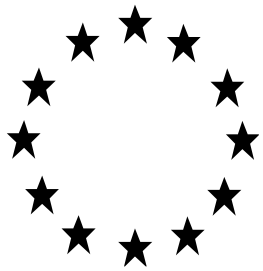
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



VACSOL AQUA 6118

Product type PT8

Penflufen and Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-WX057180-05

Evaluating Competent Authority: SE

Date: [04/11/2020]

Minor amendment SE CA [18/11/2020]
After uploading the PAR in R4BP3 [4/11/2020] minor errors were corrected on the 18/11/2020. These included correcting classification to Aquatic Chronic 2, adding pictogram GHS05, and correcting the address to the manufacturer of the product.

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SE CA: The UK CA evaluated Vacsol Aqua 6118, but due to Brexit ECHA transferred the case to SE CA in January 2020. The case transfer occurred when the UK CA had already prepared a draft PAR. The risk assessment and methods used in the evaluation were laid out by the UK CA. Overall, the SE CA agrees with the conclusion made by the UK CA.

1 CONCLUSION

1.1 SUMMARY OF DECISIONS AND RESTRICTIONS

It is concluded after evaluation, that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product subject to the following conditions:

1.1.1 Usage area

User	Usage area
Industrial	Vacsol Aqua 6118 is a preventative wood preservative treatment against larvae of the house longhorn beetle (Hylotrupes bajulus) and brown rot fungi. The intended uses for Vacsol Aqua 6118 are applications of: • Double vacuum and vacuum pressure application- Preventative treatment of wood and constructional timbers in Use Classes 1, 2 and 3 (general timber). • Dipping- Deluge/Enclosed Spray - Preventative treatment of wood and constructional timbers in Use Classes 1 & 2 (general timber). The product can be applied to both softwood and hardwood.

1.1.2 Authorised Uses

Authorisation is granted for the prevention and control of larvae of the house longhorn beetle (Hylotrupes bajulus) and brown rot fungi.

1.1.3 Pest and Application Rate

The applicant has provided sufficient data to demonstrate the efficacy of Vacsol Aqua 6118 as a PT 08 wood preservative against the following target pests:

Preventative against larvae of the house longhorn beetle (Hylotrupes bajulus) on general timber.
Preventative against brown rot fungi on general timber

The product can be applied to both softwood and hardwood.

The application rates assessed are as follows:

Double Vacuum (low pressure)
Dilute to 1.50 to 5% with water and apply by double vacuum at the following retentions:
All expressed as kgm^{-3} as concentrate in the analytical zone.
-Use class 1, 2 and 3 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 3.7 – 4.65 kg m^{-3}.

Vacuum Pressure (high pressure)
Dilute to 0.62 to 1.25% with water and apply by vacuum pressure at the following retentions:
-Use class 3 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 3.7 – 4.65 kg m^{-3}.

Dipping
Dilute to 10% with water and apply by automated dipping system at the following retentions:
-Use class 1 and 2 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 10g/m^2

Deluge/ Enclosed Spray
Dilute to 10-20% with water and apply by enclosed spray/ deluge system at the following retentions:
-Use class 1 and 2 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 10g/m^2 concentrate.

An anti-foam will be required for double-vacuum, high pressure and spray applications. It may not be required for dipping. A silicon antifoam should be used at between 0.005-0.025% (depending on the solution strength).

1.1.4 Active Substance Details

Permethrin and penflufen are not considered to be candidates for substitution or exclusion in accordance with Articles 10 and 5 respectively of the BPR (EU) Regulation 528/2012. Therefore, this product has not been subject to a comparative assessment and the product can be authorised for a maximum of 10 years.

1.2 NECESSARY ISSUES ACCOUNTED FOR IN THE PRODUCT LABEL

For the prevention against larvae of house longhorn beetle (Hylotrupes bajulus) and brown rotting fungi
For industrial use only.
For double vacuum or vacuum pressure treatment of wood in use classes 1 2 and 3
For dipping or deluge/Enclosed spray treatment of wood in use classes 1 and 2.

All vacuum-pressure impregnation, double-vacuum, dipping and deluge treatment must only be undertaken at industrial sites where:

- Application processes are 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).
  Freshly treated timber shall be stored after treatment under shelter AND on impermeable hard standing to prevent losses to soil, sewer, or water, and that any losses from the application of the product shall be collected for reuse or disposal.

- Treated timber must not be placed over/near surface water bodies

For use only in wood in Use Class 1 (situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting) or Use Class 2 (situation in which the wood or wood-based product is under cover and fully protected from the weather but occasional, non-persistent, wetting may occur. This can include outdoor placement of timber under a roof to prevent any exposure to rain and driven rain), Use Class 3 (situation in which the wood or wood-based product is not covered and not in contact with the ground. It is either continuously exposed to weather or protected from the weather but subject to frequent wetting).

The following PPE requirements are appropriate for industrial users for the different types of treatment of Vacsol Aqua 6118:

- Automated dipping - impermeable coveralls and new gloves every cycle
- Deluge / Enclosed spray treatment - coated coveralls and new gloves every cycle
- Double vacuum pressure treatment - coated coveralls and new gloves every cycle
- Vacuum pressure treatment - gloves

1.3 REQUIREMENT FOR FURTHER INFORMATION

The following data are required post authorisation within 3 years:

- Validation data or other evidence to confirm the availability of a chiral method of analysis that enables the quantitation of all four permethrin isomers (1R-cis, 1R-trans, 1S-cis, and 1S-trans) in soluble concentrate formulations.
- Data must be provided to demonstrate the frozen storage stability of 2-PE in leachate samples over 23 months.
- Data must be provided to demonstrate the frozen storage stability of Dimethyl myristyl amine, distilled in leachate samples over 23 months.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
Vacsol Aqua 6118	SE

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Lonza Cologne GmbH
	Address	Nattermannallee 1, 50829, Koln, Germany
Authorisation number	5637	
Date of the authorisation	2020-10-21	
Expiry date of the authorisation	2025-10-20	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Arch Timber Protection Ltd (A Lonza Company)
Address of manufacturer	Wheldon Road WF10 2JT, Castleford, United Kingdom
Location of manufacturing sites	Leeds Road HD2 1YU, Huddersfield, United Kingdom

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

Active substance	Penflufen
Name of manufacturer	Lanxess Deutschland GmbH
Address of manufacturer	Kennedyplatz 1 50569 Köln, Deutschland
Location of manufacturing sites	Bayer AG Alte Heerstr., 41538 Dormagen, Germany

Active substance	Permethrin
Name of manufacturer	Tagros Chemicals India Limited
Address of manufacturer	Jhaver Centre, IV Floor, Rajha Annamalai Building, No. 72, Marshalls Road, Egmore, Chennai - 600 008, India
Location of manufacturing sites	Tagros Chemicals India Limited A4 / 1 & 2 Sipcot Industrial Complex, Pachayankuppam, 607 005, Cuddalore, Tamil Nadu, India

Active substance	Permethrin

Name of manufacturer	Lanxess Deutschland GmbH
Address of manufacturer	Kennedyplatz 1
Location of manufacturing sites	Bayer Vapi Private Limited. Plot # 306/3 II Phase, GIDC, Vapi – 396 195 Gujarat, India

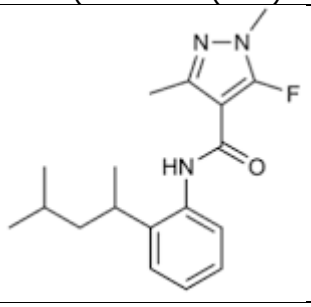
2.1.2 Product (family) composition and formulation

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

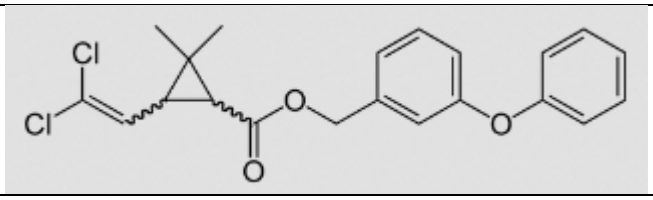
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Penflufen
IUPAC or EC name	5-Fluoro-1,3-dimethyl-N-{2-[(2RS)-4-methylpentan-2-yl]phenyl}-1H-pyrazole-4-carboxamide
EC number	619-823-7
CAS number	494793-67-8
Index number in Annex VI of CLP	N/A
Minimum purity / content	98% (1:1 ratio (R:S) ratio of enantiomers)
Structural formula	

Main constituent(s)	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)- 2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	93% w/w sum of all permethrin isomers. Total cis range: 25 – 28% ratio Total trans range: 72-75% ratio 1Rcis range: 7.9 – 8.3% w/w 1Scis range: 15.8 – 16.7% w/w 1Rtrans range: 45.4 – 46.1% w/w 1Strans range: 22.5 – 23.0 % w/w

Structural formula	

2.1.2.2 Candidate(s) for substitution

The actives are not considered as a candidate for substitution.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Penflufen	5-Fluoro-1,3-dimethyl-N-[2-(4-methylpentan-2-yl)phenyl]pyrazole-4-carboxamide	Active substance	494793-67-8	-	0.38 (pure 0.375)
Permethrin	3-Phenoxybenzyl (1RS,3RS;1RS,3SR)-3(2,2 dichlorovinyl)-2,2dimethyl - cyclopropane carboxylate	Active substance	52645-53-1	258-067-9	0.40 (pure 0.375)
Dimethyl myristyl amine, distilled; [N,N-dimethyl-C12-16-(even numbered)-alkyl-1-amines	Dimethyl myristyl amine, distilled; [N,N-dimethyl-C12-16-(even numbered)-alkyl-1-amines	Surfactant	68439-70-3	270-414-6	<4.80
Diethylene glycol monophenyl ether	2-(2-phenoxyethoxy) ethanol	Solvent	104-68-7	203-227-5	<1.92
Ethoxylated iso-tridecanol	Ethoxylated iso-tridecanol	Surfactant	69011-36-5	500-241-6	<3.00
2-Phenoxyethanol	2-Phenoxyethanol	Solvent	122-99-6	204-589-7	<3.84
Confidential	Confidential	Non-active substance	Confidential	Confidential	Up to 100

The full formulation composition details are contained within the Confidential Annex.

2.1.2.4 Information on technical equivalence

The notified source of Penflufen (Lanxess Deutschland GmbH) is the same as that considered in the Assessment Report for the active substance approval.

The notified sources of Permethrin (Caldic Denmark, acting for Tagros Chemicals and Bayer SAS) are the same as that considered in the Assessment Report for the active substance approval.

The notified source of Permethrin (Lanxess Deutschland GmbH) is the same as that considered in the Assessment Report for the active substance approval.

2.1.2.5 Information on the substance(s) of concern

Please see section 2.1.2.3 and the Confidential annex for further details.

2.1.2.5.1 Assessment of endocrine disruption (ED) properties

None of the active substances in Vacsol Aqua 6118 have indications on potential endocrine disruption (ED) properties. An assessment of ED properties for non-active co-formulants in the product is included in the Confidential annex. None of the co-formulants have indications on ED properties.

2.1.2.6 Type of formulation

Soluble Concentrate (SL)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Skin corrosion/irritation: - Category 2 Serious eye damage/eye irritation: - Category 1 Aquatic Acute 1 Aquatic Chronic 2
Hazard statement	H315 - Causes skin irritation H318 - Causes serious eye damage H400 -Very toxic to aquatic life H411 -Toxic to aquatic life with long lasting effects
Labelling	
GHS09 pictogram	
Signal words	Danger
Hazard statements	H315 - Causes skin irritation H318 - Causes serious eye damage H400 -Very toxic to aquatic life H411 -Toxic to aquatic life with long lasting effects
Precautionary statements	P264 - Wash hands and skin thoroughly after handling. P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection. P302 + P352 - IF ON SKIN: Wash with plenty of water and soap. P332 + P313 - If skin irritation occurs: Get medical advice. P362 + P364 - Take off contaminated clothing and wash it before reuse. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER/doctor. P273 Avoid release to the environment P391 'Collect Spillage' P501 'Dispose of contents/ container to ...' (in accordance with local/ regional/ national/ international regulation - to be specified)'
Note	**EUH208 - Contains permethrin. May produce an allergic reaction.**

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Industrial preventative treatment

Product Type	PT08 (Wood preservative)
Where relevant, an exact description of the authorised use	Fungicide Insecticide
Target organism (including development stage)	Hylotrupes bajulus – House longhorn beetle - Larvae Basidiomycetes – Brown rot fungi - Hyphae
Field of use	Indoor Indoor application of the wood preservative. Vacsol Aqua 6118 is a preventative wood preservative treatment against larvae of the house longhorn beetle (Hylotrupes bajulus) and brown rot fungi. The intended uses for Vacsol Aqua 6118 are applications of: Double vacuum and vacuum pressure application- Preventative treatment of wood and constructional timbers (all categories) in Use Classes 1, 2 & 3 and Dipping- Deluge/enclosed Spray - Preventative treatment of wood and constructional timbers (all categories) in Use Classes 1 & 2 The product can be applied to both softwood and hardwood. 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 fully protected from the weather but occasional, non-persistent, wetting may occur. This can include outdoor placement of timber under a roof to prevent any exposure to rain and driven rain). Use Class 3 (situation in which the wood or wood-based product is not covered and not in contact with the ground. It is either continuously exposed to weather or protected from the weather but subject to frequent wetting).
Application method(s)	Closed system: Double vacuum Closed system: Vacuum pressure Open system: Industrial dipping Spraying: Deluge/enclosed Spray
Application rate(s) and frequency	Double vacuum (low pressure)

	3.7 – 4.65 kg m-3. - Dilution 1.50 to 5% - One application before timber is placed into service. Vacuum pressure (high pressure) 3.7 – 4.65 kg m-3 - Dilution 0.62 to 1.25% - One application before timber is placed into service. Industrial dipping 10 g m-2 - Dilution 10% - One application before timber is placed into service. Deluge/ enclosed Spray 10 g m-2 - Dilution 10-20% - One application before timber is placed into service.
Category(ies) of users	Industrial
Pack sizes and packaging material	HDPE IBC (1000 L) HDPE IBC (640L) HDPE Poly Keg (25L)

2.1.4.2 Use-specific instructions for use – Use #1. Industrial preventative treatment

See Section 2.1.5.1

2.1.4.3 Use-specific risk mitigation measures Use #1. Industrial preventative treatment

See Section 2.1.5.2

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment Use #1. Industrial preventative treatment

See Section 2.1.5.3

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging Use #1. Industrial preventative treatment

See Section 2.1.5.4

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage Use #1. Industrial preventative treatment

See Section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

For industrial use only.

For the prevention of brown rotting fungi and larvae of house longhorn beetle (Hylotrupes bajulus).

The product is supplied as a concentrate to be applied to timber by vacuum pressure, double vacuum, dipping or enclosed deluge spray system after dilution with water.

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).

The IBC containing the Vacsol Aqua 6118 is connected via a bottom locking run off valve directly to the treatment plant system. With the aid of automatic dosage equipment, concentrate is pumped from the IBC to the mixing tank or storage tank, along with the exact amount of water needed to make the relevant volume of treatment solution. The storage tank is topped up as required. This could be done with a smaller volume (25 L container).

For double vacuum and vacuum pressure treatment, the diluted ready to use product is pumped into the impregnation cylinder to carry out the desired treatment.

For enclosed deluge systems the diluted ready to use product is applied in an enclosed chamber by means of flow coat or automatic spraying. Timber enters and exits the system on a conveyor with no manual handling.

Dipping is conducted only in industrial dip plants with no manual dipping, i.e. all wood is mechanically handled during the process.

An anti-foam will be required for double-vacuum, high pressure and spray applications. It may not be required for dipping. A silicon antifoam should be used at between 0.005-0.025% (depending on the solution strength).

The product should be diluted with water and applied at a retention rate as follows: -

Expressed as kgm-3 as concentrate in the analytical zone.

Double vacuum (low pressure)

Dilute to 1.5 to 5%:

-Use class 1 and 2 Retentions: 3.7 – 4.65 kg m^{-3}.

Vacuum Pressure (high pressure)

Dilute to 0.62 to 1.25% with water and apply by vacuum pressure at the following retentions:

-Use class 3 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 3.7 – 4.65 kg m^{-3}.

Dipping

Dilute to 10%.

-Use class 1 and 2 Retentions: 10g/m^2

Deluge/ enclosed Spray Dilute to 20% -Use class 1 and 2 Retentions (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 10g/m^2

2.1.5.2 Risk mitigation measures

All vacuum-pressure impregnation, double-vacuum, dipping and deluge treatment must only be undertaken at industrial sites where:

- Application processes are 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.
- Do not apply near bodies of surface water or in the area of water protection zones. [where relevant provide for appropriate distance stipulations]
  Freshly treated timber shall be stored after treatment under shelter AND on impermeable hard standing to prevent losses to soil, sewer, or water, and that any losses from the application of the product shall be collected for reuse or disposal.
- Treated timber must not be placed over/near surface water bodies

The following phrases must appear on the label:

- Wear protective chemical resistant gloves* (glove material to be specified by the authorisation holder within the product information).
  *new gloves must be worn at the start of each treatment cycle

- A protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information)

- The use of eye protection during handling of the product is mandatory

The following PPE requirements are appropriate for industrial users for the different types of treatment of Vacsol Aqua 6118:

- Automated dipping - impermeable coveralls and new gloves every cycle
- Deluge / enclosed spray treatment - coated coveralls and new gloves every cycle
- Double vacuum pressure treatment - coated coveralls and new gloves every cycle
- Vacuum pressure treatment - gloves

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with soap and water. If skin irritation or rash occur: Get medical advice.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Environmental precautions: Shut off source of leak if safe to do so. If spillage occurs at a timber treatment plant site, follow on site emergency procedures. If contamination of drainage systems or water course occurs, immediately inform appropriate authorities.

Clean-up methods: Recover the product where possible. Absorb spillage in earth or sand. Place in an appropriate container. Seal containers and label them. Remove contaminated material to safe location for subsequent disposal.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Rinse empty container with water and reuse water in treatment process.

Containers (IBCs) should be returned to the supplier for recycling. If this is not possible the container should be disposed of via an authorised waste disposal company in accordance with national legislation.

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

Shelf life of 2 years

2.1.6 Other information

Through their customer service activities and in their literature for treated wood, the authorization holder should inform about the restrictions of the treated wood, i.e. that the product should **not** be used:

- for treatment of timber placed over/near surface water bodies

The mixture contains 2.06% components with unknown acute oral toxicity, 26.75% components with unknown acute inhalation toxicity and 19.27% components with unknown acute dermal toxicity.

Content of the substances of concern (SoC), worst case:
Dimethyl myristyl amine, distilled; [N,N-dimethyl-C12-16-(even numbered)-alkyl-1-amines: < 4.80%
Diethylene glycol monophenyl ether: < 1.92%
Ethoxylated iso-tridecanol: < 3.00%
2-Phenoxyethanol: < 3.84%

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
IBC	640 L, 1000 L	HDPE	Standard	Specialised professional (industrial)	Yes
Poly Keg	25 L	HDPE	Standard	Specialised professional (industrial)	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substances have been submitted as part of this application. Please see Annex 3.1 for the list of studies used to support the product.

2.1.8.2 Access to documentation

The applicant Lonza Cologne GmbH has access to all submitted studies listed in Annex 3.1

Penflufen

Reference is made in this submission to the active substance data package owned by the supplier Lanxess Deutschland GmbH. The Letter of Access from Lanxess Deutschland GmbH has been provided, giving the right to access to the Penflufen data in the PT8 active substance dossier for the Vacsol Aqua 6118 application.

Permethrin

Letters of Access from Janssen PMP and Lanxess have been provided, giving Lonza Cologne GmbH the right to access to the Permethrin data in the PT8 active substance dossier for the Vacsol Aqua 6118 application.

2.2 Assessment of the biocidal product (family)

2.2.1 Physical, chemical and technical properties

Vacsol Aqua 6118 is a soluble concentrate (SL) formulation and was not the representative formulation considered for BPR inclusion for either of the two active substances. The physical, chemical and storage stability data submitted to support the biocidal product are summarised in the following table.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA Comments
Physical state at 20 °C and 101.3 kPa	OPPTS 830-6303	Vacsol Aqua 6118	Slightly yellowish clear liquid	IUCLID 3.4 Study No:	Acceptable
Colour at 20 °C and 101.3 kPa	OPPTS 830-6302	Vacsol Aqua 6118	RAL 1013 Oyster white	IUCLID 3.4 Study No:	Acceptable
Odour at 20 °C and 101.3 kPa	OPPTS 830-6304	Vacsol Aqua 6118	Sweetish	IUCLID 3.4 Study No:	Acceptable
Acidity / alkalinity	CIPAC MT 191	Vacsol Aqua 6118	Not performed as the pH value lay in range of 4 – 10	IUCLID 3.4 Study No:	Acceptable
pH	CIPAC MT 75.3	Vacsol Aqua 6118	pH (1 % dilution): 6.42 pH (neat): 6.92	IUCLID 3.4 Study No:	Acceptable
Relative density / bulk density	OECD 109 resp. EU A.3	Vacsol Aqua 6118	1.0171		Acceptable
Storage stability test – **accelerated storage for 14 days at 54 °C**	CIPAC MT 46.3	Vacsol Aqua 6118	**Parameter** / **Time (days)**: **0** / **14** Physical state: yellow liquid / yellow liquid Odour: sweetish / sweetish	IUCLID 3.4 Study No:	Acceptable. The product was stable following accelerated storage. Following storage, the active

<table>
<tr>
<td></td>
<td>OPPTS 830-6302, -6304

CIPAC MT 75.3

CIPAC MT 41

GC-FID</td>
<td></td>
<td>
<table>
<tr><td>Colour</td><td>RAL 1013</td><td>RAL 1013</td></tr>
<tr><td>pH (1%)</td><td>6.42</td><td>6.27</td></tr>
<tr><td>pH (neat)</td><td>6.92</td><td>6.83</td></tr>
<tr><td>Dilution stability (27% in water)</td><td>no separation</td><td>no separation</td></tr>
<tr><td>Penflufen content</td><td>0.363%</td><td>0.356%</td></tr>
<tr><td>Permethrin content</td><td>0.368%</td><td>0.384%</td></tr>
</table>

900 mL of test item was stored in a HDPE bottle for 14 days at 54 °C. No changes or deterioration of the packaging was observed following storage.
</td>
<td></td>
<td>substance contents were within the tolerance limits as specified in BPR Guidance (May 2018). The GC-FID analytical method has been acceptably validated in Study No: (see section 2.2.4 below).</td>
</tr>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>CIPAC MT 46.3

OPPTS 830-6302, -6304

CIPAC MT 75.3

CIPAC MT 41

GC-FID</td>
<td>Vacsol Aqua 6118</td>
<td>
<table>
<tr><th rowspan="2">Parameter</th><th colspan="2">Time (months)</th></tr>
<tr><th>0</th><th>24</th></tr>
<tr><td>Physical state</td><td>yellow liquid</td><td>yellow liquid</td></tr>
<tr><td>Odour</td><td>sweetish</td><td>sweetish</td></tr>
<tr><td>Colour</td><td>RAL 1013</td><td>RAL 1013</td></tr>
<tr><td>pH (1%)</td><td>6.42</td><td>6.24</td></tr>
<tr><td>pH (neat)</td><td>6.92</td><td>6.79</td></tr>
<tr><td>Dilution stability (27% in water)</td><td>no separation</td><td>no separation</td></tr>
<tr><td>Penflufen content</td><td>0.363%</td><td>0.369%</td></tr>
<tr><td>Permethrin content</td><td>0.368%</td><td>0.370%</td></tr>
</table>
</td>
<td></td>
<td>Acceptable.
The product was stable following ambient temperature storage. Following storage, the active substance contents were within the tolerance limits as specified in BPR Guidance (May 2018). The GC-FID analytical method has been acceptably validated in Study No: (see section 2.2.4 below).</td>
</tr>
</table>

			The test item was stored in a HDPE bottle for 24 months at 20 ± 2 °C. No changes or deterioration of the packaging was observed following storage.		
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Vacsol Aqua 6118	No additional phases or separated material were observed after the storage of the test item for 7 days at -0.4 ± 0.2 °C.	IUCLID 3.4 Study	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Waiver	-	Products are in opaque packaging, therefore light is not expected to have any detrimental effect on the products.	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	Vacsol Aqua 6118	Accelerated storage stability tests indicate that detrimental effects are not expected as a result of temperature or humidity.	IUCLID 3.4 Study No:	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	Vacsol Aqua 6118	See accelerated storage results.	IUCLID 3.4 Study No:	Acceptable
Wettability	-	-	-	-	Not relevant for SL formulation.
Suspensibility, spontaneity and dispersion stability	-	-	-	-	Not relevant for SL formulation.
Wet sieve analysis and dry sieve test	-	-	-	-	Not relevant for SL formulation.

Emulsifiability, re-emulsifiability and emulsion stability	-	-	-	-	Not relevant for SL formulation.
Disintegration time	-	-	-	-	Not relevant for SL formulation.
Particle size distribution, content of dust/fines, attrition, friability	-	-	-	-	Not relevant for SL formulation.
Persistent foaming	CIPAC MT 47	27% dilution in water + 0.005% defoamer	0 mL foam after 1 minute for a 27 % dilution in water with 0.005% defoamer added. Mean (n=2) 96.5 mL foam after 1 minute for a 27 % dilution in water with no defoamer added. Applicant noted that 27 % was the initial planned maximum in-use concentration, this was later changed to 20 %. An additional study confirmed that the initial foam generation is consistent across all dilutions, with the slowest foam decay rate observed at the highest concentration tested (27 %):	IUCLID 4.17 Study No:	Acceptable. The applicant has confirmed that use of an antifoaming agent will be recommended to customers where necessary. Based on previous experience, the anti-foam will be required for double-vacuum, high pressure and spray applications. It may not be required for dipping. A silicon antifoam should be used at between 0.005-0.025% (depending on the solution strength).

<table>
<tr><td></td><td></td><td></td><td>
Table 1: Foam decay rate without Antifoam
<table>
<tr><th rowspan="2">Time point</th><th colspan="2">0.6% w/v</th><th colspan="2">10% w/v</th><th colspan="2">20% w/v</th><th colspan="2">27% w/v</th><th colspan="2">External test house results (27% w/v)</th></tr>
<tr><th>Average foam Volume (ml)</th><th>Foam decrease in %</th><th>Average foam Volume (ml)</th><th>Foam decrease in %</th><th>Average foam Volume (ml)</th><th>Foam decrease in %</th><th>Average foam Volume (ml)</th><th>Foam decrease in %</th><th>Average foam Volume (ml)</th><th>Foam decrease in %</th></tr>
<tr><td>0 sec</td><td>114</td><td>-</td><td>118</td><td>-</td><td>112</td><td>-</td><td>111</td><td>-</td><td>97.5</td><td>-</td></tr>
<tr><td>10 sec</td><td>102</td><td>11</td><td>96</td><td>19</td><td>100</td><td>11</td><td>103</td><td>7</td><td>97.5</td><td>0</td></tr>
<tr><td>1 min</td><td>65</td><td>43</td><td>12</td><td>90</td><td>12</td><td>89</td><td>85</td><td>23</td><td>96.5</td><td>1</td></tr>
<tr><td>3 min</td><td>21</td><td>82</td><td>2</td><td>98</td><td>0</td><td>100</td><td>63</td><td>43</td><td>62.5</td><td>36</td></tr>
<tr><td>12 min</td><td>8</td><td>93</td><td>0</td><td>100</td><td>0</td><td>100</td><td>28</td><td>75</td><td>13.5</td><td>86</td></tr>
</table>
Table 2: Foam decay rate with Antifoam
<table>
<tr><th rowspan="2">Time point</th><th colspan="2">0.6% w/v</th><th colspan="2">10% w/v</th><th colspan="2">20% w/v</th><th colspan="2">27% w/v</th><th colspan="2">External test house results (27% w/v)</th></tr>
<tr><th>Average foam Volume (ml)</th><th>Foam decrease in %</th><th>Average foam Volume (ml)</th><th>Foam decrease in %</th><th>Average foam Volume (ml)</th><th>Foam decrease in %</th><th>Average foam Volume (ml)</th><th>Foam decrease in %</th><th>Average foam Volume (ml)</th><th>Foam decrease in %</th></tr>
<tr><td>0 sec</td><td>47</td><td>-</td><td>76</td><td>-</td><td>55</td><td>-</td><td>62</td><td>-</td><td>47</td><td>-</td></tr>
<tr><td>10 sec</td><td>19</td><td>83</td><td>63</td><td>47</td><td>39</td><td>65</td><td>45</td><td>59</td><td>47</td><td>52</td></tr>
<tr><td>1 min</td><td>0</td><td>100</td><td>0</td><td>100</td><td>0</td><td>100</td><td>0</td><td>100</td><td>0</td><td>100</td></tr>
<tr><td>3 min</td><td>0</td><td>100</td><td>0</td><td>100</td><td>0</td><td>100</td><td>0</td><td>100</td><td>0</td><td>100</td></tr>
<tr><td>12 min</td><td>0</td><td>100</td><td>0</td><td>100</td><td>0</td><td>100</td><td>0</td><td>100</td><td>0</td><td>100</td></tr>
</table>
CONFIDENTIAL
</td><td></td><td></td></tr>
<tr><td>Flowability/Pourability/Dustability</td><td>-</td><td>-</td><td>-</td><td>-</td><td>Not relevant for SL formulation.</td></tr>
<tr><td>Burning rate — smoke generators</td><td>-</td><td>-</td><td>-</td><td>-</td><td>Not relevant for SL formulation.</td></tr>
<tr><td>Burning completeness — smoke generators</td><td>-</td><td>-</td><td>-</td><td>-</td><td>Not relevant for SL formulation.</td></tr>
<tr><td>Composition of smoke — smoke generators</td><td>-</td><td>-</td><td>-</td><td>-</td><td>Not relevant for SL formulation.</td></tr>
<tr><td>Spraying pattern — aerosols</td><td>-</td><td>-</td><td>-</td><td>-</td><td>Not relevant for SL formulation.</td></tr>
<tr><td>Physical compatibility</td><td>Waiver</td><td>-</td><td>No claims of compatibility are made on the label.</td><td>-</td><td>Acceptable</td></tr>
<tr><td>Chemical compatibility</td><td>Waiver</td><td>-</td><td>No claims of compatibility are made on the label.</td><td>-</td><td>Acceptable</td></tr>
<tr><td>Degree of dissolution and dilution stability</td><td>CIPAC MT 41</td><td>Vacsol Aqua 6118 (27%)</td><td>No separation material or phases were observed in the test solution.</td><td>IUCLID 3.4 Study No:</td><td>Acceptable. Noted that the test concentration used is slightly above the maximum in use</td></tr>
</table>

					concentration specified on the label.
Surface tension	OECD 115 EU A.5	Vacsol Aqua 6118	32.18 - 32.54 mN/m Product can be classified as surface active	IUCLID 3.8 Study No:	Acceptable
Viscosity	OECD 114 / DIN 53015	Vacsol Aqua 6118	48.405 ± 0.183 mPa·s at 20.0 °C (47591 mm^2/s) and 16.742 ± 0.038 mPa·s at 40.0 °C (16460 mm^2/s)	IUCLID 3.9 Study No:	Acceptable. Classification as an aspiration hazard is not required.

Conclusion on the physical, chemical and technical properties of the product
The physical, chemical and technical properties of Vacsol Aqua 6118 are acceptable for soluble concentrate (SL) formulations. The storage stability studies for 2 weeks at 54 °C, 24 months at 20 °C and 7 days at -0.4 °C are acceptable in commercial packaging.

2.2.2 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA Comments
Explosives	Case	-	Test item does not contain any compounds (at > 1 %w/w) with any structures or groups associated with explosive properties.	IUCLID 4.1 Expert Statement	Acceptable
Flammable gases	-	-	-	-	Not relevant for SL formulation.
Flammable aerosols	-	-	-	-	Not relevant for SL formulation.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA Comments
Oxidising gases	-	-	-	-	Not relevant for SL formulation.
Gases under pressure	-	-	-	-	Not relevant for SL formulation.
Flammable liquids	Case	-	A liquid is considered flammable if the Flashpoint is not more than 60 °C. Vacsol Aqua 6118 is a water-based product containing 72.4% water in the concentrate (>95% for the dilute) with other co-formulants. All co-formulants in Vacsol Aqua 6118 have flash points in excess of 1000 °C. Based on this evidence the formulated product flash point will be higher than 60 °C and therefore Vacsol Aqua 6118 is not classified as a Flammable liquid.	IUCLID 4.2	Acceptable
Flammable solids	-	-	-	-	Not relevant for SL formulation.
Self-reactive substances and mixtures	Waiver	-	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.	IUCLID 4.8	Acceptable
Pyrophoric liquids	-	-	-	-	Product is an aqueous solution and will not auto-ignite
Pyrophoric solids	-	-	-	-	Not relevant for SL formulation.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA Comments
Self-heating substances and mixtures	-	-	-	-	Not relevant for SL formulation.
Substances and mixtures which in contact with water emit flammable gases	Case	-	The study does not need to be conducted because the substance is known to be soluble in water to form a stable mixture.	IUCLID 4.2	Acceptable - product is a water-based soluble concentrate.
Oxidising liquids	Case	-	Test item does not contain any compounds with any structures or groups associated with oxidising properties.	IUCLID 4.4 Expert Statement	Acceptable
Oxidising solids	-	-	-	-	Not relevant for SL formulation.
Organic peroxides	Waiver	-	The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	IUCLID 4.15	Acceptable
Corrosive to metals	Waiver	-	In the submitted dossier, study #17041003G978 reports that Vacsol Aqua 6118 had a pH of between 6.27-6.92, for both concentrate and dilute solutions. Since the pH recorded was >4 and <10, it falls outside the range of acidity and alkalinity normally associated with corrosivity. The pH is actually close to neutral as was the intention to avoid the product being corrosive.	IUCLID 4.16	Acceptable. Product is pH neutral, is used as a dilute aqueous solution, , does not contain any substances that have the characteristics to form complexes with metals, with no deterioration of packaging observed during the accelerated storage test.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA Comments
			Vacsol Aqua 6118 contains a negligible amount of chlorine from permethrin which is highly unlikely to cause any issue. Vacsol Aqua 6118 does not contain any substances that have the characteristics to form complexes with metals and mixtures containing such substances. UKCA has advised that a waiver solely based on lacking substances classified as corrosive to metals is not acceptable. We appreciate the reasoning based on the complexity of metal corrosivity, however Vacsol Aqua 6118 is a relatively simple mixture and has been formulated to not be corrosive to metals. Lonza has long experience of developing such products and there is no reason based on the development work and the final formulation to consider that the product will be corrosive. In addition the product is supplied as a concentrate but only used when significantly diluted in water. The strongest solution strength applied for is 20% for enclosed spray applications. So, this solution would have 14.5%		

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA Comments
			water from the concentrate plus the added 80% water used for dilution making even the strongest solution almost 95% water. Dilutions used for low- and high-pressure impregnation treatments would have even more water. These heavily diluted aqueous solutions are not likely to have metal corrosivity properties. Taking the various points into account, Vacsol Aqua 6118 should not be considered for classification as corrosive to metals and no further testing is required.		
Auto-ignition temperatures of products (liquids and gases)	Waiver	-	Vacsol Aqua 6118 is formulated, transported, and stored at ambient temperatures. Vacsol Aqua 6118 concentrate contains no volatile substances and is approximately 70% water. In use it is further diluted in water such that at the maximum employed solution strength the solution is 95% water. There is no possibility in normal use that the product or the diluted solution will contact hot surfaces. Even if it were to contact a hot surface, the nature	IUCLID 4.17	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA Comments
			of the water-based formulation will mean it will not ignite. Further to this, section 4.17.1 of the guidance directs the reader to Reach Guidance Chapter R.7a, section R.7.1.12.1. The Reach Guidance directs that the study does not need to be conducted: …….for liquids non-flammable in air, e.g. no flash point up to 200°C. The CLP legislation, however, defines a flammable liquid as a liquid having a flash point of not more than 60°C. According to the CLP legislation, there are no flammable liquids in the formulation. There are, however, three components with flash points < 200°C, but these are all well in excess of the CLP definition of flammable (the lowest of these is 128°C). Together these liquids make up only approximately 10% of the concentrate formulation. In the diluted solution they represent less than 2% of the total, even at the highest solution strength. None of these components are volatile and each has a boiling point well in excess of water.		

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA Comments
			Vacsol Aqua 6118 will not auto-ignite and no testing is required.		
Relative self-ignition temperature for solids	-	-	-	-	Not relevant for SL formulation.
Dust explosion hazard	-	-	-	-	Not relevant for SL formulation.

Conclusion on the physical hazards and respective characteristics of the product
No classification is required from a chemistry perspective for the biocidal product Vacsol Aqua 6118.

2.2.3 Methods for detection and identification

Analytical methods for the active and impurities in the technical material

The sources of the active substances are the same as those considered for BPR inclusion, therefore methods of analysis for the active substance and impurities have already been considered. No further consideration is required from a chemistry perspective.

Analytical methods for the active substance in the biocidal product

Study Code:
Title: Validation of an Analytical Method using GC/FID for the determination of Penflufen and Permethrin in the test item VACSOL AQUA 6118

A GC/FID method for the determination of penflufen and permethrin in the biocidal product VACSOL AQUA 6118 was validated. The reference items were separated with a ZB-5 (30 m x 0.25 mm x 0.25 µm) column. For linear calibration, a dilution series in THF was prepared, using a stock solution. For the determination of penflufen and permethrin in the test item, 100 ± 5 mg test item (or blank matrix) were weighed into a 5 mL measuring flask and the flask was filled up to 5 mL with THF after addition of 250 µL ISTD stock solution (1000 mg/L in THF) resulting in a nominal concentration of the test item 20 g/L.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues							
Analyte	**Method**	**Linearity**	**LOQ**	**Recovery rate (%)***			**Specificity**
				Fortification level	**Range [mean, n]**	**Repeatability (% RSD)**	
Penflufen	GC/FID	5.00 – 100 mg/L (6 – 133 % nominal content) n = 5 x 2 r = 0.9999	70 mg/L (0.34 %)	70 mg/L (0.34 %)	92.8 - 96.0 [94.5, n=2]	0.8 (n=5) acceptable Horwitz %RSD = 3.12	Spectra of the blank, standard solutions and test solutions were provided showing <3 % interference
Permethrin	GC/FID	10 - 250 mg/L (50 – 250 % nominal content) n = 10 r = 0.9998	72 mg/L (0.35 %)	72 mg/L (0.35 %)	92.6 - 96.9 [95.8, n = 2]	1.72 (n=5) acceptable Horwitz %RSD = 3.12	Spectra of the blank, standard solutions and test solutions were provided showing <3 % interference

*As initial recovery results were below 95 % (mean recoveries of 76 - 91%), the determination was repeated with addition of methanol (> 200 µL) or THF to the test solutions in order to improve the dissolution of penflufen and permethrin in the blank matrix.

The mean recovery for penflufen was 94.5 %, i.e. slightly below the acceptable range of 95 - 105 % for a nominal active substance content of <1 %. Nevertheless, the method can be considered satisfactorily validated in accordance with the ECHA BPR Guidance (May 2018) and the EU guidance document SANCO/3030/99 rev. 4.

Chiral methods of analysis

The CAR states a validated chiral method of analysis for the permethrin enantiomers in the product formulation is required. This has not been provided for the biocidal product Vacsol Aqua 6118 and will be set as a post-authorisation data requirement.

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Methods of analysis for the determination of permethrin residues in air, soil and water have previously been evaluated at EU level and accepted for active substance approval. Methods for detection in body fluids and tissues are not required as the active substance is not considered toxic or highly toxic. Methods for detection in food/feed of plant and animal origin are not required due to lack of exposure *via* the intended uses.

Methods of analysis for the determination of penflufen residues in soil, air and water have previously been evaluated at EU level and accepted for active substance approval. Methods for detection in body fluids and tissues are not required as the active substance is not considered toxic or highly toxic. Methods for detection in food/feed of plant and animal origin are not required due to lack of exposure *via* the intended uses.

Conclusion on the methods for detection and identification of the product
The analytical method for the determination of permethrin and penflufen in the biocidal product family are acceptable. Data or waivers are required to meet the data requirement for a validated chiral method of analysis for the permethrin enantiomers in the product formulation. These have not been provided and therefore will be set as a post-authorisation data requirement. The analytical methods for the monitoring of residues have been either evaluated at EU level and accepted for BPR inclusion or are not relevant for the biocidal product 'Vacsol Aqua 6118'.

2.2.4 Efficacy against target organisms

2.2.4.1 Function and field of use

Vacsol Aqua 6118 is a wood preservative (PT 08) intended for preventive treatment of softwood and hardwood timbers. The product can be applied by either double vacuum and vacuum pressure application in use classes 1,2 and 3 or by dipping (deluge/enclosed spray) in use classes 1 and 2.

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

Vacsol Aqua 6118 is used as a preventative treatment to control wood brown rotting fungi and larvae of house longhorn beetle (Hylotrupes bajulus).

2.2.4.3 Effects on target organisms, including unacceptable suffering

The product Vacsol Aqua 6118 is for professional (industrial) use. It is supplied as a concentrate to be applied to timber by vacuum pressure, double vacuum, dipping or enclosed deluge after dilution with water.

The product is applied at the following rates:

Closed systems

- ***Double Vacuum (low pressure)*** - Dilute to 1.50 to 5% with water and apply by Double vacuum at the following retentions: Use class 1, 2 and 3 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 3.7 – 4.65 kg m-3.

- ***Vacuum Pressure (high pressure)*** - Dilute to 0.62 to 1.25% with water and apply by vacuum pressure at the following retentions: Use class 3 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 3.7 – 4.65 kg m-3.

Open systems

- ***Dipping*** - Dilute to 10% with water and apply by automated dipping system at the following retentions: Use class 1 and 2 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 10g/m2 concentrate.

- ***Deluge/ enclosed spray*** - Dilute to 20% with water and apply by enclosed spray/ deluge system at the following retentions: Use class 1 and 2 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 10g/m2 concentrate.

An anti-foam will be required for double-vacuum, high pressure and spray applications. It may not be required for dipping. A silicon antifoam should be used at between 0.005-0.025% (depending on the solution strength).

2.2.4.4 Mode of action, including time delay

Vacsol Aqua 6118 has both fungicidal and insecticidal effect.

The following information on the mode of action of the active substances has been taken from the respective PT8 Assessment Reports:

- ***Penflufen*** - Penflufen is an SDHI fungicide (Succinate dehydrogenase inhibitor). Its biochemical mode of action has been shown to rely on the inhibition of the enzyme succinate dehydrogenase (complex II) within the fungal mitochondrial respiratory chain, thus blocking electron transport.

- ***Permethrin*** - The target organisms ingest a small amount of the treated wood which, once ingested, results in death of the target pests. As an insecticide, Permethrin when formulated as a wood preservative, is an axonic poison, binding to protein in nerves (voltage-gated sodium channel). Normally, this protein opens causing stimulation of the nerve and closes to terminate the nerve signal. Pyrethroids bind to this gate and prevent it from closing normally which results in continuous nerve stimulation. Efficacy data on permethrin-based products indicates effects on different species at different exposure scenarios at a concentration range in product of 0.01 to 0.5%. Lethality (knockdown) is the only recognised effect, and in situ concentration-dependence of the effect has been demonstrated. However, the threshold concentration is species dependant. The toxic value for the cis-isomer is approximately 8 times lower than the trans-isomer, however different ratio isomer mixtures commercially available (typically 25:75 to 75:25) exhibit similar toxic values for wood-boring insects.

2.2.4.5 Efficacy data

Efficacy testing has been undertaken in accordance with European standard EN 599-1. The test substance in the efficacy tests is X10022. X10022 is technically equivalent to Vacsol Aqua 6118. Both actives are stated for X10022 being 0.375% pure, whereas the other figures (permethrin 0.400% and penflufen 0.3788%) refer to the assay used in the product Vacsol Aqua 6118, e.g. permethrin (93.7%) and penflufen (99%).

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and field of use envisaged	**Test substance**	**Test organism(s)**	**Test method/ Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Preventative treatment of timber by vacuum pressure, double vacuum dipping or enclosed deluge after dilution with water. Protection of timber in use classes 1, 2 and 3 against larvae of house longhorn beetle (Hylotrupes bajulus) and brown rotting fungi.	X10022 (Charge: 1579)	*Hylotrupes bajulus* (European house borer)	EN 46-1 with evaporative ageing according to EN 73. Tested on Scots pine (*Pinus sylvestris*). 100ml/m^2 product applied at 10% concentration. 1time brushing application.		
	X10022 (Charge: 1579)	*Hylotrupes bajulus* (European house borer)	EN 46-1 with leaching ageing according to EN 84. Tested on Scots pine (*Pinus sylvestris*). 100ml/m^2 product applied at 10% concentration. 1time brushing application.	.	
	X10022 (Charge: ReR1461 22.10.15)	*Hylotrupes bajulus* (European house borer)	EN 47 with evaporative ageing according to EN 73. Tested on Scots pine (*Pinus sylvestris*). Concentrations tested (% w/w): 0.00, 0.38, 0.46, 0.56, 0.65, 0.74.	.	
	X10022 (Charge:	*Hylotrupes bajulus* (European house borer)	EN 47 with leaching ageing according to EN 84. Tested on Scots pine (*Pinus sylvestris*).		

	ReR1461 22.10.15)		Concentrations tested (% w/w): 0.00, 0.38, 0.46, 0.56, 0.65, 0.74.		
	X10022 (Charge: ReR1461 22.10.15)	Wood destroying basidiomycetes (*Coniophora puteana, Poria placenta* and *Gloeophyllum trabeum*)	EN 113 with evaporative ageing according to EN 73. Tested on Scots pine (*Pinus sylvestris*). Concentrations tested (% w/w): 0.00, 0.37, 0.45, 0.55, 0.65, 0.73.		
	X10022 (Charge: ReR1461 22.10.15)	Wood destroying basidiomycetes (*Coniophora puteana, Poria placenta* and *Gloeophyllum trabeum*)	EN 113 with leaching ageing according to EN 84. Tested on Scots pine (*Pinus sylvestris*). Concentrations tested (% w/w): 0.00, 0.37, 0.45, 0.55, 0.65, 0.73.		

Conclusion on the efficacy of the product

The efficacy of Vacsol Aqua 6118 has been demonstrated by testing according to the requirements in EN 599-1 for a wood preservative to be used on softwood.

The product claim efficacy against larvae of house longhorn beetle (Hylotrupes bajulus) and brown rot fungi (Hyphae).

The product Vacsol Aqua 6118 can be applied in two ways:

- The first is application via double vacuum or vacuum pressure application as a preventative treatment of wood and construction timbers in use classes 1, 2 and 3 (softwood and hardwood).

- The second application is via dipping, deluge or enclosed spray as a preventative treatment of wood and construction timbers in use classes 1 and 2 (softwood and hardwood).

The applicant has provided tests addressing the requirements of EN 599 for claims against larvae of house longhorn beetle (Hylotrupes bajulus) and brown rot fungi, as summarised in the table below:

UC 1, 2 and 3 (pressure treatment processes)	*Hylotrupes bajulus*	EN 47 with evaporative ageing according to EN 73
UC 3 (pressure treatment processes)	*Hylotrupes bajulus*	EN 47 with leaching ageing according to EN 84
UC 2 & 3 (pressure and superficial treatment processes)	*Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta*	EN 113 with evaporative ageing according to EN 73
UC 3 (pressure and superficial treatment processes)	*Coniophora puteana* *Gloeophyllum trabeum* *Poria placenta*	EN 113 with leaching ageing according to EN 84
UC 1, 2 and 3 (superficial treatment processes)	*Hylotrupes bajulus*	EN 46-1 with evaporative ageing

		according to EN 73
UC 3 (superficial treatment processes)	*Hylotrupes bajulus*	EN 46-1 with leaching ageing according to EN 84

Acceptable efficacy has been shown for Vacsol Aqua 6118 at the stated application rates:

- Double Vacuum (low pressure) - Use class 1, 2 and 3 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 3.7 – 4.65 kg m-3.
- Vacuum Pressure (high pressure) - Use class 3 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 3.7 – 4.65 kg m-3.
- Dipping - Use class 1 and 2 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 10g/m2 concentrate.
- Deluge/ enclosed spray - Use class 1 and 2 (brown rotting fungi and house longhorn beetle [Hylotrupes bajulus]): 10g/m2 concentrate.

2.2.4.6 Occurrence of resistance and resistance management

The following information on the occurrence of resistance of the active substances has been taken from the respective PT8 Assessment Reports:

Penflufen - For penflufen the assessment report acknowledges that it is a novel substance for wood preservation so specific information is not available. However, the assessment report does not state any case of field resistance to SDHI fungicides. Furthermore, no data was found in the literature regarding resistance for penflufen as wood preservative.

Permethrin - There are no reported cases of development of resistance involving the use of permethrin in wood preservation. However, cases of resistance have been documented in a wide variety of insects when permethrin has been used as a general insecticide as documented for the PT18 use of permethrin. The level of resistance is less than tenfold in some of the species, but high levels of resistance have been observed such as in cockroaches. In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms. As such it is good practice that authorization holders and professional end-users report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management. 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.

2.2.4.7 Known limitations

No known limitations

2.2.4.8 Evaluation of the label claims

According to the data submitted the following claims are acceptable:

1. Preventative against larvae of house longhorn beetle (Hylotrupes bajulus) on general timber.
2. Preventative against brown rot fungi on general timber.

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

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

2.2.5 Risk assessment for human health

2.2.5.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Vacsol Aqua 6118 is classified for skin irritation category 2 (H315)
Justification for the value/conclusion	Specific test data on the formulation is not available, therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.2.3, Annex I: Table 3.2.3 was followed. The following component is classified for skin irritation/corrosion: Dimethyl myristyl amine (CAS 68439-70-3), 4.80%, skin corrosive/irritating cat 1B (H314) Therefore, the following formula was used: Skin corrosive category 1A, 1B or 1C = >5% for category 1 and >1% but < 5% for category 2 Skin corrosive category 1 = 4.80% Therefore, the substance should be classified for skin irritation category 2 and the co-formulant dimethyl myristyl amine is identified as a substance of concern, as it drives the classification. (A further co-formulant is classified for skin irritation cat 2 (H315) but does not contribute to the overall classification)
Classification of the product according to CLP	Skin irritation Category 2 (H315)

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Vacsol Aqua 6118 is classified for eye damage category 1 (H318)
Justification for the value/conclusion	Specific test data on the formulation is not available therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.3.3, Annex I: Table 3.3.3 was followed. Co-formulants with cat 1 eye damage classification: Diethylene glycol monophenyl ether (CAS 104-68-7), 1.92%, eye damage category 1 (H318) Ethoxylated iso-tridecanol (CAS 69011-36-5), 3.00%, eye damage category 1 (H318)

	Co-formulant with cat 1 skin corrosion classification: Dimethyl myristyl amine (CAS 68439-70-3), 4.80%, skin corrosive/irritating cat 1B (H314) Therefore, the following calculation shall be used: Eye effects category 1 and/or skin effects category 1A, 1B or 1C = > 3% for category 1 and >1% but < 3% for category 2. 4.80% + 3.00% + 1.92% = 9.72% Therefore, the product should be classified for eye damage category 1 and dimethyl myristyl amine, diethylene glycol monophenyl ether and ethoxylated iso-tridecanol are identified as substances of concern as these are contributing to the classification. Further one co-formulant carry classification for eye irritation category 2, but it does not contribute to the overall classification.
Classification of the product according to CLP	Eye damage category 1 (H318)

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Vacsol Aqua 6118 contains no ingredients that are classified for respiratory tract irritation
Classification of the product according to CLP	Not classified

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Vacsol Aqua 6118 is not a skin sensitiser
Justification for the value/conclusion	No skin sensitisation study on Vacsol Aqua 6118 is available. The skin sensitising potential of the product is based on the sensitising potential of its ingredients. Only one ingredient is classified for skin sensitisation and is present in the product at 0.4% (the active substance permethrin). This is below the generic concentration for classification (1%); however, it is above the generic concentration limit for elicitation (10% of the generic concentration limit; 0.1%) Therefore, the product is not a skin sensitiser but the addition labelling provision for elicitation should be included: EUH208- contains permethrin may cause an allergic reaction.

	Information on the skin sensitising potential is available for all ingredients from supplied safety data sheets, REACH dossiers and/or read-across to structurally similar substances.
Classification of the product according to CLP	No classification for skin sensitisation but the additional labelling provision for elicitation should be included: EUH208- contains permethrin may cause an allergic reaction.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not a respiratory sensitiser
Justification for the value/conclusion	No ingredients of Vacsol Aqua 6118 are classified for respiratory sensitisation
Classification of the product according to CLP	Not classified

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	> 2000 mg/kg
Justification for the selected value	Specific test data on the formulation is not available therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.1.3, the calculation under Annex I: 3.1.3.6.1. was followed. Classification by calculation using information from ECHA's C&L Inventory and submitted MSDS. Oral LD50 values or converted acute toxicity point estimates used. ATEmix calculated as 5347.6 mg/kg, this is > 2000 mg/kg, therefore no classification for acute oral toxicity is required. For more information on the classification calculations refer to the Confidential Annex.
Classification of the product according to CLP	Not classified

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	> 20 mg/l

Justification for the selected value	Specific test data on the formulation is not available therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.1.3, the calculation under Annex I: 3.1.3.6.2.3 was followed. Classification by calculation using information from ECHA's C&L Inventory and MSDS submitted. Inhalation LC50 values or converted acute toxicity point estimates used. ATEmix calculated as 851,74 mg/l, this is > 20 mg/l, therefore no classification for acute inhalation toxicity is required. For more information on the classification calculations refer to the Confidential Annex.
Classification of the product according to CLP	Not classified

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not classified
Justification for the selected value	Specific test data on the formulation is not available therefore classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.1.3, the calculation under Annex I: 3.1.3.6.1. was followed. Classification by calculation using information from ECHA's C&L Inventory and MSDS submitted. Dermal LD50 values or converted acute toxicity point estimates used. No components are classified for this endpoint. Therefore, no classification is proposed for the product.
Classification of the product according to CLP	Not classified

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Value(s)*	Justification for the selected value(s)
Penflufen, 0.375%	Default 75%	EFSA Journal 2012; 10 (4): 2665)
Permethrin, 0.375%	Default 75%	EFSA Journal 2012; 10 (4): 2665)
2-Phenoxyethanol	Default 75%	The CAR for 2-Phenoxyethanol (refers to the 75 % default value, EFSA Journal 2012).

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

The following ingredients of Vacsol Aqua 6118 have been identified as substances of concern:

Component	Classification	% w/w	SOC band	Reason	Action required
Dimethyl myrystil amine 68439-70-3	Acute tox. Cat4-H302 Corr/irrit. Cat 1B-H314 Aquatic toxicity –H410	4.80	A	Skin irrit 2	Application of S-phrases/P-statements normally associated with concerned R-phrases and H-statements
Diethylene glycol monophenyl ether 104-68-7	Eye damage – Cat 1 - H318	≥ 1.37 to ≤ 1.92	B	Eye damage 1	Qualitative exposure and risk assessment 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
2-Phenoxyethanol 122-99-6		≤ 3.84	C	Active substance with completed CAR	Full quantitative risk assessment by using EU IOELVs (when available), DNELs or other reference values (e.g. AELs, AECs (AELs should be available in CAR)
Ethoxylated iso-tridecanol (90 %) 69011-36-5	Acute toxicity, Cat 4 -H302 Eye damage, Cat 1-H318	3.00	B	Eye damage 1	Qualitative exposure and risk assessment 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

Available toxicological data relating to a mixture

Available toxicological data relating to a mixture that a substance(s) of concern is a component of.

The components 2-phenoxyethanol (122-99-6), which has been identified as a substance of concern Band C, and diethylene glycol monophenyl ether (104-68-7), which has been identified as a substance of concern band B, are parts of a mixture. Details of the mixture are summarised in the Confidential annex.

Component	% w/w	Comments
2-Phenoxyethanol 122-99-6	≤ 3.836	Substance of concern (Band C) – Active substance - Full quantitative risk assessment by using EU IOELVs (when available), DNELs or other reference values (e.g. AELs, AECs (AELs should be available in CAR)
Diethylene glycol monophenyl ether 104-68-7	≥ 1.37 to ≤ 1.918	Substance of concern (Band B) – contributes to classification for eye damage category 1 - Qualitative exposure and risk assessment 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

2.2.5.2 Exposure assessment

'Vacsol Aqua 6118' is a soluble concentrate (SL) formulation containing 0.375 % w/w penflufen and 0.375 % w/w permethrin that is diluted with water prior to application. 'Vacsol Aqua 6118' also contains 3.84 % w/w 2-phenoxyethanol as a substance of concern which has toxicological reference values set. As such, a quantitative exposure assessment will be completed for penflufen and permethrin, as well as the substance of concern 2-phenoxyethanol.

The product is intended for professional use in an industrial setting only. It is assumed that industrial users are used to handling these product types regularly, they have access to relevant safety information and they can be expected to wear personal protective equipment (PPE). The product can be applied double vacuum treatment, vacuum pressure treatment, automated dipping or deluge / enclosed spray treatment.

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

Summary table: relevant paths of human exposure							
Exposure path	Primary (direct) exposure			Secondary (indirect) exposure			
	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	yes	no	no	no	yes	yes	no
Dermal	yes	no	no	no	yes	yes	no
Oral	no	no	no	no	no	yes	yes

Intended uses

Overview of the proposed application methods and retention rates for 'Vacsol Aqua 6118'

Application method	Dilution	Maximum in-use concentration	Maximum retention rate[1]
Automated dipping	10%	0.0375 % w/w for penflufen & 0.0375 % w/w for permethrin 0.3836 % w/w 2-phenoxyethanol (SoC)	10 g concentrate/m^2 (containing 0.0375 g penflufen /m^2, 0.0375 g permethrin/m^2 & 0.3863 g 2-phenoxyethanol)
Deluge / enclosed spray treatment	20%	0.075 % w/w for penflufen & 0.075 % w/w for permethrin 0.7672 % w/w 2-phenoxyethanol (SoC)	10 g concentrate/m^2 (containing 0.0375 g penflufen/m^2, 0.0375 of permethrin/m^2 & 0.3863 g 2-phenoxyethanol)
Vacuum pressure treatment	0.62–1.25%	0.0047 % w/w for penflufen & 0.0047 % w/w for permethrin 0.048 % w/w 2-phenoxyethanol (SoC)	4.65 kg concentrate/m^3 (containing 0.0174 kg penflufen/m^3, 0.0174 kg permethrin/m^3 & 0.1784 kg 2-phenoxyethanol/m^3)
Double vacuum pressure treatment	1.5–5%	0.01875 % w/w for penflufen & 0.01875 % w/w for permethrin 0.1918 % w/w 2-phenoxyethanol (SoC)	4.65 kg concentrate/m^3 (containing 0.0174 kg penflufen/m^3, 0.0174 kg permethrin/m^3 & & 0.1784 kg 2-phenoxyethanol/m^3)

[1] The retention requirement is expressed in g of product per m^2 for the superficial application process and kg of product /m^3 for penetrating treatment processes.

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)
0.	Mixing and loading	Primary exposure - mixing and loading product into professional wood treatment equipment	Industrial users
1.	Automated dipping	Primary exposure – automated dipping of wooden articles	Industrial users
2.	Deluge/enclosed spray	Primary exposure – enclosed deluge/flood spray treatment of wooden articles	Industrial users
3.	Vacuum pressure treatment	Primary exposure – vacuum pressure treatment of wooden articles	Industrial users
4.	Double vacuum pressure treatment	Primary exposure – double vacuum pressure treatment of wooden articles	Industrial users
5.	Sanding treated wood	Secondary exposure – adult sanding treated wood (6 hours)	Professionals
6.	Sanding treated wood	Secondary exposure – adult sanding treated wood (1 hour)	General public
7.	Chewing treated wood off-cuts	Secondary exposure – a toddler ingests residues through mouthing treated wood off-cuts	General public
8.	Playing on (weathered) playground structures	Secondary exposure – dermal and ingestion exposure of a toddler playing on treated wood structures	General public
9.	Volatilisation of active substance from indoor treated surfaces	Secondary exposure – inhalation exposure can occur from the treated wood installed indoors	General public

Industrial exposure

'Vacsol Aqua 6118' can be applied by professional users in an industrial setting via automated dipping, enclosed deluge/flood spray treatment, vacuum pressure treatment

and double-vacuum pressure treatment. Primary exposure is expected via skin contact or via inhalation. For professional users, contamination via ingestion is not expected to occur therefore the oral route is not considered further.

Scenario 0 - primary exposure during mixing and loading

Description of Scenario 0		
The product is available to customers in 25L poly kegs and in IBCs. Exposure during connecting lines to the IBCs is considered negligible, but the workers may have some exposure when using the smaller 25L poly kegs top up to the wood treatment storage tank. This is assessed using Mixing and Loading Model 7 (semi-) automated loading as described in HEEG Opinion 1.		
	Parameters	Value
Tier 1	Product concentration of penflufen (active substance)	0.375 % w/w
	Product concentration of permethrin (active substance)	0.375 % w/w
	Product concentration of 2-phenoxyethanol (substance of concern)	3.84 % w/w
	Adult bodyweight	60 kg
	Dermal penetration of penflufen, permethrin & 2-phenoxyethanol	75% (default)
	Duration of exposure	10 min
	Exposure with gloves	1.38 mg/min

Tier 1 assessment

It is assumed that gloves are worn when handling the concentrated product, as indicated by the product instructions and considering that the product is classified for irritation.

Calculations for Scenario 0

Summary table: estimated exposure to penflufen or permethrin from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/d)	**Estimated dermal uptake** (mg/d)	**Estimated oral uptake** (mg/d)	**Estimated total uptake** (mg/kg bw/d)
Scenario 0	1 (gloves)	negligible	0.0388	n.a.	0.0006
Full calculations are contained in Annex 3.2, Tables 1.1					

Summary table: estimated exposure to 2-phenoxyethanol (SoC) from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/d)	**Estimated dermal uptake** (mg/d)	**Estimated oral uptake** (mg/d)	**Estimated total uptake** (mg/kg bw/d)
Scenario 0	1 (gloves)	n.a.	0.3974	n.a	0.0066 mg/kg bw/d
Full calculations are contained in Annex 3.2, Table 1.2					

Further information and considerations on scenario 0

The concentrate is classified as H315 (causes skin irritation) and H318 (causes serious eye damage). As such, gloves, coveralls and eye protection must be worn.

2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has a toxicological reference value (AEC) set for local inhalation effects. As such, the air concentration of 2-phenoxyethanol vapour must be estimated. This calculation is carried out using the Advanced Reach Tool (ART) version 1.5 selecting "transferring liquids"; "10-100 L/min"; and "Handling that reduces contact between product and adjacent air" as the relevant activity in the model. The example activity for these parameters are refuelling a car or topping up a tank.

For substances with vapour pressures of ≤ 10 Pa, ART only calculates exposure to mist. For semi-volatile substances, this can underestimate exposure as evaporation may be the dominant exposure generating process. In order to avoid underestimation, ART suggests that a vapour pressure of 11 Pa should be used for substances with a vapour pressure between 0.01 – 10 Pa during activities with limited aerosol formation. On this basis, a vapour pressure of 11 Pa was used for 2-phenoxyethanol.

The mole fraction of 2-phenoxyethanol is calculated to be 6.76 x 10^{-3} (calculations of the mole fraction are presented in the Confidential Annex 3.6; table 1.3). The ART report can be found in Annex 3.2, Table 1.3 and a summary is provided in the table below.

Scenario 2: Local inhalation exposure		
Substance	**Mole fraction in-use solution**	**Air concentration [mg/m³]**
		Tier 1: no RPE
2-phenoxyethanol	0.007	0.0093
The ART report can be found under Annex 3.2, Table 1.3		

Scenario 1 – Primary exposure during automated dipping of wooden articles

Description of Scenario 1		
According to the applicant, the product is applied via automated dipping where operators use a forklift truck or similar equipment to lower the wood into the dipping tank. The wood stays in the solution for the desired period before being lifted out the tank by the forklift truck (or similar). The treated wood is then transferred using the forklift truck to a storage area where the wood is left to dry. As recommended in HEEG opinion 8, exposure during automated dipping has been assessed using TNsG Handling Model 1 assuming 4 dipping cycles per day. HEEG opinion 8 informs us that for water-based solutions, inhalation exposure to aerosols can be considered negligible during this process. In view of the automated nature of industrial automated dipping, it is unlikely that operators will routinely undertake manual mix/loading activities. Any manual mix/loading is therefore likely to be infrequent and represent a minor contribution to the overall level of exposure as predicted by the TNsG Handling Model 1. As such, mixing and loading has not been considered separately.		
	Parameters	Value
Tier 1	In-use concentration of penflufen (active substance)	0.0375 % w/w
	In-use concentration of permethrin (active substance)	0.0375 % w/w
	In-use concentration of 2-phenoxyethanol (substance of concern)	0.3863 % w/w
	Adult bodyweight	60 kg
	Dermal penetration of penflufen, permethrin & 2-phenoxyethanol	75% (default)
	Number of cycles/day	4
	Hand exposure (in gloves); indicative 75th percentile value[1]	1080 mg/cycle
	Potential body exposure; indicative 75th percentile value	8570 mg/cycle
Tier 2	PPE (coated coveralls)	90% protection (10% penetration)
Tier 3	PPE (new gloves)	540 mg/cycle (50% reduction of hand-in-glove exposure)
Tier 4	PPE (impermeable coveralls)	95% protection (5% penetration)

[1] In view of the industrial use of the product, PPE has been included in exposure assessments where appropriate, reflecting the underlying data.

Tier 1 assessment

It is assumed that gloves are worn (reflecting the underlying data of the model used).

Tier 2 assessment

The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by coated coveralls. According to HEEG opinion 9 it is assumed that coated coveralls would offer a protection of 90% (that is 10% penetration) where the main challenge is from contact with preservative wet wood.

Tier 3 assessment

The 'Tier 2' exposure assessment is refined by including in the calculations:

- The protection afforded when new gloves are worn at start of each cycle. In line with HEEG opinion 9 (2010), it is assumed that new gloves reduce hand-in-glove exposure by 50%.

Tier 4 assessment

The 'Tier 3' exposure assessment is refined by including in the calculations:

- The protection afforded by impermeable coveralls. According to HEEG opinion 9 it is assumed that impermeable coveralls would offer a protection of 95% (that is 5% penetration).

Calculations for Scenario 1

Summary table: estimated exposure to penflufen or permethrin from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/d)	**Estimated dermal uptake** (mg/d)	**Estimated oral uptake** (mg/d)	**Estimated total uptake** (mg/d)
Scenario 1	1 (gloves)	negligible	10.8563	n.a.	0.1809
Scenario 1	2 (gloves/coated coveralls)	negligible	2.1791	n.a.	0.0363
Scenario 1	3 (new gloves/coated coveralls)	negligible	1.5716	n.a.	0.0262
Scenario 1	4 (new gloves/ impermeable coveralls)	negligible	1.0896	n.a.	0.0182
Full calculations are contained in Annex 3.2, Tables 1.4 – 1.7					

Summary table: estimated exposure to 2-phenoxyethanol (SoC) from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/d)	**Estimated dermal uptake** (mg/d)	**Estimated oral uptake** (mg/d)	**Estimated total uptake** (mg/kg bw/d)
Scenario 1	1 (gloves)	n.a.	111.83	n.a.	1.8639
Full calculations are contained in Annex 3.2, Table 1.8					

Further information and considerations on scenario 1

The concentrate is classified as H315 (causes skin irritation) and H318 (causes serious eye damage). As such, gloves, coveralls and eye protection must be worn.

2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has a toxicological reference value (AEC) set for local inhalation effects. As such, the air concentration of 2-phenoxyethanol vapour must be estimated. This calculation is carried out using the Advanced Reach Tool (ART) version 1.5 selecting "open liquid surfaces or open reservoirs"; "activities with undisturbed surfaces"; and "open surface > $3m^2$" as the relevant activity in the model. The example activity for these parameters is tank dipping.

For substances with vapour pressures of ≤ 10 Pa, ART only calculates exposure to mist. For semi-volatile substances, this can underestimate exposure as evaporation may be the dominant exposure generating process. In order to avoid underestimation, ART suggests

that a vapour pressure of 11 Pa should be used for substances with a vapour pressure between 0.01 – 10 Pa during activities with limited aerosol formation. On this basis, a vapour pressure of 11 Pa was used for 2-phenoxyethanol.

The mole fraction of 2-phenoxyethanol is calculated to be 6.93 x 10^{-4} for the 10% dilution (calculations of the mole fraction are presented in the Annex 3.6; table 1.3). The ART report can be found in Annex 3.2, Table 1.9 and a summary is provided in the table below.

Scenario 2: Local inhalation exposure		
Substance	**Mole fraction in-use solution**	**Air concentration [mg/m³]**
		Tier 1: no RPE
2-phenoxyethanol	0.0007	0.03
The ART report can be found under Annex 3.2, Table 1.9		

Scenario 2- Primary exposure during enclosed deluge/flood spray treatment of wooden articles

Description of Scenario 2		
During industrial deluge/enclosed spray treatment, timber is placed on a conveyor belt that takes wood directly through an enclosed tunnel treatment system. The preservative is applied from various types of deluge bars or coarse spray jets. Exposure should be low during this process and be predominantly due to residues from handling freshly sprayed timber. As no specific model is available, exposure has been assessed using the TNsG Dipping Model 1 and an exposure duration of 60 minutes as recommended in HEAdhoc recommendation 6.		
	Parameters	Value
Tier 1	In-use concentration of penflufen	0.075 % w/w
	In-use concentration of permethrin	0.075 % w/w
	In-use concentration of 2-phenoxyethanol (SoC)	0.7672 % w/w
	Adult bodyweight	60 kg
	Inhalation rate	1.25 m^3/hr
	Absorption via inhalation	100%
	Dermal penetration of penflufen, permethrin & 2-phenoxyethanol	75% (default)
	Exposure duration	60 minutes/day
	Hand exposure (in gloves); indicative maximum value[1]	25.7 mg/min
	Potential body exposure; maximum value	178 mg/min
	Inhalation exposure; maximum value	< 1 mg/min
Tier 2	PPE (coated coveralls)	90% protection (10% penetration)
Tier 3	PPE (new gloves)	12.85 mg/min (50% reduction of hand-in-glove exposure)

[1] In view of the industrial use of the product, PPE has been included in exposure assessments where appropriate, reflecting the underlying data.

Tier 1 assessment

It is assumed that gloves are worn (reflecting the underlying data of the model used).

Tier 2 assessment

The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by coated coveralls. According to HEEG opinion 9 it is assumed that protective clothing for professionals (coated coveralls) would offer a protection of 90% (that is 10% penetration) where the main challenge is from contact with preservative wet wood.

Tier 3 assessment

The 'Tier 2' exposure assessment is refined by including in the calculations:

- The protection afforded when new gloves are worn at start of each cycle. In line with HEEG opinion 9 (2010), it is assumed that new gloves reduce hand-in-gloves exposure by 50%. As industrial flow coating/deluge treatment is a relatively short process, it is reasonable to assume that gloves will be worn throughout the treatment and it is therefore considered appropriate to apply the new gloves / cycle protection factor to this application method.

Calculations for Scenario 2

Summary table: estimated exposure to penflufen or permethrin from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/d)	**Estimated dermal uptake** (mg/d)	**Estimated oral uptake** (mg/d)	**Estimated total uptake** (mg kg bw/d)
Scenario 2	1 (gloves)	0.0009	6.8749	n.a.	0.1146
Scenario 2	2 (gloves/coated coveralls)	0.0009	1.4681	n.a.	0.0245
Scenario 2	3 (new gloves/ coated coveralls)	0.0009	1.0344	n.a.	0.0173
Full calculations are contained in Annex 3.2, Tables 2.0 – 2.2					

Summary table: estimated exposure to 2-phenoxyethanol from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/d)	**Estimated dermal uptake** (mg/d)	**Estimated oral uptake** (mg/d)	**Estimated total uptake** (mg kg bw/d)
Scenario 2	1 (gloves)	0.0096	70.3254	n.a.	1.1722
Full calculations are contained in Annex 3.2, Table 2.3					

Further information and considerations on scenario 2

The concentrate is classified as H315 (causes skin irritation) and H318 (causes serious eye damage). As such, gloves, coveralls and eye protection must be worn.

2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has a toxicological reference value (AEC) set for local inhalation effects. As such, the air concentration of 2-phenoxyethanol vapour must be estimated. It is not appropriate to use the indicative inhalation value from TNsG Dipping Model 1 as this model is based on non-volatile substances. As such, the Advanced Reach Tool (ART) version 1.5 is used assuming a vapour pressure of 11 Pa (please see scenario 1 for an explanation of the vapour pressure parameter). As the application method is enclosed, exposure is predominately due to handling treated objects therefore activity parameters "handling contaminated objects with a treated surface of > $3m^2$" and ">90% contamination of the surface" are considered to be the most appropriate. The example activity for these parameters is handling large treated and drying objects.

The mole fraction of 2-phenoxyethanol is calculated to be 1.38×10^{-3} for the 20% dilution (calculations of the mole fraction are presented in the Confidential Annex 3.6; Table 1.2). The ART report can be found in Annex 3.2, Table 2.4 and a summary is provided in the table below.

Scenario 2: Local inhalation exposure		
Substance	**Mole fraction**	**Inhalation exposure [mg/m³]**
		Tier 1: no RPE
2-phenoxyethanol	0.00138	0.061

Scenario 3 - Primary exposure during vacuum pressure treatment of wooden articles

Description of Scenario 3		
Exposure by industrial vacuum pressure treatment has been assessed using the TNsG Handling Model 1 as recommended in HEAdhoc recommendation 6. This model is derived from data relating to industrial timber treatment using vacuum/pressure plants applying water-based or solvent-based liquid formulations. Exposure values obtained from the model reflect the intermittent manual handling of water-wet or solvent-damp wood and associated equipment. HEAdhoc recommendation 6 informs us that for vacuum-pressure treatment, 3 cycles are performed each day. Inhalation exposure time is assumed to be 30 minutes which is the time spent with the door open for 3 cycles. In view of the automated nature of the industrial vacuum pressure treatment process, it is unlikely that operators will routinely undertake manual mixing & loading activities. Any manual mixing & loading is therefore likely to be infrequent and represent a minor contribution to the overall level of exposure as predicted by the TNsG Handling Model 1. As such, exposure from mixing/loading has not been considered separately.		
Tier 1	**Parameters**	**Value**
	In-use concentration of penflufen	0.0047 % w/w
	In-use concentration of permethrin	0.0047 % w/w
	In-use concentration of 2-phenoxyethanol (SoC)	0.048 % w/w
	Adult body weight	60 kg
	Adult inhalation rate	1.25 m³/hour
	Absorption via inhalation	100 %
	Inhalation exposure; indicative 75th percentile value	1.9 mg/m³
	Dermal penetration of penflufen, permethrin and 2-phenoxyethanol	75% (default)
	Inhalation exposure time during opening of the day for 3 cycles	30 minutes
	Number of cycles/day	3 cycles/day
	Hand exposure for water-based products (gloves); indicative 75th percentile value[1]	1080 mg/cycle
	Potential body exposure for water-based products; indicative 75th percentile value	8570 mg/cycle

[1] In view of the proposed industrial use of the product, PPE has been included in exposure assessments where appropriate, reflecting the underlying data.

Tier 1 assessment

It is assumed that gloves are worn (reflecting the underlying data of the model used).

Calculations for Scenario 3

Summary table: estimated exposure to penflufen or permethrin from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/d)	**Estimated dermal uptake** (mg/d)	**Estimated oral uptake** (mg/d)	**Estimated total uptake** (mg/kg bw/d)
3	1 (gloves)	0.0001	1.0205	n.a.	0.0170
Full calculations are contained in Annex 3.2, Table 2.5					

Summary table: estimated exposure to 2-phenoxyethanol from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg/d)	**Estimated dermal uptake** (mg/d)	**Estimated oral uptake** (mg/d)	**Estimated total uptake** (mg/kg bw/day)
3	1 (gloves)	0.0006	10.4220	n.a.	0.1737
Full calculations are contained in Annex 3.2, Tables 2.6					

Further information and considerations on scenario 3

The concentrate is classified as H315 (causes skin irritation) and H318 (causes serious eye damage). As such, gloves, coveralls and eye protection must be worn.

2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has a toxicological reference value (AEC) set for local inhalation effects. As such, the air concentration of this substance must be estimated. It is not appropriate to use the indicative inhalation value from TNsG Handling Model 1 as this model is based on non-volatile substances therefore the advanced reach tool (ART) version 1.5 is used.

As vacuum pressure treatment is an enclosed process, handling contaminated objects is considered to be the most appropriate exposure scenario. The in-use concentration of 2-phenoxyethanol is lower for vacuum pressure treatment than for deluge/enclosed spray treatment (0.048% w/w compared to 0.7672 % w/w) therefore scenario 2 forms a risk envelope and no further assessment is required. Please refer to scenario 2 for details of the local inhalation effects assessment during handling contaminated objects during deluge/enclosed spray treatment.

Scenario 4 - Primary exposure during double vacuum pressure treatment of wooden articles

Description of Scenario 4		
Exposure by industrial double vacuum pressure treatment has been assessed using the TNsG Handling Model 1 as recommended in HEAdhoc recommendation 6. This model is derived from data relating to industrial timber treatment using vacuum/pressure plants applying water-based or solvent-based liquid formulations. Exposure values obtained from the model reflect the intermittent manual handling of water-wet or solvent-damp wood and associated equipment. HEAdhoc recommendation 6 informs us that for double vacuum pressure treatment, 6 cycles are performed / day. It also informs us that the inhalation exposure time is assumed to be 30 minutes for 3 cycles (this is the time spent with the door open) therefore, based on pro-rata extrapolation, an inhalation exposure time of 60 minutes can be assumed for 6 cycles. In view of the automated nature of the industrial vacuum pressure treatment process, it is unlikely that operators will routinely undertake manual mixing & loading activities. Any manual mixing & loading is therefore likely to be infrequent and represent a minor contribution to the overall level of exposure as predicted by the TNsG Handling Model 1. As such, exposure from mixing/loading has not been considered separately.		
Tier 1	**Parameters**	**Value**
	In-use concentration of penflufen	0.01875 % w/w
	In-use concentration of permethrin	0.01875 % w/w
	In-use concentration of 2-phenoxyethanol (Soc)	0.1918 % w/w
	Adult body weight	60 kg
	Adult inhalation rate	1.25 m³/hour
	Absorption via inhalation	100 %
	Inhalation exposure; indicative 90th percentile value	1.9 mg/m³
	Dermal penetration of penflufen, permethrin & 2-phenoxyethanol	75% (default)
	Inhalation exposure time	60 minutes
	Number of cycles/day	6 cycles/day
	Hand exposure for water-based products (gloves); indicative 95th percentile value[1]	1080 mg/cycle
	Potential body exposure for water-based products; indicative 75th percentile value	8570 mg/cycle

Tier 2	PPE (coated coveralls)	90% protection (10% penetration)
Tier 3	PPE (new gloves)	540 mg/cycle (50% reduction of hand-in-glove exposure)

Tier 1 assessment

It is assumed that gloves are worn (reflecting the underlying data of the model used).

Tier 2 assessment

The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by coated coveralls. According to HEEG opinion 9 it is assumed that protective clothing for professionals (coated coveralls) would offer a protection of 90% (that is 10% penetration) where the main challenge is from contact with preservative wet wood.

Tier 3 assessment

The 'Tier 2' exposure assessment is refined by including in the calculations:

- The protection afforded when new gloves are worn at start of each cycle. In line with HEEG opinion 9 (2010), it is assumed that new gloves reduce hand-in-gloves exposure by 50%.

Summary table: estimated exposure to penflufen or permethrin from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
4	1 (gloves)	0.0004	8.1422	n.a.	0.1357
4	2 (gloves /coated coveralls)	0.0004	1.6343	n.a.	0.0272
4	3 (new gloves/coated coveralls)	0.0004	1.1787	n.a.	0.0197
Full calculations are contained in Annex 3.2, Tables 2.7 - 2.9					

Summary table: estimated exposure to 2-phenoxyethanol from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
4	1 (gloves)	0.0046	83.2892	n.a.	1.3882
Full calculations are contained in Annex 3.2, Table 3.0					

Further information and considerations on scenario 4

The concentrate is classified as H315 (causes skin irritation) and H318 (causes serious eye damage). As such, gloves, coveralls and eye protection must be worn.

2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has a toxicological reference value (AEC) set for local inhalation effects. As such, the air concentration of this substance must be estimated. It is not appropriate to use TNsG Handling Model 1 to assess the air concentration of 2-phenoxyethanol as this model is based on non-volatile substances. As such, the Advanced Reach Tool (ART) version 1.5 is used.

As double vacuum treatment is an enclosed process, handling contaminated objects is considered to be the most appropriate exposure scenario. The in-use concentration of 2-phenoxyethanol is lower for double vacuum treatment than for deluge/enclosed spray treatment (0.1918% w/w compared to 0.7672 % w/w) therefore scenario 2 forms a risk envelope and no further assessment is required. Please refer to scenario 2 for details of the local inhalation effects assessment during handling contaminated objects during deluge/enclosed spray treatment.

Combined scenarios

There are no relevant combined exposure scenarios to consider for industrial users.

Professional exposure

Professionals outside of an industrial setting may be exposed to penflufen, permethrin or SoC 2-phenoxyethanol via sanding of treated objects (secondary exposure). The rentention rate of "VacsolAqua 6118" varies between application method as summarised in the Table below. For secondary exposure, vacuum and double vacuum pressure treatment represents the worst case as these application methods result in the highest retention of product (and subsequently the highest concentration of substances /cm^3 of treated wood).

Overview of retention rates for 'Vacsol Aqua 6118'

Application method	Maximum retention rate[1]
Automated dipping or deluge / flood spray treatment	10 g concentrate/m^2 containing 0.0375 g penflufen /m^2, 0.0375 g permethrin/m^2 & 0.3863 g 2-phenoxyethanol. This is equivalent to 0.00375 mg penfulfen/cm^3, 0.00375 mg permethrin/cm^3 & 0.03863 mg 2-phenoxyethanol/cm^3.
Vacuum pressure or double vacuum pressure treatment	4.65 kg concentrate/m^3 containing 0.0174 kg penflufen/m^3, 0.0174 kg permethrin/m^3 & 0.1784 kg 2-phenoxyethanol/m^3. This is equivalent to 0.0174 mg penfulfen/cm^3, 0.0174 mg permethrin/cm^3 & 0.1784 mg 2-phenoxyethanol/cm^3.

[1] The retention requirement is expressed in g of product per m^2 for the superficial application process and kg of product /m^3 for penetrating treatment processes.

Scenario 5 – Secondary exposure (chronic) for a professional adult sanding treated timber

Description of Scenario 5

Professional (secondary) exposure for a professional adult sanding treated timber for 6 hours/day using a hand-held power sander has been estimated based on the following assumptions/parameters:

- The highest retention rate is 0.0174 mg/cm^3 for both penflufen & permethrin and 0.1784 mg/cm^3 for SoC 2-phenoxyethanol
- Exposure is via the inhalation and dermal routes
- No gloves are worn (reflecting normal commercial practice when woodworking).
- The Workplace Exposure Limit (WEL) for wood dust is 5 mg/m^3 (8-hour time-weighted average) (HSE, 2005). Inhalation exposure can be estimated based on this air concentration and assuming a duration of exposure of 6 hours along with an inhalation rate of 1.25 m^3/h
  5 mg/m^3 x 1.25 m^3/h x 6 h = 37.5 mg wood dust inhaled in 6 hours
- Assuming a density of 0.4 g/cm^3 (MOTA 4.2.5), 37.5 mg (0.0375 g) of wood dust is equivalent to 0.0375 ÷ 0.4 = 0.0938 cm^3 of treated wood.
- The surface area of both palms of hands is 410 cm² (HEAdhoc recommendation 14) and during prolonged and repeated contact 20% of the hand is contaminated (TNsG, Part 3, p. 51 and User Guidance, p. 52). The transfer efficiency from rough-sawn wood to the hands is 2% (TNsG, Part 2, p. 204).

	Parameters	Value
Tier 1	Concentration of penflufen / permethrin in treated wood	0.0174 mg/cm³
	Concentration of 2-phenoxyethanol in treated wood (SoC)	0.1784 mg/cm^3
	Dermal absorption of penflufen, permethrin & 2-phenoxyethanol	75% (default)
	Surface area of hands (palms)	410 cm^2
	Proportion of hand surface area contaminated	20%
	Transfer efficiency (wood to hands)	2%
	Workplace Exposure Limit (WEL) for wood dust (8 hour TWA)	5 mg/m^3
	Duration of inhalation exposure	6 hours
	Inhalation rate	1.25 m^3/h
	Density of wood dust	0.4 g/cm^3
	Volume of wood inhaled (from above)	0.0938 cm^3
	Adult bodyweight	60 kg

Tier 1 assessment

Systemic dose via the inhalation route (mg/kg bw/d) = volume of wood inhaled (cm^3) x concentration of a.s. in wood (mg/cm^3) x 100% absorption ÷ bodyweight (kg)

Systemic calculations for permethrin or penflufen (inhalation route):
0.0938 cm^3 x 0.0174 mg/cm^3 x 100% / 60 kg = 2.72 x 10^{-5}

Systemic calculations for SoC 2-phenoxyethanol (inhalation route):
0.0938 cm^3 x 0.1784 mg/cm^3 x 100% / 60 kg = 2.79 x 10^{-4}

Systemic dose via the dermal route (mg/kg bw/d) = active substance residue on surface (mg/cm^3) x area of hands (cm^2) x proportion of hands contaminated (%) x transfer efficiency of wood (%) x dermal absorption (%) ÷ bodyweight (kg).

Systemic calculations for permethrin or penflufen (dermal route):
0.0174 mg/cm^3 x 410cm^2 x 20% x 2% x 75% / 60 kg = 3.57 x 10^{-4}

Systemic calculations for SoC 2-phenoxyethanol (dermal route):
0.1784 mg/cm^3 x 410 cm^2 x 20% x 2% x 75% / 60 kg = 3.66 x 10^{-3}

Calculations for Scenario 5

Summary table: estimated exposure to penflufen or permethrin from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/d)**	**Estimated dermal uptake (mg/d)**	**Estimated oral uptake (mg/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 5	1 (no PPE)	0.0016	0.0214	n.a.	0.0004

Summary table: estimated exposure to 2-phenoxyethanol from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/d)**	**Estimated dermal uptake (mg/d)**	**Estimated oral uptake (mg/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 5	1 (no PPE)	0.0167	0.2194	n.a.	0.0039

Further information and considerations on scenario 5

Substance of concern 2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has a toxicological reference value (AEC) set for local inhalation effects. Secondary exposure to volatilised 2-phenoxyethanol is considered under scenario 9 and is therefore not considered further for this scenario.

Combined scenarios

There are no combined exposure scenarios foreseen for professional users.

Non-professional exposure

The product is not intended for non-professional use.

Exposure of the general public

The general public may be exposed to penflufen, permethrin or SoC 2-phenoxyethanol. The retention rate of "Vacsol Aqua 6118" varies between application methods as summarised in the Table below. For secondary exposure, vacuum and double vacuum pressure treatment represents the worst case as these application methods result in the highest retention of product (and subsequently the highest concentration of substances /cm^3 of treated wood).

Overview of retention rates for 'Vacsol Aqua 6118'

Application method	**Maximum retention rate[1]**
Automated dipping or deluge / enclosed spray treatment	10 g concentrate/m^2 containing 0.0375 g penflufen /m^2, 0.0375 g permethrin/m^2 & 0.3863 g 2-phenoxyethanol. This is equivalent to 0.00375 mg penfulfen/cm^3, 0.00375 mg permethrin/cm^3 & 0.03863 mg 2-phenoxyethanol/cm^3.
Vacuum pressure or double vacuum pressure treatment	4.65 kg concentrate/m^3 containing 0.0174 kg penflufen/m^3, 0.0174 kg permethrin/m^3 & 0.1784 kg 2-phenoxyethanol/m^3. This is equivalent to 0.0174 mg penfulfen/cm^3, 0.0174 mg permethrin/cm^3 & 0.1784 mg 2-phenoxyethanol/cm^3.

[1] The retention requirement is expressed in g of product per m^2 for the superficial application process and kg of product /m^3 for penetrating treatment processes.

Scenario 6 – Secondary exposure (acute) for a non-professional adult sanding treated timber

Description of Scenario 6
Secondary exposure for a non-professional adult sanding treated wood is considered to be within the risk envelope of a professional adult carrying out this activity based on a lower duration of activity (1 hour compared to 6 hours). As such, an additional sanding scenario for a non-professional is not necessary. Please refer to scenario 5 for predicted exposure.

Scenario 7 – Secondary exposure (acute) for a toddler chewing a treated wood off-cut

Description of Scenario 7
A toddler chews on a wood off-cut treated with 'Vacsol Aqua 6118'. Exposure is via the ingestion (oral) route.

Tier 1	**Parameters**	**Value**
	Toddler body weight	10 kg
	Concentration of penflufen / permethrin in treated timber	0.0174 mg/cm^3
	Concentration of 2-phenoxyethanol in treated timber	0.1784 mg/cm^3
	Volume of timber off-cut	4 cm x 4 cm x 1 cm (equivalent to 16 cm^3)
	Amount of penflufen / permethrin in treated off-cut	0.2784 mg
	Extraction rate from chewing	10 %
	Extracted amount of penflufen / permethrin from treated off-cut	0.02784 mg
	Oral absorption	100 %

Tier 1 assessment

It is assumed that the toddler is chewing a 4 cm x 4 cm x 1 cm treated wood off-cut (volume of 16 cm^3) and in doing so extracts 10% of the active substance (TNsG 2002, part 3, p46). The highest retention rate is 0.0174 mg / cm^3 for both penflufen and permethrin and 0.1784 mg/cm^3 for SoC 2-phenoxyethanol.

Oral ingestion calculations for penflufen or permethrin:

volume of off-cut from treated post = 4 x 4 x 1 = 16 cm^3
concentration of the penflufen or permethrin in the treated wood = 0.0174 mg /cm^3
16 cm^3 wood contain 16 x 0.0174 mg /cm^3 = 0.2784 mg penflufen or permethrin
10 % extraction from wood = 0.0278 mg penflufen or permethrin
Systemic exposure of penflufen or permethrin (ingestion) = 0.0028 mg/kg bw/day

Oral ingestion calculations for SoC 2-phenoxyethanol:

volume of off-cut from treated post = 4 x 4 x 1 = 16 cm^3
concentration of the in the treated wood = 0.1784 mg /cm^3
16 cm^3 wood contain 16 x 0.1784 mg /cm^3 = 2.8544 mg 2-phenoxyethanol
10 % extraction from wood = 0.2854 mg 2-phenoxyethanol
Systemic exposure of 2-phenoxyethanol (ingestion) = 0.0285 mg/kg bw/day

Calculations for Scenario 7

Summary table: systemic exposure to penflufen or permethrin from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/d)**	**Estimated dermal uptake (mg/d)**	**Estimated oral uptake (mg/d)**	**Estimated total uptake (mg/ kg bw/d)**
Scenario 7	1	n.a.	n.a.	0.0278	0.0028

Summary table: systemic exposure to 2-phenoxyethanol from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/d)**	**Estimated dermal uptake (mg/d)**	**Estimated oral uptake (mg/d)**	**Estimated total uptake (mg/ kg bw/d)**
Scenario 7	1	n.a.	n.a.	0.2854	0.0285

Further information and considerations on scenario 7

Substance of concern 2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has a toxicological reference value set for local inhalation effects. Secondary exposure to volatilised 2-phenoxyethanol is considered under scenario 9 and is therefore not considered further under this scenario.

Scenario 8 – Secondary exposure (chronic) for toddlers playing on weathered playground structures

Description of Scenario 8
Toddlers who play on treated wooden structures and have hand-to-mouth contact as they play may be exposed to penflufen, permethrin and SoC 2-phenoxyethanol. Potential exposures are via dermal and ingestion routes. It is assumed that 20% of the hand is contaminated during long and repeated contact with the playground structure (TNsG 2002, Part 3, p.50 and TNsG User Guidance, p.57) and a toddler has a hand surface area of 230.4 cm² (HEAdhoc recommendation 14). The transfer efficiency from rough-sawn wood to the hands is 2% (TNsG 2002, Part 2, p. 204). It is assumed that 100% ingestion of the calculated skin contamination of the hands (as described above) will occur.

Tier 1	**Parameters**	**Value**
	Concentration of penflufen or permethrin in treated timber	0.0174 mg/cm^2
	Concentration of Soc 2-phenoxyethanol in treated timber	0.1784 mg/cm^3
	Toddler body weight	10 kg
	Oral absorption	100 %
	Dermal absorption for penflufen, permethrin or 2-phenoxyethanol	75 %
	Hand surface area	230.4 cm^2
	Hand contamination	20 %
	Transfer efficiency of dried residue	2 %

Tier 1 assessment

Systemic exposure via the dermal route = concentration of a.s. on the wood surface (mg/cm^2) x surface area of hand (cm^2) x area of hand contaminated (%) x transfer coefficient (%) x dermal absorption (%) ÷ bodyweight (kg)

For penflufen or permethrin (dermal route):

0.0174 mg/cm^3 x 230.4 cm^2 x 20% x 2% x 75% / 10 kg = 0.0012 mg/kg bw/d

For 2-phenoxyethanol (dermal route):

0.1784 mg/cm^3 x 230.4 cm^2 x 20% x 2% x 75% / 10 kg = 0.0123 mg/kg bw/d

Systemic exposure via the oral route = concentration of a.s. on the wood surface (mg/cm^2) x surface area of hand (cm^2) x area of hand contaminated (%) x transfer coefficient (%) x oral absorption (%) ÷ bodyweight (kg)

For penflufen or permethrin (oral route):

0.0174 mg/cm^3 x 230.4 cm^2 x 20% x 2% x 100% / 10 kg = 0.0016 mg /kg bw/d

For 2-phenoxyethanol (oral route):

0.1784 mg/cm^3 x 230.4 cm^2 x 20% x 2% x 100% / 10 kg = 0.0164 mg/kg bw/d

Calculations for Scenario 8

Summary table: systemic exposure to penflufen / permethrin from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/d)**	**Estimated dermal uptake (mg/d)**	**Estimated oral uptake (mg/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 8	1	n.a.	0.0120	0.0160	0.0028

Summary table: systemic exposure to 2-phenoxyethanol from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/d)**	**Estimated dermal uptake (mg/d)**	**Estimated oral uptake (mg/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 8	1	n.a.	0.1233	0.1644	0.0288

Further information and considerations on scenario 8

Substance of concern 2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has a toxicological reference value set for local inhalation effects. Secondary exposure to volatilised 2-phenoxyethanol is considered under scenario 9 and is therefore not considered further under this scenario.

Scenario 9 – Secondary exposure (chronic) from inhalation of volatilised residues from indoor treated timber

The HEEG opinion 13 on the assessment of inhalation exposure to volatilised biocides provides the following screening tool to determine whether inhalation exposure can be considered not to be a potential risk. This is a worse-case scenario based on the saturated vapour concentration of the active substance.

Where mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa), for a toddler (based on an inhalation rate of 8 m^3/24 hr and bw of 10 kg) and using an AEL expressed in mg a.s./kg bw/d; if

$$0.328 \cdot \frac{mw \cdot vp}{AEL_{long-term}} \leq 1$$

then the risk from inhalation exposure is considered negligible.

When an AEC (mg a.s./m^3) is given, the following screening test is used instead; if

$$0.410.\ \frac{mw.\ vp}{AEC_{long\ term}} \leq 1$$

then the risk from inhalation exposure is considered negligible.

The assessment assumes that the individual is exposed to the saturated vapour concentration of the active substance for 24 hours a day and therefore reflects a 'worst-case' scenario. The calculation of toddler inhalation exposure represents a 'worst case' scenario as stipulated in HEEG opinion 13 and as such forms the risk envelope for the assessment of an infant, child and adult.

Penflufen has a molecular weight of 317.41 g/mol and a vapour pressure of 4.1×10^{-7} Pa at 20°C. The AEL (long term) is 0.04 mg/kg bw/d.

Therefore, applying the above equation:

$$0.328 \times \frac{317.41 \times 4.1^{-7}}{0.04}$$

= 0.001

The value of 0.001 is < 1 therefore risk from inhalation exposure to penflufen can be excluded.

Permethrin has a molecular weight of 391.28 g/mol and a vapour pressure of 2.16×10^{-6} Pa at 20°C. The AEL (long term) is 0.05 mg/kg bw/d.

Therefore, applying the above equation:

$$0.328 \times \frac{391.28 \times 2.16^{-6}}{0.05}$$

= 0.006

The value of 0.006 is < 1 therefore risk from inhalation exposure to permethrin can be excluded.

2-phenoxyethanol has a molecular weight of 138.17 g/mol and a vapour pressure of 1.0 Pa at 20°C. The AEC (long term) is 0.32 mg/m^3.

Therefore, applying the above equation:

$$0.410 \times \frac{138.17 \times 1}{0.32}$$

= 177

The value is >1 therefore risk from inhalation exposure to 2-phenoxyethanol cannot be excluded. A local inhalation effects assessment for 2-phenoxyethanol is presented below.

Further information and considerations on scenario 9

Description of Scenario 9
There is no guidance available for estimating the air concentration of volatilised residues from treated wood during secondary exposure. In the absence of specific guidance, the UK CA has used ConsExpo Web and a reverse reference approach to calculate the maximum amount of treated wood that can be present in a room before the long-term AEC for 2-phenoxyethanol is exceeded. For surface treatments (i.e. dipping and deluge), the retention rate is 10 g concentrate/m^2. For penetrating treatment processes (i.e. vacuum and double vacuum treatment), the retention rate is 4.65 kg concentrate/m^3 (equivalent to 0.00465 g/cm^3). It is reasonable to assume that only the substance contained in the outer 1 cm layer of wood is available for evaporation therefore, for the purposes of this assessment, 0.00465 g/cm^3 can be expressed as 0.00465 g/cm^2 (equivalent to 46.5 g/m^2). The amount of product available for evaporation is greater for penetrating treatments than surface treatments (46.5 g concentrate/m^2 as opposed to 10 g concentrate/m^2). As such, a product amount of 46.5 g/m^2 will be used in calculations. The air concentration of 2-phenoxyethanol in a room with treated wooden objects is estimated using the "Exposure to vapour" model in ConsExpo web with "evaporation" as the mode of release.

Tier 1	**Parameters**	**Value**
	Exposure to vapour – evaporation- constant release mode	
	Weight fraction of 2-phenoxyethanol in the concentrated product	0.0384
	Room volume[1]	20 m^3
	Ventilation rate[1]	0.6/h
	Molecular weight matrix[2]	23 g/mol
	Vapour pressure	1 Pa
	Molecular weight	138 g/mol
	Mass transfer coefficient (default)	10 m/hr
	Release area[3]	9 m^2
	Maximum amount of product available for evaporation	46.5 g concentrate / m^2
	Product amount in outer 1 cm layer of 9 m^2 (46.5 g x 9 m)	418.5 g
	Emission duration	1 day

[1] Default values for a domestic house (unspecified room) from the general fact sheet (RIVM report 320104002/2006).

[2] Molecular weight matrix calculated using ConsExpo Web guidance (page 31, RIVM report 2016-0171). As the retention rate is given in amount of concentrate/m^2, the molecular weight matrix is calculated for the concentrate. This represents a worst case compared to the molecular weight matrix for the diluted product. Detailed calculations can be found in Annex 3.6; Table 1.4.

[3] Release area calculated using a reverse reference approach (i.e. what area of treated wood can be present in a 20 m^3 room before the chronic AEC for 2-phenoxyethanol of 0.32 mg/m^3 is reached).

Tier 1 assessment

It is calculated that in a 20 m^3 room, the maximum amount of treated wood must be ≤ 9 m^2 for the air concentration to remain below the chronic AEC for 2-phenoxyethanol. As treated wood indoors is only used for e.g. windows and door frames it is unlikely that > 9m^2 of treated wood will be present, the risk of local inhalation effects from secondary exposure to 2-phenoxyethanol is considered to be acceptable. The ConsExpo web report can be found in Annex 3.2, Table 3.1.

Combined scenarios

There are no relevant combined exposure scenarios for the general public foreseen.

Dietary exposure

There is potential risk that livestock may chew treated wood or that food may be exposed to penflufen, permethrin or substance of concern 2-phenoxyethanol by direct contact with a treated wooden surface (e.g. a kitchen top or table) leading to consumer dietary exposure. It is reasonable to assume that a toddler directly chewing treated wood is likely to lead to higher oral exposure than a person exposed through consumption of contaminated food products. As such, scenario 7 forms a risk envelope for dietary exposure. Please refer to scenario 7 for predicted exposure for a toddler chewing wood treated with 'Vacsol Aqua 6118'. In the risk characterisation, systemic exposure from scenario 7 will be compared to the ADI (when available).

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

The modelling of exposures and subsequent risk characterisation during production and formulation of 'Vacsol Aqua 6118' is addressed under EU legislation (e.g. Directive 98/24/EC) and is not repeated under BPR, Regulation (EU) 528/2012 (agreed at Biocides Technical Meeting TMI06). The UK has not considered exposure from production of the biocidal product further.

Summary of exposure assessment for penflufen and permethrin

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg a.s./kg bw/day)**
Scenario 0	Industrial User Primary exposure - mixing and loading product into professional wood treatment equipment	1 (gloves)	0.0006
Scenario 1	Industrial user primary exposure – automated dipping of wooden articles	1 (gloves)	0.1809
		2 (gloves/coated coveralls)	0.0363
		3 (new gloves/coated coveralls)	0.0262
		4 (new gloves/impermeable coveralls)	0.0182
Scenario 2	Industrial user primary exposure - deluge/enclosed spray treatment of wooden articles	1 (gloves)	0.1146
		2 (gloves/coated coveralls)	0.0245
		3 (new gloves/coated coveralls)	0.0173
Scenario 3	Industrial user primary exposure - vacuum pressure treatment of wooden articles	1 (gloves)	0.0170
Scenario 4	Industrial user primary exposure - double vacuum pressure treatment of wooden articles	1 (gloves)	0.1357
		2 (gloves/coated coveralls)	0.0272
		3 (new gloves/coated coveralls)	0.0197
Scenario 5	Professional user secondary exposure - sanding treated wood	1 (no PPE)	0.0004
Scenario 6	General public secondary exposure – sanding treated wood	Covered by scenario 5	
Scenario 7	General public secondary exposure – toddler chewing treated wood off-cuts	1	0.0028

Scenario 8	General public secondary exposure – playing on (weathered) playground structures	1	0.0028
Scenario 9	General public secondary exposure – volatilisation of active substance from indoor treated surfaces	1	Negligible

Summary of exposure assessment for SoC 2-phenoxyethanol

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg a.s./kg bw/day)**
Scenario 0	Industrial User Primary exposure - mixing and loading product into professional wood treatment equipment	1 (gloves)	0.0066
Scenario 1	Industrial user primary exposure – automated dipping of wooden articles	1 (gloves)	1.8638
Scenario 2	Industrial user primary exposure - deluge/enclosed spray treatment of wooden articles	1 (gloves)	1.1721
Scenario 3	Industrial user primary exposure - vacuum pressure treatment of wooden articles	1 (gloves)	0.1737
Scenario 4	Industrial user primary exposure - double vacuum pressure treatment of wooden articles	1 (gloves)	1.3882
Scenario 5	Professional user secondary exposure - sanding treated wood	1 (no PPE)	0.0039
Scenario 6	General public secondary exposure – sanding treated wood	Covered by scenario 5	
Scenario 7	General public secondary exposure – toddler chewing treated wood off-cuts	1	0.0285
Scenario 8	General public secondary exposure – playing on (weathered) playground structures	1	0.0288
Scenario 9	General public secondary exposure – volatilisation of active substance from indoor treated surfaces	1	n/a – local inhalation effects are most critical

2.2.5.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Penflufen

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	Acute neurotoxicity	516 mg/kg bw/d	167*	None	0.3 mg/kg bw/d
AELmedium-term	1 year dog	8 mg/kg bw/d	100	None	0.077 mg/kg bw/d
AELlong-term	2 year rat	4 mg/kg bw/d	100	None	0.04 mg/kg bw/d
ARfD	Acute neurotoxicity	516 mg/kg bw/d	100	None	0.5 mg/kg bw/d
ADI	2 year rat	4 mg/kg bw/d	100	None	0.04 mg/kg bw/d

*assessment factor of 100 and additional assessment factor of 1.67 to consider first pass metabolism by the liver because the value is based on systemic exposure (neurotoxicity), whereas other AELs do not require this adjustment as they are based effects in the liver.

Permethrin

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	2 year rat	50 mg/kg bw/d	100	None	0.5 mg/kg bw/d
AELmedium-term	12 month dog	5 mg/kg bw/d	100	None	0.05 mg/kg bw/d
AELlong-term	12 month dog	5 mg/kg bw/d	100	None	0.05 mg/kg bw/d
ARfD					N/A
ADI					N/A

2-Phenoxyethanol

See Confidential Annex of the PAR.

Risk for industrial users

Systemic effects for penflufen

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 0 – mixing and loading	1 (gloves)	4	0.04	0.0006	1.5%	yes
	1 (gloves)	4	0.04	0.1809	452%	no

Scenario 1 – automated dipping	2 (gloves /coated coveralls)			0.0363	91%	yes
	3 (new gloves / coated coveralls)			0.0262	65%	yes
	4 (new gloves / impermeable coveralls)			0.0182	45%	yes
Scenario 2 – deluge/ enclosed spray	1 (gloves)	4	0.04	0.1146	286%	no
	2 (gloves / coated coveralls)			0.0245	61%	yes
	3 (new gloves / coated coveralls)			0.0173	43%	yes
Scenario 3 – vacuum pressure treatment	1 (gloves)	4	0.04	0.0170	43%	yes
Scenario 4 – double vacuum pressure treatment	1 (gloves)	4	0.04	0.1357	339%	no
	2 (gloves / coated coveralls)			0.0272	68%	yes
	3 (new gloves / coated coveralls)			0.0197	49%	yes

Systemic effects for permethrin

Task/ Scenario	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenario 0 – mixing and loading	1 (gloves)	5	0.05	0.0006	1.2%	yes
Scenario 1 – automated dipping	1 (gloves)	5	0.05	0.1809	362%	no
	2 (gloves /coated coveralls)			0.0363	73%	yes

	3 (new gloves / coated coveralls)			0.0262	52%	yes
	4 (new gloves / impermeable coveralls)			0.0182	36%	yes
Scenario 2 – deluge/ enclosed spray	1 (gloves)	5	0.05	0.1146	229%	no
	2 (gloves / coated coveralls)			0.0245	49%	yes
	3 (new gloves / coated coveralls)			0.0173	35%	yes
Scenario 3 – vacuum pressure treatment	1 (gloves)	5	0.05	0.0170	34%	yes
Scenario 4 – double vacuum pressure treatment	1 (gloves)	5	0.05	0.1357	271%	no
	2 (gloves / coated coveralls)			0.0272	54%	yes
	3 (new gloves / coated coveralls)			0.0197	39%	yes

Systemic effects for SoC 2-phenoxyethanol

Task/ Scenario	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL_{dermal} mg/kg bw/d**		**Dermal uptake mg/kg bw/d**	**Estimated dermal uptake/ AEL_{dermal} (%)**	**Acceptable (yes/no)**
Scenario 0 – mixing and loading	1 (gloves)	375	7.5		0.0066	0.1%	yes
Scenario 1 – automated dipping	1 (gloves)	375	7.5		1.8638	25%	yes
Scenario 2 – deluge/ enclosed spray	1 (gloves)	375	7.5		1.1721	16%	yes

Scenario 3 – vacuum pressure treatment	1 (gloves)	375	7.5		0.1737	2%	yes
Scenario 4 – double vacuum pressure treatment	1 (gloves)	375	7.5		1.3882	19%	yes

Combined scenarios

There are no combined scenarios foreseen for industrial users.

Local effects

Qualitative risk assessment matrix for local effects - Primary exposure during industrial use

Hazard		**Exposure**						**Risk**
Hazard Cat	*C&L*	*PT*	*Exposed group*	*Tasks*	*Expo-sure route*	*Frequency*	*RMM/PPE*	*Conclusion*
High Low	Eye Dam Cat 1 H318 Skin Irrit Cat 2 H315	8	Indust-rial	Auto-mated mixing and loading Loading and un-loading treated timber	Eye Skin	Four times per day Limited Duration (30 minutes)	Labelled as corrosive Appropriate instructions for use Packaging and automated dosing reduces exposure Technical and organizational measures (industry)/ training Protective clothing and gloves Eye protection	Acceptable Low frequency Adequate PPE including eye protection Used only by trained individuals in an industrial setting

2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has toxicological reference values (AECs) set for local inhalation effects.

Local inhalation effects for SoC 2-phenoxyethanol

Task/ Scenario	Tier	NOAEC mg/m³	AEC mg/m³	Air conc. mg/m³	Estimated air conc./ AEC (%)	Acceptable (yes/no)
Scenario 0 – mixing and loading	1 (no PPE)	48.2	0.32	0.0093	3%	yes
Scenario 1 – automated dipping	1 (no PPE)	48.2	0.32	0.030	9%	yes
Scenario 2 – deluge/ enclosed spray	1 (no PPE)	48.2	0.32	0.061	16%	yes
Scenario 3 – vacuum pressure treatment	1 (no PPE)	48.2	0.32	Covered by scenario 2		
Scenario 4 – double vacuum pressure treatment	1 (no PPE)	48.2	0.32	Covered by scenario 2		

Conclusion

Professional exposure is predicted to be within acceptable limits when appropriate PPE is worn. From the local effects assessment, gloves, coveralls and eye protection must be worn when handling the concentrate. From the risk assessment considering combined risk to penflufen and permethrin (see "Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product" section below), the following PPE is required for the different types of treatment:

- Automated dipping - impermeable coveralls and new gloves every cycle
- Deluge / enclosed spray treatment - coated coveralls and new gloves every cycle
- Double vacuum pressure treatment - coated coveralls and new gloves every cycle
- Vacuum pressure treatment - gloves

On the basis of the combined risk assessment and the local effects assessment, the following PPE phrases must appear on the SPC/label:

- Wear protective chemical resistant gloves* (glove material to be specified by the authorisation holder within the product information). *new gloves must be worn at the start of each treatment cycle

- The use of eye protection during handling of the product is mandatory.

- A protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

Risk for professional users

The product is not intended for application by professional users outside of an industrial setting. However, professional secondary exposure may occur via an adult sanding treated wood.

Systemic effects for penflufen

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 5 – sanding treated wood	1 (no PPE)		0.04	0.0004	1%	Yes

Systemic effects for permethrin

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 5 – sanding treated wood	1 (no PPE)		0.05	0.0004	0.8%	Yes

Systemic effects for SoC 2-phenoxyethanol

Task/ Scenario	Tier	Systemic NOAEL $_{dermal}$ mg/kg bw/d	AEL_{dermal} mg/kg bw/d	Estimated dermal uptake mg/kg bw/d	Estimated dermal uptake/ AEL_{dermal} (%)	Acceptable (yes/no)
Scenario 5 – sanding treated wood	1 (no PPE)	375	7.5	0.0037	0.05%	Yes

Combined scenarios

There are no combined scenarios foreseen for professional users.

Local effects

Substance of concern 2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has a toxicological reference value set for local inhalation effects. Secondary exposure to volatilised 2-phenoxyethanol is considered under scenario 9.

Conclusion

Professional exposure is predicted to be within acceptable limits.

Risk for non-professional users

The product is not intended for non-professional use.

Risk for the general public

Systemic effects for penflufen

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 6 – sanding treated wood	1		0.3	Covered by scenario 5		
Scenario 7 – chewing treated wood off-cuts	1		0.3	0.0028	0.9%	Yes
Scenario 8 – playing on (weathered) playground structures	1		0.3	0.0028	0.9%	yes
Scenario 9 – inhalation of volatilised residues	1		0.04	Negligible	n.a.	yes

Systemic effects for permethrin

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 6 – sanding treated wood	1		0.5	Covered by scenario 6		
Scenario 7 – chewing treated wood off-cuts	1		0.5	0.0028	0.6%	Yes
Scenario 8 – playing on (weathered) playground structures	1		0.5	0.0028	0.6%	yes
Scenario 9 – inhalation of volatilised residues	1		0.05	Negligible	n.a.	yes

Systemic effects for SoC 2-phenoxyethanol

Task/ Scenario	Tier	Systemic NOAEL	AEL mg/kg bw/d	Estimated uptake	Estimated uptake/ AEL	Acceptable (yes/no)

		mg/kg bw/d		mg/kg bw/d	(%)	
Scenario 6 – sanding treated wood	1	375 (dermal)	7.5 (dermal)	Covered by scenario 6		
Scenario 7 – chewing treated wood off-cuts	1	370 (oral)	3.7 (oral)	0.0285	0.8%	Yes
Scenario 8 – playing on (weathered) playground structures	1	375 (dermal)	7.5 (dermal)	0.0123	0.2%	yes
		250 (oral)	2.5 (oral)	0.0164	1%	yes
Scenario 9 – inhalation of volatilised residues	1	N/A – the critical effect for inhalation exposure is local effects				

Combined scenarios

Combined exposure is not foreseen for the general public.

Local effects

2-phenoxyethanol is potentially volatile with a vapour pressure of 1.0 Pa at 20 °C and has toxicological reference values (AECs) set for local inhalation effects. A worst case secondary exposure scenario to volatilised 2-phenoxyethanol is considered under scenario 9. This estimate forms a risk envelope for the other secondary exposure scenarios.

Local inhalation effects for SoC 2-phenoxyethanol

Task/ Scenario	Tier	NOAEC mg/m³	AEC mg/m³	Air conc. mg/m³	Estimated air conc./ AEC (%)	Acceptable (yes/no)
Scenario 9 – inhalation of volatilised residues	1	48.2	0.32	<0.32[1]	< 100%	yes

[1] A reverse reference calculation was completed for this scenario. In a room with a volume of 20 m^3, the amount of treated wood must be ≤ 9 m^2. The UK considers it unlikely that >9 m^2 of treated wood will be present in a room with this volume therefore the risk from secondary inhalation exposure is considered acceptable.

Conclusion

Exposure to the general public is predicted to be within acceptable limits.

Risk for consumers via residues in food

There is potential that livestock may chew treated wood or that food may be exposed to penflufen by direct contact with a treated wooden surface (e.g. a kitchen top or table) leading to consumer dietary exposure. It is reasonable to assume that a toddler directly chewing treated wood is likely to lead to higher exposure than a person exposed to penflufen through consumption of contaminated food products. As such, scenario 7 forms a risk envelope for dietary exposure. As a worst case, exposure has been compared to the long term dietary endpoint (ADI). If an ADI is not set, the exposure is compared to the $AEL_{long\ term}$.

Dietary exposure for penflufen

Scenario	Tier	NOAEL mg/kg bw/d	ADI mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ ADI (%)	Acceptable (yes/no)
Dietary exposure	1	4	0.04	≤0.0028	≤7%	yes

Dietary exposure for permethrin

Scenario	Tier	NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ ADI (%)	Acceptable (yes/no)
Dietary exposure	1	5	0.05	≤0.0028	≤6%	yes

Dietary exposure for SoC 2-phenoxyethanol

Scenario	Tier	NOAEL mg/kg bw/d	ADI mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ ADI (%)	Acceptable (yes/no)
Dietary exposure	1	250	2.5	≤0.0285	≤1%	yes

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

The risk assessment from combined exposure to both active substances in 'Vacsol Aqua 6118' was conducted according to Guidance on the BPR: Volume III, Part B, Risk Assessment. Since there are no indications for potential synergistic effects induced by the actives permethrin and penflufen, the toxicological effects are considered to be additive. The Hazard Quotient (ratio of internal exposure and AEL) for each active substance has been used to calculate a Hazard Index (HI) for the biocidal product (the HI is the sum of the Hazard Quotients for each substance). If the HI ≤1 the risk from combined exposure to both active substances is considered acceptable and if the HI >1 the risk from combined exposure to both active substances is considered unacceptable.

It is not relevant to include the substance of concern 2-Phenoxyethanol in the risk characterisation from combined exposure as the substance is haematotoxic, i.e. it does not

have the same effect on target organs as the active substances penflufen and permethrin (for which the AELS are derived from toxic effects on the liver).

Combined exposure to penflufen and permethrin for industrial users

Scenario	Active Ingredient	Estimated exposure / AEL (HQ)
Scenario 0 – mixing and loading	Penflufen	0.015
	Permethrin	0.012
	Cumulative risk scenario 1 (HI)	0.027 **(tier 1; gloves)**
Scenario 1 – automated dipping	Penflufen	4.52 (tier 1)
		0.91 (tier 2)
		0.65 (tier 3)
		0.45 (tier 4)
	Permethrin	3.62 (tier 1)
		0.73 (tier 2)
		0.52 (tier 3)
		0.36 (tier 4)
	Cumulative risk scenario 1 (HI)	**8.14 (tier 1; gloves)**
		1.63 (tier 2; gloves / coated coveralls)
		1.18 (tier 3; new gloves / coated coveralls)
		0.82 (tier 4; new gloves / impermeable coveralls)
Scenario 2 – deluge/enclosed treatment	Penflufen	2.86 (tier 1)
		0.61 (tier 2)
		0.43 (tier 3)
	Permethrin	2.29 (tier 1)
		0.49 (tier 2)
		0.35 (tier 3)
	Cumulative risk scenario 2 (HI)	**5.16 (tier 1; gloves)**
		1.10 (tier 2; gloves / coated coveralls)
		0.78 (tier 3; new gloves / coated coveralls)

Scenario	Active Ingredient	Estimated exposure / AEL (HQ)
Scenario 3 - vacuum pressure treatment	Penflufen	0.43 (tier 1)
	Permethrin	0.34 (tier 1)
	Cumulative risk scenario 3 (HI)	**0.77 (tier 1; gloves)**
Scenario 4 - double vacuum pressure treatment	Penflufen	3.39 (tier 1)
		0.68 (tier 2)
		0.49 (tier 3)
	Permethrin	2.71 (tier 1)
		0.54 (tier 2)
		0.39 (tier 3)
	Cumulative risk scenario 4 (HI)	**6.11 (tier 1; gloves)**
		1.23 (tier 2; gloves / coated coveralls)
		0.88 (tier 3; new gloves / coated coveralls)

From the risk assessment considering combined risk to penflufen and permethrin, the following PPE is required for the different types of treatment:

- Automated dipping - impermeable coveralls and new gloves every cycle
- Deluge / enclosed spray treatment - coated coveralls and new gloves every cycle
- Double vacuum pressure treatment - coated coveralls and new gloves every cycle
- Vacuum pressure treatment - gloves

Combined exposure to penflufen and permethrin for professional users

Scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Scenario 5 - sanding treated wood	Penflufen	0.010 (tier 1)
	Permethrin	0.008 (tier 1)
	Cumulative risk scenario 5 (HI)	**0.017 (tier 1; no PPE)**

Combined exposure to penflufen and permethrin for the general public

Scenario	Active Ingredient	Estimated exposure / AOEL (HQ)
Scenario 6 - sanding treated wood	Covered by scenario 5	
Scenario 7 – toddler chewing treated wood off-cuts	Penflufen	0.009
	Permethrin	0.006
	Cumulative risk scenario 7 (HI)	**0.015**
Scenario 8 - playing on (weathered) playground structures	Penflufen	0.009
	Permethrin	0.006
	Cumulative risk scenario 8 (HI)	**0.015**

2.2.6 Risk assessment for animal health

The biocidal product is intended for pre-treatment of timber by industrial users. Regarding potential exposure to the product during mixing and application, as the product is diluted and applied to wood only in industrial premises there is no potential for direct exposure to animals.

There is no guidance available for conducting risk assessments for animal health. For the purposes of this evaluation, an assessment is conducted which is based on the guidance for estimating livestock exposure to active substances used in biocidal products (Chapter 6 in Vol III, Part B + C). It should be noted that this guidance was developed for assessing human dietary exposure to residues in livestock and is not specifically developed for animal health risk assessment. However, it is generally recognized to be a conservative assessment that incorporates several routes of livestock exposure in confined spaces and can be considered a worst case with respect to other (non-livestock) animals.

The guidance states that animals can take up residues of the biocidal product by chewing on (e.g. horses, rabbits, goats), rubbing against (large slaughter animals) or licking (e.g. ruminants) the treated materials. In addition, volatile substances being released from the treated material may be inhaled, but this is not relevant for Vacsol Aqua 6118 since the active substances have been shown to be non-volatile.

The default values given in the guidance make assumptions based on wood consumption, the body area and licks per day. It is assumed that animals are exposed through a variety of exposures to treated wood, particularly in sheds and enclosed spaces. The extent of exposure will also depend on animal husbandry practices. Animals tend to chew or lick due to boredom or a dietary deficiency. Good animal practice will tend to limit exposures.

The wood for animal housing is generally of UC3. For UC3, Vacsol Aqua 6118 is applied by vacuum and double vacuum and has a maximum retention of 4.65 kg/m^3.

In accordance with the BPR guidance, an assessment was made using The Federal Institute for Risk Assessment (BfR) calculator for estimating external exposure of livestock animals, to determine the oral and dermal exposure estimations. Oral exposure via licking and chewing wood and dermal exposure by rubbing against treated wood were considered. The inputs to the BfR calculator is application rates of active substance in terms of g/m^3 and mg/m^2.

An uptake of 4.65 kg/m^3 will result in the following amounts of active substance and SoC in treated wood:

4.65 kg/m^3 x % w/w x 1000 g/kg

Penflufen	17.4 g/m^3
Permethrin	17.3 g/m^3
2-phenoxyethanol	178.6 g/m^3

For dermal exposure and oral licking a surface concentration is required. This is calculated based on a surface thickness of 0.05 mm, as follows:

g/m^3 x 0.05 mm x 1000 mg/g

Penflufen	0.872 mg/m^2
Permethrin	0.865 mg/m^2
2-phenoxyethanol	8.93 mg/m^2

BfR input data

Active substance	**Dermal and licking (mg/m^2)**	**Chewing (g/m^3)**
Penflufen	0.872	17.4
Permethrin	0.865	17.3
2-phenoxyethanol	8.93	178.6

Output tables from the BfR calculator can be found below in the appendix (3.7.4).

The results show that the highest external exposure for all substances and uses was found in slaughter goat (goat kid) which is used for a worst case risk assessment. Using the same approach as for human risk assessment, this value is compared to the AEL (long term).

Active substance	**goat kid external exposure (mg/kg bw)**	**AEL (mg/kg bw/d)**	**% AEL**
Penflufen	0.0154	0.04	39%
Permethrin	0.0153	0.05	31%
2-phenoxyethanol	0.1580	7.5	2%

This is a conservative assessment, as it assumes that the active substances in the treated wood are fully available and completely transferred to livestock on a single day, and that the uptake via the dermal route is of the same magnitude as uptake via the oral route (100%). Despite these conservative assumptions, the estimated external exposures are well below the long term AELs derived for long term human health risk assessment and therefore the risks to animal health can be considered acceptable.

2.2.7 Risk assessment for the environment

2.2.7.1 Effects assessment on the environment

The product contains two active substances (penflufen and permethrin) and two substances of concern (2-phenoxyethanol and Dimethyl myristyl amine, distilled).

2-phenoxyethanol is an active substance under review under PT1, 2, 4, 6 and 13 is therefore considered a non-PT active substance in the formulation and hence a substance of concern. The applicant submitted a safety data sheet with PNEC values (based on the REACH-dossier of the applicant´s supplier). PNECs have been taken from the draft Assessment report and the safety data sheet and the lowest of these values considered in the risk assessment.

Dimethyl myristyl amine, distilled (CAS 68439-70-3) is classified for the environment as Aquatic Acute Category 1 (M-factor = 100) and Aquatic Chronic Category 1 (M-factor = 1) and its % w/w in the undiluted formulation means further consideration is needed of this co-formulant as a potential substance of concern.

The quantitative environmental risk assessment was carried out for UC3 (double vacuum and vacuum pressure application) SoC dimethyl myristyl amine, distilled because it contributes to the classification of the concentrated product. The PNECs used for the environmental risk assessment are taken from the SDS for.

The PNECs for the active substances are summarised below. The PNEC values for SoCs 2-phenoxyethanol and Dimethyl myristyl amine, distilled are also provided below and in the confidential annex.

Source of PNECs: Assessment Report for Penflufen (March 2017)

PNECs	Penflufen (active substance)	M01 (metabolite)	M02 (metabolite)
$PNEC_{aquatic}$	0.00234 mg/L	0.0157 mg/L	-
$PNEC_{marine}$	-	-	-
$PNEC_{sediment}$	0.016 mg/kg wwt	-	-
$PNEC_{stp}$	1.09 mg/L	-	-
$PNEC_{soil}$ / $PNEC_{terrestrial}$	0.42 mg a.s./kg dwt (corrected to 3.4% organic matter content) 0.377 mg a.s./kg wwt	0.44 mg/kg dwt (corrected to 3.4% organic matter content) 0.39 mg/soil wwt	0.364 mg/kg dwt (corrected to 3.4% organic matter content) 0.322 mg/kg wwt
$PNEC_{oral\ bird}$	31.5 ppm (mg/kg)	-	-

$PNEC_{oral\ mammal}$	33.33 ppm (mg/kg)	-	-

log P_{ow} = 3.3
BCF = 142
PBT-assessment: P, not B or T

Penflufen has a log Kow of 3.3, which is above the trigger value of 3, indicating a potential for bioaccumulation.

Source of PNECs: Assessment Report for Permethrin (April 2014)

PNECs	Permethrin (active substance)	DCVA (metabolite)	PBA (metabolite)
$PNEC_{aquatic}$	0.00047 µg/L	0.015 mg/L	> 0.010 mg/L
$PNEC_{marine}$	-	-	-
$PNEC_{sediment}$	0.001 mg/kg dwt 0.000217 mg/kg wwt	0.055 mg/kg dwt 0.012 mg/kg wwt	0.042 mg/kg dwt 0.009 mg/kg wwt
$PNEC_{stp}$	0.00495 mg/L	-	-
$PNEC_{soil}$ / $PNEC_{terrestrial}$	0.198 mg/kg soil dwt* 0.175 mg/kg soil wwt*	4.6 mg/kg wwt	1.44 mg/kg wwt
$PNEC_{oral\ bird}$	≥16.7 mg/kg food	-	-
$PNEC_{oral\ small\ mammal}$	120 mg/kg food	-	-

log P_{ow} = 4.67 at 25°C
BCF = 500 - 570
PBT-assessment: Potentially P, not B, is T
*Revised $PNEC_{soil}$ values for Permethrin following a Working Group Meeting.

Permethrin has a log Kow of 4.67, which is above the trigger value of 3, indicating a potential for bioaccumulation.

Source of PNECs: Draft Assessment report for 2-phenoxyethanol and Safety Data Sheet.

	2-phenoxyethanol (Substance of concern)	
PNECs	Draft Assessment report	Safety data sheet
$PNEC_{aquatic}$	**0.943 mg/L**	0.943 mg/L
$PNEC_{marine}$	-	**0.094 mg/L**
$PNEC_{sediment}$	0.817 mg/kg dwt sediment 0.178 mg/kg wwt sediment	**0.724 mg/kg dwt sediment** **0.157 mg/kg wwt sediment**
$PNEC_{stp}$	**>10 mg/L**	24.8 mg/L
$PNEC_{soil}$ / $PNEC_{terrestrial}$	1.31 mg/kg soil dwt 1.15 mg/kg soil wwt	1.26 mg/kg soil dwt **1.11 mg/kg soil wwt**
$PNEC_{oral\ bird}$	-	-
$PNEC_{oral\ small\ mammal}$	-	-

Bold values used in the risk assessment
Not PBT

Dimethyl myristyl amine, distilled - (CAS 68439-70-3).
Source of PNECs: SDS for

PNECs	dimethyl myristyl amine (Substance of concern)
$PNEC_{aquatic}$	0,26 µg/l
$PNEC_{marine}$	0,03 µg/l
$PNEC_{stp}$	130 µg/l
$PNEC_{fresh\ water\ sediment}$	1,25 mg/kg dwt
$PNEC_{marin\ sediment}$	0,125 mg/kg dwt
$PNEC_{soil}$	1 mg/kg dwt

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

IUPAC name or other accepted chemical name	Dimethyl myristyl amine, distilled; [N,N-dimethyl-C12-16-(even numbered)-alkyl-1-amines]
EC number	270-414-6
CAS number	68439-70-3
Concentration (minimum and maximum, g/kg or g/l)	4.8%
Classification and Labelling according to Regulation (EC) No 1272/2008:	Acute Aq cat 1 H400 (M-factor = 100) Chr. Aq cat 1 H410 (M-factor = 1) Acute tox 4, H302, Skin Corr 1B, H314 Acute Aq cat 1 H400 Chr. Aq cat 1 H410
Classification and Labelling according to the Directive 67/548/EEC	N/A
Relevant toxicological/ecotoxicological information	Classified as acute 1 (M-Factor = 100) and chronic 1 (M-Factor = 1)
Other grounds for concern	N/A

Further Ecotoxicological studies

Data waiving	
Information requirement	Further Ecotoxicological studies

Justification	No additional data are required.

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

Data waiving	
Information requirement	Effects on other non-target organisms.
Justification	No additional data are required.

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

Data waiving	
Information requirement	Supervised trials.
Justification	No additional data are required.

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

Data waiving	
Information requirement	Acceptance by ingestion.
Justification	No additional data are required.

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

No additional data are required.

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

In line with agreed guidance (PT 8 ESD) and decisions reached at review for other biocidal actives, the application can be authorised for UC 1 and UC 2 by all application methods without further assessment of in-service emissions (as emissions can be accepted as negligible and risks can be considered as zero). No consideration of losses from application and storage at industrial pre-treatment sites has been undertaken as it is considered that all such locations will be subject to bunding in order to comply with other "major hazards" regulations. As a consequence, suitable RMM must now recommend that:

All vacuum-pressure impregnation, double-vacuum, dipping and deluge treatment must only be undertaken at industrial sites where:

1. *Application processes are 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). Freshly treated timber shall be stored after treatment under shelter AND on impermeable hard standing to prevent losses to soil, sewer, or water, and that any losses from the application of the product shall be collected for reuse or disposal

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

No new environmental fate and behaviour data on the active substances will be presented. All the endpoints have been taken from the most recent final CARs available for each active substance.

Product specific leaching data is presented in support of UC 3 applications.

Leaching behaviour (ADS)

A laboratory leaching study has been provided by the applicant in support of UC 3 for this submission (). The study was undertaken to follow the OECD '107' (ENV/JM/MONO(2009)12) guidelines and analyses the leaching of active substances penflufen and permethrin over an extended period of 61 days.

The non-GLP study assessed the leaching potential of wood treated with Vacsol Aqua 6118 by immersing the treated wood in water for 1 minute, 3 times a day, every 2/3 days. The UK CA noted a number of concerns with the study which cast doubt on the robustness of the data and suitability to use the information to refine predictions of leaching losses. The UK CA's concerns and the applicant's response is summarised below.

The UK CA noted the study only assessed the leaching behaviour of the active substances penflufen and permethrin. No leaching data was provided for the non-PT active 2-phenoxyethanol which is present in the formulation and fulfils the Substance of Concern criteria. To address this issue, the applicant has submitted separate 2-phenoxyethanol leaching data; further discussion on this is provided in subsequent paragraphs.

The UK CA noted the OECD guidelines (ENV/JM/MONO(2009)12) state that in all cases, the testing regime must be fully justified according to the intended application method, use class and use pattern of the treated wood. This justification was not provided in the study report. The applicant subsequently stated that the ESD models are based on rainfall every three days and section 3.2.4 of the OECD test guidelines state that the 3 x 1 minute dips, three times a day, every three days will give the same wood moisture content as exposure under real conditions. For this reason, and because the conclusions of the second leaching workshop (Varese, Italy, 2013) state that laboratory studies conducted to OECD 107/2009 can be submitted to support authorisation, this has been accepted by the UK CA.

The UK CA noted the leaching study was carried out at a mean product retention of 9.24 kg/m^3 which is approximately double the requested retention of 4.65 kg/m^3. The conclusion of the first leaching workshop, Arona, 2005, states leaching studies should be carried out with a maximum application rate based on efficacy testing and the label claim. The applicant justified the higher study retention stating that the test was set up prior to final efficacy data being available and when the commercial use of the product was still under discussion. Therefore, the wood was treated with the maximum retention under consideration at the time. Furthermore, the test retention is still within the range linear

extrapolation can be used to correct leaching rates as stated in the first leaching workshop. The UK CA accepts the applicant's justification.

The OECD guidelines recommend the study is conducted in the dark, however, no detail was provided in the study report regarding the light conditions. An updated study report has been submitted which confirms the test was conducted in the dark.

The UK CA highlighted concerns with the analytical method as it was only briefly reported and it was not possible to independently verify that a valid method had been used. The UK CA requested further information on the analytical methods used in the study, detailing clearly how the samples were worked-up and analysed for penflufen and permethrin. The applicant has not directly responded to the UK CA's points raised but have submitted an updated study report which includes details on how the samples were worked up; the updated information is accepted by the UK CA.

However, the UK CA also highlighted the calibration curves provided for both active substances were undertaken at concentrations significantly greater than the concentrations being detected in the study. The analytical calibration should extend over a range appropriate to the lowest and highest concentration of the analytes in the relevant analytical solutions. The penflufen curve covered a concentration range of 0 – 400 µg/L; the maximum mean leaching concentration detected in the study was 8.07 µg/L. The permethrin curve covered a concentration range of 0 – 500 µg permethrin/L n-hexane; the maximum mean leaching concentration detected in the study was 0.334 µg/L. The applicant has not provided any further justification regarding the calibration curves.

The UK CA also noted no fortification data was provided to support the accuracy and precision of the method. This data was provided in an updated study report. Three fortification levels, commencing from the a.s. respective LOQ's, were analysed with mean overall recoveries of 102% for permethrin and 105% for penflufen. Therefore, the recoveries are within the OECD recommended range.

The UK CA also requested further information on the storage conditions of the samples. The applicant confirmed the collected water samples were stored in a freezer (-18°C) and the test specimens at room temperature (20 ± 2 °C) in the dark; no information was provided on the length of storage prior to analysis. The applicant also confirmed the two peaks observed in the submitted permethrin chromatograms are two enantiomeric pairs, associated with the compound; this is accepted by the UK CA.

With the exception of the calibration curves and the sample storage duration, the UK CA considers the applicant to have suitably addressed the UK CA's concerns with the study. The UK CA is of the opinion that despite the concerns with the large concentrations used for calibration, the additional information provided regarding the extraction methodology and the acceptable recoveries demonstrated with the fortification results, including at the respective LOQ's, that this issue is unlikely to have significantly negatively impacted on the outcomes of the study. Similarly, despite no exact details were provided regarding when samples were analysed, the UK CA notes the final sampling was conducted on 10 March 2017 (initial sampling was conducted on 9 January 2017) and the study report was finalised on 31 May 2017. Therefore, the analysis must have been conducted in the intervening 2 months (and possibly earlier for the earlier sampling points). Therefore, because the samples were stored frozen until analysis and the accelerated storage stability test (see section 2.2.1) confirmed no significant degradation of penflufen and permethrin occurred, the UK CA accepts the study methodology. The results of the leaching study are shown below.

Day	Penflufen						
	Untreated specimens		Treated specimens				
	Concentration a.s. in water	Quantity emitted per immersion day	Quantity emitted per immersion day				
			x	y	z	Mean	Cumu-lative
	[µg/L]	[mg/m²]	[mg/m²]	[mg/m²]	[mg/m²]	[mg/m²]	[mg/m²]
1	<1	<0,05	0.72	0.57	0.50	0.60	0.60
3	<1	<0,05	0.42	0.42	0.37	0.41	1.00
5	<1	<0,05	0.32	0.30	0.28	0.30	1.30
8	<1	<0,05	0.30	0.26	0.25	0.27	1.57
10	<1	<0,05	0.25	0.22	0.25	0.24	1.81
12	<1	<0,05	0.25	0.22	0.21	0.23	2.04
15	<1	<0,05	0.24	0.19	0.21	0.21	2.25
17	<1	<0,05	0.22	0.17	0.19	0.19	2.44
19	<1	<0,05	0.20	0.17	0.17	0.18	2.62
22	<1	<0,05	0.19	0.16	0.16	0.17	2.79
24	<1	<0,05	0.16	0.16	0.16	0.16	2.95
26	<1	<0,05	0.16	0.16	0.16	0.16	3.11
29	<1	<0,05	0.14	0.14	0.15	0.14	3.26
31	<1	<0,05	0.13	0.14	0.12	0.13	3.39
33	<1	<0,05	0.12	0.13	0.13	0.13	3.52
36	<1	<0,05	0.13	0.14	0.13	0.13	3.65
38	<1	<0,05	0.11	0.10	0.11	0.11	3.76
40	<1	<0,05	0.10	0.09	0.10	0.10	3.86
43	<1	<0,05	0.10	0.10	0.09	0.09	3.95
45	<1	<0,05	0.10	0.10	0.10	0.10	4.05
47	<1	<0,05	0.11	0.10	0.13	0.12	4.17
50	<1	<0,05	0.15	0.11	0.13	0.13	4.30
52	<1	<0,05	0.13	0.11	0.13	0.13	4.43
54	<1	<0,05	0.12	0.11	0.12	0.12	4.55
57	<1	<0,05	0.12	0.11	0.10	0.11	4.66
59	<1	<0,05	0.11	0.11	0.13	0.12	4.78
61	<1	<0,05	0.12	0.11	0.12	0.12	4.90

Day	Permethrin						
	Untreated specimens		Treated specimens				
	Concentration a.s. in water	Quantity emitted per immersion day	Quantity emitted per immersion day				
			x	y	z	Mean	Cumu-lative
	[µg/L]	[mg/m²]	[mg/m²]	[mg/m²]	[mg/m²]	[mg/m²]	[mg/m²]
1	<0,025	<0,002	0.0032	0.0192	0.0188	0.0137	0.0137
3	<0,025	<0,002	0.0080	0.0535	0.0129	0.0248	0.0385
5	<0,025	<0,002	0.0109	0.0157	0.0212	0.0160	0.0545
8	<0,025	<0,002	0.0077	0.0098	0.0190	0.0122	0.0667
10	<0,025	<0,002	0.0033	0.0070	0.0064	0.0056	0.0723

12	<0,025	<0,002	0.0062	0.0092	0.0190	0.0115	0.0838
15	<0,025	<0,002	0.0052	0.0098	0.0082	0.0077	0.0915
17	<0,025	<0,002	0.0074	0.0112	0.0130	0.0105	0.1020
19	<0,025	<0,002	0.0080	0.0087	0.0103	0.0090	0.1110
22	<0,025	<0,002	0.0098	0.0111	0.0098	0.0102	0.1212
24	<0,025	<0,002	0.0096	0.0117	0.0102	0.0105	0.1317
26	<0,025	<0,002	0.0095	0.0097	0.0086	0.0093	0.1410
29	<0,025	<0,002	0.0037	0.0119	0.0074	0.0077	0.1487
31	<0,025	<0,002	0.0045	0.0082	0.0026	0.0051	0.1538
33	<0,025	<0,002	0.0034	0.0105	0.0069	0.0069	0.1607
36	<0,025	<0,002	0.0062	0.0059	0.0085	0.0069	0.1676
38	<0,025	<0,002	0.0062	0.0091	0.0109	0.0087	0.1763
40	<0,025	<0,002	0.0057	0.0066	0.0060	0.0061	0.1824
43	<0,025	<0,002	0.0070	0.0038	0.0057	0.0055	0.1879
45	<0,025	<0,002	0.0082	0.0027	0.0034	0.0048	0.1927
47	<0,025	<0,002	0.0039	0.0023	0.0020	0.0027	0.1954
50	<0,025	<0,002	0.0025	0.0024	0.0019	0.0022	0.1976
52	<0,025	<0,002	0.0019	0.0039	0.0019	0.0026	0.2002
54	<0,025	<0,002	0.0016	0.0022	0.0020	0.0019	0.2021
57	<0,025	<0,002	0.0027	0.0026	0.0032	0.0028	0.2049
59	<0,025	<0,002	0.0018	0.0024	0.0021	0.0021	0.2070
61	<0,025	<0,002	0.0028	0.0023	0.0024	0.0025	0.2095

As described at the beginning of this section, 2-phenoxyethanol (2-PE) is a potential substance of concern and is required to be considered in the environmental risk assessment (ERA). The applicant did not originally provide leaching data to support 2-PE, therefore, the UK CA conducted the ERA assuming 50% loss at Time 1 and 100% loss at Time 3 (service life). This resulted in unacceptable Time 1 risk based on the 2-PE PEC/PNEC values alone. The applicant has therefore submitted separate 2-PE leaching data to refine the assessment.

The 2-PE data submitted is from an NT509 semi-field leaching study (, report number:) conducted from June 2017 to June 2018. 2-PE was not analysed for initially. Therefore, the analysis was conducted in June 2019 on previously stored, frozen leachate samples. The applicant also reported the penflufen and permethrin semi-field results. However, the UK CA has not considered the semi-field permethrin and penflufen data in this evaluation for the following reasons:

1. The data was submitted very late in the evaluation specifically to address the UK CA's 2-PE concerns.
2. The study is ongoing with only ca.1 years' worth of results available
3. An acceptable environmental risk assessment was obtained using the laboratory leaching data for penflufen and permethrin which is more worst-case. It is noted the quantity of penflufen leached over 61 days of the laboratory study is equivalent to ca.1 rain year of the semi-field study. The cumulative quantity of permethrin observed in the laboratory study had not been reached in the semi-field study.

To address the UK CA's concerns over the potential for 2-PE degradation, in the field and/or when frozen during the extended period of sample storage, the applicant has also submitted additional storage stability study (). The UK CA's chemistry specialist has confirmed the study indicates 2-PE is stable under both environmental conditions and the storage conditions for the 14 days tested. Therefore, the UK CA considers the additional

storage stability data may be used to support an interim authorisation (subject to an acceptable ERA), with a requirement set for data to demonstrate the frozen storage stability over 23 months as a post-authorisation data requirement.

The NT509 study was conducted according to the relevant guidelines. Three test sets, treated with Vacsol Aqua 6118 by vacuum pressure impregnation (VPI), were used in the study, with a combined average retention of 9.58 kg/m^3 (similar to the rate tested in the laboratory OECD 107 test). The results are presented below; the concentration of 2-PE in all samples was <LOQ (100 µg/L).

Exposure period	Precipitation		Rain days	Untreated specimens		Treated specimens – concentrations in water			
	Quantity	Cumu-lative		Conc. In water	Quantity emitted	a	b	c	Mean results
	[mm]	[mm]	[days]	[µg/L]	[mg/m^2]	[µg/L]	[µg/L]	[µg/L]	[mg/m^2]
14/06/17 – 26/06/17	52	52	27	<100	<0.6	<100	<100	<100	<0.6
26/06/17 - 30/06/17	77	129	67	<100	<0.6	<100	<100	<100	<0.6
30/06/17 – 26/07/17	107	236	123	<100	<0.6	<100	<100	<100	<0.6
26/07/17 – 23/10/17	167	403	210	<100	<0.6	<100	<100	<100	<0.6
23/10/17 – 18/01/18	202	605	315	<100	<0.6	<100	<100	<100	<0.6
18/01/18 – 14/06/18	209	814	424	<100	<0.6	<100	<100	<100	<0.6

The applicant used the leaching data to produce an environmental risk assessment in support of their application. However, due to a difference of opinion in interpretation of the leaching data, only the UK CA's exposure assessment is presented in this PAR; reference is made to the applicant's leaching rate derivation and calculations for completeness.

In line with the applicant's "Tier 1" approach, 100% loss of actives is considered at Time 3 (service life); 75% loss has been considered at Time 2 (365 d) for ECHA informational purposes (the outcomes of the Time 2 assessment have not been used for decision making). The UK CA has used the two leaching studies to determine refined leaching rates for all compounds for the purposes of a Tier 2 assessment of risks at Time 1.

It is noted the applicant's "Tier 1" Time 3 calculations fail the House scenario (in soil), primarily due to the penflufen metabolites PEC/PNEC ratios. The applicant then goes on to provide their own "Tier 2" calculations based on leaching rates derived from the leaching studies. However, the UK CA notes in the applicant's calculations degradation of the metabolites was not considered. The UK CA has provided a more refined assessment which does take into account potential degradation of metabolites, but still relies on the default 100% loss at Time 3.

Furthermore, it is noted in the applicant's "Tier 1" Time 3 calculations they differentiate between the double-vacuum impregnation (DVI) and vacuum pressure impregnation (VPI)

methods. The applicant states that, even though the methods have the same retention *rate*, the product will be concentrated in the outer 3mm of the wood from the DVI method and, therefore, the ESD scenarios need to be amended to reflect there being a lower *concentration* in the wood. Whilst the UK CA accepts the DVI method could mean a lower a.s. *concentration* in the wood if it is retained only in the outer 3mm (as opposed to throughout the wood for the VPI method), the UK CA has concerns with this approach as we are not aware that such a differentiation has been used in the past for other products applied via both DVI and VPI methods. In addition, the UK CA notes that the ESD does not differentiate between the DVI and VPI methods in the scenario calculations and to do so calls into question the appropriateness of conducting only one leaching study to address losses from two treatment methods. Even if some differentiation between methods were to be accepted, since both treatment methods have been requested the more conservative one would still need to result in an acceptable risk assessment in order to be able to recommend authorisation for the product.

Therefore, as a conservative Tier 1 assessment to address losses from either treatment method, the UK CA has considered 100% loss over Time 3 (including degradation). The exception to this is for the groundwater calculations, where the separate penflufen (laboratory) and 2-PE leaching (semi-field) study data was used to refine the default leaching rate for the purposes of a Tier 2 groundwater assessment. Further information on the groundwater leaching rates is provided in section 2.2.7.2 and Annex 3.7.2. The different approaches used by the UK CA to derive the PEC values for the difference compartments are summarised in the table below.

Environmental compartment	**Time 1 (30 days)**	**Time 2 (365 days)**	**Time 3 (7300 days)**
Soil	Active substances: Leaching study data considered Metabolites: Non-degraded parent PEC_{soil} converted	Active substances: 75% loss considered Metabolites: Non-degraded parent PEC_{soil} converted	Active substances: 100% loss considered Metabolites: Parent leaching rate converted, input into calculator spreadsheet
STP	Active substances: Leaching study data considered Metabolites: No calculations necessary as metabolites not formed in STP	Active substances: 75% loss considered Metabolites: No calculations necessary as metabolites not formed in STP	Active substances: 100% loss considered Metabolites: No calculations necessary as metabolites not formed in STP
Surface water and sediment	Active substances: Leaching study data considered Metabolites: Non-degraded parent $PEC_{SW/sed}$ converted	Active substances: 75% loss considered Metabolites: Non-degraded parent $PEC_{SW/sed}$ converted	Active substances: 100% loss considered Metabolites: Non-degraded parent $PEC_{SW/sed}$ converted
Groundwater	Active substances and relevant metabolites modelled together in PEARL. Tier 1 – 100% loss considered Tier 2 – leaching study data considered (penflufen (and metabolites) and 2-PE only)		

Further information on the Time 1 leaching rates derived from the leaching studies and the default Time 2 and Time 3 leaching rates is provided below.

The applicant has calculated Time 1 leaching rates by dividing the quantity leached over 29 days by 29 for penflufen and permethrin. The UK CA considers it appropriate to add one day of the 29-31 day leaching rate to the quantity leached over 29 days for penflufen and permethrin. For 2-PE, The UK CA has treated the less-than test results as absolute values (i.e. 0.6 mg/m^2) and added 3 days of the 27-67 day leaching rate to the 27 day quantity leached. The UK CA's Time 1 leaching rate calculations are as follows:

1. Penflufen:
    1. Quantity leached over 29 days: 3.26 mg/m^2
    2. Quantity leached over 31 days: 3.39 mg/m^2
    3. Calculated quantity leached over 30 days ($Q^*_{leach,Time\ 1}$): 3.26 + (((3.39 – 3.26) / (31 – 29)) * (30 – 29)) = 3.322 mg/m^2 = 0.111 mg/m^2/d
2. Permethrin:
    1. Quantity leached over 29 days: 0.1486 mg/m^2
    2. Quantity leached over 31 days: 0.1537 mg/m^2
    3. Calculated quantity leached over 30 days ($Q^*_{leach,Time\ 1}$): 0.1486 + (((0.1537 – 0.1486) / (31 – 29)) * (30 – 29)) = 0.1513 mg/m^2 = 0.0050 mg/m^2/d
3. 2-PE:
    1. Quantity leached over 27 days: 0.6 mg/m^2
    2. Quantity leached over 67 days: 1.2 mg/m^2
    3. Calculated quantity leached over 30 days ($Q^*_{leach,Time\ 1}$): 0.6 + (((1.2 – 0.6) / (67 – 27)) * (30 – 27)) = 0.643 mg/m^2 = 0.021 mg/m^2/d

The UK CA has corrected the leaching rates from the test retention rate (penflufen and permethrin: 9.24 kg/m^3, 2-PE: 9.58 kg/m^3) to the requested retention rate (4.65 kg/m^3). The UK CA notes the 2-PE test retention is slightly greater than the maximum correction factor of 2 (detailed in the conclusions of the first leaching workshop, Arona, 2005) that is permissible without an additional assessment factor being applied. However, because the test was conducted at a higher retention than is being sought (and so is more likely to overestimate leaching) and the results were all <LOQ, the UK CA considers this acceptable on this occasion without application of an additional correction factor. The corrected leaching results are presented below.

The Time 2 and Time 3 default leaching rates have been calculated based on a product retention of 4.65 kg/m^3, a penflufen product concentration of 0.38%, a permethrin product concentration of 0.40% and a 2-PE product concentration of 3.836%. A default conversion factor of 40 has been used (as detailed in the TAB) to convert the quantity from kg/m^3 to kg/m^2. The values are summarised below.

Time period	Default loss (%) or derived from leaching study	Penflufen mg/m²	Permethrin mg/m²	2-PE mg/m²
Time 1 – (30 d)	From leaching study	1.672	0.076	0.312
Time 2 – (365 d)	75% loss	331.31	348.75	3345
Time 3 - (7300 d)	100% loss	441.75	465.00	4459
	From leaching study[a)]	59.698	n/a	26.765

[a)] Considered in the PEC_{GW} calculations only. See section 2.2.7.2 and Annex 3.7.2 for further info.

For the penflufen and permethrin metabolite calculations, the UK CA notes the approach in their respective CARs was to convert the non-degraded parent PEC value by the molecular

weight correction factor and the percentage maximum occurrence in soil. However, the UK CA notes for Vacsol Aqua 6118, this method results in unacceptable risk for the House scenario at Time 3. Therefore, for Time 3, the UK CA has converted the parent *leaching* rate to a metabolite leaching rate by multiplying the values by the appropriate molecular weight correction factor and maximum occurrence in soil (and updated the chemical properties accordingly in the PEC calculator Excel sheet); the Time 1 and Time 2 values are calculated using the non-degraded PEC values as per the CARs. The molecular weights and the maximum occurrences in soil are presented in the substance property tables below. The final leaching rates are as follows:

Time period	Penflufen		Permethrin	
	M01	M02	DCVA	PBA
Time 3 (7300 d)	78.88[a)]	44.06	28.08	38.19

[a)] Calculated as follows as an example: 441.75 * (333.4 / 317.41) * 0.17

Dimethyl myristyl amine was identified as a substance of concern during the commenting phase of the mutual recognition process therefore should be considered in the environmental risk assessment (ERA). The dimethyl myristyl amine leaching data was submitted to refine the assessment.
The dimethyl myristyl amine data submitted is from an NT509 semi-field leaching study ().

Leaching data have been submitted for dimethyl myristyl amine. Levels of C12 and C14 dimethyl myristyl amine were measured in the leachate and summed. It is considered justified to use the analysis of C12/C14 to assess the leaching of the substance as these constitute ca 90% of the substance and due to the increasing sorptive properties and decreasing water solubility with chain length, the degree of leaching of the C16 alkylamine will be negligible.

For dimethyl myristyl amine distilled, initially a conservative Tier 1 assessment was performed assuming 50% loss of the total loading over Time 1, 75% over Time 2 and 100% over Time 3. Leaching rates were calculated based on a product retention of 4.65 kg/m^3 and a dimethyl myristyl amine, distilled product concentration of 4.8%. The default conversion factor of 40 was used to convert the quantity from kg/m^3 to kg/m^2. The values are summarised below.

Time period	Default loss (%)	Dimethyl myristyl amine, distilled mg/m^2
Time 1 – (30 d)	50% loss	2790
Time 2 – (365 d)	75% loss	4185
Time 3 (7300 d)	100% loss	5580

The Tier 1 assessment indicated an unacceptable risk in some environmental compartments at Time 1, therefore the results of a leaching study, were interrogated to obtain more realistic Tier 2 estimates of potential leaching over this timeframe.

Semi-field data have been undertaken in accordance with NT 509 build guidelines in order to determine short-term and long-term leaching of the components of the Vacsol Aqua 6118 product. The method of application of the product to the test panel specimens was via vacuum-pressure impregnation in accordance with EN 252 and the test formulation was reported to contain 4.8% dimethyl myristyl amine, distilled. The mean retention of the product was reported as 9.58 kg/m^3 (equivalent to 459.8 g/m^3 as dimethyl myristyl amine, distilled). Furthermore, the test facility reports that the rate is broadly equivalent

to 6.12 g of dimethyl myristyl amine, distilled per exposed wood area (0.8155 m^2). Three test sets and one untreated set were used and collected precipitation was analysed at nine time points in line with NT 509 methodology.

Field testing was carried out for two calendar years (14.06.2017 – 14.06.2019) during which time 1404 mm of rain was collected. The data have been normalised using an annual precipitation of 700 mm (per m^2) according to the agreed EU approach. Assuming normalised annual EU rainfall of 700 mm, the experimental period is equivalent to leaching over a period of 732 days (based on 365 days/700 mm x 1404 mm).

The water (leachate) samples were at ambient environmental temperatures for an average of 11 days (median of 9 days) before transfer to frozen storage at -18° C. The applicant provided argumentations as to why the SoC is expected to be stable under these conditions. Dimethyl myristyl amine is not susceptible to hydrolysis or photolysis. Furthermore, although readily biodegradable, conditions in the leachate would not be supportive of biodegradation (rainwater runoff is collected in clean vessels that are not aerated), and the transfer to -18°C would arrest biodegradation. As previously discussed, a stability study was carried out for 2-phenoxy ethanol and despite this substance being readily biodegradable, it did not degrade under the environmental conditions to which it was exposed. An identical study is being carried out with dimethyl myristyl amine and degradation is not anticipated. The SE CA considers the additional storage stability data may be used to support an interim authorisation (subject to an acceptable ERA), with a requirement set for data to demonstrate the frozen storage stability over 23 months as a post-authorisation data requirement.

Test duration (days)	**Cumulative precipitation (mm)**	**Notional "rain days"**	**Cumulative loss**
			Dimethyl myristyl amine, (mg/m^2)**
12	52	27.1	0.02*
16	129	67.3	0.02*
42	236	123.1	0.02*
131	403	210.1	0.02*
218	605	315.5	0.093
365	814	424.4	0.093
499	997	519.9	0.093
643	1208	629.9	3.17
730	1404	732.1	3.17

*Reported as <0.02
** See confidential annex

As the study was performed at a retention rate of 9.58 kg product/m^3, for the calculation of the leaching rate an adjustment was performed to the proposed retention rate of 4.65 kg/m^3. Detections in leachate after 27.1 and 67.3 notional 'rain days' were below the LOQ, therefore a simplified worst-case approach was taken to calculate a leaching rate for Time 1. It was assumed that 50% of the total quantity leached would be released over the initial 30 days (an assumption in line with that used for standard 1st tier calculations). After adjustment of the retention rate this gives a total quantity leached over the initial 30 days (Tier 2 $Q^*_{leach,Time\ 1}$) of 0.769 mg/m^2.

Testing for distribution and dissipation in soil (ADS)

Data reported in the CAR is sufficient for the risk assessment

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

Data reported in the CAR is sufficient for the risk assessment

Testing for distribution and dissipation in air (ADS)

Data reported in the CAR is sufficient for the risk assessment

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

Acute aquatic toxicity

Data waiving	
Information requirement	Acute aquatic toxicity
Justification	No additional data are required.

Chronic aquatic toxicity

Data waiving	
Information requirement	Chronic aquatic toxicity
Justification	No additional data are required.

Measured aquatic bioconcentration

No additional data are required.

Estimated aquatic bioconcentration

No additional data are required.

Data waiving	
Information requirement	Aquatic bioconcentration
Justification	No additional data are 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 additional data are required.

2.2.7.2 Exposure assessment

General information

Assessed PT	PT 8
Assessed scenarios	Scenario 1: Use Class 1 (situation in which the wood or wood-based product is inside a construction, not exposed to the weather and wetting). Scenario 2: Use Class 2 (situation in which the wood or wood-based product is under cover and fully protected from the weather but occasional, non-persistent, wetting may occur. This can include outdoor placement of timber under a roof to prevent any exposure to rain). Scenario 3: Use Class 3 (situation in which the wood or wood-based product is not covered and not in contact with the ground. It is either continuously exposed to weather or protected from the weather but subject to frequent wetting).
ESD(s) used	Emission Scenario Document for Product Type 8: OECD Series on Emission Scenario Documents No 2, Revised ESD for Wood Preservatives (September 2013)
Approach	Scenario 1: Assumes negligible emissions to environmental compartments from in-service use; Scenario 2: Assumes negligible emissions to environmental compartments from in-service use; Scenario 3: Average consumption based using House, Noise Barrier and Bridge Over Pond as representative emission models. The Fence scenario has not been considered as the House scenario provides the most conservative terrestrial risk assessment.
Distribution in the environment	There will be no application and storage emissions in UC1 – 3. Labelling and associated literature must state that all treatment of timber be undertaken at industrial site where: 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). Freshly treated timber shall be stored after treatment under shelter on impermeable hard standing to prevent losses to soil, sewer, or water, and that any losses from the application of the product shall be collected for reuse or disposal. In-service calculations are unnecessary for UC1 and UC2 as there are negligible emissions during service life: treated wood is protected from weather and wetting therefore only

	negligible leaching is predicted; there is no obvious route to the wider environment. UC3 applications are typically assumed to reach soil, STP, surface water, sediment and groundwater compartments. Distribution will be calculated in line with ECHA Guidance on ERA, Volume IV, Part B and the ESD referenced above.
Groundwater simulation	None undertaken for UC1 and UC2: there is negligible leaching from timbers protected from weather and wetting. Actives do not reach the soil compartment and thus Tier 1 porewater screening and, where necessary, Tier 2 FOCUS PEARL modelling are not required. UC3 assessment of 2-PE, Penflufen and Permethrin (and metabolites) has been performed using FOCUS PEARL 4.4.4 modelling as this is relevant for these organic molecules.
Confidential Annexes	No – not in relation to environmental emissions and risk assessment
Life cycle steps assessed	Scenario 1 & 2: UC1 & UC2 application to wood Production: **No** – assessed at review Formulation: **No** – formulated within a closed system (see remarks) Use: **No** – industrial treatment plants will be assumed to have no connection to mains drainage and all freshly treated wood to be held under cover. Service life: **Yes,** but it will assume negligible emissions and therefore zero risk. Scenario 3: UC3 application to wood Production: **No** – assessed at review Formulation: **No** – formulated within a closed system (see remarks) Use: **No** – industrial treatment plants will be assumed to have no connection to mains drainage and all freshly treated wood to be held under cover. Service life: **Yes**, using representative ESD scenarios.
Remarks	Life cycle steps must be considered for all products but, in this case, production of each a.s. has been considered to have been addressed within their EU evaluation documents (for PT8 or other PTs): manufacture will occur within closed systems. With regard to the formulation of the biocidal product, the mixing process takes place within closed systems. All residue (product and raw materials) is collected after rinsing and washing with water for appropriate disposal via an authorised company.

Emission estimation

Scenario 1 & 2 : UC 1 & UC 2 [same application rates and application methods]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: UC 1 (wood or wood based product inside a construction, not exposed to weather and wetting) applied by vacuum-pressure impregnation at industrial plants Plus Scenario 2: UC 2 (wood or wood based product under cover and not exposed to weather (rain and driven rain) but where occasional but not persistent wetting can occur) applied by vacuum-pressure impregnation at industrial plants			
Application rate of biocidal product	4.65	Kg / m^3	Exposure negligible so risk is 0. Therefore, UC 1 and 2 not further considered. The non-PT a.s. and SoC concentrations were obtained from the applicant's confidential annex.
Concentration of a.s. in the product	-		
Penflufen	0.379	% w/w	
Permethrin	0.400	% w/w	
[2-phenoxyethanol (non-PT active substance)]	*[3.836]*	*[% w/w]*	
[Dimethyl myristyl amine, distilled (SoC)]	*[4.8]*	*[% w/w]*	

Scenario 3: UC3 [general uses]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 3: UC 3 (wood or wood based product out of contact with ground but not under cover and exposed to weather or protected but subject to frequent wetting) applied by double vacuum or vacuum pressure impregnation at industrial plants			
Application rate of biocidal product	4.65	Kg/m3	
Concentration of a.s. in the product			
Penflufen	0.379	% w/w	This is the *technical* concentration
Permethrin	0.400	% w/w	This is the *technical* concentration
[2-phenoxyethanol]	*[3.836]*	*[% w/w]*	*[Non-PT a.s.;* concentration obtained from the applicant's

			confidential annex.*]*
Dimethyl myristyl amine, distilled (SoC)]	*[4.8]*	*[% w/w]*	*[SoC concentration obtained from the applicant's confidential annex.]*

Calculations for Scenario 3

Emissions modelling for PT8 products determine local emissions in terms of $Elocal_{compartment}$ in mg/d. In-service losses result from leaching loss from treated wood exposed to weather or wetting episodes. This is variable in nature; the loss in mg/d represents an average value derived by modelling losses over time windows over which there will be average weather patterns. In all compartments except groundwater, risks are considered at Time 1 (30 d) and Time 3 (service life depending on application method). As discussed above, an additional assessment at Time 2 (365 d) will be included for ECHA information purposes.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 3	Y	Y	N	N	Y	N	Y	Y	NA

Use class 3 includes House, Fence, Noise Barrier and Bridge Over Pond scenarios. The Fence scenario has not been considered as the House scenario produces the worst-case terrestrial risk assessment. The applicant states that a use restriction will be applied to the product to prevent use of treated timber over or near surface water and so, therefore, have not conducted Bridge Over Pond calculations. Whilst the UK CA accepts the applicant's justification, the UK CA has included the Bridge Over Pond scenario calculations for completeness.

The endpoints used by the UK CA were obtained from the a.s. CARs and are presented below. The UK CA approach was to use the lowest and most conservative tier of assessment necessary to demonstrate an acceptable risk for each compartment and time period. Higher tier approaches were only provided where required. For the penflufen and permethrin metabolite calculations, the UK CA notes the approach in their respective CARs was to convert the non-degraded parent PEC value by the molecular weight correction factor and the maximum occurrence in soil, SW or sediment percentage. However, the UK CA notes for Vacsol Aqua 6118, this method results in unacceptable risk for the House scenario at Time 3. Therefore, for Time 3, the UK CA has converted the parent daily *leaching* rate to a metabolite leaching rate by multiplying the values by the molecular weight correction factor and maximum occurrence in soil (and updated the chemical properties accordingly in the ESD Excel calculation sheet); the leaching rates are provided

in the leaching section above. This is so degradation of the metabolites can be considered in the Time 3 calculations. The Time 1 and Time 2 values are calculated using the non-degraded PEC values as per the CARs; as are the Bridge Over Pond $PEC_{SW/sed}$ metabolite calculations for simplicity.

Penflufen chemical properties (from penflufen PT8 CAR, March 2017)			
Input	Value	Unit	Remarks
Molecular weight	317.41	g/mol	
Vapour pressure (at 20°C)	4.1E-07	Pa	
Water solubility (at 20°C)	10.9	mgl^{-1}	
Log Octanol/water partition coefficient	3.3		pH4, pH7 & pH9
Organic carbon/water partition coefficient	Koc: 279.9 Kom: 162.4	lkg^{-1}	
1/n	0.92		
Henry's Law Constant (20 °C)	1.19E-5	Pa/m3/mol	pH7.1
Biodegradability	Not readily biodegradable		
DT_{50} for degradation in soil	214 (12°C) 113 (20°C)	d	
DT_{50} for degradation in surface water	140	d (12°C)	

Penflufen metabolites M01 (Penflufen-3-hydroxy-butyl) and M02 (BYF 14182-pyrazolyl-AAP) chemical properties (from penflufen PT8 CAR, March 2017)			
	M01	**M02**	**Unit**
Molecular weight	333.4	275.3	g/mol
Vapour pressure (at 20°C)	1.3E-9	2.3E-6	Pa (20°C)
Water solubility (at 20°C)	95	3.6	mg/l (20 °C)
Log Octanol/water partition coefficient	1.7	2.1	Log 10
Organic carbon/water partition coefficient	Koc: 38.2 Kom: 22.2	Koc: 1006 Kom: 583.5	l/kg
1/n	0.93	0.747	
DT_{50} for biodegradation in soil	180 (12°C) 95 (20°C)	311 (12°C) 164 (20°C)	d
Maximum occurrence in soil	17.0	11.5	%
Maximum occurrence in surface water	12.8	0 – not a water metabolite	%
Formation fraction	0.58 from parent	0.08 from parent 1.00 from M01	

Permethrin chemical properties (from permethrin PT8 CAR (Doc IIB), April 2014)			
Input	Value	Unit	Remarks
Molecular weight	391.29		

Vapour pressure (at 20°C)	2.16E-06	Pa	
Water solubility (at 20°C)	0.00495	mgl^{-1}	
Log Octanol/water partition coefficient (at 25°C)	4.67		
Organic carbon/water partition coefficient	Koc: 26930.85 Kom: 15621.14	lkg^{-1}	
1/n	0.9		
Henry's Law Constant (at 25°C)	> 4.5 E-02	$Pam^{-3}mol^{-1}$	
Ready Biodegradability	No		
DT_{50} for degradation in soil	106 (12°C) 56.1 (20°C)	d	
DT_{50} for degradation in surface water	40.6	d (12°C)	

Permethrin metabolites DCVA (2,2-dimethyl-3-(2,2,dichlorovinyl) cyclopropane carboxylic acid) and PBA (3-Phenoxybenzoid acid) chemical properties (from permethrin PT8 CAR (Doc IIB), April 2014)

	DCVA	**PBA**	**Unit**
Molecular weight	209.07	214.22	g/mol
Vapour pressure (at 20°C)	2.60E-01	4.21E-04	Pa (20°C)
Water solubility (at 20°C)	127.6	16.91	mg/l (20 °C)
Organic carbon/water partition coefficient	Koc: 188.53 Kom: 109.36	Koc: 37.55 Kom: 21.78	l/kg
1/n	0.9	0.9	
DT_{50} for biodegradation in soil	175 (12ºC) 92.19 (20°C)	2.5 (12ºC) 1.34 (20°C)	d
Maximum occurrence in soil	11.3	15	%
Maximum occurrence in surface water	62.6	28.8	%
Maximum occurrence in sediment	21.7	16.4	%
Formation fraction	0.113 from parent	0.15 from parent	

2-phenoxyethanol chemical properties (from 2-phenoxyethanol PT 1, PT 2 and PT 4 CAR, February 2018)

Input	Value	Unit	Remarks
Molecular weight	138.17	$gmol^{-1}$	
Vapour pressure (at 20°C)	1.0	Pa	Purity 99.9%
Water solubility (at 20°C)	25	gL^{-1}	
Log Octanol/water partition coefficient	1.2	-	
Organic carbon/water partition coefficient	Koc: 40.74 Kom: 23.63	Lkg^{-1}	
1/n	1.0		
Biodegradability	Yes	-	Fulfils 10 day window
DT_{50} for degradation in soil	30 (12ºC) 14.1 (20ºC)	d	Default for biodegradable compound

DT_{50} for degradation in surface water	15	d (12°C)	

Dimethyl myristyl amine, distilled chemical properties			
Input	Value	Unit	Remarks
Molecular weight	271.482	$gmol^{-1}$	
Vapour pressure (at 20°C)	0.9	Pa	
Water solubility (at 20°C)	11	mgL^{-1}	
Log Octanol/water partition coefficient	1.7	-	At pH7, 99.8% will be protonated therefore mean value for protonated form was used
Organic carbon/water partition coefficient, Koc (soil)	16836 (Kom 9766)	Lkg^{-1}	Mean of two available
Organic carbon/water partition coefficient, Koc (sediment)	25003	Lkg^{-1}	Value for sediment (Kd 600, 2.4%oc)
Organic carbon/water partition coefficient, Koc (sewage sludge)	2301	Lkg^{-1}	Value for sewage (Kd 693, 30.1%oc)
1/n	1.71 (1.3 used in PEARL modelling)		Mean of two available values Value in PEARL set to the maximum permitted value of 1.3)
Biodegradability	Yes	-	
DT_{50} for degradation in soil	16.9 (12ºC) 8.91 (20ºC)	d	
DT_{50} for degradation in surface water	15	d (12°C)	Default for biodegradable compound

Calculated PEC values

For simplicity, the applicant's PEC values have been removed from the PAR and the UK CA's PEC values are presented below. The PEC_{soil} values account for degradation, calculated according to ESD equations 3.11 and 3.12 (i.e. are not time-weighted average (TWA) values). The Bridge Over Pond values were calculated based on the guidance available at the time of submission and so consider TWA degradation (PEC_{SW} and PEC_{sed}) and sorption (PEC_{SW} only), according to ESD equations 3.18 and 3.19. The UK CA's calculator spreadsheets used are embedded in section 3.7.3.

The applicant has performed calculations for dimethyl myristyl amine, distilled and these are also given below. The calculator spreadsheets have also been embedded in section 3.7.3.

Scenario 3 (UC 3): Double-Vac and Vac-Pressure Wood									
	Penflufen								
	Time 1			Time 2			Time 3		
	A.s.	M01[a)]	M02[a)]	A.s.	M01[b)]	M02[b)]	A.s.	M01	M02
PEC_{Soil} mg/kg wwt									
House	9.01E-3	1.69E-3	9.44E-4	1.10E-0	3.34E-1	1.87E-1	1.06E-1	1.59E-2	1.53E-2
Noise Barrier	3.37E-3	6.32E-4	3.52E-4	4.12E-1	1.25E-1	7.00E-2	3.96E-2	5.94E-3	5.73E-3
PEC_{STP} mg/l									
Noise barrier[c)]	5.65E-5	n/a	n/a	9.21E-4	n/a	n/a	6.14E-5	n/a	n/a
PEC_{SW} µg/l									
Bridge Over Pond	7.78E-3	2.25E-3	n/a	9.62E-1	4.45E-1	n/a	1.16E-1	5.94E-1[d)]	n/a
PEC_{Sed} mg/kg wwt									
Bridge Over Pond	5.47-5	n/a	n/a	6.76E-3	n/a	n/a	8.16E-4	n/a	n/a
PEC_{GW} µg/l									
-	The PEC_{GW} values are presented separately below								

[a)] PEC calculated from non-degraded parent T1 PEC value: House = 9.46E-3 mg/kg wwt, Noise Barrier (soil) = 3.54E-3 mg/kg wwt and Bridge Over Pond (SW) = 1.67E-2µg/l. In line with the CAR, metabolite PECsed values are not required and have not been calculated.

[b)] PEC calculated from non-degraded parent T2 PEC value: House = 1.87, NB (soil) = 0.702 and BOP (SW) = 3.31. In line with the CAR, metabolite PECsed values have not been calculated.

[c)] Degradation is not considered for PECstp

[d)] PEC calculated from non-degraded parent T3 PEC value: BOP (SW) = 4.42. In line with the CAR, metabolite PECsed values have not been calculated.

Scenario 3 (UC 3): Double-Vac and Vac-Pressure Wood									
	Permethrin								
	Time 1			Time 2			Time 3		
	A.s.	DCVA[a)]	PBA[a)]	A.s.	DCVA[b)]	PBA[b)]	A.s.	DCVA	PBA
PEC_{Soil} mg/kg wwt									
House	3.90E-4	2.60E-5	3.53E-5	7.50E-1	1.19E-1	1.62E-1	5.51E-2	3.33E-3	4.52E-3
Noise Barrier	1.46E-4	9.72E-6	1.32E-5	2.81E-1	4.46E-2	6.07E-2	2.06E-2	1.25E-3	1.69E-4
PEC_{STP} mg/l									
Noise barrier[c)]	7.34E-7	n/a	n/a	2.77E-4	n/a	n/a	1.85E-5	n/a	n/a
PEC_{SW} µg/l									
Bridge Over Pond	1.03E-4	2.54E-4	1.20E-4	1.49E-1	1.17E-0	5.50E-1	1.18E-2	1.56E-0[d)]	7.33E-1[d)]
PEC_{Sed} mg/kg wwt									
Bridge Over Pond	1.89E-4	5.17E-5	4.00E-5	2.76E-1	2.38E-1	1.84E-1	2.17E-2	3.17E-1[d)]	2.45E-1[d)]
PEC_{GW} µg/l									
-	The PEC_{GW} values are presented separately below								

[a)] PEC calculated from non-degraded parent PEC value: House = 4.30E-4 mg/kg wwt, Noise Barrier (soil) = 1.61E-4 mg/kg wwt, Bridge Over Pond (SW) = 7.6E-4 µg/L and Bridge Over Pond (sed) = 4.46E-4 mg/kg wwt

[b)] PEC calculated from non-degraded parent PEC value: House = 1.97 mg/kg wwt, Noise Barrier (soil) = 0.739 mg/kg wwt, Bridge Over Pond (SW) = 3.49 µg/L and BOP (sed) = 2.05 mg/kg wwt

[c)] Degradation is not considered for PECstp

[d)] PEC calculated from non-degraded parent T3 PEC value: Bridge Over Pond (SW) = 4.65 µg/L and Bridge Over Pond (sed) = 2.73 mg/kg wwt

Scenario 3 (UC 3): Double-Vac and Vac-Pressure Wood			
	2-phenoxyethanol		
	Time 1	**Time 2**	**Time 3**
PEC_{Soil} mg/kg wwt			
House	1.27E-3	2.24E-0	1.50E-1
Noise Barrier	4.77E-4	8.40E-1	5.60E-2
PEC_{STP} mg/l l			
Noise barrier	1.38E-3	1.21E-3	8.08E-5
PEC_{SW} µg/l			
Bridge Over Pond	1.03E-3	1.86E-0	1.31E-1
PEC_{Sed} mg/kg wwt			
Bridge Over Pond	1.72E-6	3.11E-3	2.20E-4
PEC_{GW} µg/l			
-	The PEC_{GW} values are presented separately below		

Scenario 3 (UC 3): Double-Vac and Vac-Pressure Wood				
	Dimethyl myristyl amine, distilled			
	Time 1		**Time 2**	**Time 3**
	Tier 1	**Tier 2**		
PEC_{Soil} mg/kg wwt				
House	9.08	2.5E-3	1.58	0.105
Noise Barrier	3.49	9.37E-4	0.592	0.0395
PEC_{STP} mg/l				
Noise barrier	6.02E-3	1.66E-6	7.41E-4	4.95E-5
PEC_{SW} µg/l				
Bridge Over Pond	3.09	8.53E-4	0.782	0.055
PEC_{Sed} mg/kg wwt				
Bridge Over Pond	5.028	1.39E-3	1.27	0.09
PEC_{GW} µg/l*				
House	30.5	8.42E-3	5.32	0.355
Noise Barrier	11.4	3.15E-3	1.99	0.133

*PEC_{GW} values calculated using the PEARL model are presented separately below

PEC_{GW}

In line with their respective CARs, the UK CA has conducted PEC_{GW} calculations using PEARL v4.4.4 for penflufen, M01, M02, permethrin, DCVA, PBA and 2-phenoxyethanol. The UK CA has broadly followed the approach detailed in the ESD for UC 3 (House), with a minor difference over application dates. The UK CA template for PEARL applications models 10 applications occurring on the first of month from February to November as standard,

rather than the 10 evenly distributed events as per the ESD. Since the simulation of continuous leaching as a series of 10 applications is a simple work around due to the limitations of the PEARL model, and that this had little impact on results compared to simulating daily amounts (~300 applications per year as tested in the ESD) the UK CA considers this a minor deviation. In addition, in the UK CA calculations no account has been taken of the Fweatherside factor (as per ENV27 of the TAB). The UK CA calculations are therefore likely to be conservative because Fweatherside has not been used.

The UK CA has done a Tier 1 and Tier 2 groundwater assessment for penflufen and 2-PE (the permethrin PEC_{GW} calculations passed at first tier). The first tier is based on 100% loss of the active substances, as per the other environmental compartment PEC calculations. However, this resulted in concentrations >0.1 µg/L for 2-PE and penflufen metabolites M01 and M02. Therefore, the UK CA conducted a Tier 2 groundwater assessment for penflufen and 2-PE. The penflufen Tier 2 assessment was based on a DFOP fit of the cumulative leaching data from the laboratory study data and the 2-PE assessment was refined using the average quantity leached during the semi-field study. Further information on how the UK CA derived the Tier 2 leaching rates is provided in Annex 3.7.2. The Tier 2 penflufen DFOP fit calculated the amount of penflufen leached over 20 years as being 59.698 mg/m^2. The 2-PE Tier 2 leaching rate was 26.765 mg/m^2. The UK CA therefore used these values to conduct the Tier 2 PEC_{GW} calculations. A summary of the UK CA's PEARL application rate calculations are as follows:

Tier 1 (100% loss)	**Tier 2 (refined from leaching study data)**
Penflufen: 4. $Q^*_{leach,Time3}$ = 441.75 mg/m^2 5. Annual loss = 441.75 / 20 = 22.09 mg/m^2/y 6. Annual loss from House = 22.09 * 2000 = 44175 mg/ha/y = 0.044175 kg/ha/y 7. PEARL (monthly) application rate = 0.044175 / 10 = <u>0.0044175</u> kg/ha	Penflufen: 8. $Q^*_{leach,Time3}$ = 59.698 mg/m^2 9. Annual loss = 59.698 / 20 = 2.985 mg/m^2/y 10. Annual loss from House = 2.985 * 2000 = 596.981 mg/ha/y = 0.00597 kg/ha/y 11. PEARL (monthly) application rate = 0.00597 / 10 = <u>0.000597</u> kg/ha
Permethrin: 12. $Q^*_{leach,Time3}$ = 465 mg/m^2 13. Annual loss = 465 / 20 = 23.25 mg/m^2/y 14. Annual loss from House = 22.25 * 2000 = 46500 mg/ha/y = 0.0465 kg/ha/y 15. PEARL (monthly) application rate = 0.0465 / 10 = <u>0.00465</u> kg/ha	n/a
2-PE: 16. $Q^*_{leach,Time3}$ = 4459 mg/m^2 17. Annual loss = 4459 / 20 = 222.97 mg/m^2/y 18. Annual loss from House = 222.97 * 2000 = 445935 mg/ha/y = 0.445935 kg/ha/y 19. PEARL (monthly) application rate = 0.445935 / 10 = <u>0.0445935</u> kg/ha	2-PE: 20. $Q^*_{leach,Time3}$ = 26.765 mg/m^2 21. Annual loss = 26.765 / 20 = 0.134 mg/m^2/y 22. Annual loss from House = 0.134 * 2000 = 2676.5 mg/ha/y = 0.0026765 kg/ha/y 23. PEARL (monthly) application rate = 0.0026765 / 10 = <u>0.00026765</u> kg/ha

Additional calculations for Dimethyl myristyl amine, distilled have been performed by the applicant. A summary of the inputs is as follows:

Tier 1 (100% loss)	Tier 2 (refined from leaching study data)
Dimethyl myristyl amine, distilled: 24. $Q^*_{leach,Time3}$ = 5580 mg/m^2 25. Annual loss = 5580 / 20 = 279 mg/m^2/y 26. Annual loss from House = 279 * 2000 = 558000 mg/ha/y = 0.558 kg/ha/y 27. PEARL (monthly) application rate = 0.558 / 10 = 0.0558 kg/ha	

The UK CA's PEC_{GW} results are as follows (values >0.1 µg/L highlighted in bold):

	PEC_{GW} (µg/L)					
	Penflufen					
	Tier 1			**Tier 2**		
	Penf.	**M01**	**M02**	**Penf.**	**M01**	**M02**
Châteaudun	0.032908	**2.444903**	0.034908	0.001797	**0.280626**	0.002200
Hamburg	0.085216	**3.947621**	**0.123624**	0.005368	**0.457632**	0.011347
Jokioinen	0.018387	**3.814081**	0.036973	0.000648	**0.425381**	0.002375
Kremsmünster	0.047187	**2.359564**	0.033416	0.002795	**0.271171**	0.002109
Okehampton	0.079649	**2.500058**	0.042036	0.005121	**0.298562**	0.003112
Piacenza	0.075456	**2.388604**	**0.106042**	0.004789	**0.271600**	0.010657
Porto	0.038705	**1.576343**	0.009203	0.002186	**0.180962**	0.000624
Sevilla	0.002669	**1.550253**	0.014772	0.000095	**0.174796**	0.000925
Thiva	0.014995	**2.126219**	0.040415	0.000690	**0.240528**	0.002671
	Permethrin					
	Perm.	**DCVA**	**PBA**	**Perm.**	**DCVA**	**PBA**
Châteaudun	<0.001	<0.001	<0.001	n/a		
Hamburg	<0.001	0.001605	<0.001			
Jokioinen	<0.001	<0.001	<0.001			
Kremsmünster	<0.001	<0.001	<0.001			
Okehampton	<0.001	0.001507	<0.001			
Piacenza	<0.001	0.001417	<0.001			
Porto	<0.001	<0.001	<0.001			
Sevilla	<0.001	<0.001	<0.001			
Thiva	<0.001	<0.001	<0.001			
	2-phenoxyethanol					
	2-PE			**2-PE**		
Châteaudun	0.052084			<0.001		
Hamburg	**0.173743**			<0.001		
Jokioinen	**0.111814**			<0.001		
Kremsmünster	0.093123			<0.001		
Okehampton	**0.228481**			<0.001		
Piacenza	**0.164098**			<0.001		
Porto	0.094884			<0.001		
Sevilla	0.009572			<0.001		

Thiva	0.011410	<0.001

The applicant's PEC_{GW} results for Dimethyl myristyl amine, distilled are as follows:

	Dimethyl myristyl amine, distilled	
	Dimethyl myristyl amine, distilled	
Châteaudun	<0.001	n/a
Hamburg	<0.001	
Jokioinen	<0.001	
Kremsmünster	<0.001	
Okehampton	<0.001	
Piacenza	<0.001	
Porto	<0.001	
Sevilla	<0.001	
Thiva	<0.001	

As can be seen, the M01 Tier 2 PEC_{GW} values are still >0.1 µg/L. However, the UK CA notes the M01 values are significantly less than the PEC_{GW} values calculated in the pesticide penflufen EU evaluation (EFSA Journal 2012;10(8):2860). The maximum M01 PEC_{GW} value calculated in the pesticide EU evaluation was 1.417 µg/L (Hamburg) which is greater than the maximum Tier 2 Vacsol Aqua 6118 PEC_{GW} of 0.457 µg/L (Hamburg). The toxicological relevance assessment conducted according to the SANCO/221/2-rev.10 (2003) during the EU pesticide assessment (Appendix 6 to the DAR and Addendum and Corrigendum 1 to Volume 3) concluded there was an acceptable margin of safety (in adults) of 85 for this metabolite and the PEC_{GW} value (1.417 µg/L). Although the direct application of the SANCO guidance for biocidal products is not explicitly mentioned in any relevant guidance as far as the UK is aware, TAB entry ENV19 does indirectly indicate that the relevance of metabolites can be assessed under BPR, and that non-relevant metabolites may be acceptable in groundwater above the 0.1µg/l limit (subject to a final drinking water risk assessment). Note that for the uses being assessed here the worst case PEC_{GW} value is below the threshold of 0.75µg/l that triggers a drinking water assessment (according to the SANCO guidance). Taking into account the earlier conclusions on the non-relevance of M01 under the PPP assessment and the lower concentrations predicted at Tier 2 for the PT8 use, the UK CA considers this adequate to address the risk to groundwater posed by Vacsol Aqua 6118 use.

Primary and secondary poisoning

Primary poisoning

Not required as the product is not a solid formulation used outside.

Secondary poisoning

Penflufen has a log Kow of 3.3, which is above the trigger value of 3, indicating a potential for bioaccumulation. Permethrin has a log Kow of 4.67, which is above the trigger value of 3, indicating a potential for bioaccumulation. 2-PE has a log Kow of 1.2 and so is below the trigger indicating further consideration of this compound is not required. The UK CA has therefore conducted secondary poisoning assessments on penflufen and permethrin; because Vacsol Aqua treated wood is not to be applied near surface water, PEC_{fish} values

have not been calculated (only $PEC_{earthworm}$). The UK CA has used the following equations to derive a $PEC_{earthworm}$ value, in-line with equations 100 to 104 of the ECHA Guidance on the BPR, Volume IV B:

$$C_{earthworm} = \frac{\left(BCF_{earthworm} \times C_{porewater}\right) + \left(C_{soil} \times F_{gut} \times CONV_{soil}\right)}{1 + \left(F_{gut} \times CONV_{soil}\right)}$$

Where C_{soil} = $PEClocal_{soil}$
$C_{porewater}$ = $PEClocal_{soil,\ porewater}$
F_{gut} = 0.1 (ECHA guidance default)
$CONV_{soil}$ = RHO_{soil} / (F_{solid} x RHO_{solid}) = 1700 / (0.6 x 2500) = 1.13
$BCF_{earthworm}$ = (0.84 + (0.012*Kow))/$RHO_{earthworm}$
And $RHO_{earthworm}$ is taken to be 1 kg_{wwt}. l^{-1}

The penflufen and permethrin secondary poisoning input parameters and resulting $PEC_{earthworm}$ are as follows:

	Penflufen	**Permethrin**
Log Kow	3.3	4.67
Kow	1995.26	46773.51
BCF (earthworm)	24.78	562.12
PEC_{soil} (House Time 3)[a)]	0.106 mg/kg	0.055 mg/kg
$PEC_{porewater}$ (House Time 3)[a)]	0.0209 mg/L	1.16E-4 mg/L
$PEC_{earthworm}$	0.476 mg/kg	0.064 mg/kg

[a)] Maximum worst-case UC 3 values; includes degradation.

2.2.7.3 Risk characterisation

Atmosphere

Conclusion:

In line with their respective CARs, atmosphere exposure is expected to be negligible and so no further consideration has been undertaken in this PAR.

Sewage treatment plant (STP)

Scenario 3 (UC 3): Double-Vac and Vac-Pressure Wood			
Noise barrier PEC/PNEC	**Time 1**	**Time 2**	**Time 3**
Penflufen	5.18E-5	8.45E-4	5.63E-5
M01	n/a	n/a	n/a
M02	n/a	n/a	n/a
Permethrin	1.48E-4	5.60E-2	3.73E-3
DCVA	n/a	n/a	n/a
PBA	n/a	n/a	n/a
2-PE	1.38E-4	1.21E-4	8.08E-6
Dimethyl myristyl amine, distilled	4.63E-2	5.70E-3	3.81E-4
Total[a)]	4.66E-02	6.27E-02	4.18E-03

[a)] Sum of PEC/PNEC values of all substances for the purposes of a Tier 1 mixture toxicity assessment

Conclusion:
The risk to STP is acceptable for all components, including the SoCs 2-phenoxyethanol and dimethyl myristyl amine, distilled. The cumulative risk for all components from Vacsol Aqua 6118 use is also acceptable.

Aquatic compartment

Scenario 3 (UC 3): Double-Vac and Vac-Pressure Wood			
Bridge Over Pond PEC/PNEC - SW	**Time 1**	**Time 2**	**Time 3**
Penflufen	3.32E-03	4.11E-01	4.96E-02
M01	1.43E-04	2.83E-02	3.79E-02
M02	n/a	n/a	n/a
Permethrin	2.19E-01	**3.17E+02**	**2.51E+01**
DCVA	1.69E-05	7.78E-02	1.04E-01
PBA	1.20E-05	5.50E-02	7.33E-02
2-PE	1.09E-06	1.97E-03	1.39E-04
Dimethyl myristyl amine, distilled (Tier 1)	**1.19E+01**	**3.01E+00**	2.12E-01
Total[a)]	**12.1**	**321**	**25.6**

Dimethyl myristyl amine, distilled (Tier 2)	3.28E-3	**-**	-
Total[a)]	0.23	**-**	

[a)] Sum of PEC/PNEC values of all substances for the purposes of a Tier 1 mixture toxicity assessment

Scenario 3 (UC 3): Double-Vac and Vac-Pressure Wood			
Bridge Over Pond PEC/PNEC - Sediment	**Time 1**	**Time 2**	**Time 3**
Penflufen	3.42E-03	4.23E-01	5.10E-02
M01	n/a	n/a	n/a
M02	n/a	n/a	n/a
Permethrin	8.71E-01	**1.27E+03**	**1.00E+02**
DCVA	4.31E-03	**1.98E+01**	**2.64E+01**
PBA	4.45E-03	**2.05E+01**	**2.72E+01**
2-PE	1.10E-05	1.98E-02	1.40E-03
Dimethyl myristyl amine, distilled (Tier 1)	**1.86E+01**	**4.70E+00**	3.33E-01
Total[a)]	**19.51**	**1315.5**	**153.99**

Dimethyl myristyl amine, distilled (Tier 2)	5.15E-3	**-**	-
Total[a)]	0.89	**-**	**-**

Conclusion:

The Bridge Over Pond calculations demonstrate unacceptable risk at Time 3 for surface water and sediment; the risk is driven by permethrin (and its metabolites). Due to the high level of exceedance and the applicant proposing suitable RMM to prevent Vacsol Aqua treated wood being placed over or near surface water, the UK CA has not attempted to refine the permethrin risk assessment by refining the default leaching rates. However, it is noted the laboratory leaching study provided records much lower quantities of permethrin being leached from the treated wood and this is further supported by data from the semi-field study. Therefore, the Time 3 risk assessment above is likely to be significantly over-estimating the risk posed to surface water and sediment because it assumes 100% loss over service life and simulates a static pond system; a simple 'Step 3' assessment (as detailed in the conclusions of the second leaching workshop) of the permethrin laboratory leaching data predicts approximately 25% a.s. loss after 20 years.

The UK CA also notes there is a potential secondary exposure pathway to surface water and sediment from STP release from the Noise Barrier scenario. This risk assessment has not been presented by the UK CA as the Bridge Over Pond scenario is considered to provide the worst-case aquatic risk assessment and standard evaluation practise is not to consider the secondary exposure route to surface water via STP from the Noise Barrier scenario. Although the Time 3 Bridge Over Pond scenario is predicting very high levels of exceedance in the surface water and sediment compartments that need to be mitigated, this is at least in part due to the fact that the permethrin leaching rate is based on the default 100% loss (and a conservative Step 3 assessment of the permethrin laboratory study data indicates approximately 25% a.s. loss and so this approach is extremely conservative) and the scenario is static.

Additional Tier 1 calculations provided by the applicant for dimethyl myristyl amine, distilled indicate an unacceptable risk at Time 1, but this compound has a negligible impact on the risk at Time 3, where the risk assessment is driven by permethrin and its metabolites for the reasons given above. It must also be borne in mind that Tier 1 worst case leaching rates were used in the initial calculations. Based on the sorptive nature of the compound such leaching rates are considered highly unrealistic. The Tier 1 leaching rates were therefore refined using data from a leaching study. These refined Tier 2

leaching rates gave an acceptable risk at Time 1 in surface water and sediment for both dimethyl myristyl amine, distilled, and for the sum of the components.

Terrestrial compartment

Scenario 3 (UC 3): Double-Vac and Vac-Pressure Wood			
House PEC/PNEC	**Time 1**	**Time 2**	**Time 3**
Penflufen	2.39E-02	**2.92E+00**	2.81E-01
M01	4.33E-03	8.56E-01	4.08E-02
M02	2.93E-03	5.79E-01	4.75E-02
Permethrin	2.23E-03	**4.29E+00**	3.15E-01
DCVA	5.64E-06	6.11E-02	7.24E-04
PBA	2.45E-05	1.12E-01	3.14E-03
2-PE	1.14E-03	**2.02E+00**	1.35E-01
Dimethyl myristyl amine, distilled (Tier 1)	**1.03E+01**	**1.79E+00**	1.2E-01
Total[a)]	**10.33**	**12.63**	0.94

Dimethyl myristyl amine, distilled (Tier 2)	2.83E-3	**-**	-
Total[a)]	0.04	**-**	-

Scenario 3 (UC 3): Double-Vac and Vac-Pressure Wood			
Noise Barrier PEC/PNEC	**Time 1**	**Time 2**	**Time 3**
Penflufen	8.94E-03	**1.09E+00**	1.05E-01
M01	1.62E-03	3.21E-01	1.52E-02
M02	1.09E-03	2.17E-01	1.78E-02
Permethrin	8.34E-04	**1.61E+00**	1.18E-01
DCVA	2.11E-06	9.70E-03	2.72E-04
PBA	9.18E-06	4.21E-02	1.17E-01
2-PE	4.30E-04	7.57E-01	5.05E-02
Dimethyl myristyl amine, distilled (Tier 1)	**3.85E+00**	6.7E-01	4.48E-02
Total[a)]	**3.87**	**4.72**	0.47

Dimethyl myristyl amine, distilled (Tier 2)	1.06E-3	**-**	-
Total[a)]	0.01	**-**	-

[a)] Sum of PEC/PNEC values of all substances for the purposes of a Tier 1 mixture toxicity assessment

Conclusion:

The combined Time 1 and Time 3 risk to soil from all compounds is acceptable. Based on the default leaching rates, the risk from Time 2 is unacceptable; however, Time 2 is not used for decision making and its results included for information purposes only. It is noted the Time 2 exposure and risk could be reduced by using leaching data.

Additional Tier 1 calculations provided by the applicant for dimethyl myristyl amine, distilled indicate an unacceptable risk at Time 1 for the House Scenario and Noise Barrier Scenarios with an acceptable risk demonstrated at Time 3. The risk indicated at Tier 1 is an artefact of the extreme worst-case leaching rate assumed (50% of total loading over 30 days), which is highly unrealistic for a highly sorptive compound with a Koc of 16836 ml/g.

Also, the addition of this compound to the risk assessment leads to an unacceptable cumulative risk at Time 1 for both the House and Noise Barrier Scenarios. The Tier 1 leaching rates were refined using data from a leaching study. These refined Tier 2 leaching rates give an acceptable risk at Time 1 in soil for both the House and Noise barrier scenarios for both dimethyl myristyl amine, distilled, and for the sum of the components.

Groundwater

Conclusion:
As detailed in section 2.2.7.2 above, PEC_{GW} values were <0.1 µg/L for all compounds except penflufen metabolite M01. However, the M01 PEC_{GW} values were less than the values calculated during the penflufen EU assessment where a toxicological relevant assessment concluded safe-use for the more conservative values. Therefore, the UK CA considers the risk to groundwater from Vacsol Aqua 6118 use acceptable.

Tier 1 PEC_{GW} values calculated by the applicant for the SoC dimethyl myristyl amine, distilled were <0.001 µg/L in all PEARL 4.4.4. FOCUS scenarios.

Primary and secondary poisoning

Primary poisoning

Not required as the product is not a solid formulation used outside.

Secondary poisoning

	PEC/PNEC$_{birds}$	**PEC/PNEC$_{mammals}$**
Penflufen	1.51E-2	1.43E-2
Permethrin	3.84E-3	5.35E-4

Conclusion: The risk from primary poisoning is not required; the risk from secondary poisoning is acceptable.

Mixture toxicity

The UK CA has identified two environmentally relevant substances of concern, 2-phenoxyethanol and dimethyl myristyl amine (see section 2.2.7 and the Confidential

Annex). For dimethyl myristyl amine, it is not necessary to conduct a risk assessment as UC1 and 2 result in negligible environmental exposure. However Dimethyl myristyl amine, distilled is a SoC as it triggers the classification of the formulation and this SoC a quantitative risk assessment for environment for UC3 has been carried out. As 2-phenoxyethanol is present above 0.1% in the formulation it meets the criteria under other grounds for concern according to the BPR Environment guidance Vol IV parts B & C (2017).

A mixture assessment is required as the product contains two active substances (permethrin and penflufen) and two substance of concern (2-phenoxyethanol and dimethyl myristyl amine). The cumulative assessment has been undertaken within the Risk Characterisation section where the PEC/PNEC ratios of the active substance(s), relevant metabolites and relevant substances of concern have been summed. The summed Time 1 and Time 3 PEC/PNEC values for all compartments were <1.00 and therefore, the cumulative assessment is acceptable; Time 2 is not currently used for decision making purposes and is included for information only.

Aggregated exposure (combined for relevant emission sources)

Aggregated toxicity for the product and its a.s. has not been considered as the concept has not been agreed as a part of a harmonised approach to product assessment and no appropriate guidance is currently available. However, it is noted that UC 1 and UC 2 exposure is negligible and so any aggregated exposure is likely to be negligible.

Overall conclusion on the risk assessment for the environment of the product
Vacsol Aqua 6118 is an industrial wood preservative to be applied by double vacuum and vacuum pressure (UC 1 – 3) and dipping/enclosed deluge-spray systems (UC 1 – 2). A maximum target retention of rate of 4.65 kgm^{-1} was requested by the applicant for UC 1 – 3. Vacsol Aqua 6118 contains 0.379% penflufen and 0.4% permethrin. It also contains 3.836% of the non-PT active substance 2-phenoxyethanol. Leaching data submitted was used to conduct the Time 1 risk assessment. Default 100% loss was considered at Time 3, with the exception of the groundwater calculations where refined penflufen and 2-PE leaching rates were considered. **The UK CA can recommend interim authorisation for Use Classes 1, 2 and 3.** The potential emissions for UC 1 and 2 from treated wood to the outer environment are considered negligible and as such, environmental risk is considered to be zero for all compartments. Use Class 3 authorisation can also be recommended as the Time 1 and Time 3 cumulative assessments resulted in PEC/PNEC values <1.0 for the terrestrial and STP compartments. The aquatic assessment did not result in an acceptable risk assessment and so RMM is required to prevent treated wood being placed over or near water. The following phrases (applicable to UC 1-3) must appear on labelling and associated literature: "A*ll vacuum-pressure impregnation, double-vacuum, dipping and deluge treatment must only be undertaken at industrial sites where:* *Application processes are 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.* *Do not apply near bodies of surface water or in the area of water protection zones. [where relevant provide for appropriate distance stipulations]* *Freshly treated timber shall be stored after treatment under shelter <u>AND</u> on impermeable hard standing to prevent losses to soil, sewer, or water, and that any losses from the application of the product shall be collected for reuse or disposal."* *"Treated timber must not be placed over/near surface water bodies"* A post-authorisation data requirement is required for data to demonstrate the frozen storage stability of 2-PE in leachate samples over 23 months.

2.2.8 Measures to protect man, animals and the environment

Measures to protect man, animals and the environment are specified in the body of the assessment. They are stipulated to be included in label directions.

2.2.9 Assessment of a combination of biocidal products

Not Applicable

3 ANNEXES[1]

3.1 List of studies for the biocidal product

Author(s)	Year and Report date	Title and Report number	Source (where different from company) and Study sponsor	Data Protection Claimed (Yes/No)
Author:	Year: 2018	Title: Determination of the accelerated storage of Vacsol Aqua 6118 according to CIPAC MT 46.3 Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2018	Title: Determination of the accelerated storage of Vacsol Aqua 6118 according to CIPAC MT 46.3 Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2017	Title: Determination of the Density of VACSOL AQUA 6118 according to OECD 109 resp. EU A.3 Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2018	Title: Determination of the stability of liquid formulations of VACSOL AQUA 6118 at O °C according to CIPAC MT 39.3 Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes

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

Author:	Year: 2018	Title: Determination of the accelerated storage of Vacsol Aqua 6118 according to CIPAC MT 46.3 Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2019	Title: Determination of the Storage of Vasol Aqua 6118 at room temperature (duration 24 months) Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2018	Title: Determination of the accelerated storage of Vacsol Aqua 6118 according to CIPAC MT 46.3 Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2018	Title: Determination of the surface tension of an aqueous solution of VACSOL AQUA 6118 according to OECD 115 resp. EU A.5 Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2018	Title: Detrermination of Vicosity of Vacsol Aqua 6118 Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2017	Title: Statement concerning Oxidsing Properties Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2017	Title: Determination of the persistent foaming of Vacsol Aqua 6118 Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2017	Title: Statement concerning Oxidsing Properties	Company Owner: Arch Timber Protection (A Lonza Company)	Yes

		Report no. 17041003G		
Author:	Year: 2017	Title: Validation of an analytical Method using GC/FID for the determination of Penflufen and Permethrin in the test time Vacsol Aqua 6118 Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2016	Title: Determination of the toxic values against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 47 (2005) in combination with evaporative ageing procedure according to EN 73 (2014) Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2016	Title: Determination of the toxic values against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 47 (2005) in combination with leaching procedure according to EN 84 (1997) Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2016	Title: Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with evaporative ageing procedure according to EN 73 (2014) Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes

Author:	Year: 2016	Title: Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with leaching procedure according to EN 84 (1997) Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2017	Title: Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2016) after evaporative ageing procedure according to EN 73 (2014) Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2017	Title: Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2016) after leaching procedure according to EN 84 (1997) Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2017	Title: OECD Guidance on the estimation of emission from wood perservative treated wood to the environment. Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2019	Title: NT Build 509 “Leaching of active Ingredients from Preservative-Treated Timber Semi-Field Testing	Company Owner: Arch Timber Protection (A Lonza Company)	Yes

		Report no. 31/17/3018/01A		
Author:	Year: 2019	Title: Accelerated Storage Stability Study - 2-Phenoxyethanol in Leachate Water Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes
Author:	Year: 2020	Title: NT Build 509 “ Leaching of active ingredients from Preservative-Treated Timber - Semi-Field Testing Report no.	Company Owner: Arch Timber Protection (A Lonza Company)	Yes

3.2 Output tables from exposure assessment tools

Table 1.1 Scenario 0, Tier 1. Primary exposure to penflufen or permethrin during mixing and loading. PPE: gloves

General Exposure Calculator			
In-Use	active substance [a.s.]	0.38	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		1.38	mg min^{-1}
task duration		10	min
glove penetration		100.00	%
Actual deposit on hands[in-use product]		13.8000	mg
Rest of body exposure			
indicative value		0.00	mg min^{-1}
task duration		10	min
potential dermal deposit on body		0.00	mg
clothing penetration		0.00	%
Actual deposit on body [in-use product]		0.0000	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		10	min
shoe penetration		0.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**13.8000**	mg
active substance		**0.0518**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**0.0388**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		0.00	mg m^{-3}
task duration		0	min
volume of air inhaled during task		0.0000	m^3
in-use product inhaled		**0.0000**	mg
active substance inhaled		**0.0000**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		0.0388	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0006**	mg kg^{-1}d^{-1}
Dose - with RPE			
assigned inhalation protection factor		10	
active substance inhaled		0.0000	mg
total systemic exp. - skin & inhalation		0.0388	mg d^{-1}
Total systemic dose[a.s.]- with RPE		**0.0006**	mg kg^{-1}d^{-1}

Table 1.2 Scenario 0, Tier 1. Primary exposure to 2-phenoxyethanol during mixing and loading. PPE: gloves

General Exposure Calculator			
In-Use	active substance [a.s.]	3.84	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		1.38	mg min^{-1}
task duration		10	min
glove penetration		100.00	%
Actual deposit on hands[in-use product]		13.8000	mg
Rest of body exposure			
indicative value		0.00	mg min^{-1}
task duration		10	min
potential dermal deposit on body		0.00	mg
clothing penetration		0.00	%
Actual deposit on body [in-use product]		0.0000	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		10	min
shoe penetration		0.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**13.8000**	mg
active substance		**0.5299**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**0.3974**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		0.00	mg m^{-3}
task duration		0	min
volume of air inhaled during task		0.0000	m^3
in-use product inhaled		**0.0000**	mg
active substance inhaled		**0.0000**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		0.3974	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0066**	mg $kg^{-1}d^{-1}$
Dose - with RPE			
assigned inhalation protection factor		10	
active substance inhaled		0.0000	mg
total systemic exp. - skin & inhalation		0.3974	mg d^{-1}
Total systemic dose[a.s.]- with RPE		**0.0066**	mg $kg^{-1}d^{-1}$

Table 1.3 Scenario 0, Tier 1. Estimated air concentration of 2-phenoxyethanol using ART version 1.5

Emission sources: Near field ✓ Duration (mins): 10
Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	11 Pa
Liquid mole fraction	0.007
Activity coefficient	1
Activity emission potential	
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 10 - 100 l/minute
Containment level	Handling that reduces contact between product and adjacent air. Note: This does not include processes that are fully contained by localised controls (see next questions).
Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	Only good natural ventilation

Mechanistic model results

The predicted 75th percentile full-shift exposure is 0.0093 mg/m³.

The inter-quartile confidence interval is 0.0047 mg/m³ to 0.018 mg/m³.

Table 1.4 Scenario 1, Tier 1. Primary exposure to penflufen or permethrin during automated dipping. PPE: gloves

General Exposure Calculator			
In-Use	active substance [a.s.]	0.03750	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		1080.00	mg $cycle^{-1}$
task duration		4	cycles
glove penetration		100.00	%
Actual deposit on hands[in-use product]		4320.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		4	cycles
potential dermal deposit on body		34280.00	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		34280.0000	mg
Foot exposure			
indicative value		0.00	mg $cycle^{-1}$
task duration		4	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**38600.0000**	mg
active substance		**14.4750**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**10.8563**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		0.00	mg m^{-3}
task duration		240	min
volume of air inhaled during task		5.0000	m^3
in-use product inhaled		**0.0000**	mg
active substance inhaled		**0.0000**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		10.8563	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.1809**	mg $kg^{-1}d^{-1}$

Table 1.5 Scenario 1, Tier 2. Primary exposure to penflufen or permethrin during automated dipping. PPE: gloves and coated coveralls

General Exposure Calculator			
In-Use	active substance [a.s.]	0.03750	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		1080.00	mg $cycle^{-1}$
task duration		4	cycles
glove penetration		100.00	%
Actual deposit on hands[in-use product]		4320.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		4	cycles
potential dermal deposit on body		34280.00	mg
clothing penetration		10.00	%
Actual deposit on body [in-use product]		3428.0000	mg
Foot exposure			
indicative value		0.00	mg $cycle^{-1}$
task duration		4	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**7748.0000**	mg
active substance		**2.9055**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**2.1791**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		0.00	mg m^{-3}
task duration		240	min
volume of air inhaled during task		5.0000	m^3
in-use product inhaled		**0.0000**	mg
active substance inhaled		**0.0000**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		2.1791	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0363**	mg $kg^{-1}d^{-1}$

Table 1.6 Scenario 1, Tier 3. Primary exposure to penflufen or permethrin during automated dipping. PPE: new gloves and coated coveralls

General Exposure Calculator			
In-Use	active substance [a.s.]	0.0375	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		540.00	mg $cycle^{-1}$
task duration		4	cycles
glove penetration		100.00	%
Actual deposit on hands[in-use product]		2160.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		4	cycles
potential dermal deposit on body		34280.00	mg
clothing penetration		10.00	%
Actual deposit on body [in-use product]		3428.0000	mg
Foot exposure			
indicative value		0.00	mg $cycles^{-1}$
task duration		4	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**5588.0000**	mg
active substance		**2.0955**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**1.5716**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		0.00	mg m^{-3}
task duration		120	min
volume of air inhaled during task		2.5000	m^3
in-use product inhaled		**0.0000**	mg
active substance inhaled		**0.0000**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		1.5716	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0262**	mg $kg^{-1}d^{-1}$

Table 1.7 Scenario 1, Tier 4. Primary exposure to penflufen or permethrin during automated dipping. PPE: new gloves and impermeable coveralls

General Exposure Calculator			
In-Use	active substance [a.s.]	0.0375	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		540.00	mg $cycle^{-1}$
task duration		4	cycles
glove penetration		100.00	%
Actual deposit on hands[in-use product]		2160.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		4	cycles
potential dermal deposit on body		34280.00	mg
clothing penetration		5.00	%
Actual deposit on body [in-use product]		1714.0000	mg
Foot exposure			
indicative value		0.00	mg $cycles^{-1}$
task duration		4	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**3874.0000**	mg
active substance		**1.4528**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**1.0896**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		0.00	mg m^{-3}
task duration		120	min
volume of air inhaled during task		2.5000	m^3
in-use product inhaled		**0.0000**	mg
active substance inhaled		**0.0000**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		1.0896	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0182**	mg $kg^{-1}d^{-1}$

Table 1.8 Scenario 1, Tier1. Primary systemic exposure to 2-phenoxyethanol during automated dipping. PPE: gloves

General Exposure Calculator			
In-Use	active substance [a.s.]	0.3863	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		1080.00	mg $cycle^{-1}$
task duration		4	cycle(s)
glove penetration		100.00	%
Actual deposit on hands[in-use product]		4320.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		4	cycle(s)
potential dermal deposit on body		34280.00	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		34280.0000	mg
Foot exposure			
indicative value		0.00	mg $cycle^{-1}$
task duration		4	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**38600.0000**	mg
active substance		**149.1118**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**111.8339**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		0.00	mg m^{-3}
task duration		30	min
volume of air inhaled during task		0.6250	m^3
in-use product inhaled		**0.0000**	mg
active substance inhaled		**0.0000**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		111.8339	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**1.8639**	mg $kg^{-1}d^{-1}$

Table 1.9 Scenario 1, Tier1. Estimated air concentration of 2-phenoxyethanol using ART version 1.5

Details for Activity dipping

Emission sources: Near field ✓
Far field

Duration (mins): 60

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	11 Pa
Liquid mole fraction	0.000693
Activity coefficient	1
Activity emission potential	
Activity class	Activities with relatively undisturbed surfaces (no aerosol formation)
Situation	Open surface > 3 m²
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	No
General housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	Only good natural ventilation

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 75th percentile full-shift exposure is 0.03 mg/m³.

The 90% confidence interval is 0.0059 mg/m³ to 0.17 mg/m³.

Table 2.0 Scenario 2, Tier 1. Primary exposure to penflufen or permethrin during enclosed deluge/flood spray treatment. PPE: gloves

General Exposure Calculator			
In-Use	active substance [a.s.]	0.075	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		25.70	mg min^{-1}
task duration		60	min
glove penetration		100.00	%
Actual deposit on hands[in-use product]		1542.0000	mg
Rest of body exposure			
indicative value		178.00	mg min^{-1}
task duration		60	min
potential dermal deposit on body		10680.00	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		10680.0000	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		60	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**12222.0000**	mg
active substance		**9.1665**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**6.8749**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		1.00	mg m^{-3}
task duration		60	min
volume of air inhaled during task		1.2500	m^3
in-use product inhaled		**1.2500**	mg
active substance inhaled		**0.0009**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		6.8758	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.1146**	mg $kg^{-1}d^{-1}$

Table 2.1 Scenario 2, Tier 2. Primary exposure to penflufen or permethrin during enclosed deluge/flood spray treatment. PPE: gloves and coated coveralls.

General Exposure Calculator			
In-Use	active substance [a.s.]	0.075	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		25.70	mg min^{-1}
task duration		60	min
glove penetration		100.00	%
Actual deposit on hands[in-use product]		1542.0000	mg
Rest of body exposure			
indicative value		178.00	mg min^{-1}
task duration		60	min
potential dermal deposit on body		10680.00	mg
clothing penetration		10.00	%
Actual deposit on body [in-use product]		1068.0000	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		60	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**2610.0000**	mg
active substance		**1.9575**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**1.4681**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		1.00	mg m^{-3}
task duration		60	min
volume of air inhaled during task		1.2500	m^3
in-use product inhaled		**1.2500**	mg
active substance inhaled		**0.0009**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		1.4691	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0245**	mg $kg^{-1}d^{-1}$

Table 2.2 Scenario 2, Tier 3. Primary exposure to penflufen or permethrin during enclosed deluge/flood spray treatment. PPE: new gloves and coated coveralls.

General Exposure Calculator			
In-Use	active substance [a.s.]	0.075	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		12.85	mg min^{-1}
task duration		60	min
glove penetration		100.00	%
Actual deposit on hands[in-use product]		771.0000	mg
Rest of body exposure			
indicative value		178.00	mg min^{-1}
task duration		60	min
potential dermal deposit on body		10680.00	mg
clothing penetration		10.00	%
Actual deposit on body [in-use product]		1068.0000	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		60	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**1839.0000**	mg
active substance		**1.3793**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**1.0344**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		1.00	mg m^{-3}
task duration		60	min
volume of air inhaled during task		1.2500	m^3
in-use product inhaled		**1.2500**	mg
active substance inhaled		**0.0009**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		1.0354	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0173**	mg $kg^{-1}d^{-1}$

Table 2.3 Scenario 2, Tier 1. Primary exposure to 2-phenoxyethanol during enclosed deluge/flood spray treatment. PPE: gloves

General Exposure Calculator			
In-Use	active substance [a.s.]	0.7672	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		25.70	mg min^{-1}
task duration		60	min
glove penetration		100.00	%
Actual deposit on hands[in-use product]		1542.0000	mg
Rest of body exposure			
indicative value		178.00	mg min^{-1}
task duration		60	min
potential dermal deposit on body		10680.00	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		10680.0000	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		60	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**12222.0000**	mg
active substance		**93.7672**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**70.3254**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		1.00	mg m^{-3}
task duration		60	min
volume of air inhaled during task		1.2500	m^3
in-use product inhaled		**1.2500**	mg
active substance inhaled		**0.0096**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		70.3350	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**1.1722**	mg $kg^{-1}d^{-1}$

Table 2.4 Scenario 2, Tier 1. Estimated air concentration of 2-phenoxyethanol using ART version 1.5

Emission sources:	Near field ✓	Duration (mins):	480
	Far field		

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	11 Pa
Liquid mole fraction	0.00138
Activity coefficient	1
Activity emission potential	
Activity class	Handling of contaminated objects
Situation	Activities with treated/contaminated objects (surface > 3 m²)
Contamination level	Contamination > 90 % of surface
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	No
General housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	Any size workroom

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	Only good natural ventilation

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 75th percentile full-shift exposure is 0.061 mg/m³.

The 90% confidence interval is 0.012 mg/m³ to 0.33 mg/m³.

Table 2.5 Scenario 3, Tier 1. Primary exposure to penflufen or permethrin during vacuum pressure application. PPE: gloves

General Exposure Calculator			
In-Use	active substance [a.s.]	0.0047	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		1080.00	mg $cycle^{-1}$
task duration		3	cycles
glove penetration		100.00	%
Actual deposit on hands[in-use product]		3240.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		3	cycles
potential dermal deposit on body		25710.00	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		25710.0000	mg
Foot exposure			
indicative value		0.00	mg $cycle^{-1}$
task duration		3	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**28950.0000**	mg
active substance		**1.3607**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**1.0205**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		1.90	mg m^{-3}
task duration		30	min
volume of air inhaled during task		0.6250	m^3
in-use product inhaled		**1.1875**	mg
active substance inhaled		**0.0001**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		1.0205	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0170**	mg $kg^{-1}d^{-1}$

Table 2.6 Scenario 3, Tier 1. Primary exposure to 2-phexoyethanol during vacuum pressure application. PPE: gloves

General Exposure Calculator			
In-Use	active substance [a.s.]	0.0480	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		1080.00	mg $cycle^{-1}$
task duration		3	cycle(s)
glove penetration		100.00	%
Actual deposit on hands[in-use product]		3240.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		3	cycle(s)
potential dermal deposit on body		25710.00	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		25710.0000	mg
Foot exposure			
indicative value		0.00	mg $cycle^{-1}$
task duration		3	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**28950.0000**	mg
active substance		**13.8960**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**10.4220**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		1.90	mg m^{-3}
task duration		30	min
volume of air inhaled during task		0.6250	m^3
in-use product inhaled		**1.1875**	mg
active substance inhaled		**0.0006**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		10.4226	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.1737**	mg $kg^{-1}d^{-1}$

Table 2.7 Scenario 4, Tier 1. Primary exposure to penflufen or permethrin during double vacuum pressure application. PPE: gloves

General Exposure Calculator			
In-Use	active substance [a.s.]	0.01875	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		1080.00	mg $cycle^{-1}$
task duration		6	cycles
glove penetration		100.00	%
Actual deposit on hands[in-use product]		6480.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		6	cycles
potential dermal deposit on body		51420.00	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		51420.0000	mg
Foot exposure			
indicative value		0.00	mg $cycle^{-1}$
task duration		6	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**57900.0000**	mg
active substance		**10.8563**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**8.1422**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		1.90	mg m^{-3}
task duration		60	min
volume of air inhaled during task		1.2500	m^3
in-use product inhaled		**2.3750**	mg
active substance inhaled		**0.0004**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		8.1426	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.1357**	mg $kg^{-1}d^{-1}$

Table 2.8 Scenario 4, Tier 2. Primary exposure to penflufen or permethrin during double vacuum pressure application. PPE: gloves and coated coveralls

General Exposure Calculator			
In-Use	active substance [a.s.]	0.01875	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		1080.00	mg $cycle^{-1}$
task duration		6	cycles
glove penetration		100.00	%
Actual deposit on hands[in-use product]		6480.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		6	cycles
potential dermal deposit on body		51420.00	mg
clothing penetration		10.00	%
Actual deposit on body [in-use product]		5142.0000	mg
Foot exposure			
indicative value		0.00	mg $cycle^{-1}$
task duration		6	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**11622.0000**	mg
active substance		**2.1791**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**1.6343**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		1.90	mg m^{-3}
task duration		60	min
volume of air inhaled during task		1.2500	m^3
in-use product inhaled		**2.3750**	mg
active substance inhaled		**0.0004**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		1.6348	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0272**	mg $kg^{-1}d^{-1}$

Table 2.9 Scenario 4, Tier 3. Primary exposure to penflufen or permethrin during double vacuum pressure application. PPE: new gloves and coated coveralls

General Exposure Calculator			
In-Use	active substance [a.s.]	0.01875	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		540.00	mg $cycle^{-1}$
task duration		6	cycles
glove penetration		100.00	%
Actual deposit on hands[in-use product]		3240.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		6	cycles
potential dermal deposit on body		51420.00	mg
clothing penetration		10.00	%
Actual deposit on body [in-use product]		5142.0000	mg
Foot exposure			
indicative value		0.00	mg $cycle^{-1}$
task duration		6	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**8382.0000**	mg
active substance		**1.5716**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**1.1787**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		1.90	mg m^{-3}
task duration		60	min
volume of air inhaled during task		1.2500	m^3
in-use product inhaled		**2.3750**	mg
active substance inhaled		**0.0004**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		1.1792	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0197**	mg $kg^{-1}d^{-1}$

Table 3.0 Scenario 4, Tier 1. Primary exposure to 2-phenoxyethanol during double vacuum pressure application. PPE: gloves

General Exposure Calculator			
In-Use	active substance [a.s.]	0.1918	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		1080.00	mg $cycle^{-1}$
task duration		6	cycle(s)
glove penetration		100.00	%
Actual deposit on hands[in-use product]		6480.0000	mg
Rest of body exposure			
indicative value		8570.00	mg $cycle^{-1}$
task duration		6	cycle(s)
potential dermal deposit on body		51420.00	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		51420.0000	mg
Foot exposure			
indicative value		0.00	mg $cycle^{-1}$
task duration		6	cycles
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**57900.0000**	mg
active substance		**111.0522**	mg
Skin penetration		75.00	%
Total dermal systemic exp. [a.s.]		**83.2892**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		1.90	mg m^{-3}
task duration		60	min
volume of air inhaled during task		1.2500	m^3
in-use product inhaled		**2.3750**	mg
active substance inhaled		**0.0046**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		83.2937	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**1.3882**	mg $kg^{-1}d^{-1}$

Table 3.1 Scenario 9, Tier 1. Estimated air concentration of 2-phenoxyethanol using ConsExpo Web

Inhalation		
Exposure model	Exposure to vapour - Evaporation	
Exposure duration	1	day
Product in pure form	No	
Molecular weight matrix	23	g/mol
The product is used in dilution	No	
Product amount	419	g
Weight fraction substance	0.0384	
Room volume	20	m^3
Ventilation rate	0.6	per hour
Inhalation rate	8	m^3/day
Application temperature	20	°C
Vapour pressure	1	Pa
Molecular weight	138	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Constant	
Release area	9	m^2
Emission duration	1	day
Absorption model	n.a.	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for scenario Secondary inhalation		
Inhalation		
Mean event concentration	0.32	mg/m^3
Peak concentration (TWA 15 min)	0.32	mg/m^3
Mean concentration on day of exposure	0.32	mg/m^3
Year average concentration	0.32	mg/m^3
External event dose	0.26	mg/kg bw
External dose on day of exposure	0.26	mg/kg bw

3.3 New information on the active substance

No new information has been provided on the active substances

3.4 Residue behaviour

N/A

3.5 Summaries of the efficacy studies

See Section 2.2.4.5

3.6 Confidential annex

See separate document.

3.7 Other