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

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



**Embasol Houtwormdood**

Product type(s) : 8 (wood preservative)

permethrin as included in the Union list of approved active substances

Case Number in R4BP: [BC-EL024071-57]

Evaluating Competent Authority: the Netherlands

Date: 17/09/2020Table of Contents

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# CONCLUSION

The product Embasol Houtwormdood containing permethrin (0.25% w/w/ or 2 g/L) is used for preventive treatment of wood in use class 1 and for curative treatment of wood against the larvae of wood boring beetles by industrial users, professionals and non-professionals. Application methods for preventive treatment are superficial (brushing , spraying and dipping) and penetrative ((double) vacuum-pressure impregnation). Application methods for curative treatment are superficial (brushing and spraying), and penetrative (injection). Curative injection treatment could only be authorized in combination with curative superficial application.

Preventive treatment of wood in use class 2 was also applied for, but this was not assessed as in line with efficacy guidance part B/C and EN599-1 fungicidal activity would also be required.

Embasol Houtwormdood is a colourless liquid with a density of 0.7974 g/cm3 (20°C). The pH of a 1% dilution of the product is 6.3. It has a surface tension of 24.62mN/m at 20°C and a viscosity of 1.6 mPa s at 20°C and 1.4 mPa s at 40°C.

Shelf-life: 24 months for tinplate/metal packaging or 12 months for HDPE packaging.

Based on the low viscosity and the high amount of H304 classified components the product is classified with aspiration hazard (H304). No other classification based on physical chemical properties is identified.

The product is sufficiently efficacious against larvae of wood boring beetles in both preventive 125 ml/m2 or 1.56-3.18 kg/m3) and curative ( 250-300 ml/m2 or 1.56-7.63 kg/m3) applications.

Conclusion Human Health

The risk assessment for human health, for professional and industrial use concluded that:

-Acceptable risk levels are obtained when PPE are prescribed for application via **coarse spraying. Protective gloves and impermeable coverall** should be used to obtain safe use.

-Acceptable risk levels are obtained when PPE are prescribed for application **via injection by an injector. Protective gloves** should be used to obtain safe use.

-Acceptable risk levels are obtained without the need for PPE for injection by pouring.

-Acceptable risk levels are obtained when PPE are prescribed for application via **brushing**. **Protective gloves** should be used to obtain safe use.

-Acceptable risk levels are obtained when PPE are prescribed for application via **dipping. Protective gloves** should be used to obtain safe use.

-Acceptable risk levels are obtained when PPE are prescribed for application via **vacuum treatment. Protective gloves** should be used to obtain safe use.

-Acceptable risk levels are obtained when PPE are prescribed for application via **double vacuum treatment. Protective gloves and coverall** should be used to obtain safe use.

The risk assessment for human health, for non-professional use concluded that:

-Acceptable risk levels are obtained without the need for PPE for injection by pouring.

-Acceptable risk levels are obtained without the need for PPE for application via brushing.

Borehole injection should always be combined with a curative superficial treatment (spraying or brushing/rolling).

The combination of borehole treatment (injection or pouring) was not acceptable in combination with spraying, not even with PPE (protective gloves and impermeable coverall). Therefore, this combination is not authorized.

The combination of borehole treatment (injection or pouring) was acceptable in combination with brushing, with the use of gloves.

For secondary exposure to the general public, it can be concluded that risk levels are acceptable.

For indirect exposure from treated wood, it can be assumed that the exposure to animals is negligible, given that the treated timber is mainly used in constructions indoor and/or under a roof. Exposure to animals would only sporadically occur, as access to the timber is limited in such cases. Furthermore, chewing of treated wood is included in the risk assessment for human health and considers the most vulnerable group, i.e. infants. As cats are sensitive to permethrin, the following risk mitigation measure has been added: “Avoid prolonged contact of pets, particularly cats, to treated surfaces”

Conclusion Environment

No environmental risks have been identified for industrial use provided that a risk mitigation measure is included in the SPC stating that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing surface, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal.

No environmental risks for professional or non-professional have been identified provided that a risk mitigation measure is included in the SPC stating that residual fluids, brushes, and rinse water applied for cleaning have to be discharged as hazardous waste. Furthermore, run-off to soil or surface water needs to be prevented in order to protect water living organisms. Therefore treatment of wood with this product needs to take place indoors or under roof. Alternatively, during treatment the soil underneath and around the object to be treated needs to be covered with plastic.

A potential risk exists for bats roosting on treated wood. A warning needs to be added to the SPC indicating that the product must not be used in areas where bats reside.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| Embasol Houtwormdood | The Netherlands |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Hoetmer B.V. |
| **Address** | Nijverheidstraat 12NL-3316 AP DordrechtThe Netherlands |
| **Pre-submission phase started on** | / |
| **Pre-submission phase concluded on** | / |
| **Authorisation number** | NL-0017730-0000 (NL) |
| **Date of the authorisation** | 23-12-2020 (NL) |
| **Expiry date of the authorisation** | 23-12-2030 (NL) |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | Glanssa Hygiëne Products |
| **Address of manufacturer** | Curieweg 11, 4691 ST Tholen, The Netherlands |
| **Location of manufacturing sites** | Curieweg 114691 ST TholenNetherlands |

|  |  |
| --- | --- |
| **Name of manufacturer** | Kurt Obermeier GmbH & Co. KGBerghäuser Straße 70D - 57319 Bad Berleburg |
| **Address of manufacturer** | Berghäuser Straße 70, D - 57319 Bad Berleburg, Germany |
| **Location of manufacturing sites** | IndustrieStraße 1, D-57319 Bad Berleburg Germany |

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

|  |  |
| --- | --- |
| **Active substance** | Permethrin (Preventol HS 75) |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1 50569 Köln Germany |
| **Location of manufacturing sites** | Bayer Vapi Private Ltd. - Plot 306/3, II Phase, GIDC Vapi 396 195 Gujarat - India |
|  |  |

|  |  |
| --- | --- |
| **Active substance** | Permethrin |
| **Name of manufacturer** | Tagros Chemicals India Limited |
| **Address of manufacturer** | “Jhaver Centre”, Rajah Annamalai Building, IV Floor, 72, Marshalls Road, Chennai-600 008, Egmore, India |
| **Location of manufacturing sites** | A4/1&2, SIPCOT Industrial Complex, Kudikadu, Cuddalore, Tamil Nadu, India |
|  |  |

### Product composition and formulation

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

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

Yes [ ]

No [x]

#### Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **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** | 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 stereoisomers1R,cis permethrin content = 5.0 - 10.0 %w/w1S,cis permethrin content = 15.0 - 20.0 %w/w1R,trans permethrin content = 45.0 - 55.0 %w/w1S,trans permethrin content = 17.0 - 27.0 %w/w |
| **Structural formula** |  |

#### Candidate(s) for substitution

Not applicable

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

| **Common name** | **IUPAC/EC****name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Permethrin  | m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 0.269(0.25 pure active) |
| Distillates(petroleum), hydrotreated light  | Distillates (petroleum), hydrotreated light | Non-active ingredient | 64742-47-8 | 265-149-8 | 95.731 |

#### Information on technical equivalence

Not relevant. The source of active substance is the reference source.

#### Information on the substance(s) of concern

See section 2.1.2.3. Furthermore, for more specific information please see section 2.2.6. Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern) and more specific information please be refered to the confidential annex.

#### Endocrine disrupting properties

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders). It means that an ED hazard assessment should be included in the PAR. Applicants should perform screening for co-formulants contained in the product, and where an alert is identified, perform further ED evaluation. The screening and/or evaluation is carried out in accordance with the EFSA/ECHA ED guidance (http://www.efsa.europa.eu/en/press/news/180607). The assessment was already in a stage where the applicant could not be requested to perform a screening.

Detailed information on e.g. how a screening was performed for co-formulant(s) if an alert for ED property is found, information type and source from which the alert was found, the outcome of further ED assessment, and the conclusion of the eCA is included in

• “Others” in section 2.2.6.1 “Assessment of effects” for human health aspect

• “Further Ecotoxicological studies” in section 2.2.8.1 “Effects assessment on the environment” for environment aspect

• Confidential Annex can be used in case the ED assessment contains confidential information.

Based on the screening none of the co-formulants triggered an alert for potential endocrine disruption properties. Hence, no further ED assessments are required for Embasol Houtwormdood.

#### Type of formulation

|  |
| --- |
| AL: Any other liquid (Ready-to-use formulation) |

### Hazard and precautionary statements[[2]](#footnote-2)

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

**Professional use**

| **Classification** |
| --- |
| Hazard category | Asp. Tox. 1 Aquatic Acute 1Aquatic Chronic 1  |
| Hazard statement | H304 : May be fatal if swallowed and enters airways.H400 : Very toxic to aquatic life.H410 : Very toxic to aquatic life with long lasting effects. |
|  |
| **Labelling** |
| Signal words | Danger |
| Hazard statements | H304 : May be fatal if swallowed and enters airways.H410 : Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | P273 : Avoid release to the environment.P301+P310 : IF SWALLOWED : immediately call a poison center or doctor/physician.P331 : Do NOT induce vomiting.P405 : Store locked up.P501 : Dispose of content/container to…. |
| Additional labeling requirements | EUH066: Repeated exposure may cause skin dryness or cracking.EUH208: Contains permethrin. May produce an allergic reaction. |
|  |
| Note | Based on its contribution to the H304 classification, the substance ‘Distillates (petroleum), hydrotreated light’ need to be declared on the label (Art 18 (3), CLP)Hazard pictograms:GHS08 and GHS09 |

Non-professional use

| **Classification** |
| --- |
| Hazard category | Asp. Tox. 1 Aquatic Acute 1Aquatic Chronic 1  |
| Hazard statement | H304 : May be fatal if swallowed and enters airways.H400 : Very toxic to aquatic life.H410 : Very toxic to aquatic life with long lasting effects. |
|  |
| **Labelling** |
| Signal words | Danger |
| Hazard statements | H304 : May be fatal if swallowed and enters airways.H410 : Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | P101 : If medical advice is needed, have product container or label at hand.P102 : Keep out of reach of children.P273 : Avoid release to the environment.P301+P310 : IF SWALLOWED : immediately call a poison center or doctor/physician.P331 : Do NOT induce vomiting.P405 : Store locked up.P501 : Dispose of content/container to…. |
| Additional labeling requirements | EUH066: Repeated exposure may cause skin dryness or cracking.EUH208: Contains permethrin. May produce an allergic reaction. |
|  |
| Note | Based on its contribution to the H304 classification, the substance ‘Distillates (petroleum), hydrotreated light’ need to be declared on the label (Art 18 (3), CLP)Products for non-professional use must be fitted with a child-resistant fastening and tactile warnings of danger.  |

### Authorised use(s)

#### Use description[[3]](#footnote-3)

Table 1. Use # 1 – Preventive wood preservative with insecticidal activity for industrial use

|  |  |
| --- | --- |
| **Product Type** | PT8 – wood preservatives (preservatives) |
| **Where relevant, an exact description of the authorised use** | Insecticide |
| **Target organism (including development stage)** | Other - Wood boring beetles - larvae |
| **Field of use** | IndoorPermitted is only the use of Embasol Houtwormdood for preventive treatment of wood destined for use under roof (use class 1) against attack by insects. |
| **Application method(s)** | Open system: ImmersionClosed system: pressure process (vacuum-pressure impregnation)Closed system: vacuum impregnation (double vacuum impregnation) |
| **Application rate(s) and frequency** | 125 mL of the product/m2 wood for superficial treatment1.56 - 3.18kg of the product /m3 for penetrative treatmentOnly 1 application is required |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | Jerrycan 25L – HDPE (opaque)Drum 200L – HDPE (opaque)IBC 1000L – HDPE (opaque) |

#### Use-specific instructions for use[[4]](#footnote-4)

|  |
| --- |
| Immersion method: Dip the wood to be treated in a dipping tank filled with Embasol Houtwormdood. Immerse till the required uptake is reached. Retention rate: 125 ml/m2.Closed system: pressure process (vacuum-pressure impregnation)The wood to be treated is placed in the vacuum-pressure cylinder. After the wood is placed and the cylinder is closed, a vacuum is made in the cylinder. After e.g. 15 minutes of vacuum the cylinder is filled with Embasol Houtwormdood. Thereafter, when the cylinder is full, Embasol Houtwormdood is pumped under pressure in the cylinder and in the wood under high pressure till the required uptake is reached. Then the cylinder is emptied and an post-vacuum is made in order to get the wood 'surface dry' out of the cylinder. Retention rate: 1.56-3.18 kg/m3.Closed system: vacuum impregnation (double vacuum impregnation)The wood to be treated is placed into the vacuum cylinder. After the wood is placed and the cylinder is closed, a vacuum is made in the cylinder. After 15/20 minutes of pre-vacuüm the cylinder is filled with Embasol Houtwormdood. When the cylinder is full, the wood stands in the liquid till the required uptake is reached. Subsequently the cylinder is emptied and a post-vacuum is created in order to get the wood 'surface dry' out of the cylinder. Retention rate: 1.56-3.18 kg/m3. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Immersion method : Wear protective chemical resistant gloves during product handling phaseClosed system: pressure process (vacuum-pressure impregnation):Wear protective chemical resistant gloves during product handling phase.Closed system: vacuum impregnation (double vacuum impregnation):Wear protective chemical resistant gloves and coverall during product handling phase.Freshly industrial-treated timber shall be stored after treatment under shelter or on impermeable hard standing surface, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal. |

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

|  |
| --- |
| See general directions for use. |

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

|  |
| --- |
| See general directions for use. |

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

|  |
| --- |
| See general directions for use. |

Table 2. Use #2 Preventive wood preservative with insecticidal activity for use by professionals and trained professionals

|  |  |
| --- | --- |
| **Product Type** | PT8 – wood preservative (preservatives) |
| **Where relevant, an exact description of the authorised use** | Insecticide |
| **Target organism (including development stage)** | Other - Wood boring beetles - larvae  |
| **Field of use** | IndoorPermitted is only the use of Embasol Houtwormdood for preventive treatment of wood destined for use under roof (use class 1) against attack by insects. |
| **Application method(s)** | Brushing, spraying |
| **Application rate(s) and frequency** | 125 mL of the product/m2 wood Only 1 application required |
| **Category(ies) of users** | Professionals and trained professionals |

|  |  |
| --- | --- |
| **Pack sizes and packaging material** | Can/Tin 5L – metalJerrycan 5, 10 and 25L – HDPE (opaque)Drum 200L – HDPE (opaque)IBC 1000L – HDPE (opaque) |

#### Use-specific instructions for use

|  |
| --- |
| Spraying: Apply Embasol Houtwormdood with a (automatic) spraying apparatus under low pressure in coarse droplets, in a way that trickling down is avoided. Retention rate: 125 ml/m2.Brushing : The wood surface to be treated is brushed or rolled with a brush or roller. Apply one or two coats of the undiluted product depending on the uptake per coat. Apply in a way that trickling down is avoided. Retention rate: 125 ml/m2.Avoid release of the product or residues of the product to the environment. Discharge of leftover and residues containing the product (e.g. solvents used for cleaning of brushes) to the sewer or surface water is not permitted. Leftover and residues containing the product (e.g. solvents used for cleaning of brushes) need to be removed as chemical waste. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.Keep children and pets away from treated surfaces until dried.Spraying:Wear protective chemical resistant gloves and coverall during product handling phase. Dispose of protective gloves after use.Brushing :Wear protective chemical resistant gloves during product handling phase. |

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

|  |
| --- |
| See general directions for use  |

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

|  |
| --- |
| See general directions for use |

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

|  |
| --- |
| See general directions for use  |

Table 3. Use #3 Curative wood preservative with insecticidal activity for use by professionals and trained professionals

|  |  |
| --- | --- |
| **Product Type** | PT8 – wood preservative (preservatives) |
| **Where relevant, an exact description of the authorised use** | Insecticide |
| **Target organism (including development stage)** | Other - Wood boring beetles - larvae  |
| **Field of use** | IndoorCurative wood preservation for indoor application and outdoor application within the scope of an extensive curative treatment (e.g. timbered house, wooden roof frames, log house constructions).Outdoor applications are not intended for wood that:- is either continually exposed to the weather or; - is protected from the weather but subject to frequent wetting and;- is subject to leaching |
| **Application method(s)** | Brushing, injection, spraying |
| **Application rate(s) and frequency** | Brushing & Spraying: 250-300 mL of the product/m2 wood Injection: Depending on the dimensions of beams, the severity of the attack and the used injectors/injection holes. For the borehole method you will have 26 holes per m². For a beam of 30 x 30 cm with injectors of 6 mm 6.36 mL will be used per borehole and with an injector of 10 mm 17.67 mL will be used per borehole. For a beam of 80 x 80 cm with an injector of 6 mm 16.96 ml will be used per borehole and with an injector of 10 mm 47.12 mL will be used per borehole. With the new patented injection method the average uptake per linear meter for a beam of 30 cm (30 x 30 cm) is 0.3 liter Embasol Houtwormdood and for a beam of 80 cm 1.5 liter per linear meter.Curative treatment by injection should always be combined with a curative superficial treatment by brushing at an application rate of 250-300 mL/m2 to ensure efficacy.Only 1 application required.For curative treatment it is advisable to check periodically and at least one year after the treatment whether active attack is still present. If the borers are still active, retreat the wood, perhaps locally. |
| **Category(ies) of users** | Professionals and trained professionals |

|  |  |
| --- | --- |
| **Pack sizes and packaging material** | Can/Tin 5L – metalJerrycan 5, 10 and 25L – HDPE (opaque)Drum 200L – HDPE (opaque)IBC 1000L – HDPE (opaque) |

#### Use-specific instructions for use

|  |
| --- |
| Outdoor applications are not intended for wood that:- is either continually exposed to the weather or; - is protected from the weather but subject to frequent wetting and;- is subject to leachingRemove varnishes, paints or wax films completely. Clean all the timber present. For timber attacked by House longhorn beetles, it is desirable to first open the tunnels and brush out the bore-dust as much as possible. Remove the bore-dust and wood layers damaged by the insect for subsequent disposal by burning. Clean the remaining wood surface with a wire-brush. Spray: Apply Embasol Houtwormdood with a (automatic) spraying apparatus under low pressure in coarse droplets, in a way that trickling down is avoided. Retention rate: 250-300 ml/m2.Brush : The wood surface to be treated is brushed or rolled with a brush or roller. Apply one or two coats of the undiluted product depending on the uptake per coat. Apply in a way that trickling down is avoided. Retention rate: 250-300 ml/m2.Injection : Inject the wood according to the classic borehole method or through the new patented injection system with low pressure. **Borehole method:**TimberDrill holes in the timber with a diameter of 6-10 mm, depending on the diameter of the injection plug to be used, till a depth of 3/4 of the beam thickness. The holes must be drilled 20 cm apart from each other in the horizontal direction and 15 cm in the vertical direction in cross bond. Put wood-injection-plugs into the holes and inject with the help of a high pressure (5 bar) injector, Embasol Houtwormdood into the wood. Treat the rest of the timber with Embasol Houtwormdood.Beam endsDrill holes in the timber with a diameter of 6-10 mm, depending on the diameter of the injection plug to be used. In horizontal beams drill holes vertically, in vertical beams drill holes under a 45° angle till a depth of 3/4 of the beam thickness. The holes must be drilled 5 cm apart from each other perpendicular to the grain and 20 cm parallel to the grain in cross bond. Drill the holes staggered. Drill the first row of holes approx. 10 cm from the wall. 2 rows are sufficient unless the specifications say otherwise. Put wood-injection-plugs into the holes and inject with the help of a high pressure (5 bar) injector, Embasol Houtwormdood into the wood. Treat the rest of the timber with Embasol Houtwormdood by brushing.  With the new patented method smaller drillholes are drilled into the wood (max. 6 mm), or fly out openings of the beetles are being used. With this method only a few holes are made in the wood.Thereafter the system is being connected to the holes by small hoses and through low pressure for a certain period of time the required amount of wood preservative is injected in the wood.Retention rate: Depending on the dimensions of beams, the severity of the attack and the used injectors/injection holes. For the borehole method you will have 26 holes per m². For a beam of 30 x 30 cm with injectors of 6 mm 6.36 ml will be used per borehole and with an injector of 10 mm 17.67 ml will be used per borehole. For a beam of 80 x 80 cm with an injector of 6 mm 16.96 ml will be used per borehole and with an injector of 10 mm 47.12 ml will be used per borehole. With the new patented injection method the average uptake per linear meter for a beam of 30 cm (30 x 30 cm) is 0,3 liter Embasol Houtwormdood and for a beam of 80 cm 1.5 liter per linear meter. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.Keep children and pets away from treated surfaces until dried.Spraying:Wear protective chemical resistant gloves and coverall during product handling phase. Dispose of protective gloves after use.Brushing :Wear protective chemical resistant gloves during product handling phaseInjection :Inject the wood according the classic borehole method or through the new patented injection system with low pressure. Wear protective chemical resistant gloves.Curative treatment by injection should always be combined with a curative superficial treatment by brushing at an application rate of 250-300 mL/m2 to ensure efficacy. Superficial treatment by spraying is not allowed due to risk for human health from the combined exposure.Avoid release of the product or residues of the product to the environment. Discharge of leftover and residues containing the product (e.g. solvents used for cleaning of brushes) to the sewer or surface water is not permitted. Leftover and residues containing the product (e.g. solvents used for cleaning of brushes) need to be removed as chemical waste. |

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

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| --- |
| See general directions for use  |

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

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| See general directions for use |

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

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| See general directions for use  |

Table 4. Use # 4 – Preventive and curative wood preservative with insecticidal activity for non-professional use

|  |  |
| --- | --- |
| **Product Type** | PT8 wood preservative (preservatives) |
| **Where relevant, an exact description of the authorised use** |  Insecticide |
| **Target organism (including development stage)** | Other - Wood boring beetles- larvae |
| **Field of use** | IndoorPermitted is only the preventive use (use class 1) and curative use of Embasol Woodwormkiller to treat wood under roof attacked by insectsCurative wood preservation for indoor application and outdoor application within the scope of an extensive curative treatment (e.g. timbered house, wooden roof frames, log house constructions) with simultaneous preventive efficacy.Outdoor applications are not intended for wood that:- is either continually exposed to the weather or; - is protected from the weather but subject to frequent wetting and;- is subject to leachingPreventive wood preservation for indoor application within the scope of curative treatment on surrounding timber. |
| **Application method(s)** | Brushing |
| **Application rate(s) and frequency** | Curative : 250 – 300 mL of the product/m2 wood Preventive : 125 mL of the product/m2 wood Frequency : One time application. For curative treatment it is advisable to check periodically and at least one year after the treatment whether active attack is still present. If the borers are still active, retreat the wood, perhaps locally.  |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Canister 0.75 – metal (tinplate)Can 2.5 and 5L -metal (tinplate)Jerrycan 5L – HDPE (opaque) |

#### Use-specific instructions for use

|  |
| --- |
| Outdoor applications are not intended for wood that:- is either continually exposed to the weather or; - is protected from the weather but subject to frequent wetting and;- is subject to leaching For preventive treatment:Brush : Brush the wood surface to be treated with a brush. The required uptake is to be reached in more than one treatment in a way that trickling down is avoided. Retention rate 125 ml/m2.For curative treatment:Remove varnishes, paints or wax films completely. Clean all the timber present. For timber attacked by House longhorn beetles, it is desirable to first open the tunnels and brush out the bore-dust as much as possible. Remove the bore-dust and wood layers damaged by the insect for subsequent disposal by burning. Clean the remaining wood surface with a wire-brush. Brush : Brush the wood surface to be treated with a brush. The required uptake is to be reached in more than one treatment in a way that trickling down is avoided. Retention rate 250 - 300 ml/m2.Avoid release of the product or residues of the product to the environment. Discharge of leftover and residues containing the product (e.g. solvents used for cleaning of brushes) to the sewer or surface water is not permitted. Leftover and residues containing the product (e.g. solvents used for cleaning of brushes) need to be removed as chemical waste. |

#### Use-specific risk mitigation measures

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| No animals or bystanders should be present during the application.Keep children and pets away from treated surfaces until dried. |

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

|  |
| --- |
| See general directions for use  |

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

|  |
| --- |
| See general directions for use |

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

|  |
| --- |
| See general directions for use  |

### General directions for use

#### Instructions for use[[5]](#footnote-5)

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| --- |
| For a good penetration the wood moisture content must be lower than 18%. Before treatment all prefabrication, such as sawing, drilling and notching must be carried out. If such work takes place after preservative treatment, further treatment of these parts must be carried out with Embasol Houtwormdood. |

#### Risk mitigation measures

|  |
| --- |
| Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals. Avoid prolonged contact of pets, particularly cats, to treated surfaces.Only to be used in well ventilated areas. Do not inhale vapour/spray.Treatment and storage need to take place under roof and on a liquid-tight floor. Discharge of the agent to sewer is not allowed. Residues containing the agent are to be disposed of as chemical waste. Wood treated with Embasol Houtwormdood may cause harm to bats. Do not use the product in areas where bats reside. |

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

|  |
| --- |
| **General information** Change contaminated, saturated clothing. When in doubt or if symptoms are observed, get medical advice. Never give anything by mouth to an unconscious person or a person with cramps. **In case of inhalation** Remove casualty to fresh air and keep warm and at rest. Provide fresh air.**In case of skin contact** After contact with skin, wash immediately with plenty of water and soap. In case of skin reactions, consult a physician. **After eye contact** Rinse immediately carefully and thoroughly with eye-bath or water. **In case of eye irritation** Consult anophthalmologist. **After ingestion** Do NOT induce vomiting. Rinse mouth thoroughly with water.Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice. |

#### Instructions for safe disposal of the product and its packaging

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| --- |
| Dispose as dangerous waste according to the local regulations.Storage needs to take place under roof and on a liquid-tight floor. Discharge of the agent to sewer is not allowed. Residues containing the agent are to be disposed of as chemical waste. |

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

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| --- |
| Store only in original, well closed containers, separate from food and feeding stuff. Store locked up.Protect from frost. Store at room temperature.Shelf-life: 24 months for tinplate/metal packaging or 12 months for HDPE packaging. |

### Other information

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| - |

### 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)** |
| canister | 0.75L | tinplate | Plastic closure with screw cap (D42) | Non-professional | Yes |
| canister | 2.5L | tinplate | Plastic closure with screw cap (D42) | Non-professional | Yes |
| canister | 5L | tinplate | Plastic closure with screw cap (D42) | Professional and non-professional | Yes |
| jerrycan | 5 liter | HDPE (opaque) | Sealable cap OV 51 | Professional and non-professional | Yes |
| jerrycan  | 10 liter | HDPE (opaque) | Sealable cap OV 51 | Professional  | Yes |
| jerrycan | 25 liter | HDPE (opaque) | Sealable cap DIN 61 | Professional  | Yes |
| drum | 200L | HDPE (opaque) | TR-sure cap (Plastiplug) | Professional | Yes |
| IBC | 1000L | HDPE (opaque) | DIN 150 filling opening with screw cap | Professional | Yes |

### Documentation

#### Data submitted in relation to product application

Physico-chemical tests and efficacy tests were performed on the product. All of these data are submitted within the current application.

No other studies have been performed. For the toxicological and ecotoxicological studies, reference is made to the active substance dossier of permethrin. No additional data are considered to be required. The studies included in the active substance dossier are applicable to the biocidal product as well considering the nature of the product (BPR regulation 528/2012). The product is classified based on CLP mixture rules.

#### Access to documentation

A letter of access to the active substance data (permethrin) is available from Lanxess and Tagros (See IUCLID)

## Assessment of the biocidal product

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

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

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

Table 3. Use # 1 – preventive wood preservative with insecticidal activity for industrial use

|  |  |
| --- | --- |
| **Product Type** | PT8 |
| **Where relevant, an exact description of the authorised use** | Permitted is only the use of Embasol Houtwormdood to treat wood destined for use under roof preventively against attack by insects. |
| **Target organism (including development stage)** | **Insects in wood:**Wood boring beetles :* *Hylotrupes bajulus* (larvae)
* *Lyctus brunneus* (larvae)
* *Anobium punctatum* (larvae)
 |
| **Field of use** | Indoor |
| **Application method(s)** | Open system: ImmersionClosed system: pressure process (vacuum-pressure impregnation)Closed system: vacuum impregnation (double vacuum impregnation) |
| **Application rate(s) and frequency** | 125mL of the product/m2 wood 1.56-3.18kg/m31.56-3.18kg/m3Only 1 application required |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | Jerrycan 25L – HDPEDrum 200L – HDPEIBC 1000L - HDPE |

Table 4. Use #2 - preventive wood preservative with insecticidal activity for use by professionals and trained professionals

|  |  |
| --- | --- |
| **Product Type** | PT8 |
| **Where relevant, an exact description of the authorised use** | Permitted is only the use of Embasol Houtwormdood to treat wood destined for use under roof preventively against attack by insects. |
| **Target organism (including development stage)** | **Insects in wood:**Wood boring beetles :* *Hylotrupes bajulus* (larvae)
* *Lyctus brunneus* (larvae)
* *Anobium punctatum* (larvae)
 |
| **Field of use** | Indoor |
| **Application method(s)** | Brushing, spraying, immersion (open system) |
| **Application rate(s) and frequency** | 125mL of the product/m2 wood Only 1 application required |
| **Category(ies) of users** | Professionals and trained professionals |
| **Pack sizes and packaging material** | Jerrycan 5, 10 and 25L – HDPEDrum 200L – HDPEIBC 1000L - HDPE |

Table 5. Use #3 - remedial wood preservative with insecticidal activity for use by professionals and trained professionals

|  |  |
| --- | --- |
| **Product Type** | PT8 |
| **Where relevant, an exact description of the authorised use** | Embasol Houtwormdood is to be used as a product for the curative treatment of wood in use class 1 and 2 for the control of insects (professional users) |
| **Target organism (including development stage)** | **Insects in wood:**Wood boring beetles :* *Hylotrupes bajulus* (larvae)
* *Lyctus brunneus* (larvae)
* *Anobium punctatum* (larvae)
 |
| **Field of use** | Indoor |
| **Application method(s)** | Brushing, spraying, injection (open system) |
| **Application rate(s) and frequency** | Brushing & spraying : 250-300mL of the product/m2 wood Injection : Depending on the dimensions of beams, the severity of the attack and the used injectors/injection holes. For the borehole method you will have 26 holes per m². For a beam of 30 x 30 cm with injectors of 6 mm 6,36 ml will be used and with an injector of 10 mm 17,67 ml. For a beam of 80 x 80 cm with an injector of 6 mm 16,96 ml will be used and with an injector of 10 mm 47,12 ml. With the new patented injection method the average uptake per linear meter for a beam of 30 cm (30 x 30 cm) is 0,3 liter Embasol Houtwormdood and for a beam of 80 cm 1,5 liter per linear meter.One time. For remedial treatment it is advisable to check periodically and at least one year after the treatment whether active attack is still present. If the borers are still active, retreat the wood, perhaps locally. |
| **Category(ies) of users** | Professionals and trained professionals |
| **Pack sizes and packaging material** | Jerrycan 5, 10 and 25L – HDPEDrum 200L – HDPEIBC 1000L - HDPE |

Table 6. Use # 4 – RTU formulation for the control of insects in wood – non-professional use

|  |  |
| --- | --- |
| **Product Type** | PT8 |
| **Where relevant, an exact description of the authorised use** | Permitted is only the use of Embasol Houtwormdood:a. to treat wood under roof (use class 1 and 2) attacked by insectsb. to treat wood destined for use under roof preventively against attack by insects. |
| **Target organism (including development stage)** | **Insects in wood:**Wood boring beetles :* *Hylotrupes bajulus* (larvae)
* *Lyctus brunneus* (larvae)
* *Anobium punctatum* (larvae)
 |
| **Field of use** | Indoor |
| **Application method(s)** | Brushing & spraying (open system) |
| **Application rate(s) and frequency** | Curative : 250-300mL of the product/m2 wood Preventive : 125mL of the product/m2 wood One time. For remedial treatment it is advisable to check periodically and at least one year after the treatment whether active attack is still present. If the borers are still active, retreat the wood, perhaps locally. |
| **Category(ies) of users** | Non-professional |
| **Pack sizes and packaging material** | Canister 0.75, 2.5 and 5L - metalJerrycan 5L – HDPE |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w) (nominal a.s content))** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual method | 0.25% w/w  | liquid | xxxx 2016 |
| Colour at 20 °C and 101.3 kPa | Visual method | 0.25% w/w  | Clear, colourless  | xxxx 2016xxxx 2016 |
| Odour at 20 °C and 101.3 kPa | Olfactory method | 0.25% w/w | Weak | xxxx 2016 |
| Acidity / alkalinity | CIPAC MT 75.3 | 0.25% w/w | 1% dilution: pH = 6.3 | xxxx 2016 |
| Relative density / bulk density | OECD 109 (hydrometer) | 0.25% w/w | 0.7974 g/cm3 at 20°C0.7619 g/cm3 at 40°C | xxxx 2016 |
| Storage stability test – accelerated storage | No data. A long-term storage stability study is available showing stability of the product at ambient conditions for 3.5 years in metal cans and for 12 months in HDPE container. The product is not intended to be stored at high temperatures. A sentence was included in the SPC to store at room temperature.  |
| Storage stability test – long term storage at ambient temperature | GIFAP NO. 17 | 0.25% w/w | A long term storage stability study was performed in metal cans for 3.5 years at room temperature. Tested parameters before storage:Appearance: clear colourless liquidState of packaging: no corrosion or leakageActive substance content: 0.251% w/wTested parameters after storage (42 months):Appearance: clear colourless liquidState of packaging: no corrosion or leakageActive substance content: 0.270% w/w (difference +7.6%)A long term storage stability study was performed in HDPE for 2 years at room temperature.Tested parameters before storage:Appearance: clear colourless liquidState of packaging: no corrosion or leakageActive substance content: 0.261% w/wTested parameters after storage (12 months):Appearance: clear colourless liquidState of packaging: no corrosion or leakage; <0.1% weight loss of packageActive substance content: 0.259% w/w (difference -0.8%)Tested parameters after storage (18 months):Appearance: clear colourless liquidState of packaging: no corrosion or leakage; 4.4% weight loss of package (plastic bottle indented)Active substance content: 0.279% w/w (difference +6.9%)Tested parameters after storage (24 months):Appearance: clear colourless liquidState of packaging: no corrosion or leakage; 6.7% weight loss of package (plastic bottle indented)Active substance content: 0.296% w/w (difference +13.4%)A shelf-life of 12 months in HDPE or 24 months in metal (tinplate) is supported. | xxxx 2016xxxx 2017 |
| eCA remark: The provided long term shelf-life studies (42 months in a metal can and 24 months in a HDPE bottle) show an increase in active substance content. No explanation was provided as to what might have caused this increase.Since the increase of the active substance content in metal is ≤10% the eCA considers the claimed shelf-life of 2 years supported for metal packagingThe shelf-life study in HDPE, however, shows already an increase of 6.9% at T18 months and an increase of 13.4% at T24 months. Moreover, the study report mentions that the HDPE bottles became indented at T18 months and T24 months. The active substance increase at T18 months is still ≤10%. However, as there is no explanation provided for the indentation in combination with an unusual increase of the active substance content the eCA considers that only a shelf life of 12 months is supported in HDPE.Shelf-life: 24 months for tinplate/metal packaging or 12 months for HDPE packaging. |
| Storage stability test – low temperature stability test for liquids | Not available. Protect from frost during storage |
| Effects on content of the active substance and technical characteristics of the biocidal product - light | Permethrin is not susceptible to breakdown by light (no absorption above 290nm). Furthermore, product is to be stored locked up, and in its original (opaque) container; therefore exposure to light is not relevant |
| Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity | Humidity : not relevant; product is to be stored in its original container therefore no exposure to humidity.Temperature : the product is not intended to be stored at high temperatures |
| eCA remark: Embasol Houtwormdood is very hydrophobic. The eCA agrees that humidity is therefore not likely to affect the stability of the product. |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | See long term storage stability data |
| Wettability | Not required for ready to use liquid  |
| Suspensibility, spontaneity and dispersion stability | Not required for ready to use clear liquid.  |
| Wet sieve analysis and dry sieve test | Not required for ready to use liquid.  |
| Emulsifiability, re-emulsifiability and emulsion stability | Not required for ready to use clear liquid. |
| Disintegration time | Not required for ready to use liquid. |
| Particle size distribution, content of dust/fines, attrition, friability | Not required for ready to use liquid. |
| Persistent foaming | Not required for ready to use liquid. |
| Flowability/Pourability/Dustability | Not required for ready to use liquid. |
| Burning rate — smoke generators | Not required for ready to use liquid. |
| Burning completeness — smoke generators | Not required for ready to use liquid. |
| Composition of smoke — smoke generators | Not required for ready to use liquid |
| Spraying pattern — aerosols | Not required as the product is not an aerosol |
| Physical compatibility | Not applicable. Currently no specific label recommendation to mix with other products |
| Chemical compatibility | Not applicable. Currently no specific label recommendation to mix with other products |
| Degree of dissolution and dilution stability | Not required for ready to use liquid. |
| Surface tension | EU Method A.5OECD 115(ring method) | 0.25% w/w | Pure test item :24.62mN/m at 20°C  | xxxx 2016 |
| Viscosity | OECD 114(rotational viscometer) | 0.25% w/w | Dynamic viscosity:1.6 mPa s at 20°C (shear rate 19.65-1199 /s) and 1.4 mPa s at 40°C (shear rate 23.81-1528 /s)(Newtonian fluid, not shear rate dependant)Kinematic viscosity:1.9943 mm2/s at 20°C and 1.5909 mm2/s at 40°C | xxxx 2016 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product is a colourless liquid with a density of 0.7974 g/cm3 (20°C). The pH of a 1% dilution of the product is 6.3. It has a surface tension of 24.62mN/m at 20°C and a viscosity of 1.6 mPa s at 20°C and 1.4 mPa s at 40°C.Shelf-life: 24 months for tinplate/metal packaging or 12 months for HDPE packaging. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | The product does not contain substance with chemical groups associated with explosive properties |
| Flammable gases | Not relevant for ready to use liquid. |
| Flammable aerosols | Not relevant for ready to use liquid. |
| Oxidising gases | Not relevant for ready to use liquid. |
| Gases under pressure | Not relevant for ready to use liquid. |
| Flammable liquids | Miniflash FLP, closed cup | 0.25% w/w permethrin | The flash point of the product is 63°C (not classified) | xxxx 2016 |
| Flammable solids | Not relevant |
| Self-reactive substances and mixtures | No chemical groups present associated with explosive or self-reactive properties |
| Pyrophoric liquids | Experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures |
| Pyrophoric solids | Not relevant for ready to use liquid. |
| Self-heating substances and mixtures | Not relevant for ready to use liquid. |
| Substances and mixtures which in contact with water emit flammable gases | Experience in production or handling shows that the substance or mixture does not react with water |
| Oxidising liquids | Not considered to have oxidizing properties based on ingredients |
| Oxidising solids | Not relevant for ready to use liquid. |
| Organic peroxides | No organic peroxides present |
| Corrosive to metals | Product does not contain substances classified as corrosive to metals |
| eCA remark: Embasol houtwormdood contains no acid, no base, no complexing agent, pH is not relevant since no water is present. However, the active substance permethrin contains halogens, Cl, although bound to carbon only and not in their free form in which they may be corrosive. Since the amount of active substance is only 0.25%w/w and a long term shelf-life study was performed in a metal can for 3.5 years, which did not show any signs of corrosion or degradation after 3.5 years, the eCA has agreed with a waiver for corrosiveness to metals study. |
| Auto-ignition temperatures of products (liquids and gases) | Auto-ignition temperature can be estimated to be >200°C, based on data for the solvent which is present in very large amount in the product. |
| Relative self-ignition temperature for solids | Not relevant for ready to use liquid. |
| Dust explosion hazard | Not relevant for ready to use liquid. |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Based on the low viscosity and the high amount of H304 classified components the product is classified with aspiration hazard (H304). No classification based on physical chemical properties is identified.  |

### Methods for detection and identification

HPLC according to standard operation procedure was used for validation of method of analysis used for permethrin determination in the product. Detection is determined via DAD at wavelength 225 nm.

Reagents and solvents: acetonitrile, demin. water and methanol

Method parameters:

Column Grom-SIL 120 ODS-4 (3 µm, 150 mm x 2 mm)

Eluent: (A) water, (B) acetonitrile

Solvent program: 50% B (0-5 min), 90% (5-25 min)

Oven: 40°C

Flow rate: 0.2 ml/min

Wavelength detection : 225 nm

Quantification by external standardization

Retention time permethrin: +/- 21.5 min

Sample preparation HPLC-DAD:

+/- 300 mg of test item is weighted into volumetric flask of 25 mL. 20 mL of methanol is added, afterwards the flask is put in an ultrasonic bath (5min.) for dissolution of the test item.

After cooling to room temperature, the flask is filled up to the mark with methanol. The filtered clear solution with test item was used for HPLC-DAD analysis.

Calibration solutions are prepared by solution of refrence substances with solvent methanol.

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| --- |
| **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 | HPLC-DAD | 80, 100 and 120% of nominal level of permethrin in the product (0.20, 0.25, 0.30% respectively); 2 replicates at each level | External standard calibration at 6 levels (15.59-43.09 mg/L); r2 =0.9992Equation: y=74.7954x + 92.9942 | Identity confirmed by HPLC-DAD.RT does not deviate >2% from calibration solution.No interference from matrix. | 98-100.1% | 99.4% | Precision: 0.19% (n=6)Horwitz equations concludes an acceptable %RSDr:%RSDR= 4.928% corresp. to% RSDr= 3.30 at analyte concentration of 0.25% w/w  | Not required | xxxx 2016 |

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| **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 | HPLC/MS/MS | Not available | Not available | Not available | Not available | Not available | Not available | 5.0 μg/kg in soil (permethrin) | CAR permethrin |

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| **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 | Not available | Not available | Not available | Not available | Not available | Not available | 5 μg/m3 air | CAR permethrin |
| permethrins | GC/ECD | Not available | Not available | Not available | Not available | Not available | Not available | 0.0001 mg/m3air | CAR permethrin |

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| **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 | HPLC/MS/MS | Not available | Not available | Not available | Not available | Not available | Not available | 0.05 µg/L for drinking and surface water | CAR permethrin |

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| **Analytical methods for animal and human body fluids and tissues** |
| **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 |
| No data required. Permethrin does not classify as toxic or highly toxic. | CAR permethrin |

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| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** |
| **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 |
| Food and feeding stuff will not be exposed to permethrin based on the proposed usage. No data required. | CAR permethrin |

### Efficacy against target organisms

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

Embasol Houtwormdood is a ready-to-use wood preservative solution (PT08) based on permethrin (0.25% w/w or 2 g/L). Field of use of the product Embasol Houtwormdood is the preventive (use class 1: situation in which the wood or wood based products is under cover, not exposed to the weather and wetting) and curative (for indoor application and outdoor application within the scope of an extensive curative treatment) control of woodboring beetles in wood.

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| **Categories** | **Matrix wording** | **Code for product** |
| **User category** | Non-professional/general publicIndustrialProfessional/Trained professional | A.10A.20A.30 |
| **Wood category** | Soft woodHardwood | B.10B.20 |
| **Wood product** | Solid wood/ Reconstituted solid wood/ Panels/ Plywood panels/ OSB panels/ Particles panels/ Fibers panels | C.10/C.11/C.20/C.21/C.22/C.23/C.24 |
| **Application aim and field of use** | Preventive treatment-use class 1Curative treatment / wood in service | D.40; E.10,D.50; E.10 |
| **Method of application and rate** | Superficial application / brush/roller/pad treatment Application rate preventive application:UC 1: 100%Retention:UC 1: 125 ml/m2 wood surfaceApplication rate curative application: 100% Retention: 250-300 ml/m2 wood surface Superficial application / spray treatment Application rate preventive application:UC 1: 100%Retention:UC 1: 125 ml/m2 wood surfaceApplication rate curative application: 100% Retention: 250-300 ml/m2 wood surface Superficial application / dipping treatment Application rate preventive application:UC 1: 100%Retention:UC 1: 125 ml/m2 wood surfaceApplication rate curative application: 100% Retention: 250-300 ml/m2 wood surface InjectionApplication rate curative application: 100% Retention: Depending on the dimensions of beams, the severity of the attack and the used injectors/injection holes.For the borehole method you will have 26 holes per m2. For a beam of 30 x 30 cm with injectors of 6 mm 6,36 ml will be used per borehole and with an injector of 10 mm 17,67 ml will be used per borehole. For a beam of 80 x 80 cm with an injector of 6 mm 16,96 ml will be used per borehole and with an injector of 10 mm 47,12 ml will be used per borehole.With the new patented injection method the average uptake per linear meter for a beam of 30 cm (30 x 30 cm) is 0,3 liter Embasol Houtwormdood and for a beam of 80 cm 1,5 liter per linear meter.Pressure process / vacuum pressure impregnationApplication rate:UC 1: 100%Retention:UC 1: 1.56-3,18 kg/m3 Pressure process / double vacuumApplication rate:UC 1: 100%Retention:UC 1: 1.56-3,18 kg /m³ | F.10       F.11      F.14     F.20      F.31      F.32 |
| **Target organisms** | Wood boring beetles-  | G.30 |

As mentioned in the table above, in addition to solid wood, the product is also intended for use on wood panels (post-manufacturing only). According to the Transitional Guidance on Efficacy Assessment for PT 8 (March 2015), biocidal treatment of wood-based panels can be achieved either during or after the manufacturing process. For post-manufacturing treatment, the product can be applied by using a “usual” surface application process or pressure process.

According to the guidance, in that case, the EN 599-1 (standard for solid wood) is appropriate for determining the retention of post manufacture treatment and therefore it is considered that no separate efficacy tests for panels are needed.

#### Function and field of use, organisms or objects to be protected

Embasol Houtwormdood is to be used as a product for preventive (use class 1) and curative treatment of wood for the control of wood boring beetles. The objects to be protected are softwood and hardwood.

#### Effects on target organisms, including unacceptable suffering

Acute toxicity with lethal effect (knock-down/mortality).

#### Mode of action, including time delay

Permethrin acts on the nervous system of insects. It interferes with sodium channels to disrupt the function of neurons, and causes muscles to spasm, culminating in paralysis and death. Permethrin can be effective by contact or ingestion and also acts as a mild repellent.

#### Efficacy data

The efficacy tests presented in this dossier to support the label claims have been conducted on the product Embasol Houtwormdood, with the exception of one test BAM 5.1/3314A, which was carried out with the formulation WTA-H-385. WTA-H-385 has a little less active (0.15% Permethrin vs 0.25% Permethrin for WTA-H-384) but the rest of the composition is equal.

Other (older) names for Embasol Houtwormdood used in the test reports are Xylamon Holzwurmtod (H-384), Xylamon Holzwurmtod (WTA-H-384), and Xylamon Woodwormkiller N.

Before any registration for Embasol Houtwormdood was applied for, tests were made internally at Desowag Bayer Holzschutz GmbH and at several institutes and the material was named WTA-H-384, DBH-H-384 (DBH stands for Desowag Bayer Holzschutz), Xylamon Holzwurmtod (H-384) and Xylamon Woodworm Killer N. After passing the needed tests in November 1984 there was the first application for registration of Embasol Houtwormdood under the name Xylamon Woodwormkiller (H-384).

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| **Experimental data on the efficacy of the biocidal product against target organism(s)** |
| **Function** | **Field of use envisaged** | **Test substance\*** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Wood preservative  | Control of insects – curative use- Superficial application,brushing | WTA-H-384 (test name for Xylamon Holzwurmtod (H-384)), now Embasol Houtwormdood | *Hylotrupes bajulus L.* | EN 22 (1975)(predecessor of EN1390 (2007)) | Wood type:Pine woodapplication rate 300mL/m2 (=240 g/m2)Test duration:12 weeks | After 12 weeks, 89% of the larvae were killed. | BAM 5.1/3313A |
| Wood preservative  | Control of insects – preventive use-Superficial application, Dipping  | Xylamon Holzwurmtod (WTA-H-384), now Embasol Houtwormdood | *Hylotrupes bajulus L.* | EN 46 (1977) (predecessor of EN 46-1 (2009) with EN 73 (evaporative ageing) | Wood type:Pine wood application rate 150 (= 120 g/m2) mL/m2 + 250 mL/m2 (=200g/m2) Test duration:24 weeks6 replicates for each treatment and 3 control treatment replicates. | After 24 weeks, 100% of the larvae were killed at both tested doses | EMPA23 10477 |
| Wood preservative  | Control of insects – preventive use-Superficial applation, Dipping  | WTA-H-385: same as H-384, except (0.15% m/m permethrin instead of 0,25% m/m permethrin) | *Hylotrupes bajulus L.* | EN 46 (1977) (predecessor of EN 46-1 (2009) | Wood type:Pine sapwood application rate 100 mL/m2 (=80g/m2)Test duration:4 weeks | After 4 weeks, 100% of the larvae were killed  | BAM 5.1/3314 A |
| Wood preservative  | Control of insects – curative use – brush application | WTA-H-384 (test name forXylamon Holzwurmtod (H-384)), now Embasol Houtwormdood | *Lyctus brunneus* | EN 20 (1975) (predecessor of EN 20(1993))- adapted for curative use | Wood type:European oakApplication rate 200mL/m2 (=160g/m2)5 replicates for product treatment for and 5 for control treatment.Test duration:5 months | After 5 months, 100% of the larvae were killed. | BAM 5.1/3313L |
| Wood preservative  | Control of insects – curative use – superficial application (pipette) | Xylamon Woodwormkiller N = Embasol Houtwormdood | *Anobium punctatum* | EN 48 | Wood type:Beech wood Application rate 300mL/m2 (240 g/m2)Test duration:12 weeks  | After 12 weeks, 100% of the larvae were killed. | PRL B8002 |
| Wood preservative | Control of insects – Preventive useimpregnation | Xylamon Woodwormkiller N = Embasol Houtwormdood  | *Anobium punctatum*  | EN 49 with EN 73 (evaporative ageing) | Wood type:Oak sapwoodApplication of solutions with different concentration (0.5 to 16% w/w)Test duration:52 weeks | Toxic values : Lowest loading preventing survival : 3.18 kg/m3Highest loading allowing survival : 1.56 kg/m3 | PJ07 31 |

\* identical to Embasol Houtwormdood; except with 0.15% permethrin

In the table in section 2.2.5.5, all tests for preventive use indicate guideline EN 73 to account for the ageing of the wood, except Study BAM 5.1/3314 A (*H. bajulus* – dipping application).

For this study, EN46 (the German ‘Abhobeltest’), ageing is not required since scraping/shaving off 2 mm respectively 4 mm of the treated surface is done. With ageing, a few cracks in the wood will appear, and some other alteration of the wood surface is possible, but these cracks and other alterations will be less deep than 4 mm. Scraping/shaving off 4 mm of the surface after ageing would mean a complete new outer surface is obtained.

For test EN46 +EN 73, the amount of eggs used in the test is too low. The standard requires at least 50 eggs to be laid on each test specimen. In the present work, the effect of the product at these high concentrations deterred beetles from laying eggs. Conform the standard 4 different sets of 5 beetle pairs were added in turn to those specimens which resulted in less than 50 eggs. The beetles were deterred from laying eggs or were premature mortal because of the high concentrations of the insecticides. Therefore, the test results are valid as the insecticide already prevents the beetles from laying eggs.

Certain tests are carried out based on previous versions of the Guidelines. Differences between the versions of these guidelines are:

**EN 22 version 1975 and EN 1390 version 2007 :**

EN 1390 (2007) is a revised and updated version of EN 22 (1975).

The scope of both standards and the principles of both test protocols are the same. There are several technical differences in the test protocols :

* the size of wood specimens used (in EN 1390 wooden blocks are made of sapwood only, they are smaller than in EN 22 and thus easier to prepare before testing.
* Number of test specimens used : 4 replicates, each infested with *12 H.bajulus* larvae prior to application of the wood preservative are required in EN 22, and 10 replicates each infested with 6 larvae are required in EN 1390.

The efficacy criteria are the same :

The test product is regarded as efficient if at least 80% mortality is recorded at the end of the test (12 or 24 weeks of exposure).

Regarding the interpretation of the test results, both standards are taken into account in the current version of standard EN 14128 (2003) “Performance criteria for products for curative uses against wood attacking organisms are determined by biological tests”, the following sentence can be read in the section 5 “Performance requirements for products against beetles : **“5.2.4 New tests shall be carried out against *Hyloptrupes bajulus* according to ENV 1390, however, former results from EN 22 tests shall remain valid.”**

**EN 46 version 1977 and EN 46-1 version 2009:**

EN 46-1 (2009) is a revised and updated version of EN 46 (1977)

This standard has been renamed EN 46-1 “Part 1 : Application by surface treatment (laboratory method)” when a second test protocol, described in the standard EN 46-2 “Part 2 : Ovicidal effect (laboratory method), has been set up. In EN 46-1, young larvae are used whereas eggs are used in EN 46-2. Consequently, the standards EN 46 (1977) and EN 46-1 (2007) describe the same test protocols. Few editorial and technical changes occurred over time, but these do not impact the issue of the test nor the assessment criteria used for the determination of the test product efficacy.

Additionally, the Annex G “Validity of test results from former standards after their revision” of the standard “EN599-1 (2009)”Efficacy of wood preservatives as determined by biological tests – Part 1 : Specification according to use class” mentions that, for products which have been successfully used in practice for at least 10 years, no limitations apply to the validity of the test results after revision of former European standards.

The methodological differences existing between old versions of the test standards and the revised ones (current versions) do not affect the validity of the tests.

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| **Conclusion on the efficacy of the product** |
| Evaluation of retentions with regard to the study reports:**Preventive : 125 ml Embasol Houtwormdood/m2**This retention is supported by the test studies from EMPA ref.nr. 23’10477 and from BAM ref. nr. 5.1/3314 A, Although the tested quantities in the EMPA report were above the claimed retention of 125 ml Embasol Houtwormdood (being 150 ml/m2 and 250 ml/m2, both with 100% mortality), the lower retention is certified through the test report from the BAM with the WTA-H- 385. This product is equal to Embasol Houtwormdood, the only difference is the amount of permethrin (0.15% for WTA-H-385 vs. 0.25% for Embasol Houtwormdood). The retentions for this product were 99-108 ml/m2 and gave 100% mortality. Although no ageing is performed in this test, the artificial ageing is replaced by scraping/shaving off 2 mm respectively 4 mm of the treated surface. Ageing generates a few cracks in the wood, which will be no more than 4 mm and some alteration of the wood surface will be seen but also less than 4 mm deep. Scraping/shaving off 4 mm of the surface after ageing would lead to a complete new surface. An average retention of 125 ml/m2 is prescribed for preventive treatment. **Preventive : 1.56 – 3.18 kg Embasol Houtwormdood/m3**This retention is supported by the EN 49 test study from the Building Research Advisory Service with ref.nr. PJ 07 31.**Curative : 250 – 300 ml Embasol Houtwormdood/m2**For the curative retention 3 test study reports (BAM 5.1/3313L, Building Research Advisory Service PRL/B8002(1) and BAM 5.1/3313A) are available for the support of the retention.From the BAM 5.1/3313A, it can be learned that 300 ml/m2 gave a mortality of 89% and that 250 ml/m2 gave a mortality of 75% with Hylotrupes bajulus after testing 12 weeks. Therefore the retention interval of 250-300 ml/m2 can be justified.The Building Research Advisory Service study test tested only a retention of 300 ml/m2 for Anobium punctatum and gave a 100% mortality.The BAM 5.1/3313L gave 100% mortality for Lyctus brunneus at a retention of 200 ml/m2.Looking at the Building Research Advisory Service study in combination with the BAM 5.1/3313L study it justifies that the retention tested at the Building Research Advisory Service is most likely an overdose.Based on all this study results and the assessment together justification for the retention interval 250-300 ml/m2 is present.Curative Injection: 1.56 – 7.63 Embasol Houtwormdood/m3With a beam of 30 x 30 cm you will have 13.5 m2 in 1 m3 of wood. This means with 26 boreholes per m2 that you will have an uptake of 2.23 liter (6 mm injectors) till 6.20 liter (10 mm injector) per m3 of wood.With a beam of 80 x 80 cm you will have 6.28 m2 in 1 m3 of wood. This means with 26 boreholes per m2 that you will have an uptake of 2.77 liter (6 mm injectors) till 7.69 liter (10 mm injector) per m3 of wood.With the new patented method the average uptake is 3.33 liter Embasol Houtwormdood per m3 for a 30 x 30 cm beam and 2.34 liter Embasol Houtwormdood per m3 for a 80 x 80 cm beam.If we assume that the curative uptake for penetration processes like injection is somewhere between 1 and 2.4 times the preventive uptake for penetration processes (300 ml/m2 divided by 125 ml/m2 [curative superficial uptake dived by preventive superficial uptake]), resulting in an interval from 1.56 kg/m3 till 7.63 kg/m3, the retentions mentioned and derived from practice for injection are justified.  |

#### Occurrence of resistance and resistance management

There are no reported cases of development of resistance involving the use of permethrin in wood preservation. Because of the anticipated low level of selection pressure from the proposed uses, no specific strategy for management of the development of resistance is required

#### Known limitations

For preventive treatment: For a good penetration the wood moisture content must be lower than 18%.

#### Evaluation of the label claims

The label claims are supported by results of efficacy tests.

1. Industrial use, penetrating or superficial treatment (preventive):

For industrial use, Embasol Houtwormdood can be applied to treat soft- and hardwood preventively against wood boring beetles, both through superficial and penetrating applications.

For penetrating applications the closed system applications vacuum pressure and double vacuum treatment can be used. For superficial applications open system applications can be used, such as immersion process.

According to the EN599, the requirements to cover a preventive treatment claim against wood boring beetles (general) is set by performing EN 46, EN 49 and EN 22 for superficial applications. For penetrating processes, EN 47, EN 49 and EN 20 should be performed to cover a general wood boring beetle claim. All tests should be accompanied by using artificial ageing (EN 73).

Penetrating treatment:

The required retention for the vacuum pressure and double vacuum treatment is set at 1.56 – 3.18 kg/m³ and is derived from the PJ0731, (EN 49 + EN 73) report.

Superificial treatment:

The retention for the immersion process is 125 ml/m² and is derived from results of the EMPA 23 10477 (EN 46 + EN 73), the BAM 5.1/3314 A (EN 46 no ageing, shaving off 2 and 4 mm of the wood surface after treatment) and the PJ07 31 (EN 49 + EN 73).

Based on the results from the PJ07 31 (EN 49 + EN 73), the retention would be set to 6.15-12.55 g/m². This is obtained by taking into account the conversion factor to transform results from penetrating treatments to a retention that can be applied for superficial treatment.

The EMPA 23 10477 report (EN 46 +EN 73) shows a retention of 150 ml Embasol Houtwormdood /m² results in 100% mortality and the BAM 5.1/3314A report (EN 46 without ageing but after shaving off 2 and 4 mm of the wood surface after treatment) shows a retention of 100 ml WTA-H385 /m² results in 100% mortality.

Test formulation WTA-H385 is equal to formulation WTA-384, the only difference is the amount active substance: WTA-H385 contains only 0.15% permethrin, while WTA-H384  (=Embasol Houtwormdood) contains 0.25% permethrin.

BAM 5.1/3314 A (EN 46 after shaving of 2 mm and 4 mm of the treated wood before testing) is a much more severe test as the EN 46 with ageing (EN 73). This is explained in the summary of efficacy results, and is based on the fact that ageing would only cause some cracks in wood surface which will not be deeper than 4mm. In addition, some alteration of wood surface may be visible but this will also not exceed 4 mm in depth. Shaving off the wood surface by 4 mm will therefore be worst case, as this would leave an entire ‘new’ or fresh wood surface for beetles to attack.

Based on these test results, a retention of 100 ml/m² can be proposed to be efficacious (or even less high, since the permethrin concentration in WTA-H385 is 1.67 times lower than the content in Embasol Houtwormdood). An average retention of both tests (EN49 +EN 73 and EN49 with shaving) is taken for superficial preventive treatment, by proposing a retention of 125 ml/m².

Although no tests are available to cover preventive treatment against *Lyctus brunneus*, a general claim for the preventive applications against wood boring beetles can be made, based on the results obtained from efficacy by curative treatments:

Test results for curative treatment against all three species are available. From these results, it can be seen that *Hylotrupes Bajulus* and *Anobium Punctatum* are less sensitive towards Embasol Houtwormdood compared to *Lyctus brunneus*. A retention of 300 ml/m² is required for curative treatment of *Hylotrupes Bajulus* and *Anobium Punctatum*, while a retention of 200 ml/m² is sufficient for curative treatment of *Lyctus Brunneus.* A higher dose is required to treat *Hylotrupes Bajulus* and *Anobium Punctatum*, making these 2 species less sensitive than *Lyctus brunneus* to the product Embasol Houtwormdood.

In conclusion, to obtain efficacious results against wood boring beetles (general claim) by superficial treatment, a retention rate of 125 ml/m2 is required.

1. Professional use, superficial treatment (preventive or curative):

For professional use, soft- and hardwood can be treated both preventively and curatively with Embasol Houtwormdood against wood boring beetles. It can be applied through brushing and/or spraying, the required retention depends on whether application is done as preventive or as curative treatment.

According to the EN599, the requirements to cover a preventive treatment claim against wood boring beetles is set by performing EN 46, EN 49 and EN 20 for superficial applications. All tests should be accompanied by using artificial ageing (EN 73).

According to the EN14128, the requirements to cover a curative treatment claim against wood boring beetles is set by performing EN22 and EN48.

- For preventive treatment a retention of 125 ml/m2 is required (see industrial use- superficial treatment).

- For a curative treatment a retention of 250-300 ml/m² is required. This can be derived from the reports PRL B8002 (EN48 *Anobium punctatum*),  BAM 5.1/3313L (EN 20 *Lyctus Brunneus*), BAM 5.1/3313A (EN22 *Hylotrupes Bajulus*).

From BAM 5.1/3313L (EN 20*)* a retention of 200 ml/m² was found to be sufficient to obtain 80% mortality for *Lyctus Brunneus*. From PRL B8002 (EN48) and BAM 5.1/3313A (EN22), a retention of 300 ml/m² was found to be sufficient to obtain 80% mortality for *Anobium Punctatum* and *Hylotrupes Bajulus* after 12 weeks. Based on these results and based on the practical knowledge that a curative treatment generally requires about twice the retention of a preventive treatment, a retention of 250-300 ml/m² was derived to conclude Embasol Houtwormdood is efficacious as fast acting insecticide for curative treatments against wood boring beetles.

For curative treatment, professional users can also use an injection application. The application rate is dependent on the dimensions of the beams, the severity of the attack and the type of injectors used and/or the type of injection holes. Since there are not yet reports/standards in regards to testing injection available, the retention is based on knowledge of what is used in practice.

For the borehole method, 26 holes per m² are assumed. For a beam of 30 x 30 cm treated with injectors of 6 mm, 6.36 ml of product will be used or with an injector of 10 mm, 17.67 ml of product will be used. For a beam of 80 x 80 cm treated with an injector of 6 mm, 16.96 ml of product will be used or with an injector of 10 mm, 47.12 ml of product will be used.

With the new patented injection method, the average retention per linear meter for a beam of 30 cm (30 x 30 cm) is 0.3 liter Embasol Houtwormdood and for a beam of 80 cm is 1.5 liter of product per linear meter. This is based on decades of experience in practice. Embasol Houtwormdood is registered and has been used in the different markets/countries for more than 33 years.

The data provided to support the stand-alone use by injection is considered to be insufficient to demonstrate efficacy for the authorisation of this method by itself. Application by injection can only be authorised at the claimed application rate if the treatment is combined with a curative superficial treatment (by brushing or spraying) at an application rate of 250-300 mL/m2.

1. Non-professional use, superficial treatment (preventive or curative):

For non-professional use, soft- and hardwood can be treated with Embasol Houtwormdood, both preventively as well as curatively against wood boring beetles. Embasol Houtwormdood can be applied by non-professionals using a brushing/painting application The retentions as mentioned above are required, being 125 ml/m² for preventive use (see industrial use- superficial treatment) and 250-300 ml/m² for curative use (see professional use- superficial treatment).

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

The product Embasol Houtwormdood is not intended to be authorised for use with other biocidal product(s).

### Risk assessment for human health

No toxicological studies have been performed on the product. The effects of the product on human health can be derived from information on the individual substances in the mixture. Active substance effects are described in the CAR for permethrin. Information on co-formulants is taken from public data (*i.e.* MSDS and data derived from ECHA on classification and labelling on notified and registered substances).

A human health risk assessment has been performed in accordance with the Technical notes for guidance -Human exposure to biocidal products - Guidance on exposure estimation (TNGs) and the CAR for permethrin (PT8).

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

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| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | None of the ingredients are classified for skin corrosion or skin irritation |
| Justification for the value/conclusion | Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008  |
| Classification of the product according to CLP  | No classification of the product proposed |

***Eye irritation***

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| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | None of the ingredients are classified for eye irritation |
| Justification for the value/conclusion | Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008 |
| Classification of the product according to CLP  | No classification of the product proposed |

***Respiratory tract irritation***

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| **Conclusion used in the Risk Assessment – Respiratory tract irritation** |
| Value/conclusion | None of the substances in the product is classified for respiratory tract irritation |
| Justification for the conclusion | Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008 |
| Classification of the product according to CLP  | No classification of the product proposed |

***Skin sensitization***

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| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | The active substance is classified as a skin sensitizer cat 1 but is present below the threshold for classification of the mixture |
| Justification for the value/conclusion | Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008 |
| Classification of the product according to CLP  | No classification of the product proposed |

***Respiratory sensitization (ADS)***

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| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | None of the substances in the product is classified for respiratory sensitization |
| Justification for the value/conclusion | Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008 |
| Classification of the product according to CLP  | No classification of the product proposed |

***Acute toxicity***

*Acute toxicity by oral route*

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| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | The active substance is classified as acute oral tox cat 4, based on its concentration classification of the mixture is not triggered |
| Justification for the selected value | Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008 |
| Classification of the product according to CLP  | No classification of the product proposed |

*Acute toxicity by inhalation*

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| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | The active substance is classified as acute inhalation tox cat 4; based on its concentration classification of the mixture is not triggered |
| Justification for the selected value | Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008 |
| Classification of the product according to CLP  | No classification of the product proposed |

*Acute toxicity by dermal route*

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | None of the substances in the product is classified for acute dermal toxicity |
| Justification for the selected value | Application of criteria on mixture classification based on ingredients as set out in the CLP Regulation 1272/2008 |
| Classification of the product according to CLP  | No classification of the product proposed |

***Information on dermal absorption***

|  |
| --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Value(s) | For the active substance the default value of 70% is used |
| Justification for the selected value(s) | Dermal absorption of permethrin is 3% according to the CAR of permethrin. According to the EFSA Guidance on Dermal absorption (2017), a default value can be used when no data is available for dermal absorption performed on the formulation. For a ready to use solvent based formulation, a default value of 70% is to be used. This value is taken into account in the risk assessment.  |

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

The product is classified as H304 (Asp Tox 1), due to the presence of the substance ‘Distillates (petroleum), hydrotreated light’ SoC (Band A) classified as H304 in combination with low viscosity of the product formulation. In accordance to the SoC guidance, H304 classification fall in Band A. For the evaluation of exposure to SoC (Band A), it is considered sufficient to apply appropriate P-phrases associated with the concerned H-phrase. It this particular case, following P-phrases are included:

P301+P310 : IF SWALLOWED : immediately call a poison center or doctor/physician;

P331 : Do NOT induce vomiting;

P405 : Store locked up

For all information on substances of concern, please refer to the confidential annex.

***Available toxicological data relating to a mixture***

None.

***Other***

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

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

b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

c) the adverse effect is a consequence of the endocrine mode of action.

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

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

Subsequently, it was examined if there are any concerns for adverse effects to meet the critaria a.

From this criteria ED screening was performed by NL CA for co-formulants contained in Embasol Houtwormdood.

None of the co-formulants triggered an alert for ED property. and therefore no further ED assessment was required.

#### Exposure assessment

Embasol Houtwormdood is ready to use liquid containing 0.25% (2 g/L) permethrin as an active substance. The proposed field of use of Embasol Houtwormdood is PT8: preventive and curative treatment of wood as protection against insects (indoor use or under shelter). Applications can be done by coarse spraying and brushing (professional and non-professional use), dipping (industrial and professional use), injection (professional use) or by pressure process / (double) vacuum pressure impregnation (industrial use).

The user can be dermally exposed to permethrin during application of the formulation by coarse spraying, brushing, dipping/drenching or by pressure process / (double)vacuum pressure impregnation. As the vapour pressure of permethrin is very low (2.155 x 10-6 Pa at 20 °C), and no aerosol forming is expected during brushing, dipping/drenching, injection or impregnation operations, respiratory exposure during these applications is considered to be negligible. During the application by coarse spraying respiratory exposure to droplet particles is possible; these particles are expected to be outside respirable range (> 50 μm), a fraction of the particles will be inhalable (i.e. enters the nose and mouth and will be available for deposition in the respiratory tract).

**Identification of main paths of human exposure towards active substance(s) 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 | yes | yes | yes | n.a | n.a | yes | n.a |
| Dermal | yes | yes | yes | n.a | n.a | yes | n.a |
| Oral | no | no | no | n.a | n.a | yes | n.a |

*\* Label statement : not to be used on the materials which may come into contact with food and drinks*

***List of scenarios***

Seven scenarios are modelled for the primary exposure due to application (professional and non-professional); i.e :

- 1 application scenario covering application by coarse spraying for professional applicators (dermal and inhalation exposure),

- 1 for injection via wood injector (pressure impregnation) for professional applications (dermal and inhalation exposure)

- 1 for injection via pouring (no pressure) for professional applications (dermal exposure)

* 1 for brushing (dermal exposure) applications (covering both professional and non-professional applications),
* 1 for dipping/drenching (dermal exposure) applications (professional/industrial only)
* 1 for vacuum/pressure processes (industrial use only) and
* 1 for double vacuum/pressure processes (industrial use only)

The models used are based on the TNsG Part 2, (2002) (+User Guidance v.1, 2002) and on the CAR of permethrin (Ireland, 2014). However, this is assumed to be less worse case than e.g spray applications and therefore its risk is assumed to be covered.

Several pathways of indirect exposure have been assessed in the CAR of permethrin for PT8:

-  Adult handling treated timber – acute exposure

-  Adult cutting/sanding treated wooden posts – acute and chronic exposure

-  Infant chewing treated wood off-cut – acute exposure

-  Child playing on the playground structure – chronic exposure

* -  Infant playing on weathered playground structure and mouthing – chronic
* exposure

-  Infant, child and adult inhalation of volatilised residues – chronic exposure

* Inhalation exposure due to the inhalation of volatilized residues is expected to be negligible due to the very low vapour pressure of permethrin (2.155 x 10-6 Pa at 20 °C).

| **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. | Application – coarse spraying | Spraying Model 2/ TNsG Part 2, (2002) (based on CAR permethrin) | Professional users |
| 2.a. | Application – injection with injector | Subsoil treatment Model 2 / TNsG Part 2, (2002) | Professional users |
| 2.b. | Application - injection by pouring | Mixing and loading Model 4 / TNsG Part 2, (2002) | Professional users |
| 3. | Application – brushing | Consumer product painting model 3 / TNsG Part 2, (2002) (based on CAR permethrin) | Professional and Non-professional users |
| 4. | Application – dipping/drenching | Handling Model 1 / TNsG Part 2, (2002) | Industrial/Professional user |
| 5. | Application – vacuum pressure | Handling model 1 / TNsG Part 2, (2002) | Industrial user |
| 6. | Application – double vacuum pressure | Handling model 1 / TNsG Part 2, (2002) | Industrial user |
| 7. | Adult handling treated timber – acute exposure scenario   | Based on the draft final CAR of permethrin the following assumptions are made:All the permethrin applied to the timber sits on the timber surface for dermal contact scenariosAll of the permethrin applied to the surface is dislodgeableTransfer efficiency of 2% for rough sawn wood100 contacts/day | Bystanders adult (secondary exposure) |
| 8. | Adult cutting/sanding treated wooden posts – acute and chronic exposure scenarios | TNsG Part 2, (2002) | Bystanders adult (secondary exposure) |
| 9. | Infant chewing treated wood off-cut – acute exposure scenario | TNsG Part 2, (2002) | Bystanders infants(secondary exposure) |
| 10. | Child – playing on playground structure outdoors  | TNsG Part 2, (2002) | Bystanders children (secondary exposure) |
| 11. | Infant – playing on weathered structure and mouthing  | TNsG Part 2, (2002) | Bystanders infants (secondary exposure) |

**Output tables from exposure assessment tools are included in Annex 3.2**

***Industrial/Professional exposure***

*Scenario [1] : Application : coarse spraying (professional user)*

| **Description of Scenario [1]** |
| --- |
| The application solution is applied to the wood by coarse spraying. The calculation is based on Spraying Model 2 (TNsG Part 2, (2002) in accordance with the draft final CAR on permethrin. Dermal exposure is considered. A body weight of 60kg and a breathing rate of 0.021 m3/min is considered for applicators. A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873). The concentration of permethrin in Embasol Houtwormdood is 0.25%. Inhalation by coarse spraying was negligible as described previously. The exposure duration is considered to be 80 minutes.Inhalation exposure from coarse spraying is considered negligible. Therefore, permethrin exposure via inhalation route is not considered.  |
|  | Parameters1 | Value |
| Tier 1(potential exposure) | Potential dermal body exposure – in-use product | 222 mg/min (TNsG 2002)  |
| Potential hand exposure – in-use product | 273 mg/min (TNsG 2002)\* |
| Inhalation exposure | 76 mg/m3 (TNsG 2002) |
| Exposure duration | 80 minutes |
| Tier 2(clothing covering body; gloves) | Potential dermal body exposure – in-use product | 222 mg/min (TNsG 2002)  |
| Default reduction factor clothing | 90% |
| Potential hand exposure (inside gloves) – in-use product | 7.80 mg/min (TNsG 2002) |
| Tier 3 (impermeable coverall gloves  | Potential dermal body exposure – in-use product | 222 mg/min (TNsG 2002)  |
| Default reduction factor clothing | 95% |
|  |  |

\*max value for deposition outside of protective glove

**Calculations for Scenario [1]**

|  |
| --- |
| **Summary table: estimated exposure from professional uses** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(internal)****(mg/kg/day)** | **Estimated dermal uptake (internal)****(mg/kg/day)**  | **Estimated oral uptake** | **Estimated total uptake****(internal)****(mg/kg/day)** |
| 1.coarse spraying | 1/no PPE | 0.005 | 1.155 | n.a. | 1.160 |
| 1.coarse spraying | 2/gloves+coverall | 0.005 | 0.0700 | n.a. | 0.075 |
| 1.coarse spraying | 3/ gloves + impermeable coverall | 0.005 | 0.044 | n.a. | 0.049 |

*Scenario [2a] : Application : injection with injector (professional user)*

| **Description of Scenario [2a]** |
| --- |
| The application solution is applied to the wood by professional users using a wood injector. The calculation is based on Subsoil treatment Model 2 (TNsG Part 2, (2002). Both dermal and inhalation exposure are considered. A body weight of 60kg is considered for applicators. A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873). The concentration of permethrin in Embasol Houtwormdood is 0.25%. The exposure duration is considered to be 80 minutes.  |
|  | Parameters | Value |
| Tier 2(gloves) | Actual hand exposure (inside gloves) – in-use product | 8 mg product/min (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure |
| Indicative inhalation exposure (non-volatile compounds) | 0.57 mg product/m3 (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure) |
| Exposure duration | 80 minutes (recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure) |

*Scenario [2b] : Application : injection by pouring (professional user)*

| **Description of Scenario [2b]** |
| --- |
| The application solution is applied to the wood by professional users by pouring (no pressure). The calculation is based on Mixing and loading Model 4 (TNsG Part 2, (2002). Only dermal exposure is considered relevant for non-volatile compounds. A body weight of 60kg is considered for applicators. A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873). The concentration of permethrin in Embasol Houtwormdood is 0.25%. The number of loadings per day is set at 100.  |
|  | Parameters | Value |
| Tier 1(potential exposure) | Potential hand exposure – in-use product | 10 mg product/loading (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure) |
| Number of loadings | 100 (Recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure) |

**Calculations for Scenario [2a, 2b]**

|  |
| --- |
| **Summary table: estimated exposure from professional uses** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(internal)****(mg/kg/day)** | **Estimated dermal uptake (internal)****(mg/kg/day)**  | **Estimated oral uptake** | **Estimated total uptake****(internal)****(mg/kg/day)** |
| 2a. injection (injector) | 2/gloves | 0.00004 | 0.019 | n.a | 0.019 |
| 2b. injection (pouring) | 1/ no PPE | n.a. | 0.029 | n.a | 0.029 |

*Scenario [3] : Application : brushing (professional user)*

| **Description of Scenario [3]** |
| --- |
| The application solution is applied to the wood by brushing by professional users. The calculation is based on Consumer product painting model 3 (TNsG Part 2, (2002) in accordance with the draft final CAR on permethrin. Only dermal exposure is considered; inhalation exposure is considered to be negligible based on the low vapour pressure and lack of aerosol forming during brush applications. A body weight of 60kg is considered for applicators. A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873). The concentration of permethrin in Embasol Houtwormdood is 0.25%. The exposure duration is considered to be 4 hours (CAR on permethrin). The application area is calculated using the median work rate of 7.6 min/m² (acc. to TNsG 2002 "Consumer product painting Model 3" and the exposure duration of 240 min. Calculation: 1/7.6 min/m² \*240 min = 31.6 m²  |
|  | Parameters1 | Value |
| Tier 1(potential exposure) | Potential dermal body exposure – in-use product | 0.2382 mg product/ m2 (TNsG 2002)  |
| Potential hand exposure – in-use product | 0.5417 mg product/ m2 (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure) |
|  | Potential inhalation exposure | 0.0016 mg product/m3 |
| Tier 2(gloves) | Default reduction factor for gloves | 90% |

**Calculations for Scenario [3]**

|  |
| --- |
| **Summary table: estimated exposure from professional uses** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(internal)****(mg/kg/day)** | **Estimated dermal uptake (internal)****(mg/kg/day)** | **Estimated oral uptake** | **Estimated total uptake****(internal)****(mg/kg/day)** |
| 3.brush | 1/ no PPE | 0.0002 | 0.0719 | n.a | 0.0721 |
| 3.brush | 2/gloves | 0.0002 | 0.0269 | n.a | 0.0272 |

*Scenario [4] : Application : dipping/drenching (industrial/professional user)*

| **Description of Scenario [4]** |
| --- |
| The application solution is applied to the wood by dipping or drenching by a professional/industrial user. The calculation is based on Handling Model 1 (TNsG Part 2, (2002). Only dermal exposure is considered; inhalation exposure is considered to be negligible. A body weight of 60kg is considered for applicators. A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873). The concentration of permethrin in Embasol Houtwormdood is 0.25%. Four cycles per day are considered. The exposure values considered are those for solvent based formulations.  |
|  | Parameters1 | Value |
| Tier 1(potential exposure) | Potential dermal body exposure – in-use product | 158 mg/cycle (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure, solvent based)  |
| Potential hand exposure – in-use product | 26000 mg/cycle (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure)\* |
| Tier 2(gloves) | Actual hand exposure (inside gloves) – in-use product | 260 mg/cycle (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure)\* |

*\* The hand exposure without gloves is recalculated form actual exposure inside gloves using a factor 100 for the use of gloves and is equal to 26000 mg/min. Gloves are assumed as a standard in the dipping models*

**Calculations for Scenario [4]**

|  |
| --- |
| **Summary table: estimated exposure from professional uses** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(internal)****(mg/kg/day)** | **Estimated dermal uptake (internal)****(mg/kg/day)** | **Estimated oral uptake** | **Estimated total uptake****(internal)****(mg/kg/day)** |
| 4.dipping | 1/no PPE | negligible | 3.052 | n.a. | 3.052 |
| 4.dipping | 2/ gloves | negligible | 0.049 | n.a. | 0.049 |

*Scenario [5] : Application : vacuum treatment (industrial user)*

| **Description of Scenario [5]** |
| --- |
| The application solution is applied to the wood by vacuum-pressure treatment by industrial users. The calculation is based on Handling model 1 (TNsG Part 2, (2002) in accordance with the draft final CAR on permethrin. Both dermal and inhalation exposure are considered. A body weight of 60kg is considered for applicators. A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873). The concentration of permethrin in Embasol Houtwormdood is 0.25%. Three cycles per day are considered. The exposure values considered are those for solvent based formulations. The exposure duration for inhalation exposure is set at 30 minutes (opening of door, for 3 cycles)  |
|  | Parameters1 | Value |
| Tier 1(potential exposure) | Potential body exposure – in-use product | 158 mg/cycle (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure, solvent based)  |
| Potential hand exposure – in-use product | 26000 mg/cycle (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure, solvent based)\* |
| Potential inhalation exposure – in-use product | 0.6 mg/m3 (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure, solvent based)  |
| Tier 2(gloves) | Hand exposure inside gloves – in use product | 260 mg/cycle (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure, solvent based ) |

*\* The hand exposure without gloves is recalculated form actual exposure inside gloves using a factor 100 for the use of gloves and is equal to 26000 mg/min. Gloves are assumed as a standard in the vacuum/pressure models*

**Calculations for Scenario [5]**

|  |
| --- |
| **Summary table: estimated exposure from industrial uses** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake (internal)** | **Estimated oral uptake** | **Estimated total uptake** |
| **(internal)** | **(mg/kg/day)** | **(internal)** |
| **(mg/kg/day)** |   | **(mg/kg/day)** |
| 5.vacuum | 1/no PPE | 1.56E-05 | 2.29 | n.a. | 2.29 |
| 5.vacuum | 2/gloves | 1.56E-05 | 0.037 | n.a. | 0.037 |

*Scenario [6] : Application : double vacuum treatment (industrial user)*

| **Description of Scenario [6]** |
| --- |
| The application solution is applied to the wood by double vacuum-pressure treatment by industrial users. The calculation is based on Handling model 1 (TNsG Part 2, (2002) in accordance with the draft final CAR on permethrin. Both dermal and inhalation exposure are considered. A body weight of 60kg is considered for applicators. A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873. The concentration of permethrin in Embasol Houtwormdood is 0.25%. Six cycles per day are considered. The exposure values considered are those for solvent based formulations. The exposure duration for inhalation exposure is set at 60 minutes (opening of door, for 6 cycles) |
|  | Parameters1 | Value |
| Tier 1(potential exposure) | Potential body exposure – in-use product | 158 mg/cycle (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure, solvent based)  |
| Potential hand exposure – in-use product | 26000 mg/cycle (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure, solvent based)\* |
|  | Potential inhalation exposure – in-use product | 0.6 mg/m3 (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure, solvent based)  |
| Tier 2(gloves+ coveral) | Default reduction factor coverall | 90% |
| Hand exposure inside gloves – in use product | 260 mg/cycle (TNsG 2002, recommendation no. 6of the BPC Ad hoc Working Group on Human Exposure, solvent based) |

*\* The hand exposure without gloves is recalculated form actual exposure inside gloves using a factor 100 for the use of gloves and is equal to 26000 mg/min. Gloves are assumed as a standard in the vacuum/pressure models*

**Calculations for Scenario [6]**

|  |
| --- |
| **Summary table: estimated exposure from industrial uses** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake (internal)** | **Estimated oral uptake** | **Estimated total uptake** |
| **(internal)** | **(mg/kg/day)** | **(internal)** |
| **(mg/kg/day)** |   | **(mg/kg/day)** |
| 6.double vacuum | 1/no PPE | 1.56E-05 | 4.58 | n.a. | 4.58 |
| 6.double vacuum | 2/gloves + coverall | 1.56E-05 | 0.048 | n.a. | 0.048 |

**Further information and considerations on scenario [1,2a, 2b, 3, 4, 5, 6]**

The product is classified as H304 (Asp Tox 1), due to the presence of a SoC (Band A) classified as H304 in combination with low viscosity of the product formulation.

 For the evaluation of exposure to SoC (Band A), it is considered sufficient to apply appropriate P-phrases associated with the concerned H-phrase. It this particular case, following P-phrases are included:

P301+P310 : IF SWALLOWED : immediately call a poison center or doctor/physician;

P331 : Do NOT induce vomiting;

P405 : Store locked up

In addition, it was noted by the eCA the local effects should also be assessed , considering the BPC opinion on the application for approval of permethrin (ECHA/BPC/003/2014) as PT 8, included the statement: *The possibility of skin sensitisation to non-professionals from products containing permethrin should be addressed by a risk assessment at product authorisation since the active substance is classified as a potential sensitiser. Below a table is added describing the local effects and qualitative risk characterization.*

**Local effects:**

Product Embasol Houtwormdood is not classified for skin sensitization, but is labelled with EUH0208 based on the permethrin concentration. No other local effects are linked to the product. Based on a co-formulant classification with EUH066 is triggered.

|  |  |  |
| --- | --- | --- |
| **Hazard** | **Exposure** | **Risk** |
| **HazardCategory** | **Effectsintermsof C&L** | **Additionalrelevanthazardinformation** | **PT** | **Who is exposed?** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** |
| EUH208, EUH066 | Not classified | Potential of skin sensitizing effects due to presence of permethrin | 8 | professional users | Application of RTU liquid viaSpraying, brushing, dipping or injection  | skin | Frequency:dailyDuration:Spraying and injection (injector):80 minBrushing:240 minDipping:120 minInjection (pouring):Few minutes per day (100 loads per day) | Low , splashes on hands during use | None required, product is not classified as skin sensitizing. use instructions may include: wash hands after usefor systemic exposure results, following PPE are already required:gloves +coverall during sprayinggloves during injection (injector)gloves during dippingfor brushing no PPE are prescribed, gloves may be worn during use but are not obligatory | Acceptable:No classification for hazard categories, use instructions will be followed by professional users.  |
| EUH208, EUH066 | Not classified | Potential of skin sensitizing effects due to presence of permethrin | 8 | Industrial users | Application of RTU liquid via(double) vacuum treatment, dipping | skin | Frequency:dailyDuration:Double vac.: 6 cycles /day Vac. treat.: 3 cycles/day Dipping: 4 cycles/day(30 min per cycle) | Low , splashes on hands or body during use | None required, product is not classified as skin sensitizing. use instructions may include: wash hands after usefor systemic exposure results, following PPE are already required:gloves +coverall during double vacuum treatmentgloves during vacuum treatment and dipping treatment | Acceptable:No classification for hazard categories, use instructions will be followed by industrial users  |

*Scenario [3b] : Application : brushing (non-professional user)*

| **Description of Scenario [3]** |
| --- |
| The application solution is applied to the wood by brushing by non-professional users. The calculation is based on the BEAT model “Austrian wood preservatives water-based/solvent-based” (Austrin-BfR), in accordance with HEAdhoc Recommendation no. 10, 2016.. The BEAT model provides no data on inhalation, for inhalation exposure estimate “Consumer product painting model 3” (TNsG 2002) is used.A body weight of 60kg is considered for applicators. A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873). The concentration of permethrin in Embasol Houtwormdood is 0.25%. The exposure duration is 150 min (acc. to TNsG 2002 User Guidance, vers. 1, p. 51 for non-professionals).  |
|  | Parameters1 | Value |
| Tier 1(potential exposure) | Potential dermal body exposure – in-use product | 1.12 µl/min (solvent-based) |
| Potential hand exposure – in-use product | 9.14 µl/min |
|  | Indicative value for inhalation exposure | 1.63 mg/m3 |

\* see calculation below

Calculation :

Inhalation exposure

1.63 mg/m3 x 0.25% a.s x 1.25 m3/h x (150 min/60 min) = 0.0127 /60 kg = 0.0002 mg/kg bw/day

Dermal exposure

(1.12 + 9.14 µl/min) x 150 min x 0.7974 g/ml x 0.25% x 70% = 2.15 mg/kg / 60 kg = 0.036 mg/kg bw/day

**Calculations for Scenario [3b]**

|  |
| --- |
| **Summary table: estimated exposure from non-professional uses** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(internal)****(mg/kg/day)** | **Estimated dermal uptake (internal)****(mg/kg/day)** | **Estimated oral uptake** | **Estimated total uptake****(internal)****(mg/kg/day)** |
| 3.brush | 1/ no PPE | 0.0002 | 0.036 | n.a | 0.036 |

**Further information and considerations on scenario [2c, 3]**

The product is classified as H304 (Asp Tox 1), due to the presence of a SoC (Band A) classified as H304 in combination with low viscosity of the product formulation.

 For the evaluation of exposure to SoC (Band A), it is considered sufficient to apply appropriate P-phrases associated with the concerned H-phrase. It this particular case, following P-phrases are included:

P301+P310 : IF SWALLOWED : immediately call a poison center or doctor/physician;

P331 : Do NOT induce vomiting;

P405 : Store locked up

In addition , it was noted by the eCA the local effects should also be assessed , considering the BPC opinion on the application for approval of permethrin (ECHA/BPC/003/2014) as PT 8, included the statement: *The possibility of skin sensitisation to non-professionals from products containing permethrin should be addressed by a risk assessment at product authorisation since the active substance is classified as a potential sensitiser. Below a table is added describing the local effects and qualitative risk characterization.*

**Local effects:**

Product Embasol Houtwormdood is not classified for skin sensitization, but is labelled with EUH0208 based on the permethrin concentration. No other local effects are linked to the product. Based on a co-formulant classification with EUH066 is triggered.

|  |  |  |
| --- | --- | --- |
| **Hazard** | **Exposure** | **Risk** |
| **HazardCategory** | **Effectsintermsof C&L** | **Additionalrelevanthazardinformation** | **PT** | **Who is exposed?** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** |
| EUH208 and EUH066 | Not classified | Potential of skin sensitizing effects due to presence of permethrin | 8 | Non-professional users | Application of RTU liquid via brushing or injection (pouring) | skin | Frequency:Low: 1 to few times/ yearDuration:Brushing:240 minInjection:Few minutes per day (100 loads per day) | Low , splashes on hands during use | None required, product is not classified as skin sensitizing. use instructions may include: wash hands after use | Acceptable:No classification for hazard categories, low frequency of use of the product by non-professional users. |

***Exposure of the general public***

*Scenario [7] : secondary exposure – handling of treated wood (adult) – acute exposure*

| **Description of Scenario [7]** |
| --- |
| This scenario models dermal exposure following handling of treated wood (acute exposure). Following further assumptions are made, in line with the CAR for permethrin :All the permethrin applied to the timber sits on the timber surface for dermal contact scenarios and all of the permethrin applied to the surface is dislodgeable.The surface loading of the wood is calculated based on the concentration of 0.25% permethrin (2g/L) and an application rate of 300mL in-use solution per m2 wood. A body weight of 60kg is considered for adult bystanders. A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873) |
|  | Parameters | Value |
| Tier 1 | Surface loading wood | 0.06 mg permethrin/cm2 |
| Exposure frequency | 100 contacts/day (CAR permethrin) |
| Exposed area | 164 cm2(20% of the hands contaminated, based on the hand surface of 820 cm2 according to the HEEG Opinion on default factors) |
| Transfer efficiency | 2%(rough sawn wood; TNsG 2002)  |

**Calculations for Scenario [7]**

|  |
| --- |
| **Summary table: systemic exposure from non-professional uses** |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake****(internal)****mg/kg/day\*** | **Estimated oral uptake** | **Estimated total uptake****(internal)****mg/kg/day** |
| 7.handling | 1/no PPE | n.a | 0.23 | n.a | 0.23 |

\* see calculation below

Calculation :

Embasol Houtwormdood is ready to use liquid containing 0.25% (2 g/L) permethrin as an active substance. For the application on wood, 300 ml Embasol Houtwormdood per m2 wood surface is used. Thus, taking into account a concentration of 2 g/L and the use of 300 ml product/m2 (equal to 23.9 mg product/cm2 based on a density of 0.7974 g/cm3), the application rate of the active substance is 0.6 g/m2 (i.e. 0.06 mg/cm2).

Exposure = 164 cm2 x 0.06 mg/cm2 x 100 contacts x 70% x 2% = 13.776 mg permethrin/ day /60 kg = 0.23 mg/kg/day

*Scenario [8] : secondary exposure – Adult cutting/sanding treated wooden posts – acute and chronic exposure scenarios*

| **Description of Scenario [8]** |
| --- |
| This scenario models dermal and inhalation exposure for adults sanding (powered sander) wooden posts (4 cm x 4 cm x 2.5 m) for one hour. The posts have been treated with Embasol Houtwormdood (0.25% permethrin or 2g/L) in accordance with the use prescriptions. A body weight of 60kg is considered for adult bystanders. A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873) |
|  | Parameters | Value |
| Tier 1 | Volume wooden post | 0.004 m3 |
| Product uptake by the wood | 3.18 kg/m3 (Embasol Houtwormdood label ) |
| Inhalation exposure | 5 mg/m3 (occupational limit for wood dust) |
| Density wood dust | 0.4 g/cm3 |
| Inhalation rate | 1.25 m3/hour  |
| Active substance residue on wood surface  | 0.008 mg/cm2 |
| Transfer rate | 2% (rough sawn wood; TNsG 2002) |
| Exposed area | 84 cm2(20% of the hand palms contaminated, based on the hand surface of 840 cm2 according to the HEEG Opinion on default factors) |

**Calculations for Scenario [8]**

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(internal)****mg/kg/day\*** | **Estimated dermal uptake****(internal)****mg/kg/day\*** | **Estimated oral uptake** | **Estimated total uptake****(internal)****mg/kg/day** |
| 8. sanding | 1/no PPE | 0.0000028 | 0.0012 | n.a | 0.0012 |

\* see calculation below

Calculation :

Assumptions:

A person (non-professional, 60 kg bw) is sanding the surface of treated wood posts

(4 cm × 4 cm × 2.5 m, surface area = 4032 cm², volume = 4000 cm³) for an outdoor play area. The volume of the treated part of the post is 3008 cm3. Assuming a product uptake by the wood of 3.18 kg/m3 and that the product contains 0.25% of the active substance, the treated wood contains 0.008 mg active substance/cm3.

**Inhalation Exposure** :

The concentration of permethrin in the post is 0.008 mg/cm3x 4000 cm3/ 3008 cm3 = 0.011 mg/cm3.

Therefore, inhalation exposure to active substance is 0.011 mg/cm3x 5mg/cm3 x 1.25 m3x 1 hour = 0. 0002 mg permethrin / 60 kg = 0.0000028 mg/kg bw/day.

**Dermal exposure :**

= 84 cm2 x 0.06 mg/cm2 x 70% x 2% = 0.071 mg permethrin / 60 kg = 0.0012 mg/kg bw/day

*Scenario [9] : secondary exposure – Infant chewing treated wood off-cut – acute exposure scenario*

| **Description of Scenario [9]** |
| --- |
| Infant picks up and chews wood off-cut (4 cm x 4 cm x1 cm), which has been treated with Embasol Houtwormoood (0.25% permethrin or 2g/L) in accordance with the use prescriptions. A body weight of 8kg is considered for infants (HEEG Opinion on default factors).  |
|  | Parameters | Value |
| Tier 1 | Volume off-cut wood | 16 cm3 |
| Product uptake by the wood | 1.56-3.18 kg/m3 (Embasol Houtwormdood label ) |
| Extraction by chewing | 10% |

**Calculations for Scenario [9]**

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(internal)****mg/kg/day** | **Estimated dermal uptake****(internal)****mg/kg/day** | **Estimated oral uptake****(internal)****mg/kg/day)\*** | **Estimated total uptake****(internal)****mg/kg/day** |
| 9. chewing | 1/no PPE | n.a | n.a | 0.0016 | 0.0016 |

\* see calculation below

Calculation :

3.18 kg/m3 x 0.25%= 0.008 mg permethrin/cm3 x 16cm3 x 10% = 0.013mg permethrin/event / 8kg = 0.0016 mg/kg bw/d.

 Since the oral absorption of permethrin is 100%, the systemic exposure does not need to be corrected for oral absorption.

*Scenario [10] : secondary exposure – child playing on playground structure (chronic exposure)*

| **Description of Scenario [10]** |
| --- |
| This scenario models a child playing on playground structure outdoors. The structures are made of wood, which has been treated with wood preservative and there is prolonged and repeated contact of wood with hands*.* Following further assumptions are made, in line with the CAR for permethrin :All the permethrin applied to the timber sits on the timber surface for dermal contact scenarios and all of the permethrin applied to the surface is dislodgeable.The surface loading of the wood is calculated based on the maximum use rate of 300mL Embasol Houtwormdood (0.25% or 2g/L permethrin) per m2 wood.A body weight of 23.9kg is considered for children (HEEG Opinion on default factors). A dermal absorption of 70% is considered for permethrin (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873) |
|  | Parameters | Value |
| Tier 1 | Surface loading wood | 0.06 mg permethrin/cm2 |
| Exposed area | 85.56cm2(20% of the hands contaminated, based on the hand surface of 427.8 cm2 according to the HEEG Opinion) |
| Transfer efficiency | 2%(rough sawn wood; TNsG 2002) |

**Calculations for Scenario [10]**

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake****(internal)****mg/kg/day\*** | **Estimated oral uptake** | **Estimated total uptake****(internal)****mg/kg/day** |
| 10. playground | 1/no PPE | n.a | 0.003 | n.a | 0.003 |

\* see calculation below

Calculation :

Exposure = 85.56 cm2 x 0.06 mg/cm2 x 70% x 2% = 0.0719 mg permethrin/ day / 23.9 kg = 0.003 mg/kg/day

*Scenario [11] : secondary exposure – infant playing on and mouthing weathered structure (chronic exposure)*

| **Description of Scenario [11]** |
| --- |
| Infant playing on and mouthing weathered structure. The structure is made of wood, which has been treated with wood preservative and there is prolonged and repeated contact with the wood*.* Following further assumptions are made, in line with the CAR for permethrin :All the permethrin applied to the timber sits on the timber surface for dermal contact scenarios and all of the permethrin applied to the surface is dislodgeableThe surface loading of the wood is calculated based on the maximum use rate of 300mL Embasol Houtwormdood (0.25% or 2g/L permethrin) per m2 wood. A body weight of 8kg is considered for infants (HEEG Opinion on default factors). As a highly worst case, it is assumed that 100% of the product on the hands will be ingested and the oral absorption is considered to be 100%. |
|  | Parameters | Value |
| Tier 1 | Surface loading wood | 0.06 mg/cm2 |
| Exposed area |  39.36 cm2(20% of the hand contaminated, based on the hand surface of 196.8 cm2 according to the HEEG Opinion) |
| Transfer efficiency | 2%(rough sawn wood; TNsG 2002) |

**Calculations for Scenario [11]**

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake****(mg/kg bw/day)** | **Estimated oral uptake****(internal)****mg/kg/day\*** | **Estimated total uptake****(internal)****mg/kg/day** |
| 11. weathered structure | 1/no PPE | n.a | n.a. | 0.006 | 0.006 |

\* see calculation below, as a highly worst case, it is assumed that 100% of the product on the hands will be ingested and the oral absorption is considered to be 100%.

Calculation :

Exposure oral = 39.36 cm2 x 0.06 mg/cm2 x 2% = 0.047 mg permethrin/ day / 8 kg = 0.006 mg/kg/day

***Monitoring data***

Not available.

***Dietary exposure***

Not relevant. Label statement: not to be used on the materials which may come into contact with food and drinks.

***Summary of exposure assessment***

|  |
| --- |
| **Scenarios and values to be used in risk assessment** |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake** |
| **(e.g. professionals, non-professionals, bystanders)** |
| 1 | Professional user - spray treatment  | 2/gloves+coverall | 0.075 |
| 1 | Professional user - spray treatment  | 3/ gloves + impermeable coverall | 0.049 |
| 2a | Professional user - injection injector | 2/gloves | 0.019 |
| 2b | Professional user - injection pouring | 1/no PPE | 0.029 |
|  | Professional user - injection pouring | 2/gloves | 0.0029 |
| 3a | Professional user - brushing treatment  | 1/no PPE | 0.072 |
| 3a | Professional user - brushing treatment  | 2/gloves | 0.0272 |
| 3b | Non-professional user - brushing treatment | 1/no PPE | 0.036 |
| 4 | Professional/industrial user - dipping treatment  | 2/ gloves | 0.049 |
| 5 | Industrial user - vacuum treatment  | 2/gloves | 0.037 |
| 6 | Industrial user - double vacuum treatment  | 2/gloves + coverall | 0.048 |
| 7 | Bystander adult (acute – handling treated wood | 1/no PPE | 0.23 |
| 8 | Bystander adult (chronic– cutting/sawing treated wood- | 1/no PPE | 0.0012 |
| 9 | Bystander infant (acute – chewing treated wood) | 1/no PPE | 0.0016 |
| 10 | Bystander child (chronic – playing on treated wood) | 1/no PPE | 0.003 |
| 11 | Bystander infant (chronic – playing and mouthing treated wood) | 1/no PPE | 0.006 |

Borehole injection should always be combined with a curative superficial treatment (spraying or brushing/rolling). The resulting exposure from the combined operation is calculated and included in the table below.

|  |  |  |  |
| --- | --- | --- | --- |
| 1 + 2a | Professional user - spray treatment + injection injector  | 3/ gloves + impermeable coverall | 0.068 |
| 1 + 2b | Professional user - spray treatment + injection pouring | 3/ gloves + impermeable coverall | 0.052 |
| 3a + 2a | Professional user - brushing treatment + injection injector | 2/gloves | 0.046 |
| 3a + 2b  | Professional user - brushing treatment + injection pouring | 2/gloves | 0.03 |

#### Risk characterisation for human health

**Reference values to be used in Risk Characterisation for permethrin**

|  |  |  |
| --- | --- | --- |
| **Reference**  | **Reference** | **Value (mg/kg/day)** |
| AELshort-term | CAR permethrin | 0.5 |
| AELmedium-term | 0.05 |
| AELlong-term | 0.05 |

***Risk for industrial/professional users***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/** | **Tier** | **AEL** | **Estimated uptake** | **Estimated uptake/ AEL**  | **Acceptable** |
| **Scenario** | **mg/kg bw/d** | **mg/kg bw/d** | **(%)** | **(yes/no)** |
| **SCENARIO 1– coarse spraying** |
| permethrin | 2/gloves+coverall | 0.05 | 0.075 | 151% | no |
| permethrin | 3/ gloves + impermeable coverall | 0.05 | 0.049 | 98.8% | yes |
| **SCENARIO 2a– injection injector** |
| permethrin | 2/gloves | 0.05 | 0.019 | 37.4% | yes |
| **SCENARIO 2b– injection pouring** |
| permethrin | 1/no PPE | 0.05 | 0.029 | 58.3% | yes |
| **SCENARIO 3– brushing** |
| permethrin | 1/no PPE | 0.05 | 0.072 | 144% | no |
| permethrin | 2/gloves | 0.05 | 0.0272 | 54.4% | yes |
| **SCENARIO 4– dipping** |
| permethrin | 2/ gloves | 0.05 | 0.049 | 98% | yes |
| **SCENARIO 5– vacuum treatment** |
| permethrin | 2/gloves | 0.05 | 0.037 | 73% | yes |
| **SCENARIO 6– double vacuum treatment** |
| permethrin | 2/gloves + coverall | 0.05 | 0.048 | 97% | yes |

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/** | **Tier** | **AEL** | **Estimated uptake** | **Estimated uptake/ AEL**  | **Acceptable** |
| **Scenario** | **mg/kg bw/d** | **mg/kg bw/d** | **(%)** | **(yes/no)** |
| **SCENARIO 1– coarse spraying + SCENARIO 2a– injection injector** |
| Scenario 1 | 3/ gloves + impermeable coverall | 0.05 | 0.049 | 98.8% | yes |
| Scenario 2a | 2/gloves | 0.05 | 0.019 | 37.4% | yes |
| Combi |  |  | 0.0681 | 136.2% | no |
| **SCENARIO 1– coarse spraying + SCENARIO 2b– injection pouring** |
| Scenario 1a | 3/ gloves + impermeable coverall | 0.05 | 0.049 | 98.8% | yes |
| Scenario 2b | 2/gloves | 0.05 | 0.0029 | 5.8% | yes |
| Combi | 3/ gloves + impermeable coverall |  | 0.0523 | 104.6% | no |
| **SCENARIO 3– brushing + SCENARIO 2a– injection injector** |
| Scenario 3 | 2/gloves | 0.05 | 0.0272 | 54.4% | yes |
| Scenario 2a | 2/gloves | 0.05 | 0.019 | 37.4% | yes |
| combi | 2/gloves |  | 0.0459 | 91.8% | yes |
| **SCENARIO 3– brushing + SCENARIO 2b– injection pouring** |
| Scenario 3 | 2/gloves | 0.05 | 0.0272 | 54.4% | yes |
| Scenario 2b | 2/gloves | 0.05 | 0.0029 | 5.8% | yes |
| combi | 2/gloves |  | 0.0301 | 60.2% | yes |

**Local effects**

Product is classified with EUH208 and EUH066. Use instructions will be followed by professional users, moreover PPE is prescribed due to systemic effects. In conclusion, the risk for local effects is considered acceptable.

**Conclusion**

For professional and industrial use, it can be concluded that:

Acceptable risk levels are obtained when PPE are prescribed for application via **coarse spraying. Protective gloves and impermeable coverall** should be used to obtain safe use.

Acceptable risk levels are obtained when PPE are prescribed for application **via injection by an injector. Protective gloves** should be used to obtain safe use.

Acceptable risk levels are obtained without the need for PPE for injection by pouring.

Acceptable risk levels are obtained when PPE are prescribed for application via **brushing**. **Protective gloves** should be used to obtain safe use.

Acceptable risk levels are obtained when PPE are prescribed for application via **dipping. Protective gloves** should be used to obtain safe use.

Acceptable risk levels are obtained when PPE are prescribed for application via **vacuum treatment. Protective gloves** should be used to obtain safe use.

Acceptable risk levels are obtained when PPE are prescribed for application via **double vacuum treatment. Protective gloves and coverall** should be used to obtain safe use.

Borehole injection should always be combined with a curative superficial treatment (spraying or brushing/rolling).

The combination of borehole treatment (injection or pouring) was not acceptable in combination with spraying, not even with PPE (protective gloves (for both borehole treatment and spraying) and impermeable coverall (for spraying).

The combination of borehole treatment (injection or pouring) was acceptable in combination with brushing, with the use of gloves (for both borehole treatment and brushing).

***Risk for non-professional users***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/** | **Tier** | **AEL** | **Estimated uptake** | **Estimated uptake/ AEL**  | **Acceptable** |
| **Scenario** | **mg/kg bw/d** | **mg/kg bw/d** | **(%)** | **(yes/no)** |
| **SCENARIO 3b - brushing** |
| permethrin | 1/no PPE | 0.5 | 0.036 | 7.2% | yes |

**Local effects**

Product is classified with EUH208 and EUH066. Due to the low frequency of use of the product by non-professional users, the risk for local effects is considered acceptable.

**Conclusion**

For non-professional use, it can be concluded that:

Acceptable risk levels are obtained without the need for PPE for application via brushing.

***Risk for the general public***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/** | **Tier** | **AEL** | **Estimated uptake** | **Estimated uptake/ AEL**  | **Acceptable** |
| **Scenario** | **mg/kg bw/d** | **mg/kg bw/d** | **(%)** | **(yes/no)** |
| **SCENARIO 7– bystander adult – acute (handling treated wood)** |
| permethrin | 1/no PPE | 0.5 | 0.23 | 46% | yes |
| **SCENARIO 8– bystander adult – chronic (cutting/sawing treated wood)** |
| permethrin | 1/no PPE | 0.05 | 0.0012 | 2.4% | yes |
| **SCENARIO 9 – bystander infant – acute (chewing treated wood)** |
| permethrin | 1/no PPE | 0.5 | 0.0016 | 0.3% | yes |
| **SCENARIO 10– bystander child - chronic (playing on treated wood)** |
| permethrin | 1/no PPE | 0.05 | 0.003 | 6% | yes |
| **SCENARIO 11 – bystander infant– chronic (playing/mouthing treated wood)** |
| permethrin | 1/no PPE | 0.05 | 0.006 | 12% | yes |

**Conclusion**

For secondary exposure to the general public, it can be concluded that risk levels are acceptable.

### Risk assessment for animal health

Not relevant for products used in industrial environment.

For treatments performed by professionals or non-professionals, the use instructions can include to assure no animals are present during the treatment.

For indirect exposure from treated wood, it can be assumed that the exposure to animals is negligible, given that the treated timber is mainly used in constructions indoor and/or under a roof. Exposure to animals would only sporadically occur, as access to the timber is limited in such cases. Furthermore, chewing of treated wood is included in the risk assessment for human health and considers the most vulnerable group, i.e. infants.

As cats are sensitive to permethrin, the following risk mitigation measure has been added: “Avoid prolonged contact of pets, particularly cats, to treated surfaces”

### Risk assessment for the environment

#### Effects assessment on the environment

As the product is applied indoors or under roof, direct emission to the environment due to spillage during application and/or leaching of the active substance from preserved wood is unlikely. During treatment, the soil underneath and around the object to be treated needs to be covered with plastic.

For industrial treatment, no release to STP is allowed during the application step. This is also not allowed in general as described in the ESD for PT8. The release of wood preservatives from the treating installation or where the treated timber is stored into a surface water drain or drain connected to a Sewage Treatment Plant (STP) is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the license to operate the treatment process.

In addition, the exposure during storage of wood at industrial sites is not allowed. The label shall contain the following info: *freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing surface, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal.*

The OECD Emission Scenario Document (ESD) for PT8 states the following (paragraph 177) : “For indoor treatments by spraying, brushing and injection, no scenarios are proposed in this document because related emissions to the environment are considered to be negligible”.

The primary receiving compartment is the air. However, direct exposure to the air during application is considered to be negligible, due to dilution and rapid degradation of permethrin in the troposphere by photochemical processes. Emission to the indoor air during application of the product is considered to be completely released to outdoor air by venting the room.

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

|  |
| --- |
| **PNEC values for the a.s. permethrin and the major metabolites PBA and DCVA (according to assessment report, 2014[[6]](#footnote-6))** |
| **Substance** | **Compartment** | **Value** | **Unit** |
| Permethrin | Fresh water  | 4.7 x10-4 | µg/L |
| Sediment | 2.17 x 10-4  | mg/kgwwt  |
| STP | 4.95  | µg/L |
| Soil | 0.175 | mg/kgwwt\* |
| Birds | 16.7 | mg/kgfood |
| Mammals | 120 | mg/kgfood |
| 3-Phenoxybenzoic acid (PBA) | Fresh water  | 0.01 | mg/L |
| Sediment | 0.009  | mg/kgwwt  |
| Soil  | 1.44  | mg/kgwwt  |
| DCVA | Fresh water  | 0.015 | mg/L |
| Sediment | 0.012  | mg/kgwwt  |
| Soil  | 4.6 | mg/kgwwt  |

\* The IE (RMS for permethrin) evaluation of the permethrin confirmatory data was discussed at the BPC Meeting in early March 2017. IE can inform the CG members that an ENV WG e-consultation was requested by BPC Members during the BPC meeting in March, regarding the PNECsoil. The e-consultation concluded on the 13th March.

It was agreed that the conclusions of this e-consultation could be announced at CG-22 in the event of a clear majority opinion. The opinions received from MSs in the e-consultation provided a clear majority opinion in relation to the proposed PNECsoil.

The MSs were in favour of using an AF of 50 and deriving the PNECsoil for permethrin on the soil micro-organism study.  The new PNECsoil is 0.198 mg/kg dwt, corresponding to 0.175 mg/kg wwt.

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

No information is available on the ecotoxicity of the biocidal product. Regarding the classification of the product, CLP mixture rules were used.

***Further Ecotoxicological studies***

No new data available

|  |
| --- |
| **Data waiving** |
| Information requirement | - |
| Justification | Valid data available on each of the componentsand synergistic effects between any of the components are not expected. No additional data required. |

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

No new data available

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

No new data available

|  |
| --- |
| **Data waiving** |
| Information requirement | - |
| Justification | Trials on other target organisms is not needed on the basis of intended uses, data available on the active substance or risk assessment. |

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

No new data available

|  |
| --- |
| **Data waiving** |
| Information requirement | - |
| Justification | Product is not a bait or granule |

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

No new data available. No refinement with a higher tier field study is required.

***Endocrine disruption activity of non-active substances***

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

No further ecotoxicological studies are available for Embasol Houtwormdood. The product was not tested for potential endocrine disruption properties. Embasol Houtwormdood contains the active substance permethrin and various co-formulants (see confidential annex).

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

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

* ECHA data for identification of ED and PBT, under REACH or BPR or CLP
* Identified as ED by United States EPA (<https://comptox.epa.gov/dashboard/>)
* Identified as ED by the United Nations Environment (July 2017) Programme(<http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y> and <https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y>)

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

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

Reference is made to section ‘fate and distribution in exposed environmental compartments’.

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

No new data available

|  |
| --- |
| **Data waiving** |
| Information requirement | - |
| Justification | Generation of studies on fate and behaviour is not needed on the basis of intended uses, data available on the active substance or risk assessment. |

***Leaching behaviour (ADS)***

Not relevant. The product is intended for treatment on timber used indoor or under a roof. Significant leaching to any environmental compartment is not expected. Leaching due to storage of treated wood at industrial sites is prevented by appropriate RMM.

***Testing for distribution and dissipation in soil (ADS)***

No new data available

|  |
| --- |
| **Data waiving** |
| Information requirement | - |
| Justification | Generation of studies on distribution/dissipation in soil is not needed on the basis of intended uses, data available on the active substance or risk assessment. |

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

No new data available

|  |
| --- |
| **Data waiving** |
| Information requirement | - |
| Justification | Generation of studies on distribution/dissipation in water and sediment is not needed on the basis of intended uses, data available on the active substance or risk assessment. |

***Testing for distribution and dissipation in air (ADS)***

No new data available

|  |
| --- |
| **Data waiving** |
| Information requirement | - |
| Justification | Generation of studies on distribution/dissipation in air is not needed onthe basis of intended uses, data available on the active substance or risk assessment. |

***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

|  |
| --- |
| **Data waiving** |
| Information requirement | - |
| Justification | Product is not to be sprayed near surface waters |

***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. Product is not to be sprayed outside, and will not need to be investigated on the potential to generate formation of dust, due to the properties of the product and based upon the uses.

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT8 |
| Assessed scenarios | Preventive and curative treatment of wood by (trained) professionals in use classes 1 and 2 by immersion, vacuum pressure impregnation, brushing, spraying, injectionPreventive and curative treatment of wood by non-professionals in use classes 1 and 2 by brushing and spraying  |
| ESD(s) used | OECD Series on Emission Scenario Documents Number 2. Emission Scenario Document wood preservatives. OECD report ENV/JM/MONO(2013)21. Organisation for Economic Co-operation and Development, Paris, 27 September 2013. |
| Approach | Qualitative assessment |
| Distribution in the environment | Assessed qualitatively |
| Groundwater simulation | Not performed |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: NoFormulation NoUse: YesService life: NoWaste : No |
| Remarks | None |

***Emission estimation***

No scenarios are proposed in the ESD for preventive and curative treatment of wood by (trained) professionals applied in use classes 1 and 2 by immersion, brushing, spraying, injection and preventive and curative treatment of wood by non-professionals in use classes 1 and 2 by brushing and spraying, because emission to the environment is negligible as preserved wood is not exposed to weather. The emissions to the environment, during these treatments and from treated wood after the treatments, are considered to be negligible as well. Risk mitigation measures are included in the PAR and SPC in order to minimise the risks for the environment for the waste phase (residual fluids, brushes, and rinse water applied for cleaning). During treatment, the soil underneath and around the object to be treated needs to be covered with plastic.

For industrial treatment, no release to STP is allowed during the application step. This is also not allowed in general as described in the ESD for PT8. The release of wood preservatives from the treating installation or where the treated timber is stored into a surface water drain or drain connected to a Sewage Treatment Plant (STP) is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the license to operate the treatment process.

In addition, the exposure during storage of wood at industrial site is not allowed. The label shall contain the following info: *freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing surface, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal.*

***Primary and secondary poisoning***

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

#### Risk characterisation

***Atmosphere***

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

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

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

***Terrestrial compartment (incl. groundwater)***

The proposed applications of the product and indoor/under roof in service use of the treated wood will not result in exposure of the soil compartment in case treatment of wood takes place indoors or under roof and when used in accordance with the proposed label (SPC). The risk for soil organisms and non-target arthropods (including bees) is considered acceptable when used in accordance with the proposed label (SPC).

***Primary and secondary poisoning***

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

Bats are directly exposed to treated wood via skin contact (i.e. beams). An active substance can be subsequently oraly ingested when furs and feet are cleaned.

In an acute toxicity study with bats (see AR of permethrin) a permethrin product was applied to the plywood lining of a steel cage 6 weeks to 14 months before bats (*Pipistrellus pipistrellus*) were introduced. The plywood was grooved to allow bats to climb and hang. Negative (solvent) controls were included in the experimental design. Wild caught bats (10 per cage) were introduced and fed ad libitum. No obvious harm was caused to the bats roosting for 16 to 22 weeks in cages lined with permethrin treated plywood. The effects on reproduction were not taken into account.

As the active substance is considered not bioaccumulative, the risk for the primary poisoning of birds and mammals (including bats) is considered acceptable. The pro­posed application meets the standards for birds and mammals (including bats).

Note that a risk assessment for bats roosting on treated wood may be relevant for products applied on wood with use classes 1 and 2. Wood treated with Embasol Houtwormdood may be harmful to juvenile bats as these can be more sensitive than adult bats. A warning needs to be added to the SPC indicating that the product must not be used in areas where bats reside.

***Mixture toxicity***

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

***Aggregated exposure (combined for relevant emmission sources)***

Although permethrin may be released from multiple sources, aggregated exposure assessment is not deemed necessary as there is no overlap in space and time for Embasol Houtwormdood to be considered (product intended for treatment of wood used indoor and/or under a roof).

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| For industrial use:No environmental risks have been identified provided that a risk mitigation measure is included in the SPC stating that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing surface, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal.For professional or non-professional use:No environmental risks have been identified provided that a risk mitigation measure is included in the SPC stating that residual fluids, brushes, and rinse water applied for cleaning have to be discharged as hazardous waste. Furthermore, run-off to soil or surface water needs to be prevented in order to protect water living organisms. Therefore treatment of wood with this product needs to take place indoors or under roof. Alternatively, during treatment the soil underneath and around the object to be treated needs to be covered with plastic. A potential risk exists for bats roosting on treated wood. A warning needs to be added to the SPC indicating that the product must not be used in areas where bats reside. |

### Measures to protect man, animals and the environment

Recommended methods and precautions

#### Identity of relevant combustion products in cases of fire

No data

#### Specific treatment in case of an accident

**General information**

Change contaminated, saturated clothing. When in doubt or if symptoms are observed, get medical advice. Never give anything by mouth to an unconscious person or a person with cramps. In case of inhalation remove casualty to fresh air and keep warm and at rest. Provide fresh air.

**In case of skin contact**

After contact with skin, wash immediately with plenty of water and soap. In case of skin reactions, consult a physician.

**After eye contact**

Rinse immediately carefully and thoroughly with eye-bath or water.

**In case of eye irritation**

Consult an ophthalmologist.

**After ingestion**

Do NOT induce vomiting. Rinse mouth thoroughly with water.

**Environmental precautions:**

For industrial use:

Freshly industrial-treated timber shall be stored after treatment under shelter or on impermeable hard standing surface, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal.

For professional or non-professional use:

To protect water living organisms, run-off to soil or surface water needs to be prevented. Therefore treatment of wood with this product needs to take place indoors or under roof. Alternatively, during treatment the soil underneath and around the object to be treated needs to be covered with plastic.

Avoid release of the product or residues of the product to the environment. Discharge of leftover and residues containing the product (e.g. solvents used for cleaning of brushes) to the sewer or surface water is not permitted. Leftover and residues containing the product (e.g. solvents used for cleaning of brushes) need to be removed as chemical waste.

Wood treated with Embasol Houtwormdood may cause harm to bats. Do not use the product in areas where bats reside.

#### Possibility of destruction or decontamination following release

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect in suitable containers en remove as in Section 2.2.9.4.

#### Procedures for waste management of the biocidal product and its packaging

Avoid release to the environment. Remove contents/container as hazardous waste in accordance with Local Authority Regulations.

#### Procedures for cleaning application equipment where relevant

Discharge of leftover and residues containing the product (e.g. solvents used for cleaning of brushes) to the sewer or surface water is not permitted. These should be removed as hazardous waste.

#### Assessment of a combination of biocidal products

Not intended to be authorised for the use with other biocidal products.

#### Comparative assessment

Not relevant

# Annexes[[7]](#footnote-7)

## List of studies for the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **Title** | **Testing laboratory** | **Report no.** | **Report date** |
| xxxx  | 2017 | Long term stability test of wood preservation formulation – Embasol Houtwormdood | xxxx | 31/17/3000/01B | 4/2019 |
| xxxx | 2016 | OECD 109 Density of liquids and solids OECD 114 Viscosity of LiquidsPhysical state, Color, Odour | xxxx | UB10533 | 2016-04-15 |
| xxxx | 2016 | Verification of long term stability of wood preservation formulation – Embasol Houtwormdood | xxxx | 31/16/2655/02 | 2016-04-20 |
| xxxx | 2016 | Measurement of the surface tension on the wood preservative EMBASOL HOUTWORMDOOD in accordance to OECD 115/ EC method A5  | xxxx | 402/16/1073F/a-e  | 2016-04-29 |
| xxxx | 2016 | Embasol Houtwormdood\_Flashpoint | xxxx |  | 2016-12-14 |
| Anonymous | 1980 | Prufungszeugnis 5.1/3313 A | xxxx | 5.1/3313 A | 1980-11-26 |
| Anonymous | 1983 | Untersuchungsbericht 23 10477 | xxxx | 23 10477 | 1983-02-21 |
| Anonymous | 1980 | Prufungszeugnis 5.1/3314 A | xxxx | 5.1/3314 A | 1980-10-14 |
| Anonymous | 1982 | Prufungszeugnis 5.1/3313 L | xxxx | 5.1/3313 L | 1982-02-24 |
| Anonymous | 1981 | Determination of eradicant action against *Anobium punctatum* | xxxx | PRL/B8002 | 1982-02-24 |
| Anonymous | 1982 | Determination of the toxic values against *Anobium punctatum* by egg laying and larval survival | xxxx | PJ 07 31 | 1982-09-22 |
| Anonymous | 1984 | Gutachten | xxxx | 32 0155 5 84 | 1984-03-28 |
| Anonymous | 1984 | Bewertungs- unde Veröffentlichungsverfahren der LIGNUM f¨r Holzschutmmittle unde Spezial-Anstrichstoffer für Holz | xxxx | 8307 | 1984-01-25 |

1.
2.
3.

## Output tables from exposure assessment tools

**Primary exposure**

Scenario 1: Application – coarse spraying - professional



Scenario 2a: Application – injection with injector – professional



Scenario 2b: Application - injection by pouring – professional



Scenario 3: Application – brushing – professional / non-professional



Scenario 4: Application – dipping/drenching – professional



Scenario 5: Application – vacuum pressure – professional



Scenario 6: Application – double vacuum pressure – professional



**Secondary exposure**

Scenario 7: Adult handling treated timber – acute exposure scenario



Scenario 8: Adult cutting/sanding treated wooden posts – acute and chronic exposure scenarios



Scenario 10: Child – playing on playground structure outdoors



Scenario 11: Infant – playing on weathered structure and mouthing



**Summaries of the efficacy studies (B.5.10.1-xx)[[8]](#footnote-8)**

See IUCLID file

## Confidential annex

See separate document

## Other

None

1. Please fill in here the identifying product name from R4BP 3. [↑](#footnote-ref-1)
2. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-2)
3. Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence. [↑](#footnote-ref-3)
4. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-4)
5. [↑](#footnote-ref-5)
6. Assessment Report Permethrin, April 2014. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Permethrin, Product-Type 18. [↑](#footnote-ref-6)
7. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-7)
8. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-8)