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

PRODUCT ASSESSMENT REPORT OF A MAJOR CHANGE OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



 



  

SARPECO 9-PLUS, RESISTOL 6217, RESISTOL 6216,

PREV’CONSTRUCT PLUS

Product type 8

Tebuconazole, 3-iodo-2-propynylbutylcarbamate (IPBC), permethrin, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3- dioxolan-2-yl]methyl]-1H-1,2,4-triazole (Propiconazole)

Case Number in R4BP: BC-EJ023250-62 Evaluating Competent Authority: BE Date: 12/06/22

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/ eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter**  **/ page** |
| NA-APP | BE-CA | BC-EJ023250- 62 | 18.04.2019 | Initial assessment | / |
| NA-MAC | *BE-CA* | BC- QX051824-01 | 25.09.2020 | *Addition of the application of the product SARPECO 9-PLUS by vacuum pressure process for industrial preventive treatment of wood intended for use classes 1, 2, 3.1 and 3.2 against wood-destroying insects including termites and wood destroying fungi*  *(white rot and brown rot fungi).* | See highlight |
| NA-MRS with SPAIN-CA | BE-CA | BC-QX051824-01 | 31.03.2021 | Modification due to discussion with cMSs | See highlight |
| NA-MAC | BE-CA | BC-NG070837-28 |  | Addition of the application of the product SARPECO 9-PLUS by brushing process for industrial preventive treatment of wood intended for use classes 1, 2 and 3.1 against wood-destroying insects including termites and wood destroying fungi (white rot and brown rot fungi). | See highlight |

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# CONCLUSION

BE eCA considers that the product SARPECO 9-PLUS (additional name RESISTOL 6217,

RESISTOL 6216, PREV’CONSTRUCT PLUS), formulated by BERKEM DEVELOPPEMENT,

containing the active substances Tebuconazole (1.1% w/w), IPBC (1.0% w/w), permethrin (2.0% w/w), Propiconazole (1.1% w/w) may be authorized as wood preservative (PT8). The conclusions of each assessment are summarized below.

The biocidal product SARPECO 9-PLUS is a slightly yellow limpid liquid with characteristic odour. At ambient temperature the product has a long term stability for 24 months and is stable under cold and accelerated storage conditions. The product should be protected from direct exposition to light. Physical and chemical compatibility with other products is not relevant. The contact with oxidizing agents has to be avoided. No classification related to physico-chemical risks is necessary.

Sarpeco 9-Plus product is effective against wood-destroying insects including termites and wood destroying fungi (white rot and brown rot fungi) in preventive treatment. The field of use covers use class 1, use class 2 and use classes 3.1 and 3.2. The application rate is 100 g/m². The product is intended to be diluted at 5% w/w in water for use class 1; at 6.5% w/w in water for use class 2 and 3.1 (softwood) and at 14.5% w/w in water for use class 3.1 (hardwood) in surface treatment. The product is also shown to be efficacious in penetrative treatment, with 0.8% dilution in water for softwood (application rate 600 kg/m³) and 1.45

% dilution in water for hardwood (application rate 500 kg/m³).

Normal use of SARPECO 9-PLUS by industrial professionals has a sufficiently large safety margin for application by vacuum pressure when using proper PPE (chemical resistant gloves, impermeable coverall). For double vacuum pressure, there is a concern for combined exposure to several active substances within a biocidal product.

Normal use of SARPECO 9-PLUS by industrial professionals has a sufficiently large safety margin for application by fully automated dipping and fully automated spraying when using proper PPE (chemical resistant gloves, impermeable coverall). The use of the same PPE is recommended for the potentially secondary exposure (cleaning/ maintenance of the system). For automated dipping and automated spraying, there is a concern for combined exposure to several active substances within a biocidal product.

Normal use of SARPECO 9-PLUS by industrial professionals has a sufficiently large safety margin for application by industrial brushing when using proper PPE (chemical resistant gloves).

Normal use of SARPECO 9-PLUS has a sufficiently large safety margin for the secondary exposed general public.

The risk characterisation indicates that the uses of the biocidal product Sarpeco 9-Plus by the industrial processes - automated spraying, brushing short dipping and vacuum pressure/double vacuum

- and the uses of treated wood in UC 1, UC 2 and UC3 do not represent unacceptable risks to the environment if appropriate risk mitigation measures are considered.

The assessment of the endocrine disrupting (ED) properties of the substances used in the biocidal product SARPECO 9-PLUS was performed according to the Regulation (EU) 528-2012 and Regulation (EU) 2017-2100. Based on the existing knowledge and the data provided by the applicant, and pending the final decision regarding the ED properties of Tebuconazole and Propiconazole, BE eCA considers that there is no indication of concern regarding the ED properties of the substances used in the biocidal product SARPECO 9-PLUS.

# ASSESSMENT REPORT

## SUMMARY OF THE PRODUCT ASSESSMENT

### Administrative information

###### Identifier of the product / product family

|  |  |
| --- | --- |
| **Identifier** | **Country (if relevant)** |
| SARPECO 9-PLUS RESISTOL 6217  RESISTOL 6216  PREV’CONSTRUCT PLUS | Belgium |

###### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | BERKEM DEVELOPPEMENT |
| **Address** | Marais Ouest, F-24680, Gardonne, FR |
| **Authorisation number** | BE2019-0017 | |
| **Date of the authorisation** | 18/04/2019 | |
| **Expiry date of the authorisation** | 28/07/2025\* | |

*\**Amendment to extend the expiry date until 28/07/2025 in accordance with 'CA-May18-Doc.4.1

###### Manufacturer of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | ADKALIS |
| **Address of manufacturer** | Marais Ouest F-24680 Gardonne FR |
| **Location of manufacturing sites** | Marais Ouest F-24680 Gardonne FR |

###### Manufacturers of the active substances

|  |  |
| --- | --- |
| **Active substance** | Tebuconazole |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1 D-50569 Koln, Germany |
| **Location of manufacturing sites** | Bayer Corp., Agriculture Division - Hawthorn Road, P.O. Box 4913  MO 64120-001 Kansas City, US. |

|  |  |  |
| --- | --- | --- |
| **Active substance** | 3-iodo-2-propynylbutylcarbamate (IPBC) | |
| **Name of manufacturer** | LANXESS Deutschland GmbH | TROY Chemical Company BV |
| **Address of manufacturer** | Kennedyplatz 1 D-50569 Koln, Germany | Uiverlaan 12e, 3140 AC Maasluis, Netherlards |

|  |  |  |
| --- | --- | --- |
| **Location of manufacturing sites** | Shanghai Hui long Chemicals Co., Ltd, Dengta Jiazhu Rd. 201815 District Shangai, China | One Avenue L Newark, 07105 New Jersey,  USA |

|  |  |  |
| --- | --- | --- |
| **Active substance** | Permethrin | |
| **Name of manufacturer** | LANXESS Deutschland GmbH | Caldic Denmark A/S (Acting for TAGROS Chemicals India Ltd) |
| **Address of manufacturer** | Kennedyplatz 1 D-50569 Köln Germany | Odinsvej 23, DK-8722 Hedensted, Denmark |
| **Location of manufacturing sites** | Bilag Industries Limited,  Plot #306/3, II Phase, GIDC, Vapi - 396 195, Gujarat, India | Tagros Chemicals India Limited, A4/1&2, SIPCOT Industrial Complex, Kudikadu, Cuddalore, Tamil Nadu, India |

|  |  |  |
| --- | --- | --- |
| **Active substance** | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4- triazole (Propiconazole) | |
| **Name of manufacturer** | LANXESS Deutschland GmbH | JANSSEN PMP |
| **Address of manufacturer** | Kennedyplatz 1 D-50569 Köln Germany | Turnhoutseweg 30 2340 Beerse, BE |
| **Location of manufacturing sites** | CH-1870 Monthey, Switzerland | North Area of Dongsha Chem-Zone  Zhangjiagan- Jiangsu, 215600- P.R. China |

### 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 ☒

###### Identity of the active substances

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Tebuconazole |
| **IUPAC or EC name** | (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4- triazol-1-ylmethyl)-pentan-3-ol. Ratio (1:1) |
| **EC number** | 403-640-2 |
| **CAS number** | 107534-96-3 |
| **Index number in Annex VI of CLP** | 603-197-00-7 |
| **Minimum purity / content** | ≥ 950 g/kg |

|  |  |
| --- | --- |
| **Structural formula** | H H3C CH  O 3  CH3  Cl N  N  N |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | 3-iodo-2-propynylbutylcarbamate (IPBC) |
| **IUPAC or EC name** | 3-Iodo-2-propynyl butyl carbamate |
| **EC number** | 259-627-5 |
| **CAS number** | 55406-53-6 |
| **Index number in Annex VI of CLP** | 616-212-00-7 |
| **Minimum purity / content** | 980 g/kg |
| **Structural formula** | O  I C C CH2 O C NH CH2 CH2 CH2 CH3 |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Permethrin |
| **IUPAC or EC name** | 3-phenoxybenzyl(1RS)-cis,trans-3-(2,2-dichlorovinyl)- 2,2-dimethylcyclopropanecarboxylate  or  3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate |
| **EC number** | 258-067-9 |
| **CAS number** | 52645-53-1 |
| **Index number in Annex VI of CLP** | 613-058-00-2 |
| **Minimum purity / content** | ≥93% w/w sum of all permethrin isomers  Cis:trans permethrin % ratio = 22-28:72-78 cis:trans. 1Rcis permethrin content = 5.0 – 10.0% w/w.  1Scis permethrin content = 15.0 – 20.0% w/w. 1Rtrans permethrin content = 45.0 – 55.0% w/w.  1Strans permethrin content = 17.0 – 27.0% w/w. |
| **Structural formula** |  |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2- yl]methyl]-1H-1,2,4-triazole (Propiconazole) |
| **IUPAC or EC name** | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2- yl]methyl]-1H-1,2,4-triazole |
| **EC number** | 262-104-4 |
| **CAS number** | 60207-90-1 |
| **Index number in Annex VI of CLP** | 613-205-00-0 |

|  |  |
| --- | --- |
| **Minimum purity / content** | Min 930 g/kg |
| **Structural formula** | Cl  N  Cl C CH2 N  O O N  C3H7 |

###### Candidate(s) for substitution

The biocidal product SARPECO 9-PLUS contains four active substances: propiconazole, IPBC, tebuconazole and permethrin.

IPBC and propiconazole are not PBT candidates.

According to the CAR of Permethrin for PT8, this substance (various isomer mixtures) is not a PBT candidate nor are its individual constituent isomers. Permethrin is considered to fulfill the T criteria, but does not fulfill the B criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the cis isomer) and therefore fulfill the P criteria.

Annex I Assessment Report for tebuconazole, PT8 states that tebuconazole is considered to be very persistent (vP) and toxic (T) but not bioaccumulative. In conclusion, tebuconazole shall be considered a candidate for substitution using the criteria in Article 10(1). However, tebuconazole is not considered as meeting the exclusion criteria according to Article 5(1). Therefore tebuconazole can be considered to meet the criteria in Article 10(1)d, notably it meets two of the criteria for being PBT in accordance with Annex XIII to regulation (EC) No 1907/2006.

Under Article 23(1) of Regulation 528/2012 Member States are required to perform a comparative assessment for biocidal products containing an active substance that is a candidate for substitution in accordance with Article 10(1) . Please report to the relevant section (2.2.11).

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Common name** | **IUPAC name** | **Function** | **CAS**  **number** | **EC**  **number** | **Content (%)** |
| Tebuconazole | (RS)-1-(4-chlorophenyl)-4,4- dimethyl-3-(1H-1,2,4-triazol-1- ylmethyl)-pentan-3-ol. Ratio (1:1) | Active substance | 107534-  96-3 | 403-640-  2 | 1.1  (technical content) |
| 1.045  (pure content) |
| IPBC | 3-Iodo-2-propynyl butyl carbamate | Active substance | 55406-  53-6 | 259-627-  5 | 1  (technical content) |
| 0.98  (pure content) |
| Permethrin | 3-phenoxybenzyl(1RS)-cis,trans- 3-(2,2-dichlorovinyl)-2,2- dimethylcyclopropanecarboxylate | Active substance | 52645-  53-1 | 258-067-  9 | 2  (technical content) |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Common name** | **IUPAC name** | **Function** | **CAS**  **number** | **EC**  **number** | **Content (%)** |
|  |  |  |  |  | 1.86  (pure content) |
| Propiconazole | 1-[[2-(2,4-dichlorophenyl)-4- propyl-1,3-dioxolan-2- yl]methyl]-1H-1,2,4-triazole | Active substance | 60207-  90-1 | 262-104-  4 | 1.1  (technical content) |
| 1.023  (pure content) |
| Alcohol C11, ethoxylated | C11-Oxoalcohol, ethoxylated | Surfactant | 127036-  24-2 | 931-927-  7 | 3.56 |
| For the full composition, please see the confidential Annex. | | | | | |

###### Information on technical equivalence

Two sources listed in 2.1.1.4 are technical equivalences:

* + - * + Technical Equivalence IPBC : EU-0017138-0000 for

Location manufacturing site: Shanghai Hui long Chemicals Co., Ltd, Dengta Jiazhu Rd. 201815 District Shangai, China

* + - * + Technical Equivalence propiconazole : EU-0003416-0000 for

Location manufacturing site : Jiangsu Seven continent Green Chemical Co. Ltd, North Area of Dongsha Chem-Zone - Zhangjiagang, Jiangsu, 215600, China

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

The biocidal product contains a substance of concern: Alcohol C11, ethoxylated (N°CAS 127036-24-2). This substance participates to the product classification as H318, Eye dam. Category 1.

###### Type of formulation

ME- Micro emulsion

### Hazard and precautionary statements

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

|  |  |
| --- | --- |
| **Classification** | |
| Hazard category | Eye Dam 1  Skin Sens 1  Repr. 1BSTOT RE 2  Aquatic Acute cat. 1 Aquatic Chronic cat. 1 |
| Hazard statement | H318 H317  H360DH373 H400  H410 |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H318: Causes serious eye damage  H317: May cause an allergic skin reaction H360D : May damage the unborn child  H373: May cause damage to organs (Larynx) through prolonged or repeated exposure  H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | **P201** Obtain special instructions before use  **P260** Do not breathe dust/ fume/ gas/ mist/ vapour/ spray  P272 Contaminated work clothing should not be allowed out of the workplace.  **P273** Avoid release to the environment **P280** Wear protective gloves/protective clothing/eye protection/face protection  P302 + P352 IF ON SKIN: Wash with plenty of water/...  **P305 + P351 + P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  **P308 + P313** IF exposed or concerned: Get medical advice/attention  **P310** Immediately call a POISON CENTER/doctor P314 Get medical advice/attention if you feel unwell.  P333 +P313 If skin irritation or rash occurs: Get medical advice/attention.  P362+P364 Take off contaminated clothing and wash it before reuse  **P391** Collect spillage P405 Store locked up  P501 Dispose contents/container in accordance with all local, national and international regulations |
|  | |
| **Notes** |  |
|  | |
| **Risk Mitigation measures** | 1. "Do not apply the product on wood which may come into   contact with food, feedstuff or livestock”  “ Treated wood should not be intended for uses involving contact with food, feed or livestock”   1. “Contain permethrin (pyrethroids), may be lethal to cats. Cats must avoid contact with treated object/area” 2. The biocidal product may only be applied to wood, which will not be used above or close to surface waters. 3. The freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing or both to prevent direct losses to soil, sewer or water. 4. Application should be conducted within a contained area on impermeable hard standing with bunding and any losses from the application of the product should be collected for reuse or disposal. 5. A non-biocidal topcoat must be applied on treated wood used outdoor, above ground (use class 3.1 and 3.2) to avoid leaching of active substances. |

### Authorised use

###### Use description

|  |  |
| --- | --- |
| **Table 1. Use # 1 – preventive use** | |
| **Product Type** | PT 8 : wood preservatives |
| **Where relevant, an exact description of the authorised use** | The SARPECO 9-PLUS product is effective against wood-destroying insects including termites and wood destroying fungi (white rot and brown rot fungi) in preventive treatment. |
| **Target organism (including development stage)** | * Wood boring insects (representative insect: *Hylotrupes bajulus*, recently hatched larvae) * Termites (*Reticulitermes santonensis* de Feytaud) * White rot fungi (Coriolis versicolor) * Brown rot fungi (*Coniophora puteana, Poria placenta, Gloeophyllum trabeum*) |
| **Field of use** | * Use class 1: situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting * Use class 2: situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but where occasional, but non persistent, wetting can occur * Use class 3: situation in which wood or wood-based product is above ground and exposed to the weather (particularly rain).   + 3.1: wood or wood-based products will not remain wet for long periods. Water will not accumulate   + 3.2: wood and wood-based products will remain wet for long periods. Water may accumulate. |
| **Application method(s)** | The product SARPECO 9-PLUS could be applied for a surface treatment by fully automated dipping, fully automated spraying and industrial brushing and for a penetrative treatment by vacuum pressure. |
| **Application rates and frequency** | Surface treatment:  The product is intended to be diluted at 5% w/w in water for use class 1; at 6.5% w/w in water for use class 2; at 6.5% w/w and at 14.5% w/w in water for use class 3.1 for, respectively, softwood and hardwood.  The application rate of the diluted product is 100 g/m². Penetrative treatment:  The product is intended for use classes 1, 2, 3.1 and 3.2 for softwood  and hardwood.  For softwood, the product is intended to be diluted 0.8% in water for an application rate of 600 g/m³.  For hardwood, the product is intended to be diluted 1.45% in water for an application rate of 500 g/m³. |
| **Category of users** | Professional user (industrial application)1 |
| **Pack sizes and packaging material** | Please see the relevant section. |

1 The relevant user category is industrial. In BE « industrial » user is not allowed, only

« professional » user can be targeted.

###### Use-specific instructions for use

The product Sarpeco 9-Plus can be applied by fully automated dipping, fully automated spraying and industrial brushing for surface treatment and by vacuum pressure for penetrative treatment.

Homogenize before use.

The fixation step, following the application is at minimum 4 hours.

The treated wood has to be dried during 24 to 48 hours in ventilated place.

Wood intended to be used in outdoors has to be protected by a resistant paint or varnish.

###### Use-specific risk mitigation measures

Appropriate and suitable personal protective equipment (PPE) is required: chemical resistant gloves and impermeable coverall:

* Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
* Wear impermeable coverall during product handling phase (norms specified by the authorisation holder within the product information).
* In addition, wear safety goggles when handling concentrated product.

Use in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to the draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until the treated articles are surface dry. The untreated wood may only be lowered by a separate lifting unit into the dipping tank.

Use in fully automated spraying where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the spraying process place to the draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the spraying process, and must not be manually handled until the treated articles are surface dry.

Contact with the skin is to be avoided as the product may produce an allergic reaction. Do not combine different types of application.

Do not apply the product on wood which may come into contact with food, feedstuff or livestock Treated wood should not be intended for uses involving contact with food, feed or livestock.

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

Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber.

* All application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).
* Application solutions must be collected and reused or disposed of as hazardous waste. They

must not be released to soil, ground- and surface water or any kind of sewer.

* Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, 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

Any contaminated water/soil shall be collected, contained and treated as hazardous waste Any losses from the application of the product shall be collected for reuse or disposal.

Treated wood should not be intended for uses close or above surface water.

A non-biocidal topcoat must be applied on treated wood used outdoor, above ground (use class 3) to avoid leaching of active substances.

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

|  |
| --- |
| First aid in general:  Move the affected person into fresh air. Keep warm and at rest. In case of suspected poisoning, you must immediately call a doctor. Tell the doctor that no specific antidote is known, a symptomatic treatment is necessary. NEVER give anything by the mouth to an unconscious person.  General safety and hygiene measures:  Observe the precautions generally taken with chemicals.  If inhaled: In case of massive inhalation move the patient into the fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration and call a doctor. Give nothing by the mouth.  In case of contact with eyes: Wash thoroughly with soft, clean water during 15 minutes holding the eyelids open. Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  In case of skin contact: In case of allergic reaction, seek a medical advice. Remove contaminated clothing and shoes and wash thoroughly contaminated body parts and hair with soap and water. Destroy or thoroughly clean the soiled clothes and shoes before each re-use.  IF ON SKIN: Wash with plenty of water  In case of swallowing: If the swallowed quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor. Remain at rest. Do not induce vomiting. Consult a doctor and show him the label. In case of accidentally swallowing, call a doctor to judge the necessity for monitoring and for a subsequent treatment in hospital. Show the label.  Emergency measures to protect the environment:  Do not discharge the product into drains or into the environment. Prevent entry into waters or soil.  Contain spills by covering with absorbing material.  Store absorbing material used to absorb spills in drums for waste disposal.  Prevent all product entry into drains or waterways.  Place containers or drums for disposal of waste recovered in accordance with applicable regulations.  If the product contaminates waterways, lakes, rivers or drains, alert the competent authorities in accordance with regulatory procedures into force. |

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

Completely empty containers. The product residue, washing water, packaging and any other waste related to the treatment should be considered as hazardous waste.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company. Do not contaminate the ground or water with waste; do not dispose of waste into the environment.

Dispose of empty containers in an incinerator approved for chemicals by the competent authorities. Damaged containers should be placed in specially marked larger ones. Check possibilities of recycling large empty containers.

Codes of wastes (Decision 2001/573/EC; Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste): 030205 other wood preservatives containing dangerous substances.

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

Storage conditions: Keep container tightly closed in original package in a dry and well-ventilated place. Protect from light.

The contact with oxidizing agents has to be avoided.

At ambient temperature the product has a long term stability for 24 months and is stable under cold and accelerated storage conditions.

### General directions for use

###### Instructions for use

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| --- |
| Please refer to 2.1.4.2 |

###### Risk mitigation measures

Please refer to 2.1.4.3

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

|  |
| --- |
| Please refer to 2.1.4.4 |

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

Please refer to 2.1.4.5

* + - 1. *Conditions of storage and shelf-life of the product under normal conditions of storage*

|  |
| --- |
| Please refer to 2.1.4.6 |

### Other information

The product is intended to be used on wood or wood-based products up to use class 3.2

1. "Do not apply the product on wood which may come into contact with food, feedstuff

or livestock”

“ Treated wood should not be intended for uses involving contact with food, feed or livestock”

1. “Contain permethrin (pyrethroids), may be lethal to cats. Cats must avoid contact with treated object/area”
2. The freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing or both to prevent direct losses to soil, sewer or water.
3. Application should be conducted within a contained area on impermeable hard standing with bunding and any losses from the application of the product should be collected for reuse or disposal.
4. A non-biocidal topcoat must be applied on treated wood used outdoor, above ground (use class 3.1 and 3.2) to avoid leaching of active substances.

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non- professional)** | **Compatibility of the product with the proposed packaging materials**  **(Yes/No)** |
| Can/Tin | 25 L | HDPE | HDPE  closure with PE gasket | Professional | Yes |
| Drum | 60 L | HDPE | HDPE  closure with PE gasket | Professional | Yes |
| Drum | 220 L | HDPE | HDPE  closure with PE gasket | Professional | Yes |
| IBC  (Intermediate Bulk Container) | 640 L | HDPE | HDPE  closure with PE gasket | Professional | Yes |
| IBC | 1000 L | HDPE | HDPE  closure with PE gasket | Professional | Yes |

### Documentation

###### Data submitted in relation to product application

The whole list of data submitted by the applicant is included in the Annex 1.

###### Access to documentation

The applicant has submitted 7 Letters of Access to granting access to the dossier of active substances:

* Permethrin: one from Lanxess Deutschland GmbH, and one from Tagros Chemicals India ltd.
* Tebuconazole: one from Lanxess Deutschland GmbH
* Propiconazole: one from Lanxess Deutschland GmbH, and one from JANSSEN PMP
* IPBC: one from Lanxess Deutschland GmbH, and one from TROY Chemical Company BV.

## ASSESSMENT OF THE BIOCIDAL PRODUCT

### Intended use as applied for by the applicant

|  |  |
| --- | --- |
| **Table 2. Use # 1 – preventive treatment** | |
| **Product Type** | PT08 - Wood preservatives (Preservatives) |
| **Where relevant, an exact description of the authorised use** | The Sarpeco 9-Plus product is effective against wood-destroying insects including termites and wood destroying fungi (white rot and brown rot fungi) in preventive treatment. |
| **Target organism (including development stage)** | Hylotrupes bajulus L.-Larvae-House longhorn beetle Lyctus brunneus-Larvae-Powder post beetles  Anobium punctatum De Geer-Larvae-Common furniture beetle Reticulitermes sp.-Adults-Termites  Coniophora puteana-Spores and spore producing structures-Wood rotting fungi  Poria placenta-Spores and spore producing structures-Wood rotting fungi  Gloeophyllum trabeum-Spores and spore producing structures-Wood rotting fungi  Coriolus versicolor-Spores and spore producing structures-Wood rotting fungi |
| **Field of use** | Indoor, Outdoor Use class 1 to 3 |
| **Application methods** | Automated spraying -  The product application is operated in a closed system.  Industrial brushing –  The product is applied manually with a brush by industrial operators wearing appropriate and suitable personal protective equipment.  Dipping -  The product application is operated in an open system.  Autoclave vacuum and pressure -  The product application is operated in a closed system by vacuum impregnation. |
| **Application rate(s) and frequency** | Spraying: 100 g/m² - max 14.5% dilution- 1 application.  Brushing: 100 g/m² - max 14.5% dilution- 1 application.  Dipping: 100 g/m² - max 14.5% dilution - 1 application. Autoclave: 500 kg/m3 – max 1.45% - 1 application. |
| **Category of users** | Professional |
| **Pack sizes and packaging material** | Can /Tin - Plastic: HDPE - 25L Drum - Plastic: HDPE - 60L Drum - Plastic: HDPE - 220L  IBC (intermediate bulk container) - Plastic: HDPE - 640L IBC (intermediate bulk container) - Plastic: HDPE - 1000L |

### Physical, chemical and technical properties

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (%**  **(w/w)** | **Results** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | Organoleptic observations at 21.6°C |  | Limpid liquid |  |
| Colour at 20 °C and 101.3 kPa | Organoleptic observations at 21.6°C |  | Pale yellow |  |
| Odour at 20 °C and 101.3 kPa | Organoleptic observations at 21.6°C |  | Characteristic odor |  |
| Acidity / alkalinity | CIPAC MT 75.3 |  | Lab2009\_009  pure: pH= 6.67  1% dilution:  pH = 6.76 |  |
| Relative density / bulk density | OECD 109 |  | D20 = 1.024  4 |  |
|  |  | +-0.001 |
| Storage stability test – **accelerated storage** | CIPAC MT 46-3 |  | Organoleptic observations: |  |
|  | 54+-1°C, 14 days |  |
|  | HPLC/DAD for a.s. dosages | T0: colourless, slightly turbid liquid  T2w: slightly yellowish, slightly turbid liquid |
|  |  | Active substances determination: Permethrin: T0=2.125% T2w=2.142%  Variation of 0.8% of active substance concentration |
|  |  | Tebuconazole: |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (%**  **(w/w)** | **Results** | **Reference** |
|  |  |  | T0=1.100% |  |
| T2w=1.099% |
| Variation of |
| 0.1% of active |
| substance |
| concentration |
| Propiconazole : |
| T0=1.088% |
| T2w=1.104% |
| Variation of |
| 1.5% of active |
| substance |
| concentration |
| IPBC : |
| T0=1.006% |
| T2w=0.999% |
| Variation of |
| 0.7% of active |
| substance |
| concentration |
| (all |
| concentrations |
| of active |
| substances at |
| the beginning |
| of the stability |
| study are |
| within the |
| authorized |
| concentration |
| variation of |
| declared |
| concentrations) |
| pH undiluted: |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (%**  **(w/w)** | **Results** | **Reference** |
|  |  |  | T0=6.4 T2w=5.5  pH 1%  dilution: T0=6.3 T2w=4.9 |  |
| Storage stability test – **long term storage** | Storage at ambient |  | Permethrin: |  |
| **at ambient temperature** | temperature during 2 | T0=2.06% |
|  | years | T2y=2.04% |
|  |  | Variation of |
|  | HPLC/UV for a.s. dosage | 1% of active |
|  |  | substance |
|  |  | concentration |
|  |  | Tebuconazole: |
|  |  | T0=1.14% |
|  |  | T2y=1.11% |
|  |  | Variation of |
|  |  | 2.6% of active |
|  |  | substance |
|  |  | concentration |
|  |  | Propiconazole : |
|  |  | T0=1.1% |
|  |  | T2y=1.1% |
|  |  | No variation of |
|  |  | active |
|  |  | substance |
|  |  | concentration |
|  |  | IPBC : |
|  |  | T0=0.99% |
|  |  | T2y=0.98% |
|  |  | Variation of |
|  |  | 1% of active |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (%**  **(w/w)** | **Results** | **Reference** |
|  |  |  | substance concentration  (all concentrations of active substances at the beginning of the stability study are within the authorized concentration variation of  declared concentrations) |  |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  0 +-2°C at 7 days |  | Organoleptic observations: |  |
|  | HPLC/DAD for a.s. dosages | T0: colourless, slightly turbid liquid  T1w: slightly yellowish, slightly turbid liquid |
|  |  | Active substances determination: |
|  |  | Permethrin: T0=2.125% T2w=2.154%  Variation of 1.4% of active substance  concentration |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (%**  **(w/w)** | **Results** | **Reference** |
|  |  |  | Tebuconazole: |  |
| T0=1.100% |
| T2w=1.101% |
| Variation of |
| 0.1% of active |
| substance |
| concentration |
| Propiconazole : |
| T0=1.088% |
| T2w=1.104% |
| Variation of |
| 1.5% of active |
| substance |
| concentration |
| IPBC : |
| T0=1.006% |
| T2w=1.005% |
| Variation of |
| 0.1% of active |
| substance |
| concentration |
| (all |
| concentrations |
| of active |
| substances at |
| the beginning |
| of the stability |
| study are |
| within the |
| authorized |
| concentration |
| variation of |
| declared |
| concentrations) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (%**  **(w/w)** | **Results** | **Reference** |
|  |  |  |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal  product - **ligh**t | Avoid direct exposition of the product to sunlight |  | - |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Temperature effect: see the stability tests above  The formulation is an aqueous micro-emulsion concentrate to be diluted with water. So, the humidity is not likely to have any impact on the  stability of the formulation. |  | - |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | There is no reactivity towards container material. Polyethylene containers have been used since many years without having negative influence on the  contained product. |  | - |  |
| Wettability | The product is liquid |  | - |  |
| Suspensibility, spontaneity and dispersion stability | The product is liquid |  | - |  |
| Wet sieve analysis and dry sieve test | The product is liquid |  | - |  |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 30°C +-2°C |  | No cream or oil were observed during various stages of emulsification test (initial emulsification, standing after 30 min, 2h, 24h, re-  emulsification, |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (%**  **(w/w)** | **Results** | **Reference** |
|  |  |  | final emulsion stability after 30 min)  The liquid remains homogenous slightly yellow  limpid liquid |  |
| Disintegration time | The product is liquid |  | - |  |
| Particle size distribution, content of dust/fines, attrition, friability | The product is liquid |  | - |  |
| Persistent foaming | CIPAC MT 47.2 |  | Undiluted test item : Volume of foam after  10 seconds : 5 mL  Volume of foam after 1 minute : 0 mL  0.8% dilution: Volume of foam after  10 seconds : 0 mL  15% dilution: Volume of foam after  10 seconds : 0 mL |  |
| Flowability/Pourability/Dustability | The product is liquid |  | - |  |
| Burning rate — smoke generators | The product is not a smoke generator |  | - |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (%**  **(w/w)** | | | **Results** | **Reference** |
| Burning completeness — smoke generators | The product is not a smoke generator |  | | | - |  |
| Composition of smoke — smoke generators | The product is not a smoke generator |  | | | - |  |
| Spraying pattern — aerosols | The product is not an aerosol |  | | | - |  |
| Physical compatibility | No physical incompatibility |  | | | - |  |
| Chemical compatibility | Avoid contact with oxidizing agents |  | | |  |  |
| Degree of dissolution and dilution stability | The product is liquid |  |  |  | - |  |
| Surface tension | OECD 115 |  | | | Surface Tension = 70.3 mN.m-1 for pure product  Surface Tension = 27.2 mN.m-1 for test item diluted at 15% w/w |  |
| Viscosity | OECD 114 |  | | | Kinematic viscosity =  7.04 mPa.s at 20°C  Kinematic viscosity =  4.22 mPa.s at 40°C |  |

|  |
| --- |
| Conclusion on the physical, chemical and technical properties of the product |
| The biocidal product SARPECO 9-PLUS is a slightly yellow limpid liquid with characteristic odour. The pH of the undiluted product is 6.67 and diluted to 1% is 6.76. The relative density is D420 = 1.024. At ambient temperature the product has a long term stability for 24 months and is stable under cold and accelerated storage conditions. The product should be protected from direct exposition to light. At 20°C the surface tension is 70.3 mN/m and the viscosity is 7.04 mPa.s. At 40°C the viscosity is 4.22 mPa.s. Physical and compatibility with other products is not relevant. The contact with oxidizing agents has to be avoided. |

### Physical hazards and respective characteristics

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (%**  **(w/w)** | **Results** | **Reference** |
| Explosives | Waived | The product does not contain any components associated with explosive properties. | | |
| Flammable gases | Waived | The product is liquid | | |
| Flammable aerosols | Waived | The product is liquid | | |
| Oxidising gases | Waived | The product is liquid | | |
| Gases under pressure | Waived | The product is liquid | | |
| Flammable liquids | ISO Standard 3679  (closed cup) | Formulation LAB 2009\_009 | Flash point > 110.0°C (the  boiling temperature of the product) | Physico-chemical tests on SARPECO 9-PLUS (Lab2009\_009),  January 2016 |
| Flammable solids | Waived | The product is liquid | | |
| Self-reactive substances and mixtures | Waived | The product does not contain any components associated with self-reactive properties | | |
| Pyrophoric liquids | Waived | By experience, the product does not ignite within a few minutes when coming into contact with air | | |
| Pyrophoric solids | Waived | The product is liquid | | |
| Self-heating substances and mixtures | Waived | The product is liquid and in general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. | | |
| Substances and mixtures which in  contact with water emit flammable gases | Waived | The product is an aqueous solution | | |
| Oxidising liquids | Waived | The product does not contain any components that have  oxidative properties and furthermore there are no structural indications of oxidising potential. | | |
| Oxidising solids | Waived | The product is liquid | | |
| Organic peroxides | Waived | The product does not contain any compound with bivalent –  O-O- structure | | |
| Corrosive to metals | Waived | The product does not contain any component able do corrode metals. | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (%**  **(w/w)** | **Results** | **Reference** |
| Auto-ignition temperatures of products (liquids and gases) | Waived | The formulation does not contain any components that have auto-ignition properties and furthermore there are no structural indications of auto-ignition | | |
| Relative self-ignition temperature for solids | Waived | The product is liquid | | |
| Dust explosion hazard | Waived | The product is liquid | | |

|  |
| --- |
| Conclusion on the physical hazards and respective characteristics of the product |
| The flashpoint of the solution is higher than 110.0°C. The product has no self-reacting properties and does not react with air and is not self-heating since it is a liquid at room temperature. It is not able to react with metals and is not corrosive. The product is not oxidizing nor explosive. No classification related to physico-chemical risks is necessary. |

* + 1. **Methods for detection and identification**

Belgium SARPECO 9-PLUS PT8

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 | |
|  | | |  | | |  | | |  | | |  | | |  | | |  | | |  | |  | | |  | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Analytical methods for monitoring, for detection in soil, in air, in water, in animal and human body fluids and tissues and residues in food and feeding stuff are described and defined in the CARs of active substances.

The product contains a substance of concern: Alcohol C11, ethoxylated (N°CAS 127036-24- 2). The provider of this substance has not developed a method of detection. However, there are some peer review publications available on the method of analysis of such non-ionic tension-active ingredients. The most often used and robust method is liquid chromatography coupled with mass spectrometry detection. Moreover, the norm ASTM D4252-89 (2017) “Standard Test Methods for Chemical Analysis of Alcohol Ethoxylates and Alkylphenol Ethoxylates” is available to describe the possible methods of analysis of such compounds.

The SoC is a Band B Soc, meaning only qualitative assessment, meaning that there is no need in precise concentration determination.

Moreover in view of the APCP TAB from 2020, even if it cannot be officially taken into account in view of the submission date of the dossier, analytical methods are not required for SoC that cannot be formed during storage and their concentration remains unchanged. Here is the justification of the applicant: *“indeed, a microemulsion (the formulation of the product) is a thermodynamically stable dispersion of two immiscible liquids, stabilized by a surfactant.*

*If the surfactant was not stable during the storage stability /shelf life studies, the product would not be thermodynamically stable and so the solution would not be colourless and would present a deposit or phase separation at the end of the test.*

*According to the observations done at the end of the stability/shelf life studies, we can concluded that the substance Alcohol C11, ethoxylated (CAS 127036-24-2) is stable.*

*The substance Alcohol C11, ethoxylated (CAS 127036-24-2) is obtained through complex controlled chemical reactions by our supplier, and cannot be obtained naturally during manufacture or storage of our biocidal product .*

*So it is chemically and scientifically impossible that the amount of the substance Alcohol C11, ethoxylated (CAS 127036-24-2) could naturally increase during manufacture or storage of our biocidal product.*

It is why as eCA we have decided to follow a pragmatic approach and not request an analytical method for the SoC detection.

We propose to include the justification of the applicant to the PAR.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The content in active substances permethrin, tebuconazole, propiconazole and IPBC can be determined in the product using a validated HPLC with an UV/DAD detector. The identity of the analyte is confirmed by comparison of the retention times. The standard regression is linear and the method is repeatable. The mean recovery rates are in the range of 98.6 – 99.1% for permethrin; 99.8 – 100.4% for tebuconazole, 99.8 – 101.3% for propiconazole and 97.7 – 97.8% for IPBC. The limit of quantification (LOQ) is 0.0860 mg/mL for permethrin, 0.0970 mg/mL for tebuconazole, 0.0632 mg/mL for propiconazole and 0.0775 mg/mL for IPBC. |

### Efficacy against target organisms

###### Function and field of use

The product Sarpeco 9-Plus is a concentrated micro-emulsion (ME) for professional use only in wood preservation (PT8). Sarpeco 9-Plus contains 4 active substances with the following nominal concentrations w/w: Permethrin 2%, Propiconazole 1.1%, Tebuconazole 1.1% and IPBC 1%.

The product is intended to be used for preventive treatment against fungi and insects for classes 1, 2, 3.1 and 3.2 and can be applied by surface treatment (brushing, short dipping, automated spraying) and deep penetration (vacuum pressure/double vacuum). The targeted wood includes construction wood used outdoor. A top coat is required to be applied after treatment with the product for use class 3.1 and 3.2.

The efficacy claimed by the applicant is “effective against wood rotting basidiomycetes (brown and white rot fungi), xylophage insects and termites in preventive treatment of wood construction”. According to the applicant, the product Sarpeco 9-Plus is to be diluted 0.8% to 14.5% w/w with water according to the application method and type of wood. The table below resumes the claim matrix for the product Sarpeco 9-Plus.

**Table 2.2.5.1.1 Categories and codes for product for Sarpeco 9-Plus.**

|  |  |  |
| --- | --- | --- |
| User category | Industrial application | A.20 |
| Wood category | Softwood and hardwood | B.10, B.20 |
| Wood product | Solid wood | C.10, C.20, C.21, C.22, C.23, C.24 |
| Application aim | Preventive treatment use class | D.40 |

|  |  |  |
| --- | --- | --- |
| Field of use | Use class 1 to 3 included | E.10 – E.30 |
| Method of application | Surface treatment (brushing, automated spraying and short dipping) and penetrative treatment (vacuum and double vacuum pressure) | F10, F.11, F.14, F30 |
| Target organisms | Brown and white rot fungi, xylophage insects and termites (subterranean) | G.10, G.11, G.30, G.51 |

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

Sarpeco 9-Plus is intended to be used in order to protect wood for the following fields of use:

* Use class 1: situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting
* Use class 2: situation in which the wood or wood-based product is under cover and not exposed to the weather (particularly rain and driven rain) but where occasional, but non persistent, wetting can occur
* Use class 3: situation in which wood or wood-based product is above ground and exposed to the weather (particularly rain). The use class 3 is subdivided in two sub- categories, and the applicant claims both of them:
  + 3.1: wood or wood-based products will not remain wet for long periods.

Water will not accumulate

* + 3.2: wood or wood-based products will remain wet for long periods. Water may accumulate.

The target organisms claimed for the product Sarpeco 9-Plus are wood-boring insects (tested specie is *Hylotrupes bajulus: :* according to the Transitional Guidance on Efficacy Assessment for Product Type 8 Wood Preservatives (March 2015), which was in force when the application for authorisation of SARPECO 9-PLUS was submitted, efficacy against *H. bajulus* is sufficient to cover a general claim against wood boring beetles for preventive treatment), termites (tested specie is *Reticulitermes santonensis*) and fungi, including white rot and brown rot fungi (tested organisms are *Coriolus versicolor*, *Gloeophyllum trabeum*, *Coniophora puteana* and *Poria placenta*)*.*

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

The following information is available for active substances from the Assessment Reports for inclusion to Annex I for each active substance.

Propiconazole (CAS N° 60207-90-1)

Propiconazole may be used in the preventive treatment of wood against fungi. Propiconazole is a triazole molecule acting by inhibition of demethylation during the ergosterol biosynthesis.

Tebuconazole (CAS N°10734-96-3)

Tebuconazole has been evaluated for its use in wood preservation (Product Type

8 of the Biocidal Products Directive) up to use class 4a and 4b. As a fungicide, tebuconazole interferes with basic metabolism of the fungal cell wall and contents (see

also propiconazole, the other triazole molecule). In combination products e.g., with propiconazole, especially well-balanced efficacy against a broad range of wood rotting fungi can be achieved combined with minimising the amounts of each active.

IPBC (CAS N° 55406-53-6)

IPBC is a fungicide used for wood preservation (PT8) up to and including use class 3. IPBC is active against wood rotting and wood disfiguring fungi by interfering with the cell membrane permeability. IPBC has a carbamate structure. The target sites of carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee). IPBC is, in most cases, combined in the formulated products with other active substances like other fungicides (propiconazole, tebuconazole, carbendazim) or insecticides, e.g. permethrin.

Permethrin (CAS N°52645-53-1)

Permethrin has an efficacy against wood-destroying insects (including termites) during both larval and adult life-cycle stages. Permethrin is included into pyrethroids molecule family, responsible for a continuous nerve stimulation of insects ingesting permethrin treated wood, resulting in a lethal effect. Permethrin-based products are intended to be used by automated spraying, vacuum pressure, double vacuum pressure, flow coating and dipping treatment. From the four active substances present in this biocidal product, permethrin is the only demonstrating an insecticide effect.

The biocidal product Sarpeco 9-Plus, containing the four active substances described above, is intended to be used in preventive treatment against fungi (basidiomycetes) and wood boring insects, including termites.

###### Mode of action, including time delay

The following information is available for active substances from CAR reports for the active substances contained in the Sarpeco 9-Plus product.

Propiconazole (CAS N° 60207-90-1)

Propiconazole-based products can be applied by vacuum-pressure, double- vacuum, spraying, brushing and industrial dipping for constructions outdoors. Wood indoors may be treated by brushing, spraying and professional injection. The targeted fields of use are use class 2 and use class 3.

Tebuconazole (CAS N°10734-96-3)

Tebuconazole – based products can be applied by vacuum pressure, double vacuum, automated spraying, flow coating, dipping and spraying and in situ outdoors brushing. As mentioned in the Assessment Report for inclusion to Annex I, Tebuconazole is not recommended for treatment of wood inside housing areas (with the exception of window frames and external doors, which will usually be treated on or before installation).

IPBC ( CAS N° 55406-53-6)

IPBC- containing products can be applied by vacuum pressure, double vacuum, automated spraying, flow coating, dipping and spraying, in situ outdoors brushing.

Permethrin (CAS N°52645-53-1)

Permethrin-based products are intended to be used by automated spraying, vacuum pressure, double vacuum pressure, flow coating and dipping treatment.

According to the applicant and the label claim, the product Sarpeco 9-Plus can be applied by the short dipping and automated spraying for surface treatment and by vacuum pressure and double vacuum pressure for penetrative treatment. The application rate depends on the targeted use class and organisms. The fixation step, following the application is at minimum 4 hours. The treated wood has to be dried during 24 to 48 hours in ventilated place. Wood intended to be used in outdoors has to be protected by a resistant paint or varnish.

###### Efficacy data

To support the claims for product Sarpeco 9-Plus, the applicant has submitted two tests to prove the efficacy of the product against wood rot fungi, four tests to prove the efficacy against wood boring insects and four tests to prove the efficacy against termites in particular.

For the insecticide (including termites) claims, the applicant has tested the formulation named Lab 2005 031, containing 2% of permethrin, the only active substance responsible for insecticide action. Applicant has provided an analysis report (report n° ) proving that the concentration of permethrin in the tested formulation is within the variation admitted to not affect the efficacy.

For the fungicide claims, the tested formulation is Lab 2007 151, containing 1% of IPBC, propiconazole, tebuconazole and permethrin. Applicant has provided an analysis report (report n° ) proving that the concentration of permethrin, propiconazole, tebuconazole and IPBC in the tested formulation is within the variation admitted to not affect the efficacy.

According to the EN 599 norm, Annex A, the application rates can be derived from tested formulations different from the product asking the authorization, with the condition that the variation in co-formulants between the products does not affect the efficacy.

To prove the insecticide action for surface treatment for use class 1,2 and 3, the tests n° and n° have been submitted. As proposed in the EN 599-1 (2009), the

test follows EN 46 norm, carried after ageing procedure EN 73 for use class 1 and 2; and EN 84 for use class 3, on recently hatched larvae of *Hylotrupes bajulus*. This insect is considered to present the most resistance to permethrine and thus is considered as insect of reference to prove the insecticide action. Indeed, for a known insecticide like permethrin, preventive test done on *Hylotrupes bajulus* is enough to validate the preventive efficacy against *Anobium punctatum* and *Lyctus*, but not enough to validate the efficacy against termites. The efficacy of permethrin as a wood preservative is known since 1977. The suggested toxic values against *Anobium punctatum* is 42,2 to 96,3 g permethrin/m3, against *Lyctus brunneus* (according to EN 20 or BS 5217:1975) is 200 mg permethrin/kg of solution. So for a retention of 50 Kg/m3 of solution (equivalent to 100 g/m²), a toxic value is 10 g permethrin/m3. The suggested toxic values against *Hylotrupes bajulus* (according to EN 46) is 90 to 140 g permethrin/m3. In conclusion, permethrin has, more or less, an equivalent activity against beetle *Hylotrupes bajulus* (which is the less sensitive), *Anobium punctatum* and *Lyctus brunneus* (which is the most sensitive). The application method is brushing procedure. However, eCA Belgium is of opinion that this method could be extended to all usual surface treatment, such as short dipping and aspersion, with the condition to respect the application rate. The results show 100% mortality at the end of the test in comparison with the positive control, where almost 100% of larvae remains alive at the end of the test.

To prove the insecticide action for penetrating treatment for use class 1,2 and 3, the tests n° and n° have been submitted. As proposed in the EN 599-1 (2009), the

test follows EN 47 norm, carried after ageing procedure EN 73 for use class 1 and 2; and EN 84 for use class 3, on recently hatched larvae of *Hylotrupes bajulus*. The application method is vacuum pressure treatment. The results show 100% mortality at the end of the test in comparison with the positive control, where almost 100% of larvae remains alive at the end

of the test. For use class 1 and 2 the preservative retention mean is 0.83 kg/m³ and for use class 3 it is 0.85 kg/m³.

To prove the termiticide action for surface treatment for use class 1,2 and 3 the tests n° and n° have been submitted. As proposed in the EN 599-1 (2009), the

test follows EN 118 norm, carried after ageing procedure EN 73 for use class 1 and 2; and EN

84 for use class 3, on *Reticulitermes santonensis* de Feytaud . The application method is brushing procedure. The results show no damage > 1 for 5 treated samples and damage = 2 for only one treated sample. The positive controls demonstrate damage rate of 4, meaning heavy attack.

To prove the termiticide action for penetrating treatment for use class 1, 2 and 3 the tests n° and n° have been submitted. As proposed in the EN 599-1 (2009), the

test follows EN 117 norm, carried after ageing procedure EN 73 for use class 1 and 2; and EN

84 for use class 3, on *Reticulitermes santonensis* de Feytaud. The application method is vacuum pressure treatment. The results show no damage rating >1 at the application rate of

4.8 kg/m³ for all use classes claimed by the applicant.

To prove the fungicide action for use class 2, the test n° has been submitted. For

the use class 3, the test n° has been submitted. As proposed in the EN 599-1

(2009), the test follows EN 113 norm, carried after ageing procedure EN 73 for use class 2; and EN 84 for use class 3, on *Coniophora puteana, Poria placenta, Gloeophyllum trabeum* and *Coriolus versicolor*. The application method is vacuum pressure treatment. According to the results, the mid toxic value for the most tolerant fungus for pine wood is between 3.25 kg/m³ (*Poria placenta*, from the test n° ) and for beech wood is 7.215 kg/m³ (*Coriolus versicolor*, from the test n° ).

The table below summarize the principal information of the tests provided by the applicant.

**Table 2.2.5.5.1 summary of experimental data provided by the applicant**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use and method of application**  **envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure**  **time** | **Test results: effects** | **Reference** |
| *Insecticide* | *E.10 E.20*  *F.14 F.12* |  | *Hylotrupes bajulus*  (recently hatched larvae) | EN 46 after  EN 73 ageing procedure | Brushing procedure  Concentration of the product tested: 5% w/w  Retention permethrin  : 0.1 g/m²  Solution retention: 100 g/m² | - 100%  mortality at the end of the test   * untreated control: 7% of mortaility at the end of the test * validity criteria (100% of   mortality) reached |  |
|  |  |  |  |  | BRV 100 g/m² of tested product = 0.1 g of permethrin/m² |
| *Insecticide* | *E.20 E.30*  *F.14 F.12* |  | *Hylotrupes bajulus*  (recently hatched larvae) | EN 46 after  EN 84 ageing procedure | Brushing procedure  Concentration of the product tested: 5% w/w | - 100%  mortality at the end of the test  - untreated control: 3% of  mortaility at the |  |
|  |  |  |  | Retention permethrin  : 0.1 g/m² |
|  |  |  |  | Solution retention: |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | 100 g/m² | end of the test  - validity criteria (100% of  mortality) reached  BRV 100 g/m² of tested product = 0.1 g of permethrin/m² |  |
| *Insecticide* | *E.10 E.20*  *F.30* |  | *Hylotrupes bajulus*  (recently hatched larvae) | EN 47 after  EN 73 ageing procedure | Vacuum pressure treatment  Concentration of the product tested: 0 – 0.33% w/w | - 100% mortality at the end of the test with the product retention rate of  0.83 kg/m³  - Untreated control: 12%  mortality (26  living larvae, 4 dead) |  |
|  |  |  |  | Solution retention: 0 – 2.2 kg/m³ |
| *Insecticide* | *E.20 E.30*  *F.30* |  | *Hylotrupes bajulus*  (recently hatched larvae) | EN 47 after  EN 84 ageing procedure | Vacuum pressure treatment  Concentration of the product tested: 0 – 0.33% w/w | - 100% mortality at the end of the test with the product retention rate of  0.85 kg/m³  - Untreated control: 0%  mortality (30 living larvae) |  |
|  |  |  |  | Solution retention: 0 – 2.3 kg/m³ |
| *Termiticide* | *E.10 E.20*  *F.12 F.14* |  | *Reticulitermes santonensis* de Feytaud | EN 118 after  EN 73 ageing procedure | Brushing procedure  Concentration of the product tested: 5% w/w | * No damage > 1 (except only one sample) for the retention rate of 200 g/m² * untreated control: damage   = 4 |  |
|  |  |  |  | Solution retention: 200 g/m² |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  | - validity criteria (no damages of rating >2) reached |  |
| *Termiticide* | *E.20 E.30*  *F.12 F.14* |  | *Reticulitermes santonensis* de Feytaud | EN 118 after  EN 84 ageing procedure | Brushing procedure  Concentration of the product tested: 5% w/w | * No damage > 1 (except only one sample) for the retention rate of 200 g/m² * untreated control: damage   = 4   * validity criteria (no damages of rating >2) reached |  |
|  |  |  |  | Solution retention: 200 g/m² |
| *Termiticide* | *E.10 E.20*  *F.30* |  | *Reticulitermes santonensis* de Feytaud | EN 117 after  EN 73 ageing procedure | Vacuum pressure treatment  Concentration of the product tested: 0 – 0.93% w/w | The lowest concentration with no damage >1 is 0.71% w/w (corresponding to 4.83 kg/m³ retention rate) |  |
|  |  |  |  | Solution retention: 0 – 6.40 kg/m³ | The next lowest concentration is 0.55  % w/w (corresponding to  3.89 kg/m³) |
| *Termiticide* | *E.20 E.30*  *F.30* |  | *Reticulitermes santonensis* de Feytaud | EN 117 after  EN 84 ageing procedure | Vacuum pressure treatment  Concentration of the product tested: 0 – 0.93% w/w | The lowest concentration with no damage >1 is 0.71% w/w (corresponding to 4.79 kg/m³ retention rate) |  |
|  |  |  |  | Solution retention: 0 – 6.5 kg/m³ | The next lowest concentration is 0.55  % w/w |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  | (corresponding to  3.88 kg/m³) |  |
| *Fungicide* | *E.20 F.30* |  | *Coniophora puteana*  *Poria placenta*  *Gloeophyllum trabeum* | EN 113 after  EN 73 ageing procedure | Vacuum pressure treatment  Concentration of the product tested for pine wood: 0 –  0.59% w/w | The m.t.v for *Coniophora puteana* is 2.8 kg/m³ (tested formulation concentration 0.37% w/w) |  |
|  |  | *Coriolus versicolor* |  | Concentration of the product tested for beech wood: 0 – 1.80% w/w  Solution retention for pine wood:  0 - 4.4 kg/m³  Solution retention for beech wood:  0 – 11.7 kg/m³ | The m.t.v for *Poria placenta*  is between 3.46 and  3.04 kg/m³ (tested formulation concentration 0.44 - 0.39% w/w)  The m.t.v for *Gloeophyllum trabeum*  is 2.75 kg/m³ (tested formulation concentration 0.37% w/w) |
|  |  |  |  |  | The m.t.v for *Coriolus versicolor* is between 7.77 and  6.66 kg/m³ (tested formulation concentration 1.17 - 1.03% w/w) |
| *Fungicide* | *E.20 E.30*  *F.30* |  | *Coniophora puteana*  *Poria placenta*  *Gloeophyllum trabeum* | EN 113 after  EN 84 ageing procedure | Vacuum pressure treatment  Concentration of the product tested for pine wood: 0 –  0.59% w/w | The m.t.v for *Coniophora puteana* is 2.87 kg/m³ (tested formulation concentration 0.37% w/w) |  |
|  |  | *Coriolus versicolor* |  |  | The m.t.v for *Poria placenta* |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | Concentration of the product tested for beech wood: 0 – 1.80% w/w  Solution retention for pine wood:  0 – 4.4 kg/m³  Solution retention for beech wood:  0 – 11.7 kg/m³ | is between 3.42 and  3.03 kg/m³ (tested formulation concentration 0.44 - 0.39% w/w)  The m.t.v for *Gloeophyllum trabeum*  is 2.88 kg/m³ (tested formulation concentration 0.37% w/w)  The m.t.v for *Coriolus versicolor* is between 7.74 and  6.69 kg/m³ (tested formulation concentration 1.17 - 1.03% w/w) |  |

Tests carried according to the EN 46 protocol after both procedure ageing EN 73 and EN 84 show an efficacy against wood boring insects at the retention rate of 100 g/m² of the tested formulation (2% permethrin), diluted at 5% w/w. From this, the BRV for **insecticide action for the product Sarpeco 9-Plus in surface treatment is 5 g/m²**.

Tests carried according to the EN 47 protocol after both procedure ageing EN 73 and EN 84 show an efficacy against wood boring insects at the retention rate of 0.85 kg/m³ of tested formulation (2% permethrin). From this, the BRV for **insecticide action for the product Sarpeco 9-Plus in penetrative treatment is 0.85 kg/m³**.

Tests carried according to the EN 118 protocol after both procedure ageing EN 73 and EN 84 **show an efficacy** against termites at the retention rate of 200 g/m² of the tested formulation (2% permethrin), diluted at 5% w/w. According to the EN 599, point 5.2.7 open the possibility for dose reduction, but only when supported by additional evaluation method. It is why the applicant has submitted a field test IRG/WP 18-10931 with a formulation containing 1%, permethrin, diluted at 5% (see the Conf. annex for more details) to support the claimed application rate. The test demonstrates the efficacy against non-European wood (Kempas, Koompassia malaccensis) and termite (Coptotermes curvignathus) species with 0.05% permethrin. The concentration of permethrin that will be authorised with the product Sarpeco

-9 plus is twice higher, so it should leave a safety margin for inter-species variation concerning wood and termites. The product Sarpeco-9 Plus is thus effective against termites in surface treatment with application rate of 5 g/m².

Tests carried according to the EN 117 protocol after both procedure ageing EN 73 and EN 84 show an efficacy against termites at the retention rate situated between 3.9 and 4.8 kg/m³ of tested formulation (2% permethrin). From this, the BRV for **termiticide action for the product Sarpeco 9-Plus in penetrative treatment is 4.36 kg/m³ for use classes 1 and 2 and 4.33 kg/m³ for use class 3**.

Tests carried according to the EN 113 protocol after both procedure ageing EN 73 and EN 84 on the tested formulation (1% of each active substance) show an efficacy against fungi at the

m.t.v = 3.225 kg/m³ for the softwood and at the m.t.v = 7.215 kg/m³ for the hardwood. From this, the mid toxic value for the **fungicide action for the product Sarpeco 9-Plus in penetrative treatment is 3.225 kg/m³ for the pine wood and 7.214 kg/m³ for the beech wood.** As explained in EN 599-1:2009 norm, at 5.2.15, in order to derive the critical value, the biological reference value in grams per square meter shall be deemed to be equivalent to twice the biological reference value established in kilograms per cubic metre in the EN 113 test. From this, the toxic value for the **fungicide action for the product Sarpeco 9-Plus in surface treatment is 6.45 g/m² for the pine wood and 14.428 g/m² for the beech wood**.

The applicant has submitted the following dilution rates according to the use class and wood type.

**Table 2.2.5.5.2 Summary of efficacious retention rates submitted by the applicant.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Use class | Type of wood | Critic values for surface treatment  (g/m²) | Critic values for penetrative treatment (Kg/m³) | |
| Without termites | With termites |
| Use class 1 | Softwood | 5 | 0.85 | 4.36 |
| Hardwood |
| Use class 2 | Softwood | 6.5 | 3.25 | 4.36 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Hardwood |  |  |  |
| Use class 3.1 | Softwood | 6.5 | 3.25 | 4.33 |
| Hardwood | 14.5 | 7.22 | 7.22 |
| Use class 3.2 | Softwood | / | 3.25 | 4.33 |
| Hardwood | / | 7.22 | 7.22 |

As the values calculated from the submitted efficacy tests are equal or very slightly below the values (less than 10%) of retention rate proposed by the applicant, the proposed application doses are accepted.

The claimed consumption of the product Sarpeco 9-Plus is 100 g/m² or 500 – 600 kg/m³, according to the wood type. Based on the application rates calculated from the submitted tests, the following dilutions are accepted in the aim to reach the claimed consummation:

* Use class 1, surface treatment : **5%** dilution in water
* Use class 2, surface treatment : **6.5%** dilution in water
* Use class 3.1, surface treatment: **6.5%** dilution in water for softwood and **14.5%**

dilution in water for hardwood

* Use class 1, 2, 3.1, 3.2, penetrative treatment: **0.8%** dilution in water for softwood (600 kg/m³) and **1.45** % dilution in water for hardwood (500 kg/m³).

The product shall be dosed by an automatic pump in a system vacuum pressure. These values are indicative values, that shall be adapted according the type of wood, the product absorption ability and inherent parameters of vacuum pressure systems.

In view of available information on active substances and efficacy tests provided by the applicant, eCA Belgium believes that the efficacy of Sarpeco 9-Plus is sufficiently demonstrated.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Conclusion on the efficacy of the product** | | | | |
| The Sarpeco 9-Plus product is effective against wood-destroying insects including termites and wood destroying fungi (white rot and brown rot fungi) in preventive treatment.  The field of use covers use class 1, use class 2, use class 3.1 and use class 3.2.  **Table 2.2.5.1.1 Categories and codes for product for Sarpeco 9-Plus.** | | | | |
|  | User category | Industrial application | A.20 |  |
|  | Wood category | Softwood and hardwood | B.10, B.20 |  |
|  | Wood product | Solid wood | C.10, C.20, C.21, C.22, C.23, C.24 |  |
|  | Application aim | Preventive treatment use class | D.40 |  |
|  | Field of use | Use class 1 to 3 included | E.10 – E.30 |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Method of application | Surface treatment (brushing, automated spraying and short dipping) and penetrative treatment (vacuum and double vacuum pressure) | F10, F.11, F.14, F30 |  |
|  | Target organisms | Brown and white rot fungi, xylophage insects and termites (subterranean) | G.10, G.11, G.30, G.51 |  |
| The following dilutions of the biocidal product can be used:   * Use class 1, surface treatment (application rate 100 g/m²) : **5%** dilution in water * Use class 2, surface treatment (application rate 100 g/m²) : **6.5%** dilution in water * Use class 3.1, surface treatment (application rate 100 g/m²): **6.5%** dilution in water for softwood and **14.5%** dilution in water for hardwood * Use class 1, 2, 3.1, 3.2, penetrative treatment: **0.8%** dilution in water for softwood (application rate 600 kg/m³) and **1.45** % dilution in water for hardwood (application rate 500 kg/m³). | | | | |

###### Occurrence of resistance and resistance management

The biocidal product Sarpeco 9-Plus contains four active substances: IPBC (carbamate molecule), propiconazole and tebuconazole (triazole molecules) and permethrin (pyrethroid molecule).

According to the CAR for IPBC, the risk of resistance formation against Carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee).

According to the CAR for propiconazole, the resistance to the triazole fungicides is a normal phenomenon embodied in the natural process of the evolution of biological systems and fungicides of these type have a similar resistance risk but probably different resistance factors. The risk of resistance against triazole fungicide occurrence is regarded to be medium. However, there are no specific resistance prevention measures for biocides identified. It is recommended to pay attention to prevention of the evolution of tolerant fungal strains and report to Competent Authorities any new information on development of fungal resistance to a triazole fungicide.

According to the CAR of permethrin, there are no reported cases of resistance occurring for the use of permethrin in wood preservation. However, several cases of resistance have been documented in a wide variety of insects when for the use as a general (PT18). It is recommended to report any observed resistance incidents. Additionally, pest management strategies are advised in the use of permethrin for wood preservation in order to combat any potential for the onset of resistance.

###### Known limitations

According to the applicant, treated wood has to be protected by a coating after biocidal product application and sufficient drying (see also : 2.2.5.4 Mode of action, including time delay). More precisely:

* + - * + Treated wood used indoor (use class 1) (carpentries, beams, …) are, in general, protected with a coating like woodstain, paint, varnish before use for decorative and/or durability purpose.
        + Treated wood used outdoor (use class 3.1 and 3.2) (window frames, claddings ….) must be protected with a coating like woodstain, paint, varnish. This obligation is mentioned in their technical documentation.

###### Evaluation of the label claims

As stated at the point 2.2.5.5 and in the conclusion of efficacy of the product, eCA Belgium believes that the efficacy of Sarpeco 9-Plus is sufficiently demonstrated at the doses claimed by the applicant for surface and penetrative treatment. The label is in agreement with the conclusions of the efficacy for this product.

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

Not relevant.

### Risk assessment for human health

#### 2.2.6.1 Assessment of effects on Human Health

##### Skin corrosion and irritation

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified.  One **ingredient** of the product SARPECO 9-PLUS is classified as SKIN IRRIT. 2. Please refer to the confidential annex for information on the substance and his concentration. |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

The only ingredient of the mixture classified as skin irritant category 2 shall be ≥10% in order to classify the mixture as skin irritant category 2. As the concentration of this ingredient is inferior to 10%, the mixture is not classified for the Skin Corrosion/irritation.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | The product is not expected to be irritating to skin. |
| Justification for the value/conclusion | Estimation by calculation according Guidance on the Application of the CLP criteria (version 5, July 2017) when data are available for all ingredients or only for some ingredients of the mixture. |

|  |  |
| --- | --- |
|  | In order to classify the mixture as Skin irritant category 2, the ingredient of the mixture classified as skin irritant category 2 should be ≥ 10% |
| Classification of the product according to CLP and DSD | No classification needed |

##### Eye Irritation

|  |  |
| --- | --- |
| Information requirement | Study scientifically unjustified.  Information on active substance1: IPBC (CAS: 55406-53-6)  Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H331 – Acute Tox. 3 (inhalation), H317- Skin Sens. 1, H318 – Eye Dam. 1, H372 – STOT RE 1 (Larynx)  Information on co-formulant2:  Classification (Health hazard only): H302 – Acute Tox. 4, H318 – Eye Dam. 1.  In addition, some others ingredients of the product SARPECO 9-PLUS are classified as EYE IRRIT. 2. Please refer to the confidential annex for information on the substances and their concentration. |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

1 Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP06

2 SDS provided by the applicant

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Ingredient** | | **Classification** | **Concentration triggering classification of a mixture** | **Concentration (% w/w)** |
| **Name** | **CAS N°** |
| IPBC | 55406-53-6 | Eye Dam. 1, H318 | 3% (cat.1)  1% – 3% (cat.2) | 1 |
| Alcohol C11, ethoxylated | 127036-24-2 | Eye Dam. 1, H318 | 3% (cat.1)  1% – 3% (cat.2) | Confidential information |

The concentration of at least one substance classified as H318 is above the concentration triggering the classification of the mixture (3%). Therefore, the mixture is classified for the Serious eye damage/eye irritation with the hazard statement **H318 « Causes serious eye damage».** According the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (July 2017, Version 3.0), for professional/industrial users, the following precautionary statements are :

- Highly recommended : **P280, P305 + P351 + P338, P310 (in combination with P305+P351+P338).**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | The sum of concentration of ingredients classified as H318 is above the concentration triggering the classification of the mixture (3%). |
| Justification for the value/conclusion | As the mixture itself has not been tested to determine its eye irritation/damage properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the classification of the mixture has to be done by using the rules laid down in Regulation (EC) No 1272/2008 (CLP).  Estimation by calculation according Guidance on the Application of the CLP criteria (version 5, July 2017) when data are available for all ingredients or only for some ingredients of the mixture. |
| Classification of the product according to CLP and DSD | Eye Dam. 1 H318 |

##### Respiratory tract irritation

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

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Conclusion | Not irritating to the respiratory tract |
| Justification for the conclusion | According to the harmonized classification and labelling of the active substances IPBC, Propiconazole, tebuconazole, and permethrin, the active ingredients are not irritant to the respiratory tract. None of the other ingredients have respiratory tract irritation properties. |
| Classification of the product according to CLP and DSD | No classification needed |

##### Skin sensitization

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified.  Information on active substance1: IPBC (CAS: 55406-53-6)  Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H331 – Acute Tox. 3 (inhalation), H317- Skin Sens. 1, H318 – Eye Dam. 1, H372 – STOT RE 1 (Larynx)  Information on active substance2: Propiconazole (CAS: 60207-90-1) |

|  |  |
| --- | --- |
|  | Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H317- Skin Sens. 1, H360D – Repr. 1B  Information on the active substance3 : Permethrin (CAS: 52645-53-1)  Classification (Health hazard only): H302 – Acute Tox. 4, H317 – Skin Sens 1, H332 – Acute Tox. 4. |
| Justification | As the mixture itself has not been tested to determine its skin sensitization properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the classification of the mixture has to be done by using the bridging rules. |

1 Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP06

2 Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP13

Note : ATP 13 was published in the EU Official Journal on 4 October 2018 and has enter into force 20 days after publication. The changes will apply from 1 May 2020. In accordance with CA-May13-Doc.5.4.rev 1 (amended as per CA-March16-Doc.4.1) and CA/35/2013, the hazard and precautionary statements should then reflect the updated harmonised C&L.

3 AR for permethrin (RMS: IE, January 2014) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – CLP00

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Ingredient** | | **Classification** | **Generic concentration limits triggering classification of a mixture** | **Concentration (% w/w)** |
| **Name** | **CAS N°** |
| IPBC | 55406-53-6 | Skin Sens. 1, H317 | 1% | 1 |
| Propiconazole | 60207-90-1 | Skin Sens. 1, H317 | 1% | 1.1 |
| Permethrin | 52645-53-1 | Skin Sens. 1, H317 | 1% | 2 |

The mixture is classified as a skin sensitiser because the mixture contains three ingredients classified as a skin sensitiser with a concentration present equal or above the appropriate generic concentration limit.

So the mixture is classified for the Skin sensitization with the hazard statement **H317 « May cause an allergic skin reaction ».** According the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (July 2017, Version 3.0), for professional/industrial users, the following precautionary statements are :

* Highly recommended : **P280**.
* Recommended: P261 (but may be omitted if P260 is given on the label), P333+P313, P362+P364, P501.
* Optional: P272.
* Recommended for inclusion in the safety data sheet : P302+P352 Remark : P321 is not recommended since no specific treatment is known

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Sensitizing |
| Justification for the value/conclusion | The mixture is classified as a skin sensitiser because the mixture contains ingredients classified as a skin sensitiser with a concentration present equal or above the appropriate generic concentration limit. |
| Classification of the product according to CLP and DSD | Skin Sens. 1 H317 |

##### Respiratory sensitization (ADS)

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

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitizing to the respiratory tract |
| Justification for the value/conclusion | According to the harmonized classification and labelling of the active substances IPBC, Propiconazole, tebuconazole, and permethrin, the active ingredients are not sensitizing to the respiratory tract. None of the other ingredients have respiratory sensitization properties |
| Classification of the product according to CLP and DSD | No classification needed |

##### Acute toxicity

1. *Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified.  Information on active substance1: IPBC (CAS: 55406-53-6)  Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H331 – Acute Tox. 3 (inhalation), H317- Skin Sens. 1, H318 – Eye Dam. 1, H372 – STOT RE 1 (Larynx)  Information on active substance2: Propiconazole (CAS: 60207-90-1)  Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H317- Skin Sens. 1, H360D – Repr. 1B  Information on active substance3: Tebuconazole (CAS: 60207-90-1) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H361d – Repr. 2  Information on the active substance4 : Permethrin (CAS: 52645-53-1)  Classification (Health hazard only): H302 – Acute Tox. 4, H317 – Skin Sens 1, H332 – Acute Tox. 4.  Information on co-formulant5:  Registration Name: Alcohol C11, ethoxylated, CAS No. : 127036-24-2, EC No. : /, Registration Number: 02-2119494838-16-0000  Classification (Health hazard only): H302 – Acute Tox. 4, H318 – Eye Dam. 1. |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

1 AR for IPBC (RMS: DK, February 2008) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP06

2 Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP13

Note : ATP 13 was published in the EU Official Journal on 4 October 2018 and has enter into force 20 days after publication. The changes will apply from 1 May 2020. In accordance with CA-May13-Doc.5.4.rev 1 (amended as per CA-March16-Doc.4.1) and CA/35/2013, the hazard and precautionary statements should then reflect the updated harmonised C&L.

3 AR For Tebuconazole (RMS : DK, November 2007) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP07

4 AR for permethrin (RMS: IE, January 2014) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – CLP00

5 SDS provided by the applicant

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Ingredient** | | **Classification** | **Converted acute toxicity point estimate** | **Concentration (% w/w)** |
| **Name** | **CAS N°** |
| IPBC | 55406-53-6 | Acute Tox. 4, H302 | 500 mg/kg1 | 1 |
| Propiconazole | 60207-90-1 | Acute Tox. 4, H302 | 500 mg/kg1 | 1.1 |
| Tebuconazol | 107534-96-3 | Acute Tox. 4, H302 | 500 mg/kg1 | 1.1 |
| Permethrine | 52645-53-1 | Acute Tox. 4, H302 | 500 mg/kg1 | 2 |
| Alcohol C11, ethoxylated | 127036-24-2 | Acute Tox. 4, H302 | 500 mg/kg1 | Confidential information |

*1Based on Guidance on the Application of the CLP Criteria, version 5, July 2017. “(d) When only range data (or acute toxicity hazard category information) are available for components in a mixture, they may be converted to point estimates in accordance with Table 3.1.2 when calculating the classification of the new mixture using the formulas in sections 3.1.3.6.1 and 3.1.3.6.2.3.”*

The ATE (Acute Toxicity Estimate) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula :

Toxicity : 100

= ∑𝑖

𝐶𝑖

𝐴𝑇𝐸 𝑚𝑖𝑥𝑡𝑢𝑟𝑒

𝑛 𝐴𝑇𝐸𝑖

where:

Ci = concentration of ingredient i (% w/w or % v/v) i = the individual ingredient from 1 to n

n = the number of ingredients

ATEi = Acute Toxicity Estimate of ingredient i. So ATE mixture = 5.707 mg/kg

The ATE for the mixture is > 2.000 mg/kg, so the mixture is not classified for the acute oral toxicity.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Calculated: 5707 mg/kg |
| Justification for the selected value | As the mixture itself has not been tested to determine its acute oral toxicity properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the classification of the mixture has to be done by using the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

|  |  |
| --- | --- |
|  | Estimation by calculation according Guidance on the Application of the CLP criteria (version 5, July 2017) when data are available for all ingredients or only for some ingredients of the mixture. |
| Classification of the product according to CLP and DSD | No classification needed. |

1. *Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified.  Information on active substance1: IPBC (CAS: 55406-53-6)  Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H331 – Acute Tox. 3 (inhalation), H317- Skin Sens. 1, H318 – Eye Dam. 1, H372 – STOT RE 1 (Larynx)  Information on the active substance2 : Permethrin (CAS: 52645-53-1)  Classification (Health hazard only): H302 – Acute Tox. 4, H317 – Skin Sens 1, H332 – Acute Tox. 4. |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

1 AR for IPBC (RMS: DK, February 2008) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP06

2 AR for permethrin (RMS: IE, January 2014) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – CLP00

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Ingredient** | | **Classification** | **Converted acute toxicity point estimate** | **Concentration (% w/w)** |
| **Name** | **CAS N°** |
| IPBC | 55406-53-6 | Acute Tox. 3, H331 | 0.5 mg/l1 | 1 |
| Permethrin | 52645-53-1 | Acute Tox. 4, H332 | 1.5 mg/l1 | 2 |

The ATE (Acute Toxicity Estimate) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula considering vapours :

Toxicity : 100

= ∑𝑖

𝐶𝑖

where:

𝐴𝑇𝐸 𝑚𝑖𝑥𝑡𝑢𝑟𝑒

𝑛 𝐴𝑇𝐸𝑖

Ci = concentration of ingredient i (% w/w or % v/v) i = the individual ingredient from 1 to n

n = the number of ingredients

ATEi = Acute Toxicity Estimate of ingredient i.

So considering vapours : 100

𝐴𝑇𝐸 𝑚𝑖𝑥𝑡𝑢𝑟𝑒

= 1

0.5

+ 2

1.5

So ATE mixture = 30.3 mg/l

The ATE for the mixture is > 5 mg/l, so the mixture is not classified for the acute inhalation toxicity.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Calculated: 30.3 mg/l |
| Justification for the selected value | As the mixture itself has not been tested to determine its acute oral toxicity properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the classification of the mixture has to be done by using the rules laid down in Regulation (EC) No 1272/2008 (CLP).  Estimation by calculation according Guidance on the Application of the CLP criteria (version 5, July 2017) when data are available for all ingredients or only for some ingredients of the mixture. |
| Classification of the product according to CLP and DSD | No classification needed |

1. *Acute toxicity by dermal route*

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Ingredient** | | **Classification** | **Converted acute toxicity point estimate** | **Concentration (% w/w)** |
| **Name** | **Cas N°** |
| None of the ingredients have acute dermal toxicity properties | | | | |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not applicable. None of the ingredients have acute dermal toxicity properties |
| Justification for the selected value | According to the harmonized classification and labelling of the active substance permethrin, the active ingredient has no acute dermal toxicity properties. None of the other ingredients have acute dermal toxicity properties. |
| Classification of the product according to CLP and DSD | No classification needed |

##### Specific target organ toxicity – single exposure

*Narcotic effects*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified.  One ingredient of the product SARPECO 9-PLUS is classified as SKIN IRRIT. 2. Please refer to the confidential annex for information on the substance and its concentration. |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

The mixture is not classified as H336 ‘May cause drowsiness or dizziness’ because the concentration of the concerned ingredient is not above the generic concentration limit triggering the classification of the mixture fixed to be at 20%.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – STOT SE – Narcotic effects** | |
| Value | Ingredient at concentration < 20% |
| Justification for the selected value | Estimation by calculation according Guidance on the Application of the CLP criteria (version 5, July 2017) when data are available for all ingredients or only for some ingredients of the mixture.  In order to classify the mixture as STOT SE 3, the concern ingredient of the mixture classified as STOT SE 3 should be ≥ 20%. |
| Classification of the product according to CLP and DSD | No classification needed |

##### Reproductive toxicity

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified  Information on active substance1: Tebuconazole (CAS: 60207-90-1) Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H361d – Repr. 2  Information on active substance2: Propiconazole (CAS: 60207-90-1)  Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H317- Skin Sens. 1, H360D – Repr. 1B |
| Justification | There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

1 AR For Tebuconazole (RMS : DK, November 2007) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP07

2 Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP13

Note : ATP 13 was published in the EU Official Journal on 4 October 2018 and has enter into force 20 days after publication. The changes will apply from 1 May 2020. In accordance with CA-May13-Doc.5.4.rev 1 (amended as per CA-March16-Doc.4.1) and CA/35/2013, the hazard and precautionary statements should then reflect the updated harmonised C&L.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Ingredient** | | **Classification** | **Generic concentration limits triggering classification of a mixture** | **Concentration (% w/w)** |
| **Name** | **Cas N°** |
| Tebuconazole | 107534-96-3 | Repr. 2, H361d | ≥ 3% | 1.1 |
| Propiconazole | 60207-90-1 | Repr. 1B, H360D | ≥ 0.3% | 1.1 |

The mixture is classified as **H360D ‘May damage the unborn child**’ because the concentration of the concerned ingredient is superior to the generic concentration limit triggering the classification of the mixture fixed to be at 0.3%. According the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (July 2017, Version 3.0), for professional/industrial users, the following precautionary statements are :

* + highly recommended (for category 1A and 1B) : **P201, P280, P308+P313.**
  + Recommended : P501.
  + Optional : P405.
  + Optional where P201 is assigned : P202.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment –Reproductive toxicity** | |
| Value | Propiconazole: 1.1% |
| Justification for the selected value | The concentration of the concerned ingredient is above the generic concentration limit triggering the classification of the mixture fixed to be at 0.3%. |
| Classification of the product according to CLP and DSD | Repr. 1B, H360D |

##### Specific target organ toxicity – repeated exposure

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified.  Information on active substance1: IPBC (CAS: 55406-53-6)  Classification (Health hazard only): H302 – Acute Tox. 4 (oral), H331 – Acute Tox. 3 (inhalation), H317- Skin Sens. 1, H318 – Eye Dam. 1, H372 – STOT RE 1 (Larynx) |
| Justification | As the mixture itself has not been tested to determine its specific target organ toxicity – repeated exposure properties and as there is no data on similar mixtures to adequately characterise the hazards of the mixture, the classification of the mixture has to be done by using the bridging rules. |

1 AR for IPBC (RMS: DK, February 2008) and Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) – ATP06

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Ingredient** | | **Classification** | **Generic concentration limits triggering classification of a mixture** | **Concentration (% w/w)** |
| **Name** | **Cas N°** |
| IPBC | 55406-53-6 | STOT RE1, H372 | Category 1: ≥ 10%  Category 2: ≥ 1%  and < 10% | 1 |

The mixture is classified as **H373 ‘May cause damage to organs (larynx) through prolonged or repeated exposure**’ because the concentration of the concerned ingredient is equal the generic concentration limit triggering the classification of the mixture fixed to be at 1%. According the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (July 2017, Version 3.0) the following precautionary statements are :

* Highly recommended : **P260.**
* Recommended: P314, P501.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Specific target organ toxicity - repeated** | |
| Value | IPBC: 1% |
| Justification for the selected value | The concentration of the concerned ingredient is equal the generic concentration limit triggering the classification of the mixture fixed to be at 1%. |
| Classification of the product according to CLP and DSD | Classification as STOT RE 2, H373 |

##### Information on dermal absorption

Dermal absorption studies are provided for propiconazole, tebuconazole and permethrin. No dermal absorption study with the biocidal product have been performed for IPBC.

1. **Dermal absorption of propiconazole**

The BE CA proposes to use a dermal absorption value of 16% for the in-use dilution of SARPECO 9-PLUS for superficial treatment (dilution at 14.5%) based on the in-vitro study provided. Applying a pro-rata approach for dilution at 5% leads to a calculated dermal absorption of 35%.

BE proposes to use the default value of 75% for concentrated and in-use dilution of SARPECO 9-PLUS for penetrative treatment, BE CA proposes to use a default dermal absorption value of 75%. Please refer to the confidential annex for more information.

1. **Dermal absorption of Tebuconazole**

The BE CA proposes to use a dermal absorption value of 15% for the in-use dilution of SARPECO 9-PLUS for superficial treatment (dilution at 14.5%) based on the in-vitro study provided. Applying a pro-rata approach for dilution at 5% leads to a calculated dermal absorption of 33%.

BE proposes to use the default value of 75% for concentrated and in-use dilution of SARPECO 9-PLUS for penetrative treatment, BE CA proposes to use a default dermal absorption value of 75%. Please refer to the confidential annex for more information.

1. **Dermal absorption of IPBC**

The BE CA proposes a default dermal absorption of 75%. Please refer to the confidential annex for more information.

1. **Dermal absorption of Permethrin**

The BE CA proposes to use a dermal absorption value of 12% for the in-use dilution of SARPECO 9-PLUS for superficial treatment (dilution at 14.5%) based on the in-vitro study provided. Applying a pro-rata approach for dilution at 5% leads to a calculated dermal absorption of 25%.

BE proposes to use the default value of 75% for concentrated and in-use dilution of SARPECO 9-PLUS for penetrative treatment, BE CA proposes to use a default dermal absorption value of 75%. Please refer to the confidential annex for more information.

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Value(s) used in the Risk Assessment – Dermal absorption** | | | |
| Mixing and Loading (concentrated product) | | | | |
| Substance | Propiconazole | Tebuconazole | IPBC | Permethrin |
| Values | 75% | 75% | 75% | 75% |
| Superficial treatment (dilution at 14.5%) | | | | |
| Substance | Propiconazole | Tebuconazole | IPBC | Permethrin |
| Values | 16% | 15% | 75% | 12% |
| Superficial treatment (dilution at 5%) | | | | |
| Substance | Propiconazole | Tebuconazole | IPBC | Permethrin |
| Values | 35% | 33% | 75% | 25% |
| Penetrative treatment | | | | |
| Substance | Propiconazole | Tebuconazole | IPBC | Permethrin |
| Values | 75% | 75% | 75% | 75% |

Please note that the calculations were considered for the two dilutions for superficial treatment (14.5% and 5%) and the different dermal absorption values. In the end, only the worst case is presented in the exposure section. This worst case is the superficial treatment at 14.5% with the associated dermal absorption values. Comparison could be found in annex 3.2.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Value(s) used in the Risk Assessment – Inhalation absorption and oral absorption** | | | |
| Substance | Propiconazole | Tebuconazole | IPBC | Permethrin |
| Value for inhalation absorption | 100% (default) | 100% (default) | 100% (default) | 100% (default) |
| Value for oral absorption | 100% (default) | 100% (default) | 100% (default) | 100% (default) |

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

Apart from the active substances, the biocidal product contains a substance of concern: Alcohol C11, ethoxylated (N°CAS 127036-24-2). This substance participates to the product classification as H318, Eye dam. Category 1.

The applicant provided the Safety Data Sheet (SDS) of the substance. According the information provided the substance is a polymer with a proposed classification as Acute Tox. 4 (H302) and Eye Dam. 1 (H318).

Proposed classification/labelling in accordance with Regulation (EC) N° 1272/2008:

|  |  |  |
| --- | --- | --- |
| Danger Category | Acute Tox. 4, Eye Dam. Cat.1 | |
| Pictogram(s) Signal word(s) | GHS05, GHS07  Danger | |
| H statements | H302  H318 | Harmful if swallowed  Causes serious eye damage |

There is no limit values available.

##### Available toxicological data relating to a mixture

Not applicable.

#### 2.2.6.2 Exposure assessment

SARPECO 9-PLUS is a wood preservative for industrial use only which has 3 functions: fungicide, insecticide and anti-termite. Its fields of use are Use classes 1, 2, 3.1 and 3.2 to protect wood construction (joinery, window frames, sidings, etc). The biocidal product is a water-based concentrate that will be diluted in water. The product is intended to be applied by industrial spraying process, by industrial dipping process, by vacuum pressure process or by industrial brushing.

SARPECO 9-PLUS contains four active substances : IPBC at 1.0% (w/w), Propiconazole and Tebuconazole each at 1.1% w/w and Permethrin at 2.0% w/w.

SARPECO 9-PLUS contains one substance of concern: alcohol C11, ethoxylated (N°CAS: 127036-24-2). This substance participates to the classification of the product as eye damage category 1 (H318).

According the annex A of the document “Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 2.1 February 2017” : a qualitative exposure and risk assessment should be done in order to determine whether S- phrases/P-statements normally associated with concerned R-phrases/H statements are sufficient or whether other risk mitigation measures should be applied. The qualitative risk assessment can be found in the section *2.2.6.3 Risk characterization for human health*.

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table: relevant paths of human exposure** | | | | | | | |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industri al use** | **Profession al use** | **Non- profession al use** | **Industria l use** | **Profession al use** | **Gener al public** | **Via food** |
| Inhalation | Yes | n.a. | n.a. | yes | yes | yes | n.a. |
| Dermal | Yes | n.a. | n.a. | yes | yes | yes | n.a. |
| Oral | No | n.a. | n.a. | no | no | yes | no |

**Primary exposure:**

**Industrial use :**

**Spraying :**

This type of superficial application process is typically used in sawmills and carpentry / joinery shops. Concentrates of the wood preservative are diluted, with water, to prepare a ready for use treatment solution. The wood, whether in debarked logs or fully or partly machined timber are moved through one or more longitudinal or transversal boxes on a continuously moving conveyor system. The product is applied as a spray which is usually as a coarse spray using a particle spray size to ensure the wetting of the timber with the correct amount of wood preservative. The spray boxes are relatively contained and splashguards surround the spraying boxes to eliminate any droplets of spray from entering the rest of the mill area and may have local exhaust ventilation. After the timber has been treated it is stacked or sorted, either mechanically or manually, either dries on the conveyor belt or in the post treatment drip dry conditioning area before being moved off-site to manufacturers or used on site.

The treatment apparatus is typically established in a contained or bunded area fabricated from materials resistant to the wood preservative product. Provision is made for the collection, recycling and reuse of wood preservative collected from the conveyor or drip dry area. Mixing, loading and application of the product are fully automated process.

Mixing and Loading

The mixing and loading is a fully automated process (pumping process) in a closed system. The product SARPECO 9-PLUS is delivered in 640L and 1000L containers or in 60 and 220L drums or in 25L cans. There is no manual interaction needed. Mixing occurs in a tank to which the product and water are automatically supplied in the required quantities via hoses. It is considered that the Mixing and Loading process is not associated with significant exposure to the operator. No exposure calculation is needed.

Application

Automated spraying, flow coating (deluge) is an industrial automated process. The wood is mechanically moved through one or more longitudinal or transversal boxes on a continuously moving conveyor system. The product is applied as a spray which is usually as a coarse spray using a particle spray size to ensure the wetting of the wood with the

correct amount of wood preservative. The spray boxes are relatively contained and splashguards surround the spraying boxes to eliminate any droplets of spray from entering the rest of the area and may have local exhaust ventilation. After the treatment of the wood, before removing treated wood from the system, excessive treatment solution is allowed to drain off. A potential source of exposure might be via evaporation of the product from opening the system after treatment. However, the active substances contained in SARPECO 9-PLUS have very low volability (IPBC Vp 2.36 10-3 Pa at 25°C, Tebuconazole Vp 1.7 10-6 Pa at 20°C, Propiconazole Vp 5.6 10-5 Pa at 25°C, Permethrin Vp 2.16 10-6 Pa at 20°C) and the process occurs at ambient temperature. No separate exposure calculation is made for this activity.

The model applied for post-application handling may cover potential exposure during the treatment process itself. The exposure calculation for the application stage is covered by post application.

Post-application: Handling of treated (wet) articles

Post-application exposure to the product may occur during the manual handling of treated (wet) wood. Unloading of the wood occurs mechanically on a continuously moving conveyor system. After treatment, the wood is transported mechanically to the storage place. The handling phase includes a cycle of loading, waiting, unloading and removal of treated timber to storage. Dermal contamination can occur through direct contact with the surface of treated wood and through contact with ancillary equipment and the contaminated process system.

**Dipping :**

Dipping and immersion are superficial application processes and are typically used in sawmills and carpentry / joinery shops. They are batch processes and are usually automatic in operation. In either case they involve the submerging of a pack or single piece (only in small scale operations) of wood into a dipping tank filled with ready for use wood preservative solution. Packs of wood are typically loaded on automatic equipment (e.g. a hydraulic mast) and lowered into the dipping tank. The immersion period lasts anything from a very short period of a few minutes to over one hour depending on the end use application of the treated commodity and the application rate of SARPECO 9- PLUS. After the required immersion period the packs or pieces of wood, which are slightly raised at one end to aid liquid run off, are hoisted out of the liquid and usually held above the open tank for excess liquid to fall back into the dipping tank and be re-used. When the excess liquid has been drained, the pieces or packs of wood are moved to a post treatment conditioning location which is usually bunded and the timber is allowed to dry before being moved off-site or used on site. Any further drips are contained and recycled. Some installations may have local exhaust ventilation. Mixing, loading and application of the product are fully automated process.

Mixing and Loading

The mixing and loading is a fully automated process (pumping process) in a closed system. The product SARPECO 9-PLUS is delivered in 640L and 1000L containers or in 60 and 220L drums or in 25L cans. There is no manual interaction needed. Mixing occurs in a tank to which the product and water are automatically supplied in the required quantities via hoses. It is considered that the Mixing and Loading process is not associated with significant exposure to the operator. No exposure calculation is needed.

Application

The application process itself occurs in a large tank, which is opened. Loading and unloading with wood occurs mechanically by forklift trucks. For the actual dipping process timber stacks are loaded onto a forklift integrated in the dipping system. Before removing treated wood from the dipping system, excessive treatment solution is allowed to drain off above the tank. Afterwards it is transported mechanically to the storage place. A

potential source of exposure might be via evaporation of the product from the open dipping tank. However, the active substances contained in SARPECO 9-PLUS have very low volability (IPBC Vp 2.36 10-3 Pa at 25°C, Tebuconazole Vp 1.7 10-6 Pa at 20°C, Propiconazole Vp 5.6 10-5 Pa at 25°C, Permethrin Vp 2.16 10-6 Pa at 20°C) and the process occurs at ambient temperature. No separate exposure calculation is made for this activity. However, the model applied for post-application handling may cover potential exposure during the treatment process itself. The exposure calculation for the application stage is covered by post application.

Post-application: Handling of treated (wet) articles

Post-application exposure to the product may occur during the manual handling of treated (wet) wood. Timber to be treated is generally stacked to large batches which are transported mechanically by forklift trucks. After treatment, they remain on the forklift above the tank for a certain while (initial drying), before they are transported mechanically by a forklift truck to the storage place for final drying and fixation. The handling phase includes a cycle of loading, waiting, unloading and removal of treated timber to storage. Dermal contamination can occur through direct contact with the surface of treated wood and through contact with ancillary equipment and the contaminated process system.

**Vacuum pressure :**

These types of processes are used to overcome the resistance of the wood to taking up the wood preservative liquid. They use combinations of vacuum and low or high pressures to force the liquid into the timber to achieve the desired depth of penetration of the wood preservative. The treatments are carried out in vessels or autoclaves which may be cylindrical or rectangular in cross-section and designed to be capable of safe operation depending on whether the process to be used is a vacuum pressure or double vacuum / low pressure one. The treatment installations include the treatment vessel, the storage tanks and provision for bunding and containment to prevent loss of preservative. Typically,

* the vacuum pressure process involves the following stages – vacuum – flood with preservative liquid – apply pressure (ranging between 800 and 1400 kPa) – pressure released – final vacuum applied – vacuum released and excess liquid from the timber in the treatment vessel is emptied. 300 – 600 treatment solution l/m3 applied.
* the double vacuum / low pressure involves the following stages – vacuum – flood with preservative liquid – apply low pressure (up to 200 kPa)- pump off liquid – final vacuum to leave timber touch dry and empty the treatment vessel. There are many variations in the processes but they can all be considered in one emission scenario because the process descriptions and the emission pathways are similar. Generally the following stages are involved:

1. The untreated wood, typically as packs of timber, is loaded onto bogies or tram cars that are moved into the treatment vessel using mechanical means such a winch or forklift truck.
2. The vessel door is closed and the door seal provides a liquid and air-tight seal. A vacuum is applied to remove most of the air from the cylinder and the air contained in the wood cells.
3. The treatment solution is usually a dilution of a concentrated product in the treatment plant to the required working strength (either heated or at ambient temperature depending on the system) is then pumped into the cylinder and the pressure is raised. The total treating time and cycles will vary, depending on the species of wood, the commodity being treated, and the desired product retention, but in all instances the treating process remains a closed system.
4. A final vacuum may be applied to remove the excess preservative that would otherwise drip from the wood into the vessel.
5. The final steps in the process are the unloading of the wood from the treatment vessel; its placing in a post treatment conditioning area before being either moved off -

site or fabricated on site. Mixing, loading and application of the product are fully automated process.

Mixing and Loading

The mixing and loading is a fully automated process (pumping process) in a closed system. The product SARPECO 9-PLUS is delivered in 640L and 1000L containers or in 60 and 220L drums or in 25L cans. There is no manual interaction needed. Mixing occurs in a tank to which the product and water are automatically supplied in the required quantities via hoses. It is considered that the Mixing and Loading process is not associated with significant exposure to the operator. No exposure calculation is needed.

Application

The application process itself occurs in a large cylinder, which is closed. Loading and unloading with wood occurs mechanically by forklift trucks. A potential source of exposure might be via evaporation of the product from opening the system after treatment. However, the active substances contained in SARPECO 9-PLUS have very low volability (IPBC Vp 2.36 10-3 Pa at 25°C, Tebuconazole Vp 1.7 10-6 Pa at 20°C, Propiconazole Vp

5.6 10-5 Pa at 25°C, Permethrin Vp 2.16 10-6 Pa at 20°C) and the process occurs at ambient temperature. No separate exposure calculation is made for this activity. However, the model applied for post-application handling may cover potential exposure during the treatment process itself. The exposure calculation for the application stage is covered by post application.

Post-application: Handling of treated (wet) articles

Post-application exposure to the product may occur during the manual handling of treated (wet) wood. Timber to be treated is generally stacked to large batches which are transported mechanically by forklift trucks. After treatment, they remain in the cylinder for a certain while (initial drying), before they are transported mechanically by a forklift truck to the storage place for final drying and fixation. The handling phase includes a cycle of loading, waiting, unloading and removal of treated timber to storage. Dermal contamination can occur through direct contact with the surface of treated wood and through contact with ancillary equipment and the contaminated process system.

**Industrial brushing :**

Mixing and Loading

For mixing and loading, the concentrated product from the original packaging is poured through a funnel into a drum, then the drum is completed with water. No significant exposure to the operator is expected as the product is poured through a funnel and as the mixing of the concentrated product and water is performed in a drum which is hermetically sealed.

Application

During the product application by brushing process, the ready to use product applied by a brush on wood to be protected.

Post-application: Handling of treated (wet) articles

After the treatment there is no contact of treated wood and operators because there is no handling of treaded surfaces. Only accidental exposure of operator could occur during this period.

Cleaning

During the cleaning process operator could be exposed to residual product in the brush.

**Professional use:**

The product is not intended to be used by professional users. No primary exposure is foreseen.

**Non-professional use:**

**Secondary exposure:**

**General consideration:**

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

* For propiconazole

Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on Propiconazole (RMS FI, November 2007).

* For tebuconazole

Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on Tebuconazole (RMS DK, November 2007).

* For IPBC

Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on IPBC (RMS DK, February 2008).

* For Permethrin:

Remark: the mw (molecular weight) and vp (vapour pressure) come from the Assessment Report on Permethrin (RMS IE, April 2014).

The result of this equation is lower than 1 for propiconazole, tebuconazole and permethrin. The **exposure to volatilised residues indoor** can be considered **negligible** for professional and general public for these active substances.

The result of this equation is higher than 1 for IPBC. The **exposure to volatilised residues** indoor cannot be considered negligible for professional and general public for these active substances. This exposure is therefore considered into the scenarios **for IPBC only**.

According the efficacy assessment of this product, the maximum application rate is 100 g/m² for preventive treatment. This value would be used for the secondary exposure.

**Industrial secondary exposure** is foreseen mainly during the cleaning/maintenance of the system. Any sort of maintenance/repair work on the system (hoses, valves etc.) may potentially lead to exposure. Cleaning may also potentially lead to exposure. However it is assumed that this type of tasks will be done by others professionals compared to application tasks (primary exposure). The exposure is considered lower than the exposure resulting of the application of the product. As no model are available in order to estimate the exposure, if PPE are required for the application task, it is advice to use the same PPE for the potentially secondary exposure.

**Professional secondary exposure** is foreseen for this product when activities are performed on the treated wood. The exposed professional for this type of work is supposed different than the professional doing the primary exposure. This task will induce an inhalation and dermal exposure.

**General public secondary exposure** is possible for this product. There are different situations where indirect exposure may be expected.

* Acute exposure
  + Non-professional user manipulating the treated wood (Processing treated dried wood)
  + Toddler chewing wood off-cut
* Chronic exposure: toddler playing and mouthing weathered playground structure outdoors.

##### List of scenarios

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table: scenarios** | | | |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure Description of scenario** | **Exposed group**  (e.g. professionals, non- professionals, bystanders) |
| 1. | Mixing and Loading | **Primary exposure :** Liquid manual loading/pouring | Industrial |
| 2. | Automated spraying - deluge | **Primary exposure :** Professional automated spraying | Industrial |
| 2bis. | Fully automated spraying | **Primary exposure :** Professional fully automated spraying | Industrial |
| 3. | Automated dipping | **Primary exposure :** Professional automated dipping | Industrial |
| 3bis. | Fully automated dipping | **Primary exposure :** Professional fully automated dipping | Industrial |
| 4. | Automated vacuum pressure | **Primary exposure :** Professional vacuum pressure impregnation | Industrial |
| 4bis. | Double vacuum pressure | **Primary exposure :** Professional double-vacuum treatment of wood | Industrial |
| 10. | Industrial Brushing | **Primary exposure :** Application of the product by brushing | Industrial |
| 11. | Cleaning of the brush equipment | **Primary exposure:** post-application, Cleaning of the brush equipment | Industrial |
| 5. | Processing  Treated dried wood | **Secondary exposure:** Professional sanding treated dried wood | Professional |
| 6. | Processing  Treated dried wood | **Secondary exposure:** Adult non-professional – sanding treated wood posts (acute exposure) | General public |
| 7. | Chewing wood off- cut | **Secondary exposure:** toddler chewing wood offcut (acute exposure) | General public |
| 8. | Playing and mouthing playgroun d structure | **Secondary exposure**: toddler playing and mouthing weathered playground structure outdoors (chronic exposure) | General public |
| 9. | Inhalation volatized residues  (IPBC  only) | **Secondary exposure** : General public - Inhalation volatized residues indoors (chronic exposure) | General public  Adult, child, toddler, infant |

##### Industrial exposure

*Scenario 1: Mixing and Loading*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 1: for packaging of 25L - Liquid manual loading/pouring** | | |
| For packaging between 60L and 1000L, the mixing and loading will be automated. This exposure could be determined with the model RISKOFDERM Toolkit connecting lines.  For packaging of 25L, a manual loading cannot be excluded. According to the HEEG opinion 1 on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale, M&L model 7 could be used.  Exposure to small packaging result in a worst-case situation and therefore, is considered the appropriated model for this task. | | |
|  | Parameters | Value |
| Tier 1 (No PPE) | % of active substance in the biocidal product Permethrin  Tebuconazole Propiconazole  IPBC | 2.0%  1.1%  1.1%  1% |
| Body weight1 | 60 kg |
| Inhalation rate1 | 1.25 m3/h |
| Potential dermal exposure on hands (no gloves)2 | 101 mg/min |
| Penetration through PPE (body) = no PPE1 | 100% |
| Dermal absorption : Permethrin Tebuconazole Propiconazole  IPBC | 75%  75%  75%  75% |
| Indicative inhalation exposure (non-volatile compounds)2 | 0.94 mg/m3 |
| Exposure duration2 | 10 min |
| Penetration through RPE | 100% |
| Tier 2 a  (PPE - gloves) | Indicative dermal exposure on hands (inside gloves)2 | 1.01 mg/min |
| Tier 2 b (PPE – gloves and impermeable coveralls | Relative penetration of clothing –  impermeable coveralls1 | 5 % |
| Tier 2 c (PPE – gloves, impermeable coveralls and respiratory protective equipment | Relative penetration of respiratory protection  – filtering half masks / FFP11 | 25 % |

1 Biocide Human Health Exposure Methodology, version 1, October 2015

2 HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale

***Calculations for scenario 1: Mixing and Loading***

Please for details calculations refer to annex 3.2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from application of product by Mixing and Loading** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Active substance** | **Estimated inhalation uptake (µg/kg bw/d)** | **Estimated dermal uptake (µg/kg bw/d)** | **Estimated oral uptake (µg/kg bw/d)** | **Estimated total uptake (µg/kg bw/d)** |
| Scenario 1: Mixing and Loading | 1 /No PPE | Permethrin Tebuconazole Propiconazole  IPBC | 0.065  0.036  0.036  0.033 | 252.500  138.875  138.875  126.250 | -  -  -  - | 252.565  138.911  138.911  126.283 |
|  |  | Permethrin | 0.065 | 2.525 | - | 2.590 |
|  | 2a / Gloves | Tebuconazole  Propiconazole IPBC | 0.036  0.036  0.033 | 1.389  1.389  1.262 | -  -  - | 1.425  1.425  1.295 |
|  | 2b / Gloves | Permethrin | 0.065 | 2.525 | - | 2.590 |
|  | + | Tebuconazole | 0.036 | 1.389 | - | 1.425 |
|  | impermeable coveralls | Propiconazole IPBC | 0.036  0.033 | 1.389  1.262 | -  - | 1.425  1.295 |
|  | 2c / Gloves | Permethrin Tebuconazole Propiconazole IPBC | 0.016  0.009  0.009  0.008 | 2.525  1.389  1.389  1.262 | -  -  -  - | 2.541  1.398  1.398  1.270 |
|  | + |
|  | impermeable |
|  | coveralls + |
|  | filtering half |
|  | masks |
|  | (FFP11) |

*Scenario 2 and 2bis: Automated spraying and fully automated spraying*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 2: Automated spraying** | | |
| According to the Biocides Health Exposure Methodology, version no 1 of October 2015 and according to Recommendation no 6, Methods and models to assess exposure to biocidal products in different product types, version 3: Model no 28 – Professional deluging – Dipping model 1.  However during the bilateral discussion, it was decided that the handling model 1 was more appropriate for an automated spraying process, since operator exposure should be low during the spraying process and be predominantly due to residues from handling freshly sprayed timber. The same approach than for dipping process was therefore applied:  Handling model 1 for dermal exposure. The default values form the water-based products are used. | | |
|  | Parameters | Value |
| Tier 1 (No PPE) | % of active substance in the biocidal product Permethrin  Tebuconazole  Propiconazole IPBC | 2.0%  1.1%  1.1%  1% |
| Dilution of the applied product | 14.5% (worst case) |
| Body weight1 | 60 kg |
| Inhalation rate1 | 1.25 m3/h |
| Indicative body dermal exposure2 | 8570 mg/cycle |
| Potential dermal exposure on hands (no gloves)3 | 108 000 mg/cycle |
| Penetration through PPE (body) = no PPE1 | 100% |
| Dermal absorption : Permethrin Tebuconazole Propiconazole  IPBC | 12%  15%  16%  75% |
| Indicative inhalation exposure (non-volatile compounds)2 | negligible |
| Exposure duration2 | 4 dipping cycle per day |
| Penetration through RPE | 100% |
| Tier 2 a  (PPE - gloves) | Indicative dermal exposure on hands (inside gloves)2 | 1080 mg/cycle |
| Tier 2 b (PPE – gloves and impermeable coveralls | Relative penetration of clothing –  impermeable coveralls1 | 5 % |

1 Biocide Human Health Exposure Methodology, version 1, October 2015

2 Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

3 Calculated according HEEG opinion on the assessment of Potential & Actual Hand Exposure, 2008, using a multiplication factor of 100 for the conversion of actual to potential hand exposure.

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 2bis: Fully automated spraying** | | |
| According to the Biocides Health Exposure Methodology, version no 1 of October 2015 and according to Recommendation no 6, Methods and models to assess exposure to biocidal products in different product types, version 3: Model no 28 – Professional deluging – Dipping model 1.  However during the bilateral discussion, it was decided that the handling model 1 was more appropriate for an automated spraying process, since operator exposure should be low during the spraying process and be predominantly due to residues from handling freshly sprayed timber. In addition, according HEEG opinion 18 - for exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4.  The same approach than for dipping process was therefore applied:  Handling model 1 for dermal exposure. The default values form the water-based products are used. | | |
|  | Parameters | Value |
| Tier 1 (No PPE) | % of active substance in the biocidal product Permethrin  Tebuconazole Propiconazole IPBC | 2.0%  1.1%  1.1%  1% |
| Dilution of the applied product | 14.5% (worst case) |
| Body weight1 | 60 kg |
| Inhalation rate1 | 1.25 m3/h |
| Indicative body dermal exposure2 | 8570 mg/cycle |
| Potential dermal exposure on hands (no gloves)3 | 108 000 mg/cycle |
| Penetration through PPE (body) = no PPE1 | 100% |
| Dermal absorption : Permethrin Tebuconazole Propiconazole  IPBC | 12%  15%  16%  75% |
| Indicative inhalation exposure (non-volatile compounds)2 | negligible |
| Exposure duration2 | 4 dipping cycle per day |
| Penetration through RPE | 100% |
| Similar approach than for Fully automated dipping (Recomm. No 6 v3, No 20), HEEG opinion 18: professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place | Dermal exposure is assumed to decrease by a factor of 4. |

|  |  |  |
| --- | --- | --- |
| Tier 2 a  (PPE - gloves) | Indicative dermal exposure on hands (inside gloves)2 | 1080 mg/cycle |
| Tier 2 b (PPE – gloves and impermeable coveralls | Relative penetration of clothing –  impermeable coveralls1 | 5 % |

1 Biocide Human Health Exposure Methodology, version 1, October 2015

2 Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

3 Calculated according HEEG opinion on the assessment of Potential & Actual Hand Exposure, 2008, using a multiplication factor of 100 for the conversion of actual to potential hand exposure.

***Calculations for scenario 2 and 2bis: Automated spraying and fully automated spraying***

Please for details calculations refer to annex 3.2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from application of product by Automated spraying** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Active substance** | **Estimated inhalation uptake (µg/kg bw/d)** | **Estimated dermal uptake (µg/kg bw/d)** | **Estimated oral uptake (µg/kg bw/d)** | **Estimated total uptake (µg/kg bw/d)** |
| Scenario 2: Automated spraying | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 2704.42  1859.29  1983.24  8393.04 | -  -  -  - | 2704.42  1859.29  1983.24  8393.04 |
|  |  | Permethrin | - | 223.88 | - | 223.88 |
|  | 2a / Gloves | Tebuconazole  Propiconazole IPBC | -  -  - | 153.92  164.18  694.80 | -  -  - | 153.92  164.18  694.80 |
|  | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 34.997  24.061  25.665  108.612 | -  -  -  - | 34.997  24.061  25.665  108.612 |
| Scenario 2bis : **Fully** automated spraying | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 676.106  464.823  495.811  2098.260 | -  -  -  - | 676.106  464.823  495.811  2098.260 |
|  | 2a / Gloves | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 55.97  38.479  41.045  173.70 | -  -  -  - | 55.97  38.479  41.045  173.70 |
|  | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 8.749  6.015  6.416  27.153 | -  -  -  - | 8.749  6.015  6.416  27.153 |

*Scenario 3 and 3bis: Automated dipping and fully automated dipping*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 3: Automated dipping** | | |
| According to the Biocides Health Exposure Methodology, version no 1 of October 2015 and according to Recommendation no 6, Methods and models to assess exposure to biocidal products in different product types, version 3: Model no 19/20 – Professional automated dipping, immersion of wooden articles / Fully automated dipping – Handling model 1 for dermal exposure. The default values form the water-based products are used.  According to the HEEG opinion 8, inhalation exposure resulting from aerosol formation should be negligible. For non-volatile compounds, the assessment of vapour is not necessary. | | |
|  | Parameters | Value |
| Tier 1 (No PPE) | % of active substance in the biocidal product Permethrin  Tebuconazole  Propiconazole IPBC | 2.0%  1.1%  1.1%  1% |
| Dilution of the applied product | 14.5% (worst case) |
| Body weight1 | 60 kg |
| Inhalation rate1 | 1.25 m3/h |
| Indicative body dermal exposure2 | 8570 mg/cycle |
| Potential dermal exposure on hands (no gloves)3 | 108 000 mg/cycle |
| Penetration through PPE (body) = no PPE1 | 100% |
| Dermal absorption : Permethrin Tebuconazole Propiconazole  IPBC | 12%  15%  16%  75% |
| Indicative inhalation exposure (non-volatile compounds)2 | negligible |
| Exposure duration2 | 4 dipping cycle per day |
| Penetration through RPE | 100% |
| Tier 2 a  (PPE - gloves) | Indicative dermal exposure on hands (inside gloves)2 | 1080 mg/cycle |
| Tier 2 b (PPE – gloves and impermeable coveralls | Relative penetration of clothing –  impermeable coveralls1 | 5 % |

1 Biocide Human Health Exposure Methodology, version 1, October 2015

2 Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

3 Calculated according HEEG opinion on the assessment of Potential & Actual Hand Exposure, 2008, using a multiplication factor of 100 for the conversion of actual to potential hand exposure.

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 3bis: Fully automated dipping** | | |
| According to the Biocides Health Exposure Methodology, version no 1 of October 2015 and according to Recommendation no 6, Methods and models to assess exposure to biocidal products in different product types, version 3: Model no 19/20 – Professional automated dipping, immersion of wooden articles / Fully automated dipping – Handling model 1 for dermal exposure. The default values form the water-based products are used.  Fully automated dipping (model 20): According to the HEEG opinion 18 - for exposure assessment for professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place the dermal exposure is assumed to decrease by a factor of 4.  According to the HEEG opinion 8, inhalation exposure resulting from aerosol formation should be negligible. For non-volatile compounds, the assessment of vapour is not necessary. | | |
|  | Parameters | Value |
| Tier 1 (No PPE) | % of active substance in the biocidal product Permethrin  Tebuconazole Propiconazole  IPBC | 2.0%  1.1%  1.1%  1% |
| Dilution of the applied product | 14.5% (worst case) |
| Body weight1 | 60 kg |
| Inhalation rate1 | 1.25 m3/h |
| Indicative body dermal exposure2 | 8570 mg/cycle |
| Potential dermal exposure on hands (no gloves)3 | 108 000 mg/cycle |
| Penetration through PPE (body) = no PPE1 | 100% |
| Dermal absorption : Permethrin Tebuconazole Propiconazole  IPBC | 12%  15%  16%  75% |
| Indicative inhalation exposure (non-volatile compounds)2 | negligible |
| Exposure duration2 | 4 dipping cycle per day |
| Penetration through RPE | 100% |
| Fully automated dipping (Recomm. No 6 v3, No 20), HEEG opinion 18: professional operators undertaking industrial treatment of wood by fully automated dipping where all steps in the treatment and drying process are mechanised and no manual handling takes place | Dermal exposure is assumed to decrease by a factor of 4. |
| Tier 2 a | Indicative dermal exposure on hands (inside gloves)2 | 1080 mg/cycle |

|  |  |  |
| --- | --- | --- |
| (PPE - gloves) |  |  |
| Tier 2 b (PPE – gloves and impermeable coveralls | Relative penetration of clothing –  impermeable coveralls1 | 5 % |

1 Biocide Human Health Exposure Methodology, version 1, October 2015

2 Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

3 Calculated according HEEG opinion on the assessment of Potential & Actual Hand Exposure, 2008, using a multiplication factor of 100 for the conversion of actual to potential hand exposure.

***Calculations for scenario 3 and 3bis: Automated dipping and fully automated dipping***

Please for details calculations refer to annex 3.2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from application of product by Automated dipping** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Active substance** | **Estimated inhalation uptake (µg/kg bw/d)** | **Estimated dermal uptake (µg/kg bw/d)** | **Estimated oral uptake (µg/kg bw/d)** | **Estimated total uptake (µg/kg bw/d)** |
| Scenario 3: Automated dipping | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 2704.42  1859.29  1983.24  8393.04 | -  -  -  - | 2704.42  1859.29  1983.24  8393.04 |
|  |  | Permethrin | - | 223.88 | - | 223.88 |
|  | 2a / Gloves | Tebuconazole Propiconazole  IPBC | -  -  - | 153.92  164.18  694.80 | -  -  - | 153.92  164.18  694.80 |
|  | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole  IPBC | -  -  -  - | 34.997  24.061  25.665  108.612 | -  -  -  - | 34.997  24.061  25.665  108.612 |
| Scenario 3bis : **Fully** automated dipping | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 676.106  464.823  495.811  2098.260 | -  -  -  - | 676.106  464.823  495.811  2098.260 |
|  | 2a / Gloves | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 55.97  38.479  41.045  173.70 | -  -  -  - | 55.97  38.479  41.045  173.70 |
|  | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 8.749  6.015  6.416  27.153 | -  -  -  - | 8.749  6.015  6.416  27.153 |

*Scenario 4 and 4bis : Automated vacuum pressure and double vacuum pressure*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 4: Automated vacuum pressure** | | |
| According to the Biocides Health Exposure Methodology, version no 1 of October 2015 and according to Recommendation no 6, Methods and models to assess exposure to biocidal products in different product types, version 3: Model no 21 – Professional double-vacuum treatment of wood – Handling model 1. The default values from the water-based products are used.  According to TNsG 2002 User Guidance version 1: vacuum pressure impregnation = 3 cycles/day. | | |
|  | Parameters | Value |
| Tier 1 (No PPE) | % of active substance in the biocidal product Permethrin  Tebuconazole Propiconazole  IPBC | 2%  1.1%  1.1%  1% |
| Dilution of the applied product | 1.45% (worst case for penetrating treatment) |
| Body weight1 | 60 kg |
| Inhalation rate1 | 1.25 m3/h |
| Indicative body dermal exposure2 | 8570 mg/cycle |
| Potential dermal exposure on hands (no gloves)3 | 108 000 mg/cycle |
| Penetration through PPE (body) = no PPE1 | 100% |
| Dermal absorption : Permethrin Tebuconazole Propiconazole  IPBC | 75%  75%  75%  75% |
| Indicative inhalation exposure (non-volatile compounds)2 | 1.9 mg/m3 |
| Exposure duration2 | 3 cycle per day  30 min (for inhalation) |
| Tier 2 a  (PPE - gloves) | Penetration through RPE | 100% |
| Indicative dermal exposure on hands (inside gloves)2 | 1080 mg/cycle |
| Tier 2 b (PPE – gloves and impermeable coveralls | Relative penetration of clothing –  impermeable coveralls1 | 5 % |
| Tier 2 c (PPE – gloves, impermeable coveralls and respiratory protective equipment | Relative penetration of respiratory protection  – filtering half masks / FFP11 | 25 % |

1 Biocide Human Health Exposure Methodology, version 1, October 2015

2 Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

3 Calculated according HEEG opinion on the assessment of Potential & Actual Hand Exposure, 2008, using a multiplication factor of 100 for the conversion of actual to potential hand exposure.

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 4bis: Double vacuum pressure** | | |
| According to the Biocides Health Exposure Methodology, version no 1 of October 2015 and according to Recommendation no 6, Methods and models to assess exposure to biocidal products in different product types, version 3: Model no 21 – Professional double-vacuum treatment of wood – Handling model 1. The default values from the water-based products are used.  According to TNsG 2002 User Guidance version 1: double-vacuum pressure impregnation  = 6 cycles/day. | | |
|  | Parameters | Value |
| Tier 1 (No PPE) | % of active substance in the biocidal product Permethrin  Tebuconazole Propiconazole  IPBC | 2%  1.1%  1.1%  1% |
| Dilution of the applied product | 1.45% (worst case for penetrating treatment) |
| Body weight1 | 60 kg |
| Inhalation rate1 | 1.25 m3/h |
| Indicative body dermal exposure2 | 8570 mg/cycle |
| Potential dermal exposure on hands (no gloves)3 | 108 000 mg/cycle |
| Penetration through PPE (body) = no PPE1 | 100% |
| Dermal absorption : Permethrin Tebuconazole Propiconazole  IPBC | 75%  75%  75%  75% |
| Indicative inhalation exposure (non-volatile compounds)2 | 1.9 mg/m3 |
| Exposure duration2 | 6 cycle per day  60 min (for inhalation) |
| Penetration through RPE | 100% |
| Tier 2 a  (PPE - gloves) | Indicative dermal exposure on hands (inside gloves)2 | 1080 mg/cycle |
| Tier 2 b (PPE – gloves and impermeable coveralls | Relative penetration of clothing –  impermeable coveralls1 | 5 % |
| Tier 2 c (PPE – gloves, impermeable coveralls and respiratory | Relative penetration of respiratory protection  – filtering half masks / FFP11 | 25 % |

|  |  |  |
| --- | --- | --- |
| protective equipment |  |  |

1 Biocide Human Health Exposure Methodology, version 1, October 2015

2 Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 3, February 2017

3 Calculated according HEEG opinion on the assessment of Potential & Actual Hand Exposure, 2008, using a multiplication factor of 100 for the conversion of actual to potential hand exposure.

***Calculations for scenario 4 and 4bis : Automated vacuum pressure and double vacuum pressure.***

Please for details calculations refer to annex 3.2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from application of product by vacuum pressure** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Active substance** | **Estimated inhalation uptake (µg/kg bw/d)** | **Estimated dermal uptake (µg/kg bw/d)** | **Estimated oral uptake (µg/kg bw/d)** | **Estimated total uptake (µg/kg bw/d)** |
| Scenario 4: automated vacuum pressure | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | 0.006  0.003  0.003  0.003 | 1267.699  697.234  697.234  633.849 | -  -  -  - | 1267.705  697.237  697.237  633.852 |
|  |  | Permethrin | 0.006 | 104.943 | - | 104.949 |
|  | 2a / Gloves | Tebuconazole  Propiconazole IPBC | 0.003  0.003  0.003 | 57.719  57.719  52.472 | -  -  - | 57.722  57.722  52.475 |
|  | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole  IPBC | 0.006  0.003  0.003  0.003 | 16.405  9.023  9.023  8.202 | -  -  -  - | 16.411  9.026  9.026  8.205 |
|  | 2c / Gloves + | Permethrin Tebuconazole Propiconazole IPBC |  |  | -  -  -  - |  |
|  | impermeable | 0.001 | 16.405 | 16.406 |
|  | coveralls + | 0.001 | 9.023 | 9.024 |
|  | filtering half | 0.001 | 9.023 | 9.024 |
|  | masks (FFP11) | 0.001 | 8.202 | 8.203 |
| Scenario 4bis : double vacuum pressure | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | 0.011  0.006  0.006  0.006 | 2535.400  1394.469  1394.469  1267.699 | -  -  -  - | 2535.411  1394.475  1394.475  1267.705 |
|  | 2a / Gloves | Permethrin Tebuconazole Propiconazole IPBC | 0.011  0.006  0.006  0.006 | 209.888  115.438  115.438  104.944 | -  -  -  - | 209.899  115.444  115.444  104.950 |
|  | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 0.011  0.006  0.006  0.006 | 32.810  18.045  18.045  16.405 | -  -  -  - | 32.821  18.051  18.051  16.411 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | 2c / Gloves + impermeable coveralls + filtering half masks (FFP11) | Permethrin Tebuconazole Propiconazole IPBC | 0.003  0.002  0.002  0.001 | 32.810  18.045  18.045  16.405 | -  -  -  - | 32.813  18.047  18.047  16.406 |

*Scenario 10: Industrial brushing*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 10: Industrial brushing** | | |
| The scenario concerns professional brush treatment. The recommendation 10 of the ad hoc working group on Human exposure (for non-professional) is used because this is a review of the study described in the recommendation 6 for professional user as discussed during the peer review process. | | |
|  | Parameters | Value |
| Tier 1 (No PPE) | % of active substance in the biocidal product Permethrin  Tebuconazole Propiconazole  IPBC | 2%  1.1%  1.1%  1% |
| Dilution of the applied product | 14.5% (worst case for superficial treatment) |
| Body weight1 | 60 kg |
| Inhalation rate1 | 1.25 m3/h |
| Indicative body dermal exposure2 | 1.7 µl/min = 1.7 mg/min considering a density of 1 (diluted product in water) |
| Potential dermal exposure on hands (no gloves)2 | 4.07 µl/min = 4.07 mg/min considering a density of 1(diluted product in water) |
| Penetration through PPE (body) = no PPE1 | 100% |
| Dermal absorption : Permethrin Tebuconazole Propiconazole  IPBC | 12%  15%  16%  75% |
| Indicative inhalation exposure (non-volatile compounds)2 | 1.63 mg/m2 |
| Exposure duration3 | 240 minutes (working day) |
| Tier 2 a  (PPE - gloves) | Penetration through RPE | 100% |
| Relative penetration of gloves1 | 10 % |
| Tier 2 b (PPE – gloves and impermeable coveralls | Relative penetration of clothing –  impermeable coveralls1 | 5 % |
| Tier 2 c (PPE – gloves, impermeable coveralls and respiratory protective equipment | Relative penetration of respiratory protection  – filtering half masks / FFP11 | 25 % |

1 Biocide Human Health Exposure Methodology, version 1, October 2015

2 Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling

***Calculations for scenario 10 : Industrial brushing***

Please for details calculations refer to annex 3.2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from scenario 10: industrial brushing** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Active substance** | **Estimated inhalation uptake (µg/kg bw/d)** | **Estimated dermal uptake (µg/kg bw/d)** | **Estimated oral uptake (µg/kg bw/d)** | **Estimated total uptake (µg/kg bw/d)** |
| scenario 10: industrial brushing |  | Permethrin | 0.39 | 5.02 | - | 5.41 |
|  | 1 /No PPE | Tebuconazole  Propiconazole | 0.22  0.22 | 2.76  2.76 | -  - | 2.98  2.98 |
|  |  | IPBC | 0.20 | 2.51 | - | 2.71 |
|  |  | Permethrin | 0.39 | 1.83 | - | 2.23 |
|  | 2a / Gloves | Tebuconazole  Propiconazole | 0.22  0.22 | 1.01  1.01 | -  - | 1.22  1.22 |
|  |  | IPBC | 0.20 | 0.92 | - | 1.11 |
|  | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 0.39  0.22  0.22  0.20 | 0.43  0.23  0.23  0.21 | -  -  -  - | 0.82  0.45  0.45  0.41 |
|  | 2c / Gloves + |  |  |  |  |  |
|  | impermeable | Permethrin | 0.10 | 0.43 | - | 0.53 |
|  | coveralls + | Tebuconazole | 0.05 | 0.24 | - | 0.29 |
|  | filtering half | Propiconazole | 0.05 | 0.24 | - | 0.29 |
|  | masks | IPBC | 0.05 | 0.21 | - | 0.26 |
|  | (FFP11) |  |  |  |  |  |

*Scenario 11: Industrial brushing -post application, Cleaning of the brush equipment*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 11: post application, Cleaning of the brush equipment** | | |
| The used scenario concerns the process of washing out of a brush according to HEEG opinion no. 11 - Primary exposure scenario – washing out of a brush which has been used to apply a paint, as proposed in Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Version 4, page 45. | | |
|  | Parameters | Value |
| Tier 1 (No PPE) | % of active substance in the biocidal product Permethrin  Tebuconazole Propiconazole  IPBC | 2%  1.1%  1.1%  1% |
| Dilution of the applied product | 14.5% (worst case for superficial treatment) |
| Density of paint | 1,02 g/ml |
| Body weight1 | 60 kg |
| Dermal absorption : Permethrin Tebuconazole Propiconazole  IPBC | 12%  15%  16%  75% |
| HEEG opinion 11 - Exposure model Primary exposure scenario - washing out of a brush which has been used to apply a paint2  Annex - General exposure calculator for washing out of brushes | Relevant parameters available in the annex.  Excel calculator sheet. |
| Tier 2 a  (PPE - gloves) | Relative penetration of gloves1 | 10 % |

1 Biocide Human Health Exposure Methodology, version 1, October 2015

2 Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, Methods and models to assess exposure to biocidal products in different product types, version 4, May 2020 + HEEG opinion no. 11.

***Calculations for scenario 11: Industrial brushing -post application, Cleaning of the brush equipment***

Please for details calculations refer to annex 3.2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from cleaning of the brush equipment** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Active substance** | **Estimated inhalation uptake**  **(µg/kg bw/d)** | **Estimated dermal uptake**  **(µg/kg bw/d)** | **Estimated oral uptake**  **(µg/kg bw/d)** | **Estimated total uptake**  **(µg/kg bw/d)** |
|  |  | Permethrin | - | 0.781 | - | 0.781 |
|  | 1 /No PPE | Tebuconazole  Propiconazole | -  - | 0.539  0.575 | -  - | 0.539  0.575 |
|  |  | IPBC | - | 2.526 | - | 2.526 |
|  |  | Permethrin | - | 0.078 | - | 0.078 |
|  | 2a / Gloves | Tebuconazole  Propiconazole | -  - | 0.054  0.057 | -  - | 0.054  0.057 |
| Scenario 11 |  | IPBC | - | 0.253 | - | 0.253 |
| Industrial brushing -post application, Cleaning of the brush equipment |  |  |  |  |  |  |
| 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 0.078  0.054  0.057  0.253 | -  -  -  - | 0.078  0.054  0.057  0.253 |
|  | 2c / Gloves + | Permethrin Tebuconazole Propiconazole IPBC | -  -  -  - | 0.078  0.054  0.057  0.253 | -  -  -  - | 0.078  0.054  0.057  0.253 |
|  | impermeable |
|  | coveralls + |
|  | filtering half |
|  | masks (FFP11) |

*Combined scenarios for industrial exposure*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure from industrial exposure** | | | | |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non- professionals, bystanders)** | **Tier/PPE** | **Active substance** | **Estimated total uptake**  **(µg / kg bw)** |
| Combined exposure  Scenarios 1+2 | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole  IPBC | 37.59  25.48  27.09  109.91 |
| Combined exposure  Scenarios 1+2bis | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole  IPBC | 11.34  7.44  7.84  28.49 |
| Combined exposure  Scenarios 1+3 | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole  IPBC | 37.59  25.48  27.09  109.91 |
| Combined exposure  Scenarios 1+3bis | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole  IPBC | 11.34  7.44  7.84  28.49 |
| Combined exposure  Scenarios 1+4 | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole  IPBC | 19.00  10.45  10.45  9.50 |
| Combined exposure  Scenarios 1+4bis | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole  IPBC | 35.41  19.48  19.48  17.70 |
| Combined exposure  Scenarios 1+10+11 | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole  IPBC | 2.77  1.93  1.93  1.96 |

##### Professional exposure

*Scenario 5: Secondary exposure: Professional – sanding treated wood posts*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 5 – Professional – sanding treated wood posts** | | |
| Professional – sanding treated wood (chronic exposure)  Exposure of professional towards dust during sanding of treated wood was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50.  Concentration of active substance in the wood dust = Total deposit of product into respiratory track / task x % of active substance in the biocidal product  Active substance concentration on hand = Total deposit of product on hands/ task x % of active substance in the biocidal product  Exposureinhalation = Concentration of active substance in the wood dust x Inhalatory uptake / Body weight  Exposuredermal = Active substance concentration on hand x Dermal uptake / Body weight  Total systemic exposure = Exposuredermal + Exposureinhalation | | |
|  | Parameters | Value |
| Tier 1 | Size of the treated wood  Volume wooden post1: 4 cm x 4 cm x 250 cm = 4000 cm3 Surface area wooden post: 4032 cm2, if the surface area of the  2 ends of the post is included  Volume of treated wood in the post: 393 cm3 (superficial treatment, only penetration in the 1 mm outermost layer: volume of the post – volume of the untreated inner core of the post = 4x4x250 -3.8x3.8x249.8 = 393 cm3). | 393 cm3 |

|  |  |  |
| --- | --- | --- |
|  | Biocidal product concentration in the outer 1 mm layer  Product specific information: application rate SARPECO 9-PLUS  /worst case = 100 g/m2 | 102.59 mg bp/cm3 |
| The default values of the surface of treated wood is 4032 cm2 |  |
| The biocidal product concentration on a 4032 cm2 layer is 10 mg/cm2 x 4032 cm2 = 40320 mg per 4032 cm2 |  |
| We have the default values of the size of treated wood: 4032 cm2 which corresponds to 393 cm3 (superficial treatment/worst case), thus the concentration biocidal product per volume unit is 40320 /393 cm3 = 102.59 mg/cm3. |  |
| % of active substance in the biocidal product. According the applicant : 100g/m2, diulion at 14.5% | 0.29% |
| Permethrin | 0.1595% |
| Tebuconazole | 0.1595% |
| Propiconazole | 0.145% |
| IPBC |  |
| **Exposureinhalation** | |
| Inhalation rate2 | 1.25 m3/h |
| Body weight adult2 | 60 kg |
| Exposure for wood dust during sanding for 60 min1 | 5 mg/m3 |
| Duration of the work | 360 minutes (6 hours) |
| Density of wood3 | 0.4 g/cm3 |
| Volume of wood dust | 37.5.10-3/0.4=  0.09375 cm3 |
| Total deposit of biocidal product into respiratory track | 10 mg bp |
| Inhaled wood dust amount : inhalation rate x duration of the work (hours) x exposure for wood dust during sanding for 6 hours = 1.25 x 6 x 5= 37.5 mg |  |
| Volume of wood dust : Inhaled wood dust amount (g) / density of wood = 37.5x10-3/0.4=0.09375 cm3 |  |
| Total deposit of biocidal product into respiratory track : Volume of wood dust x Biocidal product concentration in the outer 1 mm layer = 0.09375 x 102.59 = 10 mg |  |
| Inhalatory uptake | 100% |
| Exposuredermal | |
| Hand inner surface area (half of both hands area2) | 410 cm2 |
| % of hand contaminated during sanding4 | 20% |
| Biocidal product concentration on wood surface | 10 mg bp /cm2 |
|  | Transfer coefficient (rough sawn wood, dried fluid)2 | 2% |
| Dermal uptake : |  |

|  |  |  |
| --- | --- | --- |
|  | Permethrin Tebuconazole Propiconazole IPBC | 12%  15%  16%  75% |
| Total deposit of biocidal product on hands/ task  Biocidal product concentration on wood surface x Hand inner surface area x % of hand contaminated during sanding x Transfer coefficient (%) : 10 mg/cm2 x 410 cm2 x 20/100 x 2/100 = 16 mg | 16 mg bp |

1 TNsG on Human Exposure (2002) Part 3, Page 50

2 Biocides Human Health Exposure Methodology, Oct 2015

3 MOTA, 2013 from TM III 2008

4 TNsG 2002, User Guidance version 1, p52

**Calculations for Scenario 5 : Professional – sanding treated wood posts**

Please for details calculations refer to annex 3.2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from sanding treated wood posts for professional (chronic exposure)** | | | | | | |
| **Exposure scenario** | **Tier/P PE** | **Active substance** | **Estimated inhalation uptake**  **(µg/kg bw/d)** | **Estimated dermal uptake**  **(µg/kg bw/d)** | **Estimated oral uptake**  **(µg/kg bw/d)** | **Estimated total uptake**  **(µg/kg bw/d)** |
| Scenario 5 : | Tier 1 | Permethrin | 0.465 | 0.095 | - | 0.560 |
| Professional – sanding treated wood posts  (chronic | No PPE | Tebuconazole Propiconazole  IPBC | 0.256  0.256  0.232 | 0.065  0.070  0.297 | -  -  - | 0.321  0.326  0.529 |
| exposure) |  |  |  |  |  |  |

##### Non- professional exposure

The product is not intended to be used by non-professional and sould not be available for non- professional. Therefore the assessment of non-professional exposure is not relevant.

##### Exposure of the general public

*Scenario 6: Secondary exposure: Adult – Processing treated dried wood*

|  |
| --- |
| **Description of Scenario 6 – Processing treated dried wood – General public** |
| Adult non-professional – sanding treated wood (acute exposure)  Exposure of professional towards dust during sanding of treated wood was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50. |

|  |  |  |
| --- | --- | --- |
| Concentration of active substance in the wood dust = Total deposit of product into respiratory track / task x % of active substance in the biocidal product  Active substance concentration on hand = Total deposit of product on hands/ task x % of active substance in the biocidal product  Exposureinhalation = Concentration of active substance in the wood dust x Inhalatory uptake / Body weight  Exposuredermal = Active substance concentration on hand x Dermal uptake / Body weight  Total systemic exposure = Exposuredermal + Exposureinhalation | | |
|  | Parameters | Value |
| Tier 1 | Size of the treated wood  Volume wooden post1: 4 cm x 4 cm x 250 cm = 4000 cm3 Surface area wooden post: 4032 cm2, if the surface area of the  2 ends of the post is included  Volume of treated wood in the post: 393 cm3 (superficial treatment, only penetration in the 1 mm outermost layer: volume of the post – volume of the untreated inner core of the post = 4x4x250 -3.8x3.8x249.8 = 393 cm3). | 393 cm3 |
|  | Biocidal product concentration in the outer 1 mm layer  Product specific information: application rate SARPECO 9-PLUS  /worst case = 100 g/m2  The default values of the surface of treated wood is 4032 cm2 The biocidal product concentration on a 4032 cm2 layer is 10  mg/cm2 x 4032 cm2 = 40320 mg per 4032 cm2  We have the default values of the size of treated wood: 4032 cm2 which corresponds to 393 cm3 (superficial treatment), thus the concentration biocidal product per volume unit is 40320 /393 cm3 = 102.5954198mg/cm3. | 102.59 mg bp/cm3 |
|  | % of active substance in the biocidal product. According the applicant : 100g/m2, diulion at 14.5% | 0.29% |
|  | Permethrin | 0.1595% |
|  | Tebuconazole | 0.1595% |
|  | Propiconazole IPBC | 0.145% |
|  | **Exposureinhalation** | |
|  | Inhalation rate2 | 1.25 m3/h |
|  | Body weight adult2 | 60 kg |
|  | Exposure for wood dust during sanding for 60 min1 | 5 mg/m3 |
|  | Duration of the work | 60 minutes (1 hour) |
|  | Density of wood3 | 0.4 g/cm3 |
|  | Volume of wood dust | 6.25.10-3/0.4=  0.015625 cm3 |
|  | Total deposit of biocidal product into respiratory track | 2 mg bp |

|  |  |  |
| --- | --- | --- |
|  | Inhaled wood dust amount : inhalation rate x duration of the work (hours) x exposure for wood dust during sanding for 6 hours = 1.25 x 1 x 5= 6.25 mg  Volume of wood dust : Inhaled wood dust amount (g) / density of wood = 6.25x10-3/0.4=0.015625 cm3  Total deposit of biocidal product into respiratory track : Volume of wood dust x Biocidal product concentration in the outer 1 mm layer = 0.015625 x 102.59 = 2 mg |  |
| Inhalatory uptake | 100% |
| Exposuredermal | |
| Hand inner surface area (half of both hands area2) | 410 cm2 |
| % of hand contaminated during sanding4 | 20% |
| Biocidal product concentration on wood surface | 10 mg bp /cm2 |
|  | Transfer coefficient (rough sawn wood, dried fluid)2 | 2% |
| Dermal uptake : |  |
| Permethrin | 12% |
| Tebuconazole | 15% |
| Propiconazole | 16% |
| IPBC | 75% |
| Total deposit of biocidal product on hands/ task | 16 mg bp |
| Biocidal product concentration on wood surface x Hand inner |  |
| surface area x % of hand contaminated during sanding x |  |
| Transfer coefficient (%) : 10 mg/cm2 x 410 cm2 x 20/100 x |  |
| 2/100 = 16 mg |  |

1 TNsG on Human Exposure (2002) Part 3, Page 50

2 Biocides Human Health Exposure Methodology, Oct 2015

3 MOTA, 2013 from TM III 2008

4 TNsG 2002, User Guidance version 1, p52

**Calculations for Scenario 6 : Processing treated dried wood – General public**

Please for details calculations refer to annex 3.2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from Processing treated dried wood – General public** | | | | | | |
| **Exposure scenario** | **Tier/P PE** | **Active substance** | **Estimated inhalation uptake**  **(µg/kg bw/d)** | **Estimated dermal uptake**  **(µg/kg bw/d)** | **Estimated oral uptake**  **(µg/kg bw/d)** | **Estimated total uptake**  **(µg/kg bw/d)** |
| Scenario 6 : | Tier 1 | Permethrin | 0.077 | 0.095 | - | 0.173 |
| Processing treated dried wood – General  public (adult - | No PPE | Tebuconazole Propiconazole IPBC | 0.043  0.043  0.039 | 0.065  0.070  0.297 | -  -  - | 0.108  0.113  0.336 |
| acute exposure) |  |  |  |  |  |  |

*Scenario 7 - Toddler chewing wood off-cut*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 7 – Toddler chewing wood off-cut** | | |
| Toddler, general public – Toddler chewing wood off-cut (acute exposure)  The relevant exposure route is oral. This is an incidental event and the exposure duration is therefore best described as acute. This scenario is considered to represent the worst case for secondary oral exposure  Exposure of toddler chewing wood off-cut was estimated using the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50.  Maximum absorption of active substance = Application rate SARPECO 9-PLUS x % of active substance in the biocidal product  Extraction from wood = Maximum absorption of active substance x Surface area of the wood chip  Systemic exposure = Extraction From wood x Extraction of active substance when chewing x Oral uptake / Body weight | | |
|  | Parameters | Value |
| Tier 1 | Size of the wood chip1  Volume: 4 cm x 4 cm x 1 cm= 16 cm3  Surface area: 48 cm2 (worst case = treated at 2 sides of the chips) | 16 cm3 |
|  | 48 cm2 |
|  | % of active substance in the biocidal product. According the |  |
|  | applicant : 100g/m2, diulion at 14.5% | 0.29% |
|  | Permethrin | 0.1595% |
|  | Tebuconazole | 0.1595% |
|  | Propiconazole IPBC | 0.145% |
|  | Application rate SARPECO 9-PLUS / worst case = 100 | 10 mg/ cm2 |
|  | g/m2 |  |
|  | Extraction of active substance when chewing1 | 10% |
|  | Oral uptake | 100% |
|  | Body weight toddler2 | 10 kg |

1 TNsG 2002, User Guidance version 1, p56

2 Biocides Human Health Exposure Methodology, Oct 2015

**Calculations for Scenario 7 : Toddler chewing wood off-cut**

Please for details calculations refer to annex 3.2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from Toddler chewing wood off-cut** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Active substance** | **Estimated inhalation uptake**  **(µg/kg bw/d)** | **Estimated dermal uptake**  **(µg/kg bw/d)** | **Estimated oral uptake**  **(µg/kg bw/d)** | **Estimated total uptake**  **(µg/kg bw/d)** |
| Scenario 7 | Tier 1 | Permethrin | - | - | 13.920 | 13.920 |
| : Toddler chewing wood off- cut | No PPE | Tebuconazole Propiconazole IPBC | -  -  - | -  -  - | 7.656  7.656  6.960 | 7.656  7.656  6.960 |
| (toddler - |  |  |  |  |  |  |
| acute |  |  |  |  |  |  |
| exposure) |  |  |  |  |  |  |

*Scenario 8 – Toddler– playing on and mouthing weathered structure outdoors*

|  |  |  |
| --- | --- | --- |
| **Description of Scenario 8 – Toddler– playing on and mouthing weathered structure outdoors** | | |
| Toddler, general public – Toddler– playing on and mouthing weathered structure outdoors (chronic exposure)  The relevant exposure routes are dermal and oral. Duration can be up to chronic, assuming that playing in the environment may happen daily. This scenario is considered to represent the worst case for secondary chronic exposure.  Exposure of toddler playing on and mouthing weathered structure outdoors the example calculation provided in the TNsG on Human Exposure (2002) Part 3, Page 50.  Active concentration on hand = Application rate SARPECO 9-PLUS x % of active substance in the biocidal product x Hand surface area x % of hand contaminated x Transfer coefficient  Exposuredermal = Active substance concentration on hand x Dermal uptake / Body weight Exposureoral = Active substance concentration on hand x Oral uptake / Body weight  Total systemic exposure = Exposuredermal + Exposureoral | | |
|  | Parameters | Value |
| Tier 1 | Application rate SARPECO 9-PLUS / worst case | 10 mg/ cm2 |
|  | = 100 g/m2 |  |
|  | % of active substance in the biocidal product. | 0.29%  0.1595%  0.1595%  0.145% |
|  | According the applicant : 100g/m2, diulion at |
|  | 14.5% |
|  | Permethrin |
|  | Tebuconazole |
|  | Propiconazole |
|  | IPBC |

|  |  |  |
| --- | --- | --- |
|  | Hand surface area2 | 230.4 cm2 |
| % of hand contaminated1 | 20% |
| Transfer coefficient (rough sawn wood, dried fluid)2 | 2% |
| Dermal uptake : Permethrin Tebuconazole Propiconazole IPBC | 12%  15%  16%  75% |
| Oral uptake | 100% |
| Body weight2 | 10 kg |

1 TNsG 2002, User Guidance version 1, p53

2 Biocides Human Health Exposure Methodology, Oct 2015

**Calculations for Scenario 8 : Toddler– playing on and mouthing weathered structure outdoors**

Please for details calculations refer to annex 3.2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from toddler playing on and mouthing weathered structure outdoors** | | | | | | |
| **Exposure scenario** | **Tier/ PPE** | **Active substance** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake**  **(mg/kg bw/d)** | **Estimate d total uptake** |
| Scenario 8 : | Tier 1 | Permethrin | - | 0.321 | 2.673 | 2.994 |
| Toddler playing on and  mouthing weathered | No PPE | Tebuconazole  Propiconazole IPBC | -  -  - | 0.220  0.235  1.002 | 1.470  1.470  1.336 | 1.690  1.705  2.338 |
| structure |  |  |  |  |  |  |
| outdoors |  |  |  |  |  |  |
| (toddler - |  |  |  |  |  |  |
| chronic |  |  |  |  |  |  |
| exposure) |  |  |  |  |  |  |

*Scenario 9 – Inhalation of volatized residues indoors (IPBC only)*

|  |
| --- |
| **Description of Scenario 9– Inhalation of volatized residues indoors (IPBC only)** |
| For Permethrin, propiconazole and tebuconazole : exposure to volatilized residues indoor can be considered negligible based on HEEG opinion 13 (see above). |

|  |  |  |
| --- | --- | --- |
| However, for IPBC, based on HHEG opinion 13, exposure to volatilized residues indoor can not be considered negligible and have been calculated.  A model for inhalation of volatilized residues from treated wood indoors is worked out in the TNsG 2002, User Guidance version 1 p52. The model assumes a moderately ventilated room and residence time of 18 h/day. As a worst-case an inhalation exposure is taken as 1% of the saturated vapour pressure of the active substance.  However, following bilateral discussion, 1% of the saturated vapour pressure is not considered appropriated anymore. 90 % reduction was agreed and therefore, is used.  Saturated vapour concentration = vapour pressure x molecular weight  Gas constant x temperature in degrees Kelvin Systemic dose = 10% SVC x inhalation rate x duration / Body Weight  The body weight and inhalation rate have been updated according Biocide Human Health Exposure Methodology, October 2015. | | |
|  | Parameters | Value |
| Tier 1 | Vapour pressure1 | IPBC: 4.5x10-3 Pa (20°C) |
| No PPE |
| Molecular weight1 | IPBC: 281.1 g/mol |
|  | Gas constant | 8.314 J/mol/K |
|  | Temperature (degrees Kelvin) | 298 K |
|  | Saturated vapour concentration (SVC) | IPBC  4.5x10-3 x 281.1 / (8.314x298) = |
|  |  | 5x10-3 mg/m3 |
|  | Body weight2 | Adult: 60 kg |
|  |  | Child: 23.9 kg |
|  |  | Toddler: 10 kg |
|  |  | Infant : 8 kg |
|  | Inhalation rate2 | Adult: 1.25 m3 air/h |
|  |  | Child: 1.32 m3 air/h |
|  |  | Toddler: 1.26 m3 air/h |
|  |  | Infant : 0.84 m3 air/h |
|  | Duration | 18 hours |

1 Assessment Report on IPBC (RMS DK, February 2008)

2 Biocides Human Health Exposure Methodology, Oct 2015

**Calculations for Scenario 9 – Inhalation of volatized residues indoors**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated exposure from general public inhalation volatized residues indoors** | | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Active substance** | **Estimated inhalation uptake**  **(µg/kg bw/d)** | **Estimated dermal uptake**  **(µg/kg bw/d)** | **Estimated oral uptake**  **(µg/kg bw/d)** | **Estimated total uptake**  **(µg/kg bw/d)** |
| Scenario 9 | Tier 1 | IPBC only adult child toddler infant | 1.915  5.076  11.579  9.650 | -  -  -  - | -  -  -  - | 19.15  50.76  115.79  96.50 |
| : general  public | No PPE |
| inhalation |  |
| volatized |  |
| residues |  |
| indoors |  |
| (chronic |  |
| exposure) |  |

*Combined scenarios*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: combined systemic exposure from general public uses** | | | | | | |
| **Scenarios combined** | **Tier/PPE** | **Active substance** | **Estimated inhalation uptake**  **(µg/kg bw/d)** | **Estimated dermal uptake**  **(µg/kg bw/d)** | **Estimated oral uptake**  **(µg/kg bw/d)** | **Estimated total uptake**  **(µg/kg bw/d)** |
| Scenario 8+9 (toddler) | 1 /No PPE | IPBC | 115.79 | 1.002 | 1.336 | 118.134 |

##### Monitoring data

Not applicable

##### Dietary exposure

No exposure is foreseen as regards to the intended use of the product. However the following RMM was found on the label and is highly advised in order to avoid any misuses of the product:

"Do not apply the product on wood which may come into contact with food, feedstuff or

livestock”.

In addition, during the bilateral discussion for the authorization of this product, the following RMM was added :

“ Treated wood should not be intended for uses involving contact with food, feed or livestock”.

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

Occupational exposure during production and formulation of biocidal product is not covered by the BPR. It is expected that production and formulation are performed in conformity with European and national worker protection legislation.

##### Summary of exposure assessment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios and values to be used in risk assessment** | | | | |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non- professionals, bystanders)** | **Tier/PPE** | **Active substance** | **Estimated total uptake**  **(µg / kg bw)** |
| 1. Mixing and Loading | Professionals –  Primary exposure | 1 /No PPE | Permethrin Tebuconazole | 252.565  138.911 |
|  |  |  | Propiconazole | 138.911 |
|  |  |  | IPBC | 126.283 |
|  | Professionals –  Primary exposure | 2a / Gloves | Permethrin Tebuconazole | 2.590  1.425 |
|  |  |  | Propiconazole | 1.425 |
|  |  |  | IPBC | 1.295 |
|  | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole | 2.590  1.425 |
|  |  |  | Propiconazole | 1.425 |
|  |  |  | IPBC | 1.295 |
|  | Professionals –  Primary exposure | 2c / Gloves + impermeable coveralls  + filtering half masks (FFP11) | Permethrin Tebuconazole Propiconazole IPBC | 2.541  1.398  1.398  1.270 |
| 2. Automated | Professionals – | 1 /No PPE | Permethrin | 2704.42 |
| spraying | Primary exposure |  | Tebuconazole | 1859.29 |
|  |  |  | Propiconazole | 1983.24 |
|  |  |  | IPBC | 8393.04 |
|  | Professionals – | 2a / Gloves | Permethrin | 223.88 |
|  | Primary exposure |  | Tebuconazole | 153.92 |
|  |  |  | Propiconazole | 164.18 |
|  |  |  | IPBC | 694.80 |
|  | Professionals – | 2b / Gloves + | Permethrin | 34.997 |
|  | Primary exposure | impermeable coveralls | Tebuconazole | 24.061 |
|  |  |  | Propiconazole | 25.665 |
|  |  |  | IPBC | 108.612 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 2bis. Fully | Professionals – | 1 /No PPE | Permethrin | 676.106 |
| automated spraying | Primary exposure |  | Tebuconazole Propiconazole | 464.823  495.811 |
|  |  |  | IPBC | 2098.260 |
|  | Professionals –  Primary exposure | 2a / Gloves | Permethrin Tebuconazole | 55.97  38.479 |
|  |  |  | Propiconazole | 41.045 |
|  |  |  | IPBC | 173.70 |
|  | Professionals – | 2b / Gloves + | Permethrin | 8.749 |
|  | Primary exposure | impermeable coveralls | Tebuconazole | 6.015 |
|  |  |  | Propiconazole | 6.416 |
|  |  |  | IPBC | 27.153 |
| 3. Automated | Professionals – | 1 /No PPE | Permethrin | 2704.42 |
| dipping | Primary exposure |  | Tebuconazole | 1859.29 |
|  |  |  | Propiconazole | 1983.24 |
|  |  |  | IPBC | 8393.04 |
|  | Professionals –  Primary exposure | 2a / Gloves | Permethrin Tebuconazole | 223.88  153.92 |
|  |  |  | Propiconazole | 164.18 |
|  |  |  | IPBC | 694.80 |
|  | Professionals – | 2b / Gloves + | Permethrin | 34.997 |
|  | Primary exposure | impermeable coveralls | Tebuconazole | 24.061 |
|  |  |  | Propiconazole | 25.665 |
|  |  |  | IPBC | 108.612 |
| 3bis. Fully automated dipping | Professionals –  Primary exposure | 1 /No PPE | Permethrin Tebuconazole Propiconazole | 676.106  464.823  495.811 |
|  |  |  | IPBC | 2098.260 |
|  | Professionals –  Primary exposure | 2a / Gloves | Permethrin Tebuconazole | 55.97  38.479 |
|  |  |  | Propiconazole | 41.045 |
|  |  |  | IPBC | 173.70 |
|  | Professionals – | 2b / Gloves + | Permethrin | 8.749 |
|  | Primary exposure | impermeable coveralls | Tebuconazole | 6.015 |
|  |  |  | Propiconazole | 6.416 |
|  |  |  | IPBC | 27.153 |
| 4. automated vacuum pressure | Professionals –  Primary exposure | 1 /No PPE | Permethrin Tebuconazole Propiconazole | 1267.705  697.237  697.237 |
|  |  |  | IPBC | 633.852 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Professionals – | 2a / Gloves | Permethrin | 104.949 |
| Primary exposure |  | Tebuconazole | 57.722 |
|  |  | Propiconazole | 57.722 |
|  |  | IPBC | 52.475 |
| Professionals – | 2b / Gloves + | Permethrin | 16.411 |
| Primary exposure | impermeable coveralls | Tebuconazole | 9.026 |
|  |  | Propiconazole | 9.026 |
|  |  | IPBC | 8.205 |
| Professionals – | 2c / Gloves + | Permethrin | 16.406 |
| Primary exposure | impermeable coveralls  + filtering half masks (FFP11) | Tebuconazole Propiconazole IPBC | 9.024  9.024  8.203 |
| 4bis : double | Professionals – | 1 /No PPE | Permethrin | 2535.411 |
| vacuum pressure | Primary exposure |  | Tebuconazole Propiconazole | 1394.475  1394.475 |
|  |  |  | IPBC | 1267.705 |
|  | Professionals –  Primary exposure | 2a / Gloves | Permethrin Tebuconazole | 209.899  115.444 |
|  |  |  | Propiconazole | 115.444 |
|  |  |  | IPBC | 104.950 |
|  | Professionals – | 2b / Gloves + | Permethrin | 32.821 |
|  | Primary exposure | impermeable coveralls | Tebuconazole | 18.051 |
|  |  |  | Propiconazole | 18.051 |
|  |  |  | IPBC | 16.411 |
|  | Professionals – | 2c / Gloves + | Permethrin | 32.813 |
|  | Primary exposure | impermeable coveralls  + filtering half masks (FFP11) | Tebuconazole Propiconazole IPBC | 18.047  18.047  16.406 |
| 5. Professional  – sanding treated wood posts | Professionals –  Secondary exposure | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | 0.560  0.321  0.326  0.529 |
| 6. Non- | General public | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | 0.173  0.108  0.113  0.336 |
| professional - | (adults) – secondary |  |
| processing | acute exposure |  |
| Treated dried |  |  |
| wood |  |  |
| 7. Chewing | General public | 1 /No PPE | Permethrin | 13.920 |
| wood off-cut | (toddlers) – secondary acute exposure |  | Tebuconazole Propiconazole IPBC | 7.656  7.656  6.960 |
| 8. Playing and | General public | 1 /No PPE | Permethrin | 2.994 |
| mouthing | (toddlers) – |  | Tebuconazole | 1.690 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| playground structure | secondary chronic exposure |  | Propiconazole IPBC | 1.705  2.338 | |
| 9. Inhalation volatized residues indoors | General public – secondary chronic exposure | 1 /No PPE | IPBC | adult child toddler infant | 19.15  50.76  115.79  96.50 |
| 10. Industrial brushing | Professionals –  Primary exposure | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | 0.920  0.630  0.672  2.835 | |
| Professionals –  Primary exposure | 2a / Gloves | Permethrin Tebuconazole Propiconazole IPBC | 0.355  0.242  0.257  1.068 | |
| Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 0.092  0.061  0.065  0.247 | |
| Professionals –  Primary exposure | 2c / Gloves + impermeable coveralls  + filtering half masks (FFP11) | Permethrin Tebuconazole Propiconazole IPBC | 0.081  0.055  0.058  0.241 | |
| 11. post- application, Cleaning of the brush equipment | Professionals –  Primary exposure | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | 0.781  0.539  0.575  2.526 | |
| Professionals –  Primary exposure | 2a / Gloves | Permethrin Tebuconazole Propiconazole IPBC | 0.078  0.054  0.057  0.253 | |
| Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 0.078  0.054  0.057  0.253 | |
| Professionals –  Primary exposure | 2c / Gloves + impermeable coveralls  + filtering half masks (FFP11) | Permethrin Tebuconazole Propiconazole IPBC | 0.078  0.054  0.057  0.253 | |

***Calculation sheet for exposure can be found in annex 3.7***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios and values to be used in risk assessment – combined scenario** | | | | |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non- professionals, bystanders)** | **Tier/PPE** | **Active substance** | **Estimated total uptake**  **(µg / kg bw)** |
| Combined exposure  Scenarios 1+2 | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 37.59  25.48  27.09  109.91 |
| Combined exposure  Scenarios 1+2bis | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 11.34  7.44  7.84  28.49 |
| Combined exposure  Scenarios 1+3 | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 37.59  25.48  27.09  109.91 |
| Combined exposure  Scenarios 1+3bis | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 11.34  7.44  7.84  28.49 |
| Combined exposure  Scenarios 1+4 | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 19.00  10.45  10.45  9.50 |
| Combined exposure  Scenarios 1+4bis | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 35.41  19.48  19.48  17.70 |
| Combined exposure  Scenarios 8+9 | General public (toddler) – secondary chronic exposure | 1 /No PPE | IPBC | 118.13 |
| Combined exposure  Scenarios 1+10+11 | Professionals –  Primary exposure | 2b / Gloves + impermeable coveralls | Permethrin Tebuconazole Propiconazole  IPBC | 2.77  1.50  1.50  1.62 |

* + - 1. *Risk characterisation for human health*

##### Reference values to be used in Risk Characterisation

The following AEL values were derived during assessment of the active substance for the purpose of inclusion into Annex I of 98/8/EC for use as a wood preservative. Please refer to the Assessment Report of **Permethrin** (RMS IE, April 2014) for more information. ADI and ARfD values were not derived.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | 2-year rat toxicity study | 50 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.5 mg/kg bw/d |
| AELmedium-term | 1-year, oral, dog | 5 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.05 mg/kg bw/d |
| AELlong-term | 1-year, oral, dog | 5 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.05 mg/kg bw/d |

The following AOEL value was derived during assessment of the active substance for the purpose of inclusion into Annex I of 98/8/EC for use as a wood preservative. Please refer to the Assessment Report of **Tebuconazole** (RMS DK, November 2007) for more information. ADI and ARfD values were not derived.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AOELshort/long-  term | 1-year, oral, dog | 3 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.03 mg/kg bw/d |

AOEL values were derived during assessment of the active substance **Propiconazole** for the purpose of inclusion into Annex I of 98/8/EC for use as a wood preservative (RMS FI, November 2007).

However, this values were reviewed during the assessment of the active substances for use as PT9 (in 2013) and PT7 (in 2015).

Please refer to the Assessment Report of **Propiconazole** (PT 7 - RMS FI, January 2015) for more information.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AELshort-term | Developmental study, rat | 30 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.3 mg/kg bw/d |
| AELmedium-term | 2-generation study, rat | 8 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.08 mg/kg bw/d |
| AELlong-term | 2 years study, rat | 4 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.040  mg/kg bw/d |
| ADI | 2 years study, rat | 4 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.040  mg/kg bw/d |
| ARfD | Developmental study, rat | 30 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.3 mg/kg bw/d |

The following AOEL values were derived during assessment of the active substances for the purpose of inclusion into Annex I of 98/8/EC for use as a wood preservative. Please refer to the Assessment Report of **IPBC** (RMS DK, February 2008) for more information. ADI and ARfD values were not derived.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AOELshort-term | 90-day, oral rat | 35 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.35 mg/kg bw/d |
| AOELlong-term | 2-year, oral, rat | 20 mg/kg bw/d | 100  (inter-& intra- specific differences) | No (100%) | 0.2 mg/kg bw/d |

##### Risk for industrial users

*Systemic effects*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scena rio** | **Tier** | **Active substance** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **µg/kg bw/d** | **Estimated uptake**  **µg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptabl e**  **(yes/no)** |
| **Primary** | | | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Scenario 1 | 1 /No PPE | Permethrin  Tebuconazole | 5  3 | 50  30 | 252.565  138.911 | 505.13  463.04 | No No |
|  |  | Propiconazole  IPBC | 4  20 | 40  200 | 138.911  126.283 | 347.28  63.14 | No Yes |
|  | 2a / Gloves | Permethrin | 5 | 50 | 2.590 | 5.18 | Yes |
|  |  | Tebuconazole | 3 | 30 | 1.425 | 4.75 | Yes |
|  |  | Propiconazole | 4 | 40 | 1.425 | 3.56 | Yes |
|  |  | IPBC | 20 | 200 | 1.295 | 0.64 | Yes |
|  | 2b / Gloves | Permethrin | 5 | 50 | 2.590 | 5.18 | Yes |
|  | +  impermeable coveralls | Tebuconazole Propiconazole | 3  4 | 30  40 | 1.425  1.425 | 4.75  3.56 | Yes Yes |
|  | IPBC | 20 | 200 | 1.295 | 0.64 | Yes |
|  | 2c / Gloves | Permethrin | 5 | 50 | 2.541 | 5.08 | Yes |
| +  impermeable coveralls + | Tebuconazole Propiconazole | 3  4 | 30  40 | 1.398  1.398 | 4.66  3.49 | Yes Yes |
| filtering half  masks | IPBC | 20 | 200 | 1.270 | 0.63 | Yes |
| (FFP11) |  |  |  |  |  |  |
| Scenario 2 | 1 /No PPE | Permethrin  Tebuconazole | 5  3 | 50  30 | 2704.42  1859.29 | 5408.85  6197.64 | No  No |
|  |  | Propiconazole | 4 | 40 | 1983.24 | 4958.11 | No |
|  |  | IPBC | 20 | 200 | 8393.04 | 4196.52 | No |
|  | 2a / Gloves | Permethrin | 5 | 50 | 223.88 | 447.76 | No |
|  |  | Tebuconazole | 3 | 30 | 153.92 | 513.06 | No |
|  |  | Propiconazole | 4 | 40 | 164.18 | 410.45 | No |
|  |  | IPBC | 20 | 200 | 694.80 | 347.4 | No |
|  | 2b / Gloves | Permethrin | 5 | 50 | 34.997 | 69.99 | Yes |
|  | +  impermeable coveralls | Tebuconazole Propiconazole | 3  4 | 30  40 | 24.061  25.665 | 80.20  64.16 | Yes Yes |
|  | IPBC | 20 | 200 | 108.612 | 54.31 | Yes |
| Scenario 2 bis | 1 /No PPE | Permethrin  Tebuconazole | 5  3 | 50  30 | 676.106  464.823 | 1352.21  1549.41 | No  No |
|  |  | Propiconazole | 4 | 40 | 495.811 | 1239.53 | No |
|  |  | IPBC | 20 | 200 | 2098.260 | 1049.13 | No |
|  | 2a / Gloves | Permethrin | 5 | 50 | 55.97 | 111.94 | No |
|  |  | Tebuconazole | 3 | 30 | 38.479 | 128.26 | No |
|  |  | Propiconazole | 4 | 40 | 41.045 | 102.61 | No |
|  |  | IPBC | 20 | 200 | 173.70 | 86.85 | Yes |
|  | 2b / Gloves  +  impermeable | Permethrin  Tebuconazole | 5  3 | 50  30 | 8.749  6.015 | 17.50  20.05 | Yes  Yes |
|  | coveralls | Propiconazole | 4 | 40 | 6.416 | 16.04 | Yes |
|  |  | IPBC | 20 | 200 | 27.153 | 13.58 | Yes |
| Scenario 3 | 1 /No PPE | Permethrin  Tebuconazole | 5  3 | 50  30 | 2704.42  1859.29 | 5408.85  6197.64 | No  No |
|  |  | Propiconazole | 4 | 40 | 1983.24 | 4958.11 | No |
|  |  | IPBC | 20 | 200 | 8393.04 | 4196.52 | No |
|  | 2a / Gloves | Permethrin | 5 | 50 | 223.88 | 447.76 | No |
|  |  |  |  |  | 153.92 | 513.06 | No |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Tebuconazole | 3 | 30 | 164.18 | 410.45 | No |
| Propiconazole | 4 | 40 | 694.80 | 347.4 | No |
| IPBC | 20 | 200 |  |  |  |
| 2b / Gloves  +  impermeable | Permethrin  Tebuconazole | 5  3 | 50  30 | 34.997  24.061 | 69.99  80.20 | Yes  Yes |
| coveralls | Propiconazole | 4 | 40 | 25.665 | 64.16 | Yes |
|  | IPBC | 20 | 200 | 108.612 | 54.31 | Yes |
| Scenario 3 bis | 1 /No PPE | Permethrin  Tebuconazole | 5  3 | 50  30 | 676.106  464.823 | 1352.21  1549.41 | No  No |
|  |  | Propiconazole | 4 | 40 | 495.811 | 1239.53 | No |
|  |  | IPBC | 20 | 200 | 2098.260 | 1049.13 | No |
|  | 2a / Gloves | Permethrin | 5 | 50 | 55.97 | 111.94 | No |
|  |  | Tebuconazole | 3 | 30 | 38.479 | 128.26 | No |
|  |  | Propiconazole | 4 | 40 | 41.045 | 102.61 | No |
|  |  | IPBC | 20 | 200 | 173.70 | 86.85 | Yes |
|  | 2b / Gloves  +  impermeable | Permethrin  Tebuconazole | 5  3 | 50  30 | 8.749  6.015 | 17.50  20.05 | Yes  Yes |
|  | coveralls | Propiconazole | 4 | 40 | 6.416 | 16.04 | Yes |
|  |  | IPBC | 20 | 200 | 27.153 | 13.58 | Yes |
| Scenario 4 | 1 /No PPE | Permethrin  Tebuconazole | 5  3 | 50  30 | 1267.705  697.237 | 2535.41  2324.12 | No  No |
|  |  | Propiconazole | 4 | 40 | 697.237 | 1743.09 | No |
|  |  | IPBC | 20 | 200 | 633.852 | 316.93 | No |
|  | 2a / Gloves | Permethrin | 5 | 50 | 104.949 | 209.90 | No |
|  |  | Tebuconazole | 3 | 30 | 57.722 | 192.41 | No |
|  |  | Propiconazole | 4 | 40 | 57.722 | 144.31 | No |
|  |  | IPBC | 20 | 200 | 52.475 | 26.24 | Yes |
|  | 2b / Gloves  +  impermeable | Permethrin  Tebuconazole | 5  3 | 50  30 | 16.411  9.026 | 32.82  30.09 | Yes  Yes |
|  | coveralls | Propiconazole | 4 | 40 | 9.026 | 22.56 | Yes |
|  |  | IPBC | 20 | 200 | 8.205 | 4.10 | Yes |
|  | 2c / Gloves | Permethrin | 5 | 50 | 16.406 | 32.81 | Yes |
|  | +  impermeable coveralls + | Tebuconazole Propiconazole | 3  4 | 30  40 | 9.024  9.024 | 30.08  22.56 | Yes Yes |
|  | filtering half masks | IPBC | 20 | 200 | 8.203 | 4.40 | Yes |
|  | (FFP11) |  |  |  |  |  |  |
| Scenario 4 bis | 1 /No PPE | Permethrin  Tebuconazole | 5  3 | 50  30 | 2535.411  1394.475 | 5070.82  4648.25 | No  No |
|  |  | Propiconazole | 4 | 40 | 1394.475 | 3486.19 | No |
|  |  | IPBC | 20 | 200 | 1267.705 | 633.852 | No |
|  | 2a / Gloves | Permethrin | 5 | 50 | 209.899 | 419.80 | No |
|  |  | Tebuconazole | 3 | 30 | 115.444 | 384.81 | No |
|  |  | Propiconazole | 4 | 40 | 115.444 | 288.611 | No |
|  |  | IPBC | 20 | 200 | 104.950 | 52.47 | Yes |
|  | 2b / Gloves  +  impermeable | Permethrin  Tebuconazole | 5  3 | 50  30 | 32.821  18.051 | 65.64  60.17 | Yes  Yes |
|  | coveralls | Propiconazole | 4 | 40 | 18.051 | 45.13 | Yes |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | IPBC | 20 | 200 | 16.411 | 8.20 | Yes |
| 2c / Gloves | Permethrin | 5 | 50 | 32.813 | 65.62 | Yes |
| +  impermeable coveralls + | Tebuconazole Propiconazole | 3  4 | 30  40 | 18.047  18.047 | 60.16  45.12 | Yes Yes |
| filtering half  masks | IPBC | 20 | 200 | 16.406 | 8.20 | Yes |
| (FFP11) |  |  |  |  |  |  |
| Scenario 10 | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | 5  3  4  20 | 50  30  40  200 | 0.92  0.63  0.67  2.83 | 1.83  2.10  1.68  1.41 | Yes  Yes  Yes  Yes |
| 2a / Gloves | Permethrin Tebuconazole Propiconazole IPBC | 5  3  4  20 | 50  30  40  200 | 0.11  0.07  0.08  0.32 | 0.21  0.24  0.19  0.16 | Yes  Yes  Yes  Yes |
| 2b / Gloves  +  impermeable coveralls | Permethrin Tebuconazole Propiconazole IPBC | 5  3  4  20 | 50  30  40  200 | 0.03  0.02  0.02  0.07 | 0.06  0.06  0.05  0.04 | Yes  Yes  Yes  Yes |
| 2c / Gloves  +  impermeable coveralls + filtering half masks (FFP11) | Permethrin Tebuconazole Propiconazole IPBC | 5  3  4  20 | 50  30  40  200 | 0.02  0.02  0.02  0.07 | 0.05  0.05  0.04  0.04 | Yes  Yes  Yes  Yes |
| Scenario 11 | 1 /No PPE | Permethrin Tebuconazole Propiconazole IPBC | 5  3  4  20 | 50  30  40  200 | 0.78  0.54  0.57  2.53 | 1.56  1.80  1.44  1.26 | Yes  Yes  Yes  Yes |
| 2a / Gloves | Permethrin Tebuconazole Propiconazole IPBC | 5  3  4  20 | 50  30  40  200 | 0.08  0.05  0.06  0.25 | 0.16  0.18  0.14  0.13 | Yes  Yes  Yes  Yes |

*Combined scenarios*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Task/ Scenario** | **Tier** | **Active substance** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg µw/d** | **Estimated uptake**  **µg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptabl e**  **(yes/no)** |
| **Primary** | | | | | | | |
| Scenario 1+2 | 2b / Gloves + impermea ble | Permethrin  Tebuconazole Propiconazole | 5  3  4 | 50  30  40 | 37.59  25.48  27.09 | 75.17  84.95  67.72 | Yes  Yes Yes |
|  | coveralls | IPBC | 20 | 200 | 109.91 | 54.95 | Yes |
| Scenario 1+2bis | 2b / Gloves + impermea | Permethrin  Tebuconazole | 5  3 | 50  30 | 11.34  7.44 | 22.68  24.80 | Yes  Yes |
|  | ble | Propiconazole | 4 | 40 | 7.84 | 19.60 | Yes |
|  | coveralls | IPBC | 20 | 200 | 28.49 | 14.22 | Yes |
| Scenario 1+3 | 2b / Gloves + impermea ble | Permethrin Tebuconazole  Propiconazole | 5  3  4 | 50  30  40 | 37.59  25.48  27.09 | 75.17  84.95  67.72 | Yes Yes  Yes |
|  | coveralls | IPBC | 20 | 200 | 109.91 | 54.95 | Yes |
| Scenario 1+3bis | 2b / Gloves +  impermea ble | Permethrin Tebuconazole  Propiconazole | 5  3  4 | 50  30  40 | 11.34  7.44  7.84 | 22.68  24.80  19.60 | Yes Yes  Yes |
|  | coveralls | IPBC | 20 | 200 | 28.49 | 14.22 | Yes |
| Scenario 1+4 | 2b / Gloves + impermea ble | Permethrin Tebuconazole  Propiconazole | 5  3  4 | 50  30  40 | 19.00  10.45  10.45 | 38.00  34.83  26.13 | Yes Yes  Yes |
|  | coveralls | IPBC | 20 | 200 | 9.50 | 4.75 | Yes |
| Scenario 1+4bis | 2b / Gloves + impermea ble | Permethrin Tebuconazole  Propiconazole | 5  3  4 | 50  30  40 | 35.41  19.48  19.48 | 70.82  64.92  48.69 | Yes Yes  Yes |
|  | coveralls | IPBC | 20 | 200 | 17.70 | 8.85 | Yes |
| Scenarios 1+10+11 | 2b / Gloves + impermea ble | Permethrin Tebuconazole  Propiconazole | 5  3  4  20 | 50  30  40  200 | 2.77  1.93  1.93  1.96 | 5.54  6.44  4.83  0.98 | Yes  Yes  Yes  Yes |
| coveralls | IPBC |

*Local effects*

**Mixing and loading of undiluted product.**

As the undiluted product is corrosive to eyes and sensitive, a qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is performed.

|  |  |  |
| --- | --- | --- |
| Hazard | Exposure | Risk |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hazard category | Effect s in term s of C&L | Additional relevant hazard informati on | PT | Who is exposed | Tasks, uses, processe s | Potential exposure s route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM & PPE | Concl usion on risk | Uncertainties attaced to conclusion may increase (↑) or decrease (↓) risk or both (↑↓) |
| Skin sens 1  EYE DAM1 | H317  H318 | Skin Sens 1  (medium)  EYE DAM  1 (High) | 8 | PROF/ INDUSTR IAL USERS | Mixing and Loading the concentr ated product | Dermal, Inhalatio n | Frequency depending on the uses : 1 to several tasks/day | Low (operated in closed drums) | with gloves and uncoated coveralls  without RPE | Accep table | ↓ PPE  ↓ Professional user  ↓ No direct contact expected  ↓ P sentences on the label |

Remark : for STOT RE 2, a fully quantitative risk assessment should be performed according the guidance. As the substance responsible for the classification is IBPC, the quantitative risk assessment has been done and no unacceptable risk are expected. For REPR. 1B, a fully quantitative risk assessment should also be performed according the guidance. As the substance responsible for the classification is propiconazole, the quantitative risk assessment has been done and no unacceptable risk are expected.

The P-sentences on the label are sufficient in order to protect the user. No additional RMM are needed.

**Diluted product:** No local risk is foreseen since the diluted product will not be classified as corrosive or sensitive anymore (dilution rate 14.5) according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

* EYE DAM 1 : 0.52% of component which have triggered the classification EYE DAM 1 of SARPECO 9-PLUS is inferior to the GCL of 3%
* SKIN SENS 1: maximum 0.29% of permethrin which has triggered the classification SKIN SENS 1 of SARPECO 9-PLUS is inferior to the GCL of 1%, maximum 0.1595% of propiconazole which has triggered the classification SKIN SENS 1 of SARPECO 9-PLUS is inferior to the GCL of 1%, maximum 0.145% of IBPC which has triggered the classification SKIN SENS 1 of SARPECO 9-PLUS is inferior to the GCL of 1%
* STOT RE 2 : maximum 0.145% of IBPC which has triggered the classification STOT RE 2 of SARPECO 9-PLUS is inferior to the GCL of 1%
* REPR. 1 B : maximum 0.1595% of Propiconazole which has triggered the classification REPR. 1B of SARPECO 9-PLUS is inferior to the GCL of 0.3%

*Conclusion*

Normal use of SARPECO 9-PLUS by industrial professionals has a sufficiently large safety margin for scenario 1, 2, 2bis, 3, 3 bis, 4 and 4 bis (**Mixing and loading, Automated spraying fully automated spraying, automated dipping, fully automated dipping, vacuum pressure and double vacuum pressure ; including combined scenario**) when using proper PPE (chemical resistant gloves, impermeable coverall).

In addition, safety goggles are recommended during handling of concentrated product (Mixing and loading).

Normal use of SARPECO 9-PLUS by industrial professionals has a sufficiently large safety margin for scenario 1, 10 and 11 (Mixing and loading, industrial brushing and cleaning of the brush equipment) when using proper PPE (chemical resistant gloves, impermeable coverall).

**Industrial secondary exposure** is foreseen mainly during the cleaning/maintenance of the system. Any sort of maintenance/repair work on the system (hoses, valves etc.) may potentially lead to exposure. Cleaning may also potentially lead to exposure. However it is

assumed that this type of tasks will be done by others professionals compared to application tasks (primary exposure). The exposure is considered lower than the exposure resulting of the application of the product. As no model are available in order to estimate the exposure, if PPE are required for the application task, it is advice to use the same PPE for the potentially secondary exposure.

Please note that when assessing the combined exposure to several active substances within a biocidal product (See point VI), the following application gives unacceptable results for industrial users :

* automated spraying
* automated dipping
* double vacuum pressure

Therefore, eventually, for human health, the following uses could be authorized :

* Fully automated spraying,
* Fully automated dipping,
* Vacuum pressure

##### Risk for professional users

*Systemic effects*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scena rio** | **Tier** | **Active substance** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **µg/kg bw/d** | **Estimated uptake**  **µg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptabl e**  **(yes/no)** |
| **Secondary** | | | | | | | |
| Scenario 5 | 1 /No PPE | Permethrin  Tebuconazole | 5  3 | 50  30 | 0.560  0.321 | 1.12  1.07 | Yes  Yes |
|  |  | Propiconazole | 4 | 40 | 0.326 | 0.81 | Yes |
|  |  | IPBC | 20 | 200 | 0.529 | 0.26 | Yes |

*Local effects*

No local effects are expected due to the dilution of the product.

*Conclusion*

No risk is foreseen for the secondary exposure of professional sanding treated wood posts (chronic exposure).

##### Risk for non-professional users

No exposure is foreseen. Risk is not applicable.

##### Risk for the general public

*Systemic effects*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Task/ Scenario** | **Tier** | **Active substance** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **µg/kg µw/d** | **Estimated uptake**  **µg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptabl e**  **(yes/no)** |
| **Secondary – acute phase** | | | | | | | |
| Scenario 6 (adult) | 1 /No PPE | Permethrin  Tebuconazole | 50  3 | 500  30 | 0.173  0.108 | 0.03  0.36 | Yes  Yes |
|  |  | Propiconazole | 30 | 300 | 0.113 | 0.04 | Yes |
|  |  | IPBC | 35 | 350 | 0.336 | 0.09 | Yes |
| Scenario 7 (toddler) | 1 /No PPE | Permethrin  Tebuconazole | 50  3 | 50  30 | 13.920  7.656 | 2.78  25.52 | Yes  Yes |
|  |  | Propiconazole | 30 | 300 | 7.656 | 2.55 | Yes |
|  |  | IPBC | 35 | 350 | 6.960 | 1.99 | Yes |
| **Secondary – chronic phase** | | | | | | | |
| Scenario 8 | 1 /No | Permethrin | 5 | 50 | 2.994 | 5.99 | Yes |
| (toddler) | PPE | Tebuconazole | 3 | 30 | 1.690 | 5.63 | Yes |
|  |  | Propiconazole | 4 | 40 | 1.705 | 4.26 | Yes |
|  |  | IPBC | 20 | 200 | 2.338 | 1.17 | Yes |
| Scenario 9 (general public) | 1 /No PPE | IPBC  - Adult | 20 | 200 | 19.15  50.76 | 9.57  25.38 | Yes  Yes |
|  |  | * Child * Toddler * Infant |  |  | 115.79  96.50 | 57.90  48.25 | Yes Yes |

*Combined scenarios*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Task/ Scenario** | **Tier** | **Active substance** | **Systemic NOAEL**  **mg/kg bw/d** | **AEL**  **mg/kg µw/d** | **Estimated uptake**  **µg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptabl e**  **(yes/no)** |
| **Secondary – chronic phase** | | | | | | | |
| Scenario 8+9 (toddler) | 1 /No PPE | IPBC | 20 | 200 | 118.13 | 59.07 | Yes |

*Local effects*

No local effects are expected.

*Conclusion*

Normal use of SARPECO 9-PLUS has a sufficiently large safety margin for the secondary exposed general public, for acute and chronic phase exposure, for the separate scenarios 6, , 7, 8 and 9 as well as for the combined scenarios.

##### Risk for consumers via residues in food

No exposure is foreseen as regards to the intended use of the product. However the following RMM is highly advised on the label in order to avoid any misuses of the product:

"Do not apply the product on wood which may come into contact with food, feedstuff or

livestock”.

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

***Industrial combined exposure (chronic exposure scenario)***

*The* ***Tier 1*** *concerns the acceptability of each substance. Please refer to point (I) Risk for industrial users.*

*For each active substance separately, the risk are acceptable when PPE are worn (gloves and impermeable coveralls) for Mixing and loading, Automated spraying – Deluge, automated dipping, fully automated dipping, vacuum pressure and double vacuum pressure ; including combined scenario.*

*The* ***Tier 2*** *concerns the mixture risk assessment by an additivity approach :*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Permethrin | Tebuconazole | Propiconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| Combined exposure from **M&L + Automated spaying** (gloves + impermeable coveralls) | | | | | |
| 0.75 | 0.85 | 0.68 | 0.55 | **2.83** | Tier 3B |
| Combined exposure from **M&L + FULLY Automated spraying** (gloves + impermeable coveralls) | | | | | |
| 0.23 | 0.25 | 0.20 | 0.14 | 0.81 | Acceptable |
| Combined exposure from **M&L + Automated dipping** (gloves + impermeable coveralls) | | | | | |
| 0.75 | 0.85 | 0.68 | 0.55 | **2.83** | Tier 3B |
| Combined exposure from **M&L + FULLY Automated dipping** (gloves + impermeable coveralls) | | | | | |
| 0.23 | 0.25 | 0.20 | 0.14 | 0.81 | Acceptable |
| Combined exposure from **M&L + vacuum pressure** (gloves + impermeable coveralls) | | | | | |
| 0.38 | 0.35 | 0.26 | 0.05 | **1.04** | Tier 3B |
| Combined exposure from **M&L + Double vacuum pressure** (gloves + impermeable coveralls) | | | | | |
| 0.70 | 0.65 | 0.49 | 0.09 | **1.93** | Tier 3B |
| Combined exposure from **M&L + industrial brushing + cleaning of the brush equipment** (gloves + impermeable coveralls) | | | | | |
| 0.06 | 0.06 | 0.05 | 0.01 | **0.18** | Acceptable |

 HI < 1, for combined exposure from M&L + FULLY Automated spraying (gloves + impermeable coveralls) and form M&L + FULLY Automated dipping (gloves + impermeable coveralls) and therefore the risk is acceptable.

The risk is also acceptable for application by industrial brushing (M&L + industrial brushing + cleaning of the brush equipment when gloves + impermeable coveralls are worn).

 HI ≥ 1, a **Tier 3B** approach is considered since the 4 active substances have target organs in common.

The liver is a target organ common to permethrin, propiconazole, tebuconazole and IPBC. The kidney is a target organ common to permethrin, propiconazole and IPBC.

Blood is a target organ common to propiconazole and tebuconazole.

The adrenal is a target organ common to propiconazole and tebuconazole.

Specific target organ long term AELS can be derived for each active substance based on the available data in the CARs.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Permethrin** | **Tebuconazole** | **Propiconazole** | **IPBC** |
| **General long term AEL** | 0.05 | 0.03 | 0.04 | 0.2 |
| **Specific AEL: liver** | 0.05 | 0.06 | 0.08 | 0.2 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Specific AEL: kidney** | 0.05 | - | 0.5 | 0.35 |
| **Specific AEL: Hemato** |  | 0.3 | 0.761 |  |
| **Specific AEL: adrenals** |  | 0.03 | 0.04 |  |

**Please for details calculations refer to annex 3.2.**

**TIER 3B - Liver**:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Permethrin | Tebuconazole | Propiconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| Combined exposure from **M&L + Automated spraying** (gloves + impermeable coveralls) | | | | | |
| 0.75 | 0.42 | 0.33 | 0.54 | **2.06** | **Not acceptable** |
| Combined exposure from **M&L + Automated dipping** (gloves + impermeable coveralls) | | | | | |
| 0.75 | 0.42 | 0.33 | 0.54 | **2.06** | **Not acceptable** |
| Combined exposure from **M&L + vacuum pressure** (gloves + impermeable coveralls) | | | | | |
| 0.38 | 0.12 | 0.13 | 0.05 | 0.68 | Acceptable |
| Combined exposure from **M&L + Double vacuum pressure** (gloves + impermeable coveralls) | | | | | |
| 0.70 | 0.32 | 0.23 | 0.09 | **1.35** | **Not acceptable** |

**TIER 3B - Kidney**:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Permethrin | Tebuconazole | Propiconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| Combined exposure from **M&L + Automated spraying** (gloves + impermeable coveralls) | | | | | |
| 0.75 | n.r. | 0.05 | 0.31 | **1.12** | **Not acceptable** |
| Combined exposure from **M&L + Automated dipping** (gloves + impermeable coveralls) | | | | | |
| 0.75 | n.r. | 0.05 | 0.31 | **1.12** | **Not acceptable** |
| Combined exposure from **M&L + vacuum pressure** (gloves + impermeable coveralls) | | | | | |
| 0.38 | n.r. | 0.02 | 0.03 | 0.43 | Acceptable |
| Combined exposure from **M&L + Double vacuum pressure** (gloves + impermeable coveralls) | | | | | |
| 0.70 | n.r. | 0.04 | 0.05 | 0.80 | Acceptable |

**TIER 3B – Blood**:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Permethrin | Tebuconazole | Propiconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| Combined exposure from **M&L + Automated spraying** (gloves + impermeable coveralls) | | | | | |
| n.r. | 0.08 | 0.04 | n.r. | 0.12 | Acceptable |
| Combined exposure from **M&L + Automated dipping** (gloves + impermeable coveralls) | | | | | |
| n.r. | 0.08 | 0.04 | n.r. | 0.12 | Acceptable |
| Combined exposure from **M&L + vacuum pressure** (gloves + impermeable coveralls) | | | | | |
| n.r. | 0.02 | 0.01 | n.r. | 0.04 | Acceptable |
| Combined exposure from **M&L + Double vacuum pressure** (gloves + impermeable coveralls) | | | | | |
| n.r. | 0.06 | 0.03 | n.r. | 0.09 | Acceptable |

**TIER 3B – Adrenal**:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Permethrin | Tebuconazole | Propiconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| Combined exposure from **M&L + Automated spraying** (gloves + impermeable coveralls) | | | | | |
| 0.75 | 0.85 | 0.68 | n.r. | **2.28** | **Not acceptable** |
| Combined exposure from **M&L + Automated dipping** (gloves + impermeable coveralls) | | | | | |
| 0.75 | 0.85 | 0.68 | n.r. | **2.28** | **Not acceptable** |
| Combined exposure from **M&L + vacuum pressure** (gloves + impermeable coveralls) | | | | | |
| 0.38 | 0.35 | 0.26 | n.r. | 0.89 | Acceptable |
| Combined exposure from **M&L + Double vacuum pressure** (gloves + impermeable coveralls) | | | | | |
| 0.70 | 0.65 | 0.49 | n.r. | **1.84** | **Not acceptable** |

The following application gives unacceptable results for industrial users :

* automated spraying
* automated dipping
* double vacuum pressure

Therefore, eventually, for human health, the following uses could be authorized :

* Fully automated spraying,
* Fully automated dipping,
* Vacuum pressure

***Professional exposure (chronic exposure scenario)***

*The* ***Tier 1*** *concerns the acceptability of each substance. Please refer to point (II) Risk for professional users.*

*For each active substance separately, the risk are acceptable for professional user. The* ***Tier 2*** *concerns the mixture risk assessment by an additivity approach :*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Permethrin | Tebuconazole | Propiconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| Professional – sanding treated wood posts | | | | | |
| 0.011 | 0.011 | 0.0081 | 0.003 | 0.03 | Acceptable |

 HI < 1, therefore the risk is acceptable.

***Toddler combined exposure (chronic exposure scenario)***

*The* ***Tier 1*** *concerns the acceptability of each substance. Please refer to point (IV) Risk for the general public.*

*For each active substance separately, the risk are acceptable for general public chronic exposure.*

*The* ***Tier 2*** *concerns the mixture risk assessment by an additivity approach :*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Permethrin | Tebuconazole | Propiconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Toddler (genral public) – Playing and mouthing playground structure  Remark for IPBC it is considered combined exposure including expsore to vapour (Scenario 8+9) | | | | | |
| 0.06 | 0.06 | 0.04 | 0.59 | 0.75 | Acceptable |

 HI < 1, therefore the risk is acceptable.

### Risk assessment for animal health

The product is not used on animals. Indirect exposure to the product may occur for pets and domestic animal particularly in private area. However, due to the lack of appropriate guidance, exposure is assumed to be similar to these of toddlers and children and no specific measure is needed (except for cats due to the presence of permethrin into the biocidal product).

Cats are known to be more sensible to pyrethroids than others animals due to a slower metabolisation of these substances. Intoxication are very common and may be lethal. In order to protect cats, the following Risk Mitigation Measure must be added on the label:

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

### Risk assessment for the environment

Sarpeco 9-plus is wood preservative for industrial use only which has 3 functions: insecticide, anti-termite and fungicide. Its field of use is Use Classes 1, 2, 3.1 and 3.2 to protect wood construction (joinery, window frames, sidings, etc).

The biocidal product is a water-based concentrate that will be diluted in water. The dilution rates used in this risk assessment is 14.5% ( for dipping, brushing and automated spraying) and 1.45% for vacuum pressure application. A top coat is required to be applied after treatment with the product for use classes 3.1 and 3.2.

The environmental risk assessment focusses on the use in class 3 as relevant emissions to environmental compartments.

-Use class 1 (UC 1): situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting.

-Use class 2 (UC 2): situation in which the wood-based product is under cover and fully protected from the weather but where occasional but not persistent wetting may occur.

-Use class 3 (UC 3): situation in which the wood-based product is not covered and not in contact with the ground. It is either continually exposed to the weather or is protected from the weather but subject to frequent wetting.

The product contains the active substances Permethrin at 2 % w/w, Propiconazole at 1.1 % w/w, Tebuconazole at 1.1% w/w and IPBC at 1% w/w. Sarpeco 9-plus is applied diluted with the following application rates and industrial processes:

* automated spraying (100g/m2),
* industrial brushing (100g/m²);
* short dipping (100g/m2),
* vacuum pressure/double vacuum (500-600 kg/m3).

In addition to the active substances Permethrin, IPBC, Tebuconazole and Propiconazole the product contains 6 other substances which are not considered as substance of concern for the environment. The information provided in the CAR of Permethrin, IPBC, Tebuconazole

and Propiconazole are considered enough to perform an assessment of the biocidal product Sarpeco 9-plus and therefore no new data/information on the 4 active substances is required.

###### Effects assessment on the environment

No new data relevant for the environmental evaluation, nor on the product, nor on the active substance, have been submitted.

All the data refer to the chapter 'Fate and distribution in the environment' and 'Effects on environmental organisms' are from Doc IIA as well as from Doc IIB for the active substances Permethrin, Tebuconazole, Propiconazole and IPBC. A summary is presented below for each of the active substance.

##### Environmental fate and behavior of the active substance

* **Permethrin**

**Aquatic compartment including STP and sediment**

Permethrin was observed to be hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50°C respectively. Only at pH 9.0/9.6 was permethrin observed to hydrolyse, with DT50 values for cis- and trans-permethrin estimated at 35 days and 42 days, respectively (at pH 9.6 and 25°C). Permethrin is not readily biodegradable according to OECD 301B (CO2 evolution method)/US EPA OPPTS 835.3110 and OECD 301 F (oxygen consumption). Permethrin is strongly adsorbed to soil (Mean Kf oc 73,442 L/kg (n= 10)).

Permethrin (46:54 and 53:47 cis:trans) was observed to degrade in aerobic water/sediments systems, with whole-system DT50 values of cis- and trans-permethrin calculated at 63.7 days and 27.3 days, respectively at 25°C (equivalent to corresponding values at 12 °C of 180.2 days and 77.2 days).

The degradation scheme proposed for the behavior of permethrin in aerobic water/sediment systems involves as a first step transformation along parallel pathways to 3-phenoxybenzyl alcohol (PB alcohol) and 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA), followed by transformation of 3-phenoxybenzyl alcohol to 3-phenoxybenzoic acid (PBA), with carbon dioxide and bound residues as terminal products.

Maximum observed levels of DCVA, PBA and PB alcohol in the water compartment were 62.6

%AR, 28.8%AR and 38.2 %AR respectively. DCVA and PBA were also major metabolites in the sediment compartment (21.7 % and 16.4 % respectively).

Permethrin was observed to degrade more slowly under anaerobic conditions, with whole- system DT50 values of cis- and trans-permethrin calculated at 179.4 days and 114.5 days, respectively (equivalent to corresponding values at 12 °C of 507.6 days and 323.9 days). Cis- and trans-permethrin appeared to be rather immobile in the sediment, remaining in the upper portion (0-5 cm). DT50 values determined for the cis- and trans-permethrin isomers in the sediment phase ranged from 118 to 256 days and 18 to 62 days, respectively.

Direct photolysis of permethrin (49:51 cis:trans) indicated slow degradation of the test material resulting in a DT50 value of 118 days with 12 hr sunlight per day under outdoor conditions at latitude of 50°N and the fall season.

**Atmosphere**

Volatilization of permethrin is considered to be negligible based on the vapor pressure (2.155 x 10-6 Pa at 20°C, 25:75 cis:trans) and Henry constant (4.6 x 10-3 - > 4.5 x 10-2 Pa m3

mol-1). Permethrin volatilisation loss from a soil surface over 24 hours to the atmosphere was calculated to be 0.73% assuming a temperature of 25 °C. Permethrin is rapidly degraded and would not be transported over large distances in the atmosphere in gaseous phase.

**Terrestrial compartment**

Degradation of permethrin was investigated under aerobic conditions in several soils. The range of reliable SFO DT50s ranged from 77 d to ~141 d at 12°C. The corresponding geomean DT50 was 106d. The *cis* isomer degraded more slowly than the *trans* isomer based on the *cis:trans* ratio at the time of application changing from 40:60 to 50:50 by day 30 and 78:22 by day 365. It can be expected that a DT50 value of 106 days is conservative enough to represent the degradation in soil at 12oC of permethrin samples containing a cis:trans ratio of 25:75.

The route of degradation of permethrin in soil appears to be dominated by a two-step process. Permethrin breaks down to form DCVA (max 11.3 %AR, SFO DT50 12°C 33.1-~175 d) and PBA (max 15.0 % AR, 1.7-2.5 d at 12°C), and ultimately converts to CO2.

Permethrin was observed to be relatively stable when exposed to photolysing conditions in soil. A DT50 of 200 d was estimated. No transformation product greater than 10 %AR was observed.

Permethrin is strongly adsorbed to soil (Mean Kfoc 73,441 L/kg, Koc 26,930 n = 9). Therefore, leaching is not expected to occur. The two major soil metabolites (DCVA & PBA) are expected to be more mobile. The mean Kfoc for DCVA was 93.2 L/kg (n = 5). For PBA the Kfoc was

141.2 L/kg.

* **Tebuconazole**

**Tebuconazole fate and distribution in the environment**

Tebuconazole is stable to hydrolysis. Direct photodegradation of Tebuconazole in water is low and the substance may be considered photolytically stable in both water and soil. However, indirect photolysis of Tebuconazole may occur in water. The solubility of Tebuconazole in water is 29 mg/L at 20°C.

Tebuconazole is not readily biodegradable and biodegradation half-life in surface water is estimated to be about 198 days. However, Tebuconazole will be adsorbed to the sediment and therefore a dissipation half-life in surface water is estimated to be 43 days in a water/sediment study. Tebuconazole is not metabolized rapidly in soil in laboratory experiments: the half-life for primary degradation is greater than one year. In field studies the dissipation half-life is 77 days.

Tebuconazole has a low mobility potential (Koc = 992 mL/g). The BCF bioaccumulation factor for fish varies from 31 to 93. However, the higher value includes the metabolites as well. For the risk assessment, a BCF of 78 is used since this value seems to be the highest reliable value found.

1,2,4-Triazole is the primary metabolite from the degradation of Tebuconazole. However it appears to breakdown more rapidly in soil than Tebuconazole.

The risk quotients are more favorable for the metabolites than for Tebuconazole for both the aquatic and terrestrial environment and therefore the metabolite will not be considered further in the risk assessment.

Air will not be an environmental compartment of concern for Tebuconazole used in wood preservatives because of the very low vapour pressure of this compound (1.7 10-6 Pa at 20°C)

and these wood preservatives are not applied by spraying. It should however be noted that the calculated DT50 of Tebuconazole in air is more than 2 days and it is therefore considered persistent in air.

* **Propiconazole**

**Propiconazole fate and distribution in the environment**

Propiconazole is moderately soluble in water having water solubility of around 100 mg/L at pH 7 at 20°C. Propiconazole is very slightly volatile having vapour pressure around 5.6 10-5 Pa at 25°C. Hydrolysis and direct photolysis do not play a major role in the degradation of Propiconazole in surface waters. Propiconazole is not readily biodegradable. If Propiconazole enters a water body, a large quantity will be instantaneously removed from the aqueous phase by rapid adsorption to suspended sediments. The subsequent degradation in the aquatic system will be mainly of biological nature. Dissipation half-life of 6.4 days in water and degradation half-life of 636 days in water/sediment system are used in the PEC calculations. There was no metabolite accounting > 10% of the active substance found in the water/sediment key study.

In the laboratory studies the half-life of Propiconazole in soil ranged from 29 to 72 days with a median of 45 days at 20 to 25 °C. Mineralization of Propiconazole was < 5% of the applied radioactivity in all studies and the amount of non-extractable increased even up to around 50% at 120 days but never exceeded 70% of the applied radioactivity.

The maximum dissipation half-life of 129 days in soil derived from field studies is used as the worst case in the PECsoil calculations for Propiconazole when risk after 30 days (TIME 1) is considered. The geometric mean dissipation half-life of 177 days in soil (from field studies) is used in the PECsoil calculations for Propiconazole when risk after several years (TIME 2) is considered.

In the laboratory studies there were two degradation products of Propiconazole accounting more than 10% of the active substance in soil (1,2,4-triazole and CGA 118 245). Degradation half-life of 1,2,4- triazole was around 9.3 days in soil and degradation half-life of CGA 118 245 was around 1 day in soil.

Propiconazole adsorbs very rapidly to soils with most of the short-term (24 hrs) adsorption taking place within an hour or less. With an arithmetic mean of Koc (adsorption) = 944 mL/g (Koc = 1000 mL/g in EUSES calculation) Propiconazole is regarded as slightly mobile in soil. The two degradation products of Propiconazole accounting for more than 10% in the soil degradation studies are considered mobile in soil. Arithmetic mean values for 1,2,4-triazole and CGA 118 245 are Koc (adsorption) = 69 mL/g and Koc (adsorption) = 129 mL/g, respectively.

Log Kow of Propiconazole is 3.7 implying a slight bioaccumulation potential. Propiconazole is slightly bioaccumulative to fish with a BCF of 180. Based on the estimation of BCF for terrestrial bioconcentration, Propiconazole is not bioaccumulative to terrestrial organisms.

The estimated half-life of Propiconazole in the troposphere is between 10.2 and 42 hours assuming the OH concentration (5\*105) given in the TGD (Part II, 2003, equation 28) and a 24-hour day.

* **IPBC**

**IPBC fate and distribution in the environment**

IPBC is stable to hydrolysis. Direct photodegradation of IPBC in water is low and the substance may be considered photolytically stable in water. The water solubility of IPBC is 168 mg/L at 20°C.

IPBC is not readily biodegradable but is primary biodegradable according to Zahn-Wellens test. The biodegradation half-life in surface water is estimated to about 1.4 hour at 20-22°C. IPBC is metabolised rapidly in soil in laboratory experiments, the half-life is estimated to be 2.1 hour at 20-22°C. In degradation of IPBC, the primary degradation product was propargyl- butyl-carbamate (PBC).

PBC was found in hydrolysis, aerobic soil, and anaerobic aquatic metabolism studies. In hydrolysis, PBC was the only degradation product identified.

In soil, PBC was degraded to CO2, bound soil residues and an unidentified metabolite. In anaerobic aquatic environments (sediment/water), PBC was degraded to 2-propenyl-butyl- carbamate (2-PBC) and 2 unidentified degradation product (less than 10%), CO2 and possibly CH4. The metabolite 2-PBC is only formed at a percentage > 10% in the water phase under anaerobic conditions. QSAR estimation indicates a toxicity of this metabolite is comparable to that found for IPBC. Therefore in this case it is not considered necessary to ask for experimental ecotoxicological data for this metabolite.

Iodine will be evaluated by Sweden as an active substance for disinfectant and an effect and risk assessment will therefore not be performed here.

IPBC has a medium to high mobility potential (Koc = 126 mL/g by HPLC method).

The bioaccumulation potential is not significant based on a log Pow value of 2.8.

Air will not be an environmental compartment of concern for IPBC used in wood preservatives because of the low vapor pressure of this compound (2.36 10-3 Pa at 25°C). It should also be noted that the calculated DT50 of IPBC in air is only about 15 hours and is therefore not considered persistent in air.

##### Effect assessment of the active substance

All the data refer to the chapter Effects assessment are from Doc IIA as well as from Doc IIB for the active substances Permethrin, Tebuconazole, Propiconazole and IPBC.

There has not been submitted any new data regarding the active substances. The PNEC values for IPBC have been taken from the Assessment Report for PT 8 and also including updates in the Assessment Report for PT13. For Permethrin the PNEC values have been taken from the Assessment Report for PT8. For Propiconazole the PNEC values have been taken from the Assessment Report for Propiconazole in PT 7 (January 2015), because new data has been included compared to the Assessment Report for Propiconazole in PT 8 (December 2007). For Tebuconazole the PNEC values have been taken from the Assessment Report for PT8 (November 2007).

The PNEC values used in the risk assessment are the following:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on PNEC values for active substances and their relevant metabolites** | | | | |
| **Active substance** | **PNECwater (mg.l-1)** | **PNECsediment (mg.kg-1wwt)** | **PNECsoil (mg.kg-1wwt)** | **PNECSTP**  **(mg.l-1)** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tebuconazole** | 1.0E-03 | 5.5E-01 | 1.0E-01 | 3.2E-01 |
| **Propiconazole** | 6.8E-03 | 5.4E-02 | 1.0E-01 | 1.0E+02 |
| **IPBC** | 5.0E-04 | Covered by surface water | 4.3E-03 | 4.4E-01 |
| **Permethrin** | 4.7E-07 | 2.17E-04 | 8.76E-02 | 4.95E-03 |
| **1,2,4-triazole** | n.r | n.r | 1.0E-02 | n.r |
| **PBC** | 4.13E-02 | Covered by surface water | 1.49E-01 | The one for IPBC is used as a worst case |
| **DCVA** | 1.5E-02 | 1.2E-02 | 4.6 | n.r |
| **PBA** | 1.0E-02 | 9.0E-03 | 1.44 | n.r |

n.r.: not relevant for the concerned compartment

##### 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 other constituent apart from the active substances has an influence on the environmental classification and labelling of the product.

**Harmonised environmental classification of the active substances**

The environmental classification of the active substances is the following:

|  |  |  |  |
| --- | --- | --- | --- |
| **Harmonised env. Classification for the active substances** | | | |
| **Active substance** | **Env. Classification** | **M-Factor** | **Concentration of a.s. in the product (%)** |
| **Tebuconazole** | H400, H410 | M=1  M(chronic)=10 | 1.1 |
| **Propiconazole** | H400, H410 | M=1 | 1.1 |
| **IPBC** | H400, H410 | M=10  M(chronic)=1 | 1 |
| **Permethrin** | H400, H410 | M=100  M(chronic)=10000 | 2 |

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

**Conclusion on the environmental classification and labelling of the product**

***Classification:***

Aquatic Acute cat. 1 (H400) Aquatic Chronic cat. 1 (H410)

***Labelling:***

GHS09 Warning H410

##### Further Ecotoxicological studies

No new data is available compared to CAR (see 2.2.8) and no further ecotoxicological studies are required.

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

No new data is available compared to CAR (see 2.2.8).

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

The product is not in the form of bait or granules, so none such data is required.

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

The product is not in the form of bait or granules, so none such data is required.

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

Not relevant

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

**Industrial application of the biocidal product and storage of the wood**

Emissions to the environment can occur during industrial application of the wood preservative and subsequent storage of the treated structures. In general, emissions to sewage water during applications in joineries and carpentry shops are not likely to occur, because treatment containers are stand-alone devices without direct connection to the sewage. Residues and waste solutions from application containers will be treated as special waste and will not be discharged into the public sewage system. The revised ESD for PT 8 confirms that the release of wood preservatives from treatment installations to the drain connected to an STP is not permitted in EU countries. Nevertheless, this scenario is going to be considered in this risk assessment. The same applies to the storage of treated commodities. According to the revised ESD for PT 8 it can be assumed, that most storage places are sealed and run-off from storage places will be collected and disposed of safely.

**In-service life**

Emissions may take place due to leaching from constructions built from industrially treated wood.

During the Arona Leaching Workshop in June 2005, it was agreed that a long-term assessment of in-service uses of wood should be carried out. For automated spraying and short dipping an assessment of cumulative leaching from treated wood in-service over a 15 years period was applied. For vacuum pressure /double vacuum an assessment of cumulative leaching from treated wood in-service over a 20 years period should be applied. Hence, the assessment times are 30 days (TIME 1) for short term consideration and 15 or 20 years (service life) for the longer time period (TIME 2). If a risk is identified for TIME 1, a further TIME 2 value of 365 days is calculated as well (not used for decision making) as agreed by the Environment Working Group.

Please refer to section “Fate and distribution in exposed environmental compartment” for

further details.

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

No new data was submitted or is required. Information on the active substances suffices for the environmental risk assessment of the product. Moreover, the product does not contain any other substances relevant for the environment apart from the active substance.

##### Leaching behaviour (ADS)

**Surface application (dipping/brushing/spraying)**

The applicant provided a leaching test for Sarpeco 9-plus with top coat application on treated wood surface and another one without top coat application. The two leaching tests were performed on a closely related formulation in which the concentration in permethrin is 1% whereas it is 2% in Sarpeco 9-plus. The testing were performed between 30.06.2015 and 30.06.2016 according to the NT BUILD 509 “Leaching of active ingredients from preservative- treated timber – Semi-field testing” (approved 2005-03) testing procedure. The testing studies last for 366 days with a cumulative precipitation of 640 mm (corresponding to 333.7 normalised days for a 700 mm standard rain year in Northern Europe).

The ECHA Excel files were used for the exposure assessment, one of the input parameters were the cumulative quantities leached out of 1m2 over the test periods for each active substances. Those values are summarised below. The emission for permethrin were adjusted by a factor 1.5. This factor is calculated based on the dilution of the product used for the laboratory leaching test (10%) and the dilution required for Sarpeco 9-plus (14.5%) resulting in a concentration in permethrin 1.5 higher in the wood (same application rate of 100mg/m²). The detailed calculations are presented in annex 3.7.

Following a stepwise procedure given in the 2nd EU Leaching Workshop on Wood Preservatives (June 2013, Italy), the cumulative quantities were obtained with the “Step 3” approach. It means calculation of the mean leaching rate were made using the cumulative quantity leached during the first period for TIME 1 (after about 30 days) and during the whole test for TIME 2. Then the estimated cumulative quantities for TIME 2 were calculated using the mean leaching rate previously calculated.

In accordance with the 2nd EU Leaching Workshop on Wood Preservatives (June 2013, Italy) conclusions, the leaching rates for Time 2 were determined from the study without top coat because the calculated leaching rates from the study with topcoat using the AF (X5) exceed those from the study without topcoat.

|  |  |  |
| --- | --- | --- |
| **Cumulative quantity of substance leached out of 1 m2 of treated wood for Sarpeco 9-plus (mg.m-2)** | | |
|  | TIME 1  (30 days) | TIME 2  ( 15 years) |
| **IPBC** | 1.26E-01 | 2.45E+01 |
| **Propiconazole** | 9.41E-02 | 4.28E+01 |
| **Tebuconazole** | 1.02E-01 | 4.40E+01 |
| **Permethrin** | 1.97E-03 | 6.15E-01 |

**~~No leaching test was performed on wood treated with a penetration treatment~~ ~~process (Vacuum pressure/Double vacuum)~~**~~. According to the 1st EU Leaching Workshop~~ ~~on Wood Preservatives (June 2005, Italy), extrapolation from a superficial treatment process~~ ~~to a penetration treatment process (or vice versa) is impeded by the fact that penetration~~ ~~treatment is expressed on a volume basis in kg/m3~~ ~~while superficial treatment is expressed in~~ ~~litres/m2 and no valid extrapolation method is available at the moment. Therefore, if both~~ ~~processes are mentioned in the dossier the applicant should provide a test with the penetration~~ ~~treatment process and the superficial treatment process, which is not the case for Sarpeco 9-~~ ~~plus~~.

**Penetration treatment process (Vacuum pressure/Double vacuum):**

The Applicant provided a new leaching test (Lab2009\_009 n°31/18/3210/01D) for Sarpeco 9-Plus with top coat application on treated wood surface. No leaching test was provided for

an equivalent formulation without top coat. The test was performed with the product

Sarpeco 9-Plus diluted to 1.08%. The testing were performed between 12.2017 and 02.2019 according to OECD guidance on the estimation of emission from wood-preservative treated wood to the environment: for wood held in storage after treatment and for wood commodities that are not covered and are not in contact with ground (n°107) modified: extension of test period with 9 immersion days during prolonged test period of 1year.

The ECHA Excel files were used for the exposure assessment, one of the input parameters were the cumulative quantities leached out of 1m2 over the test periods for each active substances. Those values are summarised below.

Following a stepwise procedure given in the 2nd EU Leaching Workshop on Wood Preservatives (June 2013, Italy), the cumulative quantities were obtained with the “Step 3” approach. It means calculation of the mean leaching rate were made using the cumulative quantity leached during the first period for TIME 1 (after 30 days) and extrapolated from the whole test data for TIME 2 (7300 days).

The analytical results for Propiconazole, Tebuconazole and Permethrin were most of the time below the LOQ of the analytical method. Therefore, according to TAB ENV-A18, THE LOQ of 0.05( for Propiconazole and Tebuconazole) and 0.0005 for Permethrin were used.

In accordance with the 2nd EU Leaching Workshop on Wood Preservatives (June 2013, Italy) conclusions, the leaching rates were determined from a study with top coat using an AF. Since the analytical result of the study was below the LOQ and since the LOQ value was setted to derive the emission, BE eCA consider that an AF of 2 give enough margin of safety instead of an AF 5. Applying a higher AF as in fact no effect on the outcome of the assessment.

|  |  |  |
| --- | --- | --- |
| **Cumulative quantity of substance leached out of 1 m2 of treated wood for Sarpeco 9-plus (mg.m-2)** | | |
|  | TIME 1  (30 days) | TIME 2  ( 20 years) |
| **Tebuconazole** | 0.30 | 1.18 |
| **Propiconazole** | 0.30 | 0.93\* |
| **IPBC** | 1.32 | 13.93 |
| **Permethrin** | 0.003 | 0.0150 |

\*for propiconazole, estimation to 7300d were lower than for 365 d, and so this latest value were re-used for 7300 aswell.

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

No new data was submitted or is required.

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

No new data was submitted or is required.

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

No new data was submitted or is required.

##### 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)

No new data was submitted or is required.

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

No new data was submitted or is required.

###### Exposure assessment

The environmental exposure assessments of the active substances were determined with the Emission Scenario Document (ESD) developed for Product Type 08 (wood preservatives) by OECD: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario

Document for Wood Preservatives. The emission scenarios estimate the emission of wood preservatives from two stages of their life cycle:

* + - * + Application and storage of treated wood prior to shipment;
        + Treated wood in service.

Several relevant emission scenarios have been identified based on intended uses.

In the case of application and storage of treated wood prior to shipment, the emission scenarios used for the product Sarpeco 9-plus cover:

* + - * + Industrial preventive processes - Automated spraying process (Flow-coating) or brushing
        + Industrial preventive processes - Short Dipping
        + Industrial preventive processes – Vacuum pressure

The storage scenario employed in this assessment assumes that the storage area is uncovered and unpaved. In reality **freshly treated timber must be stored on impermeable hard standing to prevent direct losses to soil or water and any losses must be collected for reuse or disposal.**

In the case of treated wood in service, the following emission scenarios have been run for use class 3 : House, Noise barrier and Bridge over pond.

For two of the emission scenarios of treated wood in service, calculations of emissions in soil have been done with substance **removal processes in soil taken into account**; according to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Part 3.

For surface treatment and for all the four Sarpeco 9-plus active substances: Permethrin, Tebuconazole, Propiconazole and IPBC, the environmental risk assessment has been calculated from semi-field leaching tests done on a similar recipe AXIL 3000 P in which solely the concentration in active is different. The retention rate in the lab test covers the retention rates to be obtained with the diluted product.

For vacuum pressure treatment, the environmental risk assessment has been calculated from a laboratory leaching test performed with the product Sarpeco 9-plus diluted to 1.08%.

##### General information

|  |  |
| --- | --- |
| Assessed PT | PT8 |
| Assessed scenarios | **Scenario 1:** (ESD PT8, Sep. 2013, §4.1.1)  Automated spraying   * Product application * Storage of treated wood prior to shipping **Scenario 2: (**ESD PT8, Sep. 2013, §4.1.3) Vacuum pressure * Product application * Storage of treated wood prior to shipping   **Scenario 3:** (ESD PT8, Sep. 2013, §4.1.2)  Short dipping   * Product application * Storage of treated wood prior to shipping   **Scenario 4:** (ESD PT8, Sep. 2013, §4.3.3)  In-service leaching from treated wood – Automated spraying/brushing, vacuum pressure/short dipping   * House * Bridge over pond * Noise barrier (The pre-treatment of the wood for use as noise barrier is not included in the application; but |

|  |  |
| --- | --- |
|  | in order to evaluate the possible risk for STP the calculations regarding in-service leaching from noise barrier are included). |
| ESD(s) used | Emission Scenario Document for Product Type 8: revised Emission Scenario Document for Wood Preservatives, (OECD 2013) |
| Approach | Scenario 1-3: Average consumption |
| Distribution in the environment | Calculated based on Vol. IV, Part B |
| Groundwater simulation | A FOCUS-PEARL-4.4.4 groundwater modelling was performed for active substances and their relevant metabolites. In the modelling the house number of 16 per hectare and the fraction of house surface exposed to weather (0.5) were applied according to the revised OECD ESD for wood preservatives (2013). |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario n°: 1 - 3 Production: No Formulation No Use: Yes  Service life: Yes |
| Remarks | The product is intended to be used for the UC 1, UC 2 and UC 3.  According to the OECD ESD PT 08 no emission scenarios are available for UC 1 and UC 2, since the potential emissions from treated wood to the outer environment are considered negligible. Therefore no emission and exposure calculation is performed for the UC 1 and UC 2. |

##### Emission estimation

Sarpeco 9-plus is a concentrate water-based wood preservative containing 2% Permethrin, 1.1% Tebuconazole, 1.1% Propiconazole and 1% IPBC. For surface treatment (dipping, brushing, spraying), 100g of diluted product are applied per square meter of wood. The worst case application rate used in the scenarios is: 100g/m2 (100ml/m2) and the dilution rate used in this risk assessment is 14.5%. During vacuum pressure application, 500Kg of the product diluted by 1.45% with water are applied per m3 of wood.

|  |  |  |
| --- | --- | --- |
| **Input parameters for calculating the local emission and concentration** | | |
| **Input** | **Value** | **Unit** |
| **Scenarios 1 – 3 -4** | | |
|  | | |
| **Application rate of biocidal product** | 0.1 | [l.m-2] |

|  |  |  |
| --- | --- | --- |
| **Quantity of a substance applied per m2 of wood (*Qai*)** | | |
| **Tebuconazole** | 1.595E-04 | [kg.m-2] |
| **Propiconazole** | 1.595E-04 | [kg.m-2] |
| **IPBC** | 1.45E-04 | [kg.m-2] |
| **Permethrin** | 2.9E-04 | [kg.m-2] |
| **First order rate constant for removal from soil (*k*)**  **(k=Ln2/DT50)** | | |
| **Tebuconazole** | 0.009 | [d-1] |
| **Propiconazole** | 0.00845 | [d-1] |
| **IPBC** | 3.54 | [d-1] |
| **Permethrin** | 0.00654 | [d-1] |
| **Cumulative quantity of substance leached out of 1 m2 of treated wood over the initial assessment period TIME 1 (30 days)** | | |
| **Tebuconazole** | 1.02E-01 | [mg.m-2] |
| **Propiconazole** | 9.41E-02 | [mg.m-2] |
| **IPBC** | 1.26E-01 | [mg.m-2] |
| **Permethrin** | 1.97E-03 | [mg.m-2] |
| **Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period TIME 2 (15 years)** | | |
| **Tebuconazole** | 4.40E+01 | [mg.m-2] |
| **Propiconazole** | 4.28E+01 | [mg.m-2] |
| **IPBC** | 2.45E+01 | [mg.m-2] |
| **Permethrin** | 6.15E-01 | [mg.m-2] |
| **Average daily flux during the storage period (*FLUXstorage*) for automated spraying and short dipping processes (see annex 3.7)** | | |
| **Tebuconazole** | 2.26E-08 | [kg.m-2.d-1] |
| **Propiconazole** | 2.10E-08 | [kg.m-2.d-1] |
| **IPBC** | 8.29E-09 | [kg.m-2.d-1] |
| **Permethrin** | 6,03E-10 | [kg.m-2.d-1] |
| **Fraction released to facility drain (*Ffacilitydrain*)** | | |
| **Tebuconazole** | 0.003 | [-] |
| **Propiconazole** | 0.03 | [-] |
| **IPBC** | 0.03 | [-] |
| **Permethrin** | 0.0001 | [-] |

|  |  |  |
| --- | --- | --- |
| **Fraction released to air (*Fair*)** | | |
| **Tebuconazole** | 0.001 | [-] |
| **Propiconazole** | 0.001 | [-] |
| **IPBC** | 0.001 | [-] |
| **Permethrin** | 0.001 | [-] |

|  |  |  |
| --- | --- | --- |
| **Input parameters for calculating the local emission and concentration** | | |
| **Input** | **Value** | **Unit** |
| **Scenarios 2** | | |
|  | | |
| **Application rate of biocidal product** | 500 | [Kg.m-3] |
| **Quantity of a substance applied per m3 of wood (*Qai*)** | | |
| **Tebuconazole** | 7.97E-02 | [kg.m-3] |
| **Propiconazole** | 7.97E-02 | [kg.m-3] |
| **IPBC** | 7.25E-02 | [kg.m-3] |
| **Permethrin** | 1.45E-01 | [kg.m-3] |
| **First order rate constant for removal from soil (*k*)**  **(k=Ln2/DT50)** | | |
| **Tebuconazole** | 0.009 | [d-1] |
| **Propiconazole** | 0.00845 | [d-1] |
| **IPBC** | 3.54 | [d-1] |
| **Permethrin** | 0.00654 | [d-1] |
| **Cumulative quantity of substance leached out of 1 m2 of treated wood over the initial assessment period TIME 1 (30 days)** | | |
| **Tebuconazole** | 3E-01 | [mg.m-2] |
| **Propiconazole** | 3E-01 | [mg.m-2] |
| **IPBC** | 1.32 | [mg.m-2] |
| **Permethrin** | 3E-03 | [mg.m-2] |
| **Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period TIME 2 (30 years)** | | |
| **Tebuconazole** | 1.18 | [mg.m-2] |
| **Propiconazole** | 9.3E-01 | [mg.m-2] |
| **IPBC** | 13.93 | [mg.m-2] |

|  |  |  |
| --- | --- | --- |
| **Permethrin** | 1.50E-02 | [mg.m-2] |
| **Average daily flux during the storage period (*FLUXstorage*) for vacuum pressure (see annex 3.7)** | | |
| **Tebuconazole** | 1.3E-08 | [kg.m-2.d-1] |
| **Propiconazole** | 1.3E-08 | [kg.m-2.d-1] |
| **IPBC** | 4.5E-08 | [kg.m-2.d-1] |
| **Permethrin** | 1.3E-10 | [kg.m-2.d-1] |
| **Fraction released to facility drain (*Ffacilitydrain*)** | | |
| **Tebuconazole** | 0.003 | [-] |
| **Propiconazole** | 0.03 | [-] |
| **IPBC** | 0.03 | [-] |
| **Permethrin** | 0.0001 | [-] |
| **Fraction released to air (*Fair*)** | | |
| **Tebuconazole** | 0.001 | [-] |
| **Propiconazole** | 0.001 | [-] |
| **IPBC** | 0.001 | [-] |
| **Permethrin** | 0.001 | [-] |

***Scenario 1:*** *Industrial processes – automated spraying/brushing*

This type of superficial application process is typically used in sawmills and carpentry / joinery shops.

The wood, whether in debarked logs or fully or partly machined timber are moved through one or more longitudinal or transversal boxes on a continuously moving conveyor system.

The product is applied as a spray which is usually as a coarse spray using a particle spray size to ensure the wetting of the timber with the correct amount of wood preservative or by brushing.

The spray/brushing boxes are relatively contained and splashguards surround the boxes to eliminate any droplets of spray from entering the rest of the mill area and may have local exhaust ventilation.

After the timber has been treated it is stacked or sorted, mechanically, either dries on the conveyor belt or in the post treatment drip dry conditioning area before being moved off-site to manufacturers or used on site.

The treatment apparatus is typically established in a contained or bunded area fabricated from materials resistant to the wood preservative product. Provision is made for the collection, recycling and reuse of wood preservative collected from the conveyor or drip dry area.

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.

Even though release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, the corresponding emission

pathway (facility drain to STP to surface water) is nevertheless a worst case assessment of which can be of relevance outside the EU.

Product application

Emissions can occur to the air directly due to spray drift and evaporation from the spray box , or the brushing boxes and from the treated (wet) wood after it exits from the spray/brushing boxes and dries on the belt or in the sorting tray, and as it is bundled for stacking at the sorting and stacking areas. Sorting is the process whereby workers sort the treated wood according to its size and appearance into different stacks where the wood is bundled for placement in the yard. Ventilation in most cases is via fans only. The emission to the environment resulting from application by brushing is considered covered by thoses evaluated for the spraying application.

Mill/carpentry floors are cemented, so run-off is generally collected and recycled via drip pads. However, unintentional spills, floor cleaning, equipment cleaning and washing waters, drag- out on tires may reach the facility drain. The facility drain is assumed to drain into the public sewage treatment plant (STP).

To estimate emissions into the air and the facility drain following industrial treatment of UC 3 woods by automated spraying, the revised ESD for PT8 describes one scenario: Application phase in automated spraying.

The *AREAwood-treated* of 20000 m2.d-1 (large plant) represents a worst case situation and is therefore used in this risk assessment.

The input parameters for calculating the local emission following an application by automated spraying process are presented in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Application phase in automated spraying process* | | | | |
| Wood area treated per day (large plant) | *AREAwood-treated* | 20000 | [m2.d-1] | D |
| Application rate: quantity of a.i. applied per 1 m2 of wood area | *Qai* | **See above** | [kg.m-²] | S |
| Fraction released to facility drain | *Ffacilitydrain* | **See above** | [--] | D |
| Fraction released to air | *Fair* | **See above** | [--] | D |
| Fraction of spray drift deposition | *Fdrift* | 0.001 | [--] | D |

D=default, S=based on information of applicant

* **Calculations**

The local emissions to air and facility drain during the day of application are calculated according to the equations 4.2 and 4.3 from the revised ESD PT8 as following:

*Elocal,air= Qai . AREAwood-treated . (Fair + Fdrift) Elocal,facilitydrain= Qai . AREAwood-treated . Ffacilitydrain*

The results are presented in the following table.

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions** | | |
| **Active substance** | **Local emission (Elocalair) [kg.d-1]** | **Local emission (Elocalfacilitydrain) [kg.d-1]** |
| **Tebuconazole** | 6.38E-03 | 9.57E-03 |
| **Propiconazole** | 6.38E-03 | 9.57E-03 |
| **IPBC** | 5.80E-03 | 8.70E-02 |
| **Permethrin** | 1.16E-02 | 5.80E-04 |

**Storage phase**

During storage, soil can be exposed – if the storage place is not covered – due to leaching from treated wood via rainfall. In addition, surface water can be exposed via rain run-off from the storage place.

The *AREAstorage* of 790 m2 (large plant) represents a worst case situation and is therefore used in this risk assessment.

The input parameters for calculating the local emissions and concentrations following leaching are presented in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emissions and concentrations** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Storage phase in automated spraying process* | | | | |
| Effective surface area of treated wood, considered to be exposed to rain, per 1m2 storage area (i.e. soil) | *AREAwood-expo* | 11 | [m2.m-2] | D |
| Surface area of the storage place (large plant) | *AREAstorage* | 790 | [m2] | D |
| Duration of the initial assessment period | *TIME1* | 30 | [d] | D |
| Duration of a longer assessment period | *TIME2* | 7300 | [d] | D |
| Duration of storage of treated wood prior to shipment | *TIMEstorage* | 3 | [d] | D |
| Average daily flux i.e. the average quantity of an active ingredient that is  daily leached out of 1 m2 of treated wood during 3 days storage period  [kg.m-2.d-1] | *FLUXstorage,spray* | **See above** | [kg.m-2.d-1] | S |
| Volume of treated wood stacked per m2 of storage area (i.e. soil) | *VOLUMEwood-*  *stacked* | 2 | [m3.m-2] | D |
| Bulk density of wet soil | *RHOsoil* | 1700 | [kg.m-3] | D |
| Soil depth | *DEPTHsoil* | 0.5 | [m] | D |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Volume of (wet) soil | *Vsoil* | 395 | [m3] | D |
| Fraction of rainwater running off the storage site | *Frunoff* | 0.5 | [-] | D |

D=default, S=based on information of applicant

* **Calculations**

The cumulative quantities of substance leached over 30 days and 7300 days (Qleach,storage,time) are calculated according to the equations 4.5 and 4.6 from the revised ESD PT8 as following:

*Qleach,storage,time1 = FLUXstorage,spray . AREAwood-expo . AREAstorage . TIME 1 Qleach,storage,time2 = FLUXstorage,spray . AREAwood-expo . AREAstorage . TIME 2*

The local emissions to surface water during the storage phase are calculated according to the equation 4.9 and 4.10 from the revised ESD PT8 as following:

*Elocal,surfacewater,time1 = Qleach,storage time1 . Frunoff / TIME 1 Elocal,surfacewater,time2 = Qleach,storage time2 . Frunoff / TIME 2*

The local concentrations into the soil and the surface water are calculated according to the equations 4.7/4.8/4.11/4.12 from the revised ESD PT8 as following:

*Clocal,surfacewater,time 1 = Elocal,surfacewater,time1 / FLOWsurfacewater Clocal,surfacewater,time 2 = Elocal,surfacewater,time2 / FLOWsurfacewater Clocal,soil,time 1 = Qleach,storage,time1 . (1 – Frunoff) / Vsoil . RHOsoil Clocal,soil,time 2 = Qleach,storage,time2 . (1 – Frunoff) / Vsoil . RHOsoil*

The results are presented in the following table (without considering removal processes).

|  |  |  |
| --- | --- | --- |
| **Resulting cumulative quantity of substance leached** | | |
| **Active substance** | **cumulative quantity of substance leached over 30 days**  **TIME 1 [kg]** | **cumulative quantity of substance leached after 20 years**  **TIME 2 [kg]** |
| **Tebuconazole** | 5.90E-03 | 1.44E+00 |
| **Propiconazole** | 5.48E-03 | 1.33E+00 |
| **IPBC** | 2.16E-03 | 5.26E-01 |
| **Permethrin** | 1.57E-04 | 3.83E-02 |

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions to surface water compartment** | | |
| **Active substance** | **Local emission due to leaching after 30 days**  **TIME 1 [kg.d-1]** | **Local emission due to leaching after 20 years**  **TIME 2 [kg.d-1]** |
| **Tebuconazole** | 9.84E-05 | 9.84E-05 |
| **Propiconazole** | 9.13E-05 | 9.13E-05 |
| **IPBC** | 3.61E-05 | 3.61E-05 |
| **Permethrin** | 2.62E-06 | 2.62E-06 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to surface water compartment** | | |
| **Active substance** | **Local concentration into surface water after 30 days**  **TIME 1[mg.l-1]** | **Local concentration into surface water after 20 years**  **TIME 2 [mg.l-1]** |
| **Tebuconazole** | 3.80E-06 | 3.80E-06 |
| **Propiconazole** | 3.52E-06 | 3.52E-06 |
| **IPBC** | 1.39E-06 | 1.39E-06 |
| **Permethrin** | 1.01E-07 | 1.01E-07 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to soil compartment** | | |
| **Active substance** | **Local concentration in soil after 30 days**  **TIME 1[kg.kgwwt-1]** | **Local concentration in soil after 20 years**  **TIME 2 [kg.kgwwt-1]** |
| **Tebuconazole** | 4.40E-09 | 1.07E-06 |
| **Propiconazole** | 4.08E-09 | 9.93E-07 |
| **IPBC** | 1.61E-09 | 3.92E-07 |
| **Permethrin** | 5.97E-10 | 1.26E-09 |

***Scenario 2:*** *Industrial processes – vacuum pressure*

These types of processes are used to overcome the resistance of the wood to taking up the wood preservative liquid. They use combinations of vacuum and low or high pressures to force the liquid into the timber to achieve the desired depth of penetration of the wood preservative.

The treatments are carried out in vessels or autoclaves which may be cylindrical or rectangular in cross-section and designed to be capable of safe operation depending on whether the process to be used is a vacuum pressure or double vacuum / low pressure one. The treatment installations include the treatment vessel, the storage tanks and provision for bunding and containment to prevent loss of preservative.

There are many variations in the processes but they can all be considered in one emission scenario because the process descriptions and the emission pathways are similar. Generally the following stages are involved:

1. The untreated wood, typically as packs of timber, is loaded onto bogies or tram cars that are moved into the treatment vessel using mechanical means such a winch or forklift truck.
2. The vessel door is closed and the door seal provides a liquid and air-tight seal. A vacuum is applied to remove most of the air from the cylinder and the air contained in the wood cells.
3. The treatment solution is usually a dilution of a concentrated product in the treatment plant to the required working strength (either heated or at ambient temperature depending on the system) is then pumped into the cylinder and the pressure is raised. The total treating time and cycles will vary, depending on the species of wood, the commodity being treated, and the desired product retention, but in all instances the treating process remains a closed system.
4. A final vacuum may be applied to remove the excess preservative that would otherwise drip from the wood into the vessel.
5. The final steps in the process are the unloading of the wood from the treatment vessel; its placing in a post treatment conditioning area before being either moved off -site or fabricated on site.

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 an STP is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process.

Even though release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, the corresponding emission pathway (facility drain to STP to surface water) is nevertheless a worst case, the assessment of which can be of relevance outside the EU.

***Product application***

At the end of the application process, the opening of the door can lead to emissions of aerosol to air.

Mill/carpentry floors are cemented, so run-off is generally collected and recycled. However, unintentional spills, floor cleaning, equipment cleaning and washing waters may reach the

facility drain.

To estimate emissions into the air and the facility drain following industrial treatment of UC 3 woods by vacuum pressure, the revised ESD for PT8 describes one scenario: Application phase

in short dipping.

The input parameters for calculating the local emission following an application by short dipping process are presented in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Application phase in short dipping process* | | | | |
| Volume of wood treated per day | *VOLUMEwood-*  *treated* | 30 | [m3.d-1] | D |
| Application rate: quantity of a.i. applied per 1 m3 of wood | *Qai* | **See values in table above** | [kg.m-3] | S |
| Fraction released to facility drain | *Ffacilitydrain* | **See above** | [--] | D |
| Fraction released to air | *Fair* | **See above** | [--] | D |

D=default, S=based on information of applicant

* **Calculations**

The local emissions to air and facility drain during the day of application are calculated according to the equations 4.14 and 4.15 from the revised ESD PT8 as following:

*Elocal,air= Qai . VOLUMEwood-product . Fair Elocal,facilitydrain= Qai . VOLUMEwood-product . Ffacilitydrain*

The results are presented in the following table.

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions** | | |
| **Active substance** | **Local emission (Elocalair) [kg.d-1]** | **Local emission (Elocalfacilitydrain) [kg.d-1]** |
| **Tebuconazole** | 2.39E-03 | 7.17E-03 |
| **Propiconazole** | 2.39E-03 | 3.59E-02 |
| **IPBC** | 2.18E-02 | 6.53E-02 |
| **Permethrin** | 4.35E-03 | 4.35E-04 |

Storage phase

Concerning storage, a distinction is made between joineries and other facilities. Joineries in which the preservation treatment is applied on wooden articles that have been made to shape, (fence panels, composites, windows, doors and door frames, floors, architrave and decorative features) do not have an open storage area. These treated commodities/articles are immediately further processed (e.g. painted) and are not stored after wood preservation treatment.

During storage at other facilities than joineries, soil can be exposed – if the storage place is not covered - due to leaching from treated wood via rainfall. In addition, surface water can be exposed via rain run-off from the storage place.

The input parameters for calculating the local emissions and concentrations following leaching are presented in the following table.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Input parameters for calculating the local emissions and concentrations** | | | |  |
| **Input** | | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Storage phase in vacuum pressure process* | | | | | |
| Effective surface area of treated wood, considered to be exposed to rain, per 1m2 storage area (i.e. soil) | | *AREAwood-expo* | 11 | [m2.m-2] | D |
| Surface area of the storage place | | *AREAstorage* | 262,5 | [m2] | D |
| Duration of the initial assessment period | | *TIME1* | 30 | [d] | D |
| Duration of a longer assessment period | | *TIME2* | 7300 | [d] | D |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Duration of storage of treated wood prior to shipment | *TIMEstorage* | 14 | [d] | D |
| Average daily flux i.e. the average quantity of an active ingredient that is  daily leached out of 1 m2 of treated wood during 14 days storage period | *FLUXstorage,dipp* | **See above** | [kg.m-2.d-1] | S |
| Bulk density of wet soil | *RHOsoil* | 1700 | [kg.m-3] | D |
| Soil depth | *DEPTHsoil* | 0.5 | [m] | D |
| Volume of (wet) soil | *Vsoil* | 350 | [m3] | D |
| Fraction of rainwater running off the storage site | *Frunoff* | 0.5 | [-] | D |

D=default, S=based on information of applicant

* **Calculations**

The cumulative quantities of substance leached over 30 days and 7300 days (Qleach,storage,time) are calculated according to the equations 4.29 and 4.30 from the revised ESD PT8 as following:

*Qleach,storage,time1 = FLUXstorage,vac-pres . AREAwood-expo . AREAstorage . TIME 1 Qleach,storage,time2 = FLUXstorage,vac-pres . AREAwood-expo . AREAstorage . TIME 2*

The local emissions to surface water during the storage phase are calculated according to the equations 4.33 and 4.34 from the revised ESD PT8 as following:

*Elocal,surfacewater,time1 = Qleach,storage time1 . Frunoff / TIME 1 Elocal,surfacewater,time2 = Qleach,storage time2 . Frunoff / TIME 2*

The local concentrations into the soil and the surface water are calculated according to the equations 4.19/4.20/4.23/4.24 from the revised ESD PT8 as following:

*Clocal,surfacewater,time 1 = Elocal,surfacewater,time1 / FLOWsurfacewater Clocal,surfacewater,time 2 = Elocal,surfacewater,time2 / FLOWsurfacewater Clocal,soil,time 1 = Qleach,storage,time1 . (1 – Frunoff) / Vsoil . RHOsoil Clocal,soil,time 2 = Qleach,storage,time2 . (1 – Frunoff) / Vsoil . RHOsoil*

The results are presented in the following table (without considering removal processes).

|  |  |  |
| --- | --- | --- |
| **Resulting cumulative quantity of substance leached** | | |
| **Active substance** | **cumulative quantity of substance leached over 30 days**  **TIME 1 [kg]** | **cumulative quantity of substance leached after 20 years**  **TIME 2 [kg]** |
| **Tebuconazole** | 1.14-03 | 2.78E-01 |
| **Propiconazole** | 2.30E-03 | 5.61E-01 |
| **IPBC** | 9.01E-03 | 2.19E-00 |
| **Permethrin** | 2.30E-05 | 5.61E-03 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Resulting local emissions to surface water compartment** | | |  |
| **Active substance** | **Local emission due to leaching after 30 days**  **TIME 1 [kg.d-1]** | **Local emission due to leaching after 20 years**  **TIME 2 [kg.d-1]** | |
| **Tebuconazole** | 1.91E-05 | 1.91E-05 | |
| **Propiconazole** | 3.84E-05 | 3.84E-05 | |
| **IPBC** | 1.5E-04 | 1.5E-04 | |
| **Permethrin** | 4.35E-04 | 4.35E-04 | |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to water compartment** | | |
| **Active substance** | **Local concentration into surface water after 30 days**  **TIME 1[mg.l-1]** | **Local concentration into surface water after 20 years**  **TIME 2 [mg.l-1]** |
| **Tebuconazole** | 7.35E-07 | 7.35E-07 |
| **Propiconazole** | 1.48E-06 | 1.48E-06 |
| **IPBC** | 5.79E-06 | 5.79E-06 |
| **Permethrin** | 1.48E-08 | 1.48E-08 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to soil compartment** | | |
| **Active substance** | **Local concentration in soil after 30 days**  **TIME 1[kg.kgwwt-1]** | **Local concentration in soil after 20 years**  **TIME 2 [kg.kgwwt-1]** |
| **Tebuconazole** | 1.28E-09 | 3.12E-07 |
| **Propiconazole** | 2.58E-09 | 6.28E-07 |
| **IPBC** | 1.01E-08 | 2.46E-06 |
| **Permethrin** | 2.58E-11 | 6.28E-09 |

***Scenario 3:*** *Industrial processes – short dipping*

Dipping and immersion are superficial application processes and are typically used in sawmills and carpentry / joinery shops. They are batch processes and are usually automatic in operation. In either case they involve the submerging of a pack or single piece (only in small scale operations) of wood into a dipping tank filled with ready for use wood preservative solution. Packs of wood are typically loaded on automatic equipment (e.g. a hydraulic mast) and lowered into the dipping tank.

The immersion period lasts min. 30 seconds to 3 minutes for Sarpeco 9-plus. After the required immersion period the packs or pieces of wood, which are slightly raised at one end to aid liquid run off, are hoisted out of the liquid and usually held above the open tank for excess liquid to fall back into the dipping tank and be re-used. When the excess liquid has been drained, the pieces or packs of wood are moved to a post treatment conditioning location which is usually bunded and the timber is allowed to dry before being moved off-site or used on site. Any further drips are contained and recycled.

Some installations may have local exhaust ventilation. 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 STP is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the licence to operate the treatment process.

Even though release of the collected waste water to a sewage treatment plant (STP) is nowadays not permitted anymore in EU member state countries, the corresponding emission pathway (facility drain to STP to surface water) is nevertheless a worst case assessment of which can be of relevance outside the EU.

After the treatment, wood must be stored in a covered and paved area to reduce the leaching during use.

***Product application***

The dipping baths are usually open and can lead to emissions to air by evaporation and codistillation with water or solvent. A distinction is made between wood preservative products dissolved in water and those using organic solvents as the carriers for the active substance. Only those using organic solvents can evaporate into the air.

Mill/carpentry floors are cemented, so run-off is generally collected and recycled. However, unintentional spills, floor cleaning, equipment cleaning and washing waters may reach the facility drain.

To estimate emissions into the air and the facility drain following industrial treatment of UC 3 woods by short dipping, the revised ESD for PT8 describes one scenario: Application phase in short dipping.

The input parameters for calculating the local emission following an application by short dipping process are presented in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Application phase in short dipping process* | | | | |
| Volume of wood treated per day | *VOLUMEwood-*  *treated* | 100 | [m3.d-1] | D |
| Application rate: quantity of a.i. applied per 1 m3 of wood | *Qai* | **See values in table above \* 40** | [kg.m-3] | S |
| Fraction released to facility drain | *Ffacilitydrain* | **See above** | [--] | D |
| Fraction released to air | *Fair* | **See above** | [--] | D |

D=default, S=based on information of applicant

* **Calculations**

The local emissions to air and facility drain during the day of application are calculated according to the equations 4.14 and 4.15 from the revised ESD PT8 as following:

*Elocal,air= Qai . VOLUMEwood-product . Fair Elocal,facilitydrain= Qai . VOLUMEwood-product . Ffacilitydrain*

The results are presented in the following table.

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions** | | |
| **Active substance** | **Local emission (Elocalair) [kg.d-1]** | **Local emission (Elocalfacilitydrain) [kg.d-1]** |
| **Tebuconazole** | 6.38E-04 | 1.91E-03 |
| **Propiconazole** | 6.38E-04 | 1.91E-02 |
| **IPBC** | 5.80E-04 | 1.74E-02 |
| **Permethrin** | 1.16E-03 | 1.16E-04 |

Storage phase

Concerning storage, a distinction is made between joineries and other facilities. Joineries in which the preservation treatment is applied on wooden articles that have been made to shape, (fence panels, composites, windows, doors and door frames, floors, architrave and decorative features) do not have an open storage area. These treated commodities/articles are immediately further processed (e.g. painted) and are not stored after wood preservation treatment.

During storage at other facilities than joineries, soil can be exposed – if the storage place is not covered - due to leaching from treated wood via rainfall. In addition, surface water can be exposed via rain run-off from the storage place.

The input parameters for calculating the local emissions and concentrations following leaching are presented in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emissions and concentrations** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Storage phase in short dipping process* | | | | |
| Effective surface area of treated wood, considered to be exposed to rain, per 1m2 storage area (i.e. soil) | *AREAwood-expo* | 11 | [m2.m-2] | D |
| Surface area of the storage place | *AREAstorage* | 700 | [m2] | D |
| Duration of the initial assessment period | *TIME1* | 30 | [d] | D |
| Duration of a longer assessment period | *TIME2* | 7300 | [d] | D |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Duration of storage of treated wood prior to shipment | *TIMEstorage* | 14 | [d] | D |
| Average daily flux i.e. the average quantity of an active ingredient that is  daily leached out of 1 m2 of treated wood during 14 days storage period | *FLUXstorage,dipp* | **See above** | [kg.m-2.d-1] | S |
| Bulk density of wet soil | *RHOsoil* | 1700 | [kg.m-3] | D |
| Soil depth | *DEPTHsoil* | 0.5 | [m] | D |
| Volume of (wet) soil | *Vsoil* | 350 | [m3] | D |
| Fraction of rainwater running off the storage site | *Frunoff* | 0.5 | [-] | D |

D=default, S=based on information of applicant

* **Calculations**

The cumulative quantities of substance leached over 30 days and 7300 days (Qleach,storage,time) are calculated according to the equations 4.17 and 4.18 from the revised ESD PT8 as following:

*Qleach,storage,time1 = FLUXstorage,dip . AREAwood-expo . AREAstorage . TIME 1 Qleach,storage,time2 = FLUXstorage,dip . AREAwood-expo . AREAstorage . TIME 2*

The local emissions to surface water during the storage phase are calculated according to the equations 4.21 and 4.22 from the revised ESD PT8 as following:

*Elocal,surfacewater,time1 = Qleach,storage time1 . Frunoff / TIME 1 Elocal,surfacewater,time2 = Qleach,storage time2 . Frunoff / TIME 2*

The local concentrations into the soil and the surface water are calculated according to the equations 4.19/4.20/4.23/4.24 from the revised ESD PT8 as following:

*Clocal,surfacewater,time 1 = Elocal,surfacewater,time1 / FLOWsurfacewater Clocal,surfacewater,time 2 = Elocal,surfacewater,time2 / FLOWsurfacewater Clocal,soil,time 1 = Qleach,storage,time1 . (1 – Frunoff) / Vsoil . RHOsoil Clocal,soil,time 2 = Qleach,storage,time2 . (1 – Frunoff) / Vsoil . RHOsoil*

The results are presented in the following table (without considering removal processes).

|  |  |  |
| --- | --- | --- |
| **Resulting cumulative quantity of substance leached** | | |
| **Active substance** | **cumulative quantity of substance leached over 30 days**  **TIME 1 [kg]** | **cumulative quantity of substance leached after 20 years**  **TIME 2 [kg]** |
| **Tebuconazole** | 5.23E-03 | 1.27E+00 |
| **Propiconazole** | 4.86E-03 | 1.18E+00 |
| **IPBC** | 1.92E-03 | 4.66E-01 |
| **Permethrin** | 1.39E-04 | 3.39E-02 |

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions to surface water compartment** | | |
| **Active substance** | **Local emission due to leaching after 30 days**  **TIME 1 [kg.d-1]** | **Local emission due to leaching after 20 years**  **TIME 2 [kg.d-1]** |
| **Tebuconazole** | 8.72E-05 | 8.72E-05 |
| **Propiconazole** | 8.09E-05 | 8.09E-05 |
| **IPBC** | 3.19E-05 | 3.19E-05 |
| **Permethrin** | 2.32E-06 | 2.32E-06 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to water compartment** | | |
| **Active substance** | **Local concentration into surface water after 30 days**  **TIME 1[mg.l-1]** | **Local concentration into surface water after 20 years**  **TIME 2 [mg.l-1]** |
| **Tebuconazole** | 3.36E-06 | 3.36E-06 |
| **Propiconazole** | 3.12E-06 | 3.12E-06 |
| **IPBC** | 1.23E-06 | 1.23E-06 |
| **Permethrin** | 8.96E-08 | 8.96E-08 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to soil compartment** | | |
| **Active substance** | **Local concentration in soil after 30 days**  **TIME 1[kg.kgwwt-1]** | **Local concentration in soil after 20 years**  **TIME 2 [kg.kgwwt-1]** |
| **Tebuconazole** | 4.40E-09 | 1.07E-06 |
| **Propiconazole** | 4.08E-09 | 9.93E-07 |
| **IPBC** | 1.52E-11 | 6.48E-09 |
| **Permethrin** | 5.970E-10 | 1.26E-09 |

***Scenario 4:*** *In-service leaching from treated wood*

During service life of UC 3 treated wood, emission into the environment can occur due to leaching of active substances out of the wood due to rainfall.

Emissions due to leaching of the active substances out of the wood may occur into the soil, the surface water and into the Sewage Treatment Plant (STP) after run-off.

The calculated concentrations (Clocal) in the receiving environmental compartments represent the concentration at the end of the assessment period taking into account removal processes of the substance from the receiving compartment for example due to degradation, volatilisation, or leaching to groundwater.

The removal processes is not taken into account in the "bridge over pond" scenario because the first order rate constant for removal from water corresponds to 0 for the 4 active substances.

House scenario

In the house, the primary receiving compartment is considered to be the soil following leaching due to rainfall. The default values for the size of the receiving soil are: 50 cm distance from the house and a soil depth of 50 cm. This correspond to a soil volume of 13 m3.

In this scenario the emissions over 30 days and 15 years are based on emissions due to leaching and emissions during the application are not taken into account.

The input parameters for calculating the local emission and concentration into the soil following leaching are presented in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission and concentration** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Service life – House scenario* | | | | |
| Treated wood area | *AREAhouse* | 125 | [m2] | D |
| Duration of the initial assessment period | *TIME1* | 30 | [d] | D |
| Duration of the long-term assessment period | *TIME2* | 5475 | [d] | D |
| Cumulative quantity of substance leached out of 1 m2 of treated wood over the initial assessment period | *Q\*leach,time1* | **See above** | [kg.m-2] | S |
| Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period | *Q\*leach,time2* | **See above** | [kg.m-2] | S |
| (wet) soil volume | *Vsoil* | 13 | [m3] | D |
| Bulk density of wet soil | *RHOsoil* | 1700 | [kgwwt.m-3] | D |
| First order rate constant for removal from soil | *k* | **See above** | [d-1] | S |

D=default, S=based on information of applicant

* **Calculations**

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT8 as following:

*Esoil,leach,time1 = AREAhouse . Q\*leach, time1 / TIME 1 Esoil,leach,time2 = AREAhouse . Q\*leach, time2 / TIME 2*

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

***C****localsoil,TIME1 = [Esoil,leach,TIME1/(Vsoil . RHOsoil . k)] - [Esoil,leach,TIME1/(Vsoil . RHOsoil . k)] . (e-TIME1 . k)*

***C****localsoil,TIME2 = [Esoil,leach,TIME2/(Vsoil . RHOsoil . k)] - [Esoil,leach,TIME2/(Vsoil . RHOsoil . k)] . (e-TIME2 . k)*

The results are presented in the following tables (considering removal processes).

**Surface treatment**

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions to soil compartment** | | |
| **Active substance** | **Local emission in soil due to leaching after 30 days**  **TIME 1 [mg.d-1]** | **Local emission in soil due to leaching after 15 years TIME 2 [mg.d-1]** |
| **Tebuconazole** | 4.25E-01 | 1.00E+00 |
| **Propiconazole** | 3.92E-01 | 9.77E-01 |
| **IPBC** | 5.25E-01 | 5.59E-01 |
| **Permethrin** | 8.21E-03 | 1.40E-02 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to soil compartment** | | |
| **Active substance** | **Local concentration in soil after 30 days**  **TIME 1[mg.kgwwt-1]** | **Local concentration in soil after 15 years**  **TIME 2 [mg.kgwwt-1]** |
| **Tebuconazole** | 5.06E-04 | 5.05E-03 |
| **Propiconazole** | 4.70E-04 | 5.25E-03 |
| **IPBC** | 6.71E-06 | 7.15E-06 |
| **Permethrin** | 1.01E-05 | 9.71E-05 |

**Vacuum pressure**

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions to soil compartment** | | |
| **Active substance** | **Local emission in soil due to leaching after 30 days**  **TIME 1 [mg.d-1]** | **Local emission in soil due to leaching after 20 years TIME 2 [mg.d-1]** |
| **Tebuconazole** | 1.25E+00 | 2.02E-02 |
| **Propiconazole** | 1.25E+00 | 1.59E-02 |
| **IPBC** | 5.50E+00 | 2.39E-01 |
| **Permethrin** | 1.25E-02 | 2.57E-04 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to soil compartment** | | |
| **Active substance** | **Local concentration in soil after 30 days**  **TIME 1[mg.kgwwt-1]** | **Local concentration in soil after 20 years**  **TIME 2 [mg.kgwwt-1]** |
| **Tebuconazole** | 1.58E-05 | 2.58E-07 |
| **Propiconazole** | 7.81E-04 | 8.41E-05 |
| **IPBC** | 6.96E-05 | 3.05E-06 |
| **Permethrin** | 7.96E-06 | 1.74E-06 |

Bridge over pond scenario

SARPECO 9-PLUS is not intended to be used for treating commodities such as bridges over water bodies but in order to describe the emission pathway into open water bodies the scenario bridge over pond has been calculated.

The bridge over pond scenario describes a wooden bridge which is located over a pond. It is assumed that the emissions of active substance following leaching due to rainfall and up directly in the adjacent static surface water. The default value for the size of the receiving water body is set to 1000 m3.

In this scenario the emissions over 30 days and 15 years are based on emissions due to leaching and emissions during the application are not taken into account.

The input parameters for calculating the local emission and concentration into the surface water following leaching are presented in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Service life – Bridge over pond scenario* | | | | |
| Treated wood area | *AREAbridge* | 10 | [m2] | D |
| Duration of the initial assessment period | *TIME1* | 30 | [d] | D |
| Duration of the long-term assessment period | *TIME2* | 5475 | [d] | D |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Cumulative quantity of substance leached out of 1 m2 of treated wood over the initial assessment period | *Q\*leach,time1* | **See above** | [kg.m-2] | S |
| Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period | *Q\*leach,time2* | **See above** | [kg.m-2] | S |
| Water volume under bridge | *Vwater* | 1000 | [m3] | D |

D=default, S=based on information of applicant

* **Calculations**

The local emissions into the water (the cumulative quantity of substance leached over 30 days and 15 years, Qleach,time) are calculated according to the equations 4.61 and 4.62 from the revised ESD PT8 as following:

*Qleach,time1 = AREAbridge . Q\*leach, time1*

*Qleach,time2 = AREAbridge . Q\*leach, time2*

The local concentrations into the water are calculated according to the equations 4.63/4.64/4.65/4.66 from the revised ESD PT8 as following:

***C****localwater,leach,TIME1 = Qleach,time1 . 0.001 / Vwater* ***C****localwater,leach,TIME2 = Qleach,time2 . 0.001 / Vwater* ***C****localwater,total,TIME1 =* ***C****localwater,leach,TIME1*

***C****localwater,total,TIME2 =* ***C****localwater,leach,TIME2*

The results are presented in the following tables.

**Surface treatment**

|  |  |  |
| --- | --- | --- |
| **Resulting cumulative quantity of substance leached to water compartment** | | |
| **Active substance** | **cumulative quantity of substance leached over 30 days**  **TIME 1 [mg]** | **cumulative quantity of substance leached after 15 years**  **TIME 2 [mg]** |
| **Tebuconazole** | 1.02E+00 | 4.40E+02 |
| **Propiconazole** | 9.41E-01 | 4.28E+02 |
| **IPBC** | 1.26E+00 | 2.45E+02 |
| **Permethrin** | 1.97E-02 | 6.15E+00 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to water compartment without considering removal processes** | | |
| **Active substance** | **Local concentration into surface water after 30 days**  **TIME 1[mg.l-1]** | **Local concentration into surface water after 15 years**  **TIME 2 [mg.l-1]** |
| **Tebuconazole** | 1.02E-03 | 4.40E-01 |

|  |  |  |
| --- | --- | --- |
| **Propiconazole** | 9.41E-04 | 4.28E-01 |
| **IPBC** | 1.26E-03 | 2.45E-01 |
| **Permethrin** | 1.97E-05 | 6.15E-03 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to water compartment considering removal processes** | | |
| **Active substance** | **cumulative quantity of substance leached over 30 days**  **TIME 1 [mg]** | **cumulative quantity of substance leached after 15 years**  **TIME 2 [mg]** |
| **Tebuconazole** | 4,37E-04 | 4,93E-03 |
| **Propiconazole** | 2,85E-04 | 1,35E-03 |
| **IPBC** | 7,77E-06 | 8,33E-06 |
| **Permethrin** | 8,54E-06 | 7,47E-05 |

**Vacuum pressure**

|  |  |  |
| --- | --- | --- |
| **Resulting cumulative quantity of substance leached to water compartment** | | |
| **Active substance** | **cumulative quantity of substance leached over 30 days**  **TIME 1 [mg]** | **cumulative quantity of substance leached after 20 years**  **TIME 2 [mg]** |
| **Tebuconazole** | 3.00E+00 | 1.18E+01 |
| **Propiconazole** | 3.00E+00 | 9.30E+00 |
| **IPBC** | 1.32E+01 | 1.39E+02 |
| **Permethrin** | 3.00E-02 | 1.50E-02 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to water compartment without considering removal processes** | | |
| **Active substance** | **Local concentration into surface water after 30 days**  **TIME 1[mg.l-1]** | **Local concentration into surface water after 20 years**  **TIME 2 [mg.l-1]** |
| **Tebuconazole** | 3.00E-03 | 1.18E-02 |
| **Propiconazole** | 3.00E-03 | 9.30E-03 |
| **IPBC** | 1.32E-02 | 1.39E-01 |
| **Permethrin** | 3.00E-05 | 1.50E-04 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to water compartment considering removal processes** | | |
| **Active substance** | **cumulative quantity of substance leached over 30 days**  **TIME 1 [mg]** | **cumulative quantity of substance leached after 20 years**  **TIME 2 [mg]** |
| **Tebuconazole** | 2.40E-06 | 3.89E-08 |
| **Propiconazole** | 1.38E-03 | 1.49E-04 |
| **IPBC** | 1.06E-05 | 4.59E-07 |

|  |  |  |
| --- | --- | --- |
| **Permethrin** | 1.35E-05 | 1.86E-06 |

Noise barrier scenario

The noise barrier scenario describes a noise barrier that is made of poles with planks in between. The medium size of a noise barrier in an urbanized area is assumed to be 1000 m long and 3 m high. It is assumed that 30% of the emissions of active substances due to leaching end up directly in the adjacent soil and 70% of the emissions are collected in the gutter and sewer, and finally enter a STP.

In this scenario the emissions over 30 days and 15 years are based on emissions due to leaching and emissions during the application are not taken into account because pre-treated wood is used for the construction of noise barriers.

The input parameters for calculating the local emission and concentration into the soil and the STP following leaching are presented in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission and concentration** | | | | |
| **Input** | **Nomenclature** | **Value** | **Unit** | **Remarks** |
| *Scenario: Service life – Noise barrier scenario* | | | | |
| Treated wood area | *AREAnoise-barrier* | 3000 | [m2] | D |
| Duration of the initial assessment period | *TIME1* | 30 | [d] | D |
| Duration of the long-term assessment period | *TIME2* | 5475 | [d] | D |
| Cumulative quantity of substance leached out of 1 m2 of treated wood over the initial assessment period | *Q\*leach,time1* | **See above** | [kg.m-2] | S |
| Cumulative quantity of substance leached out of 1 m² of treated wood over a longer assessment period | *Q\*leach,time2* | **See above** | [kg.m-2] | S |
| (wet) soil volume | *Vsoil* | 250 | [m3] | D |
| Bulk density of wet soil | *RHOsoil* | 1700 | [kgwwt.m-3] | D |
| Fraction released to soil | *Fsoil* | 0.3 | [-] | D |
| Fraction released to the STP | *FSTP* | 0.7 | [-] | D |
| First order rate constant for removal from soil | k | **See above** | [d-1] | S |

D=default, S=based on information of applicant

The local daily emissions into the STP are calculated according to the equations 3.5 and 3.6 from the revised ESD PT08 as following:

*ESTP,time 1 = AREAnoise-barrier x FSTP x Q\*leach, time1 / Time 1 ESTP,time 2 = AREAnoise-barrier x FSTP x Q\*leach, time2 / Time 2*

The local emissions into the soil are calculated according to the equations 3.5 and 3.6 from the revised ESD PT08 as following:

*Esoil,leach,time 1 = AREAnoise-barrier x FSTP x Q\*leach, time1 / Time 1 Esoil,leach,time 2 = AREAnoise-barrier x FSTP x Q\*leach, time2 / Time 2*

The local concentrations into the soil are calculated according to the equations 3.11 and 3.12 from the revised ESD PT8 as following:

***C****localsoil,TIME1 = [Esoil,leach,TIME1/(Vsoil . RHOsoil . k)] - [Esoil,leach,TIME1/(Vsoil . RHOsoil . k)] . (e-TIME1 . k)*

***C****localsoil,TIME2 = [Esoil,leach,TIME2/(Vsoil . RHOsoil . k)] - [Esoil,leach,TIME2/(Vsoil . RHOsoil . k)] . (e-TIME2 . k)*

The results are presented in the following tables (considering removal processes only for soil compartment).

**Surface treatment**

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions to STP compartment** | | |
| **Active substance** | **Local emission into STP due to leaching after 30 days**  **TIME 1 [mg.d-1]** | **Local emission into STP due to leaching after 15 years**  **TIME 2 [mg.d-1]** |
| **Tebuconazole** | 7.14E+00 | 1.69E+01 |
| **Propiconazole** | 6.59E+00 | 1.64E+01 |
| **IPBC** | 8.82E+00 | 9.40E+00 |
| **Permethrin** | 1.38E-01 | 2.36E-01 |

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions to soil compartment** | | |
| **Active substance** | **Local emission into soil due to leaching after 30 days**  **TIME 1 [mg.d-1]** | **Local emission into soil due to leaching after 15 years**  **TIME 2 [mg.d-1]** |
| **Tebuconazole** | 3.06E+00 | 7.23E+00 |
| **Propiconazole** | 2.82E+00 | 7.04E+00 |
| **IPBC** | 3.78E+00 | 4.03E+00 |
| **Permethrin** | 5.19E-02 | 1.01E-12 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to soil compartment** | | |
| **Active substance** | **Local concentration into soil after 30 days**  **TIME 1[mg.kgwwt-1]** | **Local concentration into soil after 15 years**  **TIME 2 [mg.kgwwt-1]** |
| **Tebuconazole** | 1.89E-04 | 1.89E-03 |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Propiconazole** | 1.76E-04 | 1.96E-03 |
| **IPBC** | 2.51E-06 | 2.68E-06 |
| **Permethrin** | 3.79E-06 | 3.64E-05 |

**Vacuum pressure**

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions to STP compartment** | | |
| **Active substance** | **Local emission into STP due to leaching after 30 days**  **TIME 1 [mg.d-1]** | **Local emission into STP due to leaching after 20 years**  **TIME 2 [mg.d-1]** |
| **Tebuconazole** | 2.10E+01 | 3.39E-01 |
| **Propiconazole** | 2.10E+01 | 2.68E-01 |
| **IPBC** | 9.24E+01 | 4.01E+00 |
| **Permethrin** | 2.10E-01 | 4.32E-03 |

|  |  |  |
| --- | --- | --- |
| **Resulting local emissions to soil compartment** | | |
| **Active substance** | **Local emission into soil due to leaching after 30 days**  **TIME 1 [mg.d-1]** | **Local emission into soil due to leaching after 20 years**  **TIME 2 [mg.d-1]** |
| **Tebuconazole** | 9.00E+00 | 1.45E-01 |
| **Propiconazole** | 9.00E+00 | 1.154E-01 |
| **IPBC** | 3.96E+01 | 1.72E+00 |
| **Permethrin** | 9.00E-02 | 1.85E-03 |

|  |  |  |
| --- | --- | --- |
| **Resulting local concentrations to soil compartment** | | |
| **Active substance** | **Local concentration into soil after 30 days**  **TIME 1[mg.kgwwt-1]** | **Local concentration into soil after 20 years**  **TIME 2 [mg.kgwwt-1]** |
| **Tebuconazole** | 5.98E-06 | 9.67E-08 |
| **Propiconazole** | 5.61E-04 | 3.20E-05 |
| **IPBC** | 2.63E-05 | 1.14E-06 |
| **Permethrin** | 2.98E-06 | 6.51E-07 |

##### Fate and distribution in exposed environmental compartments

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | |
| **Scenario** | | **Air** | **STP** | **Soil** | **Ground- water** | **Surface water** | **Biota** |
| Industrial processes: Automated spraying and Short dipping | Application phase | (Yes) | **Yes** | No | No | **Yes** | (Yes) |
| Storage phase | (Yes) | No | **Yes** | (Yes) | **Yes** | (Yes) |
| Service life | House | (Yes) | No | **Yes** | **Yes** | No | (Yes) |
| Bridge over pond | (Yes) | No | No | No | **Yes** | (Yes) |
| Noise barrier | (Yes) | Yes | **Yes** | (Yes) | No | (Yes) |

The compartments marked with “Yes” are those of concern for which predicted emissions and local concentrations have been determined for the active substances as well as the relevant metabolites (for the groundwater).

The compartments marked with “(Yes)” are those that might in principle be relevant, but not in the case of the present active substances and their relevant metabolites because of their substance-specific properties.

In the table below the relevant parameters from the active substance dossiers of all active substances are presented. For a general assessment of the environmental fate and behaviour of all four active substances refer to the active substances CAR.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment for the active substances** | | | | | |
| **Input** | **Unit** | **Tebuconazole** | **Propiconazole** | **IPBC** | **Permethrin** |
| Molecular weight | g/mol | 307.8 | 342.2 | 281.1 | 391.29 |
| Melting point | °C | 105 |  | 66.15 | 34 |
| Boiling point | °C |  | 250 |  | 305 |
| Vapour pressure (at 20 °C) | Pa | 1.7E-06 | 5.6E-05 | 4.5E-03 | 3.04E-06 |
| Water solubility (at 20 °C) | mg/l | 2.9E+01 | 1.00E+02 | 5.3E-03 | 5.30E-03 |
| Log Octanol/water partition coefficient | Log 10 | 3.49 | 3.72 | 2.81 | 4.67 |
| Organic carbon/water partition coefficient (Koc) | l/kg | 992 | 944 | 126 | 26930 |
| Henry’s Law Constant (at 20 °C) | Pa/m3/mol | 1.00E-05 | 9.2E-05 | 6.45E-03 | 4.5E-02 |
| Biodegradability |  | Not biodegradable | Not biodegradable | Not biodegradable | Not biodegradable |

**Input parameters (only set values) for calculating the fate and distribution in the environment for the relevant metabolites**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Input** | **Unit** | **1.2.4-Triazole** | **PBC** | **DCVA** | **PBA** |
| Molecular weight | g/mol | 69.1 | 155.2 | 209.07 | 214.22 |
| Vapour pressure (at  20 °C) | Pa | 2.2E-01 | 1.88E+01 | 2.6E-01 | 4.21E-04 |
| Water solubility (at 20 °C) | mg/l | 7.0E+05 | 2.86E+05 | 127.6 | 16.91 |
| Organic carbon/water partition  coefficient (Koc) | l/kg | 89 | 198.1 | 188.53 | 37.55 |
| Fraction transformed (soil) | - | 0.09  (Tebuconazole) 0.43  (Propiconazole) | 1 (IPBC) | 0.113  (Permethrin) | 0.15  (Permethrin) |

##### Calculated PEC values

The Predicted Environmental Concentration (PEC) calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Guidance on the BPR: Volume IV Environment, Part B Risk Assessment (active substances) (2015)).

The PECs for Tebuconazole, Propiconazole, IPBC and Permethrin in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 8, taking into account degradation processes and/or dilution (where applicable). The PEC values presented in the following tables are rounded values from EXCEL spread sheets from ECHA. The calculations for the different PECs within EXCEL are always carried out with unrounded values.

In the Assessment Reports for IPBC the reported PNEC for the sediment was derived using the equilibrium method. So the risk of the sediment compartment is the same as that assessed for surface water. Therefore, the risk of the sediment will not be considered further and the calculation of PECsediment values is not considered necessary.

Metabolites of IPBC, Propiconazole, Tebuconazole and Permethrin are considered to be transient or less persistent than their respective parent, and are less toxic. In the CARs, the risk quotients are more favorable for the metabolites than for the active substances for both the aquatic and terrestrial environment and the metabolites are not considered further in the risks assessment. The only exception concern the metabolite 1.2.4-Triazole which has a slightly higher PNECsoil than the PNECsoil of its parents (Propiconazole and tebuconazole).

Therefore, emissions and PEC values were calculated for parents only and the PECsoil values were also calculated for the parents and the metabolites as a Tier 2. In addition, the soil compartment is the one presenting the highest risks, in this way this Tier 2 (with metabolites) represents a worst case.

Furthermore, the WG-II-2018 proposed the following conclusion: ”WG agreed that at AS approval if at first tier major metabolites are found much less toxic than AS, there is no need for their full quantitative risk assessment (with the exception of groundwater assessment)”.

In this idea and taking into account the great difference in toxicity between active substances and their metabolites and also the properties of the concerned metabolites the environmental

risk assessment for metabolites is considered to be covered by the risk assessment for parents for the Sarpeco 9-plus.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Tebuconazole** | | **PECSurface water**  **(mg/l)** | **PECSTP**  **(mg/l)** | **PECSediment (mg/kgwwt)** | **PECsoil (mg/kgwwt)** |
| Industrial processes | |  | | | |
| Application phase | Automated spraying /brushing  (large plant) | 4.26E-04 | 4.26E-03 | 9.51E-03 | / |
| Short dipping | 8.50E-05 | 8.51E-04 | 1.90E-03 | / |
| Vacuum pressure | 3.13E-02 | 3.14E-01 | 3.22E+00 | / |
| Storage phase | Automated spraying /brushing  (Time 1) | 3.80E-06 | / | 8.49E-05 | 4.40E-03 |
| Automated spraying /brushing  (Time 2) | 3.80E-06 | / | 8.49E-05 | 1.07E+00 |
| Short dipping (Time 1) | 3.36E-06 | / | 7.51E-05 | 4.40E-03 |
| Short dipping (Time 2) | 3.36E-06 | / | 7.51E-05 | 1.07E+00 |
| Vacuum pressure (Time 1) | 8.39E-05 | / | 8.62E-03 | 1.28E-03 |
| Vacuum pressure (Time 2) | 8.39E-05 | / | 8.62E-03 | 3.12E-01 |
| In-service | |  | | | |
| Service life  Surface treatment | House (Time 1) | / | / | / | 5.06E-04 |
| House (Time 2) | / | / | / | 5.05E-03 |
| Noise barrier (Time 1) | 3.18E-07 | 3.18E-06 | 7.10E-06 | 1.89E-04 |
| Noise barrier (Time 2) | 7.52E-07 | 7.53E-06 | 1.63E-05 | 1.89E-03 |
| Bridge over pond (Time 1) | 4,37E-04 | / | 1,10E-05 | / |
| Bridge over pond (Time 2) | 4,93E-03 | / | 4,86E-04 | / |
| Service life  Vacuum Pressure | House (Time 1) | / | / | / | 1.60E-05 |
| House (Time 2) | / | / | / | 2.58E-07 |
| Noise barrier (Time 1) | 9.22E-05 | 9.23E-04 | 9.48E-03 | 5.98E-06 |
| Noise barrier (Time 2) | 1.49E-06 | 1.49E-05 | 1.53E-04 | 9.67E-08 |
| Bridge over pond (Time 1) | 4.93E-07 | / | 4.51E-05 | / |
| Bridge over pond (Time 2) | 7.11E-09 | / | 7.31E-07 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Propiconazole** | **PECSurface water**  **(mg/l)** | **PECSTP**  **(mg/l)** | **PECSediment (mg/kgwwt)** | **PECsoil (mg/kgwwt)** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Industrial processes | |  | | | |
| Application phase | Automated spraying /brushing  (large plant) | 4.28E-03 | 4.28E-02 | 9.11E-02 | / |
| Short dipping | 8.55E-04 | 8.55E-03 | 1.82E-02 | / |
| Vacuum pressure | 1.59E-07 | 1.59E-06 | 1.55E-05 | / |
| Storage phase | Automated spraying /brushing  (Time 1) | 3.52E-06 | / | 7.50E-05 | 4,08E-03 |
| Automated spraying /brushing  (Time 2) | 3,52E-06 | / | 7,50E-05 | 9,93E-01 |
| Short dipping (Time 1) | 3,12E-06 | / | 6,65E-05 | 4,08E-03 |
| Short dipping (Time 2) | 3,12E-06 | / | 6,65E-05 | 9,93E-01 |
| Vacuum pressure (Time 1) | 1.70E-04 | / | 1.66E-02 | 1.02E-08 |
| Vacuum pressure (Time 2) | 1.70E-04 | / | 1.66E-02 | 6.07E-07 |
| In-service | |  | | | |
| Service life  Surface treatment | House (Time 1) | / | / | / | 5.32E-04 |
| House (Time 2) | / | / | / | 2.42E-01 |
| Noise barrier (Time 1) | 2.94E-07 | 2.95E-06 | 6.27E-06 | 1.76E-04 |
| Noise barrier (Time 2) | 7.33E-07 | 7.34E-06 | 1.56E-05 | 1.96E-03 |
| Bridge over pond (Time 1) | 2,85E-04 | / | 9,97E-06 | / |
| Bridge over pond (Time 2) | 1,35E-03 | / | 2,02E-03 | / |
| Service life  Vacuum pressure | House (Time 1) | / | / | / | 1.50E-03 |
| House (Time 2) | / | / | / | 8.55E-05 |
| Noise barrier (Time 1) | 9.28E-05 | 9.29E-04 | 9.09E-03 | 2.92E-04 |
| Noise barrier (Time 2) | 1.18E-06 | 1.19E-05 | 1.16E-04 | 3.15E-05 |
| Bridge over pond (Time 1) | 1.38E-03 | / | 1.35E-05 | / |
| Bridge over pond (Time 2) | 1.49E-03 | / | 1.46E-01 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IPBC** | | **PECSurface water**  **(mg/l)** | **PECSTP**  **(mg/l)** | **PECsoil (mg/kgwwt)** |
| Industrial processes | |  | | |
| Application phase | Automated spraying /brushing  (large plant) | 4.28E-03 | 4.28E-02 | / |
| Short dipping | 8.56E-04 | 8.56E-03 | / |
| Vacuum pressure | 5.79E-06 | 5.79E-05 | / |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Storage phase | Automated spraying /brushing  (Time 1) | 1.39E-06 | / | 1.61E-03 |  | |
| Automated spraying /brushing  (Time 2) | 1.39E-06 | / | 3.92E-01 |
| Short dipping (Time 1) | 1.23E-06 | / | 1.61E-03 |
| Short dipping (Time 2) | 1.23E-06 | / | 3.92E-01 |
| Vacuum pressure (Time1) | 5.79E-06 | / | 1.01E-08 |
| Vacuum pressure (Time2) | 5.79E-06 | / | 2.46E-06 |
| In-service | |  | | | | |
| Service life  Surface treatment | House (Time 1) | / | / | 6.71E-06 |  | |
| House (Time 2) | / | / | 7.15E-06 |
| Noise barrier (Time 1) | 4.34E-07 | 4.34E-06 | 2.51E-06 |
| Noise barrier (Time 2) | 4.62E-07 | 4.62E-06 | 2.68E-06 |
| Bridge over pond (Time 1) | 7,77E-06 | / | / |
| Bridge over pond (Time 2) | 8,33E-06 | / | / |
| Service life  Vacuum pressure | House (Time 1) | / | / | 6.96E-05 |
| House (Time 2) | / | / | 3.05E-06 |
| Noise barrier (Time 1) | 4.54E-04 | 4.54E-03 | 2.61E-05 |
| Noise barrier (Time 2) | 1.97E-05 | 1.97E-04 | 1.14E-06 |
| Bridge over pond (Time 1) | 1.06E-05 | / | / |
| Bridge over pond (Time 2) | 9.38E-08 | / | / |
| **Permethrin** | | **PECSurface water**  **(mg/l)** | **PECSTP**  **(mg/l)** | **PECSediment (mg/kgwwt)** | | **PECsoil (mg/kgwwt)** |
| Industrial processes | |  | | | | |
| Application phase | Automated spraying /brushing  (large plant) | 7.69E-06 | 8.00E-05 | 4.51E-03 | | / |
| Short dipping | 1.54E-06 | 1.60E-05 | 9.02E-04 | | / |
| Vacuum pressure | 1.48E-08 | 1.48E-07 | 3.99E-05 | | / |
| Storage phase | Automated spraying /brushing  (Time 1) | 1.01E-07 | / | 5.92E-05 | | 1.17E-10 |
| Automated spraying /brushing  (Time 2) | 1.01E-07 | / | 5.92E-05 | | 2.85E-08 |
| Short dipping (Time 1) | 8.96E-08 | / | 5.25E-05 | | 1.17E-10 |
| Short dipping (Time 2) | 8.96E-08 | / | 5.25E-05 | | 2.85E-08 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Vacuum pressure (Time1) | 1.48E-08 | / | 3.99E-05 | 2.58E-11 |
| Vacuum pressure (Time2) | 1.48E-08 | / | 3.99E-05 | 2.58E-11 |
| In-service | |  | | | |
| Service life | House (Time 1) | / | / | / | 1.01E-05 |
| House (Time 2) | / | / | / | 9.71E-05 |
| Noise barrier (Time 1) | 1.83E-09 | 1.90E-08 | 1.07E-06 | 3.79E-06 |
| Noise barrier (Time 2) | 3.49E-09 | 3.63E-08 | 2.05E-06 | 3.64E-05 |
| Bridge over pond (Time 1) | 8,54E-06 | / | 4,10E-06 | / |
| Bridge over pond (Time 2) | 7,47E-05 | / | 1,75E-05 | / |
| Service life  Vacuum pressure | House (Time 1) | / | / | / | 7.96E-06 |
| House (Time 2) | / | / | / | 1.74E-06 |
| Noise barrier (Time 1) | 2.19E-07 | 2.27E-06 | 5.89E-04 | 2.98E-06 |
| Noise barrier (Time 2) | 4.50E-09 | 4.68E-08 | 1.21E-05 | 6.51E-07 |
| Bridge over pond (Time 1) | 1.35E-05 | / | 3.64E-02 | / |
| Bridge over pond (Time 2) | 1.86E-06 | / | 5.02E-03 | / |

**Relevant degradation products and their assessment for the soil compartment**

For the **Permethrin**, aquatic metabolites including 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1 cyclopropane)carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA) are far less toxic to soil organisms than the parent active ingredient and are not considered to be ecotoxicologically relevant. In addition, the rates of degradation of permethrin in these two metabolites are rather low and are therefore not taken into account for this tier 2. In this case the PECsoil values for Permethrin is considered as a worst case for the mixture toxicity.

Degradation of **IPBC** yields the primary degradate propargyl butyl carbamate (PBC) as well as iodine. PEC values have been calculated for PBC only for the soil compartment which is the compartment with the higher risk. Therefore, emissions of PBC (degradation product of IPBC) are also calculated assuming 100% formation fraction of IPBC to PBC at time 0, using the ratio between the molar mass of PBC and IPBC of 0.552 in soil.

Moreover IPBC is quickly degraded in the environment in iodine, released as iodine radical, which is not stable in soil and can be considered as a “transient metabolites”. The final reaction end-products would be iodide and iodate. According to the conclusions of the AR for IPBC PT06 (27/09/2013), a quantitative assessment should not be a requirement for the final reaction end-products of IPBC. Moreover this present evaluation is covered by the qualitative assessment proposed in the AR for IPBC PT06.

In addition, the background concentrations of iodine in the environment (and particularly in the soil compartment: see table below) are much higher than what could be calculated after degradation of the IPBC of the product Sarpeco 9-plus.

|  |  |
| --- | --- |
| **Background concentration of iodine in the environment** | |
| **Compartment** | **Background level (as iodine)** |

|  |  |
| --- | --- |
| Soil | Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg  Global mean value of 5 mg/kg |
| Groundwater | Mean concentration: 1 μg/l  Range: < 1-70 μg/l with extremes up to 400 μg/l |

The assessment of 1,2,4-triazole was proposed only for emission to soil. The emission calculation for the metabolite takes into account the maximal level of formation fraction of the substances in soil (9% and 43% for **tebuconazole** and **propiconazole** respectively, as defined for the approval of these substances) and the molar mass of each component. An assessment 1,2,4-triazole is also proposed for soil compartment.

The cumulative quantities of substance leached out of 1 m2 of treated wood for each metabolite were calculate taking into account the degradation rate and the molar mass of the metabolite and the molar mass of the parent.

We present only the PECs results for the house and noise-barrier in-service scenarii because we consider these scenarii as worst cases for the soil compartment knowing that there are RMM for the storage phase after the application phase.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PECsoil (mg/kg ww)** | **Scenario: In-service** | | | |
| **House** | | **Noise barrier** | |
| **Time 1** | **Time 2** | **Time 1** | **Time 2** |
| PBC  (from IPBC) | 1.58E-04 | 1.91E-04 | 5.93E-05 | 7.17E-05 |
| 1.2.4-Triazole  (from propiconazole) | 4.25E-05 | 6.39E-04 | 1.59E-05 | 2.39E-04 |
| 1.2.4-Triazole  (from tebuconazole) | 1.07E-05 | 1.52E-04 | 3.99E-06 | 5.69E-05 |

Emission to soil from vacuum pressure treated wood are in the same range of order for all actives. It is therefore considered to be covered by the assessment made for surface treatment application.

##### Primary and secondary poisoning

* 1. *Primary poisoning*

The product is a wood preservative (Product Type 8). The product is a water-based concentrate and is applied in liquid form by automated spraying and short dipping (industrial processes). A direct uptake of the product is unlikely.

* 1. *Secondary poisoning*

According to Vol IV, Part B the calculation of a possible risk to man via the food chain (PECoral,predator) should be conducted if the active substance shows a potential for bioaccumulation, indicated by a log Kow value >3.

A secondary exposure of man to **IPBC** relevant to the food chain can be excluded due to the minimum amount which reaches the soil. In addition, the log Kow is less than 3 and the soil area of concern is very small.

Although the log Kow of **Propiconazole** (log Kow = 3.7) reveals a slight potential for bioaccumulation, the assessment of secondary poisoning is not requested according to the active substance Assessment Report for the use of propiconazole in wood preservatives.

According to the BCF in earthworm equal to 28 and the BCF in fish equal to 78, **Tebuconazole** is not expected to bioaccumulate to terrestrial and aquatic organisms. Therefore, an assessment of secondary poisoning doesn’t need to be performed.

The reported Log Pow values for **Permethrin** of 4.6, indicating it is a fat-soluble molecule with a potential to bioconcentrate. However, experimentally derived BCF values for fish and chironomid ranged from 290 to 620 l/kg. Permethrin is not considered to fulfil the Bioaccumulative or very bioaccumulative criteria. Therefore, an assessment of secondary poisoning doesn’t need to be performed.

* + - 1. *Risk characterisation*

The environmental risk characterization for biocidal active substances in the context of Article 5 and Annex VI of Directive 98/8 involves the comparison of PEC and PNEC values for each relevant environmental compartment as well as for non-target organisms. Risk Characterisation Ratios (PEC/PNEC) are derived for the use of the wood preservative. The calculated PEC/PNEC ratios are provided for the STP, the aquatic and terrestrial compartment in the following tables. As stated in section 2.2.8.2, air is not regarded as compartment of concern for this product with the proposed use patterns; also, there are no concerns of secondary poisoning or for the groundwater compartment because of the active substances- specific properties.

If the PEC/PNEC ratio is below 1, this is interpreted as an acceptable risk to the environment. Calculated PEC/PNEC values are summarized below, values above 1 are marked with red color.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Tebuconazole** | | PEC/PNECSurface  water | PEC/PNECSTP | PEC/PNECSediment | PEC/PNECsoil |
| Industrial processes | |  | | | |
| Application phase | Automated spraying /brushing  (large plant) | 3.84E-01 | 1.20E-02 | 1.56E-02 | / |
| Short dipping | 7.70E-02 | 2.41E-03 | 3.13E-03 | / |
| Vacuum pressure | **5.47E +01** | 9.81E-01 | **5.85E+00** | / |
| Storage phase | Automated spraying /brushing  (Time 1) | 3.80E-03 | / | 1.54E-04 | 4.40E-02 |
| Automated spraying /brushing  (Time 2) | 3.80E-03 | / | 1.54E-04 | **1.07E+01** |
| Short dipping (Time 1) | 3.36E-03 | / | 1.37E-04 | 4.40E-02 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Short dipping (Time 2) | 3.36E-03 | / | 1.37E-04 | **1.07E+01** |
| Vacuum pressure (Time1) | 8.39E-02 | / | 1.57E-02 | 1.28E-02 |
| Vacuum pressure (Time 2) | 8.39E-02 | / | 1.57E-02 | **3.12E+00** |
| In-service | |  | | | |
| Service life surface treatment | House (Time 1) | / | / | / | 5.06E-03 |
| House (Time 2) | / | / | / | 5.05E-02 |
| Noise barrier (Time 1) | 3.18E-04 | 9.94E-06 | 1.29E-05 | 1.89E-03 |
| Noise barrier (Time 2) | 7.52E-04 | 2.35E-05 | 2.96E-05 | 1.89E-02 |
| Bridge over pond (Time 1) | 4,37E-04 | / | 2,00E-05 | / |
| Bridge over pond (Time 2) | 4,93E-03 | / | 8,84E-04 | / |
| Service life vacuum pressure | House (Time 1) | / | / | / | 1.60E-04 |
| House (Time 2) | / | / | / | 2.58E-06 |
| Noise barrier (Time 1) | 9.22E-02 | 2.88E-03 | 1.72E-02 | 5.98E-05 |
| Noise barrier (Time 2) | 1.49E-03 | 2.88E-03 | 2.78E-04 | 9.67E-07 |
| Bridge over pond (Time 1) | 4.93E-04 | / | 8.20E-05 | / |
| Bridge over pond (Time 2) | 7.11E-06 | / | 1.33E-06 | / |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Propiconazole** | | PEC/PNECSurface  water | PEC/PNECSTP | PEC/PNECSediment | PEC/PNECsoil |
| Industrial processes | |  | | | |
| Application phase | Automated spraying /brushing  (large plant) | 5.68E-01 | 3.87E-04 | **1.52E+00** | / |
| Short dipping | 1.14E-01 | 7.74E-05 | 3.06E-01 | / |
| Vacuum pressure | **2.34E+01** | 1.59E-02 | **2.87E+02** | / |
| Storage phase | Automated spraying /brushing  (Time 1) | 5.18E-04 | / | 1.39E-03 | 4.08E-02 |
| Automated spraying /brushing  (Time 2) | 5.18E-04 | / | 1.39E-03 | **9.93E+00** |
| Short dipping (Time 1) | 4.59E-04 | / | 1.23E-03 | 4.08E-02 |
| Short dipping (Time 2) | 4.59E-04 | / | 1.23E-03 | **9.93E+00** |
| Vacuum pressure (Time1) | 2.50E-02 | / | 3.07E-01 | 1.02E-07 |
| Vacuum pressure (Time 2) | 2.50E-02 | / | 3.07E-01 | 6.07E-06 |
| In-service | |  | | | |
|  | House (Time 1) | / | / | / | 4.70E-03 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Service life surface treatment | House (Time 2) | / | / | / | 5.25E-02 |
| Noise barrier (Time 1) | 4.32E-05 | 2.95E-08 | 1.16E-04 | 1.76E-03 |
| Noise barrier (Time 2) | 1.08E-04 | 7.34E-08 | 2.89E-04 | 1.96E-02 |
| Bridge over pond (Time 1) | 4,19E-05 | / | 1,85E-04 | / |
| Bridge over pond (Time 2) | 1,98E-04 | / | 3,73E-02 | / |
| Service life vacuum pressure | House (Time 1) | / | / | / | 1.50E-02 |
| House (Time 2) | / | / | / | 8.55E-04 |
| Noise barrier (Time 1) | 1.36E-02 | 9.29E-06 | 1.68E-01 | 2.92E-03 |
| Noise barrier (Time 2) | 1.74E-04 | 1.19E-07 | 2.15E-03 | 1.50E-02 |
| Bridge over pond (Time 1) | 1.36E-02 | / | 1.68E-01 | / |
| Bridge over pond (Time 2) | 1.74E-04 | / | 2.15E-03 | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IPBC** | | PEC/PNECSurface  water | PEC/PNECSTP | PEC/PNECsoil |
| Industrial processes | |  | | |
| Application phase | Automated spraying /brushing  (large plant) | **8.50E+00** | 9.66E-02 | / |
| Short dipping | **1.70E+00** | 1.93E-02 | / |
| Vacuum pressure | 1.16E-02 | 1.32E-04 | / |
| Storage phase | Automated spraying /brushing  (Time 1) | 2.78E-03 | / | 3.74E-01 |
| Automated spraying /brushing  (Time 2) | 2.78E-03 | / | **9.12E+01** |
| Short dipping (Time 1) | 2.46E-03 | / | 3.74E-01 |
| Short dipping (Time 2) | 2.46E-03 | / | **9.12E+01** |
| Vacuum pressure (Time1) | 1.16E-02 | / | 2.35E-06 |
| Vacuum pressure (Time 2) | 1.16E-02 | / | 5,72E-04 |
| In-service | |  | | |
| Service life surface teratment | House (Time 1) | / | / | 1.56E-03 |
| House (Time 2) | / | / | 1.66E-03 |
| Noise barrier (Time 1) | 8.68E-04 | 9.86E-06 | 5.84E-04 |
| Noise barrier (Time 2) | 9.24E-04 | 1.05E-05 | 6.23E-04 |
| Bridge over pond (Time 1) | 1,55E-05 | / | / |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Bridge over pond (Time 2) | 1,67E-05 | / | / |
| Service life vacuum pressure | House (Time 1) | / | / | 1.62E-02 |
| House (Time 2) | / | / | 7.09E-04 |
| Noise barrier (Time 1) | 1.06E-01 | 1.03E-02 | 6.07E-03 |
| Noise barrier (Time 2) | 4.58E-03 | 1.97E-04 | 2.65E-04 |
| Bridge over pond (Time 1) | 2.47E-03 | / | / |
| Bridge over pond (Time 2) | 2.18E-05 | / | / |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Permethrin** | | PEC/PNECSurface  water | PEC/PNECSTP | PEC/PNECSediment | PEC/PNECsoil |
| Industrial processes | |  | | | |
| Application phase | Automated spraying /brushing  (large plant) | **1.64E+01** | 1.62E-02 | **2.08E+01** | / |
| Short dipping | **3.28E+00** | 3.23E-03 | **4.16E+00** | / |
| Vacuum pressure | 3.15E-02 | 2.99E-05 | 1.84E-01 | / |
| Storage phase | Automated spraying /brushing  (Time 1) | 2.15E-01 | / | 2.73E-01 | 1.34E-09 |
| Automated spraying /brushing  (Time 2) | 2.15E-01 | / | 2.73E-01 | 3.25E-07 |
| Short dipping (Time 1) | 1.91E-01 | / | 2.42E-01 | 1.34E-09 |
| Short dipping (Time 2) | 1.91E-01 | / | 2.42E-01 | 3.25E-07 |
| Vacuum pressure (Time 1) | 3.15E-02 | / | 1.84E-01 | 2.95E-10 |
| Vacuum pressure (Time 2) | 3.15E-02 | / | 1.84E-01 | 7,17E-08 |
| In-service | |  | | | |
| Service life  Surface treatment | House (Time 1) | 2.15E-01 | / | 2.73E-01 | 1.34E-09 |
| House (Time 2) | 2.15E-01 | / | 2.73E-01 | 3.25E-07 |
| Noise barrier (Time 1) | 1.91E-01 | / | 2.42E-01 | 1.34E-09 |
| Noise barrier (Time 2) | 1.91E-01 | / | 2.42E-01 | 3.25E-07 |
| Bridge over pond (Time 1) | 1,82E-02 | / | 1,89E-02 | / |
| Bridge over pond (Time 2) | 1,59E-01 | / | 8,06E-02 | / |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Service life | House (Time 1) | / | / | / | 9.09E-05 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Vacuum pressure | House (Time 2) | / | / | / | 1,99E-05 |
| Noise barrier (Time 1) | 4.66E-01 | 4.59E-04 | 2.71E+00 | 3.40E-05 |
| Noise barrier (Time 2) | 9.57E-03 | 9.45E-06 | 5.58E-02 | 7.43E-06 |
| Bridge over pond (Time 1) | 2.87E+01 | / | 1.68E+02 | / |
| Bridge over pond (Time 2) | 3.96E+00 | / | 2.31E+01 | / |

**Relevant degradation products for the soil compartment :**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PEC/PNECsoil** | **Scenario: In-service** | | | |
| **House** | | **Noise barrier** | |
| **Time 1** | **Time 2** | **Time 1** | **Time 2** |
| PBC  (from IPBC) | 1.06E-03 | 1.28E-03 | 3.98E-04 | 4.81E-04 |
| 1.2.4-Triazole  (from propiconazole) | 4.25E-03 | 6.39E-02 | 1.59E-03 | 2.39E-02 |
| 1.2.4-Triazole  (from tebuconazole) | 1.07E-03 | 1.52E-02 | 3.99E-04 | 5.69E-03 |
| Summation of 1.2.4-Triazole (from propiconazole and tebuconazole) | 5.32E-03 | 7.91E-02 | 1.99E-03 | 2.96E-02 |

The above values were calculated for surface treatment application (spraying and short dipping) Application by brushing is considered covered by the application by spraying . Vacuum pressure treatment are in the same range of order and usually lower and therefore it can be assumed that there is no risk for vacuum pressure treatment as well.

##### Atmosphere

The product Sarpeco 9-plus is a water-based product and the active substances Permethrin, Tebuconazole, Propiconazole and IPBC show very low vapour pressure.

Only negligible exposure to the atmosphere is expected and no threat to the atmosphere is expected.

##### Sewage treatment plant (STP)

For Sewage Treatment Plant (STP), all PEC/PNEC ratios are lower than 1 for all the evaluated scenarios. So we can conclude that the use of Sarpeco 9-plus represent acceptable risks for STP.

##### Aquatic compartment

For the aquatic compartment (surface-water and sediment), risks were identified during the application phase (Automated spraying/brushing or short dipping) and during the service life for the bridge over pond scenario as well as for noise barrier scenario (sediment; vacuum; T1). Those risks are primarily due to the high toxicity of Permethrin to

aquatic and sediment organisms but Propiconazole, Tebuconazole and IPBC are also problematic substances.The risk identified for the sediment during service life of vacuum treated wood in the noise barrier scenario at time 1 disappear at time 2 and is therefore considered acceptable.

So we can conclude that the use of Sarpeco 9-plus represent acceptable risks for water compartment if appropriate risk mitigation measures are considered.

* Application should be conducted within a contained area on impermeable hard standing with bunding and any losses from the application of the product should be collected for reuse or disposal.
* Treated wood should not be intended for uses close or above surface water.

##### Terrestrial compartment

For the soil, the industrial storage scenario provided elevated PEC/PNEC ratios for TIME 2. According to the revised ESD for PT 8 it can be assumed, that most storage places are sealed and run-off from storage places will be collected and disposed of safely – this is not taken into account in the calculations.

So we can conclude that the use of Sarpeco 9-plus represent acceptable risks for soil compartment if appropriate risk mitigation measures are considered.

* To avoid losses to the soil the freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing or both to prevent direct losses to soil, sewer or water.
* Application should be conducted within a contained area on impermeable hard standing with bunding and any losses from the application of the product should be collected for reuse or disposal.
* A non-biocidal top coat must be applied on treated wood used outdoor, above ground (use class 3.1 and 3.2) to avoid leaching of active substances.

##### Groundwater

According to Annex VI of the BPR (point 68) a groundwater assessment has to be conducted for all active substances and all relevant metabolites. The estimations of releases of active substances and metabolites for the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software for the following substances:

* + Tebuconazole;
  + Propiconazole;
  + 1,2,4-triazole;
  + IPBC;
  + PBC;
  + Permethrin;
  + DCVA;
  + PBA;

The scenario for the groundwater exposure assessment for wood preservatives described in the supplement of the appendix 4 of the PT08-ESD, based on leaching values.

**Input parameters in FOCUS PEARL v.4.4.4**

|  |  |  |
| --- | --- | --- |
| **Crop related parameters** | | |
| Crop uptake factor | - | 0 |
| **Application Schemes** | | |
| Total leachable area | m².ha-1 | 2 000 |
| Fraction of house surface exposed to weather | - | 0.5 |
| Service life | year | 15 |
| Number of application per year | - | 10 |
| Application type | - | To the soil surface |
| Repeat interval for years | - | 1 |
| Date | - | 10/01/1901 |
| 15/02/1901 |
| 24/03/1901 |
| 29/04/1901 |
| 05/06/1901 |
| 11/07/1901 |
| 17/08/1901 |
| 22/09/1901 |
| 29/10/1901 |
| 04/12/1901 |
| **Crops Application** | | |
| Crop(s) | - | Grassland |
| Selected Locations | | CHATEAUDUN |
| HAMBURG |
| JOIKIONEN |
| KREMSMUENSTER |
| OKEHAMPTON |
| PIACENZA |
| PORTO |
| SEVILLA |
| THIVA |

According to the paragraph 580 of the PT08-ESD (2013), a groundwater assessment is only necessary for the house scenario, which can be considered to be the worst case for soil exposure, thus covering all other scenarios.

Consequently to the environmental risk assessment performed for the application phase and the storage phase, it is recommended on the label to:

* The freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing or both to prevent direct losses to soil, sewer or water.
* Application should be conducted within a contained area on impermeable hard standing with bunding and any losses from the application of the product should be collected for reuse or disposal.

Then, no emission into the soil occurs during the application and the storage (Paragraph 581 and 582 ESD PT08 (2013)). Therefore, only emissions into the soil during the service-life of the treated wood due to leaching are taken into account to estimate the contamination of the groundwater.

The results are listed in the tables below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Tebuconazole [µg.L-1]** | **Propiconazole [µg.L-1]** | **IPBC [µg.L-1]** | **Permethrin [µg.L-1]** |
| CHATEAUDUN | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| HAMBURG | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| JOIKIONEN | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| KREMSMUENSTER | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| OKEHAMPTON | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| PIACENZA | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| PORTO | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| SEVILLA | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| THIVA | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **1.2.4-Triazole**  **(from propiconazole)**  **[µg.L-1]\*** | **1.2.4-Triazole (from tebuconazole**  **[µg.L-1]\*** | **PBC [µg.L-1]** | **DCVA [µg.L-1]** | **PBA [µg.L-1]** |
| CHATEAUDUN | 0.000039 | 0.000003 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| HAMBURG | 0.000133 | 0.000011 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| JOIKIONEN | 0.000013 | 0.000001 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| KREMSMUENS  -TER | 0.000067 | 0.000005 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| OKEHAMPTON | 0.000126 | 0.000010 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| PIACENZA | 0.000174 | 0.000016 | < 1.0E-06 | 0.000001 | < 1.0E-06 |
| PORTO | 0.000085 | 0.000006 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |
| SEVILLA | 0.000005 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| THIVA | 0.000023 | 0.000001 | < 1.0E-06 | < 1.0E-06 | < 1.0E-06 |

\*The summation of the derived values for 1,2,4-Triazole from propiconazole and tebuconazole in groundwater is clearly below the trigger value of 0.1 µg/L.

Conclusion:

The calculated PECgroudwater have been compared to the drinking water standard for pesticides (set at 0.1 μg/l) for each relevant substance. For all 9 EU scenarios, PECgroundwater are all below 0.1 µg/l.

Based on these results, it can be concluded that the use of the product will not pose a significant risk of groundwater contamination.

##### Primary and secondary poisoning

There are no concerns of primary of secondary poisoning.

##### Mixture toxicity

As the biocidal product consists of more than one active substance, the environmental risk should be based on the combined risk. It is found that the model of concentration addition can be recommended as the best reference model when evaluating combined risk of chemical mixtures.

In the first tier a PEC/PNEC summation based on effect data (most sensitive organism) for the individual substances is performed for each environmental compartment of concern.

[ (PEC/PNEC)product = Σ (PEC/PNEC)individual substances] for each environmental compartment

(PEC/PNEC)product values for each environmental compartment of concern are summarized below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Sarpeco 9-plus** | | PEC/PNECSurface  water | PEC/PNECSTP | PEC/PNECSediment | PEC/PNECsoil |
| Industrial processes | |  | | | |
| Application phase | Automated spraying /brushing (large plant) | **2.58E+01** | 1.25E-01 | **2.38E+01** | / |
| Short dipping | **5.17E+00** | 2.51E-02 | **4.76E+00** | / |
| Vacuum pressure | **5.47E-01** | 9.97E-01 | **2.93E+02** | / |
| Storage phase | Automated spraying /brushing (Time 1) | 2.22E-01 | / | 1.86E-01 | 4.59E-01 |
| Automated spraying /brushing (Time 2) | 2.22E-01 | / | 1.86E-01 | **1.12E+02** |
| Short dipping (Time 1) | 1.97E-01 | / | 1.65E-01 | 4.59E-01 |
| Short dipping (Time 2) | 1.97E-01 | / | 1.65E-01 | **1.12E+02** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Vacuum pressure (Time 1) | 1,52E-01 | / | 5,07E-01 | 1,28E-02 |
| Vacuum pressure (Time 2) | 1,52E-01 | / | 5,07E-01 | 3,12E+00 |
| In-service | |  | | | |
| Service life surface treatment | House (Time 1) | / | / | / | 1.14E-02 |
| House (Time 2) | / | / | / | 1.06E-01 |
| Noise barrier (Time 1) | 5.12E-03 | 1.98E-05 | 4.31E-03 | 4.28E-03 |
| Noise barrier (Time 2) | 9.21E-03 | 3.41E-05 | 6.86E-03 | 3.95E-02 |
| Bridge over pond (Time 1) | 1,87E-02 | / | 1,91E-02 | / |
| Bridge over pond (Time 2) | 1,64E-01 | / | 1,19E-01 | / |
| Service life  Vacuum pressure | House (Time 1) | / | / | / | 1.14E-02 |
| House (Time 2) | / | / | / | 1.06E-01 |
| Noise barrier (Time 1) | 5.12E-03 | 1.98E-05 | 4.31E-03 | 4.28E-03 |
| Noise barrier (Time 2) | 9.21E-03 | 3.41E-05 | 6.86E-03 | 3.95E-02 |
| Bridge over pond (Time 1) | 1,87E-02 | / | 1,91E-02 | / |
| Bridge over pond (Time 2) | 1,64E-01 | / | 1,19E-01 | / |

**Tier 2 :**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TIER 2:**  **Sarpeco 9-plus** | **Scenario: In-service** | | | |
| **House** | | **Noise barrier** | |
| **Time 1** | **Time 2** | **Time 1** | **Time 2** |
| 1.38E-02 | 1.57E-01 | 5.15E-03 | 5.88E-02 |

Conclusion:

All Σ (PEC/PNEC) ratios are lower than 1 for the evaluated scenarios except for the “Application phase” and the “Industrial storage TIME 2” scenarios (for automated spraying, /brushing ,vacuum pressure and short dipping).

The conclusions for this section are identical to those developed above for each active substance.

**The uses of Sarpeco 9-plus by industrial processes - automated spraying, vacuum pressure and short dipping - and the uses of treated wood in UC3 do not represent unacceptable risks to the environment if appropriate risk mitigation measures are considered.**

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

Not relevant

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The risk characterisation indicates that the uses of the biocidal product Sarpeco 9-Plus by the industrial processes - automated spraying, /brushing ,short dipping and vacuum pressure - and the uses of treated wood in UC 1, UC 2 and UC3 do not represent unacceptable risks to the environment if appropriate risk mitigation measures are considered. |

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

Measures to protect cats known for being sensible to pyrethroids: “Contain permethrin (pyrethroids), may be lethal to cats. Cats must avoid contact with treated object/area”.

Measures to protect man:

* "Do not apply the product on wood which may come into contact with food, feedstuff or livestock” as no dietary exposure have been assessed based on the intended uses of Sarpeco 9-plus.

In addition, pyrethroids like permethrin are known to cause paresthesia (burning and prickling of the skin without irritation) in susceptible persons. This local effect is normally not severe and disappears when direct exposure is terminated. However, an advice is required to warn susceptible persons:

* “Pyrethroids may cause paresthesia (burning and prickling of the skin without

irritation). If symptoms persist: Get medical advice.”

*All application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump).*

*Application solutions must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer.*

*Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, 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.*

A non-biocidal topcoat must be applied on treated wood used outdoor, above ground (use class 3.1 and 3.2) to avoid leaching of active substances.

For more details, please see relevant sections of the risk assessment.

### Assessment of ED properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in SARPECO 9-PLUS:

1. Assessment of the ED properties of the active substances in SARPECO 9-PLUS:

* According to section 2.1.1 of CA-March18.Doc.7.b-final, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures.

As Permethrin and IPBC are not part of the list (CA-September18.Doc.7.5.a-final) of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.

However Tebuconazole and Propiconazole are part of the list(CA-September18.Doc.7.5.a-final) of approved active substances identified as having potential ED properties. According to CA-September18.Doc.7.5.a-final Tebuconazole and Propiconazole may be triggered for an early review depending on outcome of the ED assessment for PT8. Therefore, pending the final decision regarding the ED properties of this substances, BE eCA will not evaluated Tebuconazole and Propiconazole nor request further data, according to section 2.1.1. (19) of CA-March18.Doc.7.b-final.

1. Assessment of the ED properties of non-active substances (co-formulants) in SARPECO 9-PLUS:

* After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants has been identified as having ED properties or are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product/family regarding ED properties:

Based on the existing knowledge and the data provided by the applicant, and pending the final decision regarding the ED properties of Tebuconazole and Propiconazole, BE eCA considers that there is no indication of concern regarding the ED properties of the substances used in the biocidal product SARPECO 9-PLUS.

However if Tebuconazole and Propiconazole or one or several components are identified as having ED properties, the conditions for granting the biocidal product authorisation will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

### Assessment of a combination of biocidal products

Not relevant.

### Comparative assessment

#### Active substances in the biocidal product and criteria for substitution and exclusion

The biocidal product Sarpeco 9 PLUS contains four active substances: propiconazole, IPBC, tebuconazole and permethrin.

IPBC and propiconazole are not PBT candidates.

According to the CAR of Permethrin for PT8, this substance (various isomer mixtures) is not a PBT candidate nor are its individual constituent isomers. Permethrin is considered to fulfill the T criteria, but does not fulfill the B criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the cis isomer) and therefore fulfill the P criteria.

Annex I Assessment Report for tebuconazole, PT8 states that tebuconazole is considered to be very persistent (vP) and toxic (T) but not bioaccumulative. In conclusion, tebuconazole shall be considered a candidate for substitution using the criteria in Article 10(1). However, tebuconazole is not considered as meeting the exclusion criteria according to Article 5(1). Therefore tebuconazole can be considered to meet the criteria in Article 10(1)d, notably it meets two of the criteria for being PBT in accordance with Annex XIII to regulation (EC) No 1907/2006.

Under Article 23(1) of Regulation 528/2012 Member States are required to perform a comparative assessment for biocidal products containing an active substance that is a candidate for substitution in accordance with Article 10(1). The Belgian CA has therefore used the approach in the EU guidance on the comparative assessment of the biocidal product. In line with this Note for Guidance, the Belgian CA began the comparative assessment with the screening phase to identify whether the diversity of the active substances - mode of action combination in authorised biocidal products is adequate.

#### Screening phase of comparative assessment

###### Intended use of the biocidal product and properties of active substances

Article 23(3) and the Note for Guidance focus the comparative assessment on the uses specified in the application of the biocidal product, as the requirement for a comparative assessment is product specific.

**Table 2.9.2.1.-1 Intended uses of the biocidal product**

|  |  |
| --- | --- |
| Product Type | 8 Wood preservatives |

|  |  |
| --- | --- |
| Where relevant, an exact description of the authorised use | Preventive |
| Target organism (including, where relevant) development stage) | Xylophages insects (including termites) White and brown rot fungi |
| Field(s) of use | Outdoor use – use class1 to 3 |
| Application method(s) | Surface application: fully automated spraying/ industrial brushing;fully automated dipping Penetrative application: Vacuum Pressure |
| Category(ies) of users | Professionals |

Permethrin is responsible for the insecticidal activity only. The other 3 active substances are responsible only for fungicidal activity. The comparative assessment is focused on only fungicidal activity.

IPBC is a carbamate fungicide. The target sites of carbamates in fungi are cell membrane permeability and fatty acids.

Tebuconazole and Propiconazole are azole fungicides intended for use against wood rotting fungi (basidiomycota). The actives act by interfering with the basic metabolism of the fungal cell wall and contents.

Of the three fungicidal active substances in the biocidal product tebuconazole is highly effective against the wood rotting fungi *Coniophora puteana* and *Gloeophyllum trabeum,* but is less effective against the wood rotting fungus *Poria placenta*.

Propiconazole is effective against the wood rotting fungus *P. placenta*, but is less effective against the wood rotting fungi *C. puteana* or *G. trabeum*.

IPBC has some activity against brown wood-rotting fungi but its efficacy largely lies with its activity against blue-stain (wood staining) fungi. IPBC is usually not used stand-alone but in combination with propiconazole to achieve efficacy against wood decay. Propiconazole is effective against wood decay.

In combination products, especially well-balanced efficacy against a broad range of wood rotting fungi can be achieved with minimising the amounts of each active.

The big advantage of tebuconazole/propiconazole with respect to the single actives, is that the mixture offers advantages in efficiency as much less triazole is necessary for the long term protection of wood against decay fungi. The very high efficacy of tebuconazole towards the brown rot fungi *C. puteana*. and *G. trabeum* is well compensating the moderate effectiveness of propiconazole towards these fungi, and in case of the fungi *P.placenta* and *C. versicolor*. the 1:1 mixture of tebuconazole and propiconazole is showing even high effectiveness compared to the individual effectiveness of each single triazole.

###### Chemical diversity of the active substances – mode of action combination in authorised biocidal products

According to the information available to the Belgian CA, there are about 2583 biocidal products authorised under Product Type 8 (Wood Preservatives) of the Biocidal Products Directive and Biocidal Products Regulations (including Mutual Recognitions and same product authorisations). More than 40 active substances (insecticides and fungicides) are approved for PT8 applications. Most of these products with fungicidal activity are based on propiconazole, tebuconazole, and IPBC or a mixture of these active substances.

The Fungicide Resistance Action Committee (FRAC), an international scientific committee with an overview of the global position, has provided the following information on the potential for resistance; this has been derived from experience with plant protection products rather than wood preservative products.

**Table 2.9.2.2-1 Mode of action and risk of resistance formation for PT8 fungicidal substances in authorised biocidal products**

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance | Tebuconazole | Propiconazole | IPBC |
| Mode of action | G: sterol biosynthesis in membranes  G1: C14-  demethylase in sterol  biosynthesis | G: sterol biosynthesis in membranes  G1: C14-  demethylase in sterol  biosynthesis | F: lipid  synthesis and membrane integrity  F4: cell  membrane permeability, fatty acids (proposed) |
| FRAC code | 3 | 3 | 28 |
| Risk of  resistance formation | Medium  (resistance management required) | Medium  (resistance management required) | Low to  medium (resistance management required) |

**Occurrence of resistance**

IPBC

According to the Annex I CAR for IPBC and the Fungicide Resistance Action Committee (FRAC) Code List (<http://www.frac.info/publication/publication.htm)>the risk of resistance formation against carbamate fungicides is regarded to be low to medium.

Tebuconazole and Propiconazole

Tebuconazole and Propiconazole are DeMethylation Inhibitor (DMI) fungicides within Sterol Biosynthesis Inhibitor (SBI) Class I. According to the FRAC Code List, DMI fungicides show no cross resistance to other SBI classes. There are big differences in the activity spectra of DMI fungicides. Resistance to DMI fungicides is known in various fungal species. Several resistance mechanisms are known incl. target site mutations in cyp51 (erg 11) gene, e.g. V136A, Y137F, A379G, I381V; cyp51 promotor; ABC transporters and others. It is considered generally wise to accept that cross resistance is present between DMI fungicides active against the same fungus, and the risk of resistance formation against DMI fungicides is regarded to be medium

According to the Annex I CARs for tebuconazole and propiconazole, for wood preservation with tebuconazole-and propiconazole-containing products, cases of resistances are not reported or known up to the time being.

###### Effects of removal or substitution of tebuconazole in biocidal product

On the basis of the information provided it can be assumed that removal of tebuconazole from the biocidal product would leave a gap in the activity of the biocidal product against certain

target pests where the remaining fungicidal active substances in the biocidal product have only weak activity.(see also 2.9.2.1 – properties of active substances)

Regarding substitution by other PT 8 fungicidal active substances in biocidal products, two of these active substances are already included in the biocidal product, and on the basis of the information on their activity profiles are not considered viable substitutes for tebuconazole. Regarding substitution by the remaining PT8 fungicidal active substance, dichlofluanid, according to the Annex I CAR for dichlofluanid this fungicide is targeted against wood-staining fungi (blue-staining fungi). However, it would not be expected to be able to substitute for tebuconazole regarding activity against wood rotting fungi such as *C. puteana* or *G. trabeum.*

#### Conclusion on comparative assessment

According to section 4 of the Note for Guidance, if the outcome of the comparative assessment is not sufficiently conclusive to conclude that the criteria of Article 23(3) of BPR are met, the product could be authorised for a period not exceeding 5 years in accordance with Article 23(6).

Taking into account:

* assuming that substitution of tebuconazole by one of the remaining available fungicidal active substances would reduce the activity of the biocidal product to control certain target organisms and
* the available information on the risk of resistance formation for the PT8 remaining fungicides

the Belgian CA considers that if tebuconazole were substituted in the biocidal product the chemical diversity would be inadequate for the given PT/use/target organism combination, and there would be an increased potential for fungicide resistance where activity gaps are left. Therefore, the Belgian CA concludes that there is not an adequate chemical diversity and in line with Article 23(3)(b) and the Note for Guidance, and since tebuconazole does not meet the exclusion criteria as outlined in Article 5(1), consider it valid to conduct no further investigation at this point. As such, the comparative assessment for SARPECO 9 PLUS can be finalised at the screening stage and the application taken forward to product authorisation in accordance with Article 23(6) of BPR.

# ANNEXES

## LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

* 1. **OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS**

Human Exposure Calculation:



## NEW INFORMATION ON THE ACTIVE SUBSTANCE

No new data were submitted.

## RESIDUE BEHAVIOUR

Not relevant.

## SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)

Please refer to the table ***2.2.5.5.1 summary of experimental data.***

## CONFIDENTIAL ANNEX

Please see separate document.

## OTHER

#### Human health exposure calculations



#### Environmental Risk Assessment – Annex (see confidential annex)