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

# PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION

(submitted by the competent authority)

SC400

Product type PT8

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

Case Number in R4BP: BC-LA068634-46

Competent Authority: Denmark

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# Table of Contents

1 Conclusion....5
2 Information on the biocidal product....8
2.1 Product type(s) and type(s) of formulation....8
2.2 Uses....8
2.3 Identity and composition....12
2.4 Identity of the active substance(s)....12
2.5 Information on the source(s) of the active substance(s)....12
2.6 Candidates for substitution....12
2.7 Assessment of the endocrine-disrupting properties of the biocidal product....13
2.8 Classification and labelling....14
2.9 Letter of access....14
2.10 Data submitted in relation to product authorisation....15
2.11 Similar conditions of use across the Union....15
3 Assessment of the biocidal product....16
3.1 Packaging....16
3.2 Physical, chemical, and technical properties....17
3.3 Physical hazards and respective characteristics....25
3.4 Methods for detection and identification....29
3.5 Assessment of efficacy against target organisms....32
3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)....32
3.5.2 Mode of action and effects on target organisms, including unacceptable suffering....32
3.5.3 Efficacy data....33
3.5.4 Efficacy assessment....35
3.5.5 Conclusion on efficacy....35
3.5.6 Occurrence of resistance and resistance management....35
3.5.7 Known limitations....35
3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products....35
3.6 Risk assessment for human health....36
3.6.1 Assessment of effects on human health....36
3.6.1.1 Skin corrosion and irritation....36
3.6.1.2 Eye irritation....36
3.6.1.3 Respiratory tract irritation....37
3.6.1.4 Skin sensitisation....37
3.6.1.5 Respiratory sensitisation....38
3.6.1.6 Acute oral toxicity....38

3.6.1.7 Acute inhalation toxicity ..... 39
3.6.1.8 Acute dermal toxicity ..... 39
3.6.2 Information on dermal absorption ..... 40
3.6.3 Available toxicological data relating to substance(s) of concern ..... 40
3.6.4 Other ..... 40
3.6.4.1 Food and feeding stuffs studies ..... 40
3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product ..... 40
3.6.4.3 Other test(s) related to the exposure to humans ..... 40
3.6.5 Available toxicological data relating to endocrine disruption ..... 41
3.6.6 Exposure assessment and risk characterisation for human health ..... 41
3.6.6.1 Introductory remarks ..... 41
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 ..... 42
3.6.6.3 List of exposure scenarios Table 3.28 Summary table: exposure scenarios 44
3.6.6.4 Reference values to be used in risk characterisation ..... 45
3.6.6.5 Specific reference value for groundwater ..... 45
3.6.6.6 Professional users (including industrial users and trained professional users) ..... 45
3.6.6.7 Non-professional users ..... 50
3.6.6.8 Secondary exposure to professional bystanders and non-professional bystanders/general public ..... 54
3.6.7 Monitoring data ..... 59
3.6.8 Dietary risk assessment ..... 59
3.6.8.1 Information of non-biocidal use of the active substance and residue definitions ..... 59
3.6.8.2 Estimating livestock exposure to active substances used in biocidal products and Worst Case Consumer Exposure (WCCE) ..... 59
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 ..... 59
3.6.8.4 Estimating transfer of biocidal active substances into foods as a result of non-professional use and consumer exposure ..... 60
3.6.8.5 Maximum residue limits or equivalent ..... 60
3.6.9 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product ..... 60
3.6.10 Overall conclusion on risk assessment for human health ..... 60
*3.7* Risk assessment for animal health ..... 60
3.7.1 Risk for companion animals ..... 60
3.7.2 Risk for livestock animals ..... 60
3.8 Risk assessment for the environment ..... 61
3.8.1 Available studies and endpoints applied in the environmental risk assessment . 61

3.8.1.1 Endpoints for the active substances, metabolites and transformation product(s) ..... 61
3.8.1.2 Endpoints for the product ..... 64
3.8.1.3 Substance(s) of concern ..... 67
3.8.1.4 Screening for endocrine disruption relating to non-target organisms ..... 67
3.8.2 Emission estimation ..... 67
3.8.2.1 General information ..... 67
3.8.2.2 Emission estimation for the scenarios ..... 70
3.8.2.3 Primary poisoning ..... 72
3.8.2.4 Secondary poisoning ..... 73
3.8.3 Exposure calculation and risk characterisation ..... 73
3.8.4 Mixture toxicity ..... 75
3.8.5 Conclusion to the risk assessment ..... 75
3.8.6 Primary and secondary poisoning ..... 76
3.8.6.1 Primary poisoning ..... 76
3.8.6.2 Secondary poisoning ..... 76
3.8.7 Aggregated exposure (combined for relevant emission sources) ..... 77
3.8.8 Overall conclusion on the risk assessment for the environment ..... 77
3.9 Assessment of a combination of biocidal products ..... 78
3.10 Comparative assessment ..... 79
4 Appendices ..... 79
4.1 Calculations for exposure assessment ..... 79
4.1.1 Human health ..... 79
4.1.2 Dietary assessment ..... 82
4.1.2.1 Environment Environmental risk assessment Penflufen ..... 83
4.2 New information on the active substance(s) and substance(s) of concern ..... 86
4.3 List of studies for the biocidal product ..... 87
4.4 References ..... 89
4.4.1 References other than list of studies for the biocidal product ..... 89
4.4.2 Guidance documents ..... 89
4.4.3 Legal texts ..... 90
4.5 Confidential information ..... 90

# 1 Conclusion

SC400 is a liquid biocidal product containing penflufen as active substance. The product is used as a wood preservative by industrial users for the control of 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 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). The biocidal product does not meet the conditions laid down in Article 19(1) for the use "preventive wood protection of soft wood for use class 3 against wood rotting fungi". The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

## 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 substance penflufen, which has 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 penflufen which does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is therefore not considered as a candidate 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 manufacturer of the biocidal product is listed in section 1.3 of the SPC.

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

[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

## Conclusions of the assessments for each area

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 substance is available. More information on the analytical methods for the active substance 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 and water are available in the PT8 CAR (CA UK, 2017) for penflufen. 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 substance penflufen.

Based on the risk assessment, it is unlikely that the intended use causes any unacceptable acute or chronic risk to professional users, non-professional users and professional bystanders and non-professional bystanders/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 Penflufen and its metabolites.

The risk assessment of SC400 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

There are no post-authorisation conditions.

# 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 a 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 | Supercritical pressure impregnation | 42 g penflufen / $m^3$ wood | Industrial | N | Unacceptable risk from SC400 are found in the environmental risk assessment in the groundwater compartment, due to the penflufen metabolite M01.<br>No risk mitigation measure can currently be applied to mitigate this risk, hence use in Use Class 3 cannot be approved for the product. |
| 2 | Preventive wood protection of soft wood for Use Class 2 | PT8 | Wood rotting fungi | Supercritical pressure impregnation | 42 g penflufen / $m^3$ wood | Industrial | R | • Additional RMM: Do not use on wood which may come in direct contact with food, feed |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | and livestock (APCP, see section 3.5)<br>• 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.<br>• 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 ☐

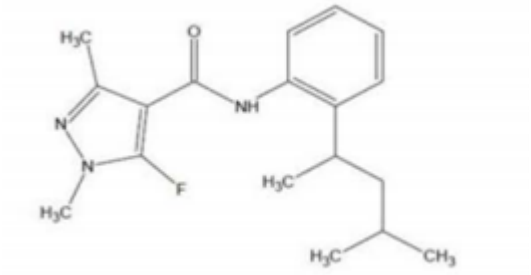
not identical ☒

to the identity and composition of the products evaluated in connection with the approval for listing of the active substance 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 substance(s)

**Table 2.3 Identity of the active substance(s)**

| **Main constituent(s)** | |
|---|---|
| **Common name** | Penflufen |
| **Chemical name** | 5-Fluoro-1,3-dimethyl-*N*-[(*2RS*)-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<br>1:1 (R:S) ratio of enantiomers |
| **Structural formula** |  |

## 2.5 Information on the source(s) of the active substance(s)

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

## 2.6 Candidates for substitution

Penflufen does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is therefore not considered as a candidate for substitution.

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

SC400 should not be considered to have endocrine disrupting properties.

The biocidal product contains the active substance penflufen, which has 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<br>Aquatic Chronic 2: H411 | Carc. 2: H351<br>Aquatic Chronic 2: H411 |
| **Hazard Pictograms** | GHS08<br>GHS09 |  |
| **Signal word(s)** | Warning | Warning |
| **Hazard statements** | H351: Suspected of causing cancer<br>H411: Toxic to aquatic life with long lasting effects | H351: Suspected of causing cancer<br>H411: Toxic to aquatic life with long lasting effects |
| **Precautionary statements** | P201: Obtain special instructions before use<br>~~P202: Do not handle until all safety precautions have been read and understood.~~<br>P280: Wear protective gloves/protective clothing/eye protection/face protection.<br>P308 + P313: IF exposed or concerned: Get medical advice/attention<br>~~P405: Store locked up.~~<br>P273: Avoid release to the environment.<br>P391: Collect spillage.<br>P501: Dispose of contents/container to hazardous waste. | P201: Obtain special instructions before use<br>P280: Wear protective gloves/protective clothing/eye protection/face protection.<br>P308 + P313: IF exposed or concerned: Get medical advice/attention<br>P273: Avoid release to the environment.<br>P391: Collect spillage.<br>P501: Dispose of contents to hazardous waste. |
| **Supplemental hazard statements** | - | |
| **Notes** | Justifications for excluding p-statements (striked through P-statements):<br>P202 is optional where P201 is assigned. For SC400, P201 is sufficient to ensure a safe use.<br>P405 is optional for industrial/professional users and is not considered relevant for the industrial use of SC400 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 dossier for penflufen for use in the evaluation of the product SC400.

## 2.10 Data submitted in relation to product authorisation

No additional data 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. an impregnation facility. SC400 is manufactured and used at Superwood A/S. The product does only exist in containers that 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. Tests for reactivity towards the container and corrosion towards metal have 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 BPR Guidance (Vol I, Parts A+B+C, version 2.0, 2018), section 3.6.1 | Test item: SC400 Batch No. CH20190215 Penflufen: 2.5% | Transparent liquid with low viscosity. | 862304_Test report_12M_SC400 |
| 3.1.1. | Physical state at 20 °C and 101.3 kPa | | | 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.<br><br>***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: SC400 Batch No. CH20190215 Penflufen: | pH (neat): 8.3 at 22 °C | 862304_Test report_12M_SC400 |
| 3.3. | Relative density / bulk density | EC method A.3 and OECD test | | 0.9178 at 20 °C (average, triplicate measurements) | |

| Numbering according to Annex III of BPR | Property | Guideline and Method | Tested product/batch (AS% w/w) | Results | Reference |
|---|---|---|---|---|---|
| | | guideline 109 – Relative density, (oscillating densitometer) | 2.5% | | |
| 3.4.1.1. | Storage stability test – **accelerated storage** | - | - | No test submitted<br><br>***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<br><br>Appearance: BPR Guidance (Vol I, Parts A+B+C, version 2.0, 2018), section 3.6.1<br><br>pH: CIPAC MT 75.3<br><br>Relative density: EC method A.3 and OECD test 109 (oscillating densitometer)<br><br>Viscosity: OECD test 114 and CIPAC MT 192 (rotational viscometer)<br><br>Analytical method: HPLC-DAD (CSA | Test item: SC400<br>Batch No. CH20190215<br>Nominal AS content: 2.5%<br>AS content: See results | Storage in 1 L stainless steel container at 17.2-24.5°C (average temperature 20 °C) for 12 months.<br><br>**Active substance content:**<br>$T_0$: 2.50% w/w<br>$T_{12\ months}$: 2.44% w/w (change: -2.4%)<br><br>**Appearance:**<br>$T_0$: Transparent colourless oily liquid.<br>$T_{12\ months}$: Transparent colourless oily liquid.<br><br>**pH** (neat)**:**<br>$T_0$: 8.3<br>$T_{12\ months}$: 7.6 (change: -0.7)<br><br>**Packaging appearance:** | 862304_Test report_12M_SC400 |

| Numbering according to Annex III of BPR | Property | Guideline and Method | Tested product/batch (AS% w/w) | Results | Reference |
|---|---|---|---|---|---|
| | | 208 method). | | $T_{12\ months}$: No impact on the packaging was observed after storage.<br><br>**Weight loss:**<br>$T_0$: 1946.5 g<br>$T_{12\ months}$: 1945.2 g<br>(change: -1.3 g, -0.1%)<br><br>**Relative density** (at 20 °C)**:**<br>$T_0$: 0.9178<br>$T_{12\ months}$: 0.9185<br>(change: + 0.1%)<br><br>**Viscosity:**<br>The product is a Newtonian liquid.<br>At 20 °C:<br>$T_0$: 5.65 mPa·s<br>$T_{12\ months}$: 5.73 mPa·s<br>(change: + 1.4%)<br><br>At 40 °C:<br>$T_0$: 3.07 mPa·s<br>$T_{12\ months}$: 3.13 mPa·s<br>(change: + 1.7%)<br><br>***rMS remark:*** The temperature deviation during the test exceeds 20 ± 2 °C that is indicated in the leading guidance. The deviation is considered as acceptable as all parameters are stable during the 12 | |

| Numbering according to Annex III of BPR | Property | Guideline and Method | Tested product/batch (AS% w/w) | Results | Reference |
|---|---|---|---|---|---|
| | | | | months storage and the average temperature during the test was held at 20 °C.<br><br>As experimental data were obtained after homogenisation of the product, the product is to be stirred/homogenised before use. | |
| 3.4.1.3. | Storage stability test – **low temperature stability test for liquids** | - | - | Not relevant see justification above<br><br>***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 as the product is stored in metal containers. The product only exists in a 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 | - |

| Numbering according to Annex III of BPR | Property | Guideline and Method | Tested product/batch (AS% w/w) | Results | Reference |
|---|---|---|---|---|---|
| | | | | should be stored at temperatures above 0 °C and below 30 °C.<br>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: SC400<br>Batch No. CH20190215<br>Penflufen: 2.5% | Metal container:<br>Weight change of 0.3 g (-0.1 %).<br><br>No reactivity toward the container observed during the long term storage test at ambient temperature for 12 months. | 862304_Test report_12M_SC400 |
| 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 nor is intended to be diluted or dispersed in water before use. | - |
| 3.5.5. | Disintegration time | - | - | Not relevant as the product is a liquid formulation. | - |

| Numbering according to Annex III of BPR | Property | Guideline and Method | Tested product/batch (AS% w/w) | Results | Reference |
|---|---|---|---|---|---|
| | | | | | |
| 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 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. | - |

| Numbering according to Annex III of BPR | Property | Guideline and Method | Tested product/batch (AS% w/w) | Results | Reference |
|---|---|---|---|---|---|
| 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 a tensiometer in combination with a Du Nuoüy-ring]* | EC method A.5 and OECD 115 | Test item: SC400<br>Batch No. CH20190215<br>Penflufen: 2.5% | 30.7 mN/m (uncorrected)<br><br>29.0 mN/m (corrected by Harkins and Jordan)<br><br>***rMS remark:*** The product is regarded as surface active since the surface tension is < 60 mN/m. | 862304_Test rapport_Rev1_fyskem_SC400 |
| 3.9. | Viscosity *[Shear rates: 20, 26, 36, 51, 71 and 100 $s^{-1}$, temperature: 20°C and 40°C]* | OECD 114 and CIPAC MT 192 - Viscosity of liquids by rotational viscometry. | | The product is a Newtonian liquid.<br><br>Dynamic viscosity:<br>At 20 °C: 5.65 mPa·s<br>At 40 °C: 3.07 mPa·s<br><br>***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 in the toxicological assessment. | 862304_Test report_12M_SC400 |

### Table 3.3 Conclusion on physical, chemical, and technical properties

| Conclusion on physical, chemical, and technical properties |
|---|
| SC400 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.<br><br>The product is a solvent based colourless transparent oily liquid.<br><br>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, viscosity and relative density 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 SC400.<br><br>The surface tension of SC400 is 29.0 mN/m at 25°C and the product is therefore regarded as surface active. The dynamic viscosity was determined to 5.65 mPa·s at 20 °C and 3.07 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.<br><br>Based on the storage stability test, a shelf-life of one year on the packaging material stainless steel can be authorised.<br><br>**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 of the formulation have been evaluated. SC400 is not explosive.<br><br>The active substance is not explosive according to the PT8 CAR (CA UK, 2017) for Penflufen. A DSC test of the active substance demonstrated an exothermal decomposition in the temperature range 270-410°C (triplicate measurements) with an energy of 240-330 J/g. Thus supporting the conclusion that the active substance is not explosive.<br><br>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 mixture of gases. |
| 4.3. | Flammable aerosols | - | - | Not relevant since the definition of aerosols is not fulfilled for the product. |
| 4.4. | Oxidising gases | - | - | Not relevant since the product |

| Numbering according to Annex III of BPR | Property | Guideline and Method | Tested product / batch (AS% (w/w) | Results |
|---|---|---|---|---|
| | | | | 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: SC400<br>Batch No. CH20190215<br>Penflufen: 2.5% | Flash point: 100.0 °C<br><br>No flammable properties, since the flash point is greater than the classification criterion 60°C for classification category 3.<br><br>Reference: 862304_Test rapport_Rev1_fyskem_SC400 |
| 4.7. | Flammable solids | - | - | Not relevant as the product is not a solid substance. |
| 4.8. | Self-reactive substances and mixtures | - | - | Test not required since no chemical groups associated with explosive or self-reactive properties are present in the product.<br><br>Penflufen is neither explosive nor self-reactive according to the PT8 CAR (CA UK, 2017).<br><br>The remaining ingredients do not contain chemical groups associated with explosive or self-reactive properties.<br><br>Therefore, the product does not have to be classified as |

| Numbering according to Annex III of BPR | Property | Guideline and Method | Tested product / batch (AS% (w/w) | Results |
|---|---|---|---|---|
| | | | | 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 mixture contains oxygen and fluorine but these elements are chemically bonded only to carbon or hydrogen.<br>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 | Test item: SC400<br>Batch No. CH20190215 | Test duration: 7 days. |

| Numbering according to Annex III of BPR | Property | Guideline and Method | Tested product / batch (AS% (w/w) | Results |
|---|---|---|---|---|
| | | Deviation from guideline: Test performed at 55 ± 5 °C instead of 55 ± 1 °C. | Penflufen: 2.5% | Measured temperature:<br>Aluminium plates: 52 - 59 °C<br>Steel plates: 55 – 58 °C<br><br>Uniform corrosion:<br>Aluminium (EN AW 7075-T6): Up to 0.004%.<br>Steel (S235JR+C): Up to 0.007%<br><br>Localised corrosion:<br>Aluminium: Not observed<br>Steel: Not observed<br><br>SC400 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 ≤ 0.007% for both aluminium and steel.<br><br>Reference: 862304_Test rapport_Rev1_fyskem_SC400<br><br>***rMS remark:*** As the observed corrosion is very low, the temperature deviation compared to the guideline are considered as acceptable in this case. |
| 4.17.1. | Auto-ignition temperatures of products (liquids and gases) | - | - | Test not required. The auto-ignition temperature is expected to be approx. 194 |

| Numbering according to Annex III of BPR | Property | Guideline and Method | Tested product / batch (AS% (w/w) | Results |
|---|---|---|---|---|
| | | | | °C based on read-across from data for the ingredients of the product.<br><br>Please refer to the confidential 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, HPLC-DAD*:*<br>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), sonicated 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 (100Å, 150mm x 4.6 mm, ID no. 145) and mobile phase using gradient elution (MilliQ water with $H_3PO_4$ pH 3/Acetonitrile 65:35 through 10:90 to 65:35). Retention time of penflufen: 9.8 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 measure | Range | Mean | RSD | Concentration tested | Number of replicates | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | ments | | | | | | | |
| Penflufen (active substance) | Range: 50 µg/ml to 250 µg/ml<br>n = 8<br>y = 1.15x + 2.8<br>$R^2$ = 0.9993)<br><br>(y: peak area, x: concentration in µg/mL) | Interference not > 3% of peak sample area in blank matrix.<br><br>Chromatograms provided (sample, blank and standard sample) | 2.5% w/w | 2 samples (triplicate measurements) | 98.6-98.8 | 98.7 | n.d.[2] | 2.5 | 6 | - | 835270_862304_Method validation report_rev1_CSA 208<br><br>and<br><br>835270_method description CSA 208 v2 |
| | | | | | | | | Range: 2.50-2.54%<br>Mean: 2.52%<br>RSD%: 0.55%<br>The precision lies within acceptable RSD% range according to the Horwitz ratio. | | | |

[2] No standard deviation determined as number of samples 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 is available. Specificity, linearity accuracy and precision were checked and are found acceptable.<br><br>No substances of concern are present in the product.<br><br>Methods for the detection of 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.<br><br>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.<br><br>**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[3] | 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<br>Retention rate:<br>42 g penflufen/$m^3$ wood | F.70 |
| **Targeted organisms** | Brown rot fungi/basidiomycetes | G.10 |

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

Two studies according to EN standards were provided to demonstrate the efficacy of SC400. EN 113 with ageing procedure EN 73 and EN 84 separately.

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.

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

## 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<br><br>Use 1: Preventive treatment against wood rotting fungi<br><br>Brown rot | SC400 | *C. puteana*<br>*G. trabeum*<br>*P. placenta* | EN 113 after EN 73 (evaporation)<br><br>The product was applied by Supercritical pressure impregnation<br>- 6 blocks tested for each treatment and each fungal strain. *C. puteana, G. trabeum* and *P. placenta* are tested on pine.<br>- Number of replicates: 4 replicates for each treatment and each fungal strain and 6 replicates for each treatment and used for correction.<br><br>CONTROLS<br>- Untreated controls: one non-treated control block included with the treated block in each test. Six virulence control blocks for each fungal strain.<br><br>The effect investigated is mass loss of the test blocks, induced by the fungal development<br><br>The method for recording effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.<br>- 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 0.023; 0.034; 0.049; 0.056; 0.116 kg/$m^3$<br><br>The test passed the virulence control and was valid.<br><br>The biological reference value b.r.v is:<br>0.042 kg penflufen /$m^3$<br><br>Mid toxic value (m.t.v) calculation are used for deviation of b.r.v. according to EN 599-1, 5.1.3<br><br>The study is validated as more than 20 % of mass loss is observed in the control | 861430-2, rev.1 - Report EN113+EN73 | 861430-2, rev.1 - Report EN113+EN73<br><br>IUCLID 6.7, .001 |
| PT8 | SC400 | *C. puteana*<br>*G. trabeum* | EN 113 after EN 84 (leaching) | Supercritical $CO_2$ impregnation. | 861430-1, rev.1 - | 861430-1, rev.1 - |

| | | | | | | |
|---|---|---|---|---|---|---|
| Use 1: Preventive treatment against wood rotting fungi<br><br>Brown rot | | *P. placenta* | The product was applied by Supercritical pressure impregnation<br>- 4 blocks tested for each treatment and each fungal strain. *C. puteana, G. trabeum* and *P. placenta* are tested on pine.<br>- Number of replicates: 4 replicates for each treatment and each fungal strain and 6 replicates for each treatment and used for correction.<br><br>CONTROLS<br>- Untreated controls: one non-treated control block included with the treated block in each test. Six virulence control blocks for each fungal strain.<br><br>The effect investigated is mass loss of the test blocks, induced by the fungal development<br>The method for recording effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.<br>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:<br>penflufen<br>0.023; 0.034; 0.049; 0.056; 0.116 kg/$m^3$<br><br>The test passed the virulence control and was valid.<br><br>The biological reference value b.r.v. was:<br>0.029 kg penflufen /$m^3$<br><br>Mid toxic value (m.t.v) calculation are used for deviation of b.r.v. according to EN 599-1, 5.1.3<br><br>The study is validated as more than 20 % of mass loss is observed in the control | Report EN113+EN84 | Report EN113+EN84<br><br>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 0.042 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<br>Retention rate:<br>42 g penflufen/$m^3$ wood | 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 substance for wood preservation so no specific information is available. The assessment report does not state any cases of field resistance to ADIH fungicides.

### 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

SC400 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, SC400. 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 substance 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 substance penflufen was examined according to the data requirements under the Biocides Regulation (EU) No 528/2012 (BPR). The toxicological properties of the active substance is summarized in the Competent Authority Report (CAR):

- Penflufen PT8 – UK (2017)

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 | SC400 does not cause skin corrosion/irritation. |
| Justification for the value/conclusion | None of the active substance and 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 | SC400 does not cause eye irritation. |

| | |
|---|---|
| Justification for the value/conclusion | None of the active substance and non-active substances in the product allow for classification for eye irritation as they are either not classified themselves 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 3.12 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 | SC400 does not cause respiratory tract irritation. |
| Justification for the conclusion | None of the active substance and non-active substances in the product allow for classification for respiratory tract irritation as they are either not classified themselves 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 3.14 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 | SC400 does not cause skin sensitisation. |
| Justification for the value/conclusion | None of the active substance and non-active substances in the product allow for classification for skin sensitisation as they are either not |

| | |
|---|---|
| | classified themselves 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 3.16 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 | SC400 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.<br>Penflufen does not meet the classification criteria for skin sensitisation. Based on this, the product is not classified for 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 sensitization 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 | SC400 is not acutely toxic via the oral route – ATEmix > 2000 mg/kg bw. |
| Justification for the selected value | None of the active substance or non-active substances are classified for acute oral toxicity, and SC400 should therefore not be classified for acute oral toxicity according to the rules laid down in Reg. (EC) no. 1272/2008. |
| 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 | SC400 is not acutely toxic via inhalation. |
| Justification for the selected value | None of the active substance or non-active substances are classified for acute inhalation toxicity, and SC400 should therefore not be classified for acute inhalation toxicity according to the rules laid down in Reg. (EC) no. 1272/2008. |
| Classification of the product according to CLP | Not classified. |

**Table 3.27 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 | SC400 is not acutely toxic via the dermal route. |
| Justification for the selected value | None of the active substance or non-active substances are classified for acute dermal toxicity, and SC400 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 toxicity by dermal 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. |

## 3.6.2 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 |
| Value(s) | 70 % |
| Justification for the selected value(s) | Default value for solvent-based dilution according to EFSA (2017) Guidance on dermal absorption[4]. |

**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 SC400. Please refer to the confidential annex of the PAR for details of the assessment.

## 3.6.4 Other

Penflufen is classified Carc. 2 (H351). Penflufen is present in SC400 at a concentration of 2.5 %, triggering the classification of SC400 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.

[4] 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.

#### 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 substance penflufen has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

In conclusion, SC400 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

SC400 is a solvent-based formulation. It is intended for industrial use only, and only at one location (Superwood A/S in Hampen) in Denmark.

It contains 2.5 % (w/w) penflufen. 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. SC400 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) enables the active substance to be carried into the $CO_2$ in the supercritical phase. After impregnation only penflufen is left in the wood. Thus, no application rate is available. The uptake of the active substance 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 42 g penflufen/$m^3$ 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

- SC400 can cause systemic effects when exposed to, but not local effects. Therefore, only a risk assessment for systemic effects has been performed. For consideration of the classification as Carc. 2 (H351), please refer to section 3.6.6.4.
- 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.

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. SC400 is currently not intended to be sold for the treatment of wood used indoors. SC400 is manufactured and used only at Superwood A/S. Although SC400 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 has a low vapour pressure ($4.1 \times 10^{-7}$ Pa at 20°C).

Strategy for livestock exposure and 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 | Yes |
| Dermal | No | n/a | Yes | Yes | n/a |
| Inhalation | No | n/a | Yes | Yes | n/a |
| **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) |
| 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**

| 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 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 SC400.

### 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 3.30 Description and input parameters**

| Description of Scenario 1 |
|---|
| The mixing/loading process is a fully automated procedure in a closed system. When the product SC400 is mixed, 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 3.31 Description and input parameters**

| **Description of Scenario 2** |
|---|
| Application of SC400 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. SC400 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 SC400. 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 SC400 penetrates the wood completely. Pressure is maintained at a plateau for a specified amount of time to ensure distribution of SC400 in the wood. System is de-pressurized. Excess SC400 is collected and reused. $CO_2$ is reused. There is no $CO_2$ or product left in the wood after the impregnation.<br>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.<br>$CO_2$ 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 3.32 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.<br><br>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 3.33 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.<br>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:<br>Conc. AS x exposed surface area ($cm^2$) x contaminated surface (%) x transfer efficiency (%)<br><br>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.<br>A wood density of 0.40 $g/cm^3$ is assumed as agreed in the Human Health TAB.<br><br>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 SC400 | 0.042 $mg/cm^3$ | - |
| | Event exposure duration | 6 hours | TNsG User Guidance, p. 52 (2002) |
| | 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 | 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) |
| | Inhalation absorption | 100 % | CAR penflufen |
| | Dermal absorption, penflufen | 70 % | Default value, EFSA Guidance on dermal absorption (2017)[5] |
| | 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) – August 2021 |
| | Area of wood to be sanded (cm$^2$) | 4 x 4 cm x 250 cm + 2 x 4 cm x 4 cm<br><br>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<br><br>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 3.34 Summary table: estimated systemic exposure and risk**

[5] Default value is for organic solvent-based formulation, as the product SC400 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 substance is 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 |
| Scenario 2 | 1/No PPE | Penflufen | - | - | - | - | - | Yes |
| Scenario 3 | 1/No PPE | Penflufen | - | - | - | - | - | Yes |
| Scenario 4 | 1/No PPE | Penflufen | None | 0.0045 | 0.00007 | 0.00456 | 11.4 | Yes |

**Combined scenarios**

Not relevant.

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

Risk characterisation (RC) for local effects is triggered when the biocidal product is classified for local effects. SC400 is not classified for any local effects.

**Outcome of qualitative local risk assessment**

Risk characterisation (RC) for local effects is triggered when the biocidal product is classified for local effects. SC400 is not classified for any local effects.

**Conclusion**

A safe use has been demonstrated when applying SC400 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. It should be noted that this conclusion is only based on the effects from penflufen. Occupational safety measures at work places may require the use of personal protective equipment against e.g. wood dust.

### 3.6.6.7 Non-professional users

SC400 is not intended for use by non-professionals. However, considering the possibility of making wood available for non-professionals (as 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.<br>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:<br>Conc. AS x exposed surface area ($cm^2$) x contaminated surface (%) x transfer efficiency (%)<br><br>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.<br>A wood density of 0.40 $g/cm^3$ is assumed as agreed in the Human Health TAB.<br><br>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 SC400 | 0.042 $mg/cm^3$ | - |
| | Event exposure duration | 1 hour | TNsG User Guidance, p. 51 (2002) |
| | 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 | 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) |
| | Inhalation absorption | 100 % | CAR penflufen |
| | Dermal absorption, penflufen | 70 % | Default value, EFSA Guidance on dermal |

| | | | |
|---|---|---|---|
| | | | absorption (2017)[6] |
| | 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) – August 2021 |
| | | | TNsG User Guidance, p. 51 (2002) –Example |
| | | | 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 3.36 Summary table: estimated systemic exposure and risk characterisation for non-professional users**

[6] Default value is for organic solvent-based formulation, as the product SC400 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 substance is embedded in the wood in its dry/solid state.

| 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 | - | 0.0045 | 0.00001 | 0.0045 | 11.3 | Yes |

**Combined scenarios**

Not relevant.

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

Risk characterisation (RC) for local effects is triggered when the biocidal product is classified for local effects. SC400 is not classified for any local effects.

**Outcome of qualitative local risk assessment**

Risk characterisation (RC) for local effects is triggered when the biocidal product is classified for local effects. SC400 is not classified for any local effects.

**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 professional bystanders and non-professional bystanders/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 SC400 in its liquid phase is expected, exposure to SC400 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 substance is bound to the outer 1 cm of the 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 substance according to TNsG User guidance (2002). The TnsG regards the scenario as unrealistic for children as opposed to infants, as they are unlikely to chew on wood. Dermal exposure is not considered. | | | |
| | Parameters | Value | Reference and justification |
| Tier 1 | Concentration of active substance in wood treated with SC400 | 0.042 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 | 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 User guidance (2002) and TNsG part III (2002) and includes dermal and oral exposure during play on timber structures.<br><br>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 (%)*<br><br>For oral exposure 50% hand-to-mouth transfer is assumed (external dermal exposure = external oral exposure).<br><br>Only the exposure to infants has been calculated as it is considered to act as a risk envelope for the other age populations. | | | |
| | Parameters | Value | Reference and justification |
| | Conc. active substance on treated surface | 0.031 $mg/cm^2$ | See calculations for scenario 4+5 |
| | Infant hand surface (palms) | 98.4 $cm^2$ | 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):<br>$0.328 \times {}^{\text{molecular weight x vapour pressure}} / _{\text{AEL long-term}} \leq 1$<br><br>Penflufen results in a value of 0.001, thus making further assessment unnecessary. | | | |
| | Parameters | Value | Reference and justification |
| Tier 1 | Saturated vapour concentration | | HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocide active substance |
| | Molecular weight | 317.41 g/mol | CAR, penflufen |
| | Vapour pressure | Penflufen: 4.1 x 10-7 Pa at 20°C | CAR, penflufen |

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 | | | | | | |
|---|---|---|---|---|---|---|---|
| **Scenario** | **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 7 Infant chewing on wood cut off | Infant | 0.0084 | Negligible | Negligible | 0.0084 | 2.8 | Yes |
| Scenario 8 Infant playing and mouthing on weathered play structures | Infant | 0.0023 | 0.003 | Negligible | 0.0055 | 13.9 | Yes |
| Scenario 9 Inhalation of volatilised residues | 1 HEEG 13 | Not relevant | Not relevant | Not relevant to perform quantitative exposure calculations | - | - | Yes |

**Combined scenarios**

A combined exposure is not relevant. The only scenarios where quantitative exposure calculations have been relevant is not candidates for combined exposure, as they are exposure estimates for different population (e.g. (non-)professional sanding vs infant playing on weathered structures) or the scenarios where exposure is negligible or accidental.

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

Risk characterisation (RC) for local effects is triggered when the biocidal product is classified for local effects. SC400 is not classified for any local effects.

**Outcome of qualitative local risk assessment**

Risk characterisation (RC) for local effects is triggered when the biocidal product is classified for local effects. SC400 is not classified for any local effects.

**Conclusion**

A safe level of exposure to the active substance penflufen was identified for all populations of the general public.

## 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 3.42 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] |

[1] Regulation (EC) No 396/2005

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

SC400 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

SC400 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.

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

SC400 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.

#### 3.6.8.5 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

Not relevant. SC400 contains one active substance and no substances of concern.

### 3.6.10 Overall conclusion on risk assessment for human health

**Table 3.43 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 without use of personal protection equipment | - 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

SC400 is a PT8 product intended for use in Use Class 2 and 3 against brown rot fungi.
It contains one active substance, Penflufen, present in a concentration of 2.5 %.

Penflufen has a harmonised environmental classification of H400 (M-factor = 1) and H410 (M-factor = 1). No other substance in the biocidal product have an environmental classification.
The concentration of the active substances alone therefore leads to the environmental classification of the product as H411 Aquatic Chronic 2.

SC400 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 biocide to be carried into the $CO_2$ in the supercritical face. After the impregnation only the biocide (penflufen) 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 determent 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 substance. The risk assessment is entirely based on the list of endpoints as published in the assessment report. Assessment report for penflufen PT8. March 2017 for which United Kingdom was the rapporteur member state.
The assessment reports is available on the ECHA website.

The exposure assessment is based on data for the active substances and leaching data for the product. The major metabolite formed in soil from penflufen is according to the final CAR report on penflufen-3-hydroxy-butyl (M01) and Penflufen-pyrazolyl-AAP (M02). M02 is not a water metabolite and will not be addressed in the water compartment.

The endpoints applied in the environmental risk assessment are summarised in the tables below.

**Endpoints and PNEC values for the active substance applied in the environmental risk assessment**

| **Endpoints and PNEC values for the active substance applied in the environmental risk assessment** | | | |
|---|---|---|---|
| | **Value** | **Unit** | **Remarks** |
| | **Penflufen** | | |
| **Fate and behaviour in the environment** | | | |
| Molecular weight | 317.41 | g/mol | |

| | | | |
|---|---|---|---|
| Melting point | 111.1 | °C | |
| Vapour pressure (at 20°C) | 4.1 x$10^{-7}$ | Pa | |
| Water solubility (at 20°C) | 10.9 (pH 7) | mg/l | |
| Log Octanol/water partition coefficient ($K_{ow}$) | 3.3 | Log 10 | |
| Organic carbon/water partition coefficient ($K_{oc}$) | 279.9 | L/kg | |
| Henry's Law Constant | 1.19x$10^{-5}$ (pH7.1) | Pa/$m^3$/mol | Is not used for the calculations |
| Characterisation of biodegradability | Not readily biodegradable | - | |
| Rate constant for STP | N/A | $h^{-1}$ | Is not used for the calculations. calculated as STP influent = STP Effluent |
| Transformation fraction and maximum radioactivity | - | - % | |
| $DT_{50}$ for biodegradation in surface water | 140 d | d or hr (at 12ºC) | Total system DegT50=419 d (at 12ºC) |
| Transformation fraction and maximum radioactivity | N/A | - % | |
| $DT_{50}$ for hydrolysis in surface water | 17.3 | d or hr (at 12ºC /pH) | Irradiated, study condition Is not used for the calculations |
| $DT_{50}$ for degradation in soil | 214 | d or hr (at 12ºC) | Derived from field studies. 119 (12 °C) used as worst case for metabolite formation |
| Transformation fraction and maximum radioactivity | - | - % | |
| $DT_{50}$ for degradation in air | N/A | d or hr | Is not used for the calculations. The exposure to air expected to be negligible |
| $DT_{50}$ for degradation in the sewer system | - | d or hr (at 12ºC) | Is not used for the calculations |
| $DT_{50}$ for degradation in manure | - | d or hr (at 12ºC) | *idem* |
| DT50 for degradation in sediment | 1000 | d or hr (at 12ºC) | |
| **Predicted no effect concentrations (PNEC)** ***[highlight in bold PNEC values derived from new endpoints]*** | | | |
| Sewage treatment plant | 1.09 | mg/L | |
| Surface water | 0.00234 | mg/L | |
| Marine water | - | mg/L | |
| Sediment | 0.016 | mg/kg wwt | |
| Marine sediment | - | mg/kg wwt | |

| | | | |
|---|---|---|---|
| Soil | 0.377 | mg/kg wwt | |
| Bird | 31.5 | | |
| Mammals | 33.33 | | |

**Endpoints and PNEC values for the metabolites and transformation products 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 | - | - | -<br>% | |
| $DT_{50}$ for biodegradation in surface water | 1000 | 1000 | d or hr (at 12ºC) | |
| Transformation fraction and maximum radioactivity | - | | -<br>% | |
| $DT_{50}$ 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 | - | | -<br>% | |
| $DT_{50}$ for degradation in air | - | - | d or hr | The exposure to air exp+ected to be negligible |

| 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) | | |
| $DT_{50}$ 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)** ***[highlight in bold PNEC values derived from new endpoints]*** | | | | |
| 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<br>Surface Water | 17.0%<br>12.8% | 0.58 from parent |
| penflufen -pyrazolyl-AAP (M02) | Soil<br>Surface Water | 11.5%<br>0.0% | 0.08 from parent<br>1 from MO1 |

### 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. 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 42 g propiconazole / $m^3$ wood and the product does not contain IPBC. If a linear interpolation is used this gives an assessment factor for:
penflufen of 42/18.1 = 2.32

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.

The test retention is outside the range of a linear extrapolation, however according to the first ECHA leaching workshop in Arona, 2005 linear extrapolation can be used to correct leaching rate if an additional assessment factor is applied. DK CA have chosen to apply an assessment factor of 2.

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.

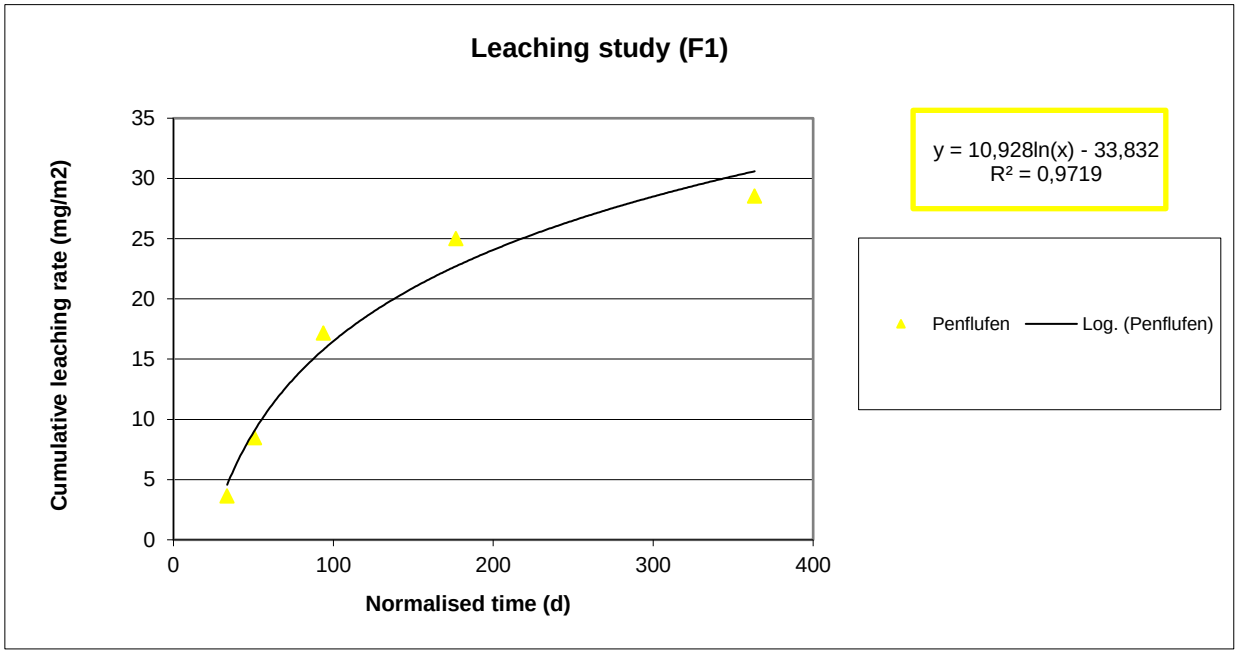
The calculated cumulative leaching rates and flux rates based on the leaching test.
The results are presented for the times which are relevant for risk assessment (Time 1 = 30 days and Time 5 = 7300).
The discussion on an additional Time of 365 days is still discussed on EU level. In this evaluation 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 of 2.32 and the assessment factor of 2.

**Table 3.44 Summery of leaching data for SC 400 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 | |
| | | Leaching [mg/m²] | Accumulative leaching [mg/m²] |
| 64.4 | 34 | 3.63 | 3.63 |
| 97.4 | 51 | 4.83 | 8.46 |
| 180 | 94 | 8.69 | 17.15 |
| 339 | 177 | 7.85 | 25.00 |
| 697 | 363 | 3.53 | 28.53 |




## Results of the leaching tests for product SC400

| Application Type | Time period | Cumulative emission | Flux Rate |
|---|---|---|---|
| | | mg/m² | mg/m²/day |
| **Penflufen** | | | |
| | Time 1: 30 days | 15.48 | 5.16E-01 |
| | Time 2: 365 days | 142.21 | 3.90E-01 |

| Application Type | Time period | Cumulative emission | Flux Rate |
|---|---|---|---|
| | | mg/m² | mg/m²/day |
| | Time 3: 1825 days | 223.83 | 1.23E-02 |
| | Time 4: 5475 days | 279.55 | 5.11E-02 |
| | Time 5: 7300 days | 294.14 | 4.03E-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

For the assessment of endocrine-disrupting properties of non-active substance(s), 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."

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 the latest version of 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 3.45 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. | 0.042 kg penflufen/ $m^3$ | [**Soil**]<br>[Pore water] |
| [1] | Noise barrier scenario | | | [**Soil**]<br>[**STP**]<br>[Pore water] |
| [1] | Bridge over pond scenario | | | [**Water**]<br>[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, Noisebarrier and Bridge scenarios.**

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| | Penflufen | | |
| **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 | % [w/w] | |
| Cumulative quantity of a substance leached out of 1 m² of treated wood over the initial assessment period (30 days) | 1.55E+01 | [mg.m$^{-2}$] | Q*leach.time1 |
| Cumulative quantity of a substance leached out of 1 m² of treated wood over the intermediate assessment period (1 year) | 1.42E+02 | [mg.m$^{-2}$] | Q*leach.time2 |
| Cumulative quantity of a substance leached out of 1 m² of treated wood over a longer assessment period (20 years) | 2.94E+02 | [mg.m$^{-2}$] | Q*leach.time3 |
| Soil volume (wet) | 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 | 0.3 | - | Fsoil |
| Fraction released to STP | 0.7 | - | F.STP |

| Resulting local emission to relevant environmental compartments | | |
|---|---|---|
| **Compartment** | **Local emission (Elocal$_{compartment}$) [mg/d]** TIME1/TIME2/TIME3 | **Remarks** |
| | **Penflufen** | |
| STP (influent) | 1083.83 / 818.17 / 84.61 | |
| Freshwater[1] | 5.16 / 3.90 / 0.40 | |
| Soil[2]<br>From House scenario | 64.51 / 48.70 / 5.04 | |

[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) | | | | 8.35E-02 | **1.65E+01** |
| House (365 days) | | | | 4.72E-01 | **9.33E+01** |
| House (7300 days) | | | | 7.04E-02 | **1.39E+01** |
| Noise barrier (30 days) | 5.23E-04 | 5.23E-05 | "Bridge" is worstcase | 3.12E-02 | **6.18E+00** |
| Noise barrier (365 days) | 3.95E-04 | 3.95E-05 | "Bridge" is worstcase | 1.77E-01 | **3.49E+01** |
| Noise barrier (7300 days) | 4.09E-05 | 1.46E-06 | "Bridge" is worstcase | 2.63E-02 | **5.21E+00** |
| Bridge over pond (30 days) | | 1.40E-04 | 9.65E-04 | | |
| Bridge over pond (365 days) | | 6.42E-04 | 4.41E-03 | | |
| Bridge over pond (7300 days) | | 7.95E-05 | 5.46E-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) | | | | 1.56E-02 | **1.98E+01** |
| House (365 days) | | | | 1.44E-01 | **1.81E+02** |
| House (7300 days) | | | | 2.97E-01 | **3.75E+02** |
| Noise barrier (30 days) | Not relevant | Covered by | | Covered by | Covered by |

| | | | | | |
|---|---|---|---|---|---|
| | compartment | "bridge" | | "house" | "house" |
| Noise barrier (365 days) | Not relevant compartment | Covered by "bridge" | | Covered by "house" | Covered by "house" |
| Noise barrier (7300 days) | Not relevant compartment | Covered by "bridge" | | Covered by "house" | Covered by "house" |
| Bridge over pond (30 days) | | 2.08E-05 | Not relevant compartment | | |
| Bridge over pond (365 days) | | 1.91E-04 | Not relevant compartment | | |
| Bridge over pond (7300 days) | | 3.95E-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) | | | | 8.74E-03 | **4.89E-01** |
| House (365 days) | | | | 8.02E-02 | **4.49E+00** |
| House (7300 days) | | | | 1.66E-01 | **9.29E+00** |
| Noise barrier (30 days) | Not relevant compartment | | | Covered by "house" | Covered by "house" |
| Noise barrier (365 days) | Not relevant compartment | | | Covered by "house" | Covered by "house" |
| Noise barrier (7300 days) | 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 | | |

**Groundwater refinement with FOCUS PEARL**

***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 | 0.018986 |
| M01 | 1.21415 |
| M02 | 0.000032 |

**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

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 part 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 =4.72E-01 mg/kg
PECporewater = 9.33E-02 mg/L
PECsw = 7.95E-05 mg/L

| **Summary table on secondary poisoning** | |
|---|---|
| **Scenario** | **$PEC_{oral\ predator}$** |
| **Scenario 1 – Aquatic food chain** | |
| **1** | 5.64E-03 [mg/kg wet fish] |
| **Scenario 1 – Terrestrial food chain** | |
| **1** | 1.06E+00 [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) | | | | 2.21E-01 | **1.65E+01** |
| House (365 days) | | | | **1.25E+00** | **9.33E+01** |
| House (7300 days) | | | | 1.87E-01 | **1.39E+01** |
| Noise barrier (30 days) | 4.80E-04 | 2.24E-02 | Covered by "bridge" | 8.29E-02 | **6.18E+00** |
| Noise barrier (365 days) | 3.63E-04 | 1.69E-02 | Covered by "bridge" | 4.69E-01 | **3.49E+01** |
| Noise barrier (7300 days) | 3.75E-05 | 6.24E-04 | Covered by "bridge" | 6.99E-02 | **5.21E+00** |
| Bridge over pond (30 days) | | 6.00E-02 | 6.03E-02 | | |
| Bridge over pond (365 days) | | 2.74E-01 | 2.76E-01 | | |
| Bridge over pond (7300 days) | | 3.40E-02 | 3.41E-02 | | |
| **Penflufen metabolite M01** | **STP** | **Water** | **Sediment** | **Soil** | **Groundwater (PEC)** |
| | | | | | [µg/l] |
| House (30 days) | | | | 4.01E-02 | **1.98E+01** |
| House (365 days) | | | | 3.68E-01 | **1.81E+02** |
| House (7300 days) | | | | 7.62E-01 | **3.75E+02** |
| Noise barrier (30 days) | Not relevant compartment | Covered by "bridge" | | Covered by "house" | Covered by "house" |
| Noise barrier (365 days) | Not relevant compartment | Covered by "bridge" | | Covered by "house" | Covered by "house" |
| Noise barrier (7300 days) | Not relevant compartment | Covered by "bridge" | | Covered by "house" | Covered by "house" |
| Bridge over pond (30 days) | | 1.33E-03 | Not relevant compartment | | |
| Bridge over pond (365 days) | | 1.22E-02 | Not relevant compartment | | |
| Bridge over pond (7300 days) | | 2.52E-02 | Not relevant compartment | | |
| **Penflufen metabolite M02** | **STP** | **Water** | **Sediment** | **Soil** | **Groundwater (PEC)** |
| | | | | | [µg/l] |
| House (30 days) | | | | 2.71E-02 | **4.89E-01** |
| House (365 days) | | | | 2.49E-01 | **4.49E+00** |
| House (7300 days) | | | | 5.15E-01 | **9.29E+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 | | |

## 3.8.4 Mixture toxicity

Not relevant

## 3.8.5 Conclusion to the risk assessment

### Atmosphere

Penflufen has a low vapour pressure of $4.1 \times 10^{-7}$ Pa and a Henry's Law constant of $1.19 \times 10^{-5}$ Pa/m$^3$/mol which indicates a very low risk of volatilisation. Thus exposure to air 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 SC400. 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.

Conclusion: The results of the risk characterisation show that there is no unacceptable risk for the aquatic compartment from the use of the product SC400.

### Terrestrial compartment

PEC/PNEC ratio are below the trigger value of one for all assessed scenarios, except for Penflufen at time 2 (365 days) in the house scenario. However as the initial (time 1, 30 days) assessment period and the longer (time 3, 20 years) show no risk in the soil

compartment the risk is considered acceptable. Furthermore time 2 is 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*).

Conclusion: The results of the risk characterisation show that there is no relevant unacceptable risk for soil from the use of the product SC400. No further assessment or risk mitigation is needed.

**Groundwater**

The calculated $PEC_{GW}$ values for 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 Penflufen and M02 are all below the threshold.
The major Penflufen metabolite M01 exceeds the 0.1 µg/L limit even after being modelled in FOCUS PEARL. The highest value is from the Hamburg scenario with a value of 1.2124 µg/L.

Conclusion: The risk to groundwater from the metabolite M01 is unacceptable.
A possible risk mitigation measure would be, that after the application of the product a top-coat would have to be applied. However as DK CA have not received a semi-field leaching test, where a top-coat is applied, showing reduced leaching, the validity of such an RMM cannot be verified in this case.
Therefore no risk mitigation measure can currently be applied, and it is concluded that the use of the SC400 in Use Class 3 cannot be 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

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] | 1.79E-04 | 1.69E-04 |
| **Scenario 1 – Terrestrial food chain** | | | |
| **1** | 3.17E-01 [mg/kg wet earthworm] | 3.37E-02 | 3.19E-02 |

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)

Penflufen is approved for use as a pesticide under Plant Protection Products (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 3.46 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.<br><br>Industrial pressure impregnation.<br><br>Wood rotting fungi. | Use of SC400 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.<br><br>Industrial pressure impregnation.<br><br>Wood rotting fungi. | As no emission is expected from use in use class 2, this use is considered acceptable. | Freshly treated timber must be stored after treatment under shelter or on a hard, impermeable surface to prevent direct losses to soil and water.<br><br>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..

# 4 Appendices

## 4.1 Calculations for exposure assessment

### 4.1.1 Human health

| Scenario 4 Sanding treated wood professionals | |
|---|---|
| | **Penflufen** |
| **Concentration in wood** | |
| Application rate [a.s.] (mg/cm²) | 0,031 |
| Area of wood to be sanded surface area (cm²)<br>(4 x 4cm x 250cm + 2 x 4cm x 4cm) | 4032 |
| Volume of outer layer (cm³)<br>(4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm) | 3008 |
| Amount in wood [a.s] (mg) | 126,3 |
| **Exposure by inhalation** | |
| Concentration of in wood dust a.s (mg/cm³) | 0,042 |
| Wood dust concentration in air (mg/m³) | 5 |
| Exposure duration (h) | 6 |
| Inhalation rate ($m^3$/h) | 1,25 |
| Retention of a.s. in wood | 100% |
| Density of wood (g/cm³) | 0,40 |
| Amount dust inhaled in 6 hours (cm³) | 0,09 |
| Inhaled [a.s] (mg) | 0,0039 |
| Body weight (kg) | 60 |
| Systemic exposure via inhalation (mg $kg^{-1}$ $day^{-1}$) | 0,00007 |
| **Dermal exposure** | |
| **A** Concentration on the wood surface (mg/$cm^2$) | 0,0313 |
| **B** Transfer coefficient (%) | 3% |
| **C** Surface of palm of hand ($cm^2$) | 410 |
| **D** Dermal absorption (%) | 70% |
| **E** Body weight (kg) | 60 |
| Systemic exposure via dermal route (mg $kg^{-1}$ $day^{-1}$) | 0,0045 |
| **Total systemic exposure** | |
| Total systemic exposure a.s. (mg $kg^{-1}$ $day^{-1}$) | 0,00456 |
| AEL (mg $kg^{-1}$ $day^{-1}$) | 0,04 |
| **% AEL** | **11,40%** |

| Scenario 5 Sanding treated wood non-professionals | |
|---|---|
| | **Penflufen** |
| **Concentration in wood** | |
| Application rate [a.s.] (mg/cm²) | 0,031 |
| Area of wood to be sanded surface area (cm²)<br>(4 x 4cm x 250cm + 2 x 4cm x 4cm) | 4032 |
| Volume of outer layer (cm³)<br>(4 x 3cm x 249cm x 1cm + 2 x 3cm x 3cm x 1cm) | 3008 |
| Amount in wood [a.s] (mg) | 126,3 |
| **Exposure by inhalation** | |
| Concentration of in wood dust a.s (mg/cm³) | 0,025 |
| Wood dust concentration in air (mg/m³) | 5 |
| Exposure duration (h) | 1 |
| Inhalation rate ($m^3$/h) | 1,25 |
| Retention of a.s. in wood | 100% |
| Density of wood (g/cm³) | 0,40 |
| Amount dust inhaled in 6 hours (cm³) | 0,02 |
| Inhaled [a.s] (mg) | 0,0004 |
| Body weight (kg) | 60 |
| Systemic exposure via inhalation (mg $kg^{-1}$ $day^{-1}$) | 0,00001 |
| **Dermal exposure** | |
| **A** Concentration on the wood surface (mg/$cm^2$) | 0,0313 |
| **B** Transfer coefficient (%) | 3% |
| **C** Surface of palm of hand ($cm^2$) | 410 |
| **D** Dermal absorption (%) | 70% |
| **E** Body weight (kg) | 60 |
| Systemic exposure via dermal route (mg $kg^{-1}$ $day^{-1}$) | 0,0045 |
| **Total systemic exposure** | |
| Total systemic exposure a.s. (mg $kg^{-1}$ $day^{-1}$) | 0,00450 |
| AEL (mg $kg^{-1}$ $day^{-1}$) | 0,04 |
| **% AEL** | **11,26%** |

| Scenario 7 Infant chewing wood cut off | |
|---|---|
| | **Penflufen** |
| Active substance % (w/w) | 2,50% |
| **Concentration in wood** | |
| Application rate [a.s.] mg/cm² | 0,031 |
| Layer thickness cm | 1,00 |
| Retention of a.s. in wood | 100% |
| Concentration in wood [a.s.] mg/cm³ | 0,042 |
| **Oral exposure** | |
| Size of the wood chip cm³ | 16 |
| Extraction of active substance when chewing | 10% |
| Extraction from wood mg a.s./day | 0,07 |
| Oral absorption % | 100% |
| Systemic exposure via oral route mg a.s. | 0,067 |
| **Systemic exposure** | |
| Body weight kg | 8 |
| Systemic exposure mg $kg^{-1}$ $day^{-1}$ | 0,0084 |
| AEL mg $kg^{-1}$ $day^{-1}$ | 0,3 |
| % AEL | **2,8%** |

| Scenario 8 Infant playing on wooden structure (e.g. playground) | |
|---|---|
| | **Penflufen** |
| Concentration of a.s. (% w/w) | 2,50% |
| **Wood contamination** | |
| Application rate [a.s.] (mg/cm²) | 0,031 |
| **Dermal exposure** | |
| Area: both palms (cm²) | 98,4 |
| Fraction of palms in contact with b.p. (%) | 40% |
| Transfer efficiency % | 3% |
| Hand deposit (mg a.s./day) | 0,04 |
| Dermal absorption (%) | 70% |
| Systemic exposure via dermal route (mg a.s.) | 0,026 |
| **Oral exposure** | |
| Hand deposit (mg a.s./day) | 0,037 |
| Transfer efficiency for hand to mouth (%) | 50% |
| Oral absorption (%) | 100% |
| Systemic exposure via oral route (mg a.s.) | 0,018 |
| **Total systemic exposure** | |
| **A** Total systemic exposure (mg a.s.) | 0,044 |
| **B** Body weight (kg) | 8 |
| Total systemic exposure (mg $kg^{-1}$ $day^{-1}$) | 0,0055 |
| AEL (mg $kg^{-1}$ $day^{-1}$) | 0,04 |

### 4.1.2 Dietary assessment

| Livestock exposure estimation - horse chewing on wood | |
|---|---|
| **Activity / Parameter** | **Penflufen** |
| **Wood** | |
| Concentration a.s. in wood (g/m³) | 42 |
| Amount of wood consumed (g/m³) | 0.000019 |
| **Exposure by oral intake** | |
| Body weight (kg) | 400 |
| **Systemic exposure via ingestion (mg/kg bw/day)** | **2.00E-06** |
| Below trigger value of 0.004 mg/kg bw/day | Yes |

### 4.1.2.1 Environment 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 4.1 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 (L/kg)** | 279.9 | 38.2 | 1006 |
| **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)** | 294.14 | | |
| **Service life (years)** | 20 | | |
| **Number of houses estimated per hectare** | 16 | | |
| **Local emission of active substance (kg/ha/year)** | 0.014707 | | |
| **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 Penflufen and Metabolites in µg/L**

| $PEC_{groundwater}$ - Output FOCUS PEARL in µg/L | |
|---|---|
| **Scenario Penflufen** | |
| Location | Grassland (crop) |
| Chateaudun | 0.006916 |
| Hamburg | 0.018986 |
| Jokioinen | 0.003186 |
| Kremsmunster | 0.010201 |

| | |
|---|---|
| Okehampton | 0.018125 |
| Piacenza | 0.016602 |
| Porto | 0.008448 |
| Sevilla | 0.000432 |
| Thiva | 0.002776 |
| **Scenario M01** | |
| Location | Grassland (crop) |
| Chateaudun | **0.742233** |
| Hamburg | **1.212415** |
| Jokioinen | **1.157983** |
| Kremsmunster | **0.721412** |
| Okehampton | **0.775311** |
| Piacenza | **0.726136** |
| Porto | **0.475480** |
| Sevilla | **0.468662** |
| Thiva | **0.641506** |
| **Scenario M02** | |
| Location | Grassland (crop) |
| Chateaudun | 0.000003 |
| Hamburg | 0.000032 |
| Jokioinen | 0.000000 |
| Kremsmunster | 0.000005 |
| Okehampton | 0.000013 |
| Piacenza | 0.000031 |
| Porto | 0.000004 |
| Sevilla | 0.000000 |
| Thiva | 0.000002 |

**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 (7.95E-05mg/L), because this

was the highest relevant concentration. According to table 23[7] 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 5.64E-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):

$$C_{earthworm} = \frac{BCF_{earthworm} \cdot C_{porewater} \cdot W_{earthworm} + C_{soil} \cdot W_{gut}}{W_{earthworm} + W_{gut}}$$ 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)** | **4.72E-01** | **mg*kgwwt$^{-1}$** | **Input from house scenario 1 year** |
| **$C_{porewater}$ (max)** | **9.33E-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.)** |

[7] ECHA-Guidance (2017 Version 2.0) 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)** |
| **$C_{earthworm}$ / $PEC_{oral\ preadator}$** | **1.06E+00** | **$mg*kg_{wet\ earthworm}^{-1}$** | **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 1.06E+00 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 4.1 List of studies for the biocidal product**

| Author (s) | Year<br><br>Report date | Reference No. *(Annex III requirement)* / IUCLID Section No. | IUCLID Document name | Title. Report No. | Type of publication | Source (where different from company)<br><br>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 | 861430-1, rev.1 - 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 | 861430-2, rev1 - Report EN113 + EN73 | Test Report. Modified EN 113 in accordance with EN 73. ReportNo.: 833801-4 | 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 | Confidential validation report | Company owner: Superwood | No | Yes |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | SC400 | | | | |
| Johannesen, S, A | 2020 | 3.1, 3.2, 3.3, 3.4, 3.9 / same | 862304_Test report_12M_SC400 | Test Report. REPORT NUMBER: 862304 12M | Confidential test report | Company owner: Superwood | No | Yes |
| Johannesen, S, A | 2019 | 3.8, 4.16, 4.6 / same | 862304_Test rapport Rev 1_fyskem_SC400 | Test Report REPORT NUMBER: 862304 PC Rev. 1 | Confidential test report | Company owner: Superwood | No | Yes |

The studies 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, Penflufen, 2021
- MSDS on SC400 in Danish
- MSDS on SC400 in English
- MSDS on Dipropylene Glycol n-Butyl Ether
- Excel spread shed on: Risk assessment for the environment on SC400
- Competent Authority Report. Penflufen PT8. UK 2017.

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.