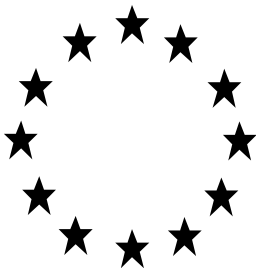
3Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION

(submitted by the [applicant / competent authority])



SC300

Product type PT8

Penflufen and IPBC as included in the Union list of approved active substances of Regulation (EU) No 582/2012

Case Number in R4BP: BC-UR068635-01

Competent Authority: Denmark

Date: 13 Januar 2023

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1 Conclusion

SC300 is a liquid biocidal product containing IPBC and penflufen as active substances. The product is used as a wood preservative by industrial users to prevent wood rotting fungi.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the use ”preventive wood protection of soft wood for use class 2 against wood rotting fungi” as stated in the Summary of Product Characteristics (SPC).

General

Detailed information on the intended use of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

A classification according to Regulation (EC) No 1272/2008[1] is necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

The biocidal product does not contain any non-active substances (so called ”co-formulants”) which are considered as substances of concern.

The biocidal product contains the active substances IPBC and penflufen, which have not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More information is available in section 2.7 of the PAR and in the confidential annex.

The biocidal product contains IPBC and penflufen which do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are therefore not considered as candidates for substitution. Therefore, a comparative assessment of the biocidal product is not required.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturers of the biocidal product are listed in section 1.3 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturers of the active substances are listed in section 1.4 of the SPC.

Conclusions of the assessments for each area

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

The intended use as applied for by the applicant has been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of the active substances is available. More information on the analytical methods for the active substances is available in section 3.4 of the PAR.

Validated analytical methods for monitoring of relevant components of the biocidal product and residues thereof in soil, air, water and animal and human body fluids are available in the PT8 CAR (CA UK, 2017) for penflufen and in the PT8 CAR (CA DK, 2008) for IPBC. Analytical method for monitoring in/on food and feeding stuff was waived as the biocidal product is not intended to come into contact with food and feeding stuff when applied according to the instructions. More information is available in section 3.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against wood rotting fungi for all intended uses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.

Since no substance of concern has been identified, the human health risk assessment is based on the active substances IPBC and penflufen.

Based on the risk assessment, it is unlikely that the intended use causes any unacceptable acute or chronic risk to industrial users and bystanders and non-professional users as well as the general public, if the directions for use, as specified in the SPC, are followed.

Dietary risk assessment

Considering the use, food or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

Considering the use, exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

Since no substance of concern has been identified, the risk assessment for the environment is based on IPBC, Penflufen and their respective metabolites.

The risk assessment of SC300 and the use in Use Class 3 has shown unacceptable risk for the groundwater compartment from the Penflufen metabolite M01 and therefore this use is not proposed for authorisation.

The use of the product in Use Class 2 can still be authorised, as no emission to the environment is expected.

Post-authorisation conditions

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Table 1.1 Post-authorisation conditions

Description	Due date
Not relevant	-

2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

Product type(s)	PT8
Type(s) of formulation	AL - Any other liquid

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number	Use description	PT	Target organisms	Application method	Application rate (min-max)	User category	Conclusion (eCA/ refMS)	Comment (eCA/refMS)
1	Preventive wood protection of soft wood for Use Class 3	PT8	Wood rotting fungi in service[2]	Supercritical pressure impregnation	25 g penflufen and 63 g IPBC /m^3 wood	Industrial	N	Unacceptable risk from SC300 are found in the groundwater compartment, due to the penflufen metabolite M01. No risk mitigation measure can currently be applied to mitigate this risk, hence use in Use Class 3 cannot be approved for the product.
1	Preventive wood protection of soft wood for Use Class 2	PT8	Wood rotting fungi in service	Supercritical pressure impregnation	25 g penflufen and 63 g IPBC /m^3 wood	Industrial	R	• Additional RMM: Do not use on wood which may come in direct contact with food (APCP, see section

[2] Originally, the applicant also claimed efficacy against blue stain fungi. Applicant withdrew this claim 28.7.2022 (in R4BP-3, communication no. NAP-C-1599881-05-00/F)

								3.4) • Additional RMM: Freshly treated timber must be stored after treatment under shelter or on a hard, impermeable surface to prevent direct losses to soil and water. • Additional RMM: Any losses should be collected for re-use or disposal.

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

2.3 Identity and composition

The identity and composition of the biocidal product are

identical ☐

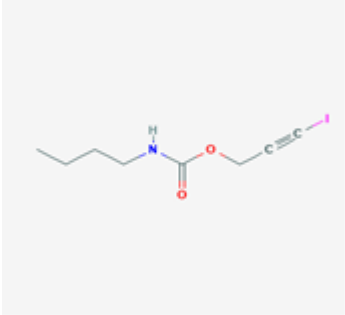
not identical ☒

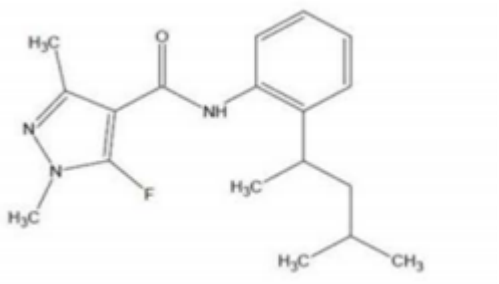
to the identity and composition of the products evaluated in connection with the approval for listing of the active substances on the Union list of approved active substances under Regulation (EU) No 528/2012.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

2.4 Identity of the active substances

Table 2.3 Identity of the active substances

Main constituent(s)	
Common name	IPBC
Chemical name	3-Iodoprop-2-ynyl *N*-butylcarbamate
EC number	259-627-5
CAS number	55406-53-6
Index number in Annex VI of CLP	616-212-00-7
Minimum purity / content	Min. 980 g/kg
Structural formula	

Main constituent(s)	
Common name	Penflufen
Chemical name	5-Fluoro-1,3-dimethyl-*N*-[2-(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	616-231-00-0
Minimum purity / content	980 g/kg 1:1 (R:S) ratio of enantiomers
Structural formula	

2.5 Information on the sources of the active substances

Is the source of IPBC the same as the ones evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☒ Yes
☐ No

Is the source of penflufen the same as the ones evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☒ Yes
☐ No

The source of penflufen and one of the sources of IPBC are the same as the ones evaluated as reference sources during the active substance approval. The two other sources of IPBC are technically equivalent sources. The evaluations are recorded by ECHA under decision no. TAP-D-1255923-24-00/F and TAP-D-1377728-13-00/F.

2.6 Candidates for substitution

IPBC and penflufen do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered candidates for substitution.

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

SC300 should not be considered to have endocrine-disrupting properties.

The biocidal product contains the active substances IPBC and penflufen, which have not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	Carc. 2: H351 Skin Sens. 1: H317 Eye Dam. 1: H318 STOT RE 2: H373 Aquatic Acute 1: H400 Aquatic Chronic 2: H411	Carc. 2 Skin Sens. 1 Eye Dam. 1 STOT RE 2 Aquatic Chronic 1
Hazard Pictograms	GHS05	
	GHS07	
	GHS08	
	GHS09	
Signal word(s)	Danger	Danger
Hazard statements	H317: May cause an allergic skin reaction. H318: Causes serious eye damage. H351: Suspected of causing cancer H373: May cause damage larynx through prolonged or repeated inhalation. H400: Very toxic to aquatic life H411: Toxic to aquatic life with long lasting effects	H317: May cause an allergic skin reaction. H318: Causes serious eye damage. H351: Suspected of causing cancer H373: May cause damage to larynx through prolonged or repeated inhalation. H410: Very toxic to aquatic life with long lasting effects
Precautionary statements	P201: Obtain special instructions before use. ~~P202: Do not handle until all safety precautions have been read and understood.~~ P260: Do not breathe mist/vapours/fume/spray. ~~P261: Avoid breathing dust/fume/gas/mist/vapours/spray.~~ ~~P272: Contaminated work clothing should not be allowed out of the workplace.~~ P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. ~~P321: Specific treatment (see..on this label)~~P ~~P314: Get medical advice/attention if you feel unwell.~~ P302+P352: IF ON SKIN: Wash with plenty of water/.. P333+P313: If skin irritation or rash	P201: Obtain special instructions before use. P260: Do not breathe vapours. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of water. P333+P313: If skin irritation or rash occurs: Get medical attention. P305+P351+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. P308+P313: IF exposed or concerned: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash it before reuse. P391: Collect spillage. P501: Dispose of contents to hazardous waste.

	occurs: Get medical advice/attention. P305+P351+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. P308+P313: IF exposed or concerned: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash it before reuse. P391: Collect spillage. ~~P405: Store locked up.~~ P501: Dispose of contents/container to hazardous waste.	
Supplemental hazard statements	-	
Notes	Justifications for excluding P-statements: P202 is optional where P201 is assigned. For SC300, P201 is sufficient to ensure a safe use. P261 may be omitted if P260 is assigned. P272 is optional for industrial/professional users. Work clothes are not brought home from industrial work sites. P302+P352 Only recommended for general public. P314 is redundant where P308+P313 is assigned. P321 is required for substances/mixtures where an antidote is known. This is not the case for any of the substances contained in SC300. P405 is optional for industrial/professional users and is not considered relevant for the industrial use of SC300 as the product is formulated in a large steel container.	

2.9 Letter of access

A letter of access has been granted by Lanxess Deutschland GmbH supporting full access to the active substance dossiers for IPBC and penflufen for use in the evaluation of the product SC300.

2.10 Data submitted in relation to product authorisation

No new data has been submitted.

2.11 Similar conditions of use across the Union

Not relevant.

3 Assessment of the biocidal product

3.1 Packaging

Information is not relevant.

The product is not transported to an 'end user' e.g. impregnation facility. SC300 is manufactured and used at Superwood A/S. exposure during manufacture of a b.p. is covered by other legislation.The product only exist in the containers which are connected to the autoclave (impregnation equipment). The autoclave and the storage tanks are placed in an indoor production facility. The actual volume of the storage tanks and pipelines is not known.

Table 3.1 Storage containers

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials (Yes/No)
Tank	2000-3000 Litre	Stainless steel	-	Industrial	Yes

3.2 Physical, chemical, and technical properties

The autoclave and the storage tanks are placed in an indoor production facility. The temperature will not exceed 30ºC at storage and the product is not used/stored at low temperature. The product is not exposed to humidity for the same reasons as it is only existing in closed system.

The storage tanks cannot 'burst' or 'fold' which means that it is only the metal itself which can influence the storage stability. The metal container which the storage stability has been performed in is stainless steel as the containers used at Superwood. Reactivity towards the container and corrosion towards metal has been performed. In addition, chemical analysis is performed weekly at Superwood A/S and the a.i. is adjusted in case it is needed.

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.1.	Appearance at 20 °C and 101.3 kPa	See below	Test item: SC300 Batch No. CH20190218 IPBC: 5.13% Penflufen: 2.51%	Transparent liquid with low viscosity.	835270_Test report_12M_SC300
3.1.1.	Physical state at 20 °C and 101.3 kPa	BPR Guidance (Vol I, Parts A+B+C, version 2.0, 2018), section 3.6.1		Oily liquid	
3.1.2.	Colour at 20 °C and 101.3 kPa			Transparent colourless	
3.1.3.	Odour at 20 °C and 101.3 kPa	-	-	The product only exists in closed systems. No one will ever smell it. See justification above **rMS remark:** Since the product is classified as Carc. 2, omission of odour is considered as acceptable.	-
3.2.	Acidity, alkalinity and pH value	CIPAC MT 75.3 - Determination of pH values.	Test item: SC300	pH (neat): 7.2 at 22 °C	835270_Test report_12M_SC300

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.3.	Relative density / bulk density	EC method A.3 and OECD test guideline 109 – Relative density (oscillating densitometer)	Batch No. CH20190218 IPBC: 5.13% Penflufen: 2.51%	0.9385 at 20 °C (average, triplicate measurements)	
3.4.1.1.	Storage stability test – **accelerated storage**	-	-	No test submitted ***rMS remark:*** Since no test was submitted to demonstrate the stability at elevated temperature, the product must be stored at temperatures below 30°C.	-
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**	Storage test according to BPR Appearance: BPR Guidance (Vol I, Parts A+B+C, version 2.0, 2018), section 3.6.1 pH: CIPAC MT 75.3 Relative density: EC method A.3 and OECD test 109 (oscillating densitometer) Viscosity: OECD test 114 (rotational viscometer) Analytical method:	Test item: SC300 Batch No. CH20190218 Nominal AS content: IPBC: 5% Penflufen: 2.5% AS content: See results	Storage in 1 L stainless steel container at 17.2 °C - 24.5 °C (average temperature 20 °C) for 12 months. **Active substance content:** <u>IPBC:</u> T_0: 5.13% w/w $T_{12\ months}$: 4.84% w/w (change – 5.7%) <u>Penflufen:</u> T_0: 2.51% w/w $T_{12\ months}$: 2.43% w/w (change – 3.2%)	835270_Test report_12M_SC300

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		HPLC-DAD (CSA 208 method)		**Appearance**: T_0: Transparent colourless oily liquid $T_{12\ months}$: Transparent colourless oily liquid **pH** (neat): T_0: 7.2 at 22 °C $T_{12\ months}$: 5.4 at 21.3 °C (change – 1.8) **Packaging appearance:** $T_{12\ months}$: No impact on the packaging was observed after storage. **Weight loss:** T_0: 1967.1 g $T_{12\ months}$: 1966.8 g (change: - 0.3 g, - 0.02%) **Relative density** (at 20 °C)**:** T_0: 0.9385 $T_{12\ months}$: 0.9392 (change: + 0.07%) **Viscosity:** The product is a Newtonian liquid. At 20 °C:	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				T_0: 6.52 mPa·s $T_{12\ months}$: 6.57 mPa·s (change: + 0.8%) At 40 °C: T_0: 3.46 mPa·s $T_{12\ months}$: 3.49 mPa·s (change: + 0.9%) ***rMS remark:*** The temperature deviation during the test exceeds 20 ± 2 °C that is indicated in the leading guidance. The deviations is considered acceptable as all parameters are stable during the 12 months storage and the average temperature during the test was held at 20 °C. As data were obtained after homogenisation of the product, the product is to be stirred/homogenised before use.	

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	-	-	Not relevant see justification above ***rMS remark:*** As no test was submitted, the storage condition 'protect from frost' must be applied to the product.	-
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	-	-	Not relevant. Stored in metal containers. The product only exists in closed system at Superwood A/S. Thus, the product is not exposed to light.	-
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	The product is mixed on production facility and used within days or weeks after mixing. Therefore, the product is not exposed to humidity. The effects on content of active substance regarding temperature was not tested. Consequently, the product should be stored at temperatures above	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				0 °C and below 30 °C. See justification above as well.	
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	BPR Guidance (Vol I, Parts A+B+C, version 2.0, 2018), section 3.6.4.2	Test item: SC300 Batch No. CH20190218 IPBC: 5.13% Penflufen: 2.51%	Metal container: Weight change of 0.3 g (- 0.02%). No reactivity toward the container observed during the long term storage test at ambient temperature for 12 months.	835270_Test report_12M_SC300
3.5.1.	Wettability	-	-	Not relevant as the product is a liquid formulation.	-
3.5.2.	Suspensibility, spontaneity, and dispersion stability	-	-	Not relevant as the product is a ready-to-use formulation, which is not intended to be diluted or dispersed before use.	-
3.5.3.	Wet sieve analysis and dry sieve test	-	-	Not relevant as the product is a ready-to-use liquid formulation.	-
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not relevant as the product is neither an emulsion or is intended to be diluted or dispersed before use.	-
3.5.5.	Disintegration time	-	-	Not relevant as the	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				product is a liquid formulation.	
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	-	-	Not relevant as the product is a ready-to-use liquid formulation, which is intended to be used for pressure impregnation only.	-
3.5.7.	Persistent foaming	-	-	Not relevant as the product is not intended to be applied in water before use. The product is a ready-to-use liquid formulation.	-
3.5.8.	Flowability/pourability/dustability	-	-	Not relevant as the product is a ready-to-use liquid formulation.	-
3.5.9.	Burning rate — smoke generators	-	-	Not relevant as the product is not intended to be used as smoke.	-
3.5.10.	Burning completeness — smoke generators	-	-	Not relevant as the product is not intended to be used as smoke.	-
3.5.11.	Composition of smoke — smoke generators	-	-	Not relevant as the product is not intended to be used as smoke.	-
3.5.12.	Spraying pattern — aerosols / spray	-	-	Not relevant as the product is a ready-to-use liquid formulation, which	-

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				is intended to be used for pressure impregnation only.	
3.6.1.	Physical compatibility	-	-	Not relevant as the product is not intended to be used with other products.	-
3.6.2.	Chemical compatibility	-	-	Not relevant as the product is not intended to be used with other products.	-
3.7.	Degree of dissolution and dilution stability	-	-	Not relevant as the product is not intended to be applied in water before use. The product is a ready-to-use liquid formulation.	-
3.8.	Surface tension *[test at 25 °C, using tensiometer in combination with a Du Nuoüy-ring]*	EC method A.5 and OECD 115	Test item: SC300 Batch No. CH20190218 IPBC: 5.13% Penflufen: 2.51%	31.0 mN/m (uncorrected) 29.3 mN/m (corrected by Harkins and Jordan) ***rMS remark:*** The product is regarded as surface active since the surface tension is < 60 mN/m	835270_Test rapport_Rev1_fyskem_SC300
3.9.	Viscosity *[Shear rates: 20, 26, 36, 51, 71 and 100 s^{-1}, temperature: 20 °C and 40 °C]*	OECD 114. CIPAC MT 192 - Viscosity of liquids by rotational viscometry.		The product is a Newtonian liquid Dynamic viscosity: At 20ºC: 6.52	835270_Test report_12M_SC300

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
				mPa·s At 40ºC: 3.46 mPa·s ***rMS remark:*** Kinematic viscosity at 40 °C was not determined for the product, as the product does not contain > 10% hydrocarbons or other components classified with H304. Therefore, the kinematic viscosity is not required for the toxicological assessment.	

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
SC300 is an AL – any other liquid, to be applied undiluted. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The product is a solvent based colourless transparent oily liquid. The results from the long term storage stability study demonstrated acceptable variation for the parameters active substance content, pH, appearance of the product and packaging material, relative density and viscosity after storage at 17.2 – 20.5 °C (average temperature: 20 °C) for 12 months. No accelerated storage stability test or stability test at low temperature were submitted for SC300. The surface tension of SC300 is 29.3 mN/m and the product is therefore regarded as surface active. The dynamic viscosity was determined to 6.52 mPa·s at 20 °C and 3.46 mPa·s at 40 °C. As the content of hydrocarbons in the product is < 10%, the kinematic viscosity is not required for the toxicological risk assessment of the product. Based on the storage stability test, a shelf-life of one year in the packaging material stainless steel can be authorised. **Implications for labelling:** Store below 30 °C [Storage condition], Protect from frost [Storage condition], Stir before use [Instruction for use].

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
4.1.	Explosives	-	-	Test not required, the explosive properties of each ingredient have been evaluated. SC300 is not explosive. Penflufen is not explosive according to the PT8 CAR (CA UK, 2017) for Penflufen. A DSC test of the active substance demonstrated an exothermic decomposition in the temperature range 270-410 °C (triplicate measurements) with an energy of 240-330 J/g. Thus supporting the conclusion that Penflufen is not explosive. The chemical structure of IPBC contains an unsaturated C-C bond, however, according to the PT8 CAR (CA DK. 2008) for IPBC, IPBC is not explosive. The remaining ingredients do not contain chemical groups associated with explosive properties and thus have no explosive properties.
4.2.	Flammable gases	-	-	Not relevant since the product is neither a gaseous substance nor a mixture of gases.
4.3.	Flammable aerosols	-	-	Not relevant since the definition of aerosols is not fulfilled for the

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				biocidal product.
4.4.	Oxidising gases	-	-	Not relevant since the product is neither a gaseous substance nor mixture of gases.
4.5.	Gases under pressure	-	-	Not relevant since the product is neither a gaseous substance nor mixture of gases.
4.6.	Flammable liquids	EC method A.9 analogous to ASTM D93 (procedure A and B) using a non-equilibrium method and Pensky-Martens apparatus (closed cup tester)	Test item: SC300 Batch No. CH20190218 IPBC: 5.13% Penflufen: 2.51%	Flash point: 100.0 ºC No flammable properties since the flash point is greater than the classification criterion 60°C for classification category 3. Reference: 835270_Test rapport_Rev1_fyskem_SC300
4.7.	Flammable solids	-	-	Not relevant as the product is not a solid substance.
4.8.	Self-reactive substances and mixtures	-	-	Test not required. Penflufen is neither explosive nor self-reactive according to the PT8 CAR (CA UK, 2017). IPBC is not explosive and contains no groups associated with self-reactive properties. Additionally, IPBC is not self-reactive according to the harmonised classification. The remaining ingredients do not contain chemical groups associated with explosive or self-reactive properties. Therefore, the product does not

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				have to be classified as self-reactive.
4.9.	Pyrophoric liquids	-	-	No pyrophoric properties, since it is known from practical handling not to be pyrophoric
4.10.	Pyrophoric solids	-	-	Not relevant as the product is not a solid substance.
4.11.	Self-heating substances and mixtures	-	-	Test not required as the product is neither a solid substance nor is a liquid adsorbed to a large surface.
4.12.	Substances and mixtures which in contact with water emit flammable gases	-	-	Not relevant, since experience in handling and use shows that the substance or mixture does not react with water; the mixture is used for treatment of wood, which contains water. Additionally, the major component of the mixture is highly soluble with water.
4.13.	Oxidising liquids	-	-	No oxidising properties and need not to be tested, since the organic substance or mixture contains oxygen and fluorine but these elements are chemically bonded only to carbon or hydrogen. The product is not an oxidising liquid.
4.14.	Oxidising solids	-	-	Not relevant as the product is not a solid substance.
4.15.	Organic peroxides	-	-	Not relevant since no organic peroxides are contained in the product.
4.16.	Corrosive to metals	UN Test C.1 Deviation from guideline: Test performed at	Test item: SC300 Batch No. CH20190218	Test duration: 7 days. Measured temperature:

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
		55 ± 5 °C instead of 55 ± 1 °C.	IPBC: 5.13% Penflufen: 2.51%	Aluminium plates: 52 – 59 °C Steel plates: 55 – 58 °C Uniform corrosion: Aluminium (EN AW 7075-T6): Up to 0.003%. Steel (S235JR+C): Up to 0.001% Localised corrosion: Aluminium: Not observed. Steel: Not observed. SC300 is not corrosive to aluminium and steel as no mass loss higher than or equal to 13.5% was observed in accordance with the UN method. Additionally, no localised corrosion was observed. Weight loss of specimen ≤ 0.003% for both aluminium and steel. Reference: 835270_Test rapport_Rev1_fyskem_SC300 ***rMS remark:*** As the observed corrosion is very low, the temperature deviation compared to guideline is considered as acceptable in this case.
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	-	Test item: SC300 Batch No. CH20190218 IPBC: 5.13% Penflufen: 2.51%	Test not required. The auto-ignition temperature is expected to be approx. 194 °C based on read-across from data for the ingredients of the product. Please refer to the confidential

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results
				annex for further details.
4.17.2.	Relative self-ignition temperature for solids	-	-	Not relevant since the product is a liquid formulation
4.17.3.	Dust explosion hazard	-	-	Not relevant since the product is a liquid formulation.

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product is not classified for physical hazards according to Regulation (EC) No. 1272/2008 (CLP regulation).

3.4 Methods for detection and identification

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

Analytical methods for the analysis of the product as such including the active substance, impurities, and residues											
Principle of the method CSA 208*:* 0.5 g test item is placed in a 100 mL volumetric flask and mixed thoroughly with 10 mL MilliQ water. The flask is filled to the mark with methanol. The flask is stoppered and placed on a shaking table for 30 min. (200-250 rpm), solicited for 15 min. and filtered (0.45 µm, PTFE). Analysis is performed by HPLC DAD at 232 nm with a Kinetex C18 5 µm column (100 Å, 150 x 4.6 mm, ID no. 145) and mobile phase using gradient elution (MilliQ water with H_3PO_4, pH3/Acetonitrile 65:35 through 10:90 to 65:35). Retention time of penflufen: 9.8 min. Retention time of IPBC: 7.6 min.											
Analyte (type of analyte e.g. active substance)	**Linearity**	**Specificity**	**Fortification range, level and number of measurements at each level**		**Recovery rate (%)**			**Precision (%)**		**Limit of Quantification LOQ** – *only for impurit(y/ies)*	**Reference**
			Level	Number of measurements	Range	Mean	RSD	Concentration tested	Number of replicates		

Penflufen (active substance)	Range: 50 µg/ml to 250 µg/ml n = 8 y = 1.15x + 2.8 R^2 = 0.9993 (y: peak area, x: concentration in µg/mL)	Interference not > 3% of peak sample area in blank matrix. Chromatograms provided (sample, blank and standard sample)	2.5% w/w	2 samples (triplicate measurements)	99.8-101.1	100.4	n.d.[3]	2.5	6	-	835270_862304_Method validation report_rev1_CSA 208 and 835270_method description_CSA 208 v2
								Range: 2.48-2.53% Mean: 2.51% RSD%: 0.67% The precision lies within acceptable RSD% range according to the Horwitz ratio.			
IPBC (active substance)	Range: 101 µg/mL to 503 µg/mL n = 8 y = 0.048x + 0.17 R^2 = 0.9994 (y: peak area, x: concentration in µg/mL)	Interference not > 3% of peak sample area in blank matrix. Chromatograms provided (sample, blank and standard sample)	4.95% w/w	2 samples (dublicate measurements)	97.7-98.8	98.3	n.d.[7]	5.0	6	-	
								Range: 5.07-5.17% Mean: 5.13% RSD%: 0.68% The precision lies within acceptable RSD% range according to the Horwitz ratio.			

[3] No standard determination determined, as number of measurements was 2.

Table 3.7 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
An analytical method CSA 208 by Johannesen (2019, 835270_862304 CSA 208 Rev. 1) for the determination of penflufen and IPBC is available. Specificity, linearity, accuracy and precision were checked and are found acceptable. No substances of concern are present in the product. Methods for the detection of IPBC and penflufen in soil, air, water, and animal and human body fluids and tissues were provided and deemed acceptable at EU level. No other data is required. The product is not intended to be used on surface in contact with food/feed of plant and animal origin; therefore, analytical method for the determination of active substance in food/feed of plant and animal origin is not required. **Implications for labelling:** Do not use on wood which may come in direct contact with food, feed or livestock [Risk mitigation measure].

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

Categories[4]	Matrix wording	Code for product
Used category	Industrial	A.20
Wood category	Softwood	B.10;
Wood product	Solid wood	C.10
Application aim and Field of use	Preventive treatment - Use Class 2 and 3	D.40, E.20, E.30
Method of application and rate	Supercritical impregnation with CO_2 as carrier Retention rate: 88 g a.i./m^3 (25 g penflufen/m^3 and 63 g IPBC/m^3)	F.70
Targeted organisms[5]	Brown rot fungi/basidiomycetes	G.10

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

IPBC has a carbamate structure. The target sites of carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee).

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

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

[4] Guidance on the BPR: Volume II Efficacy – Assessment and Evaluation (Parts B+C). version 3.0; April 2018. P. 156+

[5] Originally, the applicant also claimed efficacy against blue stain fungi. A study according to the procedure set out in EN 152 was not included in the first submission. The test was initiated during the evaluation phase of SC300 in agreement with the eCA. Results from the test did not demonstrate efficacy. Therefore, the applicant withdrew the efficacy claim on 28.7.2022 in R4BP-3, communication no. NAP-C-1599881-05-00/F. The study was not submitted to the eCA.

3.5.3 Efficacy data

Table 3.8 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
PT8 Use 1: Preventive treatment against wood rotting fungi Brown rot	SC300	*C. puteana* *G. trabeum* *P. placenta*	EN 113 after EN 73 (evaporation) The product was applied by Supercritical pressure impregnation - 6 blocks tested for each treatment and each fungal strain. *C. puteana, G. trabeum* and *P. placenta* are tested on pine. - Number of replicates: 4 replicates for each treatment and each fungal strain and 6 replicates for each treatment and used for correction. CONTROLS - Untreated controls: one non-treated control block included with the treated block in each test. Six virulence control blocks for each fungal strain. The effect investigated is mass loss of the test blocks, induced by the fungal development The method for recording effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period. - Intervals of examination: one time, after 4 months (16 weeks) exposure of the blocks to the fungal strains.	The retentions of the test product were for: penflufen 0.017; 0.022; 0.028; 0.036; 0.051 kg/m^3 IPBC 0.022; 0.052; 0.074; 0.092; 0.139 The test passed the virulence control and was valid. The biological reference value b.r.v is: <u><0.017 kg penflufen /m^3 and <0.022 kg IPBC /m^3</u> The study is validated as more than 20 % of mass loss is observed in the control	Report 833801-4 EN 113 + EN 73	Report 833801-4 EN 113 + EN 73 IUCLID 6.7, .001

PT8 Use 1: Preventive treatment against wood rotting fungi Brown rot	SC300	*C. puteana* *G. trabeum* *P. placenta*	EN 113 after EN 84 (leaching) The product was applied by Supercritical pressure impregnation - 4 blocks tested for each treatment and each fungal strain. *C. puteana, G. trabeum* and *P. placenta* are tested on pine. - Number of replicates: 4 replicates for each treatment and each fungal strain and 6 replicates for each treatment and used for correction. CONTROLS - Untreated controls: one non-treated control block included with the treated block in each test. Six virulence control blocks for each fungal strain. The effect investigated is mass loss of the test blocks, induced by the fungal development The method for recording effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period. Intervals of examination: one time, after 4 months (16 weeks) exposure of the blocks to the fungal strains.	Supercritical CO_2 impregnation. The retentions of the test product were for: penflufen 0.017; 0.022; 0.028; 0.036; 0.051 kg/m^3 IPBC 0.022; 0.052; 0.074; 0.092; 0.139 The test passed the virulence control and was valid. The biological reference value b.r.v. was: 0.025 kg penflufen /m^3 and 0.063 kg IPBC /m^3 Mid toxic value (m.t.v) calculation are used for deviation of b.r.v. according to EN 599-1, 5.1.3 The study is validated as more than 20 % of mass loss is observed in the control	Report 833801-3 EN 113 + EN 84	Report 833801-3 EN 113 + EN 84 IUCLID 6.7, .001

3.5.4 Efficacy assessment

The product has demonstrated efficacy against wood rotting fungi in service for Use Class 2 and 3 for preventive use at a retention of penflufen 0.025 kg/m^3 and IPBC 0.063 kg/m^3.

3.5.5 Conclusion on efficacy

Categories	Matrix wording	Code for product
Used category	Industrial	A.20
Wood category	Softwood	B.10;
Wood product	Solid wood	C.10
Application aim and Field of use	Preventive treatment - Use Class 2 and 3	D.40, E.20, E.30
Method of application and rate	Supercritical impregnation with CO_2 as carrier Retention rate: 25 g penflufen/m^3 and 63 g IPBC/m^3	F.70
Targeted organisms	Brown rot fungi/basidiomycetes	G.10

3.5.6 Occurrence of resistance and resistance management

For Penflufen the assessment report acknowledges that it is a novel substances for wood preservation so no specific information is available. The assessment report does not state any cases of field resistance to ADIH fungicides.

Due to the unspecific mode of action of IPBC and the combination of the active substances a development of resistance is neither to be expected nor has been ever observed.

3.5.7 Known limitations

No known limitations.

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

SC300 is not intended to be used in combination with other biocidal products.

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

No toxicological studies are available on the biocidal product, SC300. The requirement for such studies can be waived, with reference to the Guidance on the Biocidal Products Regulation: Volume III Human Health, Part A (Information Requirements), on the basis that there is sufficient toxicological data on the active substances and non-active substances to allow classification according to Regulation (EC) No. 1272/2008 (CLP), and no synergistic effects between any of the components are expected.

The toxicology of the active substances IPBC and penflufen was examined according to the data requirements under the Biocides Regulation (EU) No 528/2012 (BPR). The toxicological properties of the active substances are summarized in their respective Competent Authority Report (CAR). To ensure that the newest information available on the active substances was taken into consideration, the most recent CARs for both substances were used:

- Penflufen PT8 – UK (2017)
- IPBC PT13 – DK (2015)

DK CA submitted in June 2011 a classification proposal for IPBC to RAC for the purpose of a harmonised classification. RAC adopted its opinion 28 November 2012 by consensus for a harmonised classification of the following: Acute Tox. 3, H331; Acute Tox. 4, H302; Eye Dam. 1, H318; Skin Sens. 1, H317; STOT RE 1, H372 (larynx); Aquatic Acute 1, H400, M=10; Aquatic Chronic 1, H410, M= 1. The harmonised classification was entered in Annex VI of the CLP legislation through ATP no. 6 update (enforced June 2014).

UK CA submitted in July 2017 a classification proposal for penflufen to RAC for the purpose of a harmonised classification. RAC adopted its opinion 15 October 2018 by consensus for a harmonised classification of the following: Carc. Cat 2, H351, Aquatic Acute 1, H400, M=1; Aquatic Chronic 1, H410, M= 1. The harmonised classification was entered into Annex IV of the CLP legislation through ATP no. 15 (enforced March 2022).

3.6.1.1 Skin corrosion and irritation

Table 3.9 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	SC300 does not cause skin corrosion/irritation.
Justification for the value/conclusion	None of the active substances or non-active substances in the product allow for classification for skin irritation as they are either not classified for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP	Not classified

Table 3.10 Data waiving

Data waiving	
Information requirement	Annex III BPR, point 8.1 "Skin corrosion or skin irritation"
Justification	Testing of the biocidal product does not need to be conducted, as there are

	valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

3.6.1.2 Eye irritation

Table 3.11 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	SC300 causes serious eye damage.
Justification for the value/conclusion	SC300 contains >3% of the active substance IPBC (5%) which is classified as eye damaging. Penflufen and the non-active substances in the product do not contribute to classification for eye irritation as they are either not classified for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP	Eye Dam. 1 (H318)

Table 3.12 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.2 "Eye irritation"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

3.6.1.3 Respiratory tract irritation

Table 3.13 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	SC300 does not cause respiratory tract irritation.
Justification for the conclusion	The active substance penflufen the non-active substances in the product do not allow for classification for respiratory tract irritation as they are either not classified for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008. IPBC is classified for effects possibly relevant for the potential classification for respiratory tract irritation, but The Risk Assessment Committee (RAC) evaluated in 2012 the available information for IPBC and found that a classification for acute inhalation toxicity was more relevant. IPBC is classified acute inhalation toxic, and this has been included in the evaluation of this effect for the biocidal product.
Classification of the product according to CLP	Not classified for respiratory tract irritation.

Table 3.14 Data waiving

Data waiving	
Information requirement	There are no testing requirements for respiratory irritation according to Reg. (EU) no. 528/2012
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

3.6.1.4 Skin sensitisation

Table 3.15 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	SC300 may cause skin sensitisation.
Justification for the value/conclusion	SC300 contains >1% of the active substance IPBC (5%) which is classified as skin sensitising. Penflufen and the non-active substances in the product do not contribute to classification for skin sensitisation as they are either not classified for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP	Skin Sens. 1. (H317)

Table 3.16 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.3 "Skin sensitisation"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

3.6.1.5 Respiratory sensitisation

Table 3.17 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	SC300 does not cause respiratory sensitisation.
Justification for the value/conclusion	According to the Guidance on the Biocidal Product Regulation, Part A, Volume III, Human Health (version 1.2 May 2018), if an active substance is identified as a skin sensitiser this should be taken into account since there are currently no standard test and no OECD test guidelines available for respiratory sensitisation. As the biocidal product SC300 has been classified as Skin Sens. 1 due to the content of the active substance IPBC, available information used for the classification of this effect should be evaluated for its potential to cause respiratory sensitisation. In 2012, RAC assessed the available data for IPBC and concluded that the human data available for the assessment of the sensitising potential was not sufficient to conclude on skin

	sensitivity, as there were conflicting results and possible bias within the submitted reports/studies. At the moment there are no valid animal tests to demonstrate whether or not substances have the potential to cause respiratory sensitisation. The *Guidance on the Application of the CLP Criteria* exemplifies that measurements of Immunoglobulin E (IgE) and other specific immunological parameters in mice as well as specific pulmonary responses in guinea pigs may indicate a potential. These effects have not been observed in studies conducted with IPBC. In conclusion, and considering the lack of information, SC300 should not be considered to cause respiratory sensitisation.
Classification of the product according to CLP	Not classified.

Table 3.18 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.4 "Respiratory sensitisation" (ADS).
Justification	Currently no testing methods or test guidelines are available. Classification is therefore based on apparent evidence of potential respiratory sensitisation attained from other sources submitted in the dossier.

3.6.1.6 Acute oral toxicity

Table 3.19 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	SC300 is not acutely toxic via the oral route
Justification for the selected value	The active substance IBPC is classified as Acute Tox. 4, with an LD_{50} of 510.2 mg/kg. Considering the concentration of IPBC is 5 %, and the other substances have LD_{50} values above 2000 mg/kg, the ATE_{mix} for SC300 is 10204.
Classification of the product according to CLP	Not classified.

Table 3.20 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.5.1 "Acute toxicity by oral route"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

3.6.1.7 Acute inhalation toxicity

Table 3.21 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	SC300 does not cause acute inhalation toxicity. ATE_{mix} > 5 mg/L(dust/mist)
Justification for the selected value	The active substance IBPC is classified as Acute Tox. 3, with an LC_{50} of 0.68 mg/L. Considering the concentration of IPBC is 5 %, and the other substances

	have LC_{50} values above the classification range, the ATE_{mix} for SC300 is 13.6 mg/L.
Classification of the product according to CLP	Not classified.

Table 3.22 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.5.2 " Acute toxicity by inhalation"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected.

3.6.1.8 Acute dermal toxicity

Table 3.23 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	SC300 is not acutely toxic via the dermal route. ATE_{mix} > 2000 mg/kg
Justification for the selected value	None of the active substances or non-active substances are classified for acute dermal toxicity, and SC300 should therefore not be classified for acute dermal toxicity according to the rules laid down in Reg. (EC) no. 1272/2008.
Classification of the product according to CLP	Not classified.

Table 3.24 Data waiving

Data waiving	
Information requirement	Annex III of BPR, point 8.5.3 "Acute dermal toxicity"
Justification	Testing of the biocidal product does not need to be conducted, as there are valid data available on each of the components in the product to allow classification of the mixture according to the rules laid down in Reg. (EC) no. 1272/2008, and no synergistic effects between any of the co-formulants or active substance are expected..

3.6.2 Information on dermal absorption

Dermal absorption studies with the product have not been conducted.

Table 3.25 Value(s) used in the Risk Assessment – Dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Penflufen	IBPC
Value(s)	70 %	70%
Justification for the selected value(s)	Default value for solvent-based dilution according to EFSA (2017)	Default value for solvent-based dilution according to EFSA (2017) Guidance on dermal absorption[8].

	Guidance on dermal absorption[6].	

Table 3.26 Data waiving

Data waiving	
Information requirement	Annex III, BPR point 8.6 "Dermal absorption"
Justification	Information on dermal absorption should follow a tiered approach according to annex III, BPR point 8.6. The approach is described in the *Guidance on the Biocidal Product Regulation, Volume III Human Health, Part A* (Version 2) on page 114, and refer to the *EFSA Guidance on dermal absorption (2017)* in section. The use of the 2017 EFSA Guidance on dermal absorption was endorsed at BPC 24.

3.6.3 Available toxicological data relating to substance(s) of concern

No substances of concern (SoC) were identified in SC300. Please refer to the confidential annex of the PAR for details of the assessment.

3.6.4 Other

IPBC is classified STOT RE 1 (H372) and contained in SC300 at a concentration of 5 %, triggering the classification of SC300 as STOT RE 2, H373 (larynx).

Penflufen is classified Carc. 2 (H351). Penflufen is contained in SC300 at a concentration of 2.5 %, triggering the classification of SC300 as Carc. 2, H351.

3.6.4.1 Food and feeding stuffs studies

Not relevant.

3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Not relevant.

3.6.4.3 Other test(s) related to the exposure to humans

No other tests have been performed related to the exposure to humans.

3.6.5 Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex. Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

The active substances IPBC and penflufen have not yet been evaluated according to the

[6] EFSA (European Food Safety Authority), Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G, Ruffo F and Chiusolo A, 2017. Guidance on dermal absorption. EFSA Journal 2017; 15(6):4873, 60 pp.

scientific criteria set out in the Regulation (EU) 2017/2100.

In conclusion, SC300 should be considered not to have endocrine-disrupting properties.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

SC300 is a solvent-based formulation. It is intended for industrial use only, and only at Superwood A/S in Hampen Denmark.

It contains 2.5 % (w/w) penflufen and 5 % (w/w) IBPC. It is applied for use as wood preservative for wood intended to be used outdoors with no direct contact with the ground or water and exposed to frequent weathering (use class 2 and 3).

Wood treatment is performed industrially with CO_2 as a carrier of the product. SC300 is injected automatically into an autoclave in the supercritical phase of CO_2 and exists only in the autoclave. When the pressure is lowered, CO_2 is no longer present. The non-active substance (co-formulant) used enables the active substances to be carried into the CO_2 in the supercritical phase. After impregnation only penflufen and IPBC are left in the wood. Thus, no application rate is available. The uptake of the active substances has been determined by chemical analysis of the wood. Usually, the uptake of a biocidal product is calculated from the weight gain (weight after impregnation – weight before impregnation). This approach is not possible for CO_2 supercritical impregnated wood. The uptake is 25 g penflufen/m^3 wood and 63 g IPBC/m^3 wood.

Relevant guidance documents consulted for human health risk assessment

- *Guidance on the Biocidal Product Regulation*, Volume III Human Health, Part A (version 1.2 May 2018)
- *Guidance on the Biocidal Product Regulation*, Volume III Human Health, Part B + C (Version 4.0, December 2017)
- *Biocides Human Health Exposure Methodology Document* (October 2015)
- *Technical Notes for Guidance: Human Exposure to Biocidal Products – Guidance on Exposure Estimation* (2002)
- *Technical Agreements for Biocides (TAB)* (August 2021)
- *HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products* (HH WG III, 2017)
- *HEAdhoc Recommendation no. 5 - Non-professional use of antifouling paints: exposure assessment for a toddler*

Relevant exposure models or exposure studies used for human health risk assessment

- No exposure studies performed with the product are available
- Relevant exposure models has been obtained from *Biocides Human Health Exposure Methodology Document* (October 2015) and *Recommendation no. 6* of the BPC Ad hoc Working Group on Human Exposure

Strategy for human health risk assessment

- Primary exposure is restricted to industrial users only. As the entire process is fully automated, a quantitative exposure assessment has not been performed.
- Secondary exposure includes exposure of professional, non-professionals as well as the general public. Adults, infants and children may come into contact with treated timber and volatile residues during various activities. These activities include infants mouthing treated timber, children playing on wooden structures, adults

sanding/handling treated wood and laundering work clothes as well as inhalation of volatised residues.
- SC300 can cause both systemic and local effects when exposed to. Therefore, both a systemic and local risk assessment have been performed. For consideration of the classification as Carc. 2 (H351), please refer to section 3.6.6.4

Considerations on volatility of the active substance(s) and substance(s) of concern
Chronic exposure to wood preservatives may arise from the interior surfaces of exterior window frames and exterior doors (including their frames) treated with a wood preservative. SC300 is currently not intended to be sold for the treatment of wood used indoors. SC300 is manufactured and used only at Superwood A/S. Although SC300 is not sold to other companies, and only used for outdoor wood (specifically cladding), an assessment of the potential exposure to volatile residues indoors is considered appropriate, considering the BPR approval process does not take into account this type of restriction. As the product is applied for in use class 2, legally it would be possible to use the wood preservative for windows, exterior doors and roof structures. Penflufen and IPBC possess low vapour pressures (penflufen / IPBC: 4.1×10^{-7} Pa at 20°C / 4.5×10^{-3} Pa at 25°C).

Strategy for livestock exposure and/or dietary risk assessment
Impregnated wood must not come in contact with food, feed and livestock. No assessment has therefore been performed.

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

The main paths of exposure are listed in the table below.

Table 3.27 Summary table: main paths of human exposure

Summary table: main paths of human exposure					
Exposure path	**Primary (direct) exposure**		**Secondary (indirect) exposure**		
	Professional users (including industrial users and trained professional users)	**Non-professional users**	**Professional users** (including industrial users and trained professional users)	**Non-professional bystanders/ General public**	**Via food**
Oral	No	n/a	No	Yes	No
Dermal	No	n/a	Yes	Yes	n/a
Inhalation	No	n/a	Yes	Yes	n/a

3.6.6.3 List of exposure scenarios

Table 3.28 Summary table: exposure scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group** (e.g., professionals, non-professionals, professional bystanders, non-professional bystanders/general public)
Primary exposure		
Mixing/loading Scenario 1	Chronic primary exposure. Fully automated transfer of product.	Industrial user
Application Scenario 2	Chronic primary exposure. Fully automated pressure impregnation.	Industrial user
Post-application Scenario 3	Acute primary exposure. Maintenance/cleaning/repair of the autoclave system.	Industrial user
Secondary exposure		
Post-application Scenario 4	Chronic secondary exposure. Sanding/cutting/handling treated wood.	Professional
Post-application Scenario 5	Acute secondary exposure. Sanding treated wood.	Non-professionals
Scenario 6	Acute intermediary exposure. Laundering industrial work clothes	Industrials, non-professionals, general public
Scenario 7	Acute secondary exposure, incidental. Infant chewing wood cut-off.	General public (infant)
Scenario 8	Chronic secondary exposure. Infant playing and mouthing weathered structure outdoors.	General public (infant, toddler)
Scenario 9	Chronic secondary exposure. Inhalation of volatilised residues from treated wood indoors (restricted to windows, exterior doors and roof structures)	General public (infant, toddler, child, adult)

3.6.6.4 Reference values to be used in risk characterisation

Table 3.29 Reference values to be used in risk characterisation for penflufen

Reference	Study	NOAEL	AF	Correction for absorption	Value
$AEL_{short\text{-}term}$	Acute neurotoxicity in rat	50 mg/kg bw/day	167[1]	No correction	0.3 mg/kg bw/day
$AEL_{long\text{-}term}$	2 year rat	4.4 mg/kg bw/day	100[2]	No correction	0.04 mg/kg bw/day

[1] Assessment factor of 100 and additional assessment factor of 1.67 to consider first pass metabolism by the liver because the value is based on systemic exposure (neurotoxicity), whereas other AELS do not require this adjustment as they are based on effects in the liver.
[2] 10-fold factor for interspecies variability and a 10-fold for intraspecies variability

RAC adopted its opinion on penflufen 15. October 2018 classifying penflufen as Carc. 2 (H351). The classification is based on a non-genotoxic mode of action. A threshold of the carcinogen effect can therefore be assumed. The lowest NOAEL for the carcinogenic effect was from the two-year rat carcinogenicity study and was 5.6 mg/kg bw/day. The overall non-neoplastic NOAEL from this study was 4.0 mg/kg bw/day and concerned effects on the liver. This NOAEL is used a Point of Departure for setting the overall reference values for use in a risk assessment for biocidal products containing penflufen. The potential carcinogenic effect is therefore accounted for in the systemic risk assessment for SC300.

Table 3.30 Reference values to be used in risk characterisation for IPBC

Reference	Study	NOAEL	AF	Correction for absorption	Value
$AEL_{short\text{-}term}$	90-day gavage rat study	35 mg/kg bw/day	100[1]	No correction	0.35 mg/kg bw/day
$AEL_{long\text{-}term}$	104 week chronic toxicity/carcinogenicity study in rats	20 mg/kg bw/day	100[1]	No correction	0.2 mg/kg bw/day
$AEC_{inhalation}$	Larynx effects in a 90 day rat inhalation study	1.16[2] mg/m^3	-	-	1.16 mg/m^3

[1] 10-fold factor for interspecies variability and a 10-fold for intraspecies variability
[2] The NOAEC for the effects on the larynx concerns solid IPBC. The relevance of this value has to be considered for the specific products (LoEP, IPBC).

3.6.6.5 Specific reference value for groundwater

Not relevant.

3.6.6.6 Professional users (including industrial users and trained professional users)

Scenario 1: Mixing/loading

Fully automated transfer of product.

Table 3.31 Description and input parameters

Description of Scenario 1
The mixing/loading process is a fully automated procedure in a closed system. When the product SC300 is formulated, it is automatically loaded into a storage tank (2000-3000 litre stainless steel container) which is directly connected to the impregnation vessels through a closed loop system. There are no users present in the room during this step, and therefore no exposure.

Scenario 2: Application

Fully automated pressure impregnation

Table 3.32 Description and input parameters

Description of Scenario 2
Application of SC300 by supercritical pressure impregnation is a fully automated process. Wood is loaded to a conveyor belt. The conveyor belt transports the wood to the impregnation vessel. The impregnation vessel is closed. SC300 is transferred from the storage tank and fed to a static mixer connected to the impregnation vessel in a closed loop system. The system is slightly heated (> 35 degrees C) and pressurized with CO2 which is continuously circulated through the static mixer and the impregnation vessel. CO2 is used as carrier of the biocidal product. At pressure > ~73 bars CO_2 enters supercritical phase. Supercritical CO_2 is a 'heavy gas' with a liquid like density which means that the functions as a carrier of SC300. At the same time it has no surface tension and a gas like i.e. low viscosity which means it penetrates wood very efficiently. The system is pressurized further (>100 bars) and the CO_2 with dissolved SC300 penetrates the wood completely. Pressure is maintained at a plateau for a specified amount of time to ensure distribution of SC300 in the wood. System is de-pressurized. Excess SC300 is collected and reused. CO_2 is reused. There is no CO_2 or product left in the wood after the impregnation, only the required quantities of IPBC and penflufen. Throughout the application process there are no users present in the same room as the impregnation vessel. They will be located in an adjacent room where all technical monitoring equipment is placed. CO_2 monitoring equipment is connected to an alarm for safety reasons to ensure that there is no CO_2 left when the vessel opens. Thus, no exposure during application is expected.

Scenario 3: Post-application

Maintenance/cleaning/repair of the autoclave

Table 3.33 Description and input parameters

Description of Scenario 3
Any sort of maintenance/repair work on the system (hoses, valves etc.) does not occur. Once every 4 years a third-party inspection of the autoclave is performed. No product will be present in the autoclave/impregnation vessel. Cleaning of the system is not relevant, as the product is recycled in the system and no residues need to be removed.

Scenario 4: Post-application

Sanding/cutting/handling treated wood

Table 3.34 Description and input parameters

Description of Scenario 4			
Cutting and sanding treated wood by professionals is considered a chronic exposure scenario as this is a daily activity. Exposure data used in this scenario is derived from exposure studies conducted with amateurs without the use of gloves and presented in TNsG 2002 User Guidance - Version 1. Professionals are very likely to wear gloves, and the exposure is therefore considered an overestimation. The sanding scenario values from the abovementioned studies is extrapolated from acute settings of one-hour duration to chronic settings for the professional user by assuming that exposure time is six hours. Dermal exposure is based on the surface area exposed (both hand palms), the percentage of this area that is affected by contamination and a transfer coefficient for painted wood using the following formula: Conc. AS x exposed surface area (cm^2) x contaminated surface (%) x transfer efficiency (%) To assess exposure by inhalation it is assumed that the concentration of wood dust would not exceed the occupational exposure limit for dust at the workplace. The EU Operator Exposure Limit (OEL) for respirable hardwood dust is used as worst-case. A wood density of 0.40 g/cm^3 is assumed as agreed in the Human Health TAB. It is considered that handling of treated dry wood is covered by this scenario.			
Input parameters for Scenario 4			
	Parameters	Value	Reference and justification
Tier 1	Concentration of active substance in wood treated with SC300	Penflufen: 0.025 mg/cm^3 IPBC: 0.063 mg/cm^3	-
	Event exposure duration	6 hours	TNsG User Guidance, p. 52 (2002)– version 1
	Body weight	60 kg	HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)HEEG opinion 17 (2013) - Default human factor values for use in exposure assessments in biocidal products
	Inhalation rate	1.25 m^3/hr	HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)HEEG opinion 17 (2013) - Default human factor values for use in exposure assessments in biocidal products
	Inhalation absorption	100 %	CAR penflufen

	Dermal absorption, IPBC	70 %	Default value, EFSA Guidance on dermal absorption (2017)[7]
	Dermal absorption, penflufen	70 %	Default value, EFSA Guidance on dermal absorption (2017)[12]
	Wood dust in the air (OEL)	5 mg/m^3	TNsG User Guidance, p. 51 (2002) - General dust/m^3 of sanded treated wood (8-hour TWA)
	Density of wood dust	0.4 g/cm^3	Technical Agreements for Biocides (TAB) – Version 1August 2021
	Area of wood to be sanded (cm^2)	4 x 4 cm x 250 cm + 2 x 4 cm x 4 cm 4032	TNsG User Guidance, p. 51 (2002) – Example
	Volume of outer layer (cm^3)	4 x 3 cm x 249 cm x 1 cm + 2 x 3 cm x 3 cm x 1 cm 3008	TNsG User Guidance, p. 51 (2002) – Example
	Exposed surface area (palms of two hands)	410 cm^2	HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)
	Percent dislodgeable dried paint	3 %	Biocides Human Health Exposure Methodology, p. 171 (2015)

Calculations
Amount a.s. in the sanded wood (mg) = Concentration of a.s. in wood dust (mg/cm^3) x Volume of outer layer of wooden post (cm^3)

Application rate (mg/cm^2) = Amount a.s. in wood (mg)/area of wood to be sanded (surface area cm^2)

Outcome of systemic exposure and risk characterisation

Table 3.58 Summary table: estimated systemic exposure and risk

[7] Default value is for organic solvent-based formulation, as the product SC300 is most similar to this formulation type, however it should be considered an extreme worst case considering that the solvent is not present in the wood, and the active substances are embedded in the wood in its dry/solid state.

characterisation for professional users

Summary table: estimated systemic exposure and risk characterisation for professional users								
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated oral uptake mg/kg bw/day**	**Estimated dermal uptake mg/kg bw/day**	**Estimated inhalation uptake mg/kg bw/day**	**Estimated total uptake mg/kg bw/day**	**Estimated uptake/ AEL (%)**	**Acceptable (Yes/No)**
Scenario 1	1/No PPE	Penflufen	-	-	-	-	-	Yes
		IPBC	-	-	-	-	-	Yes
Scenario 2	1/No PPE	Penflufen	-	-	-	-	-	Yes
		IPBC	-	-	-	-	-	Yes
Scenario 3	1/No PPE	Penflufen	-	-	-	-	-	Yes
		IPBC	-	-	-	-	-	Yes
Scenario 4	1/No PPE	Penflufen	None	0.0003	0.00004	0.00034	0.85	Yes
		IPBC	None	0.0067	0.0001	0.00684	3.42	Yes

Outcome of (semi-)quantitative local exposure and risk characterisation

A risk characterisation for local effects is triggered only when the biocidal product is classified for local effects. SC300 is classified as STOT RE 2, H373 (larynx). The List of endpoints for IPBC states a NOAEC of 1.16 mg/m^3 for degeneration of the larynx. As such, a (semi-)quantitative risk assessment is possible and should be performed. It further notes that this NOAEC is only relevant for solid IPBC and that its relevance shall be evaluated on a case-by-case basis for biocidal products. Exposure by inhalation to IPBC during sanding/cutting treated wood is considered relevant. Noting that there is no information on how IPBC is bound to the wood, the assessment presents a worst case scenario.

The risk of effects on the larynx is considered acceptable.

Please see appendix 4.1.1 for exposure calculations.

Table 3.60 Summary table: estimated local exposure and risk characterisation for professional users

Summary table: estimated local exposure and risk characterisation for professional users						
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated max inhalation exposure [mg/m^3]**	**Estimated total exposure [mg/m^3]**	**Estimated exposure / AEC (%)**	**Acceptable (yes/no)**
Scenario 4	1/no PPE	-	0.00079	0.00079	0.07	Yes

Outcome of qualitative local risk assessment

Risk characterisation (RC) for local effects is triggered when the biocidal product is classified for local effects. Guidance for concluding qualitatively on the acceptability for professional exposure can be found on page 255, table 27 of *the Guidance on BPR: Vol III Parts B+C version 4.0.* SC300 is classified as skin sensitizing (Skin Sens 1, H317), eye damaging (Eye Dam 1, H318) and toxic to the larynx upon repeated exposure (STOT RE 2, H373).

Zero exposure is expected when mixing, loading and applying SC300 to wood, as this is a fully automated process. No risk of local effects is expected.

Exposure to the treated (dry) wood can occur during post-application tasks such as sawing/sanding and/or handling treated wood.

Information (e.g. tests) used for classification purposes is related to the form or physical state in which the substance is placed on the market and in which it can reasonably be expected to be used according to article 5 (1)(e) of Regulation (EC) no. 1272/2008 (CLP). As such, the classification of SC300 relates to its liquid state and not dried (solid) state within wood. Nevertheless, a qualitative risk assessment has still been performed for the three local effects in this scenario.

Skin Sens 1 (H317) is listed as a medium hazard in *Guidance on BPR: Vol III Parts B+C version 4.0*, and a high level of containment is usually required in order to manage the risk. As noted above, SC300 is classified as skin sensitizing based on studies with IPBC in liquid. The hazard potential cannot readily be transferred to its presence in wood, but additional considerations apply to this scenario which further confirms the acceptable exposure to dried SC300 in wood:
Firstly, although technically not comparable, the wood can be considered a "dilution" of SC300: The uptake of IPBC is 63 g/m^3 wood. Using a density of wood of 400 kg/m^3 (as agreed in *Technical Agreements for Biocides*, Human Health, August 2021, section 6.5, entry 35) this uptake equals 0.15 g IPBC/kg wood or 0.015 % IPBC in the treated wood. If treating the wood as a mixture, it would not be classified. Additionally, the transfer coefficient from dried painted wood is 3 % according to Biocides Human Health Exposure Methodology 2015 (p. 171). As such, the user is only exposed to 3 % of this already "diluted" formulation. Lastly, although the molecular initiating event of both induction and elicitation of skin sensitization occurs in the outer layer of the skin (in keratinocytes), the binding to these cells will have decreased due to change in structure of the matrix causing dermal absorption to be decreased as dry matrices are less absorbable than liquid matrices. According to the *Guidance on BPR*, exposure to substances with skin sensitizing potential should be no more than *equal to or less than once per week and equal to or less than few minutes per day* referring also to *practically no exposure*. Professional users are expected to handle treated wood for up to six hours per day. Ignoring the fact that the wood would not be subject to classification, the other reductions in risk as listed above also favour a longer period of acceptable exposure, even without the use of gloves. It should however be emphasized that professionals are highly likely to wear gloves.

Eye damage 2 (H318) is listed as a high hazard according to the *Guidance on BPR: Vol III Parts B+C version 4.0*, and a high level of containment is usually required in order to manage the risk. Even though exposure is for up to six hours per day and the hazard allows for only a few minutes per day or less in order to manage the risk properly, the risk of eye damage is considered very low in this scenario. The product has dried. It cannot splash into eyes. Therefore, only hand-to-eye exposure could be of relevance. The evaluation of the product's skin sensitising potential presented above is also relevant for its eye damaging potential. Again, if considering the wood as a dilution, classification for eye damage is not elicited. These considerations lead to an acceptable risk of an eye damaging effect without the use

of eye protection. Although eye protection is not required in order to mitigate a risk, the professional user is likely to use it due to the irritative nature of wood dust in eyes combined with the long exposure duration.

Larynx toxicity by repeated exposure (STOT RE 2, H373) is considered a low hazard according to the *Guidance on BPR: Vol III Parts B+C version 4.0*. Some parts of the evaluation of the product's skin sensitising potential is also relevant for its risk of larynx toxicity, such as its "dilution" factor in wood and change in matrix making less substance available for inhalation. Exposure is however very likely, if the user sands the wood. The *Guidance on BPR* lists one hour a day as a preferable maximum of exposure without use of respiratory protective equipment (RPE). In order for professional users to avoid the risk of larynx toxicity, RPE is indicated if not considering the NOAEC in the previous section which shows there is no actual risk of larynx toxicity. Taking into account the irritative effect alone by exposure to wood dust in the air, the use of RPE is however already required for occupational safety measures against this effect.

In total, the risk of skin sensitization, eye damage and larynx toxicity from repeated exposure is considered acceptable for the professional user when exposed for up to six hours per day without wearing personal protective equipment and employing risk mitigation measures.

Table 3.61 Outcome of qualitative local risk assessment

Summary table: estimated local exposure and risk characterisation for professional users								
Task/exposed group	**Concentration in b.p./treated wood**	**Local effect**	**Hazard category**	**Frequency and duration potential exposure**	**Potential degree of exposure**	**Relevant RMM and PPE**	**Conclusion risk**	**Uncertainties related to conclusion that may increase/ decrease risk**
Scenario 1+2+3 Mix/load, application of product, maintenance of equipment	5 % IPBC in b.p.	Skin Sens 1 H317 (moderate potency)	Medium	Zero exposure	Zero exposure	Not necessary.	Acceptable	No risk
		Eye Dam. 1 H318	High					
		STOT RE 2 (larynx) H373	Low					
Scenario 4 Post-application, sawing/sanding/cutting treated wood	*0.15 g IPBC/kg (0.015 %) treated wood	Skin Sens 1 H317 (moderate potency)	Medium	Up to six hours per day according to exposure model and input values	Hand exposure from contact to wood surfaces and to wood dust created during mechanical processing of the wood	Not necessary	Acceptable, see text	(*) Hazard potential not based on solid formulation (dust)
		Eye Dam. 1 H318	High			Not necessary	Acceptable, see text	(*) Hazard potential not based on solid formulation (dust)
		STOT RE 2 (larynx) H373	Low			Not necessary	Acceptable, see text	(*) Hazard potential not based on solid formulation (dust)

*IPBC uptake is 63 g/m^3 wood. Density of wood is 400 kg/m^3 (Technical Agreements for Biocides, Human Health, August 2021, section 6.5, entry 35). This corresponds to 0.15 g IPBC/kg wood or 0.015 % IPBC in treated wood.

Conclusion

A safe use has been demonstrated when applying SC300 to wood using supercritical pressure impregnation with CO_2, as this is a fully automated process. Similarly, a safe use has been demonstrated for the professional user when cutting/sanding and/or handling treated dry wood without wearing personal protective equipment and employing risk mitigation measures.

3.6.6.7 Non-professional users

SC300 is not intended for use by non-professionals. However, considering that it would be possible to make wood available for non-professionals (treated articles), they could be subject to secondary exposure like cutting/sanding and/or handling treated dry wood.

Scenario 5: Post-application

Sanding treated wood

Table 3.35 Description and input parameters

Description of Scenario 5			
Cutting and sanding treated wood by the non-professional user is considered an acute exposure scenario as non-professionals are not likely to perform this task frequently. Exposure data used in this scenario is derived from exposure studies conducted with amateurs without the use of gloves and presented in TNsG 2002 User Guidance -Version 1. Dermal exposure is based on the surface area exposed (both hand palms), the percentage of this area that is affected by contamination and a transfer coefficient for painted wood using the following formula: Conc. AS x exposed surface area (cm^2) x contaminated surface (%) x transfer efficiency (%) To assess exposure by inhalation it is assumed that the concentration of wood dust would not exceed the occupational exposure limit for dust at the workplace. The EU Operator Exposure Limit (OEL) for respirable hardwood dust is used as worst-case. A wood density of 0.40 g/cm^3 is assumed as agreed in the Human Health TAB. It is considered that handling of treated dry wood is covered by this scenario.			
Input parameters for Scenario 5			
	Parameters	Value	Reference and justification
Tier 1	Concentration of active substance in wood treated with SC300	Penflufen: 0.025 mg/cm^3 IPBC: 0.063 mg/cm^3	-
	Event exposure duration	1 hour	TNsG User Guidance 2002 –version 1
	Body weight	60 kg	HEEG opinion 17 (2013) - Default human factor values for use in exposure assessments in biocidal products
	Inhalation rate	1.25 m^3/hr	HEEG opinion 17 (2013) - Default human factor values for use in exposure assessments in biocidal products
	Inhalation absorption	100 %	CARs penflufen, IPBC
	Dermal absorption, IPBC	70 %[8]	Default value, EFSA Guidance on dermal absorption (2017)
	Dermal absorption, penflufen	70 %	Default value, EFSA Guidance on dermal absorption (2017)
	Wood dust in the air (OEL)	5 mg/m^3	TNsG User Guidance, p. 51 (2002) - General $dust/m^3$ of sanded treated wood (8-hour TWA)
	Density of wood dust	0.4 g/cm^3	Technical Agreements for Biocides (TAB) – Version 1August 2021
	Area of wood to be sanded (cm^2)	4 x 4 cm x 250 cm + 2 x 4 cm x 4 cm 4032	TNsG User Guidance, p. 51 (2002) – Example

	Volume of outer layer (cm^3)	4 x 3 cm x 249 cm x 1 cm + 2 x 3 cm x 3 cm x 1 cm 3008	TNsG User Guidance, p. 51 (2002) – Example
	Exposed surface area (palms of two hands)	410 cm^2	HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)
	Percent dislogdeable dried paint	3 %	Biocides Human Health Exposure Methodology, p. 171 (2015)

Calculations

Amount a.s. in the sanded wood (mg) = Concentration of a.s. in wood dust (mg/cm^3) x Volume of outer layer of wooden post (cm^3)

Application rate (mg/cm^2) = Amount a.s. in wood (mg)/area of wood to be sanded (surface area cm^2)

Outcome of systemic exposure and risk characterisation

Table 3.36 Summary table: estimated systemic exposure and risk characterisation for non-professional users

Summary table: estimated systemic exposure and risk characterisation for professional users								
Exposure scenario	**Tier/PPE**	**Active substance**	**Estimated oral uptake mg/kg bw/day**	**Estimated dermal uptake mg/kg bw/day**	**Estimated inhalation uptake mg/kg bw/day**	**Estimated total uptake mg/kg bw/day**	**Estimated uptake / AEL (%)**	**Acceptable (Yes/No)**
Scenario 5	1/No PPE	Penflufen	-	0.0003	0.0003	0.00031	0.77	Yes
		IPBC	-	0.0067	0.00002	0.00676	3.38	Yes

Outcome of (semi-)quantitative local exposure and risk characterisation
A risk characterisation for local effects is triggered only when the biocidal product is classified for local effects. SC300 is classified as STOT RE 2, H373 (larynx). The List of endpoints for IPBC contains a NOAEC of 1.16 mg/m^3 for degeneration of the larynx. It further more notes that this NOAEC is only relevant for solid IPBC. Its relevance should be evaluated on a case-by-case basis for biocidal products depending on the formulation. Exposure by inhalation to IPBC during sanding/cutting treated dry wood is considered relevant, and a risk assessment has therefore been performed for the professional user, as this user is considered to act as a risk envelope for the non-professional user. Please see

[8] Default value is for organic solvent-based formulation, as the product SC300 is most similar to this formulation type, however it should be considered an extreme worst case considering that the solvent is not present in the wood, and the active substances are embedded in the wood in its dry/solid state.

the section *Outcome of (semi-)quantitative local exposure and risk characterisation* for the professional user for further details.

The risk of effects on the larynx is considered acceptable.

Please see appendix 4.1.1 for exposure calculations.

Outcome of qualitative local risk assessment

Risk characterisation (RC) for local effects is triggered when the biocidal product is classified for local effects. Guidance for concluding qualitatively on the acceptability of risk for the non-professional user is located in table 26 of *the Guidance on BPR: Vol III Parts B+C version 4.0.* SC300 is classified as skin sensitizing (H317), eye damaging (H318) and for larynx toxicity upon repeated exposure (H373).

Exposure to the treated (dry) wood can occur during post-application tasks such as sawing/sanding and/or handling treated wood by a non-professional user.

Information (e.g. tests) used for classification purposes is related to the form or physical state in which the substance is placed on the market and in which it can reasonably be expected to be used according to article 5 (1)(e) of Regulation (EC) no. 1272/2008 (CLP). As such, the classification of SC300 relates to its liquid state and not dried (solid) state within wood. Nevertheless, a qualitative risk assessment has still been performed for the three local effects in this scenario.

Skin sensitizing is listed as a medium hazard in *Guidance on BPR: Vol III Parts B+C version 4.0*, and a high level of containment is usually required in order to manage the risk. As noted above, SC300 is classified as skin sensitizing based on studies with IPBC in liquid. The hazard potential cannot readily be transferred to its presence in wood, but additional considerations apply to this scenario which further confirms the acceptable exposure to dried SC300 in wood:
Firstly, although technically not comparable, the wood can be considered a "dilution" of SC300: The uptake of IPBC is 63 g/m3 wood. Using a density of wood of 400 kg/m3 (as agreed in *Technical Agreements for Biocides*, Human Health, August 2021, section 6.5, entry 35) equals 0.15 g IPBC/kg wood or 0.015 % IPBC in the treated wood. If treating the wood as a mixture, it would not be classified. Secondly, the transfer coefficient from dried painted wood is 3 % according to Biocides Human Health Exposure Methodology 2015 (p. 171). As such, the user is only exposed to 3 % of this already "diluted" formulation. Lastly, although the molecular initiating event of both induction and elicitation of skin sensitization occurs in the outer layer of the skin (in keratinocytes), the binding to these cells will have decreased due to change in structure of the matrix causing dermal absorption to be decreased as dry matrix are less absorbable than liquid. According to the *Guidance on BPR*, exposure to substances with skin sensitizing potential should be no more than *equal to or less than once per week and equal to or less than few minutes per day* referring also to *practically no exposure*, however the reductions in risk as listed above favour a longer period of exposure. Non-professional users can be expected to handle treated wood for about an hour, but given the above-listed considerations, no risk of skin sensitization is suspected and therefore no risk mitigation measures are required to assure a safe level of exposure.

Eye damage is listed as a high hazard according to the *Guidance on BPR: Vol III Parts B+C version 4.0*, and a high level of containment is usually required in order to manage the risk. Even though exposure is for up to six hours per day and the hazard allows for only a few minutes per day or less in order to manage the risk properly, the risk of eye damage is considered very low in this scenario. The product has dried. It cannot splash into eyes.

Therefore, only hand-to-eye exposure could be of relevance. The evaluation of the product's skin sensitising potential presented above is also relevant for its eye damaging potential. Again, if considering the wood as a dilution, classification for eye damage is not elicitated. These considerations lead to an acceptable risk of an eye damaging effect without the use of eye protection.

Larynx toxicity by repeated exposure is considered a low hazard according to the *Guidance on BPR: Vol III Parts B+C version 4.0*. Some parts of the evaluation of the product's skin sensitising potential is also relevant for its risk of larynx toxicity, such as its dilution factor and change in matrix making less substance available for inhalation. Exposure is likely, if the user sands the wood. The *Guidance on BPR* lists one hour a day as a preferable maximum of exposure. The non-professional user is not expected to sand wood for over an hour a day. Furthermore, the non-professional user is also not likely to sand over a longer period of time measured in days/months which is required for the effect on the larynx to develop. A semi-quantitative risk assessment has been performed for this effect showing acceptable exposure levels.

In total, the risk of skin sensitization, eye damage and larynx toxicity from repeated exposure is considered acceptable for the non-professional user without applying risk mitigation measures.

Table 3.66 Outcome of qualitative local risk assessment

Summary table: estimated local exposure and risk characterisation for non-professional users								
Task/exposed group	**Concentration in b.p./treated wood**	**Local effect**	**Hazard category**	**Frequency and duration potential exposure**	**Potential degree of exposure**	**Relevant RMM**	**Conclusion risk**	**Uncertainties related to conclusion that may increase/ decrease risk**
Scenario 5 Post-application, sawing/sanding/cutting treated wood	*0.15 g IPBC/kg (0.015 %) treated wood	Skin Sens 1 H317 (moderate potency)	Medium	Up to one hour on an irregular basis according to exposure model and input values	Hand exposure from contact to wood surfaces and to wood dust created during mechanical processing of the wood	-	Acceptable, see text	(*) Hazard potential not based on solid formulation (dust)
		Eye Dam. 1 H318	High			-	Acceptable, see text	(*) Hazard potential not based on solid formulation (dust)
		STOT RE 2 (larynx) H373	Low			-	Acceptable, see text	(*) Hazard potential not based on solid formulation (dust)

*IPBC uptake is 63 g/m^3 wood. Density of wood is 400 kg/m^3. This corresponds to 0.15 g IPBC/kg wood or 0.015 % IPBC in treated wood.

Conclusion

A safe use has been demonstrated for the non-professional user when cutting/sanding and/or handling treated dry wood without applying risk mitigation measures.

3.6.6.8 Secondary exposure to the general public

Scenario 6:

Laundering industrial work clothes

Table 3.37 Description and input parameters

Description of Scenario 6
Laundering of work clothes is a relevant intermediate task if work clothes are brought home from the work place. However, considering no primary exposure to SC300 in its liquid phase is expected, exposure to SC300 is not considered relevant. For secondary exposure through sanding/cutting/handling dried wood, exposure is considered negligible and already covered by the exposure scenarios concerning the primary task.

Scenario 7:

Infant chewing wood cut-off

Table 3.38 Description and input parameters

Description of Scenario 7			
Secondary exposure can occur if an infant chews a piece of treated wood. This scenario is considered an acute scenario. It is assumed that the active substances are bound to the outer 1 cm of wood and that this part is accessible chewing by infants. In total, it is assumed that an infant chews a 4x4x1cm piece of wood chip and in doing so releases 10% of the active substances according to TNsG User guidance, version 1, 2002. The TnsG further regards the scenario unrealistic for children as opposed to infants, as they are unlikely to chew treated wood. Dermal exposure is not considered.			
	Parameters	Value	Reference and justification
Tier 1	Concentration of active substance in wood treated with SC300	Penflufen: 0.025 mg/cm^3 IPBC: 0.063 mg/cm^3	-
	Volume off-cut from treated wood	16 cm^3	TNsG User Guidance, p. 52 (2002), example
	Extraction substance from wood by chewing	10%	TNsG User Guidance, p. 52 (2002), example
	Oral absorption	Penflufen: 100 % IPBC: 100 %	CAR, penflufen
	Body weight, infant	8 kg	HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)

Scenario 8:

Infant playing and mouthing weathered structure outdoors.

Table 3.39 Description and input parameters

Description of Scenario 8			
Chronic exposure to infants and toddlers can occur from playing on and mouthing weathered playing structures. Likewise, chronic exposure can occur for children playing on weathered structures. The exposure settings are based on TNsG 2002 User guidance – Version 1 and TNsG 2002, part III and implements that during play on timber structures, infants, toddlers, and children are exposed dermally and orally (via hand-to-mouth transfer route). Dermal exposure is based on the hand surface area exposed, the percentage of this area that is affected by contamination and a transfer coefficient for painted wood, using the following formula: *Conc. AS x exposed surface area (cm^2) x contaminated surface (%) x transfer efficiency (%)* For oral exposure 50% hand-to-mouth transfer is assumed (external dermal exposure = external oral exposure). Only the exposure to infants and toddlers has been calculated as they are considered to act as risk envelopes for the child.			
	Parameters	Value	Reference and justification
	Conc. active substances on treated surface	0.0021 mg/cm^2 Penflufen 0.047 mg/cm^2 IPBC	See calculations for scenario 4+5
	Infant hand surface (palms) Toddler hand surface (palms)	98.4 cm^2 115.2 cm^2	HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)
	Hand area contaminated	40 %	HEAdhoc Recommendation no. 5, Non-professional use of antifouling paints: exposure assessment for a toddler, 40 % transfer coefficient for hand to dry paint.
	Transfer efficiency from wood	2%	Biocides Human Health Exposure Methodology Guidance, p. 171 (2015) -Transfer coefficients – Dislodgeable residues

Scenario 9:

Inhalation of volatilised residues from treated wood used indoors (restricted to windows, exterior doors and roof structures)

Table 3.40 Description and input parameters

Description of Scenario 9

Long-term exposure to volatilised residues can be neglected if the following Tier 1 screening tool is ≤ 1 (HEEG Opinion 13; endorsed TM IV, 2011, amended TM III, 2013):

$$0.328 \times {}^{\text{molecular weight x vapour pressure}}/_{\text{AEL long-term}} \leq 1$$

A value of 0.001 is calculated for penflufen, thus making further assessment unnecessary. Since this is not the case for IPBC (a value of >2 is obtained with use of the maximum vapour pressure at 25°C), further assessment with regards to long-term inhalation exposure to volatilised residues is considered.

Henry's law can be used to approximate the partitioning of substances between the liquid phase and the atmosphere:

$C_{air}/C_{liquid} = kH/RT$ (see parameters in table below), or:

$C_{air} = kH/RT * C_{liquid}$

Systemic inhalatory exposure of adults is calculated by correcting the concentration in air for the daily respiratory rate and adult body weight.

Chronic exposure to wood preservatives may arise from the interior surfaces of exterior window frames and exterior doors (including their frames) treated with a wood preservative. As a worst case, inhalation exposure is set to 100% of the saturated vapour pressure/concentration (SVC) according to HEEG opinion 13.

SVC = (vp (Pa) x mw (g/mol)) / (8.31 (gas constant, J/mol.K) x T (K))

The calculation is highly conservative and is designed as a screening tool for identifying a risk. Furthermore the vapour pressure of IPBC is in general considered to be low (<0.5 kPa).

The tier 2 exposure calculations were performed in ConsExpo based on default input values obtained from ConsExpo factsheets as well as information on the composition of the product. This exposure calculation is highly conservative as well. The model used is the Exposure to Vapour –Evaporation which is intended for liquids and not dried paints. Furthermore, the default input values are designed for use when painting and inhalation during the application, not the volatilised residues from the dried surfaces. Additionally, considering that only exterior window frames and doors are subject to treatment with wood preservatives, only a very minimum of release area is considered for the exposure calculation. Finally, it is highly conservative to assume 24h of exposure per day and given the vapour pressure of IPBC is given at 25°C, the vapour pressure will be even lower at a lower temperature (20 °C). The calculations include the lowest and highest vapour pressure for IPBC.

For details on the exposure calculations please refer to Appendix 4.1.1. Only the results from use of the maximum vapour pressure is included in the results and forwarded to the risk characterisation.

	Parameters	Value	Reference and justification
Tier 1	Saturated vapour concentration		HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocide active substance
	Molecular weight	Penflufen: 317.41 g/mol IPBC: 281.1 g/mol	CAR, penflufen CAR, IPBC
	Vapour pressure	Penflufen: 4.1 x 10-7 Pa at 20°C IPBC: 2.36 x 10^{-3} - 4.5 x 10^{-3} Pa at **25°C**	CAR, penflufen CAR, IPBC
	Henry's law constant (H)	6.45 x 10^{-3} Pa*m^3/mol	-

	Ideal gas constant (R)		8.315 J/K mol	-
	Temperature (T)		298 K (25°C)	-
	Concentration in liquid		100 %	
	Adult	Body weight	60 kg	HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)
		Inhalation rate	16 m^3/day	
	Child	Body weight	23.9 kg	
		Inhalation rate	12 m^3/day	
	Toddler	Body weight	10 kg	
		Inhalation rate	8 m^3/day	
	Infant	Body weight	8 kg	
		Inhalation rate	5.4 m^3/day	
Tier 2	ConsExpo Web			
	Model		Exposure to vapour -evaporation	ConsExpo model documentation https://www.rivm.nl/bibliotheek/rapporten/2017-0197.pdf#page=35 Worst case –Overestimation, as this model is for liquids and argued against for dried paints.
	Room size		20 m^3	ConsExpo General Fact sheets, https://www.rivm.nl/bibliotheek/rapporten/090013003.pdf Worst case room size and ventilation rate in a house. Used for consumer painting with a brush, not for volatilised residues long term. Realistically, 300 m3 is a small house and would be more appropriate
	Ventilation rate		0.6/h	
	Product is substance in pure form		100 % weight fraction	Solvent is only used to transfer active substances to the autoclave
	Exposure duration		Set to 1 day	ConsExpo General Fact sheets, default values https://www.rivm.nl/bibliotheek/rapporten/2017-0197.pdf#page=35
	Emission duration		Set to 1 day	
	Mass transfer		10 m/hr	

	Release area	1 m^2	SC300 is only intended for outdoor use on wood, making only window frames and outside doors relevant as release areas indoors. 1 m^2 seems as a reasonable estimate in relation to the small room volume.
	Product amount	Application rate x release area	0.047 mg/cm2= 470 mg/m2

Outcome of systemic exposure and risk characterisation

Table 3.41 Summary table: estimated systemic exposure and risk characterisation for general public

Summary table: combined systemic exposure and risk characterisation for general public									
Scenarios combined	**Tier/PPE**		**Active substance**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)**	**Acceptable (Yes/No)**
Scenario 7 Infant chewing on wood cut off	Infant		IPBC	0.0126	Negligible	Negligible	0.0126	3.6	Yes
			Penflufen	0.005	Negligible	Negligible	0.005	1.7	Yes
Scenario 8 Infant playing and mouthing on weathered play structures	Infant (scenario a)		IPBC	0.00347	0.00485	Negligible	0.0083	4.2	Yes
			Penflufen	0.00016	0.00022	Negligible	0.0004	0.9	Yes
	Toddler (scenario b)		IPBC	0.0032	0.0045	Negligible	0.0078	3.9	Yes
			Penflufen	0.0001	0.0002	Negligible	0.0003	0.9	Yes
Scenario 9 Inhalation of volatilised residues	Adult	1	IPBC	Not relevant	Not relevant	0.13854	0.13854	69.3	Yes
		2	IPBC	Not relevant	Not relevant	0.0587	0.0587	29.3	Yes
	Child	1	IPBC	Not relevant	Not relevant	0.26085	0.26085	130.4	No
		2	IPBC	Not relevant	Not relevant	0.11	0.11	55.2	Yes
	Toddler	1	IPBC	Not relevant	Not relevant	0.41562	0.41562	207.8	No
		2	IPBC	Not relevant	Not relevant	0.176	0.176	88	Yes
	Infant	1	IPBC	Not relevant	Not relevant	0.35068	0.35068	175.3	No
		2	IPBC	Not relevant	Not relevant	0.1485	0.1485	74.3	Yes

Combined scenarios

Exposure to professionals cutting/sanding wood combined with inhalation of volatilised residues has been considered to cover all relevant adult combined exposure scenarios as well as toddlers playing and mouthing wooden structures combined with exposure to inhalation residues. Only the combined exposure to IPBC is considered relevant, as IPBC is the only active substance available for inhalation by vapourisation as described in scenario 9, and only the toddler is considered, as toddlers have the highest inhalation rate per kg body weight exposure and therefore can act as a risk envelope for the other populations.

For details on the exposure calculations please refer to Appendix 4.1.1.

Table 3.42 Summary table: combined systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

Summary table: combined systemic exposure and risk characterisation for general public							
Scenarios combined	**Tier/PPE**	**Estimated oral uptake [mg/kg bw/day]**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated inhalation uptake [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)**	**Acceptable (Yes/No)**
Scenario 4 + Scenario 9	1/no PPE	-	0.0067	0.058765	0.0655	32.8	Yes
Scenario 8b + Scenario 9	1/no PPE	0.003	0.006	0.176	0.184	91.9	Yes

Outcome of (semi-)quantitative local exposure and risk characterisation

Not relevant. Although SC300 is classified for local effects, these are not considered relevant to assess in relation to the exposure of the general public. Furthermore, no quantitative reference values are available for use in a (semi-) quantitative risk assessment.

Outcome of qualitative local risk assessment

Not relevant. Although SC300 is classified for local effects, these are not considered relevant to assess in relation to the exposure of the general public, as the assessment for the professional and non-professional user is considered to cover the exposure to the general public.

Conclusion

A safe level of exposure to the active substances penflufen and IPBC was identified for all populations of the general public considering the scenarios both in isolation as well as in relevant combinations.

3.6.7 Monitoring data

No monitoring data available.

3.6.8 Dietary risk assessment

3.6.8.1 Information of non-biocidal use of the active substance and residue definitions

Table 3.47 Summary table of other (non-biocidal) uses

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
Penflufen			
1.	Plant protection products	Default MRL established according to art 18(1)(b) of Regulation (EC) no. 396/2005	0.01 mg/kg [1]
IPBC			
1.	Cosmetics	Preservative	Daily recommended dose in Europe 150 µg/d (with an upper short term limit of 1000 µg/d) [2]

[1] Regulation (EC) No 396/2005
[2] SCCNFP/0826/04 Opinion on Iodopropynyl Butylcarbamate (1 July 2004)

3.6.8.2 Estimating livestock exposure to active substances used in biocidal products and Worst Case Consumer Exposure (WCCE)

SC300 is not intended for use on wood to be used in places where livestock may be exposed. Including the risk mitigation measure 'Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals.' is considered sufficient to ensure that consumers are not exposed to residues in food.

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

SC300 is not intended for preservation of wood that will come into contact with food or feedstuff. The RMM "Do not use on wood that will come in direct contact with food or animal feed." ensures that users of the product are informed of this.

3.6.8.4 Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure

SC300 is not intended for preservation of wood that will come into contact with food or feedstuff. Including the risk mitigation measure "Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals," is considered sufficient to ensure that consumers are not exposed to residues in food.

3.6.8.5 Maximum residue limits or equivalent

See section 3.6.8.1.

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

The Guidance on Human health risk assessment (ECHA Guidance on BPR: Volume III Part B, Risk Assessment – October 2015) describes a tiered approach for the risk assessment for products containing multiple active substances and/or substances of concern.

In Tier I the risk assessment is performed for each active substance separately, as currently described in above sections.
In this Tier I assessment the HQ is determined: HQ = internal exposure/ AEL, and if HQ<1 the risk is considered acceptable.

Tier II implements the worst-case scenario in combining the exposures for all the active substances in the product. The approach uses assessment of combined exposure to mixture by concentration or dose-addition.

In Tier II the HQ of the individual active substances will be added up resulting in the HI for the mixture/product.

$HI = \sum HQ_{a.s.}$
If HI ≤ 1 the risk related to use of the mixture will be considered acceptable;
If HI > 1 the risk related to use of the mixture will be considered unacceptable and refinement is needed.

When HI > 1, both risk refinement, considering RMM and Tier III could be performed in parallel.

Please refer to the output tables for the individual scenarios in section 4.1.1. All exposure scenarios have an HI ≤ 1 when considered individually. For the combined exposure, please refer to the table below (this can also be seen in the output tables in section 4.1.1).

Only exposure scenarios where a quantitative assessment has been performed has been considered. Therefore, the mixing & loading and application of products (scenario 1 and 2) and maintenance of system (scenario 3) as well as laundering (scenario 6) are considered irrelevant for this assessment. Professionals cutting/sanding wood (scenario 4) combined with inhalation of volatilised residues (scenario 9) covers non-professionals cutting/sanding, as no personal protective equipment is required, and the only difference between the two is therefore the duration of task. As penflufen is not volatile, a combined exposure of IPBC and penflufen for scenario 9 is not relevant as well. Only the toddler is considered for scenario 8 (combined with scenario 9) as the combined exposure to IPBC for toddlers is much higher than for the infant, and the toddler acts as a risk envelope.

Table 3.85 Tier 1 and tier 2

Hazard index for combined exposure to penflufen and IPBC						
Scenario number	**Exposed group**	**Tier**	**HQ IPBC**	**HQ penflufen**	**HI**	**Acceptable**
Scenario 4 Professional cutting/sanding wood + Scenario 9 Inhalation of volatilised residues	Professionals	1	0.33	0.0085	0.3385	Yes
Scenario 7 Infant chewing wood cut-off	General public	1	0.015	0.03	0.045	Yes
Scenario 8 Toddler playing and mouthing won wooden structure + Scenario 9 Inhalation of volatilised residues	General public	1	0.92	0.01	0.93	Yes

Conclusion

Safe use has been demonstrated considering the combined exposure to penflufen and IPBC without employing risk mitigation measures beyond those already applied.

3.6.10 Overall conclusion on risk assessment for human health

Table 3.45 Overall conclusion on the risk assessment for human health from systemic and local exposure

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
1	Wood preservative for industrial use in use class 2 and 3.	Acceptable	-Do not use on wood that will come in direct contact with food, feed and livestock

3.7 Risk assessment for animal health

3.7.1 Risk for companion animals

No exposure to companion animals is foreseen. Additionally, methodology for exposure to companion animals is not harmonised for use in assessment under the Biocides Regulation.

The demonstrated safe use from human exposure is considered to cover potential exposure from treated articles to companion animals.

3.7.2 Risk for livestock animals

See section: 3.6.8.2.

3.8 Risk assessment for the environment

SC300 is a PT8 product intended for use in Use Class 2 and 3 against wood rotting fungi. It contains two active substances, Penflufen and IPBC present in concentrations as 2.5 % and 5.0 % respectively.
IPBC has a harmonised environmental classification as H400 (M-factor = 10) and H410 (m-factor = 1), and Penflufen has a harmonised environmental classification of H400 (m-factor = 1) and H410 (m-factor = 1). No other substance in the biocidal product has an environmental classification.
The concentration of the active substances alone therefore leads to the classification of the product as H400 Aquatic Acute 1 and H411 Aquatic Chronic 2.

SC300 is only used industrially and is applied to the wood by supercritical CO2 process.

The carrier of the product is CO_2. The product is injected into the autoclave into the supercritical face of CO_2 and does only exist in the autoclave. When the pressure is released, the CO_2 are no longer present. The glycol used is to enable the biocides to be carried into the CO_2 in the supercritical face. After the impregnation only the biocides (penflufen and IPBC) are left in the wood. Therefore, there is no actually application rate of the product only the biocides (active substances). The uptake of the a.s. has been determined by chemical analysis of the wood. Usually, the uptake of a biocidal product is calculated from the weight gain (weight after impregnation – weight before impregnation). This approach is not possible for CO_2 supercritical impregnated wood.

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substances, metabolites and transformation product(s)

No new endpoint studies have been submitted since the approval of the active substances. The risk assessment is entirely based on the list of endpoints as published in the assessment report for penflufen PT8 (March 2017) for which United Kingdom was the rapporteur member state and the assessment report on IPBC for PT8 (22/02/2008) for which Denmark was the rapporteur member state. The latest updated end point is used for the assessment.
The assessment reports is available on the ECHA website.

IPBC has also been assessed for use in PT13 in 2015. No new endpoints in this assessment report for the calculation of the risk assessment for the environment.

The exposure assessment is based on data for the active substances and leaching data for the product.

The PECs for Penflufen, IPBC and degradation products in the environmental compartments derived in the following sections are calculated on the basis of the emission scenarios available for Product Type 8, taking into account degradation processes and/or dilution (where applicable). Although the iodine-species and PBC (IPBC metabolites) are considered far less toxic than the parent compound, these metabolites could pose an environmental risk. Therefore, PECs for these metabolites were calculated as well.

Endpoints and PNEC values for the active substances applied in the

environmental risk assessment are presented in the table below.

Endpoints and PNEC values for the active substances applied in the environmental risk assessment				
	Value		**Unit**	**Remarks**
	Penflufen	**IPBC**		
Fate and behaviour in the environment				
Molecular weight	317.41	281.1	g/mol	
Melting point	111.1	65.8-66.5	°C	
Vapour pressure (at 20°C)	4.1 $x10^{-7}$	2.36-4.5 $x10^{-3}$ Pa at 25°C	Pa	
Water solubility (at 20°C)	10.9 (pH 7)	168 (pH 7)	mg/l	
Log Octanol/water partition coefficient (K_{ow})	3.3	2.81 (25°C)	Log 10	
Organic carbon/water partition coefficient (K_{oc})	279.9	113.25	L/kg	
Henry's Law Constant	1.19$x10^{-5}$ (pH7.1)	3.38-6.45 $\times10^{-3}$ (at 25 °C)	$Pa/m^3/mol$	
Characterisation of biodegradability	Not- readily biodegradable	ready biodegradable	-	
Rate constant for STP	N/A	-	h^{-1}	
Transformation fraction and maximum radioactivity	-	-	- %	
DT_{50} for biodegradation in surface water	140 d	0.129	d or hr (at 12ºC)	
Transformation fraction and maximum radioactivity	N/A	-	- %	
DT_{50} for photolysis in water	17.3	-	d or hr (at 12ºC /pH)	
DT_{50} for degradation in soil	214	0.196	d or hr (at 12ºC)	
Transformation fraction and maximum radioactivity	-	-	- %	
DT_{50} for degradation in air	N/A	-	d or hr	
DT_{50} for degradation in the sewer system	-	-	d or hr (at 12ºC)	
DT_{50} for degradation in manure	-	-	d or hr (at 12ºC)	
DT50 for degradation in sediment	1000		d or hr (at 12ºC)	

Predicted no effect concentrations (PNEC)				
Sewage treatment plant	1.09	0.44	mg/L	
Surface water	0.00234	0.0005	mg/L	
Marine water	-		mg/L	
Sediment	0.016	0.0005	mg/kg wwt	
Marine sediment	-	-	mg/kg wwt	
Soil	0.377	0.005	mg/kg wwt	
Bird	31.5	-	mg/kg	
Mammals	33.33	-	mg/kg	

Relevant degradation products - Penflufen

The major metabolite formed in soil from penflufen is according to the final CAR report penflufen-3-hydroxy-butyl (M01) and Penflufen-pyrazolyl-AAP (M02). M02 are not formed in aquatic environments and will therefore not be addressed in the water compartment.

Endpoints and PNEC values for the metabolites and transformation products for Penflufen applied in the environmental risk assessment.

Endpoints and PNEC values for the metabolite(s) and transformation product(s) applied in the environmental risk assessment				
	Value		Unit	Remarks
	penflufen - 3-hydroxy-butyl (M01)	penflufen - pyrazolyl-AAP (M02)		
Fate and behaviour in the environment				
Molecular weight	333.4	275.3	g/mol	
Melting point			°C	
Vapour pressure (at X°C)			Pa	
Water solubility (at X°C)			mg/l	
Log Octanol/water partition coefficient (K_{ow})	1.7	2.1	Log 10	Ph5, Ph7 & pH9
Organic carbon/water partition coefficient (K_{oc})	38.2	1006	L/kg	
Henry's Law Constant (at X C)*[if measured data available]*			$Pa/m^3/mol$	
Characterisation of biodegradability			-	
Rate constant for STP			h^{-1}	
Transformation fraction and maximum radioactivity	-	-	- %	
DT_{50} for biodegradation in surface water	1000	1000	d or hr (at 12ºC)	

Endpoints and PNEC values for the metabolite(s) and transformation product(s) applied in the environmental risk assessment				
	Value		Unit	Remarks
	penflufen - 3-hydroxy-butyl (M01)	penflufen - pyrazolyl-AAP (M02)		
Transformation fraction and maximum radioactivity	-		- %	
DT_{50} for hydrolysis in surface water			d or hr (at 12ºC /pH)	
DT_{50} for degradation in soil	180	311	d or hr (at 12ºC)	From test. See CAR
Transformation fraction and maximum radioactivity	-		- %	
DT_{50} for degradation in air	-	-	d or hr	The exposure to air expected to be negligible
DT_{50} for degradation in the sewer system	-	-	d or hr (at 12ºC)	
DT_{50} for degradation in manure	-	-	d or hr (at 12ºC)	
DT50 for degradation in sediment	1000	1000	d or hr (at 12ºC)	
Predicted no effect concentrations (PNEC)				
Sewage treatment plant	-	-	mg/L	
Surface water	0.0157	-	mg/L	
Marine water	-	-	mg/L	
Sediment	-	-	mg/kg wwt	
Marine sediment	-	-	mg/kg wwt	
Soil	0.39	0.322	mg/kg wwt	
Bird	-	-	-	
Mammals	-	-	-	

Summary table on relevant metabolites from penflufen			
Metabolite/transformation- or reaction product	**Compartment**	**% Active Substance**	**Formation Fractions used in PEC_{gw}, modelling**
penflufen -3-hydroxy-butyl (M01)	Soil Surface Water	17.0% 12.8%	0.58 from parent
penflufen -pyrazolyl-AAP (M02)	Soil Surface Water	11.5% 0.0%	0.08 from parent 1 from MO1

Relevant degradation products - IPBC

Degradation of IPBC yields the primary degradate propargyl butyl carbamate (PBC) as well

as iodine. PEC values have been calculated for PBC when relevant. Regarding iodine, IPBC emissions into the environmental compartments STP, surface water and soil, respectively, have been converted to iodine (applying a molecular weight correction) and concentrations have been calculated when relevant. The resulting iodine concentrations have been compared to background concentrations found in the environment. Please refer to annex section 4.1.3.1

Input parameters (only set values)* for calculating the fate and distribution in the environment – IPBC Metabolites					
Input	**PBC**	**Iodide**	**Iodate**	**Unit**	**Remarks**
Molecular weight	155.2	126.904	174.903	g/mol	
Vapour pressure (at 25°C)	18.8	1.0x10E-06	1.0x10E-06	Pa	
Water solubility (at 25°C)	2860	1x10E+05	1x10E+05	mg/L	
Log Octanol/water partition coefficient	1.64	2.49	2.49	Log 10	
Organic carbon/water partition coefficient (Koc)	198.1	290	290	L/kg	
Biodegradability		Not applicable, inorganic substance	Not applicable, inorganic substance	-	
Solids-water partition coefficient in soil	-	5.4	7.9	cm^3/g	
Henry's Law Constant	1.02	no	No	Pa/m3/mol	
DT_{50} for biodegradation in surface water	31.2	-	-	d (at 12ºC)	
DT_{50} for biodegradation in sediment	31.4	-	-	d (at 12ºC)	
DT_{50} for degradation in soil	9.5	1000	1000	d (at 12ºC)	
Maximum formation rate in soil	100	100	14	%	
Maximum formation rate in water		100	100	%	
Maximum formation rate in sediment		100	100	%	
The ratio between the molar masses of PBC and IPBC is 0.552.					

*Values are deduced from the IPBC PT6 CAR (September 2013)

Beside PBC another transformation product from IPBC is iodine which is not a xenobiotic substance but an essential dietary trace element and is ubiquitously present in the environment. Because of iodine's natural presence in the environment, background values have to be taken into account in the environmental risk assessment. An overview on the background concentrations of iodine in the relevant environmental compartments is given in the table below. This has been taken from the Assessment Report for iodine (PT1,3,4,22), December 2013.

Background concentration of iodine in the environment	
Compartment	Background level (as iodine)
Soil	Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg Global mean value of 5 mg/kg

Groundwater	Mean concentration: 1 µg/l Range: < 1-70 µg/l with extremes up to 400 µg/l
Freshwater (river and lake)	0.5 - 20 µg/l

3.8.1.2 Endpoints for the product

There are no new additional data available for the product. The exposure assessment and classification and labelling are based on the agreed endpoints for the active substances and available information for the non-active substances.

Leaching behaviour (ADS)

Semi-field leaching studies has been performed according to NT BUILD 509. The test panels have been impregnated by supercritical pressure treatment and are exposed outdoor facing vertically south. This orientation is the worst-case leaching compared to real life situation in addition the test is conducted without an additional topcoat. The exposure arear is 0.8 m^2 pr. test rack which includes 7 test panels. 3 replicates (7 panels in each) are exposed for the weathering. Se as well the IUCLID file.

The leaching study is used for predicting the long term-leaching behaviour (7300 days = 20 years). The retention of the a.s. IPBC and penflufen has different ratios in the leaching studies, than for the efficacy studies. The leaching studies were performed on wood panels of Norway spruce at a retention of 18.1 g penflufen / m^3 wood and 43.2 g IPBC / m^3 wood.

Norway spruce, (*Picea abies* (L.) Karst.) is used by Superwood therefore the leaching studies has been performed on this wood species.

b.r.v. is 25 g penflufen / m^3 wood and 63 g IPBC / m^3 wood. If a linear interpolation is used this gives an assessment factor for:
penflufen of 25/18.1 = 1.381 and for
IPBC of 63/43.2 = 1.45

The technical documentation carried out by the applicant are not all done at the correct retention level. The results are consequently, transferred into the correct retention level applied for by extrapolation. The reason for this is that only one plant in the world is using supercritical impregnation with CO_2 as a carrier for wood impregnation and that the pilot-scale plant that were used for treating the wood samples for the performance testing had technical difficulties in reaching the correct retention level.

Furthermore, the test retention is still within the range of a linear extrapolation can be used to correct leaching rate as stated in the first ECHA leaching workshop in Arona, 2005.

Summary of data from the leaching study is presented in the table below. The leaching study is ongoing. The exposure was started 19-09-2020 and in December 2021 the accumulated rain was at 697 mm. Until 180 mm rain the leaching was rather linear (the flux was in the same range). The leaching from 180 to 697 mm rain the leaching flux was decreased. Using a logarithm extrapolation for estimation of 20 years of leaching is possible. Using a logarithm extrapolation after app. 6-month semi field leaching usually overestimates the long term TIME3 (20 years): This approach is used as a worst-case assumption.

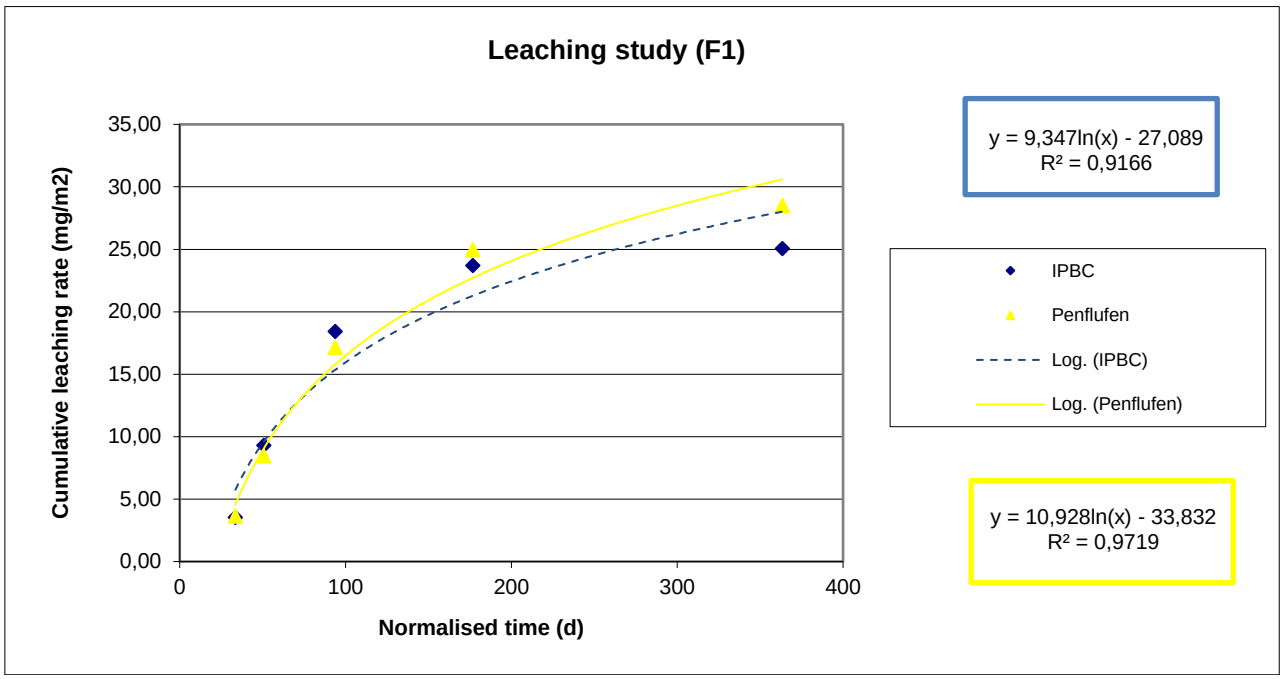
The calculated cumulative leaching rates and flux rates based on the leaching test.

The results are presented for the times which are relevant for risk assessment (Time 1 = 30 days and Time 5 = 7300).
The discussion on an additional Time of 365 days is still discussed on EU level. In this evaluation this time (Time 2 = 365 days) is already included and assessed only for completeness according to the Follow-up of the 2nd EU Leaching Workshop on wood preservatives (*CA-Sept14-Doc_5_8_-_Follow_up_2nd_EU_Leaching_Workshop_PT8*).
No additional assessment factors were added since the studies are semi field studies and no laboratory test.

For the calculation the accumulated rain amounts were re-calculated to a theoretical standardized rain amount of 700 mm/year. These were compared to the total quantity per substance leached out of 1 m^2 of wood area within the specific time interval based on a logarithmic regression (Step 2 – *The 2nd EU leaching Workshop)*. The accumulated leaching was then corrected with aforementioned linear extrapolation (1.381 for penflufen and 1.45 for IPBC).

Table 3.46 Summery of leaching data for SC 300 which are used for the environmental risk assessment.

Summary of leaching data from semi field test study					
Rainfall [mm]	Standard days 720 mm annual [days]	**Penflufen**		**IPBC**	
		Leaching [mg/m^2]	Accumulative leaching [mg/m^2]	Leaching [mg/m^2]	Accumulative leaching [mg/m^2]
64.4	34	3.63	3.63	3.55	3.55
97.4	51	4.83	8.46	5.75	9.30
180	94	8.69	17.15	9.12	18.42
339	177	7.85	25.00	5.29	23.72
697	363	3.53	28.53	1.35	25.06



Results of the leaching tests for product SC300

Application Type	Time period	Cumulative emission	Flux Rate
		mg/m²	mg/m²/day
IPBC			
	Time 1: 30 days	6.86	2.29E-01
	Time 2: 365 days	40.92	1.12E-01
	Time 3: 1825 days	62.86	3.44E-02
	Time 4: 5475 days	77.83	1.42E-02
	Time 5: 7300 days*	81.75	1.12E-02
Penflufen			
	Time 1: 30 days	4.61	1.54E-01
	Time 2: 365 days	42.32	1.16E-01
	Time 3: 1825 days	66.62	3.65E-02
	Time 4: 5475 days	83.20	1.52E-02
	Time 5: 7300 days	87.54	1.20E-02

3.8.1.3 Substance(s) of concern

No substances of concern regarding the environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)). Consequently, only the active substances were addressed in the environmental risk assessment.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

No non-active substances within the product are considered to have endocrine disrupting

properties. For more information refer to the respective section of the confidential annex.

3.8.2 Emission estimation

3.8.2.1 General information

Predicted Environmental Concentrations (PECs) were calculated according to the relevant exposure scenario documents (ESDs for PT8, release to the environment), the Guidance on the BPR: Volume IV Environment (Parts B+C) (distribution in the environment).

Release of active substances during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substances are added are disposed as solid waste and usually incinerated.

Calculated based on measured data from semi field exposure test. The exposure is vertically exposure facing south and the test set-up is without a risk mitigation of a topcoat. This test setup is considered as worst case. Only in-service is considered. There is no leaching at industrial plant into the environment. The pressure impregnation is a supercritical process using CO_2 as a carrier. Therefore, no run-off after impregnation and the timber is stored under roof after preservative treatment. At all times, the wood is dry. The following risk mitigation measures are added to reflect this:

- "Freshly treated timber must be stored after treatment under shelter or on a hard, impermeable surface to prevent direct losses to soil and water. Any losses should be collected for re-use or disposal."
- "All waste water or residues from industrial applications containing traces of the biocidal product will be collected and disposed as hazardous waste"

UC3 in service of the preservative treated wood are assumed to reach soil, STP, surface water, sediment and groundwater compartments.

UC2 in service of the preservative treated wood will not reach the environment and are not considered.

Emission to groundwater was modelled using FOCUS PEARL (version 4.4.4) based on the substance's physical-chemical parameters. Details on the assessment are presented in section 3.8.3 of the PAR and in annex section 4.1.3.1 and 4.1.3.2.

The table below summarises the receiving environmental compartments that have been identified as potentially exposed during the use of the product for the pressure treatment. Compartments highlighted in bold are directly exposed.

Emission was calculated for each intended use based on the highest efficacious concentration, i.e. in-use concentration as specified in the SPC.

The risk assessment approach is summarised below.Table 3.47 Environmental risk assessment

Environmental risk assessment				
Use number	**Scenario assessed**	**ESD applied**	**Maximum in-use concentration of the active substance(s)[1]**	**Receiving compartments**
[1]	House scenario	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.	0.025 kg penflufen/ m^3 0.063 kg IPBC / m^3	[**Soil**] [Pore water]
[1]	Noise barrier scenario			[**Soil**] [**STP**] [Pore water]
[1]	Bridge over pond scenario			[**Water**] [Sediment]

[1] The b.r.v level is used for the calculations. The leaching test has been performed without a topcoat. In many cases the wood product is coated at the manufacturing sight prior to shipment or is coated when used as façade cladding. Therefore, this level can be considered as *Maximum in-use Concentration* level calculations.

3.8.2.2 Emission estimation for the scenarios

Environmental risk assessment. Input values for House, Noise barrier and Bridge over pond scenarios.

Input parameters for calculating the local emission				
Input	**Value**		**Unit**	**Remarks**
	Penflufen	IPBC		
Scenario [1]: House scenario				
Leachable wood area (house)	125		[m²]	AREA(house)
Surface Bridge	10		[m²]	AREA(bridge)
Leachable area of noise barrier	3000		[m²]	
Duration of the initial assessment period	30		[d]	TIME1
Duration of the intermediate assessment period	365		[d]	TIME2
Duration of the long-term assessment period	7300		[d]	TIME2
Concentration of active substance in the product	5	2.5	% [w/w]	
Cumulative quantity of a substance leached out of 1 m² of treated wood over the initial assessment period	4.61 E+00	6.86E+00	[mg.m^{-2}]	Q*leach.time1
Cumulative quantity of a substance leached out of 1 m² of treated wood over the intermediate assessment period	4.23 E+01	4.09E+01	[mg.m^{-2}]	Q*leach.time2
Cumulative quantity of a substance leached out of 1 m² of treated wood over a longer assessment period	8.75 E+01	8.18E+01	[mg.m^{-2}]	Q*leach.time3
Soil volume (wet) (House scenario)	13		[m3]	V(soil)
Water volume under the bridge	1000		[m3]	V(water)
Volume of sediment compartment	3		[m^3]	V_{sed}
Volume of receiving soil (noise barrier)	250		m^3	
Bulk density of wet soil	1700		[kgwwt.m^{-3}]	RHO(soil)
Concentration of suspended matter in the surface water	0.015		[kg·m^3]	$SUSP_{water}$
Bulk density of (wet) susp. matter	1150		[kg_{wwt}.m^{-3}]	RHO_{susp}
Bulk density of (wet) sediment	1300		[kg_{wwt}.m^{-3}]	RHO_{sed}
Fraction released to soil (Noise barrier))	0.3		-	Fsoil
Fraction released to STP (Noise barrier)	0.7		-	F.STP

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$) [mg/d]** TIME1/TIME2/TIME3		**Remarks**
	IPBC	**Penflufen**	
STP (influent)	480.00 / 235.41 / 23.52	322.57 / 244.50 / 25.18	
Freshwater[1]	2.29 / 1.12 / 0.11	1.54 / 0.41 / 0.12	
Soil[2] (From House scenario)	28.57 / 14.01 / 1.40	19.20 / 14.49 / 1.50	

[1] Including sediment
[2] porewater

Resulting local emission to relevant environmental compartments. PEC's calculated with removal is indicated by a blue colour cell. Values highlighted in bold for PECgw indicate an exceedance of the 0.1 µg/L threshold.

Resulting local emission to relevant environmental compartments. PEC values					
Penflufen	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{gw}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
House (30 days)				2.48E-02	**4.91E+00**
House (365 days)				1.40E-01	**2.78E+01**
House (7300 days)				2.09E-02	**4.14E+00**
Noise barrier (30 days)	1.56E-04	1.56E-05	"Bridge" is worstcase	9.30E-03	**1.84E+00**
Noise barrier (365 days)	1.18E-04	1.18E-05	"Bridge" is worstcase	5.26E-02	**1.04E+01**
Noise barrier (7300 days)	1.22E-05	4.35E-07	"Bridge" is worstcase	7.84E-03	**1.55E+00**
Bridge over pond (30 days)		4.18E-05	2.97E-04		
Bridge over pond (365 days)		6.75E-05	4.63E-04		
Bridge over pond (7300 days)		2.37E-05	1.62E-04		
Penflufen metabolite M01	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{gw}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
House (30 days)				4.65E-03	**5.88E+00**
House (365 days)				4.27E-02	**5.40E+01**
House (7300 days)				8.84E-02	**1.12E+02**
Noise barrier (30 days)	Not relevant compartment	Covered by "bridge"	Not relevant compartment	Covered by "house"	Covered by "house"
Noise barrier (365 days)	Not relevant compartment	Covered by "bridge"	Not relevant compartment	Covered by "house"	Covered by "house"
Noise barrier (7300 days)	Not relevant compartment	Covered by "bridge"	Not relevant compartment	Covered by "house"	Covered by "house"
Bridge over pond (30 days)		6.20E-06	Not relevant compartment		
Bridge over pond (365 days)		5.88E-06	Not relevant compartment		
Bridge over pond (7300 days)		1.18E-04	Not relevant compartment		
Penflufen metabolite M02	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{gw}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
House (30 days)				2.60E-03	**1.45E-01**
House (365 days)				2.39E-02	**1.34E+00**

House (7300 days)				4.94E-02	**2.76E+00**
Noise barrier (30 days)	Not relevant compartment	Not relevant compartment	Not relevant compartment	Covered by "house"	Covered by "house"
Noise barrier (365 days)	Not relevant compartment	Not relevant compartment	Not relevant compartment	Covered by "house"	Covered by "house"
Noise barrier (7300 days)	Not relevant compartment	Not relevant compartment	Not relevant compartment	Covered by "house"	Covered by "house"
Bridge over pond (30 days)		Not relevant compartment	Not relevant compartment		
Bridge over pond (365 days)		Not relevant compartment	Not relevant compartment		
Bridge over pond (7300 days)		Not relevant compartment	Not relevant compartment		
IPBC	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{gw}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
House (30 days)				3.65E-04	**1.73E-01**
House (365 days)				1.79E-04	8.47E-02
House (7300 days)				1.79E-05	8.46E-03
Noise barrier (30 days)	1.28E-04	*		1.37E-04	6.46E-02
Noise barrier (365 days)	6.28E-05	*		6.71E-05	3.17E-02
Noise barrier (7300 days)	6.28E-06	*		6.70E-06	3.17E-03
Bridge over pond (30 days)		4.21E-06	1.37E-05		
Bridge over pond (365 days)		2.07E-06	6.70E-06		
Bridge over pond (7300 days)		2.06E-07	6.69E-07		
PBC	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{gw}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
House (30 days)				8.68E-03	**2.40E+00**
House (365 days)				4.80E-03	**1.33+00**
House (7300 days)				4.79E-04	**1.33E-01**
Noise barrier (30 days)	1.28E-04	1.28E-05	Covered by "bridge"	3.25E-03	**9.00E-01**
Noise barrier (365 days)	6.28E-05	6.28E-06	Covered by "bridge"	1.80E-03	**4.97E-01**
Noise barrier (7300 days)	6.28E-06	6.27E-07	Covered by "bridge"	1.79E-04	4.97E-02
Bridge over pond (30 days)		2.71E-05	8.81E-05		
Bridge over pond (365 days)		2.74E-05	8.88E-05		
Bridge over pond (7300 days)		2.73E-06	8.87E-06		

*: Refer to PEC values for PBC (IPBC is completely degraded to PBC in the STP)

Groundwater refinement with FOCUS PEARL

IPBC, PBC, Iodide and Iodate

IPBC concentrations in groundwater was calculated according to BPR Guidance Vol IV Env. B+C. Pore water concentrations was equalled $PEC_{groundwater}$ to estimate the risk to ground water.
Concentrations in groundwater for IPBC metabolites (PBC, Iodide, Iodate) were assessed using the same method as for IPBC.

IBPC exceeded the the 0.1 µg/l permissible concentration in groundwater at TIME1 in the house scenario, whilst PBC exceeded the limit at all times (TIME1, TIME2 and TIME3) in the house scenario, hence further refinement with FOCUS PEARL 4.4.4 was performed.

The Iodine species (Iodide and Iodate) also exceeded the permissible concentration limit in groundwater at all times for the house scenario, but they were within the normal background concentrations of 1-70 µg/l iodine, hence further assessment was not needed (see annex 4.1.3.1). The highest concentrations found are presented in the table below.

FOCUS PEARL refined Groundwater values – IPBC, PBC

PEC_{GW} – IPBC and PBC	
PEC_{GW}	[µg/l]
IPBC	< 0.000001
PBC	< 0.000001

Penflufen and major metabolites

$PEC_{groundwater}$ for Penflufen was calculated according to BPR Guidance Vol IV Env. B+C . Pore water concentrations was equalled $PEC_{groundwater}$ to estimate the risk to ground water. For the two major Penflufen metabolites M01 and M02, concentrations in porewater has been calculated as well. For detailed calculations, please refer to annex 4.1.3.2.

Both Penflufen and metabolites exceeded the 0.1 µg/l permissible concentration in groundwater for the house scenario at all times (TIME1, TIME2 and TIME3), hence a FOCUS PEARL 4.4.4 refinement was performed. The highest concentrations found are presented in the table below.

FOCUS PEARL refined Groundwater values – Penflufen, M01, M02

PEC_{GW} – Penflufen and metabolites	
PEC_{GW}	[µg/l]
Penflufen	0.003954
M01	0.326724
M02	0.000007

3.8.2.3 Primary poisoning

Not relevant for PT8. Primary poisoning is only relevant if a high acute toxicity can be expected (e.g. for some products in PT14).

There is no leaching at industrial plant into the environment. The pressure impregnation is a supercritical process using CO_2 as a carrier. Therefore, no run-off after impregnation and the timber is stored under roof after preservative treatment. At all times, the wood is dry.

Release of active substances during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substances are added are disposed as solid waste and usually incinerated.

3.8.2.4 Secondary poisoning

IPBC
IPBC and PBC do not concentrate in the food chain. Therefore, the use of IPBC does not pose any risk for secondary poisoning to fish- or worm-eating birds and mammals.

Penflufen
Although Penflufen is intended for use as a PT8 (wood preservative), and therefore does not require data for toxicity to birds and mammals according to guidance, exposure is still a potential issue and with data being already available on the toxicity of the active substance to both groups (from Annex 1 inclusion for pesticide use) the risk of secondary poisoning via fish and earthworms has been considered.

The PECfish/earthworm calculations were conducted according to ECHA Guidance on the BPR, Volume IV B. The input parameters were as follows (see annex 4.1.3.2 for more detail):

Log KOW = 3.3
BMF = 1
BCF (earthworm) = 24.78
BCF (fish) = 142

PECsoil =1.40E-01 mg/kg
PECporewater = 2.78E-02 mg/L
PECsw = 6.75E-05 mg/L

Summary table on secondary poisoning	
Scenario	**$PEC_{oral\ predator}$**
Scenario 1 – Aquatic food chain	
1	4.79E-03 [mg/kg wet fish]
Scenario 1 – Terrestrial food chain	
1	3.17E-01 [mg/kg wet earthworm]

3.8.3 Exposure calculation and risk characterisation

Summary table of PEC/PNEC values of the active substances and metabolites for the different scenarios. Blue cells indicate that PEC's where calculated considering removal, and red and bold text indicate a risk.

PEC/PNEC values					
Penflufen	**STP**	**Water**	**Sediment**	**Soil**	**Groundwater (PEC)**
					[µg/l]

House (30 days)				6.59E-02	**4.91E+00**
House (365 days)				3.72E-01	**2.78E+01**
House (7300 days)				5.55E-02	**4.14E+00**
Noise barrier (30 days)	1.43E-04	6.66E-03	Covered by "bridge"	2.47E-02	**1.84E+00**
Noise barrier (365 days)	1.08E-04	5.02E-03	Covered by "bridge"	1.39E-01	**1.04E+01**
Noise barrier (7300 days)	1.12E-05	1.86E-04	Covered by "bridge"	2.08E-02	**1.55E+00**
Bridge over pond (30 days)		1.79E-02	1.79E-02		
Bridge over pond (365 days)		2.88E-02	2.90E-02		
Bridge over pond (7300 days)		1.01E-02	1.02E-02		
Penflufen metabolite M01	**STP**	**Water**	**Sediment**	**Soil**	**Groundwater (PEC)**
					[µg/l]
House (30 days)				1.19E-02	**5.88E+00**
House (365 days)				1.10E-01	**5.40E+01**
House (7300 days)				2.27E-01	**1.12E+02**
Noise barrier (30 days)	Not relevant compartment	Covered by "bridge"	Not relevant compartment	Covered by "house"	Covered by "house"
Noise barrier (365 days)	Not relevant compartment	Covered by "bridge"	Not relevant compartment	Covered by "house"	Covered by "house"
Noise barrier (7300 days)	Not relevant compartment	Covered by "bridge"	Not relevant compartment	Covered by "house"	Covered by "house"
Bridge over pond (30 days)		3.95E-04	Not relevant compartment		
Bridge over pond (365 days)		1.28E-03	Not relevant compartment		
Bridge over pond (7300 days)		7.50E-03	Not relevant compartment		
Penflufen metabolite M02	**STP**	**Water**	**Sediment**	**Soil**	**Groundwater (PEC)**
					[µg/l]
House (30 days)				8.07E-03	**1.45E-01**
House (365 days)				7.42E-02	**1.34E+00**
House (7300 days)				1.53E-01	**2.76E+00**
Noise barrier (30 days)	Not relevant compartment	Not relevant compartment	Not relevant compartment	Covered by "house"	Covered by "house"
Noise barrier (365 days)	Not relevant compartment	Not relevant compartment	Not relevant compartment	Covered by "house"	Covered by "house"

Noise barrier (7300 days)	Not relevant compartment	Not relevant compartment	Not relevant compartment	Covered by "house"	Covered by "house"
Bridge over pond (30 days)		Not relevant compartment	Not relevant compartment		
Bridge over pond (365 days)		Not relevant compartment	Not relevant compartment		
Bridge over pond (7300 days)		Not relevant compartment	Not relevant compartment		
IPBC	**STP**	**Water**	**Sediment**	**Soil**	**Groundwater (PEC)**
					[µg/l]
House (30 days)				8.49E-02	**1.73E-01**
House (365 days)				4.17E-02	8.47E-02
House (7300 days)				4.16E-03	8.46E-03
Noise barrier (30 days)	2.91E-04	*		3.18E-02	6.46E-02
Noise barrier (365 days)	1.43E-04	*		1.56E-02	3.17E-02
Noise barrier (7300 days)	1.43E-05	*		1.56E-03	3.17E-03
Bridge over pond (30 days)		8.42E-03	Covered by freshwater**		
Bridge over pond (365 days)		4.13E-03	Covered by freshwater**		
Bridge over pond (7300 days)		4.13E-04	Covered by freshwater**		
PBC	**STP**	**Water**	**Sediment**	**Soil**	**Groundwater (PEC)**
					[µg/l]
House (30 days)				5.83E-02	**2.40E+00**
House (365 days)				3.22E-02	**1.33E+00**
House (7300 days)				3.22E-03	**1.33E-01**
Noise barrier (30 days)	2.91E-04	3.10E-04	"Bridge" is worstcase	2.18E-02	**9.00E-01**
Noise barrier (365 days)	1.43E-04	1.52E-04	"Bridge" is worstcase	1.21E-02	**4.97E-01**
Noise barrier (7300 days)	1.43E-05	1.52E-05	"Bridge" is worstcase	1.20E-03	4.97E-02
Bridge over pond (30 days)		6.57E-04	Covered by freshwater**		
Bridge over pond (365 days)		6.62E-04	Covered by freshwater**		
Bridge over pond (7300 days)		6.62E-05	Covered by freshwater**		

**The IPBC sediment PEC/PNEC is covered by the freshwater assessment as both the PEC and PNEC for IPBC is calculated by the equilibrium partitioning method, hence risk

will be the same. However the values have been calculated and are used for the mixture toxicity assessment.

3.8.4 Mixture toxicity

As the biocidal product consists of more than one active substance, the environmental risk should be based on the combined risk. It is found that the model of concentration addition can be recommended as the best reference model when evaluating combined risk of chemical mixtures.

In the first tier a PEC/PNEC summation based on effect data (most sensitive organism) for the individual substances is performed for each environmental compartment of concern.

Mixture toxicity is assessed according to the following equation:

(PEC/PNEC) product = Σ (PEC/PNEC) of the individual substances for each environmental compartment.

For the indirect release of IPBC to surface water via STP PEC/PNEC ratios of PBC are used.

The metabolites of the active substances were not considered in all other scenarios as these metabolites are considered far less potent and occur in smaller concentrations than the active substances.

(PEC/PNEC) product values for each environmental compartment of concern are summarised below for the mixture toxicity of IPBC and Penflufen.

Summary table of calculated ΣPEC/PNEC values:

IPBC + Penflufen	STP	Water	Sediment	Soil
House (30 days)				1.51E-01
House (365 days)				4.14E-01
House (7300 days)				5.97E-02
Noise barrier (30 days)	4.34E-04	6.67E-03*	Covered by "bridge"	5.65E-02
Noise barrier (365 days)	2.51E-04	5.03E-03*	Covered by "bridge"	1.55E-01
Noise barrier (7300 days)	2.54E-05	1.86E-04*	Covered by "bridge"	2.24E-02
Bridge over pond (30 days)		2.63E-02	2.64E-02**	
Bridge over pond (365 days)		3.30E-02	3.31E-02**	
Bridge over pond (7300 days)		1.05E-02	1.06E-02**	
*PBC values are used for Noisebarrier water emission				

3.8.5 Conclusion to risk assessment

Atmosphere

Penflufen has a low vapour pressure of 4.1 $x10^{-7}$ Pa and a Henry's Law constant of

$1.19x10^{-5}$ Pa/m3/mol which indicates a very low risk of volatilisation.

IPBC has a low vapour pressure of 2.36 – 4.5 x 10-3 Pa at 25°C and a Henry's Law constant of 3.38 – 6.45 x 10-3 Pa×m³/mol. This indicates a very low risk of volatilisation.

Accordingly, exposure to the atmosphere following use of SC300 is expected to be negligible.

Sewage treatment plant (STP)

The PEC/PNEC ratio for service life are below the trigger value of one.

Any losses should be collected for reuse or disposal. Therefore emissions from industrial processes to the environment are not relevant.

Conclusion: The results of the risk characterisation show that there is no unacceptable risk for the STP from the use of the product SC300. No further assessment or risk mitigation is needed.

Aquatic compartment

The PEC/PNEC ratio for service life are below the trigger value of one.

Any losses should be collected for reuse or disposal. Therefore emissions from industrial processes to the environment are not relevant.

Regarding the iodine risk assessment for surface water all predicted environmental concentrations are below or within the background concentration (Please refer to Annex 4.1.3.).

Conclusion: The results of the risk characterisation show that there is no unacceptable risk for the aquatic compartment from the use of the product SC300.

Terrestrial compartment

PEC/PNEC ratio are below the trigger value of one for all assessed scenarios.

Regarding iodine risk assessment for soil all predicted environmental concentrations are below the background concentration (Please refer to Annex 4.1.3).

Conclusion: The results of the risk characterisation show that there is no relevant unacceptable risk for soil from the use of the product SC300. No further assessment or risk mitigation is needed.

Groundwater

The calculated PEC_{GW} values for IPBC, PBC, Penflufen, M01 and M02 are all above the limit value of 0.1 µg/L as laid down for pesticides in the Drinking Water Directive 98/83/EC, when calculated according to BPR Guidance Vol IV Env. B+C.
However after being modelled with FOCUS PEARL 4.4.4, IPBC, PBC, Penflufen and M02 are all below the threshold.
The major Penflufen metabolite M01 exceeds the 0.1 µg/L limit even after refinement of the PEC calculations with FOCUS PEARL. The highest value is from the Hamburg scenario with a value of 0.3267 µg/L.

The iodine species are not below the limit, but are within the natural background values and are therefore not unacceptable.

Conclusion: The risk to groundwater from the metabolite M01 is unacceptable.
No risk mitigation measure can currently be applied, and it is concluded that the use of the product in Use Class 3 cannot approved.

3.8.6 Primary and secondary poisoning

3.8.6.1 Primary poisoning

Not relevant for PT8. Primary poisoning is only relevant if a high acute toxicity can be expected (e.g. for some products in PT14).

There is no leaching at industrial plant into the environment. The pressure impregnation is a supercritical process using CO_2 as a carrier. Therefore, no run-off after impregnation and the timber is stored under roof after preservative treatment. At all times, the wood is dry.

Release of active substances during the waste phase of the end-products is not assessed, because it is assumed that end-products to which the active substances are added are disposed as solid waste and usually incinerated.

3.8.6.2 Secondary poisoning

IPBC
IPBC and PBC do not concentrate in the food chain. Therefore, the use of IPBC does not pose any risk for secondary poisoning to fish- or worm-eating birds and mammals.

Penflufen
Although Penflufen is intended for use as a PT8 (wood preservative), and therefore does not require data for toxicity to birds and mammals according to guidance, exposure is still a potential issue and with data being already available on the toxicity of the active substance to both groups (from Annex 1 inclusion for pesticide use) the risk of secondary poisoning via fish and earthworms has been considered.

A summary of the risk for the aquatic and terrestrial food chains from use of Penflufen in the product can be found below:

Summary table on secondary poisoning

Scenario	$PEC_{oral\ predator}$	$PEC/PNEC_{birds}$	$PEC/PNEC_{mammals}$
Scenario 1 – Aquatic food chain			
1	4.79E-03 [mg/kg wet fish]	1.52E-04	1.44E-04
Scenario 1 – Terrestrial food chain			
1	3.17E-01 [mg/kg wet earthworm]	1.00E-02	9.50E-03

Conclusion: No unacceptable risk from the use of the product are found in either terrestrial of the aquatic food chain.

3.8.7 Aggregated exposure (combined for relevant emission sources)

IPBC is widely used in paints and coatings, wood preservatives and cosmetics. While paints and coatings and wood preservatives may be used in conjunction, it would not be likely for both to contain IPBC in fungicidal concentrations. Emissions from paintings and coatings and wood preservatives are only considered from outdoor use, where the main receiving compartments are soil and water. Cosmetics are applied to the skin and washed off; therefore their main receiving compartments will be STP and solid waste.

Penflufen is approved for use as a pesticide under PPP.

As a biocide penflufen is only approved in PT8 wood preservatives, where the emission is only considered for outdoor use, and the main receiving compartments are soil and water.

Penflufen is not a part of another active substance, nor is it a metabolite of another active substance or share a metabolite with other active substances.

For these reasons, and as the concept has not been agreed as a part of a harmonised approach to product assessment and no appropriate guidance is currently available, aggregated toxicity for the product and its active substances have not been considered.

3.8.8 Overall conclusion on the risk assessment for the environment

Table 3.48 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
1	Preventive wood protection (PT8) of soft wood for Use Class 3. Industrial pressure impregnation. Wood rotting fungi.	Use of SC300 in Use class 3 results in exceedance of the groundwater limit value for the penflufen metabolite M01. No risk mitigation measure can currently be applied to mitigate this risk, hence use in Use Class 3 cannot be approved for the product.	

Overall conclusion on the risk assessment for the environment			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
2	Preventive wood protection (PT8) of soft wood for Use Class 2. Industrial pressure impregnation. Wood rotting fungi.	As no emission is expected from use in use class 2, this use is considered accteptable.	Freshly treated timber must be stored after treatment under shelter or on a hard, impermeable surface to prevent direct losses to soil and water. Any losses should be collected for re-use or disposal.

3.9 Assessment of a combination of biocidal products

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

3.10 Comparative assessment

Not relevant. Neither active substance is a candidate for substitution.

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Scenario 4 Sanding treated wood professionals		
	IPBC	**Penflufen**
Concentration in wood		
Application rate [a.s.] (mg/cm²)	0,05	0,002
Area of wood to be sanded surface area (cm²) (4 x 4cm x 250cm + 2 x 4cm x 4cm)	4032	4032
Volume of outer layer (cm³) (4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm)	3008	3008
Amount in wood [a.s] (mg)	189,5	8,5
Exposure by inhalation		
Concentration of as in wood dust a.s (mg/cm³)	0,06	0,025
Wood dust concentration in air (mg/m³)	5	5
Exposure duration (h)	6	6
Inhalation rate (m^3/h)	1,25	1,25
Retention of a.s. in wood	100%	100%
Density of wood (g/cm³)	0,40	0,40
Amount dust inhaled in 6 hours (cm³)	0,09	0,09
Inhaled [a.s] (mg)	0,0059	0,0023
Body weight (kg)	60	60
Systemic exposure via inhalation (mg kg^{-1} day^{-1})	0,00010	0,00004
Dermal exposure		
A Concentration on the wood surface (mg/cm^2)	0,05	0,0021
B Transfer coefficient (%)	3%	3%
C Surface of palm of hand (cm^2)	410	410
D Dermal absorption (%)	70%	70%
E Body weight (kg)	60	60
Systemic exposure via dermal route (mg kg^{-1} day^{-1})	0,0067	0,0003
Total systemic exposure		
Total systemic exposure a.s. (mg kg^{-1} day^{-1})	0,00684	0,00034
AEL (mg kg^{-1} day^{-1})	0,20	0,04
% AEL	**3,42%**	**0,85%**
HQ	0,0342	0,0085
HI	**0,043**	

Scenario 5 Sanding treated wood non-professionals		
	IPBC	**Penflufen**
Concentration in wood		
Application rate [a.s.] (mg/cm²)	0,05	0,002
Area of wood to be sanded surface area (cm²) (4 x 4cm x 250cm + 2 x 4cm x 4cm)	4032	4032
Volume of outer layer (cm³) (4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm)	3008	3008
Amount in wood [a.s] (mg)	189,5	8,5
Exposure by inhalation		
Concentration of in wood dust a.s (mg/cm³)	0,06	0,025
Wood dust concentration in air (mg/m³)	5	5
Exposure duration (h)	1	1
Inhalation rate (m^3/h)	1,25	1,25
Retention of a.s. in wood	100%	100%
Density of wood (g/cm³)	0,40	0,40
Amount dust inhaled in 6 hours (cm³)	0,02	0,02
Inhaled [a.s] (mg)	0,0010	0,0004
Body weight (kg)	60	60
Systemic exposure via inhalation (mg kg^{-1} day^{-1})	0,00002	0,00001
Dermal exposure		
A Concentration on the wood surface (mg/cm^2)	0,05	0,0021
B Transfer coefficient (%)	3%	3%
C Surface of palm of hand (cm^2)	410	410
D Dermal absorption (%)	70%	70%
E Body weight (kg)	60	60
Systemic exposure via dermal route (mg kg^{-1} day^{-1})	0,0067	0,0003
Total systemic exposure		
Total systemic exposure a.s. (mg kg^{-1} day^{-1})	0,00676	0,00031
AEL (mg kg^{-1} day^{-1})	0,20	0,04
% AEL	**3,38%**	**0,77%**
HQ	0,0338	0,0077
HI	**0,042**	

Scenario 7 Infant chewing wood cut off		
	IPBC	**Penflufen**
Active substance % (w/w)	5,00%	2,50%
Concentration in wood		
Application rate [a.s.] mg/cm²	0,047	0,002
Layer thickness cm	1,00	1,00
Retention of a.s. in wood	100%	100%
Concentration in wood [a.s.] mg/cm³	0,063	0,025
Oral exposure		
Size of the wood chip cm³	16	16
Extraction of active substance when chewing	10%	10%
Extraction from wood mg a.s./day	0,10	0,04
Oral absorption %	100%	100%
Systemic exposure via oral route mg a.s.	0,101	0,040
Systemic exposure		
Body weight kg	8	8
Systemic exposure mg kg^{-1} day^{-1}	0,0126	0,0050
AEL mg kg^{-1} day^{-1}	0,35	0,3
% AEL	**3,6%**	**1,7%**
HQ	0,04	0,02
HI	0,053	

Scenario 8a Infant playing on wooden structure (e.g. playground)		
	IPBC	**Penflufen**
Concentration of a.s. (% w/w)	5,00%	2,50%
Wood contamination		
Application rate [a.s.] (mg/cm²)	0,047	0,002
Dermal exposure		
Area: both palms (cm²)	98,4	98,4
Fraction of palms in contact with b.p. (%)	40%	40%
Transfer efficiency %	3%	3%
Hand deposit (mg a.s./day)	0,06	0,00
Dermal absorption (%)	70%	70%
Systemic exposure via dermal route (mg a.s.)	0,039	0,002
Oral exposure		
Hand deposit (mg a.s./day)	0,055	0,002
Transfer efficiency for hand to mouth (%)	50%	50%

Oral absorption (%)	100%	100%
Systemic exposure via oral route (mg a.s.)	0,028	0,001
Total systemic exposure		
A Total systemic exposure (mg a.s.)	0,067	0,003
B Body weight (kg)	8	8
Total systemic exposure (mg kg^{-1} day^{-1})	0,0083	0,0004
AEL (mg kg^{-1} day^{-1})	0,2	0,04
% AEL	**4,2%**	**0,9%**
HQ	0,04	0,01
HI	0,05	

Scenario 8b Toddler playing on wooden structure (e.g. playground)		
	IPBC	**Penflufen**
Concentration of a.s. (% w/w)	5,00%	2,50%
Wood contamination		
Application rate [a.s.] (mg/cm^2)	0,047	0,002
Dermal exposure		
Area: both palms (cm^2)	115,2	115,2
Fraction of palms in contact with b.p. (%)	40%	40%
Transfer efficiency %	3%	3%
Hand deposit (mg a.s./day)	0,06	0,00
Dermal absorption (%)	70%	70%
Systemic exposure via dermal route (mg a.s.)	0,045	0,002
Oral exposure		
Hand deposit (mg a.s./day)	0,065	0,003
Transfer efficiency for hand to mouth (%)	50%	50%
Oral absorption (%)	100%	100%
Systemic exposure via oral route (mg a.s.)	0,032	0,001
Total systemic exposure		
A Total systemic exposure (mg a.s.)	0,078	0,003
B Body weight (kg)	10	10
Total systemic exposure (mg kg^{-1} day^{-1})	0,0078	0,0003
AEL (mg kg^{-1} day^{-1})	0,2	0,04
% AEL	**3,9%**	**0,9%**
HQ	0,04	0,01
HI	0,05	

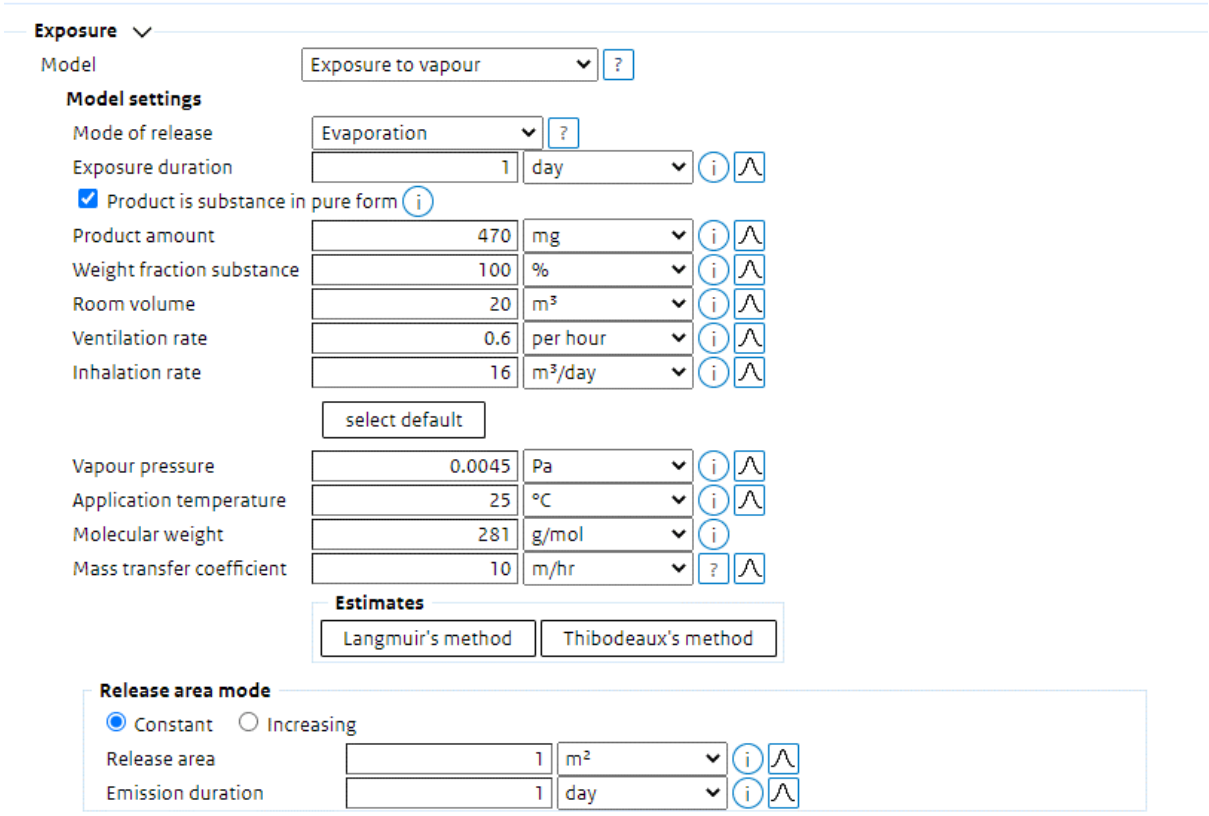
Scenario 9 Inhalation of volatilised residues SVC Tier 1	
	IPBC
Concentration a.s. % (w/w)	5,00%
Saturated vapour pressure	
Vapour pressure Pa	**2,36E-03**
Molecular weight g/mol	281,1
Gas constant	8,31
Temperature K	293
Saturated vapour concentration (SVC) mg/m^3	2,72E-01
Adult exposure by inhalation	
Inhalation rate m^3/d	16
Body weight kg	60
Systemic exposure mg/kg bw/d	0,07266
AEL mg/kg bw/d	0,2
% AEL	**36,33%**
Child exposure by inhalation	
Inhalation rate m^3/d	12
Body weight kg	23,9
Systemic exposure mg/kg bw/d	0,13680
AEL mg/kg bw/d	0,2
% AEL	**68,40%**
Toddler exposure by inhalation	
Inhalation rate m^3/d	8
Body weight kg	10,0
Systemic exposure mg/kg bw/d	0,21797
AEL mg/kg bw/d	0,2
% AEL	**108,98%**
Infant exposure by inhalation	
Inhalation rate m^3/d	5,4
Body weight kg	8
Systemic exposure mg/kg bw/d	0,18391
AEL (long-term) mg/kg bw/d	0,2
% AEL	**91,96%**

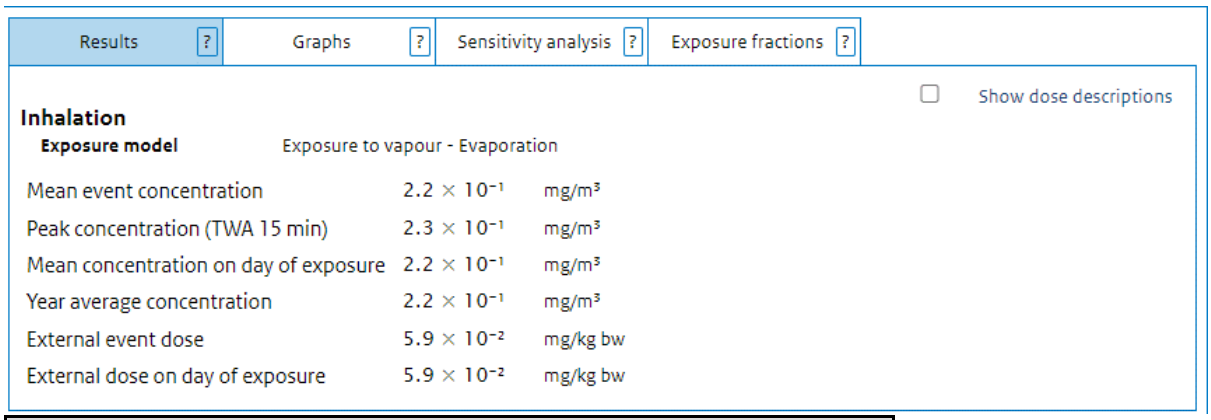
Scenario 9 Inhalation of volatilised residues SVC Tier 1	
	IPBC
Concentration a.s. % (w/w)	5,00%
Saturated vapour pressure	
Vapour pressure Pa	**4,50E-03**

Molecular weight g/mol	281,1
Gas constant	8,31
Temperature K	293
Saturated vapour concentration (SVC) mg/m^3	5,20E-01
Adult exposure by inhalation	
Inhalation rate m^3/d	16
Body weight kg	60
Systemic exposure mg/kg bw/d	0,13854
AEL mg/kg bw/d	0,2
% AEL	**69,27%**
Child exposure by inhalation	
Inhalation rate m^3/d	12
Body weight kg	23,9
Systemic exposure mg/kg bw/d	0,26085
AEL mg/kg bw/d	0,2
% AEL	**130,42%**
Toddler exposure by inhalation	
Inhalation rate m^3/d	8
Body weight kg	10,0
Systemic exposure mg/kg bw/d	0,41562
AEL mg/kg bw/d	0,2
% AEL	**207,81%**
Infant exposure by inhalation	
Inhalation rate m^3/d	5,4
Body weight kg	8
Systemic exposure mg/kg bw/d	0,35068
AEL (long-term) mg/kg bw/d	0,2
% AEL	**175,34%**

Scenario 9 Inhalation of volatilised residues ConsExpo	
Active substance	**IPBC**
Vapour pressure Pa	**4,50E-03**
Molecular weight g/mol	281,1
Mean event concentration mg/m3	2,20E-01
Adult exposure by inhalation	
Inhalation rate m^3/d	16
Systemic exposure via inhalation route mg	3,5200
Body weight kg	60

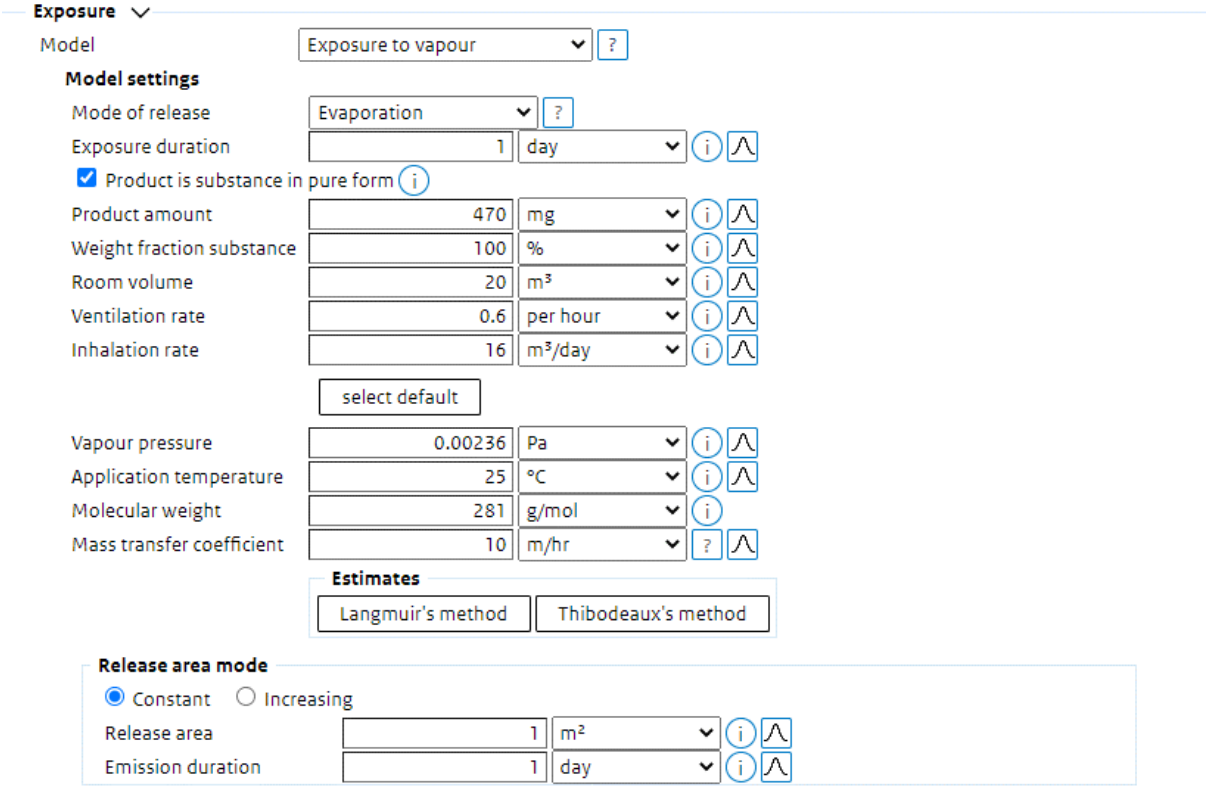
Systemic exposure mg/kg bw/d	0,0587
AEL mg/kg bw/d	0,2
% AEL	**29,33%**
Child exposure by inhalation	
Inhalation rate m^3/d	12
Systemic exposure via inhalation route mg	2,64
Body weight kg	23,9
Systemic exposure mg/kg bw/d	0,11046
AEL mg/kg bw/d	0,2
% AEL	**55,23%**
Toddler exposure by inhalation	
Inhalation rate m^3/d	8
Systemic exposure via inhalation route mg	1,7600
Body weight kg	10
Systemic exposure mg/kg bw/d	0,1760
AEL mg/kg bw/d	0,2
% AEL	**88,00%**
Infant exposure by inhalation	
Inhalation rate m^3/d	5,4
Systemic exposure via inhalation route mg	1,1880
Body weight kg	8
Systemic exposure mg/kg bw/d	0,14850
AEL (long-term) mg/kg bw/d	0,2
% AEL	**74,25%**

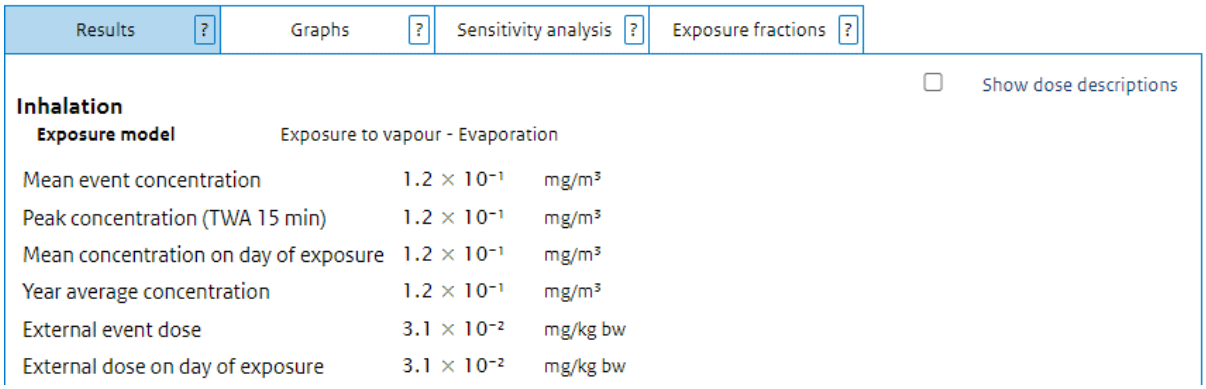




Scenario 9 Inhalation of volatilised residues ConsExpo	
Active substance	**IPBC**
Vapour pressure Pa	**2,36E-03**
Molecular weight g/mol	281,1
Mean event concentration mg/m3	1,20E-01
Adult exposure by inhalation	
Inhalation rate m³/d	16
Systemic exposure via inhalation route mg	1,9200
Body weight kg	60
Systemic exposure mg/kg bw/d	0,0320
AEL mg/kg bw/d	0,2

% AEL	**16,00%**
Child exposure by inhalation	
Inhalation rate m³/d	12
Systemic exposure via inhalation route mg	1,44
Body weight kg	23,9
Systemic exposure mg/kg bw/d	0,06025
AEL mg/kg bw/d	0,2
% AEL	**30,13%**
Toddler exposure by inhalation	
Inhalation rate m³/d	8
Systemic exposure via inhalation route mg	0,9600
Body weight kg	10
Systemic exposure mg/kg bw/d	0,0960
AEL mg/kg bw/d	0,2
% AEL	**48,00%**
Infant exposure by inhalation	
Inhalation rate m³/d	5,4
Systemic exposure via inhalation route mg	0,6480
Body weight kg	8
Systemic exposure mg/kg bw/d	0,08100
AEL (long-term) mg/kg bw/d	0,2
% AEL	**40,50%**





Scenario 4 Sanding treated wood professionals IPBC NOAEC local effect	
	IPBC
Concentration in wood	
Application rate [a.s.] (mg/cm²)	0,05
Area of wood to be sanded surface area (cm²) (4 x 4cm x 250cm + 2 x 4cm x 4cm)	4032
Volume of outer layer (cm³) (4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm)	3008
Amount in wood [a.s] (mg)	189,5
Exposure by inhalation	
Concentration of as in wood dust a.s (mg/cm³)	0,063
Wood dust concentration in air (mg/m³)	5
Wood density g/cm3	0,4
Wood dust in air cm3/m3	0,0125
Exposure max mg/m3	0,00079
NOAEC IPBC effect larynx	1,16
% NOAEC effect larynx	0,06789%

4.1.2 Dietary assessment

Livestock exposure estimation - horse chewing on wood

Activity / Parameter	Penflufen	IPBC
Wood		
Concentration a.s. in wood (g/m³)	25	63
Amount of wood consumed (g/m³)	0.000019	0.000019
Exposure by oral intake		
Body weight (kg)	400	400
Systemic exposure via ingestion (mg/kg bw/day)	**1.1875E-06**	**2.9925E-06**
Below trigger value of 0.004 mg/kg bw/day	Yes	Yes

4.1.3 Environment

4.1.3.1 Environmental risk assessment IPBC and transformation products (Iodine)

Degradation of IPBC yields the primary metabolite propargyl butyl carbamate (PBC) as well as Iodine. In the assessment report of IPBC (PT8) the risk assessment of iodine was left out, as iodine was evaluated by SE as an active substance for disinfectant. On the TM II, 2012 it was agreed to include iodine in the future evaluations and to base the calculations on the CAR of iodine.
In comparison to the other transformation product from IPBC, iodine is not a xenobiotic substance but an essential dietary trace element and is ubiquitously present in the environment. Because of iodine's natural presence in the environment, background values have to be taken into account in the environmental risk assessment.

Background values

Iodine and iodine compounds are ubiquitously distributed and there is a natural cycle of iodine species in the environment. Iodine can be present in different forms in the environment; the form of iodine is largely dependent on redox potential and pH. Iodide and iodate are the dominant iodine species in soil and surface water. The background values (as iodine) are presented below (CAR, iodine 2013)

Background concentration of iodine in the environment	
Compartment	**Background level (as iodine)**
Soil	**Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg Global mean value of 5 mg/kg**
Groundwater	**Mean concentration: 1 µg/l Range: < 1-70 µg/l with extremes up to 400 µg/l**
Freshwater (river and lake)	**0.5 - 20 µg/l**
Marine water	**45 - 60 µg/L**
Rainwater	**0.1-15 µg/l**
Freshwater sediment	**Typically: 6 mg/kg**
Marine sediment	**Typically: 3-400 mg/kg**
Air	**Atmosphere: 10-20 ng/m3 Atmospheric concentration: over land 2- 14 ng/m3; over ocean 17-52 ng/m3 Marine air contains: 100 µg/l (may refer to local inhalable air)**

PEC calculations and risk characterisation

The PEC calculations follow the available guidance documents (Revised Emission Scenario Document for Wood Preservatives (OECD, 2013); Vol IV, Part B). For the iodine risk assessment only the worst case scenarios (highest IPBC output values) for each relevant compartment has been taken into consideration.
In the evaluation of iodine released from IPBC, it is chosen to consider 100% formation of both iodide and iodate. This proposed assessment is however worst case as it is expected that much less than 100% of the different iodine species will be present. However, for calculation of soil concentrations it is assumed that the total

iodine concentration in soil is transformed into 14% iodide and 100% iodate (CAR for IPBC, PT6 (2013) and agreed to use for PT 8 products at TM II, 2012).
If 100 % transformation of IPBC is assumed, the molar fraction of PBC produced is 0.552 and for iodine (I_2) it is 0.451 (2 moles of IPBC to form one mole of I_2). Further it is assumed that all iodine is transformed either to iodide or iodate. As one mole of iodine (I_2) forms two moles of iodide (I^-) the molar fraction between iodine and iodide is 1, whereas for iodate (IO_3^-) the molar fraction is 1.38.

The calculated PECs are presented below.

Summary table on calculated PEC values IPBC <u>without degradation</u>				
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg wwt]	[µg/l]
Scenario: In situ				
PEC values IPBC				
Noise Barrier (30 days)	2.40E-04	2.40E-05	1.45E-02	-
Noise Barrier (1 years)	1.18E-04	1.18E-05	8.66E-02	-
Noise Barrier (20 years)	1.18E-05	1.18E-06	1.73E-01	-
House (30 days)	-	-	3.88E-02	-
House (1 years)			2.31E-01	-
House (20 years)	-	-	4.62E-01	-
Bridge over pond (30 days)	-	6.82E-05	-	-
Bridge over pond (1 years)		4.09E-04		-

Bridge over pond (20 years)	-	8.18E-04	-	-
PEC Values Iodide				
Noise Barrier (30 days)	8.66E-05	1.08E-05	9.17E-04	1.75E-01
Noise Barrier (1 years)	4.25E-05	5.31E-06	5.47E-03	1.04E+00
Noise Barrier (20 years)	4.24E-06	5.30E-07	1.09E-02	2.09E+00
House (30 days)	-	-	2.45E-03	4.68E-01
House (1 years)			1.46E-02	2.79E+00
House (20 years)	-	-	2.92E-02	5.58E+00
Bridge over pond (30 days)	-	3.09E-05	-	
Bridge over pond (1 years)		1.85E-04		
Bridge over pond (20 years)	-	3.69E-04	-	
PEC Values Iodate				
Noise Barrier (30 days)	1.49E-04	1.49E-05	9.04E-03	1.73E+00
Noise Barrier (1 years)	7.33E-05	7.32E-06	5.39E-02	1.03E+01
Noise Barrier (20 years)	7.32E-06	7.32E-07	1.08E-01	2.06E+01
House (30 days)	-	-	2.41E-02	4.61E+00
House (1 years)			1.44E-01	2.75E+01
House (20 years)	-	-	2.88E-01	5.50E+01
Bridge over pond (30 days)	-	4.27E-05	-	
Bridge over pond (1 years)		2.55E-04		
Bridge over pond (20 years)	-	5.09E-04	-	

Grey cells are used for risk characterisation.

PEC for sewage treatment plant

In the CAR for IPBC, the influent concentration of IPBC is considered to be relevant in order to assess predicted environmental concentrations in sewage treatment plants. For further modelling surface water concentrations it is assumed, that the whole IPBC in the STP is transformed into PBC and iodine species. Hence, the STP risk assessment is based on IPBC influent concentration with no removal/degradation or translocation processes.
A risk assessment for soils being target for iodine species emission via sewage sludge is not considered to be necessary as the house scenario is considered worst case with respect to the soil compartment.
The PEC_{STP}-value for iodine is calculated based on the PEC_{STP} values for IPBC. For iodine only 80% of the emission is discharged to the surface water, since 20% of the influent concentration is adsorbed to the sewage sludge (CAR for iodine, 2013). Therefore, the PEC_{STP}-value for iodine is calculated according the following formulas:

$PEC_{STP,iodine}$ = PEC_{STP} for IPBC * 0.451 * 80%

For the worst case ($PEC_{STP,IPBC}$ 0.240 µg/L) for the in-service scenario "noise barrier, 30 days" this results in a $PEC_{STP,iodine}$ of 0.0866 µg/L. In the Assessment Report of Iodine a $PNEC_{STP}$ of 2900 µg/L is reported. The calculated PEC STP is below the PNEC and therefore, no unacceptable risk is concluded.

PEC Surface water

For the iodine risk assessment, the "bridge over pond" scenario has been chosen as a worst case since it represents an intake into a static water body. Iodine as an inorganic compound is not biodegradable so it was assumed, that the whole IPBC emissions might accumulate during the service life.
For a 20 years' service life period this results in an concentration of 0.369 µg/L iodine (0.818 µg/L IPBC). This value is below the background concentration of iodine of 0.5 – 20 µg/L. No unacceptable risk is concluded.

PEC Sediment

In the CAR (2008) for IPBC the reported PNEC for the sediment was derived using the equilibrium method. So the risk of the sediment compartment is the same as that assessed for surface water. Therefore, the calculation of $PEC_{sediment}$ values is not considered necessary.

PEC Soil

With reference to the iodine risk assessment for soil, the same procedure as for surface water has been followed, taking the house scenario and a service life of 20 years.
The estimated concentration of Iodine was 0.209 mg/kg wwt corresponding to 0.462 mg/kg wwt IPBC. Converted to dryweight the Iodine PEC is 0.237 mg/kg dwt.

Additionally, the noise barrier and a service life of 20 years was assessed. IPBC emissions are assumed to accumulate over 20 years, and this yields to 0.078 mg/kg iodine wwt y (0.173 mg IPBC /kg wwt). Converted to dryweight the Iodine PEC for "Noise barrier 20 years" corresponds to 0.088 mg/kg dwt.

The worst case PEC value of 0.237 mg Iodine/kg dwt is below the normal background values of Iodine (0.5 – 20 mg/kg dwt), therefore no unacceptable risk for soil is concluded.

PEC for air

Exposure to air is not considered as it is assumed that iodine speciate into non-volatile iodide and iodate in the different compartments.

PEC for groundwater – Iodine species

The estimated PEC values in groundwater for the IPBC metabolites are above the 0.1 µg/L threshold. However, the estimated concentration of Iodine in groundwater for the house scenario 20 years is 39.8 µg/L is within the normal background

concentrations (1 – 70 µg/L). No unacceptable risk to groundwater is therefore expected from the IPBC Iodine metabolites.

PEC for groundwater – IPBC and PBC (FOCUS PEARL)

The PEC's of IPBC and PBC are above the 0.1 µg/l threshold laid down by the Drinking Water Directive 2006/118/EC when calculated according to ECHA-Guidance (2017 Version 2.0) BPR, Vol. IV, ENV – Part B+C. A refinement was performed with FOCUS PEARL (4.4.4). The inputs for the simulation are as shown in the table below.

Tables with input parameters and output from FOCUS PEARL for groundwater – IPBC and PBC

Table 4.1 Summary of PECgw simulations with FOCUS PEARL for IPBC and PBC

Summary of PEC_{gw} simulations with FOCUS PEARL [vs…]		
Input parameters related to active substance	**IPBC**	**PBC**
Molecular weight (g/mol)	281.1	333.4
Vapour pressure at 20°C (Pa)	4.1E-07	1.3E-09
Water solubility at 20°C (mg/L)	10.9	95
Log_{10} Octanol/water partition coefficient (-)	3.3	1.7
Organic carbon/water partition coefficient (L/kg)	279.9	38.2
Kom at 20°C	162.4	22.2
DT_{50} in soil at 20°C (d)	113	95
Coefficient for uptake by plant (-)	0	0
1/n	0.92	0.93
Molar activation energy (kJ/mol)	65.4	65.4
Formation fraction from parent	-	0.58
Input parameters related to scenario		
Cumulative leaching of AS (mg/m2)	87.54	
Service life (years)	20	
Number of houses estimated per hectare	16	
Local emission of active substance (kg/ha/year)	0.004377	
Application date	10 dates	
Application type	Soil surface	
Crop	Grass	
Area of house (m2)	125	
Fweatherside	0.5	

Table 4.2 PECgroundwater - Output FOCUS PEARL for IPBC and PBC in µg/L

$PEC_{groundwater}$ - Output FOCUS PEARL in µg/L	
Scenario IPBC	
Location	Grassland (crop)
Chateaudun	0.000000
Hamburg	0.000000
Jokioinen	0.000000
Kremsmunster	0.000000
Okehampton	0.000000
Piacenza	0.000000
Porto	0.000000
Sevilla	0.000000
Thiva	0.000000
Scenario PBC	
Location	Grassland (crop)
Chateaudun	0.000000
Hamburg	0.000000
Jokioinen	0.000000
Kremsmunster	0.000000
Okehampton	0.000000
Piacenza	0.000000
Porto	0.000000
Sevilla	0.000000
Thiva	0.000000

4.1.3.2 Environmental risk assessment Penflufen

Groundwater

The PEC's of Penflufen and its metabolites are above the 0.1 µg/l threshold laid down by the Drinking Water Directive 2006/118/EC when calculated according to ECHA-Guidance (2017 Version 2.0) BPR, Vol. IV, ENV – Part B+C. A refinement was performed with FOCUS PEARL (4.4.4) for all metabolites. The inputs for the simulation are as shown in the table below.

For the simulation leaching from a house was considered. The scenario with a service life of 20 years was chosen as the product is only intended for industrial processes. It was assumed in the modeling, that Penflufen is transformed to 58 % M01 and 8 % M02 in the soil compartment.

Tables with input parameters and output from FOCUS PEARL for groundwater – Penflufen, M01 and M02

Table 4.3 Summary of PECgw simulations with FOCUS PEARL for Penflufen and metabolites

Summary of PEC_{gw} simulations with FOCUS PEARL [vs…]			
Input parameters related to active substance	**Penflufen**	**M01**	**M02**
Molecular weight (g/mol)	317.41	333.4	275.3
Vapour pressure at 20°C (Pa)	4.1E-07	1.3E-09	2.3E-06
Water solubility at 20°C (mg/L)	10.9	95	3.6
Log_{10} Octanol/water partition coefficient (-)	3.3	1.7	2.1
Organic carbon/water partition coefficient	279.9	38.2	1006

(L/kg)			
Kom at 20°C	162.4	22.2	583.5
DT_{50} in soil at 20°C (d)	113	95	164
Coefficient for uptake by plant (-)	0	0	0
1/n	0.92	0.93	0.747
Molar activation energy (kJ/mol)	65.4	65.4	65.4
Formation fraction from parent	-	0.58	0.08
Input parameters related to scenario			
Cumulative leaching of AS (mg/m2)	87.54		
Service life (years)	20		
Number of houses estimated per hectare	16		
Local emission of active substance (kg/ha/year)	0.004377		
Application date	10 dates		
Application type	Soil surface		
Crop	Grass		
Area of house (m2)	125		
Fweatherside	0.5		

Table 4.4 PECgroundwater - Output FOCUS PEARL for Penflufen and Metabolites in µg/L

$PEC_{groundwater}$ - Output FOCUS PEARL in µg/L	
Scenario Penflufen	
Location	Grassland (crop)
Chateaudun	0.001139
Hamburg	0.003536
Jokioinen	0.000372
Kremsmunster	0.001814
Okehampton	0.003382
Piacenza	0.003125
Porto	0.001441
Sevilla	0.000058
Thiva	0.000417
Scenario M01	
Location	Grassland (crop)
Chateaudun	**0.200645**
Hamburg	**0.326724**
Jokioinen	**0.301539**
Kremsmunster	**0.193712**
Okehampton	**0.213935**
Piacenza	**0.193567**
Porto	**0.128634**
Sevilla	**0.124324**
Thiva	**0.170532**
Scenario M02	
Location	Grassland (crop)
Chateaudun	0.000000
Hamburg	0.000005
Jokioinen	0.000000
Kremsmunster	0.000001
Okehampton	0.000002
Piacenza	0.000005
Porto	0.000000
Sevilla	0.000000
Thiva	0.000000

Non-compartment-specific exposure relevant to the food chain (secondary poisoning) for Penflufen

Assessment of secondary poisoning via the aquatic food chain

Since a measured BCF fish of 142 L/kg wwt is available this value will be used for calculation of $PEC_{oral,\ predator}$.

The predicted environmental concentration in food (fish) of fish eating predators ($PEC_{oral,\ predator}$) is calculated from the PEC for surface water, the measured or estimated BCF for fish and the biomagnification factor (BMF):

$$PEC_{oral,predator} = PEC_{water} \cdot BCF_{fish} \cdot BMF \quad (76)$$

Explanation of symbols

$PEC_{oral,predator}$	Predicted Environmental Concentration in food	$[mg \cdot kg_{wet\ fish}^{-1}]$
PEC_{water}	Predicted Environmental Concentration in water	$[mg \cdot l^{-1}]$
BCF_{fish}	bioconcentration factor for fish on wet weight basis	$[l \cdot kg_{wet\ fish}^{-1}]$
BMF	biomagnification factor in fish	[-]

Table 22

For assessment via the aquatic food chain, the PEC_{water} value from: in-service: "Bridge over pond, 1 year including degradation" have been used (6.75E-05mg/L), because this was the highest relevant concentration. According to table 23[9] a BMF of 1 was chosen, and as in ECHA Guidance (2017 Version 2.0) BPR, Vol. IV, ENV – PART B+C it was assumed that 50 % of the diet of predators will come from local sources while the other 50 % will come for regional sources.

Assuming a BCF fish of 142, a PEC_{water} of 6.75E-05 mg/L and a BMF of 1, the max. **PEC oral,predator for fish eating birds and mammals results in a concentration of 4.79E-03 mg/kg wet fish**.

Assessment of secondary poisoning via the terrestrial food chain

Biomagnification may also occur via the terrestrial food chain. According to ECHA-Guidance (2017 Version 2.0) BPR, Vol. IV, ENV – Part B+C. a similar approach as for the aquatic route can be used here. The food-chain soil → earthworm → worm-eating birds or mammals is used. The PEC_{oral} is derived in the same way as for the aquatic. The same scenario is used as for the aquatic food chain i.e. 50 % of the diet comes from PEClocal and 50 % from PECregional. Since birds and mammals consume worms with their gut contents and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the amount of substance that is in this soil.

The PECoral,predator for worm-eating birds and mammals is calculated as:

$PEC_{oral,\ predator} = C_{earthworm}$ Equation 99

The total concentration in a full worm can be calculated as the weighted average of the worm's tissues (through BCF and porewater) and gut contents (through soil concentration):

[9] ECHA-Guidance (2017 Version 2.0) BPR, Vol. IV, ENV – Part B+C.

$$C_{earthworm} = \frac{BCF_{earthworm} \cdot C_{porewater} \cdot W_{earthworm} + C_{soil} \cdot W_{gut}}{W_{earthworm} + W_{gut}}$$ Equation 100

Since an estimated BCF earthworm of 24.78 L/kg earthworm is available this value will be used.
$C_{earthworm}$ was calculated according to the following equation:

$$C_{earthworm} = \frac{BCF_{earthworm} \cdot C_{porewater} + C_{soil} \cdot F_{gut} \cdot CONV_{soil}}{1 + F_{gut} \cdot CONV_{soil}}$$ Equation 103c

In the following, all data included in these calculations are listed:

Symbol	Value	Unit	Reference
C_{soil} (max)	**1.40E-01**	**mg*kgwwt^{-1}**	**Input from house scenario 1 year**
$C_{porewater}$ (max)	**2.78E-02**	**mg*L^{-1}**	**Input from house scenario 1 year**
$W_{earthworms}$	**1**	**kg_{wwt} tissue**	**Default (BPR, Vol. IV, ENV – Part B+C.)**
Fgut	**0.1**	**kg_{dwt}*kg_{wwt}^{-1}**	**Default (BPR, Vol. IV, ENV – Part B+C.)**
Fsolid	**0.6**	**m^3*m^{-3}**	**Default (BPR, Vol. IV, ENV – Part B+C.)**
$RHO_{earthworm}$	**1.0**	**kgwwt.L-1**	**Default (BPR, Vol. IV, ENV – Part B+C.)**
RHOsoil (wet)	**1700**	**kg/m^3**	**Default (BPR, Vol. IV, ENV – Part B+C.)**
RHOsolid	**2500**	**kg*m^{-3}**	**Default (BPR, Vol. IV, ENV – Part B+C.)**
$BCF_{earthworm}$	**24.78**	**L*$kg_{wet\ earthworm}^{-1}$**	**Penflufen AR (2017)**
CONVsoil	**1.133E+00**		**Output (BPR, Vol. IV, ENV – Part B+C equation 102b)**
$C_{earthworm}$ / $PEC_{oral\ preadator}$	**3.17E-01**	**mg*$kg_{wet\ earthworm}^{-1}$**	**Output (BPR, Vol. IV, ENV – Part B+C equation 103c))**

Based on the parameter above, the **max. PEC oral,predator for worm- eating birds and mammals results in a concentration of 3.17E-01 mg/kg wet earthworm**

4.2 New information on the active substance(s) and substance(s) of concern

No new information on the active substances is available.

No substance(s) of concern in the product.

4.3 List of studies for the biocidal product

Table 4.5 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
Christof, A,W	2021	10.3	Report no.906480_NT BUILD 508	Test Report NT BUILD 509 Report No.: 906480	Confidential test report	Company owner: Superwood	No	Yes
Jensen, T, Ø and Stenbæk, J	2020	6.7 / 6.7 Efficacy data	83381-3-Report EN113 + EN84	Test Report. Modified EN 113 in accordance with EN 84. Report No.: 833801-3	Confidential test report	Company owner: Superwood	No	Yes
Jensen, T, Ø and Stenbæk, J	2020	6.7 / 6.7 Efficacy data	83381-4-Report EN113 + EN73	Test Report. Modified EN 113 in accordance with EN 73. ReportNo.: 833801-4	Confidential test report	Company owner: Superwood	No	Yes
Jensen, T, Ø and Lindegaard, B	2022	6.7 / 6.7 Efficacy data	The report will be submitted February 2022		Confidential test report	Company owner: Superwood	No	Yes
Johannesen, S, A	2020	5.1 / 5 Analytical method	835270_862304_Method validation report_rev1_CSA 208	Method Validation Report. REPORT NUMBER: 835270_862304 CSA 208 Rev. 1	Confidential validation report	Company owner: Superwood	No	Yes

Johannesen, S, A	2020	5.1 / 5 Analytical method	835270_method description_CSA 208 v2	CSA 208 Determination of IPBC and Penflufen in SC300 and Penflufen in SC400	Confidential validation report	Company owner: Superwood	No	Yes
Johannesen, S, A	2020	3.1, 3.2, 3.3, 3.4, 3.9 / same	835270_Test report_12M SC300	Test Report. REPORT NUMBER: 835270 12M	Confidential test report	Company owner: Superwood	No	Yes
Johannesen, S, A	2019	3.8, 4.16, 4.6 / same	835270_Test rapport Rev 1_fyskem_SC300	Test Report REPORT NUMBER: 835270 PC Rev. 1	Confidential test report	Company owner: Superwood	No	Yes

The study reports are as well uploaded in IUCLID section 13.

4.4 References

4.4.1 References other than list of studies for the biocidal product

- Lanxess, Letter of Access for Authorisation, 2021
- MSDS on SC300 in Danish
- MSDS on SC300 in English
- MSDS on Dipropylene Glycol n-Butyl Ether
- Excel spread shed on: Risk assessment for the environment on SC300
- Competent Authority Report. Penflufen PT8. UK 2017.
- Assessment Report. IPBC PT8. DK 2008.

The References are as well uploaded in IUCLID section 13.

4.4.2 Guidance documents

- Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C), 2018
- Guidance on the BPR: Volume II Efficacy, Assessment + Evaluation (Parts B+C), 2018
- Guidance on the Biocidal Product Regulation, Volume III Human Health, Part A (version 1.2 May 2018)
- Guidance on the Biocidal Product Regulation: Volume III Human Health, Part B + C (Version 4.0, December 2017)
- Biocides Human Health Exposure Methodology Document, October 2015
- Technical Notes for Guidance: Human Exposure to Biocidal Products – Guidance on Exposure Estimation, June 2002
- Technical Agreements for Biocides (TAB) (August 2021)
- HEAdhoc Recommendation no. 14 - Default human factor values for use in exposure assessments for biocidal products (HH WG III, 2017)
- HEAdhoc Recommendation no. 5, Non-professional use of antifouling paints: exposure assessment for a toddler
- HeAdhoc Recommendation no. 6 – Methods and models (version 4)
- Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C), 2017
- ESD for PT 8: Revised Emission Scenario Document for Wood Preservatives (OECD series No. 2, 2013)

- Report of the Leaching Workshop assessing leaching from treated wood to the environment (Arona, 2005)

4.4.3 Legal texts

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

- Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.