (0.1 ug/L)	
	$PEC_{groundwater}$ (ug/L)
Scenario 1 (Tier 1)	6.06E-04

Conclusion: The indirect release to the groundwater does not lead to a concentration higher than 0.1 ug/L.

ES CA position:

Summary table on calculated PEC $_{groundwater}$ (µg/L) Comparison with the limit value of 0.1 µg/L.			Conclusion
Scenario 1	Per**m**ethrin	3,12E-03	Acceptable
	DCVA	1,12E-03	Acceptable
	PBA	7,48E-06	Acceptable

Conclusion:
The risks for the groundwater related to the use of WOOD PRESERVATIVE AEROSOL PERMETHRIN is acceptable.

Primary and secondary poisoning

Primary poisoning

Product is only used as indoor wood preservative, no direct or indirect exposure is considered to birds or other mammals.

ES CA position:
Not relevant

Secondary poisoning

Product is only used as indoor wood preservative, no direct or indirect exposure is considered to birds or other mammals.

ES CA position:
Birds (PNEC $_{oral\ bird}$≥16.7 mg.kg $_{food}$) are more sensitive species than mammals (PNEC $_{oral\ small\ mammals}$ =120 mg.kg $_{food}$). Thus, only the most conservative ratio PEC/PNECbirds is presented.
The results are summarised in the following table.

Summary table on table on secondary poisoning for permethrin				
	PEC$_{oral\ predator}$ [mg.kg $_{wet\ fish}^{-1}$]	**PEC/PNEC$_{birds}$**	**PEC $_{oral\ predator}$** [mg.kg $_{wet\ earthworm}^{-1}$]	**PEC/PNEC$_{birds}$**
Scenario 1	6.17E-03	3.37E-04	2.1E-02	1.25E-03

Conclusion: For all assessed scenarios, the RCRs are below 1 for the birds (and small mammals) in the aquatic and/or the terrestrial food chains. Therefore, the risk of secondary poisoning is acceptable when using the products WOOD PRESERVATIVE AEROSOL PERMETHRIN according to the label recommendations.

Mixture toxicity

No mixture toxicity, since no substance of concern for environmental exposure to be considered. Permethrin is the ingredient that gives Carcomin an environmental classification.

ES CA position:
Although we have considered that this product containg a substance of concern

(Hydrocarbons (C7-C9, n-alkanes, isoalkanes, cyclics (EC.920-750-0)) beside the active substance permethrin, the mixture toxicity has not been carried out due to the risk mitigation measure proposed which reduces the emissions to the environment.

Aggregated exposure (combined for relevant emmission sources)

Not relevant.

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

No unacceptable risks are identified for any of the environmental compartments. In addition, the scenario used for estimating exposure levels is conservative as the actual treated surface per application is only 1m2 instead of 2 m2 (the latter is used as default from the target spot application scenario in the ESD PT18).

ES CA position:

Scenario	STP	Surface water	Sediment	Soil	Ground water	Secondary Poisoning
1	Acceptable	Acceptable	Unacceptable	Acceptable	Acceptable	Acceptable

Environmental risk assessment

Following indirect releases to the environment via the STP, all calculated PEC/PNEC ratios were < 1 for STP, surface water, soil and groundwater. Thus the risk for these environmental compartments is acceptable. Nevertheless, regarding the exposure of the sediment, RCR values was > 1 indicating unacceptable risk to this environmental compartment.

A risk mitigation measure is proposed to prevent the exposure of the sediment compartment: During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way. In this way, the emission to the floor can be prevented. The implementation of this risk mitigation measure to prevent emissions to the environment it would be lead to an acceptable risk.

2.2.9 Measures to protect man, animals and the environment

See the summary of product characteristic.

2.2.10 Assessment of a combination of biocidal products

No applicable

2.2.11 Comparative assessment

No applicable

3 ANNEXES

3.1 List of studies for the biocidal product

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
2.1.2	See Confidential PAR	2018	Title: Statement formula and commercial name. Test facility: Henkel Ibérica, S.A., Bilbao, 72-84, 08005, Barcelona Data protection claimed → Yes
2.2.2	See Confidential PAR	2015	Scheda Tecnica Bombola (Packaging specification report)
2.2.2	See Confidential PAR	2012	Technical specification of the valve of the aerosol container.
2.2.2	See Confidential PAR	2015	Analysis report: Shelf life of Spotless insecticidal products. Storage Stability Testing of IIRD-01116.2 Anti-Woodworm Aerosol. Report LR-C-170 (R7). Test facility: Henkel Ibérica, S.A., Bilbao, 72-84, 08005, Barcelona GLP compliance → No Data protection claimed → Yes
2.2.2	See Confidential PAR	2016	Analysis report: Spray pattern on the sample Carcomin plus. Report No. 201505097. Test facility: Study performed by Stazioni Sperimentali per l'Industria – Area Business Combustibili. Innovhub GLP compliance → No Data protection claimed → Yes
2.2.2	See Confidential PAR	2019	Analysis report: ACCELERATED STORAGE STABILITY, PHYSICO-CHEMICAL CHARACTERISTICS, FORMULA Anti-Woodworm Aerosol, IIRD-01116.2 Test facility: Henkel Ibérica, S.A., Bilbao, 72-84, 08005, Barcelona GLP compliance → No Data protection claimed → Yes
2.2.2	See Confidential PAR	2019	LONG TERM STORAGE STABILITY, PHYSICO-CHEMICAL CHARACTERISTICS, FORMULA Anti-Woodworm Aerosol IIRD-01116.2. Test facility: Henkel Ibérica, S.A., Bilbao, 72-84, 08005, Barcelona GLP compliance → No Data protection claimed → Yes
2.2.2	See Confidential PAR	2020	LONG TERM STORAGE STABILITY, PHYSICO-CHEMICAL CHARACTERISTICS, FORMULA Anti-Woodworm Aerosol IIRD-01116.2. Test facility: Henkel Ibérica, S.A., Bilbao, 72-84, 08005, Barcelona GLP compliance → No Data protection claimed → Yes
2.2.2 /	See	2019	Analysis report: PRODUCT SPECIFICATIONS, FORMULA

Section No.	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
2.2.3	Confidential PAR		Anti-Woodworm Aerosol IIRD-01116.2. Test facility: Henkel Ibérica, S.A., Bilbao, 72-84, 08005, Barcelona GLP compliance → No Data protection claimed → Yes
2.2.4	See Confidential PAR	2015	Analysis report: Technical Report 15/1178. Validation of a procedure to analyse the permethrin concentration in aerosol samples using HRGC-FID. Test facility: IQS, Via Augusta 390, 08017, Barcelona GLP compliance → No Data protection claimed → Yes
2.2.4	See Confidential PAR	2020	Analysis report: Technical Report 20/0434.MOD. Answer the authorities' question about the method validation performed by IQS, code: 15/1178. Test facility: IQS, Via Augusta 390, 08017, Barcelona GLP compliance → No Data protection claimed → Yes
2.2.5	See Confidential PAR	2008	Title: Wood preservatives. Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus* (Linnaeus). Laboratory method." according to the standard EN 46-1:2006. Laboratory: CIDEMCO Sponsor: SARA LEE HOUSE HOLD and BODY CARE ESPAÑA, S.L. Nº report: 16072.3-a Unpublished.
2.2.5	See Confidential PAR	2015	Title: Determination of preventive action against *Reticulitermes* species according to EN 118:2013 Laboratory: Tecnalia Research and innovation. Sponsor: HENKEL IBERICA, S.L. Nº Report: 052084.1-a Unpublished.
2.2.5	See Confidential PAR	2008	Title: Wood preservatives. Determination of the eradication action against *Hylotrupes bajulus* (Linnaeus). Laboratory method." according to the standard UNE-EN 1390:2007. Laboratory: CIDEMCO Sponsor: SARA LEE HOUSE HOLD and BODY CARE ESPAÑA, S.L. Nº Report: 16072.2-a Unpublished.
	ECHA	2014	Competent Authority Report, Assessment Report and BPC opinion of Permethrin.
	Official Journal of the European Union	2014	COMMISSION IMPLEMENTING REGULATION (EU) No 1090/2014

3.2 Output tables from exposure assessment tools

Human exposure assessment calculations

Wood Preservative Human Exposure Ca

3.3 New information on the active substance

Not applicable.

3.4 Residue behaviour

Not applicable.

3.5 Summaries of the efficacy studies.

All efficacy tests information is summarised in the efficacy table, section 2.2.5.5.