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

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the Arch Timber Protection Ltd)

Tanasote S40

Product type 8

Copper (II) Hydroxide, Penflufen, DDACarbonate

Case Number in R4BP: [BC-KB037703-55]

Evaluating Competent Authority: Sweden

Date: [23/03/2021]

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1 CONCLUSION

The biocidal product Tanasote S40 is a PT8 oil based product intended to be used for preventive wood treatment in use classes 3 and 4. It contains 4.45% copper hydroxide (3% w/w copper), 0.68% DDACarbonate, and 0.0371% penflufen.

The product is a ready-to-use wood preservative to be used by industrial users and applied by vacuum treatment. The product was not approved for treated timber used in or near surface water bodies in use class 4.

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

Tanasote S40 is not explosive, oxidising, flammable or corrosive to metals. The physical, chemical and technical properties of Tanasote S40 are considered acceptable. No specific issues are to be expected when it is handled, stored or applied as recommended.
The claim for 2 years shelf-life in its commercial packaging (HDPE) is acceptable.

Conclusion on Efficacy

The efficacy of Tanasote S40 has been demonstrated by testing according to the requirements in EN 599-1 for a wood preservative to be used on softwood and hardwood in Use Class 3 and on softwood in Use Class 4. Acceptable efficacy has been shown for Tanasote S40 at the stated application rates.

Conclusion on Human health

The risk for industrial users of Tanasote S40 is acceptable when appropriate PPE including eye protection and chemical resistant gloves are worn. No risk is identified for professionals or non-professionals working with Tanasote S40 treated wood or for the general public.

Conclusion on risk for consumers via residues in food

There is no consumer risk due to consumption of food products from livestock that have been exposed to Tanasote S40. However, in order to ensure that there would be no consumer exposure from treated wood, the following risk mitigation measure should be added to the product label:

"Do not use on wood which may come in direct contact with food and feeding stuff"

Conclusion on environmental risk assessment

Use class 3

Product authorisation is acceptable for Tanasote S40 Use Class 3 at a maximum product retention rate of up to 100 kg/m^3.

Additionally, for the treatment of railway sleepers (Use Class 3), a maximum retention rate of up to 133 kg/m^3 is acceptable.

Use Class 4 Treatment of general timber

Product authorisation is acceptable for Tanasote S40 for Use Class 4a corresponds to wood in direct contact with ground at a maximum product retention rate of up to 133 kg/m^3.

The product cannot be approved for treated timber use in direct contact with surface water bodies in Use Class 4.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

Identifier of the product

Identifier[1]	**Country (if relevant)**

Authorisation holder

Name and address of the authorisation holder	**Name**	Lonza Cologne GmbH *(a Lonza Company)*
	Address	Nattermannallee 1 50829 Cologne, Germany
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

Manufacturer(s) of the product

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

Manufacturer(s) of the active substance(s)

Active substance	Copper hydroxide
Name of manufacturer	Spiess-Urania Chemicals GmbH
Address of manufacturer	Heidenkampsweg 77, 20097, Hamburg, Germany
Location of manufacturing sites	Spiess-Urania Chemicals GmbH Hovestr. 50, 20539 Hamburg, Germany

Active substance	DDACarbonate
Name of manufacturer	Lonza Cologne GmbH
Address of manufacturer	Nattermannallee 1, 50829 Cologne, Germany
Location of manufacturing sites	Lonza Inc., 8316 West Route 24, IL 61547, Mapleton, USA

Active substance	Penflufen

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

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

2.1.2 Product composition and formulation

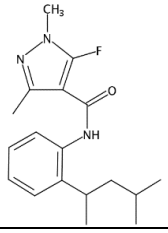
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

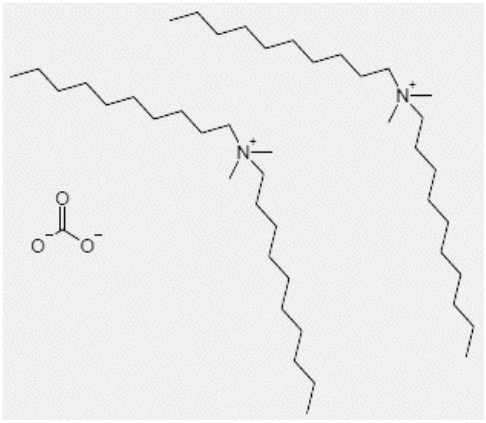
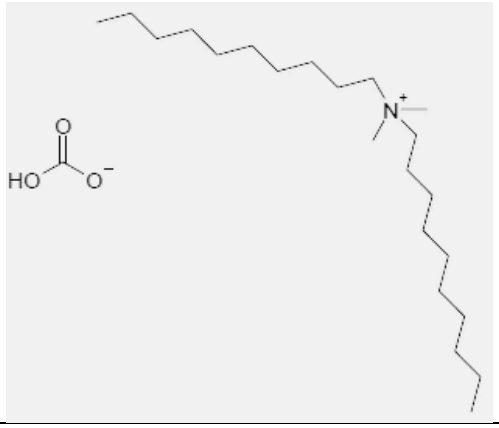
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

Identity of the active substance

Main constituent(s)	
ISO name	Copper hydroxide
IUPAC or EC name	Copper (II) hydroxide
EC number	243-815-9
CAS number	20427-59-2
Index number in Annex VI of CLP	029-021-00-3
Minimum purity / content	96.5 % (62.9 % w/w as copper)
Identity of relevant impurities in the active substance	Lead : max 0.005% w/w Cadmium : max 0.0005% w/w Arsenic : max 0.0004% w/w
Structural formula	$Cu(OH)_2$

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	DDACarbonate
IUPAC or EC name	Reaction mass of N,N-didecyl-N,N-dimethylammonium carbonate and N,N-didecyl-N,N-dimethylammonium bicarbonate
EC number	451-900-9
CAS number	894406-76-9
Index number in Annex VI of CLP	N/A
Minimum purity / content	74 % (dry weight) DDACarbonate is manufactured as min. 45 % w/w aqueous solution.
Identity of relevant impurities in the active substance	Methanol <3% w/w
Structural formula	Didecyldimethylammonium carbonate  Didecyldimethylammonium bicarbonate 

Candidate(s) for substitution

According to the most recent scientific information available, Tanasote S40 has no active substances that are candidates for substitution.

Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Copper hydroxide	Copper-dihydroxide	Active substance	20427-59-2	243-815-9	4.615 (TC) (3% w/w copper) 4.45 (pure)
Penflufen	2'-[(RS)-1,3-dimethylbutyl]-5-fluoro-1,3-dimethylpyrazole-4-carboxanilide	Active substance	494793-67-8	619-823-7	0.0379 (TC) 0.0371 (pure)
DDACarbonate	Reaction mass of N,N-didecyl-N,N-dimethylammonium carbonate and N,N-didecyl-N,N-dimethylammonium bicarbonate	Active substance	894406-76-9	451-900-9	1.5 (TK) 0.91 (TC) 0.68 (pure)
Fatty acids, C8-C10	Fatty acids, C8-C10	Solvent	68937-75-7	273-086-2	9.90

The full formulation composition is available in the Confidential annex.

Information on technical equivalence

The notified source of copper hydroxide is the same as that considered at active substance approval. Spiess-Urania Chemicals GmbH owns the active substance dossier and has provided the applicant (Lonza Cologne GmbH) with a letter of access to these data and therefore no further consideration is required.

The notified source of penflufen is the same as that considered at active substance approval. Lanxess Deutschland GmbH owns the active substance dossier and has provided the applicant (Arch Timber Protection Ltd) with a letter of access to these data and therefore no further consideration is required.

The notified source of DDACarbonate is the same as that considered at active substance approval. Lonza Cologne GmbH owns the active substance dossier and therefore no further consideration is required.

Information on the substance(s) of concern

One co-formulant was identified as substances of concern (SoC). The fatty acids, C8-C10 are classified for skin corrosivity (Skin Corr 1B) and with a concentration of 9.9 %, and in the absence of product-specific corrosivity testing, would lead to the product being classified as corrosive. However a product specific skin corrosivity study has been conducted by the applicant and concludes it is not corrosive to skin.

See Confidential annex of the PAR for further details.

2.1.2.1.1 Assessment of endocrine disruption (ED) properties

None of the active substances in Tanasote S40 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 of the PAR. None of the co-formulants have indications on ED properties.

Type of formulation

Oil miscible liquids (OL)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Serious eye damage/eye irritation (category 1) Skin corrosion/irritation (category 2) Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H315 - Causes skin irritation H318 - Causes serious eye damage H400 – Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Hazard statements	H315 - Causes skin irritation H318 - Causes serious eye damage H410 - Very toxic to aquatic life with long lasting effects
Precautionary statements	P264 - Wash hands thoroughly after handling P273 - Avoid release to the environment P280 - Wear protective gloves/eye protection P302 + P352 - IF ON SKIN: Wash with plenty of water P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 - Immediately call a POISON CENTRE P332 + P313 If skin irritation occurs: Get medical advice P362 + P364 Take off contaminated clothing and wash it before reuse P501 - Dispose of contents/ container to an authorised waste disposal plant P391 Collect spillage
Note	

2.1.4 Authorised use(s)

Use description

Table 1. Use # 1 – Industrial use (Use class 3)

Product Type	PT08 - Wood preservative (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide Insecticide
Target organism (including development stage)	Scientific name: Hylotrupes bajulus L. Common name: House longhorn beetle Development stage: Larvae Scientific name: Reticulitermes sp. Common name: Termites (genus Reticulitermes) Development stage: No data Scientific name: Basidiomycetes: Common name: Brown and white wood rotting fungi Development stage: Hyphae
Field of use	Indoor Indoor application of the wood preservative Pressure applied preventative treatment for industrial timbers. Use class 3: treatment of general timber and railway sleepers 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. For use class 3, the product can be applied to both softwood and hardwood.
Application method(s)	Closed system: Vacuum impregnation <u>Full Cell Process:</u> • Bethel process <u>Empty Cell Process:</u> • Rueping process • Lowry process
Application rate(s) and frequency	Application Rate: UC 3 (excluding termites): 48.7-100 kg/m3; UC3 (including termites): 65.4-100 kg/m3; UC3 (railway sleepers, including termites): 65.4 - 133 kg/m3 Dilution (%): 0 Number and timing of application:

	The timber is treated once, before being placed into service. No re-treatment or additional treatment is necessary during the service life of the treated article.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	IBC (intermediate bulk container) in HDPE: 1000 L

Use-specific instructions for use

See 2.1.5 General directions for use

Use-specific risk mitigation measures

See 2.1.5 General directions for use

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

See 2.1.5 General directions for use

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

See 2.1.5 General directions for use

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

See 2.1.5 General directions for use

Use description

Table 2. Use # 2 – Industrial use (Use class 4)

Product Type	PT08 - Wood preservatives (Preservatives)
Where relevant, an exact description of the authorised use	Fungicide Insecticide
Target organism (including development stage)	Scientific name: Hylotrupes bajulus L. Common name: House longhorn beetle Development stage: Larvae Scientific name: Reticulitermes sp. Common name: Termites (genus Reticulitermes) Development stage: No data Scientific name: Basidiomycetes:

	Common name: Brown and white wood rotting fungi Development stage: Hyphae Scientific name: Ascomycetes, Deuteromycetes Common name: Soft rot fungi Development stage: Hyphae
Field of use	Indoor Indoor application of the wood preservative. Pressure applied preventative treatment for industrial timbers. Use class 4: treatment of general timber. Use class 4: Situation in which the wood or wood-based product is in contact with the ground and permanently exposed to wetting. For use class 4, the product is applied to softwood only. The product must not be used to treat timber that will be placed in or near surface water bodies in use class 4.
Application method(s)	Closed system : Vacuum impregnation Full Cell Process: • Bethel process Empty Cell Process: • Rueping process • Lowry process
Application rate(s) and frequency	Application Rate: UC4 (including termites): 86.5-133 kg/m3 Dilution (%): 0 Number and timing of application: The timber is treated once, before being placed into service. No re-treatment or additional treatment is necessary during the service life of the treated article.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	IBC (intermediate bulk container) in HDPE: 1000 L

Use-specific instructions for use

See 2.1.5 General directions for use

Use-specific risk mitigation measures

See 2.1.5 General directions for use

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

See 2.1.5 General directions for use

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

See 2.1.5 General directions for use

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

See 2.1.5 General directions for use

2.1.5 General directions for use

Instructions for use

Tanasote S40 is a ready to use wood preservative which is applied to timber by one of the following pressure processes, Lowry process, Rueping cycle or Bethel cycle. Apply a long final vacuum at the end of each cycle.. The application method will depend on the type of timber or the timber end use. The timber in the vessel should be treated to the predetermined retentions based on the desired use.

Please read and understand:

• The Technical Data Sheet for Tanasote S40 which provides a summary of the product.

• The Material Safety Data Sheets for Tanasote S40

Since only efficacy data for Hylotrupes bajulus have been provided and no information is given demonstrating that this species is the least sensitive only use against Hylotrupes bajulus (House longhorn beetle) can be authorized.

The IBC containing the Tanasote S40 is connected via a bottom locking run-off valve directly to the treatment vessel.

The retentions are expressed as $kg \cdot m^{-3}$ as Tanasote S40 in the analytical zone.

UC3: (excl termite) 48.7 kg/m^3 – 100 kg/m^3

UC3 (incl termite): 65.4 kg/m^3 – 100 kg/m^3

UC3 (railway sleepers, incl termites): 65.4 kg/ m^3 – 133 kg/m^3

UC4 (incl termites): 86.5 kg/m^3 – 133 kg/m^3

Risk mitigation measures

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

A protective coverall (at least type 6, EN 13034) shall be worn.

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

There will be no application and storage emissions. 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 re-use or disposal.
- 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]

The product must not be used to treat timber that will be placed in or near surface water bodies in use class 4.

Do not use on wood which may come in direct contact with food and feeding stuff.

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

General advice - In case of accident or if you feel unwell, seek medical advice immediately (show the safety data sheet or product label where possible).

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 with soap and water. If skin irritation 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.

Instructions for safe disposal of the product and its packaging

Empty IBC containers should be returned to the manufacturer for recycling.

Do not dispose of any residue down the drain.

IBC’s must not be re-used for drinking water or containing foodstuffs.

Tanasote S40 should be disposed of in accordance with local authority requirements.

Normally in such cases the treatment plant management would first contact the product supplier to discuss re-use.

Treated wood waste should be disposed of by a method approved by the local authority.

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

Store in original container. Shelf-life: 24 months.

2.1.6 Other information

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	1000 L	HDPE	Standard	Specialised professional (industrial)	Yes

The product will be transported in stainless steel bulk tanker (30, 000 L).

2.1.8 Documentation

Data submitted in relation to product application

The studies submitted in support of the product authorisation application are listed in each sections of the IUCLID.

Access to documentation

A letter of access from Spiess Urania GmbH which gives the CA access to the copper hydroxide data for the Tanasote S40 application has been submitted.
A letter of access from Lanxess Deutschland GmbH which gives the CA access to the penflufen data for the Tanasote S40 application has been submitted.
Lonza Cologne GmbH is the owner of the data in the DDACarbonate dossier and no letter of access is required.

2.2 Assessment of the biocidal product (family)

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

Table 3. Intended use # 1 – name of the use

Product Type(s)	8 (wood Preservative)
Where relevant, an exact description of the authorised use	Pressure applied preventative treatment for industrial timbers.
Target organism (including development stage)	Wood-destroying brown rot fungi Wood-destroying white rot fungi Wood-destroying soft rot fungi Wood-destroying termites Wood destroying beetles
Field of use	**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). **Use Class 4** (situation in which the wood or wood-based product is in contact with the ground and permanently exposed to wetting)
Application method(s)	Vacuum pressure impregnation
Application rate(s) and frequency	Authorisation is requested for treatment of timber at the following retention rates in the analytical zone:- UC3: 48.7 kg/m^3 – 100 kg/m^3 UC3 (termite): 65.4 kg/m^3 – 100 kg/m^3 UC3 (railway sleepers, incl termites): 65.4 kg/m^3 – 133 kg/m^3 UC4 (incl termites): 86.5 kg/m^3 – 133 kg/m^3
Category(ies) of user(s)	Specialised professional (industrial)
Pack sizes and packaging material	HDPE IBC (1000 L) Stainless steel bulk tanker (30, 000 L).

2.2.2 Physical, chemical and technical properties

Tanasote S40 is a ready-to-use wood preservative. It is an OL (Oil miscible liquid) formulation. The physical and chemical and storage stability data submitted to support the product are summarised in the following table.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
Physical state and colour at 20 °C and 101.3 kPa	Visual	Tanasote S40 4.615 % (3% copper) copper hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonate	Homogenous dark green opaque liquid	Acceptable	
pH	CIPAC MT 75.3	Tanasote S40 4.615 % (3% copper) copper hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonate	pH at 25 °C Neat: 5.52 (apparent pH value) 1 % aq. soln: 5.60	Acceptable	
Acidity / alkalinity			Testing was not required because the pH of test item was determined to be greater than pH 4 and less than pH 10.	Acceptable	
Density	EU A.3 Pycnometer	Tanasote S40 4.615 % (3% copper) copper	920 kg/m^3 @ 20 °C Relative density: 0.921	Acceptable	

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Comments</th><th>Reference</th></tr>
<tr><td></td><td></td><td>hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonate</td><td></td><td></td><td></td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC MT 46.3</td><td>Tanasote S40 4.615 % (3% copper) copper hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonate</td><td>Storage for 8 weeks at 40 ± 2 ºC.
Packaging: 1 L HDPE bottle

<table>
<tr><td>Penflufen</td><td>% w/w</td></tr>
<tr><td>Initial
8 weeks</td><td>0.0362
0.0380
(+ 5.0%)</td></tr>
<tr><td>DDA+*</td><td>% w/w</td></tr>
<tr><td>Initial
8 weeks</td><td>0.687
0.726
(+ 5.7%)</td></tr>
<tr><td>Copper**</td><td>% w/w</td></tr>
<tr><td>Initial
8 weeks</td><td>2.95
3.04
(+ 3.1%)</td></tr>
</table>
* The conversion factor is 0.86 for DDA Carbonate to DDA^{+}.
** The conversion factor is 0.65 for copper hydroxide to copper.

There were no significant changes in the content of penflufen, DDA+ and copper of the test item during storage for 8 weeks at 40 ± 2 ºC. No observation of phase separation or precipitation were reported in the study report.</td><td>Acceptable. The product is considered stable at elevated temperature.
For OL formulations the miscibility with hydrocarbon oil (CIPAC MT 23) should also be determined. However, Tanasote S40 is a ready-to-use wood preservative and not intended to be diluted with hydrocarbon oils.</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			pH at 25 °C: Neat: 5.52 (initial), 5.31 (8 weeks) 1 % aq. soln: 5.60 (initial), 5.97 (8 weeks) Appeareance: Initial: dark green opaque, homogenous liquid 8 weeks: dark green opaque liquid Container: Initial: no signs of corrosion, degradation or seepage. After 8 weeks: no change Weight change: -0.022 %		
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Tanasote S40 4.615 % (3% copper) copper hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonate	Storage for 7 days at 0 ± 2 °C. Initial: Green opaque liquid. After 7 days: Green opaque liquid. Due to the opaque nature of the test item, a wet sieve test was performed. There was no visible solid material remaining on the 75 µm sieve after washing with water.	Acceptable. The product is considered stable at 0 °C.	

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Comments</th><th>Reference</th></tr>
<tr><td>Storage stability test – Long Term storage</td><td>CIPAC MT 75.3</td><td>Tanasote S40 4.615 % (3% copper) copper hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonate</td><td>Storage for 24 months at 25 ± 2 ºC in commercial containers (1 L white plastic (HDPE) bottles).

<table>
<tr><td>Penflufen</td><td>% w/w</td></tr>
<tr><td>Initial
24 months</td><td>0.0362
0.0372 (+2.8%)</td></tr>
<tr><td>DDA+*</td><td>% w/w</td></tr>
<tr><td>Initial
6 months
18 months

24 months</td><td>N/A[1]
0.687
0.754 (+9.8%)
0.682 (-0.73%)</td></tr>
<tr><td>Copper**</td><td>% w/w</td></tr>
<tr><td>Initial
24 months</td><td>2.95
2.90 (-1.6%)</td></tr>
</table>
[1] Not determined.
* The conversion factor is 0.86 for DDA Carbonate to DDA+.
** The conversion factor is 0.65 for copper hydroxide to copper.

pH at 25 °C:
Neat: 5.52 (initial), 6.12 (24 months)
1 % aq. soln: 5.60, 5.37 (24 months)

Appeareance:
Initial: dark green opaque, homogenous liquid</td><td>Acceptable.
No change in appearance, pH or loss of active contents were observed following storage.
The initial DDA+ content was not determined. However, results at 6, 18 and 24 months indicate that DDA carbonate is stable during storage at 25 ºC for 24 months.
The product is considered stable when stored at 25 ºC for 24 months in commercial packaging.

For OL formulations the miscibility with hydrocarbon oil (CIPAC MT 23) should also be determined. However, Tanasote S40 is a ready-to-use wood preservative and not intended to be diluted with hydrocarbon oils.</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			24 months: dark green opaque homogenous liquid Container (1 liter, white translucent plastic bottle): Initial: no signs of corrosion, degradation or seepage. 24 months: no change Weight change: +0.0011 %		
Effects on content of the active substance and technical characteristics of the biocidal product - light		Tanasote S40 4.615 % (3% copper) copper hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonate	The shelf life study was performed in translucent commercial containers. The results from the study indicate that the product is not light sensitive.	Acceptable	
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material		Tanasote S40 4.615 % (3% copper) copper hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonate	The product is compatible with HDPE containers (see results from the accelerated storage stability and shelf life study).	Acceptable	
Wet sieve analysis and dry sieve test		Tanasote S40 4.615 % (3% copper)	Test item: 100 mL Tanasote S40 (after low temperature stability study) Due to the opaque nature of	Acceptable	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
		copper hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonate	the test item, a wet sieve was performed to confirm the absence separated material. The sample was quantitatively transferred to a sieve and washed with water. Sieve: 20 cm Ø, 75 µm mesh There was no visible solid material remaining on the 75 µm sieve after washing with tap water (5 L/min for 5 min).		
Physical compatibility			Tanasote S40 is ready-to-use wood preservative and not intended to be used with other products.	Acceptable	-
Chemical compatibility			Tanasote S40 is ready-to-use wood preservative and not intended to be used with other products.	Acceptable	-
Surface tension	Method A5 OECD 115 Ring method	Tanasote S40 4.615 % (3% copper) copper hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonate	31.0 ± 0.5 mN/m @ 20 ºC (neat)	Acceptable	
Viscosity	OECD 114 Capillary viscometer	Tanasote S40 4.62 % (3% copper) copper hydroxide,	Kinematic viscosity 54.8 mm^2/s @20 °C 21.1 mm^2/s @ 40 °C	Acceptable The product contains a solvent that is classified as H304 Cat. 1 at a content >10%. However, Tanasote S40 is not classified as H304	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
		0.0379 % penflufen, 0.91 % DDACarbonate		Cat. 1 since the kinematic viscosity of the formulation at 40°C is 21.1 mm^2/s.	

Conclusion on the physical, chemical and technical properties of the product
Tanasote S40 is an oil miscible liquid (OL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. For OL formulations the miscibility with hydrocarbon oil should also be determined. However, Tanasote S40 is a ready-to-use wood preservative and not intended to be diluted with hydrocarbon oils. The appearance of the product is that of a dark green opaque liquid. No change in appearance, pH or loss of active substance contents were observed following accelerated and ambient temperature storage. There is no effect of low temperature on the stability of the formulation after 7 days at 0°C. Compatibility has been demonstrated with HDPE packaging during the accelerated and ambient storage stability studies. The product contains a solvent that is classified as H304 Cat. 1 at a content >10%. However, Tanasote S40 is not classified as H304 Cat. 1, since the kinematic viscosity of the formulation at 40°C is 21.1 mm^2/s.

2.2.3 Physical hazards and respective characteristics

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Comments**	**Reference**
Explosives		Tanasote S40	Non explosive: Based on the chemical structures of the test item components, the result for the explosive properties has been predicted negative. The remaining	Acceptable. Tanasote S40 is not considered to be explosive. According to the CLP regulation a screening procedure can be used to identify the presence of reactive	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			components are either known to be non-explosive or are present in such small amounts as to have an insignificant effect.	chemical groups which can react to produce very rapid increases in temperature or pressure. A mixture is not classified as explosive when there are no chemical groups associated with explosive properties present in the mixture.	
Flammable gases			Not relevant		
Flammable aerosols			Not relevant		
Oxidising gases			Not relevant		
Gases under pressure			Not relevant		
Flammable liquids	EC A9 Pensky-Martens closed cup method		Flash point: 158.5 °C A flash point study conducted indicated the flash point was in the same order as that of the main component, a mineral oil, i.e. above 140 °C.	Acceptable. Tanasote S40 and consist primarily of a mineral oil (approx. 76 % w/w). The main difference between the two formulations is that contains propiconazole (0.15 % w/w) instead of penflufen, and that a low amount of a water repellent is present in Tanasote S40. The absence of the low amount of propiconazole and presence of penflufen (0.0379 % w/w) and the water repellent are not expected to have a great affect on the flash point of the formulation. The flash point of 158.5 °C is significantly higher than the classification criterion (23 °C and 60 °C) in CLP.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
				Based on the flash point for and the similarity between the two formulations, Tanasote S40 is not considered flammable.	
Flammable solids			Not relevant		
Self-reactive substances and mixtures	Waiver	-	There are no substances present in the formulation that have reactive groups which are associated with self-reactive properties. Based on the composition, Tanasote S40 is not expected to be a self-reactive mixture.	Acceptable	-
Pyrophoric liquids	Waiver	-	Experience in manufacture och handling shows that Tanasote S40 does not ignite spontaneously upon contact with air at normal temperatures.	Acceptable	-
Pyrophoric solids			Not relevant		
Self-heating substances and mixtures	Waiver	-	Experience in manufacture and handling shows that Tanasote S40 does not react with oxygen/air to generate heat or self-heat.	Acceptable	-
Substances and mixtures which in contact with water emit flammable gases	Waiver	-	Experience in manufacture and handling shows that Tanasote S40 does not emit flammable gases when in contact with water.	Acceptable	-
Oxidising liquids	Waiver	Tanasote S40	Based on the chemical structures of the test item	Acceptable.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			components, the result for the oxidizing properties has been predicted negative. The remaining components are either known to be non-oxidizing or are present in such small amounts as to have an insignificant effect.	According to the "Guidance on the Application of the CLP Criteria" a theoretical evaluation of potential oxidising properties can be performed on a mixture to determine whether further testing is required. For organic substances/mixtures the testing procedure for oxidising properties need not be applied if the mixture do not contain oxygen, fluorine or chlorine bonded only to carbon or hydrogen. In addition, Tanasote S40 contains the inorganic substances copper hydroxide and DDACarbonate. These substances are, however, not classified as oxidizing substances. Based on the classification and the chemical structures of the components in the product, none of the components are considered oxidising, therefore Tanasote S40 is not considered to have oxidising properties.	
Oxidising solids			Not relevant		
Organic peroxides			Not relevant		
Corrosive to metals	UN Test C.1 (UN-MTC Part III, Section 37.4.1.1)	Tanasote S40	Test conditions: 55 ± 1 °C for 7 days Weight (steel): Before 16.4244 g After 16.4235 g Weight (aluminium):	Acceptable. No uniform or localised corrosion attach were observed. Tanasote S40 is not considered corrosive to metals.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Comments	Reference
			Before 5.4209 g After 5.4215 g No weight changes were observed for the steel and aluminium plates that were immersed in Tanasote S40. No pitting was observed for these plates but the aluminium plate had rust-brown spots on the surface.		
Auto-ignition temperatures of products (liquids and gases)	Compatible with Method A15	Tanasote S40	The auto-ignition temperature of the test item has been determined to be 268 ± 5 °C.	Acceptable.	
Relative self-ignition temperature for solids			Not relevant		
Dust explosion hazard			Not relevant		-

Conclusion on the physical hazards and respective characteristics of the product
Tanasote S40 is not explosive, oxidising, flammable or corrosive to metals. It has an auto-ignition temperature of 268 °C and is not considered auto-flammable when used according to the conditions for the product.

2.2.4 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 active substance approval. Analytical methods for the active substances and impurities in the technical materials have already been evaluated at EU level and are presented in the CAR of the active substances.

Analytical methods for the active substances in the biocidal product

Validated methods for detecting the active substances in the product Tanasote S40 are available. The validation data is displayed below for each analyte. The methods are satisfactorily validated in accordance with the EU guidance document SANCO/3030/99 rev. 4.

Penflufen

The penflufen content was determined by HPLC-DAD. To aliquots (0.5 g) of homogenized test item, an aliquot (15 mL) of methanol was added. Each sample was warmed to approximately 30 °C for 10 minutes. After warming the samples were shaken vigorously on a vortex shaker for 30 to 40 seconds and then allowed to cool for 20 to 30 minutes until the solution became essentially clear with an oily layer on the bottom. An aliquot (5.0 mL) of the upper layer of the solution was passed through a primed strata NH2 500 mg/3 mL solid phase extraction cartridge and the filtrate was analyzed.

HPLC conditions:	
Column	Zorbax Eclipse XDB-C18 (250 x 4.6 mm id)
Eluent	A: purified water, B: acetonitrile
Retention time	approx.. 6.5 min

DDACarbonate

The DDACarbonate content was determined by HPLC-DAD. Aliquots (0.5 g) of test item were weighed into glass vials, then diluted to 20.0 g with methanol, to each sample ethanolamine (0.2 g) was added. Each vial was sealed and warmed to approximately 35 °C for 10 minutes. After warming the samples were shaken vigorously on a vortex shaker for 30 to 40 seconds, ensuring the samples were thouroughly mixed. Each sample was allowed to cool for 20 to 30 minutes, until the solutions were essentially clear with an oily layer on the bottom. An aliquot (5.0 mL) of the upper layer of the solution was passed through a NH2 Hypersep 500 mg/6 mL solid phase extraction cartridge. The filtrate was allowed to settle and then analyzed.

HPLC conditions:	
Column	Spherisorb 5 µm SCX (150 x 4.6 mm id)
Eluent	0.06% ammonium formate, 0.05% ethanolamine and 0.04% benzethonium chloride in methanol
Retention time	approx. 8.8 to 9.2 min

Copper hydroxide

The copper hydroxide content was determined by ICP-MS. Aliquots (0.5 g) of test item were weighed into 100 mL volumetric flasks, 10 mL concentrated nitric acid was added and the samples were ultrasonicated for 2 minutes. Thereafter the samples were diluted to volume with slow addition of purified water. Each sample was filtered through a 0.45 µm syringe filter, then diluted by a factor of 5 with purified water and analyzed.

ICP-MS conditions:

System	Agilent Technologeis 7500cx
Acquisition mode	Spectrum (Multi tune)
Tune mode	No gas
Element / mass:	Cu: 63, 65 (confirmation mass)
Repetitions	3

Validation of the analytical methods	
Penflufen	Reference: Analytical method: HPLC-DAD Validation range: 2 – 30 mg/L (16 – 234 % of nominal penflufen content) Linearity: 5 calibration standards (in duplicate) were used for the determination of the linearity. r^2 = 1.000, slope 3.83 x 10^5, intercept -1.59 x 10^3 Specificity: Confirmed by external standard and diode array detection. No significant interference detected in the blank formulation at the retention time of penflufen. Precision: Precision was performed with 6 samples. RSD = 2.24 % (RSD_R = 4.43 % with C = 0.00357 % w/w) Accuracy: Accuracy was determined by analysis of 6 (3 x 2) independent determinations in which known amounts of the reference substance were added to a blank formulation. The accuracy results are expressed as the recovery rate. (Fortification range: 5 – 15 mg/L) Recovery range = 92.9 – 103 % (mean recovery 98.4%) RSD = 3.59%
DDACarbonate	Reference: Analytical method: HPLC-DAD Validation range: 62.5 – 313 mg/L (33- 165 % of nominal DDACarbonate content) Linearity: 6 calibration standards were used for the determination of the linearity. r^2 = 0.9999, slope 1.46 x 10^4, intercept -2.40 x 10^4 Specificity: Confirmed by external standard and diode array detection. No significant interference detected in the blank formulation at the retention time of DAD. Precision: Precision was performed with 5 samples. One result was excluded from the calculation of the mean, standard deviation and relative standard deviation as it is classified as an outlier according to the modified Thompson Tau outlier test. RSD = 1.36 % (RSD_R = 2.79 % with C = 0.761 % w/w)

	Accuracy: Accuracy was determined by analysis of 6 independent determinations in which known amounts of the reference substance were added to a blank formulation. The accuracy results are expressed as the recovery rate. (Fortification range: 127 - 255 mg/L) One result was excluded from the calculation as it was determined as an outlier according to the modified Thompson Tau outlier test. Recovery range = 98.7 – 103 % (mean recovery 99.8%) RSD = 1.68 %
Copper hydroxide	Reference: Analytical method: ICP-MS Validation range: 20 – 100 mg/L (66 – 330 % of nominal copper content) Linearity: 6 calibration standards were used for the determination of the linearity. r^2 = 0.9984, slope 5.47, intercept 9.26 Specificity: ICP-MS is a highly specific technique. The instrument was set to detect masses 63 and 65 so that the analyses were specific for copper. The good correlation between the responses for the two copper isotopes confirmed the specificity. Precision: Precision was performed with 5 samples. One result was excluded from the calculation of the mean, standard deviation and relative standard deviation as the result was considered to be an outlier according to the Grubbs outlier test. RSD = 2.20 % (RSD_R = 2.27 % with C = 2.98 % w/w) Accuracy: Accuracy was determined by analysis of 6 (3 x 2) independent determinations in which known amounts of the reference substance were added to a blank formulation. The accuracy results are expressed as the recovery rate. (Fortification range: 5 – 15 mg/L) Recovery range = 98.1 – 102 % (mean recovery 99.4%) RSD = 1.41%

Relevant impurities associated with the active substances in the product

During the evaluation of the active substances copper hydroxide and DDACarbonate, relevant impurities were identified.

Relevant impurities associated with the active substances in the product		
	Maximum amount in active substance	Maximum amount in Tanasote S40
Copper hydroxide - arsenic - cadmium - lead	 < 0.0004% < 0.0005% < 0.005%	 < 0.185 ppm < 0.231 ppm < 2.31 ppm
DDACarbonate (TK) - methanol	 < 3%	 < 0.045%

The impurities will not increase on storage, therefore, analysis of these impurities in the product post-storage is not necessary. However, validated methods are required for product authorisation. The applicant performed preliminary tests for the determination of arsenic,

cadmium and lead via ICP-OES and methanol via GC/FID. The analytical methods are described below.

As, Cd, Pb	Reference: Analytical method: ICP-OES Instrument parameters: Agilent ICP-OES 720 Plasma: Argon, 16.5 L/min Ancillary gas: Argon, 1.5 L/min Power: 1.10 kW Nebulizer pressure: 230 kPa Plasma View: Axial Repetition time: 20 sec Stabilisation time: 15 sec Wash time: 30 sec Pump speed: 15 cycles per min Wavelength: As 228.812 nm, Cd 214.439 nm, Pb 220.353 nm Calibration solution preparation: Solutions of the concentrations 0, 1, 2, 5, 7, 10, 15, 20 µg/L were prepared by dilution of a 1 mg/L Pb, As and Cd stock solution with water. To all calibration solutions, 1 mL HNO_3 (65%) was added and the mixtures were filled up to 100 mL with water. Accuracy sample preparation: A mixture of 0.5 g test item, 10 mL HNO_3 (conc.) and 100 / 200 µL of stock solution (1 mg/L Pb/As/Cd) was digested in the microwave (800 watts, ramp time 59 min, hold time 30 min, 185 °C). After digestion, the mixture was quantitatively transferred into measuring flask and the flask was filled up to 50 mL with water.
Methanol	Reference: Analytical method: GC-FID Instrument parameters: HP GC 6890N Column: Rxi-624Sil ms, 30 m * 0.32 mm * 1.8 µm Temperature: 40 °C/5 min. isothermal, 50 °C/min up to 250°C Carrier gas: H2 Injector: 250 °C, split Split ratio 5 Detector: FID, 280 °C Calibration solution preparation: Solutions of the concentrations 10, 20, 50, 100 mg/L were prepared by dilution of a 1000 mg/L stock solution with chloroform. The stock solution 1000 mg/L was prepared by dissolution of 20 mL methanol in 20 mL chloroform. Accuracy sample preparation: 0.5 g test item and 0.2 mL of 1000 mg/L methanol stock solution were filled up to 10 mL with chloroform. The solution was filtered via 0.45 µm and 0.2 µm PTFE filters before analysis.

Results from the preliminary tests are summarized in the following table:

Parameter	**As**	**Cd**	**Pb**	**MeOH**
Calibration range	5-20 µg/L (n=5)*	1-20 µg/L (n=7)*	1-20 µg/L (n=7)*	10-100 mg/L (n=4)
Slope	3.50019	15.0982	2.41068	4.06255
Intercept y-axis	15.8477	0.67441	13.8172	-5.03980
Correlation coefficient (r)	0.99502	0.99978	0.99908	0.99990
Recovery rate of QC sample**	> 125 %	102 – 114 %	< 75 %	-
Recovery rate of accuracy sample***	> 130 %	101.3 %	> 130 %	91.9 %
LOQ	≥ 1 ppm	≥ 0.2 ppm	≥ 1 ppm	≥ 0.04 %

*Measured in triplicate.
** QC samples (2 and 5 µg/L Pb/As/Cd) were measured in duplicate.
*** Accuracy samples for Pb/As/Cd (2 and 4 µg/L) were prepared by standard addition and measured in duplicate. Accuracy samples (n=3) for MeOH (20 mg/L) were prepared by standard addition.

The preliminary test of the analytical methods showed that the methods were not adequate for the quantification of the relevant impurities at low concentrations in Tanasote S40. No LOQ could be set since accuracy and precision data were insufficient. Based on the available data an estimate of the LOQ values was made. These estimated LOQ values were either higher or very close to the maximum concentration of all impurities in the test item.

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

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. Methods for detection in food/feed of plant and animal origin are not applicable due to lack of exposure via the intended uses. Therefore no further consideration is required.

Methods of analysis for the determination of DDACarbonate residues in soil and water have previously been evaluated at EU level and accepted for active substance approval. However, it should be noted that a confirmatory method in soil is required, this should be addressed by the notifier of the active substance and will therefore not be addressed by this product authorisation. 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 available due to lack of exposure via the intended uses. Therefore, these methods were not submitted with this application.

Methods of analysis for the determination of copper residues in air, soil and water have previously been evaluated at EU level and accepted for active substance approval. However, it should be noted that validation data in soil and water are required, this should be addressed by the notifier of the active substance and will therefore not be addressed by this product authorisation. Methods for detection in food/feed of plant and animal origin are not available due to lack of exposure via the intended uses. Therefore, these methods were not submitted with this application.

Conclusion on the methods for detection and identification of the product
Validated analytical methods for the determination of copper hydroxide, DDACarbonate and penflufen in Tanasote S40 were provided and was considered acceptable. Validated methods for the determination of the relevant impurities in Tanasote S40 are required for product authorisation. The applicant performed preliminary tests for the quantification of arsenic, cadmium and lead via ICP-OES and methanol via GC/FID. The methods were not adequate for the quantification of the relevant impurities at low concentrations in Tanasote S40. Due to the low concentrations of the relevant impurities and the difficulties related to the matrix (Tanasote S40), the applicant could not submit validated analytical methods for the quantification of the relevant impurities in Tanasote S40. This is considered acceptable. Analytical methods for the determination of residues for copper hydroxide, DDACarbonate and penflufen have previously been evaluated and accepted at EU level. Therefore no further consideration is required for product authorization.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Tanasote S40 is a wood preservative (product type 8) intended for preventive treatments. It is a penetrative wood preservative for timber in use classes (UC) 3 and 4 (as defined in EN 335). Tanasote S40 is a ready-to-use product and timber is impregnated under controlled conditions in vacuum/pressure treating plants.

Tanasote S40 is applied to timber by industrial pressure processes, usually by an empty-cell process (Rueping process). For treatment of oak and spruce a full-cell process is used where excess of the wood preservative is removed by an extended vacuum step at the end of the treatment process. Tanasote S40 is an oil soluble (OL) formulation and is a relatively viscous liquid. To increase the penetration of the oil based formulation into the timber a temperature of 50-70°C is applied initially in the treatment process to reduce the product's viscosity and improve penetration of the wood. The treatment is carefully controlled to obtain the recommended retention and limit the overall uptake of the product. In most cases this is achieved by using consecutive Rueping cycles with a modified vacuum pressure cycle. In the modified Rueping cycle duration times are much longer in comparison to a normal full cell process.

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

Tanasote S40 is used to control:

- Wood-destroying brown rotting fungi.
- Wood-destroying white rotting fungi.
- Wood-destroying soft rotting fungi.
- Wood-destroying termites.
- Wood destroying beetles.

Tanasote S40 is intended to be used for preventive treatments for wood in use classes 3 – 4. The product is applied to both softwood and hardwood for UC 3 and only for softwood in UC 4.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Tanasote S40 contains 4.615 % w/w copper hydroxide (equivalent to 3.0 % w/w copper), 0.0379 % w/w penflufen, and 0.75 % w/w DDACarbonate.

The product is applied by vacuum/pressure impregnation at the following retentions (in the analytical zone as described in EN 351-1:2007):

- UC3: (excluding termites): 48.7 kg/m^3 – 100 kg/m^3
- UC3 (termites): 65.4 kg/m^3 – 100 kg/m^3
- UC3 (railway sleepers, including termites): 65.4 kg/m^3 – 133 kg/m^3
- UC4 (including termites): 86.5 kg/m^3 – 133 kg/m^3

For use class 3, the product is applied to both softwood and hardwood. For use class 4, it is applied to softwood only.

The product application rates are given as ranges. The use of treated wood in particularly challenging conditions (e.g. higher risk of wetting) or where extended wood service lives are needed it may require an application rate (product retention rate) above that given in the efficacy tests, but within the range given above.

2.2.5.4 Mode of action, including time delay

Tanasote S40 has both fungicidal and insecticidal effect.

Copper Hydroxide
As the active substance is the Cu^{2+} ion, copper hydroxide is therefore described as a precursor to the release of the cupric ion. As a consequence, most copper-containing formulations are described in terms of total copper. Copper hydroxide acts by prevention of fungal infestation. Upon contact with the fungicidal layer, the spores passively take up copper II cations which will hinder germination. Copper(II) cations also act as a feeding and cell poison in insects independent from the kind of application. The threshold concentration is about 0.1 % of elemental copper. Amongst others the influence of copper(II) cations in the organism causes unspecific denaturation of proteins and enzymes. For this reason it also acts as a feeding and cell poison in insects.

Penflufen
Penflufen is a 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.

DDACarbonate
DDACarbonate is a cationic surfactant type active substance. Since it is surface active, it has fair wetting properties and reacts strongly with cell walls of microorganisms. Due to its interaction with phospholipid-bilayer structures, it severely alters the cell wall permeability, disturbs membrane-bound ion-translocation mechanisms, and may facilitate the uptake of other biocides. Against fungi, there exists a selective activity spectrum. While DDACarbonate has some efficacy toward insects in general. However, the DDACarbonates mode of action on insects is not fully understood. It is proposed that the mode of action includes disruption of the digestive process of the insect, although no definitive evidence has been identified. In the final formulations, for complete efficacy toward insects, an additional biocide is always included and efficacy testing is performed on the final formulation.

2.2.5.5 Efficacy data

Efficacy testing has been undertaken in accordance with European standard EN 599-1. The test substance in the efficacy tests is an earlier development version of Tanasote S40. The concentration of active substances and co-formulants is identical to that in Tanasote S40 with the exception of the colourant. Tanasote S40 contains no colourant. This change is permitted in accordance to EN 599-1.The composition is found in the Confidential annex to this PAR. The tests undertaken are summarised in the following table:

Experimental data on the efficacy of the biocidal product against target organism(s)							
Field of use envisaged	**Test substance**	**Target organism**	**Classification**	**Scientifical name(s)**	**Test method**	**Summary of test results**	**References**
UC3 and 4		Wood boring beetles	Coleoptera	*Hylotrupes bajulus*	EN 47 after evaporative ageing according to EN 73 Species of wood: Scots pine(*Pinus sylvestris*) (sap wood)		
UC3 and 4		Wood boring beetles	Coleoptera	*Hylotrupes bajulus*	EN 47 after leaching according to EN 84 Species of wood: Scots pine (*Pinus sylvestris*) (sap wood)		
UC3 and 4		Termites	Rhinotermitidae	*Reticulitermes santonensis*	EN 117 after evaporative ageing according to EN 73		

					Species of wood: Scots pine (*Pinus sylvestris*) (sap wood)		
UC3 and 4		Termites	Rhinotermitidae	*Reticulitermes santonensis*	EN 117 after leaching according to EN 84 Species of wood: Scots pine (*Pinus sylvestris*) (sap wood)		
UC3 and 4		Brown and white wood rotting fungi	Basidiomycetes	*Coniophora puteana* *Poria placenta* *Gloeophyllum trabeum* *Coriolus versicolor*	EN 113 after evaporative ageing according to EN 73 Species of wood: Scots pine (*Pinus sylvestris*) (sapwood) and beech (*Fagus sylvatica*)		
UC3 and 4		Brown and white wood rotting fungi	Basidiomycetes	*Coniophora puteana* *Poria placenta*	EN 113 after leaching		

				Gloeophyllum trabeum *Coriolus versicolor*	according to EN 84 Species of wood: Scots pine (*Pinus sylvestris*) (sapwood) and beech (*Fagus sylvatica*)		
UC4		Soft rot fungi	Ascomycetes, Deuteromycetes	-	ENV 807 Exposure in unsterile soil in conditions promoting soft rot decay Species of wood: Scots pine (*Pinus sylvestris*) (sapwood)		

2.2.5.6 Discussion

The refMS is concerned about the results in the submitted EN 47 studies after aging (EN 73 and EN 84 resp.), where already at the lowest tested retention of the product a 100% mortality of larvae was shown and no gnawing/impact on the wood samples after the first 4 weeks into the tests could be observed. Since no larvae survived, the trials were terminated after these 4 weeks. However, according to the standard protocol for EN 47 the test period should be 8 to 12 weeks (depending on the development stage of the larvae at the beginning of the test) and it is stated that:

"The toxic values of a preservative are expressed as the following two concentrations:

- *the lowest concentration at which no adults emerge and at which, at the end of the test, all larvae are dead;*
- *the next, lower, concentration in the series at which some adults emerge or at which, at the end of the test, live larvae are found."*

and in the BPR regulation 528/2012 Annex VI (p.118, paragraph 77) it states:

"The evaluating body shall evaluate dose-responses generated in appropriate trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect."

The refMS pointed out to the applicant that the lack of dose-respones data below the lowest retention tested, where 100% efficacy was observed, make it impossible to assess the minimum dose necessary to achieve the desired effect. The applicant replied with a written expert judgement from the laboratory responsible for the efficacy studies, which stated that it is common practice in the industry to use the untreated control as the lowest toxicity value to derive the true biological reference value (b.r.v., i.e. the lowest retention of the product where no attack on the wood samples can be detected). Furthermore, the applicant has recommended higher retention rates than the rates that were used in the efficacy tests where efficacy was demonstrated.

The BPR guidance document (section 5.5.8.2.2.6) states:

"The applicant must have the right to apply for lower or higher retentions than just the CV up to the retention rate which is limited by the human health and environmental risk assessments." (CV is the critical value and is derived from the b.r.v.. CV is the retention rate that will be used in the final treated timber).

Setting fixed retention is difficult since various factors could affect which retention rate needs to be applied, for example, differences in wood to be treated and differences in climate where the treated wood will be used. Nevertheless, the refMS is concerned that an unmotivated high retention could lead to a potential overuse of anthropogenic chemicals and this is in contradiction to the environmental quality objective of a non-toxic environment. This quality objective is also expressed in regulation 528/2012 Article 17 (p.17, paragraph 5) and Annex VI (p.118, paragraph 77) where it is stated that the recommended dose should be the minimum necessary to achieve the desired effect. Therefore, the refMS believes that this should be taken into account when designing efficacy test. And the refMS also thinks that this issue should be addressed when the guidance document is revised in the future.

Conclusion on the efficacy of the product
The efficacy of Tanasote S40 has been demonstrated by testing according to the requirements in EN 599-1 for a wood preservative to be used on softwood and hardwood in Use Class 3 and on softwood in Use Class 4. Acceptable efficacy has been shown for Tanasote S40 at the stated application rates. The minimum retentions (the critical values according to EN 599-1) derived for Tanasote S40 from the efficacy data are given below. These are the minimum application rates for Tanasote S40: • UC3: 48.7 kg/m^3 As required in EN 599-1, this is based on EN 47 after evaporative ageing according to EN 73 and leaching according to EN 84 and EN 113 after evaporative ageing according to EN 73 and leaching according to EN 84. • UC3 (against termites): 65.4 kg/m^3 As required in EN 599-1, this is based on EN 47 after evaporative ageing according to EN 73 and leaching according to EN 84, EN 117 after evaporative ageing according to EN 73 and leaching according to EN 84 and EN 113 after evaporative ageing according to EN 73 and leaching according to EN 84. • UC4 (including termites): 86.5 kg/m^3 As required in EN 599-1, this is based on EN 47 after evaporative ageing according to EN 73 and leaching according to EN 84, EN 117 after evaporative ageing according to EN 73 and leaching according to EN 84, EN 113 after evaporative ageing according to EN 73 and leaching according to EN 84 and ENV 807.

2.2.5.7 Occurrence of resistance and resistance management

Copper hydroxide

The assessment report for copper hydroxide states that according to the data submitted no development of resistance from the target fungi has been reported. Knowing that there are strains of some species of wood destroying fungi that exhibit tolerance to copper, additional biocides are used in the formulation in order to control copper-tolerant strains of fungi. According to the data submitted, no formation of resistance is expected regarding target insects. There is no evidence of insects being naturally tolerant or being able to develop resistance to copper at the level of copper used for biocidal purposes in wood preservation.

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.

DDAcarbonate

The assessment report for DDAcarbonate states that there are no known resistance against target organisms.

Resistance is normally associated with continued application at the same site where subsequent applications are shown to be less efficacious. Tanasote S40 is not intended for multiple applications (only one application per lifetime of timber structure) and the

formulation contains a combination of active substances to give the required spectrum of efficacy. This fact that Tanasote S40 will only be used for one application and that it contains multiple active substances is expected to prevent the occurence of resistance, i.e the combined action of three active substances is highly unlikely to lead to resistance against Tanasote S40 and a resistance management strategy is not required on the product label.

2.2.5.8 Known limitations

None

2.2.5.9 Evaluation of the label claims

The label claim supported by the data is:
'For industrial use only as a wood preservative for use in Use Class 3 to 4.

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

No Claims of compatibility will be made on the label.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on human health

Skin corrosion and irritation

No skin irritation study has been conducted on Tanasote S40. The applicant has proposed a read across to dermal irritation and corrosion studies conducted with a similar formulation,. The applicant proposed a read across from to Tanasote S40 based on the following justification: Tanasote S40 is essentially a dilution of, reducing components by a factor of 3/3.5, approximately 14 %. Both formulations contain three active ingredients, with propiconazole 0.18 % w/w (Skin Sens 1) in the reference formulation replaced by penflufen 0.038 % w/w (not classified for irritancy or corrosivity) in the Tanasote S40 formulation. Copper hydroxide (no skin classification but Eye Dam 1) and DDACarbonate (Skin Corr 1B) are reduced by approximately 14 %, from 5.38 % w/w to 4.62 % w/w and 0.88 % w/w to 0.75 % w/w respectively in Tanasote S40 when compared to the reference formulation. Only one co-formulant present in both formulations has a skin classification, C8-C10 fatty acid (Skin Corr 1B) which is found in the reference formula at 11.55 % w/w. This is reduced in Tanasote S40 to 9.9 % w/w. The changes in formulation are considered minor. All substances classified as irritant or corrosive were reduced in concentration for the Tanasote S40 formulation when compared to .

Based on the similarity of the formulations (see additional justification, section 1.4, in the Confidential Annex of the PAR) the SE CA agrees that the studies conducted on could be used for the assessment of skin corrosion and irritation.

Using the calculation method a skin corrosivity classification would be indicated, however the skin corrosion and skin irritation studies imply that the product is not corrosive but irritant to skin. Hence, the formulation should be classified as irritating to skin.

Summary table of in vitro studies on skin irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 439 (2015), GLP, Reliability 1	, 10 µL (26.3 µL/cm^2), 15 mins exposure	Determination of skin irritation potential of the test item using the EPISKIN™ reconstructed human epidermis model	The test item was classified as irritant. The following classification criteria apply: EU CLP and UN GHS Hazard statement H315 "Causes Skin Irritation" Category 2	No deviations deemed to have affected the integrity or validity of the study	

Summary table of in vitro studies on skin corrosion					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 431 (2015), GLP, Reliability 1	, 50 µl, 3 min + 60 min exposure	*In vitro* EPIDERM skin corrosion test	The test item was considered to be non-corrosive to the skin	No Deviation from the study plan	

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Irritant to Skin
Justification for the value/conclusion	Not corrosive in the *in vitro* guideline study OECD 431 on the related formulation. Further skin irritation assessment using the *in vitro* guideline study OECD 439 on the related indicates that the Tanasote S40 will be irritant to skin.
Classification of the product according to CLP	Skin irritation Category 2, H315 Causes skin irritation

Eye irritation

No eye irritation study has been conducted on Tanasote S40. It is proposed to predict the eye irritation potential of the formulation from information provided on the individual components. Regarding individual components, Cu (II) hydroxide (Eye Dam. 1, H318) is present in the formulation at a concentration of 4.62 %, DDACarbonate (Skin Corr 1 B, H314 and Eye Dam 1, H318) and the substance of concern C8-C10 Fatty acid (Skin Corr 1 B, H314) are present in the formulation at 0.75 % and 9.9 % respectively. According to Table 3.3.3 Regulation (EC) No 1272/2008 (CLP), a sum of ingredients classified as Cat 1 for skin corrosion and eye damage ≥ 3% triggers a classification of the mixture as serious eye damage, Cat 1, H318. On the basis of the CLP calculation method Tanasote S40 meets the criteria for classification with H318, Causes serious eye damage - Cat 1.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Eye Damage Category 1
Justification for the value/conclusion	Classification by calculation: the sum of ingredients classified Cat 1 for skin corrosion and eye damage is greater than 3%.
Classification of the product according to CLP	Eye Damage Category 1, H318 Causes serious eye damage

Respiratory tract irritation

No component in Tanasote S40 is classified as a specific organ toxicant (STOT) in category 1 or 2 as regards to respiratory tract irritation. Therefore, no classification for respiratory tract irritation is warranted.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the conclusion	None of the components in the product are classified for respiratory irritation as STOT. Therefore, the product does not meet the criteria for classification for respiratory irritation according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Skin sensitisation

No skin sensitisation study for Tanasote S40 has been conducted. It is proposed to predict the skin sensitisation potential of the formulation from information provided on the individual components. Regarding the skin sensitisation potential of the components, none of the substances present are classified for skin sensitisation.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin
Justification for the value/conclusion	None of the components in the product are classified for skin sensitisation. Therefore, the product does not meet the criteria for classification for skin sensitisation according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Respiratory sensitisation (ADS)

No respiratory sensitisation study for Tanasote S40 has been conducted. It is proposed to predict the respiratory sensitisation potential of the formulation from information provided on the individual components. Regarding the respiratory sensitisation potential of the components, none of the substances present are classified for respiratory sensitisation.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory system
Justification for the value/conclusion	None of the components in the product are classified for respiratory sensitisation. Therefore, the product does not meet the criteria for classification for respiratory sensitisation according to Regulation (EC) No 1272/2008.

Classification of the product according to CLP	Not classified

Acute toxicity

For calculations of Acute Toxicity Estimates (ATEs), see Annex 3.7.1.

Acute toxicity by oral route

No acute oral toxicity study has been conducted on Tanasote S40. It is proposed to predict the acute oral toxicity of the formulation from information provided on the individual components. On the basis of the components used in the formulation, Tanasote S40 does not meet the criteria for classification for acute oral toxicity.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Calculated ATE 10 000 mg/kg bw/day
Justification for the selected value	Classification by the calculation method: Acute Toxicity Estimate is > 2000. Therefore, the product does not meet the criteria for classification for acute oral toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Acute toxicity by inhalation

No acute inhalation toxicity study has been conducted on Tanasote S40. It is proposed to predict the acute inhalation toxicity of the formulation from information provided on the individual components. On the basis of the components used in this formulation Tanasote S40 does not meet the criteria for classification for acute inhalation toxicity.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Calculated ATE 10.8 mg/l
Justification for the selected value	Classification by the calculation method: Acute Toxicity Estimate is > 5. Therefore, the product does not meet the criteria for classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Acute toxicity by dermal route

No acute dermal toxicity study has been conducted on Tanasote S40. Instead it is proposed to predict the acute dermal toxicity of the formulation from information provided on the individual components. Tanasote S40 contains no substance classified as acute toxic by dermal route above the generic cut off values. Therefore, Tanasote S40 does not meet the criteria for classification for acute dermal toxicity.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not applicable
Justification for the selected value	Classification by the calculation method: No substances in the product are classified as acute tox by the dermal route.
Classification of the product according to CLP	Not classified

Information on dermal absorption

Penflufen
No dermal absorption study was conducted for the substance Penflufen in Tanasote S40. Instead it was proposed by the applicant that the default value of 75% (from the EFSA guidance (2012) for products containing ≤5% active substance) should be applied to the concentrate and in use diluted formulation.

SE CA accepted the value of 75% dermal absorption as the application was received before the new EFSA guidance (2017) had to be used. In addition, this value is more worst case than the default values from EFSA 2017 and would not change the outcome of the risk assessment.

DDACarbonate
No dermal absorption study was conducted for the substance DDACarbonate in Tanasote S40. Instead it wass proposed by the applicant that the default value of 75% (from the EFSA guidance (2012) for products containing ≤5% active substance) should be applied to the concentrate and in use diluted formulation. However, as concluded in the CAR, only a local risk assessment is appropriate for DDACarbonate and therefore the dermal absorption value will not be used in the risk characterisation.

Copper hydroxide
A dermal penetration study was conducted for the substance Copper hydroxide to show the potential dermal absorption level of copper from Tanasote S40. The study design was based on the following guidelines:

- OECD Guideline for the Testing of Chemicals, Guideline 428. Skin Absorption: in vitro Method (April 2004).
- OECD Environmental Health and Safety Publications, Series on Testing and Assessment no. 28. Guidance document for the conduct of skin absorption studies (March 2004).

- European Commission Guidance Document on Dermal Absorption – Sanco/222/2000/Rev. 7 (19 March 2004).
- Guidance on Dermal Absorption (EFSA Journal, 2017, 15(6): 4873).

Summary table of in vitro studies on dermal absorption					
Method, Guideline, GLP status, Reliability	**Number of skin samples tested per dose, Other relevant information about the study**	**Test substance, Doses**	**Absorption data for each compartment and final absorption value**	**Remarks** *(e.g. major deviations)*	**Reference**

OECD Test 428, OECD Guidance 28, EFSA Guidance on DA 2017; 15(6):4873 GLP, Reliability 1	No. of samples 8 No. of donors 4 Split-thickness skin 200-440 µm Absorption of copper from the test preparations was assessed by collecting fractions of the receptor fluid at the following time intervals 0-1, 1-2, 2-4, 4-8, 8-16 and 16-24 h post dose. The exposure period was terminated at 8 h post dose when the skin sample was rinsed with a 2% (v/v) commercial soap solution. At 24 hours post dose, i.e. after 16 hours monitoring period, each diffusion cell was dismantled and the skin removed. The stratum corneum was tape stripped with a maximum of 20 successive tape strips (CuDerm). Tape strips were collected (pooled) as follows: [1], [2], [3-5], [6-10],	Tanasote S40 4.615 % (3% copper) copper hydroxide, 0.0379 % penflufen, 0.91 % DDACarbonateApplied dose 26.8 g/L App. rate 10 µL/cm^2	Analysis of the receptor fluid showed that the absorption after half the duration was < 75%. According to the EFSA Guidance on Dermal Absorption 2017, if less than 75% of the absorption occurs within half the duration the following calculation should be used: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding tape strips 1 and 2). To address variability between replicates, dermal absorption should be calculated as follows: Absorption (mean value) + ks k=multiplication factor (EFSA 2017 table 1) s=sample standard deviation **<u>Results:</u>** Absorption: 0.89% $\pm$ 1,00 Correction of the result to account for variability: 0.89 + (0.92*1,00) = 1.8% Mass Balance: 109 $\pm$ 4 %	For one replicate (Cell 4), the applied formulation was no longer visible on the skin surface at washing (8 h after dose application). Furthermore, the overall mass balance for this replicate turned out to be too low. Therefore, Cell 4 was excluded from the calculations. Two deviations from the original protocol. Both on analytical criteria. This is not considered to have impact on the outcome of the sample analysis.	

	[11-15], [16-20]. Tape strips 1 and 2 were excluded when calculating the absorption value.				

In conclusion the result from the study shows a dermal absorption of copper from Tanasote S40 of 0.89%. This value was corrected to account for variability (based on the EFSA Guidance). The calculated dermal absorption value for copper from the test preparation would then be 0.89 + (0.92*1,00) = 1.8% (rounded to two significant numbers as per EFSA Guidance).

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Copper	Penflufen	DDACarbonate
Value(s)*	1.8%	75%	75%
Justification for the selected value(s)	Dermal absorption study on Tanasote S40	Default (EFSA 2012)	Default (EFSA 2012) Not relevant due to only local effects

Additional toxicological information relating to active substance(s)

Penflufen is classified as Carc 2 (15th ATP; Regulation 2020/1182). However, as the concentration of penflufen in the product (0.0379 %) is below the concentration limit for classification in a product (>1.0 %), the harmonized classification of penflufen as Carc 2 does not affect the classification of the product.

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

See Confidential Annex of the PAR, section 1.5, for details regarding substances of concern.

Available toxicological data relating to a mixture

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

No information

2.2.6.2 Exposure assessment

Tanasote S40 is a oil soluble (OL) formulation containing 3 % w/w copper (present as 4.62 % w/w Copper hydroxide (3% w/w copper)), 0.0379 % w/w Penflufen, and 0.75% w/w DDACarbonate. The product is for use as a penetrative wood preservative for timber in Use Classes (UC) 3 and 4 and is applied in vaccum/pressure plants. The function and field of use of the product is described in detail in section 2.2.5.1.

For maximum retentions in wood of Tanasote S40, see 2.1.4.1.

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

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Industrial treatment of timber	Primary exposure Application of Tanasote S40 to sawn timber using the industrial solvent-based vacuum/pressure impregnation process	Industrial user
2.	Sanding/cutting treated timber	Secondary exposure – chronic phase Adult (professional) cutting/sanding treated timber	Professional
3.	Sanding/cutting treated timber	Secondary exposure – acute phase Adult (non-professional) cutting/sanding treated timber	Non-professional
4.	Infant chewing wood offcut	Secondary exposure – acute phase Infant chewing wood offcut	General public
5	Infant playing on playground	Secondary exposure – chronic phase Infant dermal and oral (hand to mouth)	General public

According to the applicant, Tanasote S40 treated timber is not designed for use inside buildings or generally in construction of buildings nor is it intended for use in playground structures. For consistency with the general approach for PT8, an assessment for exposure via playground equipment is included.

Industrial exposure

Scenario 1

Description of Scenario 1
Primary exposure – Industrial treatment of timber (using the solvent-based vacuum pressure impregnation process data) Primary exposure of an industrial user to copper, penflufen and DDACarbonate during the application of Tanasote S40 by industrial vacuum pressure impregnation has been assessed using the Handling Model 1 (HEADhoc recommendation 6, v4; ECHA's Biocides Human Health Exposure Methodology; BHEEM, 10.4.1, p 300, 1st ed, 2015). This model is derived from data relating to industrial timber treatment plants using "standard" vacuum pressure processes applying water-based or solvent-based liquid formulations. The difference in the solution uptakes is reflected in the exposure values derived for the models. This makes sense as the timber from double vacuum has lower uptakes and hence much drier timber on removal from the vessel and hence lower exposure. It is apparent that potential exposure of treatment plant operators is related to the resulting state of the treated timber, not necessarily the product used. This is confirmed by BHEEM (p 302) where it states "exposure appears to be a function of wetness". As explained in section 2.2.5.1, the product will be used with modified treatment cycles (empty cell) which apply product to the timber to achieve penetration but then kick back significant quantities. The uptakes are significantly less than with water-based products and due to the extended final vacuum at the end of the treatment process, where excess of the wood preservative is removed, the resultant treated timber is essentially touch dry and does not drip on removal from the vessel. There is no specific model assigned for oil based products. Given that the resultant treated timber is more in line with that from a solvent-based formulation, the use of the solvent-based exposure data will be used. The applicant points out that the database for the models was derived from occupational studies in the UK 20 years ago. Whilst the basic principle of the treatment process remain, site practices have improved and there is minimal manual operation. It is highly likely that exposure values are lower today than when the studies were conducted. The calculations using the solvent-based model are presented. The treatment includes an extended final vacuum to deliver dry timber. The standard default of 3 cycles per day for vacuum pressure treatment is used (HEADhoc recommendation 6, v4). Indicative (75th percentile) exposure values derived from Handling Model 1 are used in this assessment. There is no mixing and loading as the product is ready to use and automatic dosing is used. The inhalation exposure time is 10 minutes per cycle (according to HEADhoc recommendation 6).

	Parameters	**Value**
Tier 1	In-use concentration of copper	3%
	In-use concentration of penflufen	0.0379%

	In-use concentration of DDACarbonate	0.75%
	Hand exposure (under gloves)[1]	260 mg in-use soln/cycle
	Dermal absorption of copper	1.8%
	Dermal absorption of penflufen	75%
	Dermal absorption of DDACarbonate	n.a.
	Potential body exposure[1]	158 mg in-use soln/cycle
	Air concentration in breathing zone[1]	0.6 mg in-use soln/m^3
	Inhalation rate[2]	1.25 m^3/h
	Inhalation duration	10 min/cycle
	Treatment cycle duration	7-12 hours
	Number of treatment cycles/day	3
	Operator body weight[3]	60 kg
Notes	[1]HEADhoc recommendation 6 "Methods and models – version 4"	
	[2]HEADhoc recommendation 14 "Default human factor values for use in exposure assessment for biocidal products"	

Calculations for Scenario 1

See Annex 3.2 for calculations.

Summary table: estimated exposure from industrial use					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1 Copper	I gloves	0.00019	0.011	Assumed to be negligible	0.0011
Scenario 1 Penflufen	I gloves	2.37E-06	0.0059	Assumed to be negligible	0.0059
Scenario 1 DDACb	See local effect assessment below				

Further information and considerations on scenario 1

Primary exposure (local effects) assessment for DDACarbonate
The critical toxicological effects for DDACarbonate are local effects (dermal and oral) and, in line with the approach taken in the CAR and guidance, it is not considered appropriate to derive a toxicological endpoint for systemic exposure.

Tanasote S40 treatment solution is classified as irritating to the skin (Skin Irrit 2) and causes serious eye damage (Eye Dam 1). Therefore, there is potential for local skin and eye effects and a local risk assessment is required. The Guidance on BPR (Vol III parts B+C; Section 4.3.2) indicates that risk characterisation for local effects focuses on the product, rather than the active substances only. In addition, the guidance states that risk characterisation for local effects is not required when the active substance and/or co-formulants in a product are classified for local effects but are present at concentrations that do not trigger classification of the product according to the CLP criteria.

However, a semi-quantitative local risk assessment for DDACarbonate is also included for completeness. This is in line with the approach taken in the PT8 CAR for DDACarbonate (UK; 2012). A dermal AEC (short-, medium- and longterm) was set at 0.02% (or 1.6 µg/cm^2/day) based on observation of very slight erythema at a concentration of 0.1% (or 10 µg/ cm^2/day) in a repeated dose dermal study in rat and applying an AF of 6.4. In accordance with the AR (see Table 1.2 on page 22), assessments were made by comparing the in-use concentration of DDACarbonate to the dermal AEC expressed as a concentration (%). (In the CAR, the AEC in terms of µg/cm^2/day was only used for secondary exposure scenarios).

Concentration DDACarbonate (%)	**Dermal AEC (%)**	**Exposure/AEC**
0.75	0.02	37.5

Any potential exposure of the product will lead to the dermal AEC being exceeded by nearly forty times.

The Guidance on BPR (Vol III parts B+C) recommends against a semi-quantitative risk assessment for local irritation, but when it is performed, it recommends that the NOAEC or LOAEC (in %) is compared directly to the in-use concentration, without assessment factors. With this approach, the potential exposure to DDACarbonate in the product exceeds the dermal AEC by about eight times.

Concentration DDACarbonate (%)	**Dermal LOAEC (%)**	**Exposure/AEC**
0.75	0.1	7.5

It should be noted that control measures such as coveralls and gloves have actually no effect on the *concentration* of DDACarbonate that may come into contact with the skin of the operator. For this reason, the qualitative risk assessment is most useful for local irritation effects, as it takes into account the severty of the effect and the organizational measures, labelling, PPE and other RMMs that limit exposure.

DDACarbonate is present in the product at 0.75% which is below the 1% threshold for classification of products as irritant when containing a corrosive substance.

The other corrosive substance in Tanasote S40 is the substance of concern C8-C10 fatty acid. It is present at a concentration above the threshold to classify the product as corrosive to skin, however the EPISKIN study implies only a classification as irritant.The guidance outlines a number of uncertainties and indicates that usually no local AEC should be derived and risk characterisation for local effects should not be quantitative but qualitative.

In view of having a product classification for local effects a qualitative risk characterisation for the product Tanasote S40 is undertaken (see section 2.2.6.3; Risk characterisation).

Combined scenarios

Not relevant.

Professional exposure

Scenario 2

Tanasote S40 is for industrial use only and there are no primary exposure scenarios for professional users. An assessment of secondary exposure for professional users of treated timber is presented below.

Description of Scenario 2
Adult (professional) cutting and sanding treated timber (chronic exposure). Professional (secondary) exposure to copper, penflufen and DDACarbonate for an adult (professional) sanding treated timber using a hand-held power tool has been estimated based on the following assumptions/parameters. • The highest application rate of 133 kg product/m^3 (UC4) gives a maximum retention rate of 4 kg Cu/m^3, 0.05 kg penflufen/m^3 and 1 kg DDACarbonate/m^3 present in the timber. • The exposure is through inhalation and dermal contact • No gloves are worn • When in dermal contact with treated timber, the user is exposed to the active substance contained in the outer 1 cm layer of the timber (TNsG 2002, Part 3, p. 50). • The Workplace Exposure Limit (WEL) for wood dust is 5 mg/m^3 (8-hour time-weighted average; TNsG User Guidance, Part 2, version 1 (2002).). Inhalation exposure can be estimated based on this air concentration and assuming a duration of exposure of 6 hours for professionals and an inhalation rate of 1.25 m^3/h (HEADhoc recommendation 14). • 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 (Manual of technical agreements; 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. 56). The transfer efficiency from rough-sawn wood to the hands is 2% (BHHEM, 1st ed, p 351).

	Parameters	**Value**
Tier 1	Concentration of copper in treated wood	4 mg/cm^3
	Concentration of penflufen in treated wood	0.05 mg/cm^3
	Concentration of DDACarbonate in treated wood	1 mg/cm^3
	Depth of treated timber containing a.s. to which the user is exposed	1 cm
	Dermal absorption of copper	1.8%
	Dermal absorption of penflufen	75%
	Dermal Absorption of DDACb	n.a.
	Surface area of hands	410 cm^2
	Proportion of hands surface area contaminated	20%
	Transfer efficiency wood to hands	2%
	WEL for wood dust	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 dust inhaled	0.0938 cm^3
	Adult body weight	60 kg
Notes	Concentrations of active substances are based on the highest application rate for UC4.	
	Systemic dose via inhalation (mg/kg bw/day) = volume of wood inhaled (cm^3) x concentration of a.s. in wood (mg/cm^3) x 100% absorption ÷ bodyweight (kg).	
	Systemic dose via the dermal route (mg/kg bw/day) = active substance residue on surface (mg/ cm^2) x area of hands (cm^2) x proportion of hands contaminated (%) x transfer efficiency of wood (%) x dermal absorption (%) ÷ bodyweight (kg).	

Calculation for Scenario 2

See Annex 3.2 for calculations.

Summary table: estimated secondary exposure from professional use					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg/bw**	**Estimated dermal uptake mg/kg/bw**	**Estimated oral uptake mg/kg/bw**	**Estimated total uptake mg/kg/bw**
Scenario 2 Copper	I	0.006253	0.00196	Assumed to be negligible	0.008
Scenario 2 Penflufen	I	0.0000782	0.001025	Assumed to be negligible	0.001
Scenario 2 DDACb	See Local effect assessment below				

Further information and considerations on scenario 2

Secondary exposure (local effects) assessment for DDACarbonate
The critical toxicological effects for DDACarbonate are local effects (dermal and oral) and, in line with the approach taken in the CAR, it is not considered appropriate to derive a toxicological endpoint for systemic exposure. Levels of skin loading to DDACarbonate are calculated below based on the dermal exposure parameters summarised above. Exposure *via* the oral route is not considered relevant in this scenario.

Exposure assessment (Tier 1)	
Amount of DDACarbonate on treated surface	1.00 mg/cm^2
Transfer efficiency	2%
Contaminated area of hand	20%
Skin loading of DDACarbonate on hands	0.004 mg/cm^2

Skin loading of DDACarbonate: 1.00 mg/cm^2 x 2% x 20% = 0.004 mg/cm^2

Tier 2:
The Tier 2 assessment for DDACarbonate assumes that only the preservative in the outer 1 mm of treated timber (rather than the outer 1 cm layer) is available for transfer to the worker's skin. This refinement was agreed as a higher tier approach in the CAR for DDACarbonate. On this basis, the level of skin loading of DDACarbonate will be 10x lower than that estimated above. Using this approach, the calculated level of skin loading on the hands is 0.0004 mg/cm^2.

Summary table – secondary professional local exposure		
Exposure scenario	**Tier**	**Estimated dermal exposure mg/cm^2**

Scenario 2 DDACb	I	0.004
Scenario 2 DDACb	II	0.0004

Combined scenarios

Not relevant.

Non-professional exposure

Tanasote S40 is designed and intended to be used where timber is expected to perform for long periods in high hazard situations such as poles and sleepers. It can also be used for industrial fencing in agriculture, highways and tree stakes etc, although the applicant clarified that it is not intended for uses where treated timber is directly supporting food crop products.

It is not anticipated that Tanasote S40 treated timber will be on sale to the general public as domestic uses would be very limited. However, it is possible that a person may get hold of fence posts and hence a secondary non professional exposure may occur and therefore an assessment has been conducted. Any fence posts available to the public are likely to be treated to 4 kg/m^3 copper (UC 4).

Scenario 3

Description of Scenario 3
Adult (non-professional) cutting and sanding treated timber (acute exposure).
Secondary exposure to copper, penflufen and DDACarbonate for an adult non-professional (general public) sanding treated timber using a hand-held power sander has been estimated based on the following assumptions/parameters.
• The highest application rate of 133 kg product/m^3 (UC4) gives a maximum retention rate of 4 kg Cu/m^3, 0.05 kg penflufen/m^3 and 1.0 kg DDACarbonate/m^3 present in the timber.
• The exposure is through inhalation and dermal contact
• No gloves are worn (reflecting normal practice for DIY wood working).
• When in dermal contact with treated timber, the user is exposed to the active substance contained in the outer 1 cm layer of the timber (TNsG 2002, Part 3, p. 50)
• The Workplace Exposure Limit (WEL) for wood dust is 5 mg/m^3 (8-hour time-weighted average; TNsG User Guidance, Part 2, version 1 (2002).). Inhalation exposure can be estimated based on this air concentration and assuming a duration of exposure of 1 hour for non-professional users (TNsG, Part 3, p. 51 and User Guidance, p. 56) and an inhalation rate of 1.25 m^3/h (HEADhoc recommendation 14).
• 5 mg/m^3 x 1.25 m^3/h x 1 h = 6.25 mg wood dust inhaled in 1 hour.

• Assuming a density of 0.4 g/cm^3 (Manual of technical agreements; MOTA 4.2.5), 6.25 mg (0.0063 g) of wood dust is equivalent to 0.0063 ÷ 0.4 = 0.0158 cm^3 of treated wood. • The surface area of both palms of hands is 410 cm^2 (HEADhoc recommendation 14) and during prolonged and repeated contact 20% of the hand is contaminated (TNsG, Part 3, p. 51 and User Guidance, p. 56). The transfer efficiency from rough-sawn wood to the hands is 2% (BHHEM, 1st ed, p 351).		
	Parameters	**Value**
Tier 1	Concentration of copper in treated wood	4 mg/cm^3
	Concentration of penflufen in treated wood	0.05 mg/cm^3
	Concentration of DDACarbonate in treated wood	1.0 mg/cm^3
	Depth of treated timber containing a.s. to which the user is exposed	1 cm
	Dermal absorption of copper	1.8%
	Dermal absorption of penflufen	75%
	Dermal Absorption of DDACb	n.a.
	Surface area of hands	410 cm^2
	Proportion of hands surface area contaminated	20%
	Transfer efficiency wood to hands	2%
	WEL for wood dust	5 mg/m^3
	Duration of inhalation exposure	1 hour
	Inhalation rate	1.25 m^3/h
	Density of wood dust	0.4 g/cm^3
	Volume of wood dust inhaled	0.0158 cm^3
	Adult body weight	60 kg
Notes	Concentrations of active substances are based on the highest application rate for UC4.	
	Systemic dose via inhalation (mg/kg bw/day) = volume of wood inhaled (cm^3/h) x concentration of a.s. in wood (mg/cm^3) x 100% absorption ÷ bodyweight (kg).	
	Systemic dose via the dermal route (mg/kg bw/day) = active substance residue on surface (mg/cm^2) x area of hands (cm^2) x proportion of hands contaminated (%) x transfer efficiency of wood (%) x dermal absorption (%) ÷ bodyweight (kg).	

Calculation for Scenario 3

See Annex 3.2 for calculations.

Scenario 3					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake mg/kg/bw**	**Estimated dermal uptake mg/kg/bw**	**Estimated oral uptake mg/kg/bw**	**Estimated total uptake mg/kg/bw**
Scenario 3 Copper	I	0.001053	0.00196	Assumed to be negligible	0.003
Scenario 3 Penflufen	I	0.0000132	0.001025	Assumed to be negligible	0.001
Scenario 3 DDACb	See Local effect assessment below				

Further information and considerations on scenario 3

Secondary exposure (local effects) assessment for DDACarbonate
The critical toxicological effects for DDACarbonate are local effects (dermal and oral) and, in line with the approach taken in the CAR, it is not considered appropriate to derive a toxicological endpoint for systemic exposure. Levels of skin loading to DDACarbonate are calculated below based on the dermal exposure parameters summarised above. Exposure *via* the oral route is not considered relevant in this scenario.

Exposure assessment (**Tier 1**)	
Amount of DDACarbonate on treated surface	1.00 mg/cm^2
Transfer efficiency	2%
Contaminated area of hand	20%
Skin loading of DDACarbonate on hands	0.004 mg/cm^2

Skin loading of DDACarbonate: 1.00 mg/cm^2 x 2% x 20% = 0.004 mg/cm^2

Tier 2:
The Tier 2 assessment for DDACarbonate assumes that only the preservative in the outer 1 mm of treated timber (rather than the outer 1 cm layer) is available for transfer to the worker's skin. This refinement was agreed as a higher tier approach in the CAR for DDACarbonate. On this basis, the level of skin loading of DDACarbonate will be 10x lower than that estimated above. Using this approach, the calculated level of skin loading on the hands is 0.0004 mg/cm^2.

Summary table – secondary non-professional local exposure		
Exposure scenario	**Tier**	**Estimated dermal exposure mg/cm^2**
Scenario 2 DDACb	I	0.004

Scenario 2 DDACb	II	0.0004

Combined scenarios

Not relevant.

Exposure of the general public

Scenario 4

Description of Scenario 4		
Infant chewing wood offcut As explained above it is not anticipated that Tanasote S40 treated wood will be used in domestic environments to a large extent. The assessment in scenario 3 is to cover a non-professional cutting and sanding treated fence posts. Given this has been included, the infant chewing a wood offcut needs to be included. The highest application rate of 133 kg product/m^3 (for timber in UC4; such as fence posts) gives a maximum retention rate of 4 kg Cu/m^3, 0.05 kg penflufen/m^3 and 1 kg DDACarbonate/m^3 present in the timber. Tier 1 – For infants (8 kg bodyweight) it is assumed that the infant is chewing a 4 cm x 4 cm x 1 cm wood offcut (volume of 16 cm^3) and in doing so extracts 10% of the active substance (TNsG Human Exposure, Part 3 Page 50). Tier 2 – The Tier 1 scenario is considered to be very conservative as it is rather unrealistic that an infant could chew a piece of timber 4 cm x 4 cm x 1 cm and it is unlikely that an infant would be able to generate enough saliva to extract wood preservative from the inside the block of treated wood. Treated wood is very hard and is highly likely to be distasteful to the infant. In the CAR for copper hydroxide it was agreed that it is more reasonable to assume that an infant can remove dislodgeble residues of copper from the surface of the wood and ingest this material and a dislodgeable copper concentration of 2 µg/cm^2 was agreed as a Tier 2 refinement for exposure to copper (agreed for copper in the WPCTF; Wood Preservative Copper Task Force, dossier). In line with this approach, a dislodgeable copper concentration of 2 µg/cm^2 is used in Tier 2.		
	Parameters	Value
Tier 1	Concentration of copper in treated wood	4 mg/cm^3
	Concentration of penflufen in treated wood	0.05 mg/cm^3
	Concentration of DDACarbonate in treated wood	1 mg/cm^3
	Volume of wood offcut	16 cm^3
	Oral absorption of copper	36%

	Oral absorption of penflufen	100%
	Oral absorption of DDACarbonate	100%
	Amount of active substance extracted	10%
	Infant body weight	8 kg
Tier 2	Dislodgeable copper	0.002 mg/cm^2
	Surface area of wood offcut	48 cm^2
Notes	Concentrations of active substances are based on the highest application rate for UC4	
	A human oral absorption of 36% for copper was agreed in the CAR	
	Systemic dose via oral route (mg/kg bw/day): wood volume (cm^3) x concentration of a.s. in wood (mg/cm^3) x 0.1 x oral absorption / bw	
	Dislodgeable copper concentration of 2 µg/cm^2 (as agreed for copper in the WPCTF dossier)	

Calculation for Scenario 4

See Annex 3.2 for calculations.

Scenario 4					
Exposure scenario	**Tier**	**Estimated inhalation uptake mg/kg/bw**	**Estimated dermal uptake mg/kg/bw**	**Estimated oral uptake mg/kg/bw**	**Estimated total uptake mg/kg/bw**
Scenario 4 Copper	I	n.a.	n.a.	0.288	0.288
	II	n.a.	n.a.	0.0043	0.004
Scenario 4 Penflufen	I	n.a.	n.a.	0.010	0.010
Scenario 4 DDACb	See Local effect assessment below				

Further information and considerations on scenario 4

Secondary exposure (local effects) assessment for DDACarbonate
The critical toxicological effects for DDACarbonate are local effects (dermal and oral) and, in line with the approach taken in the CAR, it is not considered appropriate to derive a toxicological endpoint for systemic exposure.
As an alternative approach, the CAR for DDACarbonate reports a saliva production rate for an infant of 3.6 ml/minute, an extraction factor of 0.61% based on leaching data on DDACarbonate (cumulative quantity of a.s. emitted; % at 7300 days, see page 92) and a duration of chewing of a 16 cm^3 offcut of 1 minute. Using these parameters, an estimate of exposure for an infant chewing treated timber is presented below.

Exposure assessment	
Concentration of DDACarbonate in treated wood	1 mg/cm^3
Amount of a.s. in 16 cm^3 offcut	16 mg
DDACarbonate extracted from wood (0.5% extraction)	0.08 mg
Oral absorption	100%
Amount of saliva produced by an infant (stimulated saliva flow)	3.6 ml/minute
Duration of chewing of off-cut	1 minute
Concentration of a.s. in saliva	**0.027 mg/ml**

Concentration of DDACarbonate in infant saliva when chewing wood offcut: (1 mg/cm^3 x 16 cm^3) x 0.61% / 3.6 ml = 0.027 mg/ml.

Additional potential exposure scenarios

For wood preservatives there are additional potential exposure scenarios for the general public. However, due to the intended use of Tanasote S40 these scenarios are not considered to be relevant.

Scenario 5– Infant playing and mouthing on a playground structure
According to the applicant *the use of Tanasote S40 treated wood is almost exclusively industrial. It is not expected that it will be readily available to the general public through timber merchants. Water based wood preservatives suitable for use class 3 and 4 would be expected to be used for playground equipment and timber in residential settings and are readily available. As most Tanasote S40 treated wood will be for specific commodities and contracts its use will have some control. There will be a limited number of treatments plants in the EU using Tanasote S40.*

Considering the above, this exposure scenario is not considered realistic for this product. However, for completeness a risk assessment for this scenario is included.

Description of Scenario 5
Infant playing and mouthing on a playground structure As explained above, use of Tanasote S40 to treat wood for playground structures is not anticipated. However, the assessment is included for completeness. UC4 wood with a retention rate of 133 kg/m^3 is considered for the risk assessment. This is a worst case assumption, as UC3 wood would be more typical for a playground structure. Tier 1 – For the first tier, it is assumed the applied wood preservative in the outer centimetre of wood is present at the surface (i.e., the application rate of 133 kg/m^3, equivalent to 133 mg/cm^3, corresponds to a surface level of 133 mg/cm^2). It is assumed that 20% of the surface area of the child's hands are exposed and that 2% of the residues at the surface transfer to hands. Tier 2 – The Tier 1 scenario is considered to be very conservative, both in terms of level of preservative at the surface vacuum treated wood (with extended vacuum) as well as 2% transfer per day of contact. In the CAR for copper hydroxide it was agreed that it is more reasonable to assume a dislodgeble copper concentration of 2 µg/cm^2 (agreed for

copper in the WPCTF; Wood Preservative Copper Task Force). In line with this approach, a dislodgeable copper concentration of 2 µg/cm^2 is used in Tier 2.		
	Parameters	Value
Tier 1	Concentration of copper on treated wood	4 mg/cm^2
	Concentration of penflufen on treated wood	0.05 mg/cm^2
	Concentration of DDACarbonate on treated wood	1 mg/cm^2
	Surface area of both hands, infant	196.8 cm^2
	Exposed area of hands	20%
	Transfer factor from wood	2%
	Dermal absorption copper	1.8%
	Dermal absorption penflufen	75%
	Oral absorption copper	36%
	Oral absorption of penflufen	100%
	Infant body weight	8 kg
Tier 2	Dislodgeable copper	0.002 mg/cm^2
Notes	Concentrations of active substances are based on UC4	
	A human oral absorption of 36% for copper was agreed in the CAR	
	Systemic dose via oral route (mg/kg bw/day): concentration of a.s. on wood (mg/cm^2) x surface area both hands (infant) x exposed area of hands x transfer factor from wood x oral absorption / bw	
	Systemic dose via dermal route (mg/kg bw/day): concentration of a.s. on wood (mg/cm^2) x surface area both hands (infant) x exposed area of hands x transfer factor from wood x dermal absorption / bw	
	Dislodgeable copper concentration of 2 µg/cm^2 (as agreed for copper in the WPCTF dossier)	
	Tier II copper calculations: Systemic dose: dislodgeable copper x surface area of hands x exposed area of hands x absorption / bw	

Calculation for Scenario 5

See Annex 3.2 for calculations.

Scenario 5

Exposure scenario	Tier	Estimated inhalation uptake mg/kg/bw	Estimated dermal uptake mg/kg/bw	Estimated oral uptake mg/kg/bw	Estimated total uptake mg/kg/bw
Scenario 5 Copper	I	n.a.	0.00707	0.141	0.148
	II	n.a.	0.000177	0.00354	0.0037
Scenario 5 Penflufen	I	n.a.	0.00372	0.00496	0.0087
Scenario 5 DDACb	See Local effect assessment below				

Further information and considerations on scenario 5

Secondary exposure (local effects) assessment for DDACarbonate
The critical toxicological effects for DDACarbonate are local effects (dermal and oral) and, in line with the approach taken in the CAR, it is not considered appropriate to derive a toxicological endpoint for systemic exposure. Levels of skin loading to DDACarbonate are calculated below based on the dermal exposure parameters summarised above.

Exposure assessment (Tier 1)	
Amount of DDACarbonate on treated surface (UC4)	1 mg/cm^2
Transfer efficiency	2%
Contaminated area of hand	20%
Skin loading of DDACarbonate on hands	0.004 mg/cm^2
Total skin loading of DDACarbonate	0.79 mg
Saliva production per minute	3.6 ml/min
Saliva generation	1 min
Concentration DDACarbonate in saliva	0.22 mg/ml

Skin loading of DDACarbonate: 1 mg/cm^2 x 2% x 20% = 0.0040 mg/cm^2
Concentration of DDACarbonate in saliva: 0.79 mg / (3.6 ml/min x 1 min) = 0.22 mg/ml

Tier 2:
The Tier 2 assessment for DDACarbonate assumes that only the preservative in the outer 1 mm of treated timber (rather than the outer 1 cm layer) is available for transfer to the infant's skin. This refinement was agreed as a higher tier approach in the CAR for DDACarbonate. On this basis, the level of skin loading of DDACarbonate will be 10x lower than that estimated above. Using this approach, the calculated level of skin loading on the hands is 0.0004 mg/cm^2 and the level in saliva estimate to be 0.022 mg/ml.

Summary table – secondary infant exposure on playground			
Exposure scenario	**Tier**	**Estimated dermal exposure mg/cm^2**	**Estimated oral concentration**

Scenario 5 DDACb	I	0.0040	0.22 mg/ml
Scenario 5 DDACb	II	0.0004	0.022 mg/ml

Scenario – Child playing on a playground structure
This scenario is covered by the scenario for infants playing on a playground structure. The child is less likely to experience hand to mouth exposure, which leads to a lower overall exposure estimate. Furthermore, the ratio of hand surface area to body weight is highest for infants compared to other age groups.

Scenario – Inhalation of volatilised residues indoors
Tanasote S40 treated timber is not designed for use inside buildings or generally in construction of buildings (as wood in use classes 1 and 2). Therefore no assessment of indoor air quality is required.

Scenario – Adult cleaning work clothes at home
For industrial vacuum pressure treatments, it is assumed that the employer would use professional means to launder contaminated work wear and contact with contaminated clothes would be insignificant. This scenario has therefore not been considered any further.

Combined scenarios
No combined exposure is expected to occur.

Monitoring data
No monitoring data have been submitted in support of this application.

Dietary exposure
Tanasote S40 is intended for application in industrial wood treatment plants by specialised professionals, and no direct dietary exposure is likely to result from the proposed application of the biocidal product and use of treated wood.

Information of non-biocidal use of the active substances
No information.

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Treated timber can be used for agricultural fencing and as such livestock may come into contact and potentially be exposed to surface residues. A livestock exposure assessment has been performed according to the Guidance on BPR (vol III, parts B+C, Appendix 6). The exposure is calculated using the The Federal Institute for Risk Assessment (BfR) calculator. This calculates exposure due to chewing on (e.g. horses, rabbits, goats), rubbing against (e.g. large slaughter animals) or licking (e.g. ruminants) the treated materials. The livestock exposure assessment is included in Annex 3.7.2.

Furthermore, a consumer risk assessment is performed due to potential indirect exposure to substances in Tanasote S40 in food products from animals exposed to treated wood.

The results from the BfR calculator refer to external exposure of animal(s). The guidance further directs that the EMA-CVMP guideline (Guideline on risk characterisation and assessment of maximum residue limits (MRL) for biocides. EMA/CVMP/SWP/90250/2010) should be used to proceed beyond external exposure. The EMA-CVMP guidance allows a human dietary exposure to be calculated from ingestion of products from exposed animals. This results in a Worst Case Consumer Exposure (WCCE) which then should be compared to the ADI or AEC for the substances.

The application of the guidances and the calculations required for consumer exposure and risk assessment is included in Annex 3.7.3.

The resulting WCCE esimates for an adult and a toddler (10 kg) are shown in the table below:

Substance	**WCCE (mg/kg bw/day)**	
	60 kg adult	10 kg child
Copper	0.0016	0.093
Penflufen	0.00002	0.0010
DDACarbonate	0.00026	0.0016

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Tanasote S40 can be used to treat wooden stakes etc. However, according to the applicant it is not intended for uses where treated timber is directly supporting food crop products. However, to fully exclude any such potential exposure from treated wood the following risk mitigation measure should be added to the product label:

- Do not use on wood which may come in direct contact with food and feeding stuff

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant.

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

Given that the modelling of exposures and subsequent risk characterisation during production and formulation of Tanasote S40 is addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under the Biocidal Products Regulations (agreed at Biocides Technical Meeting TMI06), the applicant has not considered exposure from production of the biocidal product further.

Aggregated exposure

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Summary of exposure assessment

Copper – Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/day)**
1. Copper	Primary exposure of industrial users during treatment of timber	I – Gloves	0.011
2. Copper	Secondary exposure of professional users sanding/cutting treated timber	I – No PPE	0.008
3. Copper	Secondary exposure of non-professional users sanding/cutting treated timber	I – No PPE	0.003
4. Copper	Secondary exposure of an infant chewing wood offcut	I	0.288
		II	0.004
5. Copper	Secondary exposure of an infant playing and mouthing on a playground structure	I	0.148
		II	0.0037

Penflufen – Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake(mg/kg bw/day)**
1. Penflufen	Primary exposure of industrial users during treatment of timber	I – Gloves	0.0059
2. Penflufen	Secondary exposure of professional users sanding/cutting treated timber	I – No PPE	0.001
3. Penflufen	Secondary exposure of non-professional users sanding/cutting treated timber	I – No PPE	0.001
4. Penflufen	Secondary exposure of an infant chewing wood offcut	I	0.010

		II	0.001
5. Penflufen	Secondary exposure of an infant playing and mouthing on a playground structure	I	0.0087

DDACarbonate – Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated Exposure for local Effects (mg/cm², mg/ml)**
2. DDACb	Secondary exposure of professional users sanding/cutting treated timber	I – No PPE	0.004 mg/cm² (dermal)
		II – No PPE	0.0004 mg/cm² (dermal)
3. DDACb	Secondary exposure of non-professional users sanding/cutting treated timber	I – No PPE	0.004 mg/cm² (dermal)
		II – No PPE	0.0004 mg/cm² (dermal)
4. DDACb	Secondary exposure of an infant chewing wood offcut	I	0.027 mg/ml (oral)
5. DDACb	Secondary exposure of an infant playing and mouthing on a playground structure	I	0.004 mg/cm² (dermal)
			0.22 mg/ml (oral)
		II	0.0004 mg/cm² (dermal)
			0.022 mg/ml (oral)

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Copper

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$AEL_{short\text{-}term}$	90 day (rat)	NOAEL 16.3 mg Cu/kg bw/day	50 (includes interspecies factor of 5 and intraspecies factor of 10)	25% (rat)	0.082 mg/kg bw/day
$AEL_{medium\text{-}term}$					
$AEL_{long\text{-}term}$	90 day (rat)	NOAEL 16.3 mg Cu/kg bw/day	100 (includes interspecies factor of 5 and intraspecies factor of 10 and an additional factor of 2 to extrapolate to a longterm AEL)	25% (rat)	0.041 mg/kg bw/day
ADI					0.15 mg Cu/kg bw/day (EFSA 2008)

Penflufen

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$AEL_{short\text{-}term}$	acute neurotoxity (rat)	50 mg/kg/ bw/d	167*	none	0.3 mg/kg/bw/d
$AEL_{medium\text{-}term}$	1 year chronic (dog)	7.7 mg/kg/ bw/d	100	none	0.077 mg/kg/ bw/d
$AEL_{long\text{-}term}$	2 year chronic (rat)	4.4 mg/kg/ bw/d	100	none	0.04 mg/kg/ bw/d
ADI	2 year chronic (rat)	4.4 mg/kg/ bw/d	100	none	0.04 mg/kg bw/day

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

DDACarbonate

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$AEC_{short-term, medium-term, long-term}$ (oral)	Developmental study (rat)	NOAEC of 0.2 mg/ml (equivalent to a NOAEL of 1 mg/kg bw/day)	Intraspecies toxicodynamic assessment factor of 3.2	Based on local oral effects – no correction for oral absorption	0.3 mg/kg bw/day (0.06 mg/ml)
$AEC_{short-term, medium-term, long-term}$ (dermal)	3 w study (rat) – reversible, very slight erythema	LOAEC of 10 $\mu g/cm^2$/day (0.1 %)	Intraspecies toxicodynamic assessment factor of 3.2 and an additional assessment factor of 2 for extrapolation from a LOAEC	Based on local dermal effects – no correction for dermal absorption	1.6 $\mu g/cm^2$/day (0.02 %)

Maximum residue limits or equivalent

	Sector of use	Reference value(s)	Regulation
Penflufen			
	Plant protection products	0.01 mg/kg Default MRL for all commodities	(EC) No 396/2005
Copper hydroxide			
	Plant protection products	5-30 mg/kg Range MRL for animal commodities	(EC) No 396/2005

Specific reference value for groundwater

-

Risk for industrial users

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/AEL (%)	Acceptable (yes/no)
Scenario 1 Copper	I – Gloves	0.041	0.011	27	Yes
Scenario 1 Penflufen	I – Gloves	0.04	0.0059	15	Yes

Combined scenarios

Not relevant.

Local effects

Semi-quantitative risk assessment for local effects – Primary exposure during industrial use

The purpose of the semi-quantitive risk assessment is to provide an approximation of the magnitude of the risks rather than a precise quantitive measure of the risks involved (BPR Guidance, Vol III parts B+C; p 244). For effects such as irritation, some consideration of the severity and reversibility of the effects must be considered in the overall risk characterization. As noted in the AR for DDACarbonate (p. 23), the "irritant effects are mild, reversible and immediate with no long-term consequences. They are also easy to monitor."

As described in section 2.2.6.2, the in-use concetration of DDACarbonate in the product exceeds the dermal AEC of 0.02% by nearly forty times. This magnitude is similar to that reported in the DDACarbonate AR (p. 23, exceedances of about fifty times), which however concluded that if the principles of good working practice are applied and product label instructions and recommendations respected, the risks to professional users are acceptable. When the comparison is made directly to the LOAEC, the exceedance is about eight times.
However, DDACarbonate is present in the product at 0.75% which is below the 1% threshold for classification of the product as irritant. On the other hand, the product also contains the corrosive substance of concern C8-C10 fatty acid and studies confirms that the product should be classified as skin irritant. Considering the result from the semi-quantitative assessment and the fact that the product is classified as Skin Irrit 2 and Eye Dam 1, a qualitative risk characterisation for local effects from the product itself has also been performed.

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

Hazard		**Exposure**						**Risk**
Hazard Cat	*C&L*	*PT*	*Exposed group*	*Tasks*	*Exposure route*	*Frequency*	*RMM/PPE*	*Conclusion*
High Low	Eye Dam Cat 1 H318 Skin Irrit Cat 2 H315	8	Industrial	Automated mixing and loading Loading and unloading treated timber	Eye Skin	Three times per day Limited duration (15 min)	Labeled 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

The local risk characterisation has been performed according to the BPR Guidance (vol III, parts B+C, section 4.3.2). The guidance indicates that for a product classified as Skin Irrit 2 the hazard category is Low and for a product classified as Eye Dam 1 the hazard category is High.

The potential exposure to the product is only by industrial users who normally wear protective clothing and gloves and who are trained in safe operation of the treatment plant. The product is supplied in bulk IBC's or bulk road tanker. In both cases the product is pumped into the storage tank and the operator contact during this process is limited to connection and disconnection of hoses. The impregnation process itself represents a closed system. The timber is treated in sealed treatment vessels and the job entails a cycle of loading, waiting, unloading and removal of treated timber to storage. The potential for exposure is greatest in normal operation only when opening the vessel door and removing the treated wood. In all plants the bogies loaded with treated wood are withdrawn mechanically and the operator intervention is to release straps from the packs. In some plants this is also automated. This process only occurs once per treatment cycle and is of limited duration (approximately 15 mins). For most of the cycle time the operator works on other tasks, often away from the treatment plant. The frequency is maximum three times/day and it is only for a limited time. As explained previously in the PAR, the treated timber is subject to lengthy final vacuum periods and is in a touch dry state on removal and does not drip. Dermal exposure may however occur through direct contact with the surface of treated timber and through contact with ancillary equipment and contaminated process plant. Considering that the pattern of use do not exclude that dermal exposure to

the product may occur it is concluded from the local risk characterisation that a protective coverall should be worn when handling the product.

Also, due to the eye damaging properties of the product, the treatment plant operators should wear eye protection. Taken together, provided that appropriate PPE (protective coverall, chemical resistant gloves and eye protection) is worn the exposure is expected to be low and the local risk during industrial use is considered acceptable.

Conclusion – Industrial exposure

The industrial primary exposure scenario considered above (scenario 1) shows an acceptable level of systemic exposure for copper and penflufen when appropriate chemical resistant gloves are worn. No systemic assessment is concluded for DDACarbonate as systemic effects are seen as secondary to local skin effects.

The explanation in the local effects section shows that DDACarbonate is present in the product below the threshold for classification. However, a qualitative assessment for local effects of the product was undertaken as the product is classified as Eye Dam 1 and Skin Irrit 2.

Based on the parameters of table 27, in the BPR guidance, for high hazard, as a worst case (for Eye Dam 1), the frequency and duration of exposure are acceptable. Under best practice the exposure is tightly controlled. Manual handling where exposure might occur is minimised due to optimisation of the process. There is limited opportunity for any splashes and given the long vacuum there is no aerosol formation and the timber will be touch dry. The degree of exposure is therefore low. Operators are fully trained and should wear appropriate PPE including eye protection to prevent eye exposure and chemical resistant gloves, considering the irritation potential of the product.

In conclusion, the risk for industrial users is acceptable when appropriate PPE including coverall, eye protection and chemical resistant gloves are worn and the following agreed SPC-phrases should be added in the SPC:

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)

- A protective coverall (at least type 6, EN 13034) shall be worn

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

Risk for professional users

The risk for professionals is secondary due to sanding/cutting of treated timber.

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 2 Copper	I	0.041	0.008	20	Yes
Scenario 2 Penflufen	I	0.04	0.001	2.5	Yes

Combined scenarios

Not relevant

Local effects

Task/ Scenario	Tier	AEC	Estimated Concentra-tion µg/cm²	Estimated AEC (%)	Acceptable (yes/no)
Scenario 2 DDACarbonate	I	1.6 µg/cm²	4	250	No
	II	1.6 µg/cm²	0.4	25	Yes

Conclusion – Professional exposure

The risk characterisation for professionals working with Tanasote S40 treated wood for 6 hours per day shows acceptable risk for systemic exposure to copper and penflufen. A local effects assessment shows acceptable risk for local dermal effects of DDACarbonate assuming that all the active substance in the outer 1 mm layer is available on the wood surface.

In conclusion, the risk for professionals due to secondary exposure when cutting/sanding treated timber is considered acceptable.

Risk for non-professional users

The risk for non-professionals is secondary due to cutting/sanding treated timber.

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 3 Copper	I	0.082	0.003	3.6	Yes
Scenario 3 Penflufen	I	0.3	0.001	0.33	Yes

Combined scenarios

Not relevant

Local effects

Task/ Scenario	Tier	AEC	Estimated Concentra-tion µg/cm²	Estimated AEC (%)	Acceptable (yes/no)
Scenario 3 DDACarbonate	I	Dermal 1.6 µg/cm²	4	250	No
	II	Dermal 1.6 µg/cm²	0.4	25	Yes

Conclusion – Non-professional exposure

It is deemed unlikely that non-professionals will have access to Tanasote S40 treated timber as use in the domestic environment will be limited. However, an assessment for a non-professional working with treated wood has been included and shows acceptable risks for systemic exposure to copper and penflufen. A local effects assessment shows acceptable risk for local dermal effects of DDACarbonate when assuming that all the active substance in the outer 1 mm layer is available on the wood surface.

In conclusion, the risk for non-professionals due to secondary exposure when cutting/sanding treated timber is considered acceptable.

Risk for the general public

The risk for the general public is assessed for secondary exposure of an infant chewing wood offcut and the exposure of an infant playing on a treated wood structure.

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 4 Copper	I	0.082	0.288	351	No
Scenario 4 Copper	II	0.082	0.004	4.9	Yes
Scenario 4 Penflufen	I	0.3	0.010	3.3	Yes
Scenario 5 Copper	I	0.041	0.148	361	No
Scenario 5 Copper	II	0.041	0.0037	9.4	Yes
Scenario 5 Penflufen	I	0.04	0.0087	22	Yes

Combined scenarios

Not relevant

Local effects

Task/ Scenario	Tier	AEC mg/ml (oral); µg/cm2 (dermal)	Estimated concentration mg/ml (oral); µg/cm2 (dermal)	Estimated AEC (%)	Acceptable (yes/no)
Scenario 4 DDACarbonate (oral)	I	0.06	0.027	45	Yes
Scenario 5 DDACarbonate (oral)	I	0.06	0.22	367	No

Scenario 5 DDACarbonate (oral)	II	0.06	0.022	37	Yes
Scenario 5 DDACarbonate (dermal)	I	1.6	4	250	No
Scenario 5 DDACarbonate (dermal)	II	1.6	0.4	25	Yes

Conclusion – Exposure of the general public

As a scenario for non-professionals working with treated wood was made, a scenario for an infant chewing a wood offcut was also included. However it is considered that this is an unlikely event. Should an infant pick up an offcut it is not expected to be able to chew it to any large extent and it is likely to be expelled as unpalatable. The systemic exposure for penflufen is acceptable and for copper the systemic exposure is acceptable assuming a dislodgeable copper concentration of 2 µg/cm^2. A local effects assessment shows acceptable risk for local oral effects of DDACarbonate.

The risk assessment for the infant on a playground scenario has been included, although this is not considered a likely use for wood treated with Tanasote S40. The assessment indicates that the exposure can be considered acceptable when considering reasonable refinements on amount of substance available at the surface of treated wood.

In conclusion, the risk for the general public is considered acceptable.

Risk for consumers via residues in food

Treated timber can be used for agricultural fencing and as such livestock may come into contact and potentially be exposed to surface residues. A livestock exposure assessment is included in section 2.2.7 and Annex 3.7.2. The results of this assessment require that a dietary risk assessment is performed due to potential indirect exposure to substances in Tanasote S40 from food products from animals exposed to treated wood.

The full dietary exposure and risk assessment is included in Annex 3.7.3.

It can be concluded that there is no dietary risk identified due to consumption of food products from animals that have been exposed to Tanasote S40.

Tanasote S40 can be used to treat wooden stakes etc although it is not intended for uses where treated timber is directly supporting food crop products. However, to fully exclude any potential consumer exposure from treated wood the following risk mitigation measure should be added to the product label:

- Do not use on wood which may come in direct contact with food and feeding stuff

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

A risk characterisation from combined exposure to two of the active substances in Tanasote S40 (Cu and penflufen) was conducted according to Guidance on BPR (vol III part B+C, section 4.4).

Tier 1: Risk assessment substance by substance

The above section on human health demonstrates that the HQs (Hazard Quotient; internal exposure/AEL) for each active substance are below the AEL.

The indications are that the target organs are different for copper and penflufen. The main target organ for copper is the kidney and for penflufen the main target organ is the liver. From the efficacy data it is evident that penflufen is very active and compliments the spectrum of copper. There is no evidence to suggest synergistic effects and tier 2 can progress using additive effects.

Tier 2: Assessment of combined exposure to mixture by concentration addition

The Hazard Index (HI) for the biocidal product is the sum of the HQ for each active 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.

Combined exposure by concentration addition

Task/ Scenario	**Tier**	**HQ (Cu)**	**HQ (Penflufen)**	**HI**	**Acceptable (yes/no)**
1. Primary – Industrial	I	0.27	0.15	0.42	yes
2. Secondary – Professional	I	0.20	0.025	0.23	yes
3. Secondary – Non-professional	I	0.036	0.0033	0.04	yes
4. Secondary – Infant	II	0.049	0.033	0.082	yes
5. Secondary infant	II	0.094	0.22	0.31	yes

As shown in the table, the HI for all scenarios are below 1 and therefore the combined risk related to the mixture is deemed acceptable. No further assessment is required.

2.2.7 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.

The treated timber is intended primarily for professional uses such as railway sleepers, utility poles and fencing. Therefore potential indirect exposure to livestock can be envisaged from the use on fences.

There is no available guidance on animal risk assessment. However, this assessment is based primarily on the BPR guidance (vol III, part B+C, chapter 6. Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products). 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 Tanasote S40 since the active substances have been shown to be non-volatile.

The following scenarios were included:

- Oral exposure of animals licking surfaces treated with the biocidal product

Exposure = application rate (mg/m^2) * tongue surface area * licks per day / bw

- Oral exposure of animals chewing on wood treated with the biocidal product

Exposure = application rate (mg/m^2) * wood consumption / bw

- Dermal exposure of animals rubbing on surface treated with the biocidal product

Exposure = application rate (mg/m^2) * body surface area in contact with surface / bw

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. It is not expected that Tanasote S40 treated timber will be used in this context for anything other than agricultural fencing so exposure based on this assessment is very worst case. 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.

Summary of the default data

Animal	Body weight (kg)	Body surface area in contact with treated wood (m^2)	Wood consumption (m^3/d)	Tongue surface area (m^2)	Licks per day
Horse	400	1.62	0.0000186	-	-
Beef cattle	500	1.44	-	-	-
Dairy cattle	650	1.68	-	-	-
Calf	200	0.87	-	0.008	10
Fattening pig	100	0.45	-	0.008	10
Breeding pig	260	0.84	-	0.008	10
Sheep	75	0.45	-	-	-
Lamb	40	0.3	-	-	-
Slaughter goat	13	0.15	-	-	-
Lactating goat	70	0.45	-	-	-
Rabbit	2.5	0.06	0.0000031	-	-

The BPR guidance uses a default maximum product uptake of 50 L/m^3. Tanasote S40 has a maximum retention of 133 kg/m^3 (UC4) which has been used to represent the likely treatment level for fencing. However, it should be mentioned that this is an analytical zone retention and the overall value will be less. This again leads to a worst case assumption.

An uptake of 133 kg/m^3 will give the following amounts of active substance in treated wood:

133 kg/m^3 x % w/w x 1000

Copper 3990 g/m^3
Penflufen 49.8 g/m^3
DDACb 997.5 g/m^3

For dermal exposure and oral licking a surface concentration is required. This is calculated from:

g/m^3 x 0.05 mm (0.05 x 10^{-3} m depth) x 1000

Copper 199.5 mg/m^2
Penflufen 2.49 mg/m^2
DDACb 49.88 mg/m^2

In accordance with the BPR guidance, a Tier 1 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 esposure estimations.

BfR input data

Application rates:

Active substance	Dermal mg/m²	Oral (chewing) g/m³	Oral (licking) mg/m²
Copper	199.5	3990	199.5
Penflufen	2.49	49.8	2.49
DDACb	49.88	997.5	49.88

Output tables from the BfR calculator can be found in Annex 3.7.2.

The BPR Guidance gives a trigger value of 0.004 mg/kg bw as a level below which residues can be considered insignificant unless the substance is extremely toxic. It is clear that most values in the tables in Annex 3.7.2 exceed this trigger value and a further refinement (Tier 2) was required.

The result of the calculation using the BfR calculator shows that the highest total external exposure (dermal and oral) for all substances was found in slaughter goat (goat kid). These values are used for a worst case risk assessment (Tier 1; external total exposure/$AEL_{long\text{-}term}$) for all animals. In Tier 2, the external total exposure for Cu is adjusted by 25 % (which is the agreed oral absorption value to used in risk characterisations for animals according to the CAR). This value is regarded to be conservative to be used for adjustment of total exposure as the dermal absorption for Cu in Tanasote S40 (in humans) is 1.8 %.

Tier 1:
Cu: (0.0706 / 0.041) mg/kg bw/d = **1.7**
Penflufen: (0.0009 / 0.04) mg/kg bw/d = 0.02
DDACb: (0.0176 / 0.3) mg/kg bw/d) = 0.06

Tier 2:
Cu: ((0.0706 x 0.25)/ 0.041) mg/kg bw/d = 0.43

There is no harmonised guidance for assessing the risk for animals, however, considering these assumptions it can be concluded that the risk to livestock from contact with Tanasote S40 treated wood is acceptable.

2.2.8 Risk assessment for the environment

Effects assessment on the environment

Information on the active substances in the Assessment Reports has been used in the environmental effects assessment for the biocidal product.

Ecotoxicological information on the active substances

The biocidal product contains three active substances: Penflufen, Copper Hydroxid and DDA Carbonate. The Penflufen has two metabolites: M01 (Penflufen-3-hydroxy-butyl) and M02 (Penflufen-pyrazoyl-AAP). The Assessment reports agreed at active substance approval (PT 8 dossier unless otherwise stated), to which the applicant has access, give the following ecotoxicological end points:

Penflufen

Compartment	PNEC	Unit
PNECwater	0.00234	mg/l
PNECsed (fresh water sediment)	0.016	mg/kg wwt
PNECstp	1.09	mg/l
PNECsoil	0.42	mg/kg dw (corrected to 3.4% organic matter content)
	0.377	mg/kg wwt

The penflufen metabolite M01 (Penflufen-3-hydroxy-butyl)

Compartment	PNEC	Unit
PNEC fresh water	0.0157	mg/l
PNECsoil	0.44	mg/kg dw (corrected to 3.4% organic matter content)
	0.39	mg/kg wwt

The penflufen metabolite M02 (Penflufen-pyrazoyl-AAP)

Compartment	PNEC	Unit
PNECsoil	0.364	mg/kg dw (corrected to 3.4% organic matter content)
	0.322	mg/kg wwt

DDA carbonate

Compartment	PNEC	Unit
PNECwater	0.0013	mg/l
PNECsed	0.02236	mg/kg dw
	4.861E-03	mg/kg wwt
PNECstp	0.688	mg/l
PNECsoil	0.255	mg/kg dw
	0.225	mg/kg wwt

Copper hydroxide

Compartment	PNEC	Unit
PNECwater	0.0078	mg/l
PNECsed	87 18.9	mg/kg dw (for sediment containing 5% organic matter content) mg/kg wwt (for sediment containing 5% organic matter content)
PNECstp	0.23	mg/l
PNECsoil	45.6	mg/kg dw
	40.35	mg/kg wwt

[1] These values have been calculated based on the information in the CAR for copper hydroxide. The explanation is provided in the following section.

The drinking water standard Water Inspectorate's (DWIs) allowable limit for copper 2.0 mg/L.

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

Classification of a mixture for *acute (short-term)* hazards, based on summation of classified components. The only relevant substance to include is copper hydroxide (4.615 %). It is classified as Aquatic Acute 1 – H400 (M-factor acute = 10) and present in the mixture at >0.1%. Penflufen is also classified as Aquatic Acute 1 but the concentration is less than 0.1% and thus considered as not relevant for inclusion in mixture classification.

The product Tanasote S40 is classified as Aquatic Acute 1, because one of the product components copper hydroxide in concentration 4.615 % multiplied by its corresponding M-factor(acute)=10 is 46.15 % and greater than 25 %.

Classification of a mixture for *long-term* hazards, based on summation of the concentrations of classified components. The components copper hydroxide (4.615 %) is classified as Aquatic Chronic 1 - H410 (M-factor chronic=10, according the RAC opinion 2019 ECHA/RAC/ A77-O-0000001412-86-262/F on copper compounds) and penflufen (0.0379%) is classified as Aquatic Chronic 1 – H410 (M-factor chronic=1)
The product Tanasote S40 is classified as Aquatic Chronic 1 based on the below calculation $\sum(M \times \text{Chronic 1}) \geq 25\ \%$:

$(M_{chronic}=10) x \text{Copper hydroxide}(4.615\%) + (M_{chronic}=1) x \text{Penflufen}\ (0.0379) \geq 25\%.$

The following label elements for hazardous to the aquatic environment shall be used for Tanasote S40: Signal word - Warning, Hazard statement H400 "Very toxic for aquatic life" and H410 "Very toxic to aquatic life with long lasting effects". Phrases: P273, P391, P501.

Hazard statement codes relevant for Hazardous to the Aquatic Environment for Tanasote S40

Aquatic hazard classification	Associated hazard statement
Acute 1 and Chronic 1	H400; H410

No direct ecotoxicological studies have been carried out with Tanasote S40.

Each active substance has detailed information relating to the ecotoxicity. This information has been assessed as part of the BPR authorisation process for each substance. The information on individual substances will be used to calculate ecotoxicological assessments in each relevant environmental compartment.

Further Ecotoxicological studies

No ecotoxicological studies have been carried out with Tanasote S40.

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

There is no data available but due to the method of application and use no non target organisms are believed to be at risk from the application of the product.

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

No data available but due to the method of application no non target organisms are believed to be at risk from the application of the product.

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

No data available. There are no known non-target organisms that are significant consumers of preservative treated wood.

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

This is not relevant for treated wood. The point refers to a habitat directly treated with biocide; wood preservatives are not used to treat habitats directly rather bulk wood which is then erected within a habitat. There will not be large proportions of specific habitats covered with wood due to the nature of the material and mode of deployment. Assessments are given for a number of wooden houses erected in close proximity; such constructions would not however be large enough to cover large proportions of specific habitats.

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

Use Classes 3 and 4
Emission to environmental compartments is possible at product application stage and through storage of treated wood. Placement of treated wood in service can lead to emissions to the soil, aquatic, sediment and STP compartments.

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

No new environmental fate & behaviour data on each active substance or product specific hazard data are available as they have not been considered necessary. All the endpoints have been taken from the most recent Final CARs available for each active substance.

In support of UC 3 application, product specific semi-field leaching data (to NT Build 509 methodology) has been submitted.

In support of UC 4 application, product specific laboratory leaching study (to CEN/TS 15119-2 methodology) involving full, continuous immersion of vacuum treated timber leaching data has been submitted.

Leaching behaviour (ADS)

A) Semi-field data to support UC3 applications.

The assessments presented in this document will include a T = 365 days point. This is included for information purposes as requested by ECHA. The T = 365 days points are not considered for regulatory purposes at this time.

The Time 1 (30 days) and T=365d leaching rates for Tanasote S40 treated wood exposed above ground (UC3 exposure) are derived from leaching data according to the NT Build 509 semi-field test procedure. These are reported in. The test consists of a panel of wood treated to known product retentions and then exposed to natural rainfall. The water leachate is collected and measured and the rainfall recorded. This allows a leaching rate of the active substances to be calculated. The retention achieved in the study was 98.61 $kg \cdot m^{-3}$, 2.96 kgm^{-3} copper, 0.037 $kg \cdot m^{-3}$ penflufen and 0.64 $kg \cdot m^{-3}$ DDA^{+}. The leaching rates arising from the study will be corrected for the maximum retention applied for of 100 kg/m^3 product (3 $kg \cdot m^{-3}$ copper, 0.0375 $kg \cdot m^{-3}$ penflufen, 0.645 $kg \cdot m^{-3}$ DDA^{+}). The detailed derivation of leaching rates using data from tables pages 7 (copper), 9 (penflufen), and 11 (DDA^{+}) from the test report is shown in Annex 3.7.4. It is noted in the derivation of the rates that the leaching rates over the duration of the test will be assumed to persist for all active substances over the entire assessment period of 7300 days according Approach 1 described ESD PT8 (ENV/JM/MONO(2013)21. The example to demonstrate the detailed calculations is presented in Appendix §3.7.4.1.1.1.

The assumption, that a leaching rate over the whole assessment period is fixed, is very rough. Approach 2 provides a more accurate picture of the time variable exposure values as described in the TAB 2019 v.2 ENV-A3. The daily emission due to leaching per 1 m^2 can be calculated according equation in Approach 2. The refinement using Approach 2 has been done for copper (Time 2=7300 day) for UC3, see result in the table below, the detailed calculations of copper leaching rate see on Appendix §3.7.4.1.1.2.

NT BUILD 509 Leaching Rates at Test Retention 98.61 $kg \cdot m^{-3}$						
Component	**Leaching loss (Time 1 = 30 days)**		**Leaching loss (Time = 365 days)**		**Leaching loss (Time 2 = 7300 days)**	
	$mg \cdot m^{-2}$	$mg \cdot m^{-2} \cdot day^{-1}$	$mg \cdot m^{-2}$	$mg \cdot m^{-2} \cdot day^{-1}$	$mg \cdot m^{-2}$	$mg \cdot m^{-2} \cdot day^{-1}$
Copper (Approach 1)	37.61	1.25	336.34	0.92	6726.88	0.92
Copper (Approach 2)	-	-	-	-	3259*	0.47
Penflufen	0.058	0.0019	0.29	0.00079	5.76	0.00079
DDA^{+}	0.011	0.00036	0.052	0.00014	1.03	0.00014

Rates Used for UC3 Assessment: 100$kg \cdot m^{-3}$						
Leaching at 100 kgm^{-3} = Leaching at 98.61 kgm^{-3} * 100/98.61						
Component	**Leaching loss (Time 1 = 30 days)**		**Leaching loss (Time = 365 days)**		**Leaching loss (Time 2 = 7300 days)**	
	mgm^{-2}	$mgm^{-2} \cdot day^{-1}$	mgm^{-2}	$mgm^{-2} \cdot day^{-1}$	mgm^{-2}	$mgm^{-2} \cdot day^{-1}$

Copper (Approach 1)	38.01	1.27	340.34	0.93	6806.76	0.93
Copper (Approach 2)	-	-	-	-	3305*	0.48
Penflufen	0.058	0.0019	0.29	0.00080	5.84	0.00080
DDA$^+$	0.011	0.00036	0.053	0.00014	1.04	0.00014

*This value represents leaching from end of year 1 to end of year 20

The railway sleeper scenario is recognised to be UC3, above ground leaching behaviour. Sleepers can be treated to higher retentions of 133 kg·m^{-3} product.

The rates used for railway sleepers scenario are shown below.

Rates Used for Sleeper UC3 Assessment: 133 kg·m^{-3}						
Leaching at 133 kgm^{-3} = Leaching at 98.61 kg·m^{-3} * 133/98.61.						
Component	**Leaching loss (Time 1 = 30 days)**		**Leaching loss (Time = 365 days)**		**Leaching loss (Time 2)**	
	mg·m^{-2}	mg·m^{-2} ·day^{-1}	mg·m^{-2}	mg·m^{-2} ·day^{-1}	mg·m^{-2}	mg·m^{-2} ·day^{-1}
Copper (Approach 1)	50.7	1.69	452.6	1.24	9052	1.24
Copper (Approach 2)	-	-	-	-	4396*	0.63
Penflufen	0.078	0.0026	0.4015	0.0011	8.03	0.0011
DDA$^+$	0.0147	0.00049	0.070	0.00019	1.39	0.00019

*This value represents leaching from end of year 1 to end of year 20

B) Laboratory based data to support UC4 applications.

The assessments presented in this document will include a T = 365 days point. This is included for information purposes as requested by ECHA. The T = 365 days points are not considered for regulatory purposes at this time. The T1 time point refers to 30 days, the T2 time point to 7300 days (= 20*365 days).

The Time 1 T =365 days and T = 7300 days leaching rates for Tanasote S40 treated wood exposed in ground (UC4 exposure) are derived from leaching data according to the CEN/TS 15119-2 laboratory test procedure. These are reported in, tables on p6 (copper), p7 (penflufen), p8 (DDA$^+$)). The test consists of blocks of wood treated to known product retentions and then immersed in water continuously for 30 days with leachate changes measured during an increased time intervals. The water leachate is collected and measured. The quantities of emission in the leachate are related to the surface area of the wood and the length of exposure, to estimate a flux in milligrams per square metre per day.This allows a leaching rate of the active substances to be calculated. The retention achieved in the study was 82.10 kg·m^{-3} product, 2.47 kg·m^{-3} copper, 0.062 kg·m^{-3} penflufen and 0.53 kgm^{-3} DDA$^+$. The data used for calculating leaching rates are reported in the results tables on pages 6 (copper), 7 (penflufen) and 8 (DDA$^+$). The detail of the calculation of the leaching rates is contained in Confidential Annex 3.7 of this document. The leaching rates arising from the study will be corrected for the maximum retention applied for of 4 kg·m^{-3} copper (133 kg·m^{-3} product).

CEN/TS 15119-2 Leaching Rates at Tested Retention 82.10 kgm^{-3}						
Component	**Leaching loss (Time 1 = 30 days)**		**Leaching loss (Time = 365 days)**		**Leaching loss (Time 2 = 7300 days)**	
	mgm^{-2}	mgm^{-2} day^{-1}	mgm^{-2}	mgm^{-2} day^{-1}	mgm^{-2}	mgm^{-2} day^{-1}
Copper	1614.24	55.66	4113.13	11.27	8334.32	1.14
Penflufen	13.89	0.48	35.36	0.097	67.65	0.0093
DDA^{+}	3.68	0.13	9.08	0.025	15.45	0.0021

Leaching rates scaled to the maximum applied for retention of 133 kgm^{-3} of Tanasote S40.

Leaching Rate at maximum retention = Leaching rate of wood in leaching test * Maximum retention applied for /Retention of wood in leaching test.

Rates Used for UC4 Assessment: 133kg/m^3						
Leaching at 133 kg·m^{-3} = Leaching at 82.01 kg·m^{-3} * 133/82.01						
Component	**Leaching loss (Time 1 = 30 days)**		**Leaching loss (Time = 365 days)**		**Leaching loss (Time 2 = 7300 days)**	
	mg·m^{-2}	mg·m^{-2} day^{-1}	mg·m^{-2}	mg·m^{-2} day^{-1}	mg·m^{-2}	mg·m^{-2} day^{-1}
Copper	2582.78	90.14	6581.01	18.03	13334.91	1.85
Penflufen	22.23	0.78	56.58	0.16	108.24	0.015
DDA^{+}	5.88	0.21	14.53	0.040	24.73	0.0034

The percentage emission of active substances at TIME 1 (30 days), TIME = 365 days and T2 (7300 days) based on the test data are also presented:

Comulative Quantity of Active Substance Leached in %

Active substance	**Cumulative quantity of a.s. emitted (% at TIME 1= 30 days)**	**Cumulative quantity of a.s. emitted (% at TIME = 365 days)**	**Cumulative quantity of a.s. emitted (% at TIME 2= 7300 days)**
Copper	13.77	35.12	71.12
Penflufen	9.48	24.14	46.18
DDA^{+}	0.15	0.36	0.61

Testing for distribution and dissipation in soil (ADS)

Data reported in the CAR is sufficient for the risk assessment.
No direct data on the product is available. The distribution and dissipation in soil will be calculated using substance specific data agreed for the assessment of each active substance.

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

Data reported in the CAR is sufficient for the risk assessment.

No direct data on the product is available. The distribution and dissipation in water and sediment will be calculated using substance specific data agreed for the assessment of each active substance.

Testing for distribution and dissipation in air (ADS)

Data reported in the CAR is sufficient for the risk assessment.
No direct data on the product is available. There are no volatile components in Tanasote S40; all biocidal components have very low vapour pressures and no concern in air has been noted for any of them.

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

No application other than in fixed industrial processes. There will be no application of product by open spray.

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 application other than in fixed industrial processes. There will be no application of product by open spray. There is no potential for formation of dust.

Exposure assessment

General information

Assessed PT	PT 8
Assessed scenarios	**Scenario 1:** 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). **Scenario 2:** Use Class 4a (situation in which the wood or wood based product is in contact with the ground).
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), ENV/JM/MONO(2013)21.
Approach	**Scenario 1:** Average consumption based approach from ESD using cladded house (including groundwater), noise barrier, bridge over pond and railway sleeper as representative emission scenarios.

	Scenario bridge over pond, freshly deposited sediment compartment. **Tier 1:** The leaching rates over the whole assessment periods are assumed constant for all active substances of biocidal product, the average daily leaching rates derived according to Approach 1 (see §2.2.8 "Leaching behaviour (ADS) and §3.7.4.1.1.1). **Tier 2:** The daily emission of copper due to leaching per 1 m^2 is calculated according equations in Approach 2 for Time 2 =7300 days for UC3 (see §2.2.8 "Leaching behaviour (ADS), §3.7.4.1.1.2 and TAB 2019 v.2 ENV-A3), for all other active substances and the assessment periods used Approach 1. **Scenario 2:** Average consumption based approach using Transmission/utility pole as representative emission scenario. The transmission pole was defined to represent the worst case compared to the fence post when considering emissions to soil (ESD PT8, 2013, p.77). It was agreed on (WG-IV-2017) that the scenario for railway sleepers UC3 should be used as a first tier to assess the exposure to the groundwater compartment for UC4 (TAB ENV v.2.1, 2019), however the maximum retention, which is applicable to UC4, has been used.
Distribution in the environment	There will be no application and storage emissions. 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. UC3 applications are assumed to reach soil, STP, surface water, sediment and groundwater compartments. UC4 applications are assumed to reach surface water, sediment, soil and groundwater compartments. A use restriction will be applied preventing the use of treated timber in permanent contact with water. Distribution will be calculated in line with ECHA Guidance on ERA, Volume IV, Part B and the ESD referenced above.
Groundwater simulation	Assessment of Penflufen and metabolites M01 and M02 has been performed using FOCUS PEARL 4.4.4 modelling. UC 3 cladded house (including groundwater) and railway sleeper emission scenarios.

	It was agreed on (WG-IV-2017) that the scenario for railway sleepers UC3 should be used as a first tier to assess the exposure to the groundwater compartment for UC4 (TAB ENV v.2.1, 2019), the sleeper can be treated the maximum retention (133 mg/m^3). Copper and DDACarbonate are both immobile in the soil and bind very strongly to organic matter, therefore no assessment is necessary using FOCUS PEARL. However, a pore water assessments are carried out for Copper and DDA^+ for cladded house (including groundwater) and railway sleeper emission scenarios.
Annexes	Yes – see section 3.7
Life cycle steps assessed	**Scenario 1:** 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. **Scenario 2:** UC 4a application to wood Production: **No** – assessed at review Formulation: **No** – formulated within a closed system (see remarks) Use: **No** – All industrial 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 must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water and that any losses of the product shall be collected for reuse or disposal. 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 for appropriate disposal via an authorised company.

Emission estimation

Life cycle stage: Product application and storage

Tanasote S40 is applied by Reuping (high pressure) treatment cycles.

All application must be conducted at an industrial site where the process is contained.

Industrial Application and Storage
There is the potential for environmental exposure and unacceptable environmental risk during the industrial treatment of timber and the storage of treated timber at industrial sites. To mitigate these potential risks:

Labelling and associated literature must state that all vacuum-pressure impregnation of timber be undertaken at industrial sites 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 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.*

Wood treated with Tanasote S40 will be used in both Use Classes 3 and 4a. The following information, therefore relates to both use class 3 and 4a treatments.

Detailed explanation of the methods and equations are presented in Annex 3.7.

Scenario 1

Input parameters for calculating the local emission		
Input	**Value**	**Unit**
Scenario 1: **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 Reuping (high pressure) impregnation at industrial plants		
Application rate of biocidal product	**100**	$kg \cdot m^{-3}$
Concentration of active substance in the product solution		
Copper	3.00	% w/w
Penflufen	0.0375	% w/w
DDACarbonate	0.75	% w/w
Concentration of active substance in treated wood		
Copper	3.00	$kg \cdot m^{-3}$
Penflufen	0.0375	$kg \cdot m^{-3}$
DDACarbonate	0.75	$kg \cdot m^{-3}$

Scenario 2

Input parameters for calculating the local emission		
Input	**Value**	**Unit**
Scenario 2: **UC 4a** (wood or wood-based product is not covered is not covered and in contact with the ground (4a). It is permanently exposed to wetting.		
Application rate of biocidal product	**133**	kg·m^{-3}
Concentration of active substance in the product solution		
Copper	3.00	% w/w
Penflufen	0.0375	% w/w
DDACarbonate	0.75	% w/w
Concentration of active substance in treated wood		
Copper	4	kg·m^{-3}
Penflufen	0.05	kg·m^{-3}
DDACarbonate	1	kg·m^{-3}

Calculations for Scenario 1 and 2

Life cycle stage: Treated wood in service life

Detailed explanation of the methods and equations are presented in Annex 3.7 section 3.7.5-3.7.7 and following.

Emissions modelling for PT8 products determine local emissions in terms of Elocal$_{compartment}$ in mg·d^{-1}. *In-service* losses are based upon leaching loss from treated wood exposed to weather or wetting episodes. The loss in mg·d^{-1} represents an average value derived by modelling losses over time windows over which there will be an average over weather patterns. In all compartments except groundwater, risks are considered at Time 1 (30 d) and Time 2 (7300 d) (service life depending on application method). An additional assessment at T =365 days will be included for ECHA information as discussed above.

The groundwater will be assessed in the cladded house and railway sleeper scenarios. The house scenario will be assessed at the maximum retention applicable to UC3 timbers with 100 kg·m^{-3} application rate of biocidal product. The House is not an applicable end-use for Tanasote S40, however the scenario is included to demonstrate the worst case groundwater assessment for general UC3 applications at the UC3 retention.

The railway sleeper scenario is a UC3 exposure scenario, however timber can be treated to UC4 retentions and the assessment will be conducted at 133 kg·m^{-3} using UC3 leach data.

The UC3 data scaled to the relevant UC4 retention is shown above in the leaching rate section.

The details of the equations that are used in the assessment are given in Annex 3.7, sections 3.7.2-3.7.5 and following. The biodegradation of the organic components is included in all assessments except for DDA^+ in the pore water assessment. The ageing of copper in the soil compartment is taken in to account: all copper that has been in the soil for greater than 18 months is bound to soil material and has reduced bioavailability. An ageing factor of 0.5 is applied to all long term copper PECs this includes the copper background concentrations.

Fate and distribution in exposed environmental compartments

Treated wood can be deployed above fresh-water (UC 3) and therefore leached substances can be received in the water. The substances received in the freshwater will partition between the water and solid matter in the water. Freshwater sediment is therefore a receiving compartment for UC 3.

The use of Tanasote S40 treated wood in above ground situations means that leachate could enter drains and be transported to a sewage treatment plant. The sewage treatment plant (STP) is therefore a relevant receiving compartment.

None of the substances in Tanasote S40 has high vapour pressure. Tanasote S40 is not designed to volatilise. The air is therefore not a relevant receiving compartment.

Tanasote S40 treated wood can be deployed both over soil and in soil contact. The soil is therefore a relevant receiving compartment for both UC 3 and UC 4a.

The substances leached from Tanasote S40 in to the soil could be further transported through the soil to groundwater. The groundwater is therefore a relevant receiving compartment for both UC 3 and UC 4 (see ESD (ENV/JM/MONO(2013)21).

A label instruction will direct that Tanasote S40 treated wood is not to be used in contact with water (either still or moving). The freshwater aquatic compartment is therefore not a receiving compartment for Use class 4 timbers, i.e. Use class (4b) is not included in the assessment.

Overview on emission pathways PT 8 (Treated wood in service, application – pressure treatment)

UC	Scenario	Environmental compartments considered, Primary receiving compartments are highlighted in bold letter
UC 3	House, Fence	**Soil** (direct) Ground water (leaching from soil)
	Noise barrier	**STP** Freshwater / sediment (via STP) **Soil** (direct or via STP) Ground water (leaching from soil)
	Bridge over Pond	**Freshwater** / sediment
UC 4a	Transmission Pole,	**Soil**

	Fence post	Ground water (leaching from soil)
UC 4b*	Jetty in lake, Sheet piling	**Freshwater** / sediment

* Use class (4b) is not included in the assessment of Tanasote S40, according a label instruction Tanasote S40 treated wood is not to be used in contact with water.

All the calculations have been carried out according to the methods and defaults used in the ECHA PT8 spread sheet (Excel calculation sheet (Emission Scenarios for PT 8) recommended by ECHA and available on the ECHA website (https://echa.europa.eu/en/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents).

Identification of relevant receiving compartments based on the exposure pathway								
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water
Scenario 1	Y	Y	N	N	Y	N	Y	Y
Scenario 2	N	N	N	N	N	N	Y	Y

Scenario 1 (UC 3)

Scenario 1 includes scenarios Use class 3 in the PT8 ESD for the cladded house, fencing, noise barrier, bridge over pond and additional scenario for UC 3 railway sleepers.

It must be noted that the house scenario (release to soil) is included for completeness only. The wood treated by Tanasote S40 is not suitable for house end-use as it is oil based. Tanasote S40 will be used in applications UC 3 such as ***agricultural fencing, motorway noise barriers***, ***bridge over pond*** and ***railway sleepers***.

Due to the ratio of exposed timber and the soil volume the cladded house is worst case for the terrestrial environment. If acceptable risk is shown for the cladded house then the terrestrial scenarios for the fence and the noise barrier will automatically be acceptable. In practice, the wood will not be suitable for house cladding due to the oil carrier.

The cladded house groundwater scenario is included as the worst case UC 3 agreed assessment scenario for groundwater.

The railway sleeper scenario is included as UC 3 exposure (sleepers are above ground out of soil contact), but at UC4 retentions (133 mg/m^3).

Scenario bridge over pond, freshwater and freshly deposited sediment compartment Tier 1 and Tier 2 are considered:

Tier 1:

The leaching rates over the whole assessment periods are assumed constant for all active substances of biocidal product, the average daily leaching rate derived according to Approach 1 (see §2.2.8 "Leaching behaviour (ADS) and §3.7.4.1.1.1).

Tier 2:

The daily emission of copper due to leaching per 1 m^2 is calculated according equations in Approach 2 for Time 2 =7300 days for UC3 (see §2.2.8 "Leaching behaviour (ADS),

§3.7.4.1.1.2 and TAB 2019 v.2 ENV-A3), for all other active substances and the assessment periods used Approach 1.

Scenario 2 (UC 4a)

Scenario 2 includes UC 4 scenarios the PT8 (4a): ***Transmission pole*** and ***fence post***.

The transmission pole is worst case for the terrestrial environment due to the ratio of exposed timber and the soil volume. If acceptable risk is shown for the transmission pole then the terrestrial scenario for the fence post will automatically be acceptable. Therefore, only the transmission pole calculations have been included.

The scenario for railway sleepers UC3 is used as a first tier to assess the exposure to the groundwater compartment for UC4 (ENV WG-IV-2017, TAB ENV v.2.1, 2019), however the maximum product retention rate in the treated wood is assessed (133 kg/m^3) as for UC4.

No calculations have been provided for UC (4b) scenarios the jetty in the lake and sheet piling in waterway as no use of Tanasote S40 in direct water contact is claimed. A label restriction will therefore be applied for Tanasote S40: Treated timber must not be placed in contact with water bodies.

Input parameters (only set values) for calculating the fate and distribution in the environment: Copper hydroxide			
Input	Value	Unit	Remarks
Molecular weight	97.54	g/mol	
Melting point	-	°C	No melting point – decomposes before melting (97% $Cu(OH)_2$)
Boiling point	-	°C	No boiling point – decomposes before boiling (97% $Cu(OH)_2$)
Vapour pressure (at 20°C)	< 10^{-5}	Pa	Theoretically assessed
Water solubility (at 20°C)	0.0066	mg/l	pH 8.9
Log Octanol/water partition coefficient	Not relevant but value of 8.5E-07 used in review	-	Log 10
Organic carbon/water partition coefficient (Koc)	106000	l·kg^{-1}	
Henry's Law Constant (at X C)	-	Pa·m^3·mol^{-1}	Not applicable (N/A)
k_{psusp}	30246	l·kg^{-1}	
$k_{susp-water}$	7560	m^3·m^{-3}	

$k_{soil-water}$	3180.2	$m^3 \cdot m^{-3}$	Calculated using Kd (Copper Carbonate CA report p.54) and equation 27 of the BPR guidance Vol IV as outlined in Annex 3.7.
Biodegradability	-	-	Not applicable to metals

Input parameters (only set values) for calculating the fate and distribution in the environment: Penflufen			
Input	Value	Unit	Remarks
Molecular weight	317.41	g/mol	
Melting point	111.1	°C	(99.% pure) EFSA data
Boiling point	Penflufen has no boiling point at atmospheric pressure and decomposition starts at ca. 320 °C.	°C	(99.2% pure) EFSA data
Vapour pressure (at 20°C)	4.1E-07	Pa	
Water solubility (at 20°C)	10.9	$mg \cdot l^{-1}$	
Log Octanol/water partition coefficient	3.3		Log 10. Taken from EFSA data
Organic carbon/water partition coefficient (K_{oc})	279.9	$l \cdot kg^{-1}$	
1/n	0.92		
Henry's Law Constant (at 25C)	1.19E-5	$Pa \cdot m^3 \cdot mol^{-1}$	Derived from equation in BPR Guidance
k_{psusp}	27.99	$l \cdot kg^{-1}$	
$k_{susp-water}$	7.9	$m^3 \cdot m^{-3}$	
Biodegradability			
DT_{50} for biodegradation in surface water	140	d (at 12ºC)	Geometric mean/median EFSA data
DT_{50} for hydrolysis in surface water	No DT_{50}	d or hr (at 12ºC /pH)	OECD 309 guidelines in the dark for 62 days at a temperature of 23.2 °C. Negligible degradation of penflufen was seen during the study and no

			novel metabolites of relevance were formed. Due to the lack of degradation, no kinetic analysis was performed on the results of the study and no DT50 was derived. Hydrolytically stable at 50°C and pH 4 – 9. EFSA Data
DT_{50} for photolysis in surface water	17.3	D	Direct photolysis DT50 : 17.3 experimental days Natural light, 130.6 days (Greece), 163.6 days (London). Indirect photolysis DT50: 3.98 experimental days Natural light, 33.1 days (Greece), 41.4 days (London). Photometabolite I 5-fluoro-1,3-dimethyl-1H-pyrazole-4-carboxamide (M58) 6.8% AR (70 h but still increasing) Photometabolite II 5-fluoro-1,3 dimethyl-1H-pyrazole-4-carboxylic acid 9.7% AR (70 h but still increasing). EFSA data
DT_{50} for degradation in soil	214	d (at 12ºC)	
DT_{50} for degradation in air	Not Studied	d or hr	Not studied - no data requested. EFSA document comment
DT_{50} for degradation in STP	Not Studied	-	Justification for not performing STP degradation and simulation studies has not been provided by the applicant. However, the applicant has performed water/sediment studies

			and, as such, the UK CA considers that STP studies are not required for the risk assessment.

Input parameters (only set values) for calculating the fate and distribution in the environment : M01 (Penflufen-3-hydroxy-butyl)			
Input	Value	Unit	Remarks
Molecular weight	333.4		
Vapour pressure (at 25°C)	1.3E-09	Pa	
Water solubility (at 20°C)	95	$mg \cdot l^{-1}$	
Organic carbon/water partition coefficient (K_{oc})	38.2	$l \cdot kg^{-1}$	
1/n	0.93		
k_{psusp}	4.1	$l \cdot kg^{-1}$	
$k_{susp\text{-}water}$	1.93	$m^{3} \cdot m^{-3}$	
Ready Biodegradability	-		
DT_{50} for degradation in soil	180	d (at 12ºC)	

Input parameters (only set values) for calculating the fate and distribution in the environment : M02 (Penflufen-pyrazoyl-AAP)			
Input	Value	Unit	Remarks
Molecular weight	275.3		
Vapour pressure (at 25°C)	2.3E-06	Pa	
Water solubility (at 20°C)	3.6	$mg \cdot l^{-1}$	
Organic carbon/water partition coefficient (K_{oc})	1006	$l \cdot kg^{-1}$	
1/n	0.747		
k_{psusp}	101	$l \cdot kg^{-1}$	
$k_{susp\text{-}water}$	26.1	$m^{3} \cdot m^{-3}$	
Ready Biodegradability	-		
DT_{50} for degradation in soil	311	d (at 12ºC)	

Calculation of metabolite concentrations					
Both metabolites are formed in concentrations above 10% AR in the soil compartment. For the surface water compartment only penflufen-3-hydroxy-butyl is relevant. The calculations of PEC values for the metabolites are based on the initial PEC value calculated for penflufen. The maximum "parent to metabolite conversion rate" and the "molecular weight ratio" are used for deducing a correction factor.					
Substance	Molecular weight (g/mol)	Molecular weight ratio	Max % AR	Corresponding correction factor	Compartment of occurrence
Penflufen	317.41	-	-		
MO1 Penflufen-3-hydroxy-butyl)	333.4	1.05	17.0	0.1786	soil
			1.07	0.1124	water
MO2	275.3	0.87	11.5	0.0097	soil

(Penflufen-pyrazolyl-AAP)					

Input parameters (only set values) for calculating the fate and distribution in the environment: DDACarbonate			
Input	Value	Unit	Remarks
Molecular weight	381.3		(g/mol)
Vapour pressure (at 25°C)	7.7E-03	Pa	
Water solubility (at 20°C)	7.96E+05	$mg \cdot l^{-1}$	
Log Octanol/water partition coefficient (Kow)	0.053	-	Log 10
Organic carbon/water partition coefficient (K_{oc})	4.0E+05	$l \cdot kg^{-1}$	
Henry's Law Constant (at 25° C)	1.78E-06	$Pa \cdot m^3 \cdot mol^{-1}$	
k_{psusp}	4.0E+04	$l \cdot kg^{-1}$	
$k_{susp-water}$	10000.9	$m^3 \cdot m^{-3}$	
$k_{soil-water}$	1200.2	$m^3 \cdot m^{-3}$	Calculated using K_{oc} and equations 26 and 27 of the BPR Guidance Vol IV as outlined in annex 3.7
Biodegradability	Ready biodegradable	-	-
DT50 for degradation in soil	30	d (at 12ºC)	

Calculated fate and distribution in the STP: Copper		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	1.45E-04	Figures as for Copper carbonate hydroxide
Water	13.9	
Sludge	86.1	
Degraded in STP	0	

Calculated fate and distribution in the STP: **DDACarbonate**		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	4.32E-08	Behaviour of DDACarbonate has been revised in line with
Water	7.32	

Sludge	84.5	SimpleTreat v3.1 as EU evaluation followed Appendix II of TGD (2003)

The CAR report for penflufen (2017). Fate and distribution of penflufen and relevant metabolites in the STP.

Calculated fate and distribution in the STP				
Compartment	**Percentage [%]**			**Remarks**
	Penflufen	**M01**	**M02**	
Air	1.45E-05	4.06E-09	1.38E-04	Values derived using the SimpleTreat v3.1 model
Water	96.60	99.50	88.9	
Sludge	3.37	0.48	11.1	
Degraded	0.000	0.000	0.000	

The applicant carried out a new fate and distribution in the STP for penflufen using Simple Treat 4.0. Input data used in Simple Treat 4.0 and output results are shown in Annex 3.7.8 (Simple Trear 4.0 Export file – Penflufen)

Calculated fate and distribution in the STP: Penflufen		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	0	Calculated in Simple Treat 4.0
Water	96.51	
Sludge	3.49	
Degraded in STP	0	

Calculated PEC values

The detailed description of equations used to calculation the active substance PECs in the different environmental compartments are shown in confidential Annex 3.7. A summary of the PEC values in each environmental compartment is presented in this section.

For copper, background concentrations from the copper hydroxide CAR (2011) have been considered which are detailed below.

Copper background concentrations used for PEC calculations

Compartment	**Natural/pristine background concentration**	**Regional background concentration**	**Unit**
Surface water	0.88	2.9	[$\mu g.L^{-1}$]
Ground water	0.88	2.9	[$\mu g.L^{-1}$]
Soil	10.6	21.6	[$mg.kg_{wwt}^{-1}$]

Sediment	4.56	14.7	[$mg.kg_{wwt}^{-1}$]

	Background Concentrations of Copper with ageing factor			
	Pristine	Pristine * ageing factor	Regional	Regional * ageing factor
	$mg \cdot kg^{-1}_{wwt}$	$mg \cdot kg^{-1}_{wwt}$	$mg \cdot kg^{-1}_{wwt}$	$mg \cdot kg^{-1}_{wwt}$
Soil	10.6	5.3	21.6	10.8
Sediment	4.56	-	14.7	-

The copper + background concentration will be calculated by:

Total copper concentration =

calculated copper added in the scenario + relevant copper background concentration

In the case of soil the copper ageing factor 2 is applied to long term (> 18 months) concentrations in the soil.

In order to consider the phenomenon of copper ageing in soil, an ageing factor of 2 was applied on the total copper concentrations in soil for the values calculated in TIME 2 (7300 days).

In addition, this ageing factor of 2 has been applied to the background soil copper concentration at Time 1 as, by definition, the background copper can be expected to have been present for longer than 18 months

Time 1 (30 days):
Copper concentration assessed =
calculated copper added in the scenario + relevant copper background concentration/2

Time 2 (7300 days):
Copper concentration assessed =
(calculated copper added in the scenario + relevant copper background concentration)/2

Note that the copper concentrations are specified separately in all following Tables with PECs. This allows to demonstrate the effect of the background concentrations on the final PEC results.

According Table 5-4 of the CAR for penflufen:
In calculation of PECs for soil and grownd water compartments, penflufen and its two metabolites (MO1 & MO2) are relevant. In calculation of PECs for surfacewater, penflufen with its metabolite MO1 are relevant for the STP in the noise barrier scenario.
In calculation of PECs for STP and sediment compartments only penflufen without its metabolites is relevant.

PECsoil, PECsurfacewater, PECstp and PECsediment for Scenario 1

Scenario 1, Use Class 3: Time 1

Scenario 1 (UC 3): Copper with background PECs			
	TIME 1: 30 days		
	Copper added	**Copper added + Pristine**	**Copper added + regional background**
PECsoil mg/kg wwt			
	= $PEC_{Cu\ added}$	**=$PEC_{Cu\ added}$ + Cu Pristine Background/2**	**=$PEC_{Cu\ added}$ + Cu Regional Background /2**
House	2.15E-01	5.51E+00	1.10E+01
Fence	1.79E-01	5.48E+00	1.10E+01
PECsurfacewater µg/l			
	= $PEC_{Cu\ added}$	**=$PEC_{Cu\ added}$ + Cu Pristine Background**	**=$PEC_{Cu\ added}$ + Cu Regional Background**
Noise barrier	1.27E-02	8.93E-01	2.91E+00
Bridge over pond	5.52E-03	8.86E-01	2.91E+00
PECstp µg/l			
Noise barrier	1.85E-01	-	-
PECsediment mg/kg wwt			
Noise barrier	8.36E-02	4.64E+00	1.48E+01
Bridge over pond	3.63E-02	4.60E+00	1.47E+01

Scenario 1, Use Class 3: Time 1

Scenario 1 (UC3), Organic active substances and metabolites PECs				
	TIME 1: 30 days			
	Penflufen	**M01**	**M02**	**DDA^{+}**
PECsoil mg/kg wwt				
House	3.11E-04	5.83E-05	3.26E-05	4.47E-05
Fence	2.59E-04	4.85E-05	2.71E-05	3.72E-05
PECsurfacewater µg/l				
Noise barrier	1.95-04	2.19E-05		1.75E-06
Bridge over pond	2.69E-04	3.02E-05	-	7.31E-07
PECstp µg/l				
Noise barrier	1.95E-03	-	-	2.80E-05
PECsediment mg/kg wwt				
Noise barrier	1.34E-06	-	-	1.52E-05
Bridge over pond	1.85E-06	-	-	6.35E-06

Scenario 1, Use Class 3: Time 365 days

Scenario 1 (UC3), Copper with background PECs			
	365 days		
	Copper added	**Copper added + Pristine**	**Copper added + regional background**
PECsoil mg/kg wwt			
	= $PEC_{Cu\ added}$	**=$PEC_{Cu\ added}$ + Cu Pristine Background/2**	**=$PEC_{Cu\ added}$ + Cu Regional Background*0.5**
House	1.92E+00	7.22E+00	1.27E+01
Fence	1.60E+00	6.90E+00	1.24E+01
PECsurfacewater µg/l			
	= $PEC_{Cu\ added}$	**=$PEC_{Cu\ added}$ + Cu Pristine Background**	**=$PEC_{Cu\ added}$ + Cu Regional Background**
Noise barrier	9.36E-03	8.89E-01	2.91E+00
Bridge over pond	4.94E-02	9.29E-01	2.95E+00
PECstp µg/l			
Noise barrier*	1.36E-01	-	-
PECsediment mg/kg wwt			
Noise barrier	6.15E-02	4.62E+00	1.48E+01
Bridge over pond	3.25E-01	4.88E+00	1.50E+01

Scenario 1, Use Class 3: Time 365 days

Scenario 1 (UC3), Organic Active Substances and metabolites PECs				
	365 days			
	Penflufen	**M01**	**M02**	**DDA^{+}**
PECsoil mg/kg wwt				
House	9.70E-04	2.95E-04	1.65E-04	3.47E-05
Fence	8.07E-04	2.46E-04	1.37E-04	2.89E-05
PECsurfacewater µg/l				
Noise barrier	8.11E-05	9.12E-06	-	6.82E-07
Bridge over pond	8.49E-04	9.54E-05	-	5.82E-07
PECstp µg/l				
Noise barrier	8.11E-04	-	-	1.09E-05
PECsediment mg/kg wwt				
Noise barrier	5.57E-07	-	-	5.93E-06
Bridge over pond	5.83E-06	-	-	5.06E-06

Scenario 1, Use Class 3: Time 2

Scenario 1 (UC3), Copper with background PECs			
	TIME 2: 7300 days		
	Copper added	**Copper added + Pristine**	**Copper added + regional background**
PECsoil mg/kg wwt			
	= $PEC_{Cu\ added}$ /2	**=($PEC_{Cu\ added}$ + Cu Pristine Background)/2**	**=($PEC_{Cu\ added}$ + Cu Regional Background)/2**
House	1.92E+01	2.45E+01	3.00E+01
Fence	1.60E+01	2.13E+01	2.68E+01
PECsurfacewater µg/l			
	= $PEC_{Cu\ added}$	**=$PEC_{Cu\ added}$ + Cu Pristine Background**	**=$PEC_{Cu\ added}$ + Cu Regional Background**
Noise barrier	9.36E-03	8.89E-01	2.91E+00
Bridge over pond (Tier 1)	9.89E-01	1.87E+00	3.89E+00
Bridge over pond (Tier 2)	5.05E-01	1.39E+00	3.41E+00
PECstp µg/l			
Noise barrier	1.36E-01	-	-
PECsediment mg/kg wwt			
Noise barrier	6.15E-02	4.62E+00	1.48E+01

Bridge over pond (Tier 1)	6.50E+00	1.11E+01	2.12E+01
Bridge over pond (Tier 2)	3.32E+00	7.88E+00	1.80E+01

Scenario 1, Use Class 3: Time 2

Scenario 1 (UC3), Organic active substances and metabolites PECs				
	TIME 2: 7300 days			
	Penflufen	**M01**	**M02**	**DDA^{+}**
PECsoil mg/kg wwt				
House	1.40E-03	5.90E-03	3.30E-03	3.47E-05
Fence	1.16E-03	4.91E-03	2.74E-03	2.89E-05
PECsurfacewater µg/l				
Noise barrier	8.11E-05	9.12E-06		6.82E-07
Bridge over pond	1.58E-03	1.77E-04		6.19E-07
PECstp µg/l				
Noise barrier	8.11E-04	-	-	1.09E-05
PECsediment mg/kg wwt				
Noise barrier	5.57E-07	-	-	5.93E-06
Bridge over pond	1.08E-05	-	-	5.38E-06

PECsoil for Scenario 2 (UC4a, Transmission pole).

Scenario 2 (UC4a): Copper			
	TIME 1: 30 days		
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**
PECsoil mg/kg wwt			
	= $PEC_{Cu\ added}$	**=$PEC_{Cu\ added}$ + Cu Pristine Background/2**	**=$PEC_{Cu\ added}$ + Cu Regional Background/2**
Transmission Pole	3.80E+00	9.10E+00	1.46E+01

Scenario 2 (UC4a): Organic active substance and metabolites				
	TIME 1: 30 days			
	Penflufen	**M01**	**M02**	**DDA^{+}**
PECsoil mg/kg wwt				

Transmission Pole	3.12E-02	5.86E-03	3.27E-03	6.41E-03

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Scenario 2 (UC4a): Copper PECs			
	365 days		
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**
PECsoil mg/kg wwt			
	= $PEC_{Cu\ added}$	**=$PEC_{Cu\ added}$ + Cu Pristine Background/2**	**=$PEC_{Cu\ added}$ + Cu Regional Background /2**
Transmission Pole	9.37E+00	1.47E+01	2.02E+01

Scenario 2(UC4a): Organic active substance and metabolites				
	365 days			
	Penflufen	**M01**	**M02**	**DDA^{+}**
PECsoil mg/kg wwt				
Transmission Pole	4.73E-02	1.44E-02	8.04E-03	2.46E-03

****

Scenario 2 (UC4a): Copper			
	TIME 2: 7300 days		
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**
PECsoil mg/kg wwt			
	= $PEC_{Cu\ added}$ *0.5	**=($PEC_{Cu\ added}$ + Cu Pristine Background)/2**	**=($PEC_{Cu\ added}$ + Cu Regional Background)/2**
Transmission Pole	9.48E+00	1.48E+01	2.03E+01

Scenario 2 (UC4a): Organic active substance and metabolite				
	TIME 2: 7300 days			
	Penflufen	**M01**	**M02**	**DDA^{+}**
PECsoil mg/kg wwt				

Transmission Pole	6.54E-03	2.76E-02	1.54E-02	2.07E-04

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PECs groundwater: Scenario 1 (House scenario) and Scenario 2 (Railway sleepers)

PECs Groundwater: Copper and DDA^+ - the soil pore water calculations

Assessment for Tanasote S40 at the proposed product application rate of 100 kg/m^3 Scenario 1 (House scenario) and 133 kg/m^3 Scenario 2 (Railway sleepers).

The cladded House groundwater scenario is included as the worst case UC 3 agreed assessment scenario for groundwater.

The scenario for the railway sleepers UC3 is used as a first tier to assess the exposure to the groundwater compartment for UC4 (ENV WG-IV-2017, TAB ENV v.2.1, 2019), however the maximum product retention rate in the treated wood is assessed (133 kg/m^3) as for UC4.

Copper and DDA^+ cannot be modelled using the FOCUS PEARL software. They are both ionic (and copper is an elemental metal); it is recognised that PEARL is not suitable for modelling these kinds of substances.

Copper does require a groundwater assessment, however the FOCUS PEARL model is not currently suitable for estimating the mobility of metals. The guidance on the BPR (Vol IV, Environment Parts B+C ECHA 2017, section 4.5.1) discusses risk characterisation for metals and metal compounds. It notes that there are several processes that operate specifically with metals and affect distribution over the soil compartment. These processes are not modelled within PEARL. The section notes that pore water concentration is relevant for various organisms. Other factors may contribute but it is not currently known how to account for these. Therefore, as an indication of the potential groundwater levels, a pore-water calculation for copper was conducted and results are presented in tables below.

In the assessment report for copper hydroxide PT 8 (2011, section 2.2.2.3.5, p.28) it was accepted that copper is strongly absorbed and immobile in soil. Therefore, no copper is expected to reach groundwater, and copper hydroxide as a wood preservative is not expected to pose a risk for groundwater contamination following the use of Tanasote S40.

DDA^+ is also strongly bound to soil. The high value of K_{oc} and hence $K_{soil\text{-}water}$ (see table of DDA^+ input parameters above) shows the substance to be immobile and no groundwater assessment is necessary. In addition, since the net charge of soil is negative the cationic DDA^+ will be retained by soil. The DDACarbonate CA report (2012, p.58) notes that no data is required for ground water. DDAChloride shares the same active DDA^+ cation as DDACarbonate. The DDAChloride CA report (2012, p.37) that there is little or no potential for mobility in soil and the material should not pose a risk to groundwater. The DDAChloride CA report (2012, p.47) calculates the concentration in pore water as an indication for potential for groundwater levels. This approach will be followed here.

An assessment is presented using the soil pore water calculations, for a complete picture of the impact of Tanasote S40. It should be noted that the assessment does not take the degradation of DDA^+ into account and hence the figures shown for this are worst case.

The leaching rates (corrected for retention rate) reported in §2.2.8 section "Leaching behaviour (ADS)" are used for the groundwater assessment. In tables of section Leaching Behaviour the leaching loss values (mg/m^2) are presented, these values are converted to (mg/m^2) and considered as cumulative quantities of a substances leached out of 1 m² of treated wood over the assessment period.

The cumulative quanty of active substance leached per hectare are calculated assuming the defaults in the UC3 groundwater assessment (House scenario) using equations 4.43 and 4.44 from ESD PT8 (Groundwater, ENV/JM/MONO(2013)21, p.70). A density of 16 houses per hectare is assumed. Each of the 16 houses is assumed to have an outer wooden area treated with wood preservatives and relevant for leaching of 125 m², resulting in a total (leachable) area of 2000 m² per hectare ESD PT8 (Groundwater 2013, p.176).

A depth of 50 cm is assumed for the environmental compartment under the house. The distribution of rain on the house surface due to exposure to different orientation is taken into account by inclusions of a "weatherside fraction" $F_{weatherside}$=0.5 for the leaching rate is derived from semi-field or field tests.

The analogous default values used in railway sleepers scenario are as follows: the surface area of one sleeper is $AREA_{sleepers}$= 1.59 m²; the number of sleepers in a rectangular field of 1 hectare is $N_{sleepers}$=2583 Cumulative quantity of a substance, leached over the initial assessment period on one hectare for emission scenario for treated railway sleepers in service calculated by equations 4.128 and 4.129 from ESD PT8 (Groundwater 2013, p.117-118).

The pore water concentration is calculated according to Guidance on BPR: Vol IV Environment (Parts B+C Version 2.0, October 2017, p.93, Equation 70), see further detailed in Annex 3.7.

The house groundwater assessment is not addressed in the ECHA PT8 spread sheet and is therefore given greater detail here. A similar level of detail is given to the railway sleeper scenario to be consistent in the presentation of groundwater assessments.

Scenario 1 (UC 3) House scenario

UC3 Groundwater assessment for Copper and DDA^+			
Leachable area of one house		125	m^2
Density of houses		16	$hectare^{-1}$
Weatherside fraction		0.5	
Soil volume (wet)		5000	m^3
Bulk density of wet soil		1700	$kg \cdot m^{-3}$
Cumulative quantity of substance, leached over the initial assessment period, Time1 (30 days)	Copper	3.80E-02	$kg \cdot ha^{-1}$
	DDA^+	1.09E-05	
	Copper	6.81E+00	$kg \cdot ha^{-1}$

Cumulative quantity of substance, leached over the longer assessment period, Time2 (7300 days)	DDA+	1.04E-03	
Concentration in local soil at the end of the initial assessment period, Time1 (30 days)	Copper (added)	4.47E-03	mg·kg^{-1}$_{wwt}$
	DDA+	1.27E-06	
Concentration in local soil at the end of the longer assessment period, Time2 (7300 days)	Copper (added)	8.05E-01	mg·kg^{-1}$_{wwt}$
	DDA+	1.22E-04	
$$PEClocal_{soil,porew} = \frac{PEClocal_{soil} \cdot RHO_{soil}}{K_{soil\text{-}water} \cdot 1000}$$			Guidance on BPR: Vol IV Environment Parts B+C Version 2.0 October 2017, Eq.70, p. 93
$K_{soil\text{-}water}$	Copper (added)	3180.2	m^3·m^{-3}
	DDA+	12000.2	
Concentration in porewater at the end of the initial assessment period, Time1 (30 days)	Copper (added)	2.39E-06	mg·l^{-1}
	Copper (+pristine)	8.82E-04	
	Copper (+regional)	2.90E-03	
	DDA+	6.33E-07	
Concentration in porewater at the end of the longer assessment period, Time2 (7300)	Copper (added)	4.30E-04	mg·l^{-1}
	Copper (+pristine)	1.31E-03	
	Copper (+regional)	3.33E-03	
	DDA+	1.73E-07	

Scenario 2 (UC 4a) Railway sleepers

UC4a Groundwater assessment for Copper and DDA+			
Leachable area per railway sleeper		1.59	m^2
Number of sleepers in 1 hectare		2583	hectare^{-1}
Total surface area of wood		4110	m^2
Soil volume (wet)		5000	m^3
Bulk density of wet soil		1700	kg·m^{-3}
Cumulative quantity of substance, leached over the initial assessment period, Time1 (30 days)	Copper	2.08E-01	kg·ha^{-1}
	DDA+	6.04E-05	

Cumulative quantity of substance, leached over the longer assessment period Time2 (7300 days)	Copper	3.72E+01	kg·ha^{-1}
	DDA^{+}	5.70E-03	
PECsoil, Concentration in local soil at the end of the initial assessment period Time1 (30 days)	Copper (added)	2.45E-02	mg·kg^{-1}$_{wwt}$
	DDA^{+}	7.10E-06	
PECsoil, Concentration in local soil at the end of the longer assessment period Time2 (7300 days)	Copper (added)	4.40E+00	mg·kg^{-1}$_{wwt}$
	DDA^{+}	6.70E-04	
$$PEClocal_{soil,porew} = \frac{PEClocal_{soil} \cdot RHO_{soil}}{K_{soil\text{-}water} \cdot 1000}$$			Guidance on BPR: Vol IV Environnent Parts B+C, ECHA 2017, p.93, Eq.70.
$K_{soil\text{-}water}$	Copper (added)	3180.2	m^{3}·m^{-3}
	DDA^{+}	12000.2	
PECgw, Concentration in porewater at the end of the initial assessment period Time1 (30 days)	Copper (added)	1.31E-05	mg·l^{-1}
	Copper (+pristine)	8.93E-04	
	Copper (+regional)	2.91E-03	
	DDA^{+}	1.01E-09	
PECgw, Concentration in porewater at the end of the longer assessment period Time2 (7300 days)	Copper (added)	2.35E-03	mg·l^{-1}
	Copper (+pristine)	3.23E-03	
	Copper (+regional)	5.25E-03	
	DDA^{+}	9.49E-08	

The PECgw values for the noise barrier scenario have not been determined as the risk is covered by emissions from the 'House' scenario.

The calculated copper PECgw values in both scenarios have been compared to the drinking water standard for copper (set at 2.0 mg/L) and therefore predicted emissions of copper from wood treated with Tanasote S40 are considered acceptable.

The calculated DDA^{+} PECgw values in both scenarios have been compared to the drinking water standard the EU trigger value of 0.1 µg/L (Directive 98/83/EC) and predicted emissions of DDA^{+} from wood treated with Tanasote S40 are considered acceptable.

PECs Groundwater: Penflufen and metabolites (M01 & M02) – the calculation using FOCUS PEARL

FOCUS PEARL 4.4.4 modelling for Tanasote S40 at the proposed product application rate of 100 kg/m^3 Scenario1 (House scenario) and 133 kg/m^3 Scenario 2 (Railway sleepers scenario) for Penflufen plus its two metabolites MO1 and MO2.

It can be ruled out that DDACarbonate will not reach groundwater as it is immobile, therefore there is negligible risk to groundwater and no assessment is necessary using FOCUS PEARL model, only a pore-water calculation was conducted.

Copper does require a groundwater assessment, however the FOCUS PEARL model is not currently suitable for estimating the mobility of metals. Therefore, as an indication of the potential groundwater levels, a pore-water calculation was conducted.

To assess the risk posed to groundwater from Penflufen, metabolites MO1 and MO2, PEC groundwater values were determined.

The pseudo-application rate for PEARL was determined from extrapolated cumulative loss over service life divided by service life.

In addition it should be noted that several assumptions are made in the groundwater assessment calculation that will be likely to lead to an overestimate of exposure:

- The groundwater assessment assumes that all inputs to the aquifer come from land containing buildings with a high density of treated wood. In reality, it would be expected that the aquifer would also receive inputs from areas where the density of treated wood was much lower, thus lowering the groundwater concentration via dilution.

- For the groundwater exposure assessment, all leachate losses from treated timbers are assumed to be available for leaching to groundwater with no interception by surface drainage systems. Similarly, for the surface water assessment all leachate losses are assumed to enter surface water, with no loss via vertical leaching. This represents a conservative assessment for each of compartment and in reality losses are likely to be distributed between both surface and groundwater.

- The output from the FOCUS groundwater models represent predicted concentrations at a depth of 1 m. In reality most groundwater aquifers used for water abstraction purposes will be much deeper and consequently the potential for further degradation, adsorption or dilution to occur before residues reach such an aquifer could be significant and further reduce concentrations expected under realistic use conditions.

Scenario 1: Assumptions in house scenario - FOCUS PEARL model

The following assumptions were made for all nine FOCUS scenarios:

1. Wood is treated with active substances at appropriate rates (corresponding to a product retention rate of 100 kg/m^3).

2. The housing density is 16 houses per hectare with each house having treated area of 125 m^2, which results in the total area of 2000 m^2 treated wood per hectare.

3. Emission of active substances has been modelled using data from the semi-field leaching studies.

4. All the compound enters the soil compartment in 10 equally spaced events per year to simulate the leaching.

5. Application rates entered within FOCUS PEARL 4.4.4 are based on ten equal applications throughout the year. The application rates are calculated as below.

Penflufen

Predicted annual loss for the house scenario in FOCUS PEARL modelling would be:

Cumulative quantity of a penflufen leached out of 1 m² of treated wood over a longer assessment period (extrapolated loss over 20 years: Time 2) **5.84 mg/m²** (see value leaching rate table) is devided on 20 years.

5.84 mg/m^2 /20 (20 year service life) =0.29 mg/m^2 =0.29E-6 kg/m^2 per year

Extrapolation worst case "new build" total loss from service life per year 0.29E-6 kg/m^2/yr;

0.29E-6 kg/m^2 * (16 HOUSEs per ha *125 m^2 treated wood) =
=0.29E-6 kg/m^2 x 2000 m^2/ha = 5.84E-04kg/ha/yr;

5.84E-04 kg/ha/yr /10 monthly applications/yr = 5.84E-05 kg/ha/application;

$F_{weatherside}$ *5.84E-04 kg/ha/appl = 0.5 *5,84E-05= **2.92E-05 kg/ha/application**.
Where default value for "weatherside fraction" $F_{weatherside}$ of 0.5 for leaching rate derived from semi-field tests (ESD PT8 Groundwater, p.177).

Scenario 2: Assumptions Railway scenario - FOCUS PEARL model

Penflufen

Predicted annual loss for the railway sleepers scenario in FOCUS modelling would be:

Cumulative quantity of a substance leached out of 1 m² of treated wood over a longer assessment period (Time2=20 years) is **8.03 mg/m²** (see value leaching rate table) is devided on 20 years.

8.03 mg/m^2 /20 (20 year service life) =0.402 mg/m^2 =0.402E-6 kg/m^2 per year

Extrapolation worst case "new build" total loss from service life per year 0.402E-6 kg/m^2/yr;

0.402E-6 kg/m^2/yr * $AREA_{sleepers}$ *$N_{sleepers}$ =0.402E-6 kg/m^2 *(1.59 m^2 *2583) =
=0.402E-6 kg/m^2 x 4107 m^2/ha = 1.65E-3 kg/ha/yr, where surface area of one sleeper is $AREA_{sleepers}$= 1.59 m², the number of sleepers in a rectangular field of 1 hectare is $N_{sleepers}$=2583 (ESD PT8 Growndwater, p.117-118).

Application rate calculated from the annual leaching rate converted to 10 equal applications per annum (kg/ha):
1.65E-3 kg/ha/yr /10 applications/yr = **1.65E-04 kg/ha/application.**

For wood preservation use, the predicted environmental concentration in groundwater (as represented by the 80th percentile leachate concentration at 1 m soil depth) for the Penflufen and two metabolites MO1 and MO2 are shown in the tables below;

The cumulative quantity of penflufen leached is divided by 20 years (=Time 2) to derive a yearly dose of penflufen to the soil. This is assumed to be applied to the soil in 10 equal amounts each year. The application doses for both scenarios are shown below.

Calculated application rate for penflufen used in FOCUS PEARL simulation	
Application rate (kg/ha/applic)	**Penflufen**
House dose per application (kg/ha/applic)	2.92E-05
Railway sleepers dose per application (kg/ha/applic)*	1.65E-04
* This dose calculated using the maximum retention for UC4 timbers and using UC3 leach data extrapolated.	

The outputs from FOCUS PEARL model are shown in the following two tables.

House scenario: PECgroundwater predicted for penflufen and metabolites MO1 and MO2, FOCUS PEARL 4.4.4			
Assessed retention UC3: 100kgm^{-3} product			
Soil type	**Penflufen (µg/l)**	**MO1 (µg/l)**	**MO2 (ug/l)**
Chateaudun	0.00E+00	4.34E-03	0.00E+00
Hamburg	1.00E-06	6.89E-03	0.00E+00
Jokionen	0.00E+00	4.97E-03	0.00E+00
Kremsmuenster	0.00E+00	4.35E-03	0.00E+00
Okehampton	1.00E-06	5.37E-03	0.00E+00
Piacenza	1.00E-06	4.74E-03	0.00E+00
Porto	0.00E+00	3.35E-03	0.00E+00
Sevilla	0.00E+00	1.86E-03	0.00E+00
Thiva	0.00E+00	2.93E-03	0.00E+00

Railway Sleeper scenario: PECgroundwater predicted for penflufen and metabolites MO1 and MO2, FOCUS PEARL 4.4.4			
Assessed retention: 133 kgm^{-3} product			
Soil type	**Penflufen (µg/l)**	**MO1 (µg/l)**	**MO2 (ug/l)**
Chateaudun	1.00E-06	3.13E-02	0.00E+00
Hamburg	1.70E-05	4.80E-02	0.00E+00
Jokionen	0.00E+00	3.82E-02	0.00E+00
Kremsmuenster	2.00E-06	3.04E-02	0.00E+00
Okehampton	1.80E-05	3.79E-02	0.00E+00
Piacenza	1.80E-05	3.22E-02	0.00E+00
Porto	3.00E-06	2.28E-02	0.00E+00
Sevilla	0.00E+00	1.56E-02	0.00E+00
Thiva	0.00E+00	2.22E-02	0.00E+00

The calculated PECgw values have been compared to the drinking water standard the EU trigger value of 0.1 µg/L (Directive 98/83/EC) and predicted emissions of Penflufen, metabolites MO1 & MO2 from wood treated with Tanasote S40 are considered acceptable.

Risk characterisation

In the following sections it is assumed that a PEC/PNEC ratio of < 1 is evidence that there is no risk in the specific context to which that ratio refers. In each case, overall compartment assessments are undertaken by calculating a Total PEC/PNEC for the compartment which is equal to the sum of the individual PEC/PNECs for each substance in that compartment. Copper background concentrations are taken in to account where applicable. Explicit equations to demonstrate are shown in each table.

Atmosphere

Conclusion:

All active substances of Tanasote S40 have low vapour pressures. None of the active substances are predicted to reach or remain within the air compartment and therefore no further assessment has been undertaken in line with other PT 8 products.

Sewage treatment plant (STP)

Scenario 1 (UC3: Noise barrier), PEC/PNECstp				
	Copper	**Penflufen**	**DDA^+**	**Total**
	A	**b**	**C**	
	= $PEC_{Cu\ added}/PNEC_{Cu}$	**=$PEC_{Pen}/PNEC_{Pen}$**	**=$PEC_{DDA^+}/PNEC_{DDA^+}$**	**=a+b+c+d**
PEC/PNECstp in-service				
Time 1 (30 days)	8.04E-04	1.79E-06	4.08E-08	8.06E-04
Time 2 (7300 days)	5.92E-04	7.44E-07	1.59E-08	5.92E-04
365 days	5.92E-04	7.44E-07	1.59E-08	5.92E-04

Conclusion:
None of the PEC/PNEC ratios or the sum of ratios is not greater than 1 for any time point. The risks posed to local STP can be considered acceptable from industrial application plus in-service losses.

Aquatic compartment

In all the following tables the PEC and PNEC in each respective table are understood to refer to the compartment presented in that table. This avoids over-complication of the labelling. The series of tables are delimited into groups of three by symbols: (**********).

Surface Water: Time 1 (30 days)

The surface water assessments do not include a Tier 2 assessment.

Scenario 1 (UC3), Copper PEC/PNECs			
	TIME 1: 30 days		
	Copper added	Copper added + Pristine	Copper added + Regional background
	= $PEC_{Cu\ added}/PNEC_{Cu}$	=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$	=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$
PEC/PNECsurfacewater			
Noise barrier via STP	1.63E-03	1.14E-01	3.73E-01
Bridge over pond	7.08E-04	1.14E-01	3.73E-01

Scenario 1 (UC3), Organic active substances and metabolites PEC/PNECs					
	TIME 1: 30 days				
	Penflufen	M01	M02	DDA^+	Total PEC/PNEC organic components
	A	b	c	d	
	=PEC_{Pen}/ $PNEC_{Pen}$	=PEC_{MO1}/ $PNEC_{MO1}$	=PEC_{MO2}/ $PNEC_{MO2}$	=PEC_{DDA^+}/ $PNEC_{DDA^+}$	=a+b+c+d
PEC/PNECsurfacewater					
Noise barrier via STP	8.34E-05	1.40E-06	-	1.35E-06	8.61E-05
Bridge over pond	1.15E-04	1.92E-06	-	5.62E-07	1.17E-04

Scenario 1 (UC3), Summation PEC/PNECs			
	Total PEC/PNEC TIME 1: 30 days		
	Copper added	Copper added + Pristine	Copper added + Regional background
	= $PEC_{Cu\ added}/PNEC_{Cu}$ + Total	=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$	=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$

	PEC/PNEC organic components	+ Total PEC/PNEC organic components	+ Total PEC/PNEC organic components
PEC/PNECsurfacewater			
Noise barrier via STP	1.72E-03	1.15E-01	3.74E-01
Bridge over pond	8.25E-04	1.14E-01	3.73E-01

****

Sediment: Time 1 (30 days)

Scenario 1 (UC3), Copper PEC/PNECs			
	TIME 1: 30 days		
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**
	= $PEC_{Cu\ added}/PNEC_{Cu}$	**=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$**	**=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$**
PEC/PNECsediment			
Noise barrier via STP	4.42E-03	2.46E-01	7.82E-01
Bridge over pond	1.92E-03	2.43E-01	7.80E-01

Scenario 1 (UC3), Organic active substances and metabolites PEC/PNECs					
	TIME 1: 30 days				
	Penflufen	**M01**	**M02**	**DDA^+**	**Total**
	A	**b**	**c**	**d**	
	=PEC_{Pen}/ $PNEC_{Pen}$	**=PEC_{MO1}/ $PNEC_{MO1}$**	**=PEC_{MO2}/ $PNEC_{MO2}$**	**=PEC_{DDA^+}/ $PNEC_{DDA^+}$**	**=a+b+c+d**
PEC/PNECsediment					
Noise barrier via STP	8.37E-05	-	-	3.14E-03	3.22E-03
Bridge over pond	1.15E-04	-	-	1.31E-03	1.42E-03

Scenario 1 (UC3), Summation PEC/PNECs			
	Total PEC/PNEC TIME 1: 30 days		
	Copper added	Copper added + Pristine	Copper added + Regional background
	= $PEC_{Cu\ added}/PNEC_{Cu}$ + Total PEC/PNEC organic components	=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$ + Total PEC/PNEC organic components	=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$ + Total PEC/PNEC organic components
PEC/PNECsediment Tier 1			
Noise barrier via STP	5.43E-03	1.26E-01	3.94E-01
Bridge over pond	3.34E-03	2.45E-01	7.81E-01

****

Surface Water: 365 days

The surface water assessments do not include a Tier 2 assessment.

Scenario 1 (UC3), Copper PEC/PNECs			
	365 Days		
	Copper added	Copper added + Pristine	Copper added + Regional background
	= $PEC_{Cu\ added}/PNEC_{Cu}$	=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$	=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$
PEC/PNECsurfacewater			
Noise barrier via STP	1.20E-03	1.14E-01	3.73E-01
Bridge over pond	6.34E-03	1.19E-01	3.78E-01

Scenario 1 (UC 3), Organic active substances and metabolites PEC/PNECs					
	365 Days				
	Penflufen	M01	M02	DDA^+	Total
	a	b	c	d	
	=$PEC_{Pen}/PNEC_{Pen}$	=$PEC_{MO1}/PNEC_{MO1}$	=$PEC_{MO2}/PNEC_{MO2}$	=$PEC_{DDA^+}/PNEC_{DDA^+}$	=a+b+c+d
PEC/PNECsurfacewater					
Noise barrier via STP	3.47E-05	5.81E-07	-	5.24E-07	3.58E-05
Bridge over pond	3.63E-04	6.08E-06	-	4.48E-07	3.69E-04

Scenario 1 (UC3), Summation PEC/PNECs			
	Total PEC/PNEC 365 Days		
	Copper added	Copper added + Pristine	Copper added + Regional background
	= $PEC_{Cu\ added}/PNEC_{Cu}$ + Total PEC/PNEC organic components	=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$ + Total PEC/PNEC organic components	=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$ + Total PEC/PNEC organic components
PEC/PNECsurfacewater			
Noise barrier via STP	1.24E-03	1.14E-01	3.73E-01
Bridge over pond	6.71E-03	1.20E-01	3.79E-01

****

Sediment: Time 365 days.

The sediment assessments do not include a Tier 2 assessment.

Scenario 1 (UC3), Copper PEC/PNECs			
	Time 365 Days		
	Copper added	Copper added + Pristine	Copper added + Regional background
	= $PEC_{Cu\ added}/PNEC_{Cu}$	=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$	=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$
PEC/PNECsediment			
Noise barrier via STP	3.26E-03	2.45E-01	7.81E-01
Bridge over pond	1.72E-02	2.58E-01	7.95E-01

Scenario 1 (UC3), Organic active substances and metabolites PEC/PNECs					
	Time 365 Days				
	Penflufen	M01	M02	DDA^+	Total
	a	b	c	d	
	=PEC_{Pen}/ $PNEC_{Pen}$	=PEC_{MO1}/ $PNEC_{MO1}$	=PEC_{MO2}/ $PNEC_{MO2}$	=PEC_{DDA^+}/ $PNEC_{DDA^+}$	=a+b+c+ d
PEC/PNECsediment					

Noise barrier via STP	3.48E-05	-	-	1.22E-03	1.25E-03
Bridge over pond	3.64E-04	-	-	1.04E-03	1.41E-03

Scenario 1 (UC3), Summation PEC/PNECs			
	Time 365 Days		
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**
	= $PEC_{Cu\ added}$/$PNEC_{Cu}$ + Total PEC/PNEC organic components	**=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$ + Total PEC/PNEC organic components**	**=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$ + Total PEC/PNEC organic components**
PEC/PNECsediment Tier 1			
Noise barrier via STP	4.51E-03	2.46E-01	7.82E-01
Bridge over pond	1.86E-02	2.60E-01	7.96E-01

****

Surface Water: Time 2 (7300 days)

N.B. surface water assessments include a Tier 2 assessment for Bridge over pond scenario.

Scenario 1 (UC3), Copper PEC/PNECs			
	TIME 2: 7300 Days		
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**
	= $PEC_{Cu\ added}$/$PNEC_{Cu}$	**=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$**	**=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$**
PEC/PNECsurfacewater			
Noise barrier via STP	1.20E-03	1.14E-01	3.73E-01
Bridge over pond (Tier 1)	1.27E-01	2.40E-01	4.99E-01
Bridge over pond (Tier 2)	6.48E-02	1.78E-01	4.37E-01

Scenario 1 (UC3), Organic active substances and metabolites PEC/PNECs					
	TIME 2: 7300 Days				
	Penflufen	**M01**	**M02**	**DDA^+**	**Total**
	a	**b**	**C**	**d**	
	=PEC_{Pen}/ $PNEC_{Pen}$	**=PEC_{MO1}/ $PNEC_{MO1}$**	**=PEC_{MO2}/ $PNEC_{MO2}$**	**=PEC_{DDA^+}/ $PNEC_{DDA^+}$**	**=a+b+c+d**

PEC/PNECsurfacewater					
Noise barrier via STP	3.47E-05	5.81E-07	-	5.24E-07	3.58E-05
Bridge over pond	6.75E-04	1.13E-05	-	4.76E-07	6.87E-04

Scenario 1 (UC3), Summation PEC/PNECs			
	TIME 2: 7300 Days		
	Copper added	Copper added + Pristine	Copper added + Regional background
	= $PEC_{Cu\ added}/PNEC_{Cu}$+ Total PEC/PNEC organic components	=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$+ Total PEC/PNEC organic components	=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$+ Total PEC/PNEC organic components
PEC/PNECsurfacewater			
Noise barrier via STP	1.24E-03	1.14E-01	3.73E-01
Bridge over pond (Tier 1)	1.27E-01	2.40E-01	4.99E-01
Bridge over pond (Tier 2	6.54E-02	1.78E-01	4.37E-01

****

Sediment: Time 2 (7300 days)

N.B. sediment assessments include Tier 2 assessment

Scenario 1 (UC3), Copper PEC/PNECs			
	TIME 2: 7300 Days		
	Copper added	Copper added + Pristine	Copper added + Regional background
	= $PEC_{Cu\ added}$/ $PNEC_{Cu}$	=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$	=($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$
PEC/PNECsediment Tier 1			
Noise barrier via STP	3.26E-03	2.45E-01	7.81E-01
Bridge over pond	3.44E-01	5.85E-01	1.12E+00
PEC/PNECsediment Tier 2			
	= $PEC_{Cu\ added}/PNEC_{Cu\ Tier\ 2}$	=($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu\ Tier\ 2}$	=($PEC_{Cu\ added}$ + Cu Regional Background)/ $PNEC_{Cu\ Tier\ 2}$
Bridge over pond	1.76E-01	4.17E-01	9.53E-01

Scenario 1 (UC3), Organic active substances and metabolites PEC/PNECs					
	TIME 2: 7300 Days				
	Penflufen	M01	M02	DDA^+	Total
	a	b	c	D	
	$=PEC_{Pen}/PNEC_{Pen}$	$=PEC_{MO1}/PNEC_{MO1}$	$=PEC_{MO2}/PNEC_{MO2}$	$=PEC_{DDA^+}/PNEC_{DDA^+}$	=a+b+c+d
PEC/PNECsediment					
Noise barrier via STP	3.48E-05	-	-	1.22E-03	1.25E-03
Bridge over pond	6.78E-04	-	-	1.11E-03	1.79E-03

Scenario 1 (UC3), Summation PEC/PNECs			
TIME 2: 7300 days			
	Copper added	Copper added + Pristine	Copper added + Regional background
	$= PEC_{Cu\ added}/PNEC_{Cu}$+ Total PEC/PNEC organic components	$=(PEC_{Cu\ added}$ + Cu Pristine Background)$/PNEC_{Cu}$+ Total PEC/PNEC organic components	$=(PEC_{Cu\ added}$ + Cu Regional Background)$/PNEC_{Cu}$+ Total PEC/PNEC organic components
PEC/PNECsediment Tier 1			
Noise barrier via STP	4.51E-03	2.46E-01	7.82E-01
Bridge over pond	3.46E-01	5.87E-01	**1.12E+00**
PEC/PNECsediment Tier 2			
	$= PEC_{Cu\ added}/PNEC_{Cu\ Tier\ 2}$+ Total PEC/PNEC organic components	$=(PEC_{Cu\ added}$ + Cu Pristine Background)$/PNEC_{Cu\ Tier\ 2}$+ Total PEC/PNEC organic components	$=(PEC_{Cu\ added}$ + Cu Regional Background)$/PNEC_{Cu\ Tier\ 2}$+ Total PEC/PNEC organic components
Bridge over pond	1.77E-01	4.19E-01	9.55E-01

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Conclusion:

All of the PEC/PNEC ratios for the surface water compartment are less than 1. It can be concluded that there is no risk to this compartment from the use of Tanasote S40.

All of the PEC/PNEC ratios for the sediment compartment are less than 1 with the exception of the bridge over pond (UC3), Tier 1, Time 2 (7300 days), showing a marginal risk for the total PEC/PNEC including copper regional background. The bridge over pond, sediment compartment, in Tier 2 assessment shows no risk at Time 2 (7300 days). (Note: in Tier 2 applied Approach 2, period 7300 was defined as Time 3, where 7300 days is referred to as Time 2 here). Thus, it can be concluded that there are no long term risks to the sediment compartment.

In overall conclusion, there will be no risk to the aquatic compartments from the use of the product Tanasote S40 at the given retentions.

Terrestrial compartment

Soil: Time 1 (30 days)

The soil assessments do not include a Tier 2 assessment.

Copper PEC/PNECs, Scenario 1(UC3) & Scenario 2 (UC4a)			
	TIME 1: 30 days		
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**
	= $PEC_{Cu\ added}$/$PNEC_{Cu}$	**=($PEC_{Cu\ added}$ + Cu Pristine Background*0.5)/$PNEC_{Cu}$**	**=($PEC_{Cu\ added}$ + Cu Regional Background*0.5)/$PNEC_{Cu}$**
PEC/PNECsoil			
House	5.33E-03	1.37E-01	2.73E-01
Fence	4.43E-03	1.36E-01	2.72E-01
Transmission Pole	9.42E-02	2.26E-01	3.62E-01

Organic active substances and metabolites PEC/PNECS, Scenario 1(UC3) & Scenario 2 (UC4a)					
	TIME 1: 30 days				
	Penflufen	**M01**	**M02**	**DDA^+**	**Total**
	A	**b**	**c**	**D**	
	=PEC_{Pen}/$PNEC_{Pen}$	**=PEC_{MO1}/$PNEC_{MO1}$**	**=PEC_{MO2}/$PNEC_{MO2}$**	**=PEC_{DDA^+}/$PNEC_{DDA^+}$**	**=a+b+c+d**
PEC/PNECsoil					
House	8.26E-04	1.50E-04	1.01E-04	1.98E-04	1.28E-03

Fence	6.87E-04	1.24E-04	8.42E-05	1.65E-04	1.06E-03
Transmission Pole	8.29E-08	1.50E-02	1.02E-02	2.85E-02	5.36E-02

Summation PEC/PNECs, Scenario 1(UC3) & Scenario 2 (UC4a)			
	TIME 1: 30 days		
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**
	= $PEC_{Cu\ added}$/$PNEC_{Cu}$+ Total PEC/PNEC organic components	**=($PEC_{Cu\ added}$ + Cu Pristine Background*0.5)/$PNEC_{Cu}$+ Total PEC/PNEC organic components**	**=($PEC_{Cu\ added}$ + Cu Regional Background*0.5)/$PNEC_{Cu}$+ Total PEC/PNEC organic components**
PEC/PNECsoil			
House	6.60E-03	1.38E-01	2.74E-01
Fence	5.49E-03	1.37E-01	2.73E-01
Transmission Pole	1.48E-01	2.79E-01	4.16E-01

Soil: Time 365 days

The soil assessments do not include a Tier 2 assessment.

Copper PEC/PNECs, Scenario 1 (UC3) & Scenario 2 (UC4a)			
	Time: 365 days		
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**
	= $PEC_{Cu\ added}$/$PNEC_{Cu}$	**=($PEC_{Cu\ added}$ + Cu Pristine Background*0.5)/$PNEC_{Cu}$**	**=($PEC_{Cu\ added}$ + Cu Regional Background*0.5)/$PNEC_{Cu}$**
PEC/PNECsoil			
House	4.77E-02	1.79E-01	3.15E-01
Fence	3.97E-02	1.71E-01	3.07E-01
Transmission Pole	2.32E-01	3.64E-01	5.00E-01

Organic active substances and metabolites PEC/PNECS, Scenario 1 (UC3) & Scenario 2 (UC4a)					
	Time: 365 days				
	Penflufen	**M01**	**M02**	**DDA^+**	**Total**
	a	**b**	**c**	**d**	
	$=PEC_{Pen}/PNEC_{Pen}$	**$=PEC_{MO1}/PNEC_{MO1}$**	**$=PEC_{MO2}/PNEC_{MO2}$**	**$=PEC_{DDA^+}/PNEC_{DDA^+}$**	**=a+b+c+d**
PEC/PNECsoil					
House	2.57E-03	7.57E-04	5.12E-04	1.54E-04	3.99E-03
Fence	2.14E-03	6.30E-04	4.26E-04	1.28E-04	3.32E-03
Transmission Pole	1.25E-01	3.69E-02	2.50E-02	1.09E-02	1.98E-01

Summation PEC/PNECs, Scenario 1 (UC3) & Scenario 2 (UC4a)			
	Time: 365 days		
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**
	$= PEC_{Cu\ added}/PNEC_{Cu}$ + Total PEC/PNEC organic components	**$=(PEC_{Cu\ added}$ + Cu Pristine Background*0.5)/$PNEC_{Cu}$ + Total PEC/PNEC organic components**	**$=(PEC_{Cu\ added}$ + Cu Regional Background*0.5)/$PNEC_{Cu}$ + Total PEC/PNEC organic components**
PEC/PNECsoil			
House	5.17E-02	1.83E-01	3.19E-01
Fence	4.30E-02	1.74E-01	3.11E-01
Transmission Pole	4.30E-01	5.62E-01	6.98E-01

Soil: Time 2 (7300 days)

The soil assessments do not include a Tier 2 assessment.

Copper PEC/PNECs, Scenario 1 (UC3) & Scenario 2 (UC4a)			
	TIME 2: 7300 days		
	Copper added	Copper added + Pristine	Copper added + Regional background
	= 0.5*$PEC_{Cu\ added}/PNEC_{Cu}$	=0.5*($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$	=0.5*($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$
PEC/PNECsoil			
House	4.77E-01	6.08E-01	7.45E-01
Fence	3.97E-01	5.28E-01	6.65E-01
Transmission Pole	2.35E-01	3.66E-01	5.02E-01

Organic active substances and metabolites PEC/PNECS, Scenario 1 (UC3) & Scenario 2 (UC4a)					
	TIME 2: 7300 days				
	Penflufen	M01	M02	DDA^+	Total
	a	b	c	d	
	=PEC_{Pen}/ $PNEC_{Pen}$	=PEC_{MO1}/ $PNEC_{MO1}$	=PEC_{MO2}/ $PNEC_{MO2}$	=PEC_{DDA^+}/ $PNEC_{DDA^+}$	=a+b+c +d
PEC/PNECsoil					
House	3.71E-03	1.51E-02	1.02E-02	1.54E-04	2.92E-02
Fence	3.09E-03	1.26E-02	8.52E-03	1.28E-04	2.43E-02
Transmission Pole	1.73E-02	7.08E-02	4.79E-02	9.20E-04	1.37E-01

Summation PEC/PNECs, Scenario 1(UC3) & Scenario 2 (UC4a)			
	TIME 2: 7300 days		
	Copper added	Copper added + Pristine	Copper added + Regional background
	= 0.5*$PEC_{Cu\ added}/PNEC_{Cu}$ + Total PEC/PNEC organic components	=0.5*($PEC_{Cu\ added}$ + Cu Pristine Background)/$PNEC_{Cu}$ + Total PEC/PNEC organic components	=0.5*($PEC_{Cu\ added}$ + Cu Regional Background)/$PNEC_{Cu}$ + Total PEC/PNEC organic components
PEC/PNECsoil			
House	5.06E-01	6.38E-01	7.74E-01
Fence	4.21E-01	5.53E-01	6.89E-01
Transmission Pole	3.72E-01	5.03E-01	6.39E-01

Conclusion:

All of the PEC/PNEC ratios for the soil compartment in both scenarios Scenario 1 (UC3:House,Fance) & Scenario 2 (UC4a:Transmission pole) are less than 1. It can be concluded that there is no risk to the soil compartment from the use of Tanasote S40 at the given retentions.

Groundwater

No degradation of DDA^+ or ageing of copper is taken in to account, the concentrations of these species therefore increases linearly in the soil over the assessment period. If the assessment is acceptable at 30 days and 7300 days it will also be acceptable at 365 days.

Groundater (Pore Water PEC/PNECs)				
	TIME 1: 30 days			
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**	**DDA^+**
	= $PEC_{Cu\ added}$/ $PNEC_{Cu}$	**=($PEC_{Cu\ added}$ + Cu Pristine Background)/ $PNEC_{Cu}$**	**=($PEC_{Cu\ added}$ + Cu Regional Background)/ $PNEC_{Cu}$**	**=PEC_{DDA^+}/ $PNEC_{DDA^+}$**
PEC/PNECdrinking water				
House	1.20E-06	4.41E-04	1.45E-03	6.33E-03
Sleeper	6.55E-06	4.47E-04	1.46E-03	1.01E-05

Pore Water PEC/PNECs				
	TIME 2: 7300 days			
	Copper added	**Copper added + Pristine**	**Copper added + Regional background**	**DDA^+**
	= $PEC_{Cu\ added}$/ $PNEC_{Cu}$	**=($PEC_{Cu\ added}$ + Cu Pristine Background)/ $PNEC_{Cu}$**	**=($PEC_{Cu\ added}$ + Cu Regional Background)/ $PNEC_{Cu}$**	**=PEC_{DDA^+}/ $PNEC_{DDA^+}$**
PEC/PNECdrinking water				
House	2.15E-04	6.55E-04	1.67E-03	1.73E-04
Sleeper	1.18E-03	1.62E-03	2.63E-03	9.49E-04

UC 3 at 100 kg/m³ retention rate and UC 4a at 133 kg/m³ retention rate

The calculated PEC_{gw} values for penflufen (plus its metabolite MO1 and MO2) from FOCUS PEARL 4.4.4 modelling have been compared to the drinking water standard the EU trigger value of 0.1 µg/L (Directive 98/83/EC).

As copper is inorganic, its potential emissions to drinking water have been derived by pore water calculation and then the results have been compared to its own drinking water standard of 2 mg/L.

The calculated DDA^+ PECgw values have been compared to the drinking water standard the EU trigger value of 0.1 µg/L (Directive 98/83/EC).

Conclusion: Overall, general uses of Tanasote S40 in UC 3 and UC 4a did not give rise to concerns in drinking water as values were all below individual and cumulative trigger concentrations.

Primary and secondary poisoning

Primary poisoning
Primary poisoning due the components of Tanasote S40 is assessed in the impact assessments above. No other organisms will directly consume significant amounts of the product. Primary poisoning is not noted as applicable to preservative treated wood in the BPR guidance.

Secondary poisoning
None of the three active substances meet the bio accumulative criteria. There are no other substances of environmental concern in the formulation. There will be no risk from secondary poisoning by bioaccumulation in environmental compartments or ingestion of primary consumers and take-up by organisms from these.

The product is a preventative wood preservative (PT08), which is only stored, mixed and applied in industrial timber treatment plant installations via vacuum pressure processes. Due to lack of exposure during storage, mixing and use of the biocidal product, consideration of primary and secondary poisoning is not required.

Mixture toxicity

Tiered approach

Tier 1 and Tier 2 PEC/PNEC summation

The cumulative assessment has already been undertaken within the risk characterisation section to consider the combined effects following emissions of three different actives in the formulation into the relevant environmental compartments. This assessment has also considered the major metabolites of relevance in each compartment. The cumulative assessment shows only one PECsediment/PNECsediemnt > 1 (Bridge over pond, Time2= 7300 days, Tier 1). This is noted as a conservative assessment due to the leaching rates are defined by Approach 1. A Tier 2 assessment shows no risk (PECsediment/PNECsediment < 1) (Bridge over pond, Time2= 7300 days).

Tier 1		
RQ product[1]	Acceptable risk for the environment? (Y/N)	Remarks
STP		
8.06E-04	Y	Time 1: 30 days
5.92E-04	Y	365 days
5.92E-04	Y	Time 2: 7300 days
Surface water: Noise Barrier-STP-Surface water		
3.74E-01	Y	Time 1: 30 days
3.73E-01	Y	365 days
3.73E-01	Y	Time 2: 7300 days
Surface water: Bridge over pond		
3.73E-01	Y	Time 1: 30 days
3.79E-01	Y	365 days
4.99E-01	Tier 1; Y	Time 2: 7300 days
4.37E-01	Tier 2: Y	Time 2: 7300 days
Sediment: Noise Barrier-STP-Surface water		
3.94E-01	Y	Time 1: 30 days
7.82E-01	Y	365 days
7.82E-01	Y	Time 2: 7300 days
Sediment: Bridge over pond[2]		
7.81E-01	Y	Time 1: 30 days
7.96E-01	Y	365 days
1.12E+00	**Tier 1, N**	Time 2: 7300 days

9.55E-1	**Tier 2, Y**	Time 2: 7300 days
Soil: House[3]		
2.74E-01	Y	Time 1: 30 days
3.19E-01	Y	365 days
7.74E-01	Y	Time 2: 7300 days
Soil: Fence		
2.73E-01	Y	Time 1: 30 days
3.11E-01	Y	365 days
6.89E-01	Y	Time 2: 7300 days
Soil: Transmission pole		
4.16E-01	Y	Time 1: 30 days
6.98E-01	Y	365 days
6.39E-01	Y	Time 2: 7300 days
1 N.B. all PEC/PNECs assessed include copper regional background as worst case 2 N.B. This is the only assessment where a **Tier 2** assessment is necessary 3 House scenario included for completeness only. This will not be a relevant end-use for wood treated with Tanasote S40		

Conclusion:

The summation of PEC/PNECs includes RQs for all relevant metabolites. It is concluded that there is no risk shown to arise in any of the applicable scenarios from the combination of released substances.

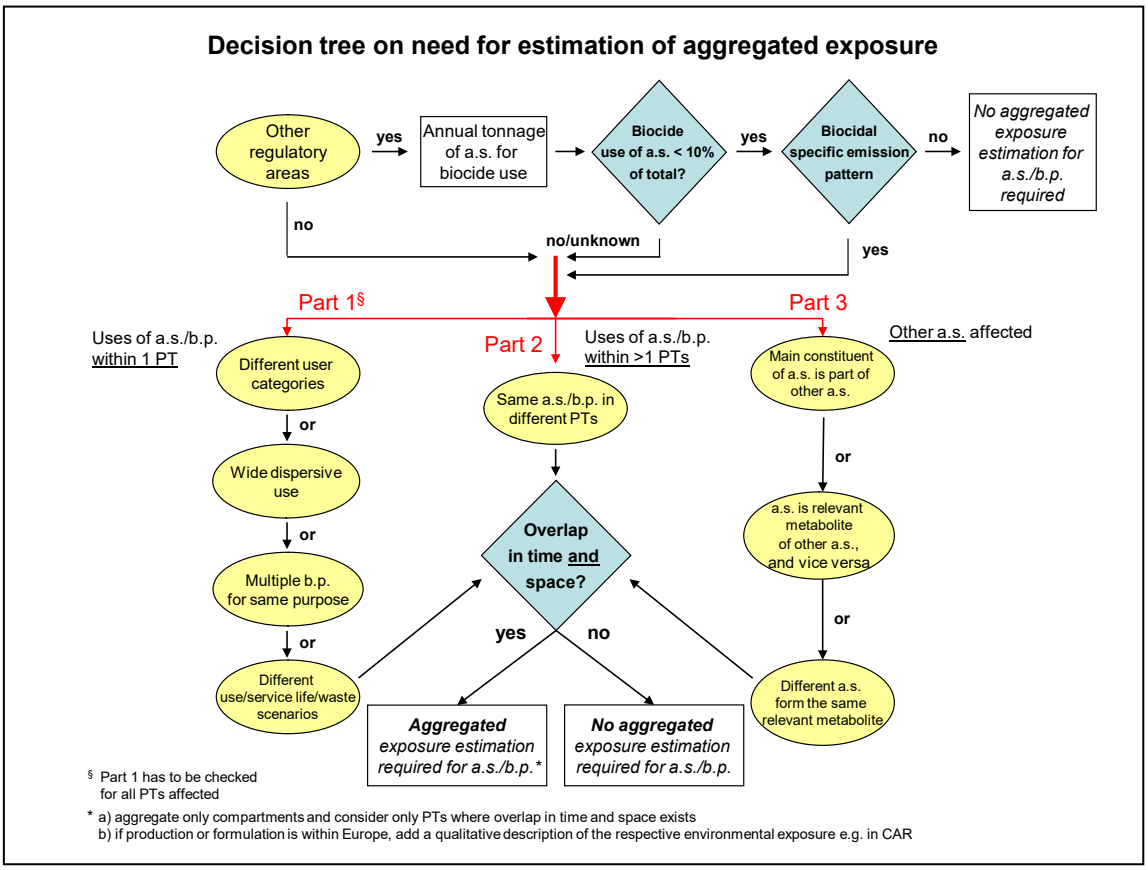
Aggregated exposure (combined for relevant emmission sources)

Penflufen is currently used in other regulatory areas, primarily as professionally applied plant protection products.

Copper is used extensively in building construction, power generation and transmission, electronic product manufacturing, and the production of industrial machinery and transportation vehicles. Copper wiring and plumbing are integral to the appliances, heating and cooling systems, and telecommunications links used widely in homes and businesses. Copper is an essential component in the motors, wiring, radiators, connectors, brakes, and bearings used in cars and trucks. The copper used in the product is derived from recycled material and therefore does not represent extra environmental burden beyond the previously mentioned uses. If not used for this product, the recycled copper would have found other uses.

DDACarbonate dissociates rapidly in aqueous solution to form the DDA^+ cation and release the carbonate and bicarbonate fractions. Quaternary ammonium compounds containing the DDA^+ cation have been supported in several PTs under BPR, they are also widely used in non-biocidal roles as surfactants, fabric softeners and anti-static agents (e.g. in shampoos).

Aggregated toxicity for the product and its active substances 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. Mixture toxicity to assess cumulative risks from use of the product containing three active substances has however, been undertaken.



Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
Use class 3 Product authorisation is acceptable for Tanasote S40 Use Class 3 at a maximum product retention rate of 100 kg/m^3. Additionally, for the treatment of railway sleepers (Use Class 3), a maximum retention rate of 133 kg/m^3 is acceptable. Use Class 4: treatment of general timber Product authorisation is acceptable for Tanasote S40 for Use Class 4a at a maximum product retention rate of 133 kg/m^3. Use Class 4: for sheet piling and jetties cannot be authorised. No assessments of the product in direct contact with the aquatic compartment have been presented. The product cannot be approved for treated timber use in direct contact with surface water bodies in use class 4.

2.2.9 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.

2.2.10 Assessment of a combination of biocidal products

This is not applicable. Tanasote S40 is not intended for use in combination with any other biocidal products.

3 ANNEXES[2]

3.1 List of studies for the biocidal product (family)

Author(s)	Year	Title and Report number	Owner	Data Protection Claimed

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

				(Yes/No)
	Year: 2018	Title: Determination of Accelerated Storage Stability Report no, GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2018	Title: Determination of Accelerated Storage Stability Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2017	Title: Determination of Physico-Chemical Properties Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2017	Title: Determination of Low Temperature Stability Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2018	Title: Determination of Accelerated Storage Stability Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2019	Title: Tanasote S-40: Determination of Long-Term Storage Stability, Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2017	Title: Determination of Physico-Chemical Properties Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2017	Title: Determination of Physico-Chemical Properties Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2017	Title: Tanasote S-40: Determination of Hazardous Physico-Chemical Properties Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2019	Title: Determination of the Corrosion of Metals by Tanasote S-40 Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2017	Title: Tanasote S-40: Determination of Hazardous Physico-Chemical Properties Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2017	Title: Tanasote S-40: Determination of Hazardous Physico-Chemical Properties Report no., GLP	Arch Timber Protection Ltd (A Lonza Company)	Yes

		Unpublished		
	Year: 2018	Title: Analytical Method validation Report no., GLP Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2019	Title: Preliminary tests for the validation of an analytical method using ICP-OES and GC/FID for the determination of Lead, Arsenic, Cadmium and Methanol in the test item Tanasote S-40 Report no., Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2018	Title: Determination of the toxic values against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 47 (2016) in combination with evaporative ageing procedure according to EN 73 (2014) Report no., Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2017	Title: Determination of the toxic values against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 47 (2016) in combination with leaching procedure according to EN 84 (1997) - Report no., Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2018	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, Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2018	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., Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes

	Year: 2018	Title: Determination of toxic values against Reticulitermes santonensis De Feytaud according to EN 117 (2012) after evaporative ageing procedure according to EN 73 (2014) - 10040 Report no., Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2018	Title: Determination of the toxic values against Reticulitermes santonensis De Feytaud according to EN 117 (2012) after leaching procedure according to EN 84 (1997) - Report no., Unpublished	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2018	Title: Determination of the protective effectiveness against soft rotting micro-fungi and other soil-inhabiting micro-organisms according to ENV 807 (2001) -, Unpublished Report no.	Arch Timber Protection Ltd (A Lonza Company)	Yes
	Year: 2020	Title: The In Vitro Percutaneous Absorption of total Copper from an Oil-based Formulation (Tanasote S40) through Human Split-Thickness Skin Report no., GLP Unpublished	Company Owner: Arch Timber Protection Limited	Yes
Author:	Year: 2017	Title: CEN/TS 15119-1 Determination of emissions from pre-servative treated wood to the environment - Part 1: Wood held in the storage yard after treatment and wood com-modities exposed in Use Class 3 (not covered, not in con-tact with the ground) Report no., Unpublished	Company Owner: Arch TimberProtection Ltd	Yes
Author:	Year: 2018	Title: CEN/TS 15119-2 Determination of emissions from pre-servative treated wood to the environment - Part 2: Wooden commodities exposed in Use Class 4 or 5 (in contact with the ground,	Company Owner: Arch Timber Protection Ltd	Yes

		fresh water or sea water) Report no., Unpublished		
Author:	Year: 2018	Title: NT BUILD 509 "Leaching of active ingredients from pre-servative-treated timber - Semi-field testing" (Approved 2005-03) Report no., Unpublished	Company Owner: Arch Timber Protection Ltd	Yes

3.2 Output tables from exposure assessment tools

3.3 New information on the active substance

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[3]

3.6 Confidential annex

See Confidential annex of the PAR, separate document PAR_Conf annex_Tanasote S40.

3.7 Other

[3] If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.